

Fátima Santos

De: Joao Garcia
Enviado: sexta-feira, 28 de Março de 2014 18:15
Para: Fátima Santos
Cc: Lisete Vargas
Assunto: FW: Iniciativa europeia | COM(2014)180 | Solicitação de parecer à ALRAs
Anexos: 1_PT_letter.pdf; COM_2014_180_PT_ACTE_f.pdf; COM_2014_180_PT_ACTE2_f.pdf; SWD_2014_65_EN_DOCUMENTDETRAVAIL_f.pdf; SWD_2014_65_EN_DOCUMENTDETRAVAIL2_f.pdf; SWD_2014_65_EN_DOCUMENTDETRAVAIL3_f.pdf; SWD_2014_66_PT_DOCUMENTDETRAVAIL_f.pdf

Importância: Alta

Por favor dar entrada.

JG

De: Comissão 4ª - CAE XII [<mailto:Comissao.4A-CAEXII@ar.parlamento.pt>]
Enviada: sexta-feira, 28 de Março de 2014 18:09
Para: chefegabinete
Assunto: Iniciativa europeia | COM(2014)180 | Solicitação de parecer à ALRAs
Importância: Alta

Exma. Senhora Presidente da Assembleia Legislativa da Região Autónoma dos Açores

No âmbito do escrutínio de iniciativas europeias, a Comissão de Assuntos Europeus recebeu no dia 24 de março de 2014, da Comissão Europeia a **Proposta de REGULAMENTO DO PARLAMENTO EUROPEU E DO CONSELHO que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho [Regulamento relativo aos controlos oficiais] e que revoga o Regulamento (CE) n.º 834/2007 do Conselho [COM(2014)180]**. Esta iniciativa tem associados dois documentos de trabalho [SWD(2014)65 e SWD(2014)66].

Tratando-se de matéria da competência e interesse específico da Assembleia Legislativa a que V. Exa. preside e tendo a Assembleia Legislativa da Região Autónoma dos Açores selecionado esta iniciativa, conforme consta da Resolução da Assembleia da República n.º 79/2013, junto envio a referida iniciativa europeia para análise e elaboração de parecer.

Nos termos da Lei n.º 43/2006, de 25 de agosto, alterada pela Lei n.º 21/2012, de 17 de maio, e de acordo com a *Metodologia de escrutínio das iniciativas europeias aprovada a 8 de janeiro de 2013*, as iniciativas selecionadas são objeto de Parecer, o qual "*deve, sobretudo, abordar as questões de substância da iniciativa e implicações que a mesma tenha para Portugal, bem como se o objeto da iniciativa recai no âmbito de matérias da competência legislativa reservada da Assembleia da República. O Parecer pode também analisar a base jurídica e a observância dos princípios da subsidiariedade e da proporcionalidade. As conclusões devem discriminar separadamente as questões suscitadas quanto à substância e quanto à observância dos princípios da subsidiariedade e da proporcionalidade.*"

Por esta iniciativa constituir uma proposta de ato legislativo e para efeitos de análise da conformidade com o princípio da subsidiariedade, nos termos do Protocolo n.º 2 anexo ao Tratado de Lisboa, o prazo de 8 semanas começa a contar no dia 25 de março de 2014, conforme carta da Comissão Europeia, que se anexa, pelo que agradeço, que o relatório dessa Assembleia seja enviado à Comissão de Assuntos Europeus até 2 de maio de 2014.

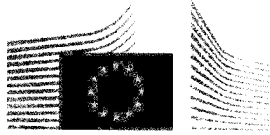
O Gabinete de Apoio a esta Comissão encontra-se disponível para qualquer esclarecimento e toda a colaboração.

Com os meus melhores cumprimentos,

Paulo Mota Pinto

Presidente da Comissão de Assuntos Europeus

ASSEMBLEIA LEGISLATIVA DA REGIÃO AUTÓNOMA DOS AÇORES	
ARQUIVO	
Entrada 6987	Proc. n.º 02-08
Data: 01/03/31	N.º 831 X



COMISSÃO EUROPEIA
SECRETARIADO-GERAL

Bruxelas, 25.3.2014
SG-Greffe(2014) D/ 4383

Assembleia da República
Palácio de S. Bento
P-1249-068 Lisboa

Transmissão nos termos do Protocolo (n.º 2) do Tratado da União Europeia e do Tratado sobre o Funcionamento da União Europeia relativo à aplicação dos princípios da subsidiariedade e da proporcionalidade

Assunto: COM(2014) 180 final, 24.3.2014

A Comissão informa que todas as versões linguísticas do projecto de acto legislativo mencionado em epígrafe foram transmitidas aos parlamentos nacionais e às câmaras dos parlamentos nacionais dos Estados-Membros.

A presente carta dá início ao procedimento previsto no Protocolo (n.º 2) relativo à aplicação dos princípios da subsidiariedade e da proporcionalidade.

No prazo de oito semanas¹ a contar da data da presente carta, pode ser dirigido aos Presidentes do Parlamento Europeu, do Conselho e da Comissão um parecer fundamentado expondo as razões pelas quais consideram que o projecto em questão não obedece ao princípio da subsidiariedade.

Pela Secretária-Geral,

Jordi AYET PUIGARNAU
Director

¹ O período compreendido entre 1 e 31 de Agosto não é incluído no cálculo do período de oito semanas.



Bruxelas, 24.3.2014
COM(2014) 180 final

2014/0100 (COD)

Proposta de

REGULAMENTO DO PARLAMENTO EUROPEU E DO CONSELHO

que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho [Regulamento relativo aos controlos oficiais] e que revoga o Regulamento (CE) n.º 834/2007 do Conselho

{SWD(2014) 65 final}

{SWD(2014) 66 final}

EXPOSIÇÃO DE MOTIVOS

1. CONTEXTO DA PROPOSTA

1.1. Justificação e objetivos da proposta

Ao longo dos últimos 10 anos, o mercado biológico tem-se caracterizado por um desenvolvimento dinâmico, impulsionado por um forte crescimento da procura. O mercado mundial de géneros alimentícios biológicos quadruplicou desde 1999. A área de produção biológica na União Europeia («União») duplicou. Todos os anos, 500 000 hectares de terreno são convertidos para a agricultura biológica. Contudo, nem a oferta interna nem o quadro legislativo acompanharam esta expansão do mercado. As regras de produção não consideram suficientemente a evolução das preocupações e expectativas dos consumidores e dos cidadãos, as regras de rotulagem são complicadas e foram identificadas deficiências no sistema de controlo e no regime de comércio. A legislação é complexa e implica um elevado nível de encargos administrativos, o que impede os pequenos agricultores de aderirem ao regime biológico da União. Algumas das isenções que eram necessárias para o desenvolvimento do setor parecem já não se justificar.

A proposta visa melhorar a legislação relativa à produção biológica, com o objetivo de:

- (1) Eliminar obstáculos ao desenvolvimento sustentável da produção biológica na União;
- (2) Garantir condições de concorrência leal para os agricultores e os operadores e permitir que o mercado interno funcione de forma mais eficiente;
- (3) Manter ou aumentar a confiança dos consumidores nos produtos biológicos.

1.2. Contexto geral

Aquando da adoção do Regulamento (CE) n.º 834/2007 do Conselho relativo à produção biológica e à rotulagem dos produtos biológicos¹, o Conselho assinalou uma série de questões sobre as quais a Comissão foi instada a apresentar um relatório ao Parlamento Europeu e ao Conselho, após a análise da experiência adquirida com a aplicação do Regulamento (CE) n.º 834/2007.

O Conselho adotou conclusões sobre o relatório da Comissão² na sua sessão «Agricultura e Pescas» de 13 e 14 de maio de 2013³ e convidou os Estados-Membros e a Comissão a desenvolverem o setor da produção biológica a um nível ambicioso através da revisão do atual quadro jurídico, a fim de melhorar as suas possibilidades de utilização, proporcionando simultaneamente um período de estabilidade e segurança, tendo em vista uma maior clarificação e simplificação, e abordando as atuais questões pendentes que necessitam de maior desenvolvimento.

A revisão da legislação relativa à produção biológica faz parte do Programa para a adequação e a eficácia da regulamentação⁴ da Comissão.

A revisão proporciona a oportunidade de adaptar as competências de execução da Comissão previstas no Regulamento (CE) n.º 834/2007 do Conselho à diferenciação entre poderes delegados e

¹ Regulamento (CE) n.º 834/2007 do Conselho, de 28 de junho de 2007, relativo à produção biológica e à rotulagem dos produtos biológicos e que revoga o Regulamento (CEE) n.º 2092/91 (JO L 189 de 20.7.2007, p. 1).

² Relatório da Comissão ao Parlamento Europeu e ao Conselho sobre a aplicação do Regulamento (CE) n.º 834/2007 do Conselho relativo à produção biológica e à rotulagem dos produtos biológicos, COM(2012) 212 final, de 11 de maio de 2012.

³ 8906/13 AGRILEG 56 — Produção biológica: Aplicação do quadro regulamentar e desenvolvimento do setor.

⁴ Comunicação da Comissão sobre a adequação da regulamentação da UE, de 12 de dezembro de 2012 — COM(2012) 746.

competências de execução da Comissão introduzida pelos artigos 290.º e 291.º do Tratado sobre o Funcionamento da União Europeia (TFUE).

1.3. Disposições em vigor neste domínio

O primeiro ato legislativo da União relativo à produção biológica foi adotado em 1991. O Regulamento (CEE) n.º 2092/91 do Conselho estabeleceu uma definição jurídica de produção biológica através de regras de produção e definiu requisitos de controlo e de rotulagem, assim como regras aplicáveis à importação de produtos biológicos. Isto constituiu uma base para proteger os consumidores e os produtores biológicos contra indicações falsas e enganosas de alegados produtos biológicos.

Essa legislação foi revista com a adoção do Regulamento (CE) n.º 834/2007 do Conselho, em junho de 2007, que, nomeadamente:

- definiu a produção biológica com maior detalhe, descrevendo os seus objetivos e princípios,
- melhorou a harmonização das regras de produção biológica na União, pondo fim às regras nacionais aplicáveis aos produtos de origem animal,
- introduziu a possibilidade de derrogações às regras sob a responsabilidade dos Estados-Membros (EM), mas com limitações estritas e por um período de tempo limitado,
- associou o sistema de controlo biológico ao sistema de controlos oficiais dos géneros alimentícios e alimentos para animais previsto no Regulamento (CE) n.º 882/2004⁵ e tornou obrigatória a acreditação dos organismos de controlo privados,
- reestruturou o regime de importação: além do reconhecimento dos países terceiros para efeitos de equivalência, a União Europeia reconhece os organismos de controlo (OC) ativos em países terceiros para efeitos de equivalência ou conformidade. O sistema anterior de autorizações individuais concedidas remessa a remessa pelos EM foi retirado do regulamento de base e está agora em fase de eliminação progressiva.

1.4. Coerência com outras políticas

A presente iniciativa persegue os objetivos da comunicação sobre regulamentação inteligente na União Europeia. Um dos objetivos da revisão consiste em simplificar a carga legislativa.

É consentânea com o quadro geral da estratégia Europa 2020, em especial no que diz respeito à prioridade de crescimento sustentável e à promoção de uma economia mais eficiente em termos de recursos, mais ecológica e mais competitiva.

Além disso, é coerente com a reforma da política agrícola comum (PAC), que configura o quadro global para o desenvolvimento da agricultura na União para o período de 2014-2020⁶. As novas

⁵ Regulamento (CE) n.º 882/2004 do Parlamento Europeu e do Conselho, de 29 de abril de 2004, relativo aos controlos oficiais realizados para assegurar a verificação do cumprimento da legislação relativa aos alimentos para animais e aos géneros alimentícios e das normas relativas à saúde e ao bem-estar dos animais (JO L 165 de 30.4.2004, p. 1).

⁶ Regulamento (UE) n.º 1307/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, que estabelece regras para os pagamentos diretos aos agricultores ao abrigo de regimes de apoio no âmbito da política agrícola comum e que revoga o Regulamento (CE) n.º 637/2008 do Conselho e o Regulamento (CE) n.º 73/2009 do Conselho (JO L 347 de 20.12.2013, p. 608); Regulamento (UE) n.º 1308/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, que estabelece uma organização comum dos mercados dos produtos agrícolas e que revoga os Regulamentos (CEE) n.º 922/72, (CEE) n.º 234/79, (CE) n.º 1037/2001, (CE) n.º 1234/2007 do Conselho (JO L 347 de 20.12.2013, p. 671) do Conselho; Regulamento (UE) n.º 1305/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) e que revoga o Regulamento (CE) n.º 1698/2005 do Conselho (JO L 347 de 20.12.2013, p. 487); Regulamento (UE) n.º 1306/2013 do Parlamento Europeu e do

disposições têm como objetivo conseguir uma competitividade sustentável com vista a alcançar um setor de produção alimentar economicamente viável, em conjunto com a gestão sustentável dos recursos naturais terrestres da União, na qual a produção biológica foi considerada um elemento essencial.

A proposta tem em conta a nova política comum das pescas no que se refere à aquicultura, que desempenha um papel fundamental na garantia da segurança alimentar sustentável a longo prazo, bem como do crescimento e do emprego, reduzindo simultaneamente a pressão exercida nas unidades populacionais de peixes selvagens, num contexto de procura global crescente de alimentos de origem aquática.

É também coerente com a proposta da Comissão de um novo regulamento do Conselho e do Parlamento relativo aos controlos oficiais⁷, que visa consolidar a abordagem integrada em todos os domínios relacionados com a cadeia alimentar através da racionalização e simplificação do quadro legislativo global, prosseguindo simultaneamente o objetivo de legislar melhor. Em especial, as definições são harmonizadas e/ou clarificadas, conforme adequado, e as disposições específicas de controlo necessárias são propostas para integração no quadro legislativo único para os controlos oficiais.

Por último, o regime de produção biológica faz parte dos regimes de qualidade dos produtos agrícolas da União, juntamente com as indicações geográficas, as especialidades tradicionais garantidas e os produtos das regiões ultraperiféricas da UE e zonas de montanha, conforme sublinhado na Comunicação da Comissão ao Parlamento Europeu, ao Conselho, ao Comité Económico e Social Europeu e ao Comité das Regiões sobre a política de qualidade dos produtos agrícolas e indicado no Regulamento (UE) n.º 1151/2012 do Parlamento Europeu e do Conselho relativo aos regimes de qualidade⁸.

2. RESULTADOS DA CONSULTA DAS PARTES INTERESSADAS E DAS AVALIAÇÕES DE IMPACTO

2.1. Consultas

A situação atual foi analisada em profundidade com base nas informações recolhidas durante uma série de audiências com as partes interessadas, para as quais a Comissão convidou mais de 70 peritos e académicos para debater pormenorizadamente os desafios atuais e futuros enfrentados pelo setor biológico.

A Comissão lançou uma consulta em linha no início de 2013. Foram obtidas cerca de 45 000 respostas ao questionário e foram recebidas cerca de 1400 contribuições livres. A maioria (96 %) das respostas

Conselho, de 17 de dezembro de 2013, relativo ao financiamento, à gestão e ao acompanhamento da Política Agrícola Comum e que revoga os Regulamentos (CEE) n.º 352/78, (CE) n.º 165/94, (CE) n.º 2799/98, (CE) n.º 814/2000, (CE) n.º 1290/2005 e (CE) n.º 485/2008 do Conselho (JO L 347 de 20.12.2013, p. 549).

⁷ Proposta de Regulamento do Parlamento Europeu e do Conselho relativo aos controlos oficiais e outras atividades oficiais que visam assegurar a aplicação da legislação em matéria de alimentos para consumo humano e animal e das regras sobre saúde e bem-estar animal, fitossanidade, material de reprodução vegetal e produtos fitofarmacêuticos e que altera os Regulamentos (CE) n.º 999/2001, (CE) n.º 1829/2003, (CE) n.º 1831/2003, (CE) n.º 1/2005, (CE) n.º 396/2005, (CE) n.º 834/2007, (CE) n.º 1099/2009, (CE) n.º 1069/2009, (CE) n.º 1107/2009, (UE) n.º 1151/2012 e (UE) n.º [...] /2013 [Serviço das Publicações: inserir número do regulamento que estabelece disposições para a gestão das despesas relacionadas com a cadeia alimentar, a saúde e o bem-estar animal, a fitossanidade e o material de reprodução vegetal] e as Diretivas 98/58/CE, 1999/74/CE, 2007/43/CE, 2008/119/CE, 2008/120/CE e 2009/128/CE (Regulamento relativo aos controlos oficiais), COM(2013) 265 final, de 6.5.2013.

⁸ Regulamento (UE) n.º 1151/2012 do Parlamento Europeu e do Conselho, de 21 de novembro de 2012, relativo aos regimes de qualidade dos produtos agrícolas e dos géneros alimentícios (JO L 343 de 14.12.2012, p. 1).

foi apresentada por cidadãos da União Europeia, enquanto as restantes 4 % foram enviadas pelas partes interessadas.

Além disso, as partes interessadas do setor foram informadas e consultadas relativamente à revisão, em várias reuniões do Grupo Consultivo «Agricultura Biológica».

Os Estados-Membros, enquanto autoridades competentes encarregadas da aplicação da legislação, foram informados e consultados sobre os aspetos técnicos da revisão.

2.2. Principais resultados das consultas

Os inquiridos na consulta pública estão preocupados sobretudo com questões ambientais e de qualidade. Gostariam que as regras europeias em matéria de produção biológica fossem reforçadas e pretendem a uniformidade das mesmas para os agricultores e outros operadores de toda a União. Por conseguinte, a maioria é a favor de acabar com as derrogações às regras. Registaram-se elevadas expectativas relativamente aos resíduos de produtos e substâncias não autorizados para utilização na produção biológica. O logótipo biológico da União Europeia foi classificado como equivalente aos logótipos nacionais enquanto forma de reconhecimento de produtos biológicos. A maioria das partes interessadas e dos cidadãos confia no sistema de controlo biológico, embora considere que poderia ser melhorado, principalmente através da introdução de certificação eletrónica. A maioria é também a favor da certificação de grupo para pequenos agricultores.

A necessidade de melhorar a legislação relativa à produção biológica é amplamente reconhecida no setor biológico. Existe também um amplo consenso quanto à ideia de que a produção biológica deve manter-se próxima dos seus princípios e objetivos, e de que devem deixar de existir derrogações às regras.

2.3. Avaliação de impacto

A avaliação de impacto comparou três cenários políticos alternativos:

- O *status quo* melhorado, com base nas melhorias e na melhor aplicação da legislação em vigor.
- A opção impulsionada pelo mercado, que visa criar as condições necessárias para responder de forma dinâmica aos novos desenvolvimentos do mercado com regras mais flexíveis. Seria possível integrar regras excecionais de longa duração nas regras de produção.
- A opção impulsionada pelos princípios, que visa reorientar a produção biológica para os seus princípios, o que teria um melhor reflexo nas regras de produção. As regras excecionais seriam suprimidas.

As três opções políticas foram avaliadas em função do seu potencial para alcançar os objetivos da PAC 2020, os objetivos políticos específicos e os objetivos operacionais para a revisão, e em termos de eficácia e eficiência. A opção impulsionada pelos princípios regista o melhor desempenho de acordo com todos os critérios avaliados, seguida da opção impulsionada pelo mercado e, por fim, o *status quo* melhorado.

Prevê-se que a opção impulsionada pelos princípios produza os seguintes resultados:

- uma perspetiva positiva do mercado, graças a uma maior confiança dos consumidores, que deverá apoiar os preços dos produtos biológicos e atrair novos intervenientes,
- a eliminação das derrogações às regras deverá contribuir para o desenvolvimento de fatores de produção biológicos, nomeadamente sementes,
- as regras de produção mais claras e simples tornarão o setor mais atrativo,

- a concorrência tornar-se-á mais leal, como resultado da maior harmonização, de regras mais simples e claras, bem como da passagem da equivalência para a conformidade para o reconhecimento dos organismos de controlo em países terceiros,
- a confiança dos consumidores aumentará através da melhoria do sistema de controlo e da harmonização das regras de produção, tendo em conta a evolução das preocupações da sociedade (sistema de gestão ambiental para os transformadores e comerciantes, bem-estar dos animais),
- espera-se que uma abordagem baseada no risco melhore a eficácia e a eficiência dos controlos e contribua, juntamente com um regime de importação mais fiável, para a prevenção de fraudes,
- os impactos ambientais positivos associados à produção biológica serão acentuados pelo fim das regras excecionais,
- as condições de bem-estar dos animais serão melhoradas através da eliminação das derrogações.

A avaliação de impacto concluiu que a opção preferida seria a opção impulsionada pelos princípios, juntamente com a inclusão das melhorias propostas no *status quo* melhorado, e com algumas subopções.

Prestou-se especial atenção à simplificação ao longo de todo o processo. A opção preferida irá:

- esclarecer as disposições sobre o âmbito de aplicação, as regras de produção, a rotulagem e os controlos,
- remover as disposições ineficazes,
- limitar a margem dos Estados-Membros para a concessão de derrogações às regras,
- simplificar o regime de importação,
- simplificar os requisitos para os pequenos agricultores, nomeadamente através da introdução da certificação de grupo.

No que se refere aos custos administrativos, a atual proposta conduzirá à supressão de 37 das atuais 135 obrigações de informação impostas às administrações e aos operadores biológicos.

3. ELEMENTOS JURÍDICOS DA PROPOSTA

3.1. Síntese da ação proposta

A produção biológica deve continuar a respeitar um conjunto de princípios que reflita fielmente as expectativas dos consumidores.

As regras específicas de produção estão reunidas num anexo do regulamento proposto, ficando assim tratada a questão da legibilidade.

As regras de produção são reforçadas e harmonizadas através da eliminação das derrogações, exceto nos casos em que sejam necessárias medidas temporárias para permitir que a produção biológica continue ou recomece em caso de circunstâncias catastróficas. As explorações agrícolas biológicas têm de ser inteiramente geridas em conformidade com os requisitos aplicáveis à produção biológica e o reconhecimento retroativo do período de conversão deixa, em princípio, de ser possível. Os ingredientes agrícolas utilizados na composição de produtos biológicos transformados devem ser exclusivamente biológicos. Com exceção das microempresas, os operadores biológicos não agricultores

ou os operadores que produzem algas marinhas ou animais de aquicultura são obrigados a desenvolver um sistema para melhorar o seu desempenho ambiental.

O sistema de controlo é melhorado através da integração de todas as disposições relativas ao controlo num único texto legislativo, ao abrigo da proposta da Comissão referente a um regulamento relativo aos controlos oficiais e outras atividades oficiais em matéria de alimentos para consumo humano e animal. Por conseguinte, deixará de ser necessário os operadores, as autoridades competentes, as autoridades de controlo e os organismos de controlo consultarem dois textos legislativos diferentes para se informarem acerca das disposições relacionadas com os controlos.

A controlabilidade é reforçada pela clarificação, simplificação e harmonização das regras de produção e pela eliminação de uma série de possíveis derrogações a essas mesmas regras.

A proposta visa afastar a possibilidade de isentar certos tipos de retalhistas, prevista no Regulamento (CE) n.º 834/2007, que levou a diferentes interpretações e práticas nos vários Estados-Membros e dificultou as operações de gestão, supervisão e controlo.

A abordagem baseada no risco para os controlos oficiais é reforçada através da eliminação do requisito de verificação anual obrigatória do cumprimento de todos os operadores, previsto no Regulamento (CE) n.º 834/2007. Isto possibilitará a adaptação da frequência de controlo através de atos delegados a adotar em conformidade com o Regulamento (UE) n.º XX/XXX (Regulamento relativo aos controlos oficiais), para que os operadores com um perfil de baixo risco possam ser inspecionados fisicamente menos de uma vez por ano e/ou sujeitos a inspeções físicas anuais reduzidas, enquanto os operadores de maior risco seriam objeto de um maior controlo. Haverá, portanto, um equilíbrio mais justo da pressão de controlo sobre os operadores, com uma diminuição dos encargos para aqueles que possuem um historial comprovado de cumprimento das regras, e uma utilização dos recursos mais eficaz e eficiente por parte das autoridades competentes, das autoridades de controlo e dos organismos de controlo.

São introduzidas disposições específicas a fim de aumentar a transparência relativamente às taxas que podem ser cobradas pelos controlos e são reforçadas as disposições relativas à publicação dos operadores, juntamente com informações sobre a situação dos mesmos em matéria de certificação.

É introduzido um sistema de certificação de grupo para os pequenos agricultores da União, com vista a reduzir as despesas de inspeção e certificação e os respetivos encargos administrativos, reforçar as redes locais, contribuir para um melhor escoamento no mercado e assegurar condições equitativas de concorrência com os operadores de países terceiros.

São introduzidas disposições específicas para uma melhor rastreabilidade e prevenção de fraudes: os operadores não podem ser controlados por diferentes autoridades ou organismos de controlo relativamente aos mesmos grupos de produtos nas diferentes fases da cadeia biológica.

São igualmente introduzidas disposições específicas para harmonizar as medidas a tomar no caso de serem detetados produtos ou substâncias não autorizados. Neste contexto, podem ocorrer situações em que os agricultores fiquem impedidos de comercializar os seus produtos como biológicos devido à presença não intencional de produtos ou substâncias não autorizados. Os Estados-Membros podem ser autorizados pela Comissão a conceder pagamentos nacionais para compensar as perdas decorrentes dessas situações. Além disso, os Estados-Membros podem recorrer aos instrumentos da política agrícola comum para cobrir, total ou parcialmente, essas perdas.

Por último, a proposta define as medidas a tomar em toda a União nas mesmas categorias amplas de incumprimento, de modo a garantir condições equitativas relativamente ao tratamento dos operadores, o bom funcionamento do mercado interno e a manutenção da confiança dos consumidores, sem, no entanto, condicionar a determinação de sanções, que é da competência dos Estados-Membros.

O regime de comércio é adaptado para melhorar a igualdade entre os operadores biológicos da União Europeia e de países terceiros e para melhor garantir a confiança dos consumidores. Continua a haver a possibilidade de celebração de acordos de equivalência com países terceiros, enquanto o sistema de equivalência unilateral é gradualmente eliminado. Propõe-se que o reconhecimento dos organismos de controlo seja progressivamente alterado para um regime de conformidade.

3.2. Base jurídica

Tratado sobre o Funcionamento da União Europeia, nomeadamente o artigo 42.º, primeiro parágrafo, e o artigo 43.º, n.º 2.

3.3. Princípios da subsidiariedade e da proporcionalidade

A proposta revê um regime de qualidade existente, estabelecido no âmbito da PAC. A produção e o comércio de produtos agrícolas e de géneros alimentícios no mercado da União Europeia e a garantia do bom funcionamento do mercado interno de produtos biológicos são matérias da competência partilhada entre a União e os Estados-Membros.

No âmbito global da PAC, a fim de garantir o desenvolvimento harmonioso do mercado único, é mais eficaz utilizar um regime de produção biológica à escala da União do que 28 regimes diferentes. Além disso, tal regime permite uma política comercial mais forte e coerente em relação aos parceiros comerciais mundiais, nomeadamente através do reforço do poder de negociação da União.

A proposta conduz a uma maior harmonização nos seguintes domínios:

- A atual margem oferecida aos Estados-Membros para a concessão de derrogações às regras, que conduz a uma concorrência desleal entre os operadores, ao risco de perda de confiança dos consumidores, à complexidade da legislação e a problemas comerciais (dificuldades para impor a conformidade), é reduzida.
- O facto de a resposta às mesmas situações de incumprimento da legislação em matéria de produção biológica poder variar entre os Estados-Membros conduz à concorrência desleal e ao funcionamento ineficaz do mercado único.

3.4. Escolha dos instrumentos

O instrumento proposto é um regulamento, uma vez que ficou comprovado que as disposições existentes proporcionam um quadro adequado para os Estados-Membros; nenhum outro tipo de medida seria adequado. Uma diretiva estabeleceria regras mais flexíveis, o que poderia conduzir a uma concorrência desleal entre os operadores e a confusão e engano dos consumidores. Um regulamento permite que os Estados-Membros adotem uma abordagem coerente e reduz os encargos administrativos, dado que os operadores são obrigados a cumprir um conjunto único de regras. Os instrumentos não vinculativos, tais como diretrizes, são considerados inadequados para colmatar as diferenças na interpretação e aplicação das regras e tendo em conta o contexto internacional.

4. INCIDÊNCIA ORÇAMENTAL

A proposta atribui um orçamento para medidas de assistência técnica. É possível consultar os detalhes da incidência orçamental na ficha financeira legislativa.

5. ELEMENTOS FACULTATIVOS: SIMPLIFICAÇÃO

A proposta prevê simplificações e clarificações e colmata várias lacunas na legislação. Implica a eliminação de 37 das 135 obrigações existentes na legislação em matéria de agricultura biológica. A

proposta implica ainda uma redução significativa dos encargos administrativos. Os atos delegados decorrentes da proposta serão elaborados de acordo com os mesmos princípios.

Relativamente às regras de produção, a proposta simplifica de forma significativa a vida dos operadores e das administrações nacionais, com uma limitação da margem dos Estados-Membros para a concessão de derrogações. São eliminadas várias disposições ineficazes, nomeadamente através do reforço da abordagem baseada no risco relativamente aos controlos. Do lado das importações, o regime de conformidade aplicável aos organismos de controlo será mais fácil de gerir para os produtores, os organismos de controlo e a Comissão.

A certificação de grupo traduz-se numa simplificação significativa para os pequenos agricultores, o que implica requisitos mais equilibrados relativamente à inspeção e manutenção de registos.

A proposta pretende facilitar a utilização da legislação. Em especial, embora as regras gerais de produção permaneçam no texto do regulamento, as regras específicas aplicáveis à produção biológica constam de um anexo do regulamento.

6. ADAPTAÇÃO

Em 2010, a Comissão adotou a COM(2010) 759 relativa à adaptação do Regulamento (CE) n.º 834/2007 do Conselho ao Tratado de Lisboa. Um debate detalhado nos trólogos de 2011 e 2012 levou, na prática, a um impasse na proposta de adaptação. A atual proposta incorpora os elementos necessários da proposta de adaptação, incluindo a arquitetura das disposições legais do ato de base, atos delegados e atos de execução. Por conseguinte, a COM(2010) 759 será retirada como obsoleta.

Proposta de

REGULAMENTO DO PARLAMENTO EUROPEU E DO CONSELHO

que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho [Regulamento relativo aos controlos oficiais] e que revoga o Regulamento (CE) n.º 834/2007 do Conselho

O PARLAMENTO EUROPEU E O CONSELHO DA UNIÃO EUROPEIA,

Tendo em conta o Tratado sobre o Funcionamento da União Europeia, nomeadamente o artigo 42.º, primeiro parágrafo, e o artigo 43.º, n.º 2,

Tendo em conta a proposta da Comissão Europeia,

Após transmissão do projeto de ato legislativo aos parlamentos nacionais,

Tendo em conta o parecer do Comité Económico e Social Europeu⁹,

Tendo em conta o parecer do Comité das Regiões¹⁰,

Deliberando de acordo com o processo legislativo ordinário,

Considerando o seguinte:

- (1) A produção biológica é um sistema global de gestão das explorações agrícolas e de produção de géneros alimentícios que combina as melhores práticas de atuação ambientais e climáticas, um elevado nível de biodiversidade, a preservação dos recursos naturais, a aplicação de normas exigentes em matéria de bem-estar dos animais e regras de produção em sintonia com a procura, por parte de um número crescente de consumidores, de produtos obtidos utilizando substâncias e processos naturais. A produção biológica desempenha, assim, um duplo papel societal, visto que, por um lado, abastece um mercado específico que responde à procura de produtos biológicos por parte dos consumidores e, por outro, fornece bens acessíveis ao público que contribuem para a proteção do ambiente e do bem-estar dos animais, bem como para o desenvolvimento rural.
- (2) A observância de normas elevadas em matéria de saúde, ambiente e bem-estar dos animais na produção de produtos biológicos é intrínseca à elevada qualidade destes produtos. Tal como sublinhado na Comunicação da Comissão ao Parlamento Europeu, ao Conselho, ao Comité Económico e Social Europeu e ao Comité das Regiões sobre a política de qualidade dos produtos agrícolas¹¹, a produção biológica faz, juntamente com as indicações geográficas, as especialidades tradicionais garantidas e os produtos das regiões ultraperiféricas da União, parte dos regimes de qualidade dos produtos agrícolas da União previstos no Regulamento (UE) n.º 1151/2012 do Parlamento

⁹ JO C [...] de [...], p. [...].

¹⁰ JO C [...] de [...], p. [...].

¹¹ COM(2009) 234 final.

Europeu e do Conselho¹² e no Regulamento (UE) n.º 228/2013 do Parlamento Europeu e do Conselho¹³, respetivamente. Neste sentido, a produção biológica tem os mesmos objetivos que a política agrícola comum («PAC»), que são inerentes a todos os regimes de qualidade dos produtos agrícolas da União.

- (3) Em especial, os objetivos da política de produção biológica estão integrados nos objetivos da PAC, garantindo que os agricultores recebem uma remuneração justa pelo cumprimento das regras de produção biológica. Além disso, a procura crescente de produtos biológicos por parte dos consumidores cria condições para o maior desenvolvimento e expansão do mercado dos produtos em causa e, por conseguinte, para um aumento da remuneração dos agricultores envolvidos na produção biológica.
- (4) A produção biológica é também um sistema que contribui para a integração dos requisitos de proteção ambiental na PAC e promove uma produção agrícola sustentável. Por esse motivo, foram introduzidas medidas que apoiam financeiramente a produção biológica no âmbito da PAC, mais recentemente ao abrigo do Regulamento (UE) n.º 1307/2013 do Parlamento Europeu e do Conselho¹⁴, tendo sido reforçadas, em especial, na recente reforma do quadro jurídico da política de desenvolvimento rural, nos termos do Regulamento (UE) n.º 1305/2013 do Parlamento Europeu e do Conselho¹⁵.
- (5) A produção biológica contribui também para alcançar os objetivos da política ambiental da União, principalmente os da estratégia de biodiversidade para 2020¹⁶, da comunicação relativa à infraestrutura verde¹⁷, da estratégia temática de proteção do solo¹⁸ e da legislação ambiental, como as Diretivas Aves¹⁹ e Habitats²⁰, a Diretiva Nitratos²¹, a Diretiva-Quadro Água²², a Diretiva relativa ao estabelecimento de

¹² Regulamento (UE) n.º 1151/2012 do Parlamento Europeu e do Conselho, de 21 de novembro de 2012, relativo aos regimes de qualidade dos produtos agrícolas e dos géneros alimentícios (JO L 343 de 14.12.2012, p. 1).

¹³ Regulamento (UE) n.º 228/2013 do Parlamento Europeu e do Conselho, de 13 de março de 2013, que estabelece medidas específicas no domínio da agricultura a favor das regiões ultraperiféricas da União e revoga o Regulamento (CE) n.º 247/2006 do Conselho (JO L 78 de 20.3.2013, p. 23).

¹⁴ Regulamento (UE) n.º 1307/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, que estabelece regras para os pagamentos diretos aos agricultores ao abrigo de regimes de apoio no âmbito da política agrícola comum e que revoga o Regulamento (CE) n.º 637/2008 do Conselho e o Regulamento (CE) n.º 73/2009 do Conselho (JO L 347 de 20.12.2013, p. 608).

¹⁵ Regulamento (UE) n.º 1305/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) e que revoga o Regulamento n.º 1698/2005 do Conselho (JO L 347 de 20.12.2013, p. 487).

¹⁶ COM(2011) 244 final, «O nosso seguro de vida, o nosso capital natural: Estratégia da União Europeia em matéria de biodiversidade até 2020».

¹⁷ SWD(2013) 155 final, «Infraestrutura verde — Valorizar o capital natural da Europa».

¹⁸ COM(2006) 231 final, «Estratégia temática de proteção do solo».

¹⁹ Diretiva 2009/147/CE do Parlamento Europeu e do Conselho, de 30 de novembro de 2009, relativa à conservação das aves selvagens (JO L 20 de 26.1.2010, p. 7).

²⁰ Diretiva 92/43/CEE do Conselho, de 21 de maio de 1992, relativa à preservação dos habitats naturais e da fauna e da flora selvagens (JO L 206 de 22.7.1992, p. 7).

²¹ Diretiva 91/676/CEE do Conselho, de 12 de dezembro de 1991, relativa à proteção das águas contra a poluição causada por nitratos de origem agrícola (JO L 375 de 31.12.1991, p. 1).

²² Diretiva 2000/60/CE do Parlamento Europeu e do Conselho, de 23 de outubro de 2000, que estabelece um quadro de ação comunitária no domínio da política da água (JO L 327 de 22.12.2000, p. 1).

valores-limite nacionais de emissão²³ e a Diretiva relativa à utilização sustentável dos pesticidas²⁴.

- (6) Tendo em conta os objetivos da política de produção biológica da União, o quadro jurídico estabelecido para a implementação da referida política deve perseguir o objetivo de garantir uma concorrência leal e o funcionamento adequado do mercado interno dos produtos biológicos, bem como o de manter e justificar a confiança dos consumidores nos produtos rotulados como tal. Além disso, deve procurar criar condições que possibilitem o desenvolvimento da política em sintonia com a evolução da produção e do mercado.
- (7) As prioridades políticas da estratégia Europa 2020, estabelecidas na Comunicação da Comissão intitulada «Europa 2020: Estratégia para um crescimento inteligente, sustentável e inclusivo»²⁵, incluem como objetivos o estabelecimento de uma economia competitiva baseada no conhecimento e na inovação, o fomento de uma economia com níveis elevados de emprego que assegure a coesão social e territorial, bem como o apoio da transição para uma economia hipocarbónica e eficiente em termos de recursos. Por conseguinte, a política de produção biológica deve facultar aos operadores os instrumentos adequados para uma melhor identificação e promoção dos seus produtos, protegendo-os simultaneamente contra práticas desleais.
- (8) Atendendo à evolução dinâmica do setor biológico, o Regulamento (CE) n.º 834/2007 do Conselho²⁶ identificou a necessidade de uma futura revisão das regras da União em matéria de produção biológica, tendo em conta a experiência adquirida com a aplicação dessas regras. Os resultados da referida revisão efetuada pela Comissão revelam que o quadro jurídico da União que rege a produção biológica deve ser melhorado no sentido de prever regras que correspondam às elevadas expectativas dos consumidores e que garantam uma clareza suficiente para os seus destinatários. Por conseguinte, o Regulamento (CE) n.º 834/2007 deve ser revogado e substituído por um novo regulamento.
- (9) A experiência adquirida até à data com a aplicação do Regulamento (CE) n.º 834/2007 mostra a necessidade de clarificar os produtos a que o presente regulamento se aplica. Essencialmente, deve abranger os produtos agrícolas, incluindo os produtos da aquicultura, enumerados no anexo I do Tratado sobre o Funcionamento da União Europeia («Tratado»). Além disso, deve abranger os produtos agrícolas transformados destinados a serem utilizados como géneros alimentícios ou alimentos para animais, uma vez que a colocação no mercado de tais produtos como biológicos constitui uma importante via de escoamento dos produtos agrícolas e assegura a visibilidade, junto do consumidor, da natureza biológica dos produtos agrícolas a partir dos quais são transformados. Do mesmo modo, o presente regulamento deve abranger outros produtos específicos que, de forma semelhante ao que acontece com os produtos agrícolas transformados, estão estreitamente ligados a produtos agrícolas, uma vez que

²³ Diretiva 2001/81/CE do Parlamento Europeu e do Conselho, de 23 de outubro de 2001, relativa ao estabelecimento de valores-limite nacionais de emissão de determinados poluentes atmosféricos (JO L 309 de 27.11.2001, p. 22).

²⁴ Diretiva 2009/128/CE do Parlamento Europeu e do Conselho, de 21 de outubro de 2009, que estabelece um quadro de ação a nível comunitário para uma utilização sustentável dos pesticidas (JO L 309 de 24.11.2009, p. 71).

²⁵ COM(2010) 2020 final.

²⁶ Regulamento (CE) n.º 834/2007 do Conselho, de 28 de junho de 2007, relativo à produção biológica e à rotulagem dos produtos biológicos e que revoga o Regulamento (CEE) n.º 2092/91 (JO L 189 de 20.7.2007, p. 1).

os produtos em questão constituem uma importante via de escoamento dos produtos agrícolas ou fazem parte integrante do processo de produção. Por último, o sal marinho deve ser incluído no âmbito de aplicação do presente regulamento, uma vez que é produzido mediante a aplicação de técnicas de produção naturais e a sua produção contribui para o desenvolvimento das zonas rurais, enquadrando-se assim nos objetivos do presente regulamento. Por razões de clareza, esses outros produtos, não enumerados no anexo I do Tratado, devem ser enumerados num anexo do presente regulamento.

- (10) A fim de completar ou alterar certos elementos não essenciais do presente regulamento, o poder de adotar atos nos termos do artigo 290.º do Tratado deve ser delegado na Comissão. É particularmente importante que a Comissão proceda às consultas adequadas durante os trabalhos preparatórios, inclusive ao nível de peritos. Ao preparar e redigir atos delegados, a Comissão deve assegurar a transmissão simultânea, atempada e adequada dos documentos relevantes ao Parlamento Europeu e ao Conselho.
- (11) A fim de contemplar novos métodos ou materiais de produção ou compromissos internacionais, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito à alteração da lista dos outros produtos abrangidos pelo âmbito de aplicação do presente regulamento. Apenas os produtos que estão estreitamente ligados a produtos agrícolas devem ser elegíveis para inclusão nessa lista.
- (12) Devido à natureza local das operações de restauração coletiva, as medidas tomadas pelos Estados-Membros e os regimes privados neste domínio são considerados adequados para garantir o funcionamento do mercado único. Por conseguinte, os géneros alimentícios preparados por estabelecimentos de restauração coletiva nas suas instalações não devem ser abrangidos pelo presente regulamento. De igual modo, os produtos da caça e da pesca de animais selvagens não devem ser abrangidos pelo presente regulamento, uma vez que não é possível controlar totalmente o processo de produção.
- (13) Os projetos de investigação demonstraram que a confiança dos consumidores é fundamental no mercado de géneros alimentícios biológicos. A longo prazo, as regras que não são fiáveis podem comprometer a confiança do público e conduzir a deficiências de mercado. Por conseguinte, o desenvolvimento sustentável da produção biológica na União deve basear-se em regras de produção sólidas e harmonizadas a nível da União. Além disso, as referidas regras de produção devem corresponder às expectativas dos operadores e consumidores no que diz respeito à qualidade dos produtos biológicos e ao cumprimento dos princípios e regras estabelecidos no presente regulamento.
- (14) O presente regulamento deve aplicar-se sem prejuízo da legislação conexa, nomeadamente no domínio da segurança da cadeia alimentar, saúde e bem-estar dos animais, fitossanidade, material de reprodução vegetal, rotulagem e ambiente. Mais especificamente, no que respeita à autorização dos produtos e substâncias que podem ser utilizados na produção de produtos biológicos, é importante salientar que esses produtos e substâncias devem ser autorizados, antes de mais, a nível da União. Por conseguinte, o presente regulamento deve ser aplicável sem prejuízo de outras disposições específicas da União relativas à autorização e colocação no mercado dos produtos e substâncias em questão.
- (15) Por uma questão de princípio, as regras gerais de produção previstas no presente regulamento devem incluir uma proibição de utilização de radiações ionizantes e de

organismos geneticamente modificados (OGM), assim como de produtos obtidos a partir de OGM ou mediante OGM. Dado que os consumidores estão cada vez mais preocupados com o impacto ambiental da transformação e do transporte dos géneros alimentícios, os operadores biológicos não agricultores e os operadores que produzem algas marinhas ou animais de aquicultura devem ser obrigados a gerir o seu desempenho ambiental segundo um sistema harmonizado. Com o objetivo de minimizar os encargos regulamentares das microempresas, conforme definidas na Recomendação 2003/361/CE da Comissão²⁷, envolvidas na produção biológica, é conveniente isentá-las deste requisito. A fim de assegurar a aplicação correta das regras gerais de produção, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento dos critérios aos quais o sistema de gestão ambiental deve corresponder.

- (16) O risco de incumprimento das regras de produção biológica é considerado mais elevado nas explorações agrícolas que incluem unidades não geridas segundo métodos de produção biológica. Por conseguinte, após um período de conversão adequado, todas as explorações agrícolas da União que pretendem tornar-se biológicas devem ser inteiramente geridas em conformidade com os requisitos aplicáveis à produção biológica. As explorações agrícolas biológicas devem ser submetidas ao mesmo período de conversão em todos os Estados-Membros, independentemente de terem ou não aderido previamente a medidas agroambientais apoiadas por fundos da União. No caso das terras em pousio, nenhum período de conversão é necessário. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que completem as regras gerais de conversão ou que completem e alterem as regras específicas de conversão.
- (17) Devem estabelecer-se regras específicas de produção no que se refere à produção vegetal, animal e aquícola, nas quais se incluem regras aplicáveis à colheita de plantas selvagens e de algas marinhas, e relativamente à produção de alimentos para animais e géneros alimentícios transformados, bem como de vinho e leveduras, de forma a garantir a harmonização e o cumprimento dos objetivos e princípios da produção biológica.
- (18) Como a produção vegetal biológica é baseada na alimentação dos vegetais essencialmente através do ecossistema dos solos, a produção hidropónica não deve ser permitida. Além disso, a produção vegetal biológica deve envolver a utilização de técnicas de produção que impeçam ou minimizem eventuais contribuições para a contaminação do ambiente.
- (19) Em matéria de gestão e fertilização dos solos, devem estabelecer-se condições para a utilização de práticas de cultivo autorizadas na produção vegetal biológica e para a utilização de fertilizantes e corretivos.
- (20) A utilização de pesticidas deve ser fortemente restringida. Deve ser dada preferência à aplicação de medidas que impeçam quaisquer danos provocados por pragas e infestantes através de técnicas que não impliquem a utilização de produtos fitofarmacêuticos, como é o caso da rotação das culturas. A presença de pragas e infestantes deve ser objeto de acompanhamento, a fim de decidir se existem fundamentos económicos e ecológicos para eventuais intervenções. A utilização de

²⁷ Recomendação 2003/361/CE da Comissão, de 6 de maio de 2003, relativa à definição de micro, pequenas e médias empresas (JO L 124 de 20.5.2003, p. 36).

determinados produtos fitofarmacêuticos deve ser permitida caso as técnicas em questão não garantam uma proteção adequada e apenas se os produtos fitofarmacêuticos tiverem sido autorizados em conformidade com o Regulamento (CE) n.º 1107/2009 do Parlamento Europeu e do Conselho²⁸, após terem sido avaliados como compatíveis com os objetivos e princípios da produção biológica, inclusive com as condições restritivas de utilização, e, consequentemente, autorizados em conformidade com o presente regulamento.

- (21) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção vegetal, no que se refere às práticas de cultivo, gestão e fertilização dos solos, fitossanidade e gestão de pragas e infestantes, gestão da produção de cogumelos e outros vegetais específicos e de sistemas de produção vegetal, origem da produção do material de reprodução vegetal e colheita de plantas selvagens.
- (22) Uma vez que a produção animal envolve naturalmente a gestão de terras agrícolas, nas quais o estrume é utilizado para a fertilização das culturas, a produção animal sem terra deve ser proibida. A escolha das raças deve ter em conta a capacidade de adaptação dos animais às condições locais, a sua vitalidade e a sua resistência às doenças, devendo ser encorajada uma ampla diversidade biológica.
- (23) O alojamento da produção biológica animal e aquícola, incluindo, se for caso disso, o meio aquático, deve satisfazer as necessidades comportamentais dos animais. Devem ser estabelecidas condições de alojamento e práticas de criação específicas relativamente a certos animais, nos quais se incluem as abelhas. As referidas condições e práticas devem assegurar um elevado nível de bem-estar dos animais, devendo, em certos aspetos, ir além das normas da União relativas ao bem-estar dos animais aplicáveis à produção animal em geral. Na maioria dos casos, os animais devem dispor de acesso permanente a áreas ao ar livre para pastoreio, devendo essas áreas ao ar livre ser, em princípio, submetidas a um sistema de rotação adequado.
- (24) Para evitar a poluição ambiental de recursos naturais, tais como o solo e a água, por nutrientes, deve ser estabelecido um limite máximo para o estrume a utilizar por hectare e para o encabeçamento por hectare. Esse limite deve estar relacionado com o teor de azoto do estrume.
- (25) Devem ser proibidas as mutilações que causem stresse, ferimentos, doenças ou o sofrimento dos animais.
- (26) Os animais devem ser alimentados com matérias-primas para alimentação animal produzidas segundo as regras de produção biológica, preferivelmente provenientes da própria exploração, e adaptadas às suas necessidades fisiológicas. Além disso, a fim de assegurar os requisitos nutricionais básicos dos animais, podem ter de ser utilizados, em condições bem definidas, certos minerais, oligoelementos e vitaminas.
- (27) A gestão da saúde animal deve basear-se essencialmente na prevenção das doenças. Além disso, devem aplicar-se medidas específicas de limpeza e desinfeção. A utilização preventiva de medicamentos alopáticos de síntese química não deve ser permitida na produção biológica, salvo em caso de doença ou lesão de um animal que

²⁸ Regulamento (CE) n.º 1107/2009 do Parlamento Europeu e do Conselho, de 21 de outubro de 2009, relativo à colocação dos produtos fitofarmacêuticos no mercado e que revoga as Diretivas 79/117/CEE e 91/414/CEE do Conselho (JO L 309 de 24.11.2009, p. 1).

exija tratamento imediato e limitada ao mínimo necessário para restabelecer o bem-estar do animal. Em tais casos, para garantir aos consumidores a integridade da produção biológica, deve ser possível adotar medidas restritivas, tais como a imposição do dobro do intervalo de segurança oficial após a utilização desses medicamentos, conforme especificado na legislação aplicável da União. No caso da apicultura, é necessário estabelecer regras específicas relativas à prevenção de doenças e ao tratamento veterinário.

- (28) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção animal, no que se refere à origem dos animais, alojamento dos animais, incluindo as superfícies mínimas das áreas interiores e exteriores e o número máximo de animais por hectare, práticas de criação, reprodução, alimentos para animais e alimentação, prevenção de doenças e tratamento veterinário.
- (29) O presente regulamento reflete os objetivos da nova política comum das pescas no que se refere à aquicultura, que desempenha um papel fundamental na garantia da segurança alimentar sustentável a longo prazo, bem como do crescimento e do emprego, reduzindo simultaneamente a pressão sobre as unidades populacionais de peixes selvagens, num contexto de procura global crescente de alimentos de origem aquática. A Comunicação de 2013 da Comissão ao Conselho e ao Parlamento Europeu intitulada «Orientações estratégicas para o desenvolvimento sustentável na aquicultura na UE»²⁹ destaca os principais desafios enfrentados pela aquicultura da União e o seu potencial de crescimento. Identifica a aquicultura biológica como um setor particularmente promissor e sublinha as vantagens competitivas decorrentes da certificação biológica.
- (30) Em relação à agricultura biológica, da qual existe já grande experiência a nível da exploração, a aquicultura biológica é um setor relativamente recente da produção biológica. Dado o interesse crescente dos consumidores pelos produtos da aquicultura biológica, é provável que o número de unidades aquícolas que se convertem em unidades de produção biológica continue a aumentar. Isto conduz a um aumento da experiência, dos conhecimentos técnicos e do desenvolvimento, resultando em melhorias ao nível da aquicultura biológica que se deveriam refletir nas regras de produção.
- (31) A fim de garantir uma compreensão comum, evitar ambiguidades e garantir a aplicação uniforme das regras no que respeita à produção aquícola biológica de animais e de algas marinhas, as referidas regras de produção devem ser acompanhadas de determinadas definições relativas à aquicultura.
- (32) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção de algas marinhas, no que se refere à adequação do meio aquático e do plano de gestão sustentável, colheita de algas marinhas selvagens, cultura de algas marinhas, e medidas de tratamento antivegetativo e limpeza dos equipamentos e instalações de produção, e no que diz respeito ao estabelecimento de regras que completem as regras específicas de produção de animais de aquicultura, no que se refere à adequação do

²⁹ COM(2013) 229 de 29.4.2013.

meio aquático e do plano de gestão sustentável, origem dos animais de aquicultura, criação de animais de aquicultura, incluindo os sistemas de confinamento aquático, os sistemas de produção e a densidade máxima de animais, reprodução, gestão dos animais de aquicultura, alimentos para animais e alimentação dos animais, prevenção de doenças e tratamento veterinário.

- (33) Os operadores que produzem alimentos para animais ou géneros alimentícios biológicos devem seguir os procedimentos adequados, baseados na identificação sistemática das fases críticas de transformação, a fim de garantir que os produtos transformados obedçam às regras de produção biológica. Os produtos biológicos transformados devem ser obtidos através de métodos de transformação que garantam a manutenção da integridade biológica e das qualidades essenciais dos produtos ao longo de todas as fases da produção biológica.
- (34) Devem ser estabelecidas disposições relativas à composição dos géneros alimentícios biológicos transformados. Em especial, os géneros alimentícios em questão devem ser produzidos sobretudo a partir de ingredientes agrícolas biológicos, com a possibilidade limitada de utilizar determinados ingredientes agrícolas não biológicos especificados no presente regulamento. Além disso, apenas deve ser permitida na produção de géneros alimentícios biológicos transformados a utilização de determinadas substâncias autorizadas em conformidade com o presente regulamento.
- (35) Os géneros alimentícios transformados só devem ser rotulados como biológicos se todos ou quase todos os ingredientes de origem agrícola forem biológicos. Todavia, devem ser previstas disposições especiais de rotulagem para os géneros alimentícios transformados que incluam ingredientes agrícolas que não possam ser obtidos biologicamente, como os produtos da caça e da pesca. Além disso, para efeitos de informação dos consumidores e para a transparência do mercado, bem como para encorajar a utilização de ingredientes biológicos, também deve ser possível, sob determinadas condições, fazer referência à produção biológica na lista dos ingredientes.
- (36) Devem ser estabelecidas disposições relativas à composição dos alimentos biológicos transformados para animais e à utilização de determinadas substâncias e técnicas na produção dos referidos alimentos para animais.
- (37) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção de alimentos para animais e géneros alimentícios transformados, no que se refere aos procedimentos a seguir, medidas preventivas a tomar, composição dos alimentos para animais e géneros alimentícios transformados, medidas de limpeza, colocação no mercado de produtos transformados, incluindo a respetiva rotulagem e identificação, separação dos produtos, ingredientes agrícolas e matérias-primas para alimentação animal biológicos dos produtos, ingredientes agrícolas e matérias-primas para alimentação animal não biológicos, lista dos ingredientes agrícolas não biológicos que podem, a título excepcional, ser utilizados para a produção de produtos biológicos transformados, cálculo da percentagem de ingredientes agrícolas e técnicas utilizadas na transformação de géneros alimentícios ou alimentos para animais.
- (38) O vinho biológico deve ser inteiramente produzido a partir de matérias-primas biológicas e apenas deve ser permitido adicionar determinadas substâncias autorizadas em conformidade com o presente regulamento. Certas práticas, processos e

tratamentos enológicos devem ser proibidos na produção de vinho biológico. Outras práticas, processos e tratamentos devem ser permitidos em condições bem definidas.

- (39) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção de vinho, no que se refere às práticas e restrições enológicas.
- (40) Inicialmente, as leveduras não eram consideradas ingredientes agrícolas nos termos do Regulamento (CE) n.º 834/2007 e, por conseguinte, não contavam para a composição agrícola de produtos biológicos. No entanto, o Regulamento (CE) n.º 889/2008 da Comissão³⁰ introduziu a obrigatoriedade do cálculo das leveduras e produtos à base de leveduras como ingredientes agrícolas para efeitos de produção biológica a partir de 31 de dezembro de 2013, o que deu à indústria tempo suficiente para se adaptar a essa regra. Assim, só devem ser utilizados na produção de leveduras biológicas substratos obtidos biologicamente e apenas determinadas substâncias devem ser autorizadas para utilização na sua produção, preparação e formulação. Além disso, os alimentos para animais e os géneros alimentícios biológicos não podem conter simultaneamente leveduras biológicas e leveduras não biológicas.
- (41) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas de produção de leveduras biológicas, no que se refere à transformação e aos substratos utilizados na sua produção.
- (42) A fim de contemplar qualquer necessidade futura de dispor de regras específicas de produção de produtos cuja produção não se enquadre em qualquer uma das categorias de regras específicas de produção estabelecidas no presente regulamento, bem como a fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento e, subsequentemente, a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras específicas de produção dos produtos em questão, incluindo alterações ou complementos das mesmas.
- (43) O Regulamento (CE) n.º 834/2007 previa várias derrogações às regras de produção biológica. A experiência adquirida com a aplicação das referidas disposições demonstrou que essas derrogações têm um impacto negativo na produção biológica. Em especial, verificou-se que a própria existência das referidas derrogações impede a produção de fatores de produção biológicos e que o elevado nível de bem-estar dos animais associado à produção biológica não é assegurado. Além disso, a gestão e o controlo das derrogações implicam encargos administrativos consideráveis, tanto para as administrações nacionais como para os operadores. Por último, a existência de derrogações criou condições para a ocorrência de distorções da concorrência e ameaçou comprometer a confiança dos consumidores. Assim, a margem para autorizar derrogações das regras de produção biológica deve ser mais restrita e limitada a casos de circunstâncias catastróficas.

³⁰ Regulamento (CE) n.º 889/2008 da Comissão, de 5 de setembro de 2008, que estabelece normas de execução do Regulamento (CE) n.º 834/2007 do Conselho relativo à produção biológica e à rotulagem dos produtos biológicos, no que respeita à produção biológica, à rotulagem e ao controlo (JO L 250 de 18.9.2008, p. 1).

- (44) A fim de permitir que a produção biológica continue ou recomece em caso de circunstâncias catastróficas, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento dos critérios de qualificação de casos de circunstâncias catastróficas e de regras específicas para a abordagem dos casos em questão e para os requisitos necessários de acompanhamento e comunicação.
- (45) Em certas condições, os produtos biológicos e não biológicos podem ser recolhidos e transportados simultaneamente. Para separar devidamente os produtos biológicos dos não biológicos durante o manuseamento e evitar qualquer mistura, devem estabelecer-se disposições específicas.
- (46) A fim de garantir a integridade da produção biológica e a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras que alterem ou completem as regras específicas aplicáveis à recolha, embalagem, transporte e armazenagem de produtos biológicos.
- (47) A utilização na produção biológica de produtos e substâncias tais como produtos fitofarmacêuticos, fertilizantes, corretivos dos solos, nutrientes, componentes da alimentação animal, aditivos alimentares ou para a alimentação animal, auxiliares tecnológicos e produtos de limpeza e desinfeção deve ser limitada ao mínimo e respeitar as condições específicas estabelecidas no presente regulamento. Deve seguir-se a mesma abordagem no que respeita à utilização de produtos e substâncias tais como aditivos alimentares e auxiliares tecnológicos na produção de géneros alimentícios biológicos transformados. Por conseguinte, devem ser estabelecidas disposições para definir qualquer utilização possível dos produtos e substâncias em questão na produção biológica em geral e, mais especificamente, na produção de géneros alimentícios biológicos transformados, de acordo com os princípios estabelecidos no presente regulamento e com determinados critérios.
- (48) A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica em geral e, mais especificamente, à produção de géneros alimentícios biológicos transformados, assim como a adaptação ao progresso técnico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de critérios suplementares para a concessão ou a retirada da autorização relativa a produtos e substâncias a utilizar na produção biológica em geral e, mais especificamente, na produção de géneros alimentícios biológicos transformados, bem como de outros requisitos para a utilização de tais produtos e substâncias autorizados.
- (49) Na ausência de regras específicas da União sobre as medidas a tomar em caso de presença de substâncias ou produtos não autorizados em produtos biológicos, foram desenvolvidas e aplicadas diferentes abordagens em toda a União. Esta situação cria incertezas para os operadores, autoridades de controlo e organismos de controlo. Pode implicar também um tratamento diferente dos operadores da União e afetar a confiança dos consumidores nos produtos biológicos. Por conseguinte, convém estabelecer disposições claras e uniformes para proibir a comercialização, como biológicos, de produtos nos quais quaisquer produtos ou substâncias não autorizados estejam presentes em níveis superiores aos especificados. Os referidos níveis devem ser estabelecidos tendo em conta, nomeadamente, a Diretiva 2006/125/CE da

Comissão³¹ relativa aos alimentos à base de cereais e aos alimentos para bebés destinados a lactentes e crianças jovens.

- (50) A fim de assegurar a eficácia, a eficiência e a transparência do sistema de produção e rotulagem biológicas, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito aos critérios e condições específicos para o estabelecimento e a aplicação dos níveis de presença de produtos e substâncias não autorizados para além dos quais os produtos não devem ser comercializados como biológicos, bem como no que diz respeito ao estabelecimento dos referidos níveis e à sua adaptação à luz do progresso técnico.
- (51) A produção biológica baseia-se no princípio geral de restrição da utilização de fatores de produção externos. Os agricultores devem tomar medidas no sentido de evitar o risco de contaminação por produtos ou substâncias não autorizados. Não obstante essas medidas, podem ocorrer situações em que os agricultores fiquem impedidos de comercializar os seus produtos agrícolas como biológicos devido à presença não intencional de produtos ou substâncias não autorizados. É, pois, adequado prever a possibilidade de os Estados-Membros poderem, em conformidade com o artigo 42.º do Tratado, ser autorizados pela Comissão a conceder pagamentos nacionais para compensar as perdas decorrentes dessas situações. Os Estados-Membros também podem recorrer aos instrumentos da política agrícola comum para cobrir, total ou parcialmente, essas perdas.
- (52) A rotulagem dos produtos agrícolas e dos géneros alimentícios deve estar sujeita às regras gerais estabelecidas no Regulamento (UE) n.º 1169/2011 do Parlamento Europeu e do Conselho³² e, em particular, às disposições destinadas a evitar rotulagens suscetíveis de confundir os consumidores ou de os induzir em erro. Além disso, devem ser estabelecidas no presente regulamento disposições específicas relativas à rotulagem dos produtos biológicos. Estas devem proteger simultaneamente os interesses dos operadores, no sentido de terem os seus produtos corretamente identificados no mercado e de beneficiarem de condições de concorrência leal, e os interesses dos consumidores, para permitir que façam escolhas informadas.
- (53) Assim, os termos utilizados para indicar os produtos biológicos devem ser protegidos contra a sua utilização na rotulagem de produtos não biológicos, em toda a União e independentemente do idioma utilizado. É conveniente que essa proteção seja igualmente aplicável aos derivados ou abreviaturas habituais desses termos, utilizados isoladamente ou combinados.
- (54) Num intuito de clareza para os consumidores em todo o mercado da União, a utilização do logótipo de produção biológica da União Europeia deve ser obrigatória para todos os géneros alimentícios biológicos pré-embalados produzidos na União. Por outro lado, deve ser possível utilizar voluntariamente o logótipo em questão no caso de produtos biológicos não pré-embalados produzidos na União ou de produtos biológicos importados de países terceiros. O modelo do logótipo de produção biológica da União Europeia deve ser definido no presente regulamento.

³¹ Diretiva 2006/125/CE da Comissão, de 5 de dezembro de 2006, relativa aos alimentos à base de cereais e aos alimentos para bebés destinados a lactentes e crianças jovens (JO L 339 de 6.12.2006, p. 16).

³² Regulamento (UE) n.º 1169/2011 do Parlamento Europeu e do Conselho, de 25 de outubro de 2011, relativo à prestação de informação aos consumidores sobre os géneros alimentícios, que altera os Regulamentos (CE) n.º 1924/2006 e (CE) n.º 1925/2006 do Parlamento Europeu e do Conselho e revoga as Diretivas 87/250/CEE da Comissão, 90/496/CEE do Conselho, 1999/10/CE da Comissão, 2000/13/CE do Parlamento Europeu e do Conselho, 2002/67/CE e 2008/5/CE da Comissão e o Regulamento (CE) n.º 608/2004 da Comissão (JO L 304 de 22.11.2011, p. 18).–

- (55) Contudo, a fim de não induzir os consumidores em erro quanto ao carácter biológico da totalidade do produto, é conveniente limitar a utilização do referido logótipo aos produtos que contenham exclusivamente, ou quase exclusivamente, ingredientes biológicos. Por conseguinte, não deve ser permitido utilizar o logótipo na rotulagem de produtos provenientes de explorações em conversão ou de produtos transformados nos quais menos de 95 % dos ingredientes de origem agrícola sejam biológicos.
- (56) A fim de evitar qualquer eventual confusão para os consumidores sobre se um produto é ou não originário da União, sempre que se utilize o logótipo de produção biológica da União Europeia, os consumidores devem ser informados do local onde foram produzidas as matérias-primas agrícolas de que é composto o produto. Neste contexto, em vez de se referir à agricultura, deve ser permitido mencionar a aquicultura no rótulo dos produtos provenientes da aquicultura biológica.
- (57) A fim de assegurar a clareza para os consumidores e garantir a comunicação das informações adequadas aos mesmos, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito à adaptação da lista de termos referentes à produção biológica prevista no presente regulamento, à determinação dos requisitos específicos em matéria de rotulagem e composição aplicáveis aos alimentos para animais e respetivos ingredientes, ao estabelecimento de novas regras sobre a rotulagem e a utilização das indicações além do logótipo de produção biológica da União Europeia, definido no presente regulamento, e à alteração do logótipo de produção biológica da União Europeia, bem como das regras correspondentes.
- (58) A produção biológica só é credível se for acompanhada de verificações e controlos eficazes em todas as fases de produção, transformação e distribuição. A produção biológica deve ser submetida a controlos oficiais ou outras atividades oficiais efetuadas em conformidade com o Regulamento (UE) n.º (XXX/XXXX) do Parlamento Europeu e do Conselho³³, a fim de verificar a sua conformidade com as regras em matéria de produção biológica e rotulagem dos produtos biológicos.
- (59) Devem ser estabelecidos requisitos específicos para garantir o cumprimento das regras aplicáveis à produção biológica. Em especial, devem ser adotadas disposições relativas à notificação das atividades dos operadores e a um sistema de certificação para identificar os operadores que cumprem as regras relativas à produção biológica e à rotulagem dos produtos biológicos. As referidas disposições devem também aplicar-se a quaisquer subcontratantes dos operadores em causa. A transparência do sistema de certificação deve ser garantida através da obrigatoriedade de os Estados-Membros tornarem pública a lista dos operadores que notificaram as suas atividades, bem como quaisquer taxas que possam ser cobradas em relação aos controlos de verificação do cumprimento das regras de produção biológica.
- (60) Os pequenos agricultores na União enfrentam, a nível individual, despesas de inspeção e encargos administrativos relativamente elevados associados à certificação biológica.

³³ Regulamento (UE) n.º XX/XXX do Parlamento Europeu e do Conselho, de [...], relativo aos controlos oficiais e outras atividades oficiais que visam assegurar a aplicação da legislação em matéria de alimentos para consumo humano e animal e das regras sobre saúde e bem-estar animal, fitossanidade, material de reprodução vegetal e produtos fitofarmacêuticos e que altera os Regulamentos (CE) n.º 999/2001, (CE) n.º 1829/2003, (CE) n.º 1831/2003, (CE) n.º 1/2005, (CE) n.º 396/2005, (CE) n.º 834/2007, (CE) n.º 1099/2009, (CE) n.º 1069/2009, (CE) n.º 1107/2009, (UE) n.º 1151/2012 e (UE) n.º [...]/2013 [Serviço das Publicações: inserir número do regulamento que estabelece disposições para a gestão das despesas relacionadas com a cadeia alimentar, a saúde e o bem-estar animal, a fitossanidade e o material de reprodução vegetal] e as Diretivas 98/58/CE, 1999/74/CE, 2007/43/CE, 2008/119/CE, 2008/120/CE e 2009/128/CE (Regulamento relativo aos controlos oficiais) (JO L ...).

Deve ser autorizado um sistema de certificação de grupo com vista a reduzir as despesas de inspeção e certificação e os respetivos encargos administrativos, reforçar as redes locais, contribuir para um melhor escoamento no mercado e assegurar condições equitativas de concorrência com os operadores de países terceiros. Por essa razão, o conceito de «grupo de operadores» deve ser introduzido e definido.

- (61) A fim de assegurar a eficácia, a eficiência e a transparência do sistema de produção e rotulagem biológicas, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito aos requisitos para a manutenção de registos pelos operadores ou grupos de operadores, aos requisitos para a publicação da lista de operadores, aos requisitos e procedimentos a aplicar para a publicação das taxas que podem ser cobradas em relação aos controlos de verificação do cumprimento das regras de produção biológica e para a supervisão, por parte das autoridades competentes, da aplicação das referidas taxas, bem como aos critérios de definição dos grupos de produtos para os quais os operadores devem ter direito a receber apenas um certificado biológico emitido pela autoridade ou organismo de controlo em questão.
- (62) A fim de assegurar que a certificação de um grupo de operadores decorre de forma eficaz e eficiente, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito às responsabilidades dos membros individuais de um grupo de operadores, à composição e ao tamanho do grupo em questão, às categorias de produtos que serão produzidos por um grupo de operadores, às condições de participação no grupo, bem como à criação e ao funcionamento do sistema de controlos internos do grupo, incluindo o âmbito, o conteúdo e a frequência dos controlos a efetuar.
- (63) A experiência com as disposições relativas à importação de produtos biológicos para a União no âmbito do Regulamento (CE) n.º 834/2007 demonstrou que é necessário rever as referidas disposições, a fim de responder às expectativas dos consumidores de que os produtos biológicos importados satisfaçam regras tão elevadas quanto as da União, bem como para melhor garantir o acesso dos produtos biológicos da União ao mercado internacional. Além disso, é necessário esclarecer as regras aplicáveis no que diz respeito à exportação de produtos biológicos, nomeadamente através da criação de um certificado de exportação e do estabelecimento de disposições para a exportação para países terceiros reconhecidos para efeitos de equivalência nos termos do Regulamento (CE) n.º 834/2007.
- (64) As disposições que regem a importação de produtos em conformidade com as regras de produção e rotulagem da União, e em relação às quais os operadores têm sido submetidos ao controlo por parte das autoridades e organismos de controlo reconhecidos pela Comissão como competentes para a realização de controlos e certificação no domínio da produção biológica nos países terceiros, devem ser mais reforçadas. Em especial, devem estabelecer-se requisitos relativos aos organismos de acreditação que acreditam organismos de controlo para efeitos de importação para a União de produtos biológicos conformes, com vista a garantir condições equitativas para a supervisão dos organismos de controlo por parte da Comissão. Além disso, é necessário prever a possibilidade de a Comissão contactar diretamente os organismos de acreditação e as autoridades competentes de países terceiros a fim de tornar mais eficiente a supervisão das autoridades de controlo e dos organismos de controlo, respetivamente.
- (65) Deve manter-se a possibilidade de os produtos biológicos obterem acesso ao mercado da União, nos casos em que esses produtos não cumpram as regras da União em

matéria de produção biológica, mas provenham de países terceiros cujos sistemas de produção biológica e de controlo tenham sido reconhecidos como equivalentes aos da União. Contudo, o reconhecimento da equivalência de países terceiros, tal como estabelecido no Regulamento (CE) n.º 834/2007, apenas deve ser concedido através de um acordo internacional entre a União e os países terceiros em questão, situação na qual também seria promovido um reconhecimento recíproco da equivalência para a União.

- (66) Os países terceiros reconhecidos para efeitos de equivalência nos termos do Regulamento (CE) n.º 834/2007 devem continuar a ser reconhecidos como tal no âmbito do presente regulamento, durante um período de tempo limitado necessário para garantir uma transição harmoniosa para o regime de reconhecimento através de um acordo internacional, desde que continuem a garantir a equivalência das suas regras de produção biológica e de controlo com as regras relevantes da União em vigor e cumpram todos os requisitos relacionados com a supervisão do seu reconhecimento por parte da Comissão. A referida supervisão deve basear-se, em particular, nos relatórios anuais que os países terceiros enviam à Comissão.
- (67) A experiência com o regime das autoridades e organismos de controlo reconhecidos como competentes para executar controlos e emitir certificados em países terceiros para efeitos de importação de produtos que oferecem garantias equivalentes revela que as regras aplicadas pelas autoridades e organismos em questão são diferentes, podendo ser difícil considerá-las como equivalentes às regras correspondentes da União. Além disso, a multiplicação das normas das autoridades e organismos de controlo dificulta uma supervisão adequada por parte da Comissão. Por conseguinte, o referido regime de reconhecimento da equivalência deve ser abolido. No entanto, deve ser concedido tempo suficiente às autoridades e organismos de controlo, de modo que possam preparar-se para obterem reconhecimento para efeitos de importação de produtos em conformidade com as regras da União.
- (68) A colocação no mercado como biológico de qualquer produto biológico importado para a União, no âmbito de qualquer regime de importação previsto no presente regulamento, deve estar sujeita à disponibilidade das informações necessárias para garantir a rastreabilidade do produto na cadeia alimentar.
- (69) A fim de assegurar uma concorrência leal entre os operadores, a rastreabilidade dos produtos importados destinados a serem colocados no mercado da União como biológicos ou a transparência do processo de reconhecimento e supervisão das autoridades e organismos de controlo no contexto da importação de produtos biológicos conformes e a fim de assegurar a gestão da lista de países terceiros reconhecidos para efeitos de equivalência nos termos do Regulamento (CE) n.º 834/2007, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito aos documentos destinados às autoridades aduaneiras de países terceiros, em especial um certificado de exportação de produtos biológicos, sempre que possível em formato eletrónico, à documentação necessária para efeitos de importação, também em formato eletrónico sempre que possível, aos critérios de reconhecimento ou retirada do reconhecimento dos organismos e autoridades de controlo no contexto da importação de produtos biológicos conformes, bem como no que diz respeito às informações a enviar pelos países terceiros, reconhecidos nos termos do referido regulamento, necessárias para a supervisão do seu reconhecimento e o exercício dessa supervisão por parte da Comissão, onde se inclui o exame *in loco*.

- (70) Devem estabelecer-se disposições para assegurar que a circulação de produtos biológicos que tenham sido objeto de um controlo num Estado-Membro e que estejam em conformidade com o presente regulamento não possa ser objeto de restrições noutro Estado-Membro. A fim de assegurar o bom funcionamento do mercado único e do comércio entre os Estados-Membros, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito ao estabelecimento de regras relativas à livre circulação dos produtos biológicos.
- (71) Para efeitos de obtenção de informações fiáveis necessárias para a aplicação do presente regulamento, os Estados-Membros devem fornecer anualmente à Comissão as informações necessárias. Por razões de clareza e de transparência, os Estados-Membros devem manter listas atualizadas das autoridades competentes e das autoridades e organismos de controlo. As listas das autoridades e organismos de controlo devem ser tornadas públicas pelos Estados-Membros e publicadas anualmente pela Comissão.
- (72) É necessário estabelecer medidas destinadas a garantir uma transição harmoniosa para algumas alterações do quadro jurídico que rege a importação de produtos biológicos para a União, tal como introduzido pelo presente regulamento. Em especial, a fim de assegurar uma transição harmoniosa do antigo para o novo quadro jurídico, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito às regras relativas aos períodos de conversão iniciados no âmbito do Regulamento (CE) n.º 834/2007, em derrogação da regra geral de que não podem ser reconhecidos retroativamente períodos anteriores como parte integrante do período de conversão.
- (73) Além disso, deve ser definida uma data para a caducidade do reconhecimento das autoridades e organismos de controlo para efeitos de equivalência e devem estabelecer-se disposições para abordar a situação até ao termo do seu reconhecimento. Devem também estabelecer-se disposições relativas aos pedidos de países terceiros para efeitos de equivalência que tenham sido apresentados nos termos do Regulamento (CE) n.º 834/2007 e que se encontrem pendentes aquando da entrada em vigor do presente regulamento.
- (74) A fim de assegurar a gestão da lista dos organismos e autoridades de controlo reconhecidos para efeitos de equivalência nos termos do Regulamento (CE) n.º 834/2007 e a fim de facilitar a conclusão da análise dos pedidos de reconhecimento de países terceiros para efeitos de equivalência que se encontrem pendentes à data de entrada em vigor do presente regulamento, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito às informações a enviar pelas referidas autoridades e organismos de controlo, necessárias para a supervisão do seu reconhecimento, e no que diz respeito ao exercício da referida supervisão por parte da Comissão, bem como no que respeita a quaisquer regras processuais necessárias para o exame dos pedidos pendentes de países terceiros.
- (75) A fim de assegurar condições uniformes para a aplicação do presente regulamento, devem ser conferidas competências de execução à Comissão no que diz respeito aos pormenores técnicos para a criação da base de dados para inventário das variedades para as quais está disponível material de reprodução vegetal obtido através do método de produção biológica, no que se refere à concessão ou à retirada da autorização dos produtos e substâncias suscetíveis de serem utilizados na produção biológica em geral e, mais especificamente, na produção de géneros alimentícios biológicos transformados, incluindo os procedimentos a seguir para a autorização e as listas dos produtos e substâncias em questão, bem como, se for caso disso, a respetiva descrição,

requisitos de composição e condições de utilização, no que diz respeito às modalidades específicas e práticas relativas à apresentação, composição e tamanho das indicações referentes aos números de código das autoridades e organismos de controlo, bem como da indicação do local onde foram produzidas as matérias-primas agrícolas, à atribuição de números de código às autoridades e organismos de controlo e à indicação do local onde foram produzidas as matérias-primas agrícolas, no que diz respeito aos pormenores e especificações respeitantes ao conteúdo, forma e modo de notificação das notificações, por parte dos operadores e grupos de operadores, da respetiva atividade às autoridades competentes e à forma de publicação das taxas que podem ser cobradas pelos controlos, no que respeita ao intercâmbio de informações entre os grupos de operadores e autoridades competentes, autoridades de controlo e organismos de controlo, e entre os Estados-Membros e a Comissão, no que diz respeito ao reconhecimento ou à retirada do reconhecimento das autoridades e organismos de controlo competentes para realizar controlos nos países terceiros e ao estabelecimento da lista dos referidos organismos e autoridades de controlo, de regras que permitam assegurar a aplicação de medidas em relação a casos de incumprimento, ou de suspeita de incumprimento, que afetem a integridade dos produtos biológicos importados, no que diz respeito ao estabelecimento de uma lista dos países terceiros reconhecidos nos termos do artigo 33.º, n.º 2, do Regulamento (CE) n.º 834/2007 e à alteração dessa mesma lista, bem como de regras que permitam assegurar a aplicação de medidas em relação a casos de incumprimento, ou de suspeita de incumprimento, que afetem a integridade dos produtos biológicos importados dos países em questão, no que diz respeito ao sistema a ser utilizado para transmitir as informações necessárias à aplicação e ao acompanhamento do presente regulamento e, ainda, no que diz respeito ao estabelecimento da lista dos organismos e autoridades de controlo reconhecidos em conformidade com o artigo 33.º, n.º 3, do Regulamento (CE) n.º 834/2007, bem como à alteração da referida lista. Essas competências devem ser exercidas em conformidade com o Regulamento (UE) n.º 182/2011 do Parlamento Europeu e do Conselho³⁴.

- (76) Devem ser atribuídas competências à Comissão para adotar atos de execução imediatamente aplicáveis quando, em casos devidamente justificados relacionados com a proteção contra práticas desleais ou práticas incompatíveis com os princípios e regras em matéria de produção biológica, com a proteção da confiança dos consumidores ou com a proteção da concorrência leal entre operadores, imperativos de urgência o exijam para garantir a aplicação de medidas em relação a casos de incumprimento, ou de suspeita de incumprimento, que afetem a integridade dos produtos biológicos importados sob o controlo de autoridades ou organismos de controlo reconhecidos.
- (77) A fim de assegurar uma transição harmoniosa entre, por um lado, as regras relativas à origem biológica do material de reprodução vegetal e aos animais para fins de reprodução, previstas no Regulamento (CE) n.º 834/2007, bem como a derrogação às regras de produção adotadas nos termos do artigo 22.º desse mesmo regulamento, e, por outro lado, as novas regras de produção aplicáveis aos vegetais e produtos vegetais e aos animais, previstas no presente regulamento, o poder de adotar determinados atos deve ser delegado na Comissão no que diz respeito à concessão de derrogações, nos casos em que as derrogações sejam consideradas necessárias, para garantir o acesso a

³⁴ Regulamento (UE) n.º 182/2011 do Parlamento Europeu e do Conselho, de 16 de fevereiro de 2011, que estabelece as regras e os princípios gerais relativos aos mecanismos de controlo pelos Estados-Membros do exercício das competências de execução pela Comissão (JO L 55 de 28.2.2011, p. 13).

material de reprodução vegetal e animais vivos para fins de reprodução que possam ser utilizados na produção biológica. Uma vez que os referidos atos são de natureza transitória, devem aplicar-se durante um período de tempo limitado.

- (78) A Comissão deve considerar a situação da disponibilidade de material de reprodução vegetal biológico e de animais para fins de reprodução e apresentar, em 2021, um relatório para esse efeito ao Parlamento Europeu e ao Conselho.
- (79) Devem estabelecer-se disposições que permitam o esgotamento das existências de produtos que tenham sido produzidos em conformidade com o Regulamento (CE) n.º 834/2007 e colocados no mercado antes de o presente regulamento entrar em vigor.
- (80) A revisão do quadro legislativo em matéria de produção biológica e rotulagem dos produtos biológicos revelou que as necessidades específicas relacionadas com os controlos oficiais e outras atividades oficiais efetuados em conformidade com o Regulamento (UE) n.º XXX/XXX (Regulamento relativo aos controlos oficiais) requerem disposições para uma melhor abordagem das situações de incumprimento. Além disso, as disposições do Regulamento (UE) n.º XXX/XXX [Regulamento relativo aos controlos oficiais] referentes às tarefas e responsabilidades das autoridades competentes, à aprovação e supervisão dos organismos delegados, à certificação oficial, às obrigações de comunicação de informações e à assistência administrativa devem ser adaptadas para satisfazer as necessidades específicas do setor da produção biológica. O Regulamento (UE) n.º XXX/XXX [Regulamento relativo aos controlos oficiais] deve, por conseguinte, ser alterado em conformidade.
- (81) Uma vez que os objetivos do presente regulamento, nomeadamente a concorrência leal e o funcionamento adequado do mercado interno de produtos biológicos, bem como a garantia da confiança dos consumidores nos produtos em questão e no logótipo de produção biológica da União Europeia, não podem ser suficientemente realizados pelos próprios Estados-Membros, podendo, ao invés, dada a necessária harmonização das regras em matéria de produção biológica, ser melhor realizados a nível da União, a União pode adotar medidas em conformidade com o princípio da subsidiariedade consagrado no artigo 5.º do Tratado da União Europeia. Em conformidade com o princípio da proporcionalidade, consagrado no mesmo artigo, o presente regulamento não excede o necessário para atingir aqueles objetivos.
- (82) É conveniente prever uma data de aplicação do presente regulamento que dê aos operadores a possibilidade de se adaptarem aos novos requisitos introduzidos,

ADOTARAM O PRESENTE REGULAMENTO:

Capítulo I

Objeto, âmbito de aplicação e definições

Artigo 1.º

Objeto

O presente regulamento estabelece os princípios da produção biológica e define as regras relativas à produção biológica e à utilização de indicações referentes à mesma na rotulagem e na publicidade.

Âmbito de aplicação

1. O presente regulamento é aplicável aos produtos agrícolas enumerados no anexo I do Tratado sobre o Funcionamento da União Europeia («Tratado») e a determinados outros produtos enumerados no anexo I do presente regulamento, na medida em que os produtos agrícolas e os outros produtos em questão se destinem a ser produzidos, preparados, distribuídos, colocados no mercado, importados ou exportados como produtos biológicos.
Os produtos da caça e da pesca de animais selvagens não são considerados produtos biológicos.
2. O presente regulamento é aplicável a qualquer operador que exerça atividades em qualquer fase da produção, preparação e distribuição dos produtos referidos no n.º 1.
As operações de restauração coletiva efetuadas por um estabelecimento de restauração coletiva, tal como definido no artigo 2.º, n.º 2, alínea d), do Regulamento (UE) n.º 1169/2011 do Parlamento Europeu e do Conselho³⁵, não são abrangidas pelo presente regulamento.
Os Estados-Membros podem aplicar regras nacionais ou, na sua ausência, normas privadas sobre a rotulagem e o controlo dos produtos provenientes de operações de restauração coletiva.
3. O presente regulamento é aplicável sem prejuízo do disposto na legislação pertinente da União nos domínios, *inter alia*, da segurança da cadeia alimentar, da saúde e do bem-estar dos animais, da fitossanidade e do material de reprodução vegetal e, em especial, no Regulamento (UE) n.º XX/XXX do Parlamento Europeu e do Conselho³⁶ (material de reprodução vegetal) e no Regulamento (UE) n.º XX/XXXX do Parlamento Europeu e do Conselho³⁷ (medidas de proteção contra as pragas dos vegetais).
4. O presente regulamento é aplicável sem prejuízo de outras disposições específicas da União relativas à colocação de produtos no mercado e, em especial, do Regulamento (UE) n.º 1308/2013 do Parlamento Europeu e do Conselho³⁸ e do Regulamento (UE) n.º 1169/2011.
5. A fim de ter em conta novas informações sobre métodos ou materiais de produção ou compromissos internacionais, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem a lista de produtos enumerados no anexo I. Apenas os produtos que estão estreitamente ligados a produtos agrícolas devem ser elegíveis para inclusão nessa lista.

³⁵ Regulamento (UE) n.º 1169/2011 do Parlamento Europeu e do Conselho, de 25 de outubro de 2011, relativo à prestação de informação aos consumidores sobre os géneros alimentícios, que altera os Regulamentos (CE) n.º 1924/2006 e (CE) n.º 1925/2006 do Parlamento Europeu e do Conselho e revoga as Diretivas 87/250/CEE da Comissão, 90/496/CEE do Conselho, 1999/10/CE da Comissão, 2000/13/CE do Parlamento Europeu e do Conselho, 2002/67/CE e 2008/5/CE da Comissão e o Regulamento (CE) n.º 608/2004 da Comissão (JO L 304 de 22.11.2011, p. 18).

³⁶ [título completo] (JO L ...).

³⁷ [título completo] (JO L ...).

³⁸ Regulamento (UE) n.º 1308/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, que estabelece uma organização comum dos mercados dos produtos agrícolas e que revoga os Regulamentos (CEE) n.º 922/72, (CEE) n.º 234/79, (CE) n.º 1037/2001, (CE) n.º 1234/2007 do Conselho (JO L 347 de 20.12.2013, p. 671).

Artigo 3.º

Definições

Para efeitos do presente regulamento, entende-se por:

- (1) «Produção biológica», a utilização de métodos de produção conformes com o presente regulamento em todas as fases de produção, preparação e distribuição;
- (2) «Biológico», resultante da produção biológica ou com ela relacionado;
- (3) «Matéria-prima agrícola», um produto agrícola que não foi submetido a qualquer operação de conservação ou de transformação;
- (4) «Medidas preventivas», medidas a tomar para garantir a qualidade dos solos, bem como a prevenção e o controlo de parasitas e infestantes, e para impedir a contaminação por produtos ou substâncias não autorizados no âmbito do presente regulamento;
- (5) «Conversão», a transição da produção não biológica para a produção biológica num determinado período de tempo;
- (6) «Operador», a pessoa singular ou coletiva responsável por assegurar o cumprimento do presente regulamento em todas as fases de produção, preparação e distribuição sob o seu controlo;
- (7) «Grupo de operadores», um grupo no qual cada operador é um agricultor que possui uma exploração de, no máximo, 5 hectares de superfície agrícola utilizada e que, para além de produzir géneros alimentícios ou alimentos para animais, pode estar envolvido na transformação de géneros alimentícios ou de alimentos para animais;
- (8) «Agricultor», a pessoa singular ou coletiva, ou o grupo de pessoas singulares ou coletivas, independentemente do estatuto jurídico concedido ao grupo em questão e aos respetivos membros pelo direito nacional, que exerce uma atividade agrícola;
- (9) «Superfície agrícola», a superfície agrícola na aceção do artigo 4.º, n.º 1, alínea e), do Regulamento (UE) n.º 1307/2013;
- (10) «Vegetais», os vegetais na aceção do artigo 3.º, ponto 5, do Regulamento (CE) n.º 1107/2009;
- (11) «Produção vegetal», a produção de produtos agrícolas vegetais, incluindo a colheita de produtos vegetais selvagens para fins comerciais;
- (12) «Produtos vegetais», os produtos vegetais na aceção do artigo 3.º, ponto 6, do Regulamento (CE) n.º 1107/2009;
- (13) «Praga», uma praga na aceção do artigo 1.º, n.º 1, do Regulamento (UE) n.º XX/XXXX (medidas de proteção contra as pragas dos vegetais);
- (14) «Produtos fitofarmacêuticos», os produtos referidos no artigo 2.º do Regulamento (CE) n.º 1107/2009;
- (15) «Produção animal», a produção de animais terrestres domésticos ou domesticados, incluindo insetos;
- (16) «Varanda», uma parte exterior adicional, coberta por um telhado e não isolada de instalações de pecuária, cujo lado mais comprido se encontra normalmente equipado com vedação de arame ou rede, com as condições climáticas exteriores, iluminação natural e artificial e piso coberto com material de cama;

- (17) «Aquicultura», a aquicultura na aceção do artigo 4.º, n.º 1, ponto 25, do Regulamento (UE) n.º 1380/2013 do Parlamento Europeu e do Conselho³⁹;
- (18) «Tratamento veterinário», qualquer tratamento curativo ou preventivo contra uma ocorrência de uma determinada doença;
- (19) «Medicamentos veterinários», os medicamentos veterinários na aceção do artigo 1.º, ponto 2, da Diretiva 2001/82/CE do Parlamento Europeu e do Conselho⁴⁰;
- (20) «Preparação», as operações de conservação ou transformação de produtos biológicos (incluindo o abate e o corte no que diz respeito aos produtos animais), assim como o acondicionamento, a rotulagem ou as alterações relativas à produção biológica introduzidas na rotulagem;
- (21) «Género alimentício», um género alimentício na aceção do artigo 2.º do Regulamento (CE) n.º 178/2002 do Parlamento Europeu e do Conselho⁴¹;
- (22) «Alimento para animais», um alimento para animais na aceção do artigo 3.º, ponto 4, do Regulamento (CE) n.º 178/2002;
- (23) «Matérias-primas para alimentação animal», as matérias-primas para alimentação animal na aceção do artigo 3.º, n.º 2, alínea g), do Regulamento (CE) n.º 767/2009 do Parlamento Europeu e do Conselho⁴²;
- (24) «Alimentos para animais em conversão», alimentos para animais produzidos durante o período de conversão, exceto os colhidos nos 12 meses seguintes ao início do período de conversão;
- (25) «Colocação no mercado», a colocação no mercado na aceção do artigo 3.º, ponto 8, do Regulamento (CE) n.º 178/2002;
- (26) «Rastreabilidade», a rastreabilidade na aceção do artigo 3.º, ponto 15, do Regulamento (CE) n.º 178/2002;
- (27) «Fases da produção, preparação e distribuição», qualquer fase desde a produção primária de um produto biológico até à sua armazenagem, transformação, transporte, venda ou fornecimento ao consumidor final e, se for caso disso, a rotulagem, publicidade, importação, exportação e atividades de subcontratação;
- (28) «Circunstâncias catastróficas», as circunstâncias decorrentes de um «fenómeno climático adverso», de um «incidente ambiental», de uma «catástrofe natural» ou de um «acontecimento catastrófico» na aceção, respetivamente, do artigo 2.º, n.º 1, alíneas h), j), k) e l), do Regulamento (UE) n.º 1305/2013;

³⁹ Regulamento (UE) n.º 1380/2013 do Parlamento Europeu e do Conselho, de 11 de dezembro de 2013, relativo à política comum das pescas, que altera os Regulamentos (CE) n.º 1954/2003 e (CE) n.º 1224/2009 do Conselho e revoga os Regulamentos (CE) n.º 2371/2002 e (CE) n.º 639/2004 do Conselho e a Decisão 2004/585/CE do Conselho (JO L 354 de 28.12.2013, p. 22).

⁴⁰ Diretiva 2001/82/CE do Parlamento Europeu e do Conselho, de 6 de novembro de 2001, que estabelece um código comunitário relativo aos medicamentos veterinários (JO L 311 de 28.11.2001, p. 1).

⁴¹ Regulamento (CE) n.º 178/2002 do Parlamento Europeu e do Conselho, de 28 de janeiro de 2002, que determina os princípios e normas gerais da legislação alimentar, cria a Autoridade Europeia para a Segurança dos Alimentos e estabelece procedimentos em matéria de segurança dos géneros alimentícios (JO L 31 de 1.2.2002, p. 1).

⁴² Regulamento (CE) n.º 767/2009 do Parlamento Europeu e do Conselho, de 13 de julho de 2009, relativo à colocação no mercado e à utilização de alimentos para animais, que altera o Regulamento (CE) n.º 1831/2003 e revoga as Diretivas 79/373/CEE do Conselho, 80/511/CEE da Comissão, 82/471/CEE do Conselho, 83/228/CEE do Conselho, 93/74/CEE do Conselho, 93/113/CE do Conselho e 96/25/CE do Conselho e a Decisão 2004/217/CE da Comissão (JO L 229 de 1.9.2009, p. 1).

- (29) «Ingrediente», um ingrediente na aceção do artigo 2.º, n.º 2, alínea f), do Regulamento (UE) n.º 1169/2011;
- (30) «Rotulagem», a rotulagem na aceção do artigo 2.º, n.º 2, alínea j), do Regulamento (UE) n.º 1169/2011;
- (31) «Publicidade», qualquer apresentação dos produtos biológicos destinada ao público, por todos os meios à exceção da rotulagem, que pretenda ou seja suscetível de influenciar e moldar atitudes, convicções e comportamentos no intuito de promover direta ou indiretamente a venda de produtos biológicos;
- (32) «Autoridades competentes», as autoridades competentes na aceção do artigo 2.º, ponto 5, do Regulamento (UE) n.º XXX/XXXX [*Regulamento relativo aos controlos oficiais*];
- (33) «Autoridade de controlo», a autoridade de controlo da produção biológica e da rotulagem dos produtos biológicos na aceção do artigo 2.º, ponto 39, do Regulamento (UE) n.º XXX/XXXX [*Regulamento relativo aos controlos oficiais*];
- (34) «Organismo de controlo», um organismo delegado na aceção do artigo 2.º, ponto 38, do Regulamento (UE) n.º XXX/XXXX [*Regulamento relativo aos controlos oficiais*], bem como um organismo reconhecido pela Comissão ou por um país terceiro reconhecido pela Comissão para efetuar controlos em países terceiros para a importação de produtos biológicos para a União;
- (35) «Incumprimento», o incumprimento do presente regulamento;
- (36) «Organismo geneticamente modificado», um organismo geneticamente modificado na aceção do artigo 2.º, ponto 2, da Diretiva 2001/18/CE do Parlamento Europeu e do Conselho⁴³, não obtido através das técnicas de modificação genética enumeradas no anexo I B da mesma diretiva, a seguir designado por «OGM»;
- (37) «Obtido a partir de OGM», derivado, no todo ou em parte, de OGM, mas não contendo nem sendo constituído por OGM;
- (38) «Obtido mediante OGM», derivado por utilizar um OGM como último organismo vivo no processo de produção, mas não contendo nem sendo constituído por OGM nem obtido a partir de OGM;
- (39) «Aditivo alimentar», um aditivo alimentar na aceção do artigo 3.º, n.º 2, alínea a), do Regulamento (CE) n.º 1333/2008 do Parlamento Europeu e do Conselho⁴⁴;
- (40) «Aditivo para a alimentação animal», um aditivo para a alimentação animal na aceção do artigo 2.º, n.º 2, alínea a), do Regulamento (CE) n.º 1831/2003 do Parlamento Europeu e do Conselho⁴⁵;
- (41) «Equivalência», que obedece aos mesmos objetivos e princípios, mediante a aplicação de regras que asseguram o mesmo nível de garantia da conformidade; «Auxiliar tecnológico», o auxiliar tecnológico na aceção do artigo 3.º, n.º 2, alínea b), do Regulamento (CE) n.º 1333/2008;

⁴³ Diretiva 2001/18/CE do Parlamento Europeu e do Conselho, de 12 de março de 2001, relativa à libertação deliberada no ambiente de organismos geneticamente modificados e que revoga a Diretiva 90/220/CEE do Conselho (JO L 106 de 17.4.2001, p. 1).

⁴⁴ Regulamento (CE) n.º 1333/2008 do Parlamento Europeu e do Conselho, de 16 de dezembro de 2008, relativo aos aditivos alimentares (JO L 354 de 31.12.2008, p. 16).

⁴⁵ Regulamento (CE) n.º 1831/2003 do Parlamento Europeu e do Conselho, de 22 de setembro de 2003, relativo aos aditivos destinados à alimentação animal (JO L 268 de 18.10.2003, p. 29).

- (42) «Enzima alimentar», uma enzima alimentar na aceção do artigo 3.º, n.º 2, alínea a), do Regulamento (CE) n.º 1332/2008 do Parlamento Europeu e do Conselho⁴⁶;
- (43) «Radiações ionizantes», as radiações ionizantes na aceção do artigo 1.º da Diretiva 96/29/Euratom do Conselho⁴⁷.

⁴⁶ Regulamento (CE) n.º 1332/2008 do Parlamento Europeu e do Conselho, de 16 de dezembro de 2008, relativo às enzimas alimentares e que altera a Diretiva 83/417/CEE do Conselho, o Regulamento (CE) n.º 1493/1999 do Conselho, a Diretiva 2000/13/CE, a Diretiva 2001/112/CE do Conselho e o Regulamento (CE) n.º 258/97 (JO L 354 de 31.12.2008, p. 7).

⁴⁷ Diretiva 96/29/Euratom do Conselho, de 13 de maio de 1996, que fixa as normas de segurança de base relativas à proteção sanitária da população e dos trabalhadores contra os perigos resultantes das radiações ionizantes (JO L 159 de 29.6.1996, p. 1).

Capítulo II

Princípios da produção biológica

Artigo 4.º

Princípios gerais

A produção biológica é um sistema de gestão agrícola sustentável baseado nos seguintes princípios gerais:

- a) Respeito pelos sistemas e ciclos da natureza e conservação e melhoria do estado dos solos, da água, do ar e da biodiversidade, da saúde dos vegetais e dos animais, assim como do equilíbrio entre eles;
- b) Contribuição para um elevado nível de biodiversidade;
- c) Utilização responsável da energia e dos recursos naturais, tais como a água, os solos, a matéria orgânica e o ar;
- d) Respeito por normas exigentes de bem-estar dos animais e, em especial, satisfação das necessidades comportamentais próprias de cada espécie;
- e) Conceção e gestão adequadas de processos biológicos baseados em sistemas ecológicos que utilizem recursos naturais internos ao sistema através de métodos que:
 - i) empreguem organismos vivos e métodos de produção mecânicos,
 - ii) pratiquem o cultivo de vegetais e a produção animal adequados ao solo ou pratiquem a aquicultura respeitando o princípio da exploração sustentável dos recursos haliêuticos,
 - iii) excluam a utilização de OGM e de produtos obtidos a partir de OGM ou mediante OGM, com exceção dos medicamentos veterinários,
 - iv) se baseiem na utilização de medidas preventivas, se for caso disso;
- f) Restrição da utilização de fatores de produção externos. Quando forem necessários fatores de produção externos ou quando não existirem as práticas e os métodos de gestão adequados referidos na alínea e), estes devem ser limitados a:
 - i) fatores de produção provenientes da produção biológica,
 - ii) substâncias naturais ou derivadas de substâncias naturais,
 - iii) fertilizantes minerais de baixa solubilidade;
- g) Adaptação do processo de produção, sempre que necessário e no âmbito do presente regulamento, tendo em conta a situação sanitária, as diferenças regionais no equilíbrio ecológico, no clima e nas condições locais, as fases de desenvolvimento e as práticas específicas de criação.

Artigo 5.º

Princípios específicos aplicáveis às atividades agrícolas e à aquicultura

No âmbito das atividades agrícolas e da aquicultura, a produção biológica deve basear-se, nomeadamente, nos seguintes princípios específicos:

- a) Manutenção e melhoria da vida dos solos, da sua fertilidade natural, estabilidade, retenção de água e biodiversidade, prevenção e luta contra a perda de matéria orgânica dos solos e a sua compactação e erosão, bem como alimentação dos vegetais essencialmente através do ecossistema dos solos;
- b) Limitação ao mínimo da utilização de recursos não renováveis e de fatores de produção externos;
- c) Reciclagem dos desperdícios e subprodutos de origem vegetal e animal, como fatores de produção na produção vegetal e animal;
- d) Preservação da fitossanidade através de medidas preventivas, nomeadamente a escolha de espécies, variedades ou material heterogéneo adequados, resistentes às pragas e às doenças, rotação adequada das culturas, métodos mecânicos e físicos e proteção dos inimigos naturais das pragas;
- e) Escolha das raças tendo em conta a capacidade de adaptação dos animais às condições locais, a sua vitalidade e a sua resistência às doenças ou problemas de saúde; prática da produção animal adaptada ao local e adequada ao solo; aplicação de práticas de criação animal que reforcem o sistema imunitário e aumentem as defesas naturais contra as doenças e que incluam, nomeadamente, o exercício regular e o acesso a áreas ao ar livre e a terrenos de pastagem, se for caso disso;
- f) Observância de um elevado nível de bem-estar dos animais, respeitando as necessidades próprias de cada espécie;
- g) Alimentação dos animais com alimentos biológicos para animais compostos por ingredientes agrícolas provenientes da produção biológica e por substâncias não agrícolas naturais;
- h) Exclusão de engenharia genética, clonagem de animais, indução artificial da poliploidia e radiações ionizantes provenientes de toda a cadeia alimentar biológica;
- i) Sanidade permanente do ambiente aquático e da qualidade do ecossistema aquático e terrestre circundante;
- j) Alimentação dos organismos aquáticos com alimentos para animais provenientes da exploração sustentável dos recursos haliêuticos, em conformidade com o Regulamento (UE) n.º 1380/2013, ou com alimentos biológicos para animais compostos por ingredientes agrícolas provenientes da produção biológica, incluindo a aquicultura biológica, e por substâncias não agrícolas naturais.

Artigo 6.º

Princípios específicos aplicáveis à transformação de alimentos para animais e de géneros alimentícios biológicos

A produção de alimentos para animais e de géneros alimentícios biológicos transformados deve basear-se, nomeadamente, nos seguintes princípios específicos:

- a) Produção de géneros alimentícios biológicos a partir de ingredientes agrícolas biológicos;
- b) Produção de alimentos biológicos para animais a partir de matérias-primas biológicas para alimentação animal;
- c) Limitação ao mínimo da utilização de aditivos alimentares, de ingredientes não biológicos com funções principalmente tecnológicas e organolépticas e de micronutrientes e auxiliares tecnológicos, de modo a serem utilizados apenas em caso de necessidade tecnológica essencial ou para fins nutricionais específicos;
- d) Limitação ao mínimo da utilização de aditivos para a alimentação animal e de auxiliares tecnológicos e apenas em caso de necessidade tecnológica ou zootécnica essencial ou para fins nutricionais específicos;
- e) Exclusão de substâncias e métodos de transformação suscetíveis de induzir em erro no que diz respeito à verdadeira natureza do produto;
- f) Transformação cuidadosa dos géneros alimentícios ou alimentos para animais, de preferência através da utilização de métodos biológicos, mecânicos e físicos.

Capítulo III

Regras de produção

Artigo 7.º

Regras gerais de produção

1. Os operadores devem cumprir as seguintes regras gerais de produção:
 - a) A totalidade da exploração agrícola ou da operação aquícola deve ser gerida em conformidade com os requisitos aplicáveis à produção biológica;
 - b) Salvo indicação em contrário no anexo II, parte IV, ponto 2.2, e parte VI, ponto 1.3, apenas os produtos e substâncias autorizados nos termos do artigo 19.º podem ser utilizados na agricultura e aquicultura biológicas, partindo do princípio que o produto ou substância em causa foi autorizado para utilização na agricultura e na aquicultura, em conformidade com as disposições pertinentes aplicáveis do direito da União, e, quando necessário, nos Estados-Membros em questão, em conformidade com as disposições nacionais baseadas no direito da União;
 - c) É proibida a utilização de radiações ionizantes para o tratamento dos géneros alimentícios biológicos, dos alimentos biológicos para animais, ou das matérias-primas neles utilizadas;
 - d) Os operadores biológicos que não as microempresas, os agricultores e os operadores que produzem algas marinhas ou animais de aquicultura devem implementar um sistema de gestão ambiental a fim de melhorar o seu desempenho ambiental.
2. A fim de garantir a aplicação correta das regras gerais de produção, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que estabeleçam os critérios a que o sistema de gestão ambiental, referido no n.º 1, alínea d), deve corresponder. Esses critérios devem ter em conta as especificidades das pequenas e médias empresas.

Artigo 8.º

Conversão

1. Os agricultores e os operadores que produzem algas marinhas ou animais de aquicultura devem respeitar um período de conversão. Durante todo o período de conversão, devem aplicar as regras em matéria de produção biológica estabelecidas no presente regulamento e, em especial, as regras específicas aplicáveis à conversão constantes do anexo II.
2. O período de conversão tem início no momento em que o agricultor ou o operador que produz algas marinhas ou animais de aquicultura notifica as autoridades competentes da sua atividade, em conformidade com o presente regulamento.

2 A. Em derrogação do n.º 2, nos casos em que as terras tenham sido deixadas em pousio antes da notificação referida no artigo 24.º, n.º 1, durante, pelo menos, o período exigido para a conversão e desde que os outros requisitos aplicáveis sejam satisfeitos, nenhum período de conversão é necessário para essas terras.

3. Não pode ser reconhecido retroativamente qualquer período anterior como parte integrante do período de conversão.
4. Os produtos obtidos durante o período de conversão não podem ser comercializados como biológicos.
5. Em derrogação do artigo 7.º, n.º 1, alínea a), durante o período de conversão, a exploração agrícola pode ser dividida em unidades claramente separadas que não sejam todas elas geridas segundo métodos de produção biológica. No que se refere aos animais, a produção biológica deve envolver espécies diferentes durante o período de conversão. No que se refere à aquicultura, pode envolver as mesmas espécies, desde que haja uma separação adequada entre os locais de produção. No que se refere aos vegetais, a produção biológica deve envolver variedades diferentes que possam ser facilmente distinguidas durante o período de conversão.
6. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que completem as regras estabelecidas no presente artigo ou que completem e alterem as regras previstas no anexo II no que diz respeito à conversão.

Artigo 9.º

Proibição de utilização de OGM

1. Na produção biológica, não podem ser utilizados OGM nem produtos obtidos a partir de OGM ou mediante OGM em géneros alimentícios ou alimentos para animais, ou como géneros alimentícios, alimentos para animais, auxiliares tecnológicos, produtos fitofarmacêuticos, fertilizantes, corretivos dos solos, material de reprodução vegetal, microrganismos e animais.
2. Para efeitos do disposto no n.º 1, no que diz respeito aos OGM ou produtos obtidos a partir de OGM ou mediante OGM em géneros alimentícios e alimentos para animais, os operadores podem confiar nos rótulos de um produto ou em quaisquer outros documentos de acompanhamento, apostos ou fornecidos nos termos da Diretiva 2001/18/CE, do Regulamento (CE) n.º 1829/2003 do Parlamento Europeu e do Conselho⁴⁸ ou do Regulamento (CE) n.º 1830/2003 do Parlamento Europeu e do Conselho⁴⁹.
3. Os operadores podem partir do princípio de que não foram utilizados OGM nem produtos obtidos a partir de OGM ou mediante OGM no fabrico dos géneros

⁴⁸ Regulamento (CE) n.º 1829/2003 do Parlamento Europeu e do Conselho, de 22 de setembro de 2003, relativo a géneros alimentícios e alimentos para animais geneticamente modificados (JO L 268 de 18.10.2003, p. 1).

⁴⁹ Regulamento (CE) n.º 1830/2003 do Parlamento Europeu e do Conselho, de 22 de setembro de 2003, relativo à rastreabilidade e rotulagem de organismos geneticamente modificados e à rastreabilidade dos géneros alimentícios e alimentos para animais produzidos a partir de organismos geneticamente modificados e que altera a Diretiva 2001/18/CE (JO L 268 de 18.10.2003, p. 24).

alimentícios e dos alimentos para animais comprados quando estes não se encontrem rotulados ou acompanhados de um documento, como previsto nos regulamentos referidos no n.º 2, a menos que tenham obtido outra informação que indique que a rotulagem dos produtos em causa não está em conformidade com os referidos regulamentos.

Artigo 10.º

Regras de produção vegetal

1. Os operadores que produzem vegetais ou produtos vegetais devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte I.
2. Cada Estado-Membro deve assegurar a criação de uma base de dados informatizada para inventário das variedades e do material heterogéneo, em conformidade com o Regulamento (UE) n.º XX/XXX (Regulamento relativo ao material de reprodução vegetal), para os quais se encontre disponível no seu território material de reprodução vegetal obtido pelo método de produção biológica.
3. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção vegetal biológica, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção vegetal no que se refere a:
 - a) Práticas de cultivo;
 - b) Gestão e fertilização dos solos;
 - c) Fitossanidade e gestão de pragas e infestantes;
 - d) Gestão da produção de cogumelos e outros vegetais específicos e de sistemas de produção vegetal;
 - e) Origem do material de reprodução vegetal;
 - f) Colheita de plantas selvagens.
4. A Comissão deve adotar atos de execução que estabeleçam as especificações técnicas para a criação da base de dados referida no n.º 2. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Artigo 11.º

Regras de produção animal

1. Os operadores no domínio da produção animal devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte II.
2. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção animal biológica, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção animal no que se refere a:
 - a) Origem dos animais;

- b) Alojamento dos animais, incluindo as superfícies mínimas das áreas interiores e exteriores e o número máximo de animais por hectare;
- c) Práticas de criação;
- d) Reprodução;
- e) Alimentos para animais e alimentação;
- f) Prevenção de doenças e tratamento veterinário.

Artigo 12.º

Regras de produção de algas marinhas e de animais de aquicultura

1. Os operadores que produzem algas marinhas e animais de aquicultura devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte III.
2. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica de algas marinhas, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção de algas marinhas no que se refere a:
 - a) Adequação do meio aquático e do plano de gestão sustentável;
 - b) Colheita de algas marinhas selvagens;
 - c) Cultura de algas marinhas;
 - d) Medidas de tratamento antivegetativo e limpeza dos equipamentos e instalações de produção.
3. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção de animais de aquicultura biológica, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção de animais de aquicultura no que se refere a:
 - a) Adequação do meio aquático e do plano de gestão sustentável;
 - b) Origem dos animais de aquicultura;
 - c) Criação de animais de aquicultura, incluindo os sistemas de confinamento aquático, os sistemas de produção, a densidade máxima de animais e, sempre que adequado, a densidade mínima de animais;
 - d) Reprodução;
 - e) Gestão dos animais de aquicultura;
 - f) Alimentos para animais e alimentação;
 - g) Prevenção de doenças e tratamento veterinário.

Artigo 13.º

Regras de produção de alimentos para animais e de géneros alimentícios transformados

1. Os operadores que produzem alimentos para animais e géneros alimentícios transformados devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte IV.
2. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção de alimentos para animais e géneros alimentícios biológicos transformados, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção de alimentos para animais e de géneros alimentícios transformados no que se refere a:
 - a) Procedimentos a seguir;
 - b) Medidas preventivas a tomar;
 - c) Composição e condições de utilização de alimentos para animais e de géneros alimentícios transformados, incluindo produtos e substâncias cuja utilização é permitida em alimentos para animais e géneros alimentícios transformados;
 - d) Medidas de limpeza;
 - e) Colocação no mercado de produtos transformados, incluindo a respetiva rotulagem e identificação;
 - f) Separação de produtos, ingredientes agrícolas e matérias-primas para alimentação animal biológicos de produtos, ingredientes agrícolas e matérias-primas para alimentação animal não biológicos;
 - g) Lista dos ingredientes agrícolas não biológicos que podem, a título excepcional, ser utilizados para a produção de produtos biológicos transformados;
 - h) Cálculo da percentagem dos ingredientes agrícolas referidos no artigo 21.º, n.º 3, alínea a), subalínea ii), e alínea b);
 - i) Técnicas utilizadas na transformação de géneros alimentícios ou alimentos para animais.

Artigo 14.º

Regras de produção de vinho

1. Os operadores que produzem produtos do setor do vinho devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte V.
2. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção de vinho biológico, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção de vinho no que se refere às práticas e restrições enológicas.

Artigo 15.º

Regras de produção de leveduras utilizadas como géneros alimentícios ou alimentos para animais

1. Os operadores que produzem leveduras destinadas a serem utilizadas como géneros alimentícios ou alimentos para animais devem cumprir, nomeadamente, as regras específicas de produção estabelecidas no anexo II, parte VI.
2. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica de leveduras, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras específicas de produção de leveduras no que se refere à transformação e aos substratos utilizados.

Artigo 16.º

Regras de produção de outros produtos

A fim de contemplar qualquer necessidade futura de dispor de regras específicas de produção para produtos que não os referidos nos artigos 10.º a 15.º e a fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica desses outros produtos adicionais e a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem o anexo II no que diz respeito às regras específicas de produção dos referidos produtos.

Artigo 17.º

Adoção de regras de produção excecionais

A fim de permitir que a produção biológica continue ou recomece em caso de circunstâncias catastróficas e de acordo com os princípios estabelecidos no capítulo II, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que prevejam os critérios de qualificação das situações em questão como catastróficas e estabeleçam regras específicas relativas à forma como lidar com as referidas situações, ao acompanhamento e aos requisitos de comunicação.

Artigo 18.º

Recolha, acondicionamento, transporte e armazenagem

1. Os produtos biológicos devem ser recolhidos, acondicionados, transportados e armazenados em conformidade com as regras definidas no anexo III.
2. Tendo em vista garantir a integridade da produção biológica e a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem ou completem as regras estabelecidas no anexo III.

Autorização dos produtos e substâncias utilizados na produção biológica

1. A Comissão pode autorizar a utilização de determinados produtos e substâncias na produção biológica e incluí-los em listas restritas, para os seguintes fins:
 - a) Enquanto produtos fitofarmacêuticos;
 - b) Enquanto fertilizantes, corretivos dos solos e nutrientes;
 - c) Enquanto matérias-primas para alimentação animal;
 - d) Enquanto aditivos para a alimentação animal e auxiliares tecnológicos;
 - e) Enquanto produtos de limpeza e desinfeção de lagos, gaiolas, tanques, pistas, edifícios e instalações dedicados à produção animal;
 - f) Enquanto produtos de limpeza e desinfeção de edifícios e instalações dedicados à produção vegetal, incluindo a armazenagem numa exploração agrícola.

Em especial, a Comissão pode autorizar a utilização de determinados produtos e substâncias na produção de géneros alimentícios biológicos transformados e incluí-los em listas restritas, para os seguintes fins:

- a) Enquanto aditivos alimentares, enzimas alimentares e auxiliares tecnológicos;
 - b) Enquanto auxiliares tecnológicos para a produção de leveduras e produtos à base de leveduras.
2. A autorização da utilização na produção biológica dos produtos e substâncias referidos o n.º 1, primeiro parágrafo, está sujeita aos princípios estabelecidos no capítulo II e aos critérios a seguir indicados, que devem ser avaliados como um todo:
 - a) A sua utilização é necessária para uma produção sustentada e essencial para a sua utilização prevista;
 - b) Todos os produtos e substâncias são de origem vegetal, animal, microbiana ou mineral, salvo quando os produtos ou substâncias das referidas proveniências não se encontrem disponíveis em quantidades suficientes ou com qualidade suficiente ou não existam alternativas;
 - c) No caso dos produtos referidos no n.º 1, primeiro parágrafo, alínea a), aplicam-se as seguintes disposições:
 - i) a sua utilização é essencial para o controlo de uma praga para a qual não existam outras alternativas biológicas, físicas ou de criação, nem práticas de cultivo ou outras práticas eficazes de gestão,
 - ii) se os produtos não forem de origem vegetal, animal, microbiana ou mineral e não forem idênticos à sua forma natural, só podem ser autorizados se as condições da sua utilização excluïrem qualquer contacto direto com as partes comestíveis da cultura;
 - d) No caso dos produtos referidos no n.º 1, primeiro parágrafo, alínea b), a sua utilização é essencial para obter ou manter a fertilidade do solo ou

para satisfazer requisitos nutricionais específicos das culturas, ou para objetivos específicos de correção do solo;

- e) No caso dos produtos referidos no n.º 1, primeiro parágrafo, alíneas c) e d), aplicam-se as seguintes disposições:
 - i) a sua utilização é necessária para preservar a saúde, o bem-estar e a vitalidade dos animais e contribuir para uma alimentação adequada que satisfaça as necessidades fisiológicas e comportamentais das espécies em questão ou a sua utilização é necessária para produzir ou conservar alimentos para animais porque não é possível produzir ou conservar alimentos para animais sem recorrer às referidas substâncias,
 - ii) os alimentos para animais de origem mineral, os oligoelementos, as vitaminas ou as provitaminas devem ser de origem natural, salvo quando os produtos ou substâncias das referidas proveniências não se encontrem disponíveis em quantidades suficientes ou com qualidade suficiente ou não existam alternativas.

A autorização da utilização na produção de géneros alimentícios biológicos transformados dos produtos e substâncias referidos no n.º 1, segundo parágrafo, está sujeita aos princípios estabelecidos no capítulo II e aos critérios a seguir indicados, que devem ser avaliados como um todo:

- a) Inexistência de alternativas autorizadas nos termos do presente artigo;
- b) Impossibilidade de produzir ou conservar os géneros alimentícios ou de satisfazer determinados requisitos nutricionais previstos com base na legislação da União sem recorrer aos produtos e substâncias em questão;
- c) Devem existir na natureza, podendo ser sujeitos apenas a processos mecânicos, físicos, biológicos, enzimáticos ou microbianos, a menos que os produtos e substâncias dessa proveniência não se encontrem disponíveis em quantidades suficientes ou com qualidade suficiente.

A autorização da utilização de produtos ou substâncias de síntese química deve ser estritamente limitada a casos em que a utilização dos fatores de produção externos referidos no artigo 4.º, alínea f), contribuiria para impactos ambientais inaceitáveis.

- 3. A fim de garantir a qualidade, a rastreabilidade e o cumprimento do presente regulamento no que respeita à produção biológica em geral e, mais especificamente, à produção de géneros alimentícios biológicos transformados, assim como a adaptação ao progresso técnico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que estabeleçam critérios suplementares para a concessão ou a retirada da autorização relativa aos produtos e substâncias referidos no n.º 1 a utilizar na produção biológica em geral e, mais especificamente, na produção de géneros alimentícios biológicos transformados, bem como outros requisitos e condições para a utilização de tais produtos e substâncias autorizados.
- 4. Sempre que um Estado-Membro considere que uma substância ou um produto deve ser aditado às listas de produtos e substâncias autorizados referidas no n.º 1, ou retirado dessas listas, ou que as especificações de utilização mencionadas nas regras de produção devem ser alteradas, o Estado-Membro em causa deve assegurar que seja enviado oficialmente à Comissão e aos outros Estados-Membros um processo com a justificação da inclusão, da retirada ou das alterações.

Os pedidos de alteração ou de retirada devem ser publicados pelos Estados-Membros.

5. A Comissão deve adotar atos de execução que autorizem ou retirem a autorização de produtos e substâncias suscetíveis de serem utilizados na produção biológica em geral e produtos e substâncias suscetíveis de serem utilizados especificamente na produção de géneros alimentícios biológicos transformados, e que estabeleçam os procedimentos a seguir para a autorização e as listas dos produtos e substâncias em questão, bem como, se for caso disso, a respetiva descrição, requisitos de composição e condições de utilização. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Artigo 20.º

Presença de produtos ou substâncias não autorizados

1. Os produtos nos quais sejam detetados produtos ou substâncias que não tenham sido autorizados em conformidade com o artigo 19.º, em níveis superiores aos estabelecidos tendo em conta, particularmente, a Diretiva 2006/125/CE, não devem ser comercializados como biológicos.
2. A fim de assegurar a eficácia, a eficiência e a transparência do sistema de produção e rotulagem biológicas, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito aos critérios e condições específicos para a aplicação dos níveis referidos no n.º 1 e no que se refere ao estabelecimento dos níveis em questão, bem como à respetiva adaptação à luz do progresso técnico.
3. Em derrogação do artigo 211.º, n.º 1, do Regulamento (UE) n.º 1308/2013, e sujeitos a uma autorização da Comissão adotada sem aplicação do procedimento referido no artigo 37.º, n.ºs 2 ou 3, do presente regulamento, os Estados-Membros podem conceder pagamentos nacionais para compensar os agricultores pelas perdas decorrentes da contaminação dos seus produtos agrícolas por produtos ou substâncias não autorizados que os impeça de comercializar esses produtos como biológicos, desde que os agricultores tenham tomado todas as medidas adequadas para evitar o risco de contaminação. Os Estados-Membros também podem recorrer aos instrumentos da política agrícola comum para cobrir, total ou parcialmente, essas perdas.

Capítulo IV

Rotulagem

Artigo 21.º

Utilização de termos referentes à produção biológica

1. Para efeitos do presente regulamento, considera-se que um produto exhibe termos referentes à produção biológica quando, na rotulagem, na publicidade ou na documentação comercial, esse produto, os seus ingredientes ou as matérias-primas para alimentação animal sejam descritos em termos que sugiram ao comprador que os mesmos foram obtidos em conformidade com o presente regulamento. Mais concretamente, os termos enumerados no anexo IV, os seus derivados ou abreviaturas, tais como «bio» e «eco», isolados ou combinados, podem ser utilizados em toda a União e em qualquer língua indicada no referido anexo para a rotulagem e publicidade de produtos que estejam em conformidade com o presente regulamento.
2. No que respeita aos produtos referidos no artigo 2.º, n.º 1, os termos referidos no n.º 1 do presente artigo não podem ser utilizados em parte nenhuma da União, nem em nenhuma língua indicada no anexo IV, na rotulagem, na publicidade e na documentação comercial de um produto que não satisfaça o disposto no presente regulamento.

Além disso, não podem ser utilizados na rotulagem e na publicidade termos, designadamente termos utilizados em marcas, nem práticas suscetíveis de induzir o consumidor ou o utilizador em erro por sugerirem que um produto ou os seus ingredientes estão em conformidade com o presente regulamento.

3. Relativamente aos géneros alimentícios transformados, os termos referidos no n.º 1 podem ser utilizados:
 - a) Na denominação de venda, desde que:
 - i) o género alimentício transformado esteja em conformidade com as regras de produção estabelecidas no anexo II, parte IV,
 - ii) pelo menos 95 %, em peso, dos seus ingredientes agrícolas sejam biológicos;
 - b) Apenas na lista dos ingredientes, caso menos de 95 % dos ingredientes agrícolas sejam biológicos e desde que os ingredientes cumpram as regras de produção estabelecidas no presente regulamento.

A lista dos ingredientes referida no primeiro parágrafo, alínea b), deve indicar quais são os ingredientes biológicos. As referências à produção biológica apenas podem figurar em relação aos ingredientes biológicos. A lista dos ingredientes deve incluir uma indicação da percentagem total de ingredientes biológicos em relação à quantidade total de ingredientes agrícolas.

Os termos referidos no n.º 1 e a indicação da percentagem referida no presente número, primeiro parágrafo, alínea b), devem figurar com a mesma cor, dimensão e tipo de letra que as restantes indicações constantes da lista dos ingredientes.

4. A fim de assegurar a clareza para os consumidores e garantir a comunicação das informações adequadas aos mesmos, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito à adaptação da lista de termos que consta do anexo IV, tendo em conta as evoluções no domínio linguístico nos Estados-Membros, e no que diz respeito ao estabelecimento de requisitos específicos em matéria de rotulagem e composição aplicáveis aos alimentos para animais e respetivos ingredientes.

Artigo 22.º

Indicações obrigatórias

1. Sempre que sejam utilizados os termos a que se refere o artigo 21.º, n.º 1:
 - a) Deve constar igualmente do rótulo o número de código da autoridade ou do organismo de controlo a que está sujeito o operador que efetuou a última operação de produção ou de preparação;
 - b) Deve constar igualmente da embalagem o logótipo de produção biológica da União Europeia a que se refere o artigo 23.º no que diz respeito aos géneros alimentícios pré-embalados, tal como definidos no artigo 2.º, n.º 2, alínea e), do Regulamento (UE) n.º 1169/2011.
2. Sempre que seja utilizado o logótipo de produção biológica da União Europeia, deve também constar no mesmo campo visual que o logótipo uma indicação do lugar onde foram produzidas as matérias-primas agrícolas que compõem o produto, devendo essa indicação assumir uma das seguintes formas, consoante o caso:
 - a) «Agricultura UE», sempre que a matéria-prima agrícola tenha sido produzida na União Europeia;
 - b) «Agricultura não-UE», sempre que a matéria-prima agrícola tenha sido produzida em países terceiros;
 - c) «Agricultura UE/não-UE», sempre que uma parte das matérias-primas agrícolas tenha sido produzida na União e outra parte num país terceiro.

A palavra «Agricultura» pode ser substituída por «Aquicultura», sempre que adequado.

A indicação «União Europeia» ou «não União Europeia» pode ser substituída ou completada pelo nome de um país, caso todas as matérias-primas agrícolas que compõem o produto nele tenham sido produzidas.

No tocante à indicação «União Europeia» ou «não União Europeia», podem não ser tidas em conta pequenas quantidades de ingredientes desde que a quantidade total dos ingredientes que não foram tidos em conta não exceda 5 % da quantidade total, em peso, das matérias-primas agrícolas.

A indicação «União Europeia» ou «não União Europeia» não pode figurar numa cor, num tamanho nem em caracteres mais destacados do que o nome do género alimentício.

3. As indicações referidas no presente artigo, n.ºs 1 e 2, e no artigo 23.º, n.º 3, devem ser inscritas num sítio em evidência, de modo a serem facilmente visíveis, claramente legíveis e indelévels.

4. A fim de assegurar a clareza para os consumidores e garantir a comunicação das informações adequadas aos mesmos, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que estabeleçam novas regras sobre a rotulagem e a utilização das indicações referidas no presente artigo, n.º 1, alínea a), e n.º 2, assim como no artigo 23.º, n.º 3.
5. A Comissão adota atos de execução relativos aos seguintes aspetos:
 - a) Modalidades específicas e práticas no que respeita à apresentação, composição e tamanho das indicações referidas no presente artigo, n.º 1, alínea a), e n.º 2, assim como no artigo 23.º, n.º 3;
 - b) Atribuição de números de código aos organismos e autoridades de controlo;
 - c) Indicação do lugar onde foram produzidas as matérias-primas agrícolas, em conformidade com o presente artigo, n.º 2, e o artigo 23.º, n.º 3.

Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Artigo 23.º

Logótipo de produção biológica da União Europeia

1. O logótipo de produção biológica da União Europeia pode ser utilizado na rotulagem, apresentação e publicidade de produtos que estejam em conformidade com o presente regulamento.
2. O logótipo de produção biológica da União Europeia é um atestado oficial, em conformidade com os artigos 85.º e 90.º do Regulamento (UE) n.º XXX/XXXX [Regulamento relativo aos controlos oficiais].
3. A utilização do logótipo de produção biológica da União Europeia é facultativa para os produtos importados de países terceiros. Além disso, sempre que o logótipo conste da rotulagem, a indicação referida no artigo 22.º, n.º 2, também deve constar da mesma.
4. O logótipo de produção biológica da União Europeia deve respeitar o modelo estabelecido no anexo V e deve cumprir as regras estabelecidas no referido anexo.
5. Podem ser utilizados logótipos nacionais e privados na rotulagem, apresentação e publicidade de produtos que estejam em conformidade com o presente regulamento.
6. A fim de assegurar a clareza para os consumidores e garantir a comunicação das informações adequadas aos mesmos, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que alterem o logótipo de produção biológica da União Europeia, bem como as regras correspondentes fixadas no anexo V.

Capítulo V

Certificação biológica

Artigo 24.º

Sistema de certificação biológica

1. Os operadores ou grupos de operadores que produzam, preparem ou armazenem produtos biológicos, que importem os referidos produtos de um país terceiro ou os exportem para um país terceiro ou que coloquem no mercado os produtos em questão devem, antes da colocação no mercado como sendo biológicos ou antes da conversão, notificar a sua atividade às autoridades competentes do Estado-Membro ou Estados-Membros em que a referida atividade é exercida.
2. Nos casos em que os operadores ou grupos de operadores subcontratam qualquer uma das suas atividades a um terceiro, tanto os operadores e grupos de operadores como o terceiro ao qual as atividades foram subcontratadas devem cumprir o disposto no n.º 1.
3. Os operadores e grupos de operadores devem manter registos sobre as diferentes atividades que realizam em conformidade com o presente regulamento.
4. As autoridades competentes devem manter uma lista atualizada dos nomes e endereços dos operadores e grupos de operadores que tenham notificado a sua atividade nos termos do n.º 1 e devem publicar a referida lista, juntamente com as informações relativas aos seus certificados biológicos, tal como referido no artigo 25.º, n.º 1. As autoridades competentes devem respeitar os requisitos de proteção de dados pessoais, nos termos da Diretiva 95/46/CE do Parlamento Europeu e do Conselho⁵⁰.
5. Os Estados-Membros devem assegurar que as taxas que podem ser cobradas pelas autoridades competentes, pelas autoridades de controlo ou pelos organismos de controlo, em conformidade com o artigo 76.º do Regulamento (UE) n.º XX/XXXX (Regulamento relativo aos controlos oficiais), sejam divulgadas ao público.
6. A fim de assegurar a eficácia, a eficiência e a transparência do sistema de produção e rotulagem biológicas, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, relativamente aos requisitos para a manutenção de registos, aos requisitos para a publicação da lista referida no presente artigo, n.º 4, e aos requisitos e procedimentos a aplicar para a publicação das taxas referidas no presente artigo, n.º 5, assim como para a supervisão, por parte das autoridades competentes, da aplicação das referidas taxas.
7. A Comissão pode adotar atos de execução para fornecer detalhes e especificações relativamente ao conteúdo, forma e modo de notificação referidos no n.º 1 e à forma de publicação das taxas referidas no n.º 5. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

⁵⁰ Diretiva 95/46/CE do Parlamento Europeu e do Conselho, de 24 de outubro de 1995, relativa à proteção das pessoas singulares no que diz respeito ao tratamento de dados pessoais e à livre circulação desses dados (JO L 281 de 23.11.1995, p. 31).

Artigo 25.º

Certificado biológico

1. Os operadores e grupos de operadores que tenham notificado a sua atividade em conformidade com o artigo 24.º, n.º 1, e cumpram o disposto no presente regulamento têm direito a receber um certificado biológico. O certificado biológico, emitido, sempre que possível, em formato eletrónico, deve permitir, pelo menos, a identificação do operador ou do grupo de operadores, do tipo ou gama de produtos abrangidos pelo certificado e do seu período de validade.
2. O certificado biológico é uma certificação oficial, na aceção dos artigos 85.º e 86.º do Regulamento (UE) n.º XXX/XXX (Regulamento relativo aos controlos oficiais).
3. Os operadores e grupos de operadores não têm direito a receber um certificado biológico de diferentes autoridades de controlo ou organismos de controlo relativamente ao mesmo grupo de produtos, mesmo quando os operadores e grupos de operadores em questão participam em diferentes fases da produção, preparação e distribuição.
4. Os membros de um grupo de operadores não têm direito a receber um certificado biológico individual relativamente a qualquer das atividades abrangidas pela certificação do grupo.
5. Os operadores devem verificar sistematicamente o certificado biológico dos operadores que são seus fornecedores.
6. A fim de assegurar a eficácia, a eficiência e a transparência do sistema de produção e rotulagem biológicas, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito aos critérios de definição dos grupos de produtos referidos no n.º 3.

Artigo 26.º

Grupo de operadores

1. Cada grupo de operadores deve estabelecer um sistema de controlos internos. O sistema em questão deve ser composto por um conjunto documentado de atividades e procedimentos de controlo, segundo o qual uma pessoa ou organismo identificado seja responsável por verificar o cumprimento do presente regulamento relativamente a cada membro do grupo.
2. As deficiências relativas à criação ou funcionamento do sistema de controlos internos referido no n.º 1, nomeadamente no que diz respeito a falhas na deteção ou resolução de incumprimentos por parte de membros individuais do grupo de operadores que afetem a integridade dos produtos biológicos, podem resultar na retirada da certificação biológica de todo o grupo.
3. Para assegurar o funcionamento efetivo e eficiente da certificação de um grupo de operadores, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito às responsabilidades dos membros individuais de um grupo de operadores, à composição e dimensão de um grupo de operadores, às categorias de produtos que serão produzidos por um grupo de operadores, às condições de participação num grupo de operadores, bem como à criação e ao

funcionamento do sistema de controlos internos do grupo, incluindo o âmbito, o conteúdo e a frequência dos controlos a efetuar.

4. A Comissão pode adotar atos de execução no que se refere ao intercâmbio de informações entre um grupo de operadores e a autoridade ou autoridades competentes, as autoridades de controlo ou os organismos de controlo, e entre os Estados-Membros e a Comissão. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Capítulo VI

Relações comerciais com países terceiros

Artigo 27.º

Exportação de produtos biológicos

1. Um produto pode ser exportado da União como biológico e ostentar o logótipo de produção biológica da União Europeia se estiver em conformidade com o presente regulamento.
No entanto, um produto destinado a ser exportado como biológico para um país terceiro reconhecido em conformidade com o artigo 31.º pode ser exportado para o país terceiro em questão se estiver em conformidade com os requisitos de colocação no mercado como biológico do referido país terceiro.
2. A fim de evitar que se criem condições desiguais para os operadores aquando da exportação para países terceiros, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito às regras específicas aplicáveis às exportações de produtos biológicos para um país terceiro reconhecido em conformidade com o artigo 31.º.
3. A fim de assegurar uma concorrência leal entre os operadores, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito aos documentos destinados às autoridades aduaneiras de países terceiros, em especial no que se refere a um certificado de exportação de produtos biológicos, emitido, sempre que possível, em formato eletrónico, que garanta que os produtos biológicos exportados estão em conformidade com o presente regulamento.

Artigo 28.º

Importação de produtos biológicos

1. Um produto pode ser importado de um país terceiro para ser colocado no mercado da União como biológico se estiverem reunidas as seguintes condições:
 - a) O produto é um produto biológico, tal como referido no artigo 2.º, n.º 1;
 - b) O produto:
 - i) está em conformidade com os capítulos II, III e IV e todos os operadores, incluindo os exportadores no país terceiro em causa, foram sujeitos ao controlo por parte das autoridades de controlo ou dos organismos de controlo reconhecidos em conformidade com o artigo 29.º, ou
 - ii) é proveniente de um país terceiro reconhecido em conformidade com:
 - o artigo 30.º, ou
 - o artigo 31.º;
 - c) Os operadores de países terceiros podem fornecer aos importadores ou às autoridades nacionais, em qualquer momento, informações que permitam

identificar o operador que efetuou a última operação com vista a assegurar a rastreabilidade do produto biológico.

2. A fim de assegurar a rastreabilidade dos produtos importados destinados a serem colocados no mercado da União como biológicos, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito aos documentos necessários para efeitos de importação, emitidos, sempre que possível, em formato eletrónico.
3. O respeito das condições e medidas relativas à importação de produtos biológicos para a União deve ser determinado nos postos de controlo fronteiriços, em conformidade com o artigo 45.º, n.º 1, do Regulamento (UE) n.º XXX/XXX (Regulamento relativo aos controlos oficiais). Os controlos físicos referidos no artigo 47.º, n.º 3, do regulamento em questão devem ser realizados com uma frequência dependente do risco de incumprimento do presente regulamento.

Artigo 29.º

Reconhecimento das autoridades e organismos de controlo

1. A Comissão pode adotar atos de execução que reconheçam ou retirem o reconhecimento às autoridades de controlo e aos organismos de controlo que cumprem os critérios estabelecidos num ato delegado adotado por força do n.º 7 e que são competentes para realizar controlos em países terceiros, e que estabeleçam uma lista das referidas autoridades de controlo e organismos de controlo. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.
2. Os organismos de controlo devem estar acreditados de acordo com a norma harmonizada relevante para «Avaliação da conformidade — Requisitos para organismos que procedem à certificação de produtos, processos e serviços», cuja referência tenha sido publicada no *Jornal Oficial da União Europeia*.
3. A acreditação referida no n.º 2 apenas pode ser concedida por:
 - a) Um organismo nacional de acreditação da União, em conformidade com o Regulamento (CE) n.º 765/2008 do Parlamento Europeu e do Conselho⁵¹; ou
 - b) Um organismo de acreditação fora da União que seja signatário de um convénio multilateral de reconhecimento sob os auspícios do Fórum Internacional para a Acreditação.
4. Sempre que examine pedidos de reconhecimento, a Comissão deve convidar a autoridade de controlo ou o organismo de controlo a fornecer todas as informações necessárias.

Os organismos de controlo ou as autoridades de controlo reconhecidos devem fornecer o certificado emitido pelo organismo de acreditação ou, respetivamente, o relatório de avaliação emitido pela autoridade competente, e, se for caso disso, relatórios sobre a avaliação *in loco*, a fiscalização e a reavaliação plurianual regulares das suas atividades.

⁵¹ Regulamento (CE) n.º 765/2008 do Parlamento Europeu e do Conselho, de 9 de julho de 2008, que estabelece os requisitos de acreditação e fiscalização do mercado relativos à comercialização de produtos, e que revoga o Regulamento (CEE) n.º 339/93 (JO L 218 de 13.8.2008, p. 30).

5. Com base nas informações referidas no n.º 4, a Comissão deve assegurar uma supervisão adequada das autoridades de controlo e dos organismos de controlo reconhecidos, reexaminando regularmente o seu reconhecimento. Para efeitos da referida supervisão, a Comissão pode solicitar informações adicionais aos organismos de acreditação ou, se for caso disso, às autoridades competentes.
6. A natureza da supervisão é determinada com base numa avaliação do risco de incumprimento.
7. A fim de assegurar a transparência dos processos de reconhecimento e supervisão, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito aos critérios a aplicar ao reconhecimento, ou à retirada do reconhecimento, dos organismos e autoridades de controlo referidos no n.º 1, bem como no que diz respeito ao exercício da supervisão por parte da Comissão, nomeadamente através de exame *in loco*.
8. A Comissão pode adotar atos de execução para garantir a aplicação de medidas em relação a casos de incumprimento, ou de suspeita de incumprimento, que afetem a integridade dos produtos biológicos importados no âmbito do reconhecimento previsto no presente artigo. As referidas medidas podem consistir, nomeadamente, na verificação da integridade dos produtos biológicos antes da colocação dos mesmos no mercado da União Europeia e, se for caso disso, na suspensão da autorização de colocação no mercado da União desses produtos como biológicos. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.
9. Por imperativos de urgência devidamente justificados relacionados com a proteção contra práticas desleais ou práticas incompatíveis com os princípios e regras em matéria de produção biológica, a proteção da confiança dos consumidores ou a proteção da concorrência leal entre os operadores, a Comissão adota atos de execução imediatamente aplicáveis em conformidade com o procedimento referido no artigo 37.º, n.º 3, a fim de tomar as medidas referidas no presente artigo, n.º 8, ou de decidir da retirada do reconhecimento às autoridades de controlo e aos organismos de controlo a que se refere o presente artigo, n.º 1.

Artigo 30.º

Equivalência no âmbito de um acordo comercial

Um país terceiro reconhecido, referido no artigo 28.º, n.º 1, alínea b), subalínea ii), primeiro travessão, é um país terceiro que a União tenha reconhecido no âmbito de um acordo comercial como tendo um sistema de produção que obedece aos mesmos objetivos e princípios, mediante a aplicação de regras que asseguram o mesmo nível de garantia da conformidade que as da União.

Artigo 31.º

Equivalência ao abrigo do Regulamento (CE) n.º 834/2007

1. Um país terceiro reconhecido, referido no artigo 28.º, n.º 1, alínea b), subalínea ii), segundo travessão, é um país terceiro que tenha sido reconhecido para efeitos de equivalência ao abrigo do artigo 33.º, n.º 2, do Regulamento (CE) n.º 834/2007,

incluindo os países reconhecidos ao abrigo da medida transitória prevista no artigo 40.º

O reconhecimento dos países terceiros referidos no primeiro parágrafo expira em [inserir data correspondente a 5 anos após a data de aplicação do regulamento].

2. Com base em relatórios anuais a enviar à Comissão pelos países terceiros referidos no n.º 1, até 31 de março de cada ano, no que se refere à execução e aplicação das medidas de controlo por eles instituídas, a Comissão, assistida pelos Estados-Membros, deve assegurar a supervisão adequada dos países terceiros reconhecidos, reexaminando regularmente o seu reconhecimento. A natureza da supervisão é determinada com base numa avaliação do risco de incumprimento.
3. Os organismos de controlo que efetuam os controlos nos países terceiros referidos no n.º 1 devem estar acreditados de acordo com a norma harmonizada relevante para «Avaliação da conformidade — Requisitos para organismos que procedem à certificação de produtos, processos e serviços», cuja referência tenha sido publicada no *Jornal Oficial da União Europeia*. Caso a acreditação não seja concedida por um organismo nacional de acreditação da União, em conformidade com o Regulamento (CE) n.º 765/2008, apenas pode ser concedida por um organismo de acreditação fora da União que seja signatário de um convénio multilateral de reconhecimento sob os auspícios do Fórum Internacional para a Acreditação.
4. A Comissão, por meio de um ato de execução, deve estabelecer uma lista dos países terceiros a que se refere o n.º 1 e pode alterar essa lista por meio de atos de execução. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.
5. A fim de assegurar a gestão da lista dos países terceiros a que se refere o n.º 4, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que diz respeito às informações a enviar pelos países terceiros em questão, necessárias para a supervisão do seu reconhecimento pela Comissão, bem como para o exercício dessa supervisão por parte da Comissão, nomeadamente através de exame *in loco*.
6. A Comissão pode adotar atos de execução para garantir a aplicação de medidas em relação a casos de incumprimento, ou de suspeita de incumprimento, que afetem a integridade dos produtos biológicos importados dos países terceiros referidos no presente artigo. As referidas medidas podem consistir, nomeadamente, na verificação da integridade dos produtos biológicos antes da colocação dos mesmos no mercado da União Europeia e, se for caso disso, na suspensão da autorização de colocação no mercado da União desses produtos como biológicos. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Capítulo VII

Disposições gerais

SECÇÃO 1

LIVRE CIRCULAÇÃO DOS PRODUTOS BIOLÓGICOS

Artigo 32.º

Não-proibição e não-restrição da comercialização de produtos biológicos

1. As autoridades competentes, as autoridades de controlo e os organismos de controlo não podem, por razões relativas à produção, à rotulagem ou à apresentação dos produtos, proibir ou restringir a comercialização de produtos biológicos controlados por outra autoridade competente, autoridade de controlo ou organismo de controlo situado noutro Estado-Membro, se os produtos em questão cumprirem os requisitos do presente regulamento. Em especial, não podem ser realizados controlos oficiais e outras atividades oficiais além dos permitidos nos termos do Regulamento (UE) n.º XXX/XXX (Regulamento relativo aos controlos oficiais), nem não podem ser cobradas taxas relativas a controlos oficiais ou outras atividades oficiais além das previstas no artigo 76.º do referido regulamento.
2. A fim de assegurar o bom funcionamento do mercado único e do comércio entre os Estados-Membros, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que estabeleçam regras relativas à livre circulação dos produtos biológicos, para efeitos de aplicação do presente artigo, n.º 1.

SECÇÃO 2

INFORMAÇÃO E APRESENTAÇÃO DE RELATÓRIOS

Artigo 33.º

Informações relativas ao setor biológico e ao comércio conexo

1. Todos os anos, os Estados-Membros devem transmitir à Comissão as informações necessárias para a execução e o acompanhamento da aplicação do presente regulamento.
2. A Comissão adota atos de execução no que se refere ao regime a utilizar para transmitir as informações referidas no n.º 1, os elementos de informação a transmitir e a data-limite para a transmissão das informações. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.

Artigo 34.º

Informações relativas às autoridades competentes, às autoridades de controlo e aos organismos de controlo

1. Os Estados-Membros devem manter uma lista, atualizada regularmente, que contenha:
 - a) Os nomes e endereços das autoridades competentes;
 - b) Os nomes e endereços das autoridades de controlo e organismos de controlo e os seus números de código.Os Estados-Membros devem tornar pública a lista referida no primeiro parágrafo, alínea b).
2. A Comissão deve publicar anualmente, na Internet, a lista das autoridades de controlo e dos organismos de controlo a que se refere o n.º 1, alínea b).

Artigo 35.º

Relatório

Até 31 de dezembro de 2021, a Comissão deve apresentar ao Parlamento Europeu e ao Conselho um relatório sobre a disponibilidade de material de reprodução vegetal biológico e de animais para fins de reprodução.

Capítulo VIII

Disposições processuais, transitórias e finais

SECÇÃO 1

DISPOSIÇÕES PROCESSUAIS

Artigo 36.º

Exercício da delegação

1. O poder de adotar atos delegados conferido à Comissão está sujeito às condições estabelecidas no presente artigo.
2. A delegação de poderes referida no [.....] pode ser revogada em qualquer momento pelo Parlamento Europeu ou pelo Conselho. A decisão de revogação põe termo à delegação dos poderes especificados nessa decisão. Produz efeitos no dia seguinte ao da sua publicação no *Jornal Oficial da União Europeia* ou numa data posterior especificada na mesma, mas não afeta os atos delegados já em vigor.
3. Assim que adotar um ato delegado, a Comissão notifica-o simultaneamente ao Parlamento Europeu e ao Conselho.
4. Os atos delegados adotados em aplicação do disposto no [.....] só entram em vigor se nem o Parlamento Europeu nem o Conselho formularem objeções no prazo de dois meses a contar da notificação do ato a estas duas instituições ou se, antes do termo desse prazo, o Parlamento Europeu e o Conselho informarem a Comissão de que não formularão objeções. O referido prazo é prorrogado por dois meses por iniciativa do Parlamento Europeu ou do Conselho.

Artigo 37.º

Procedimento de comité

1. A Comissão é assistida pelo «Comité da Produção Biológica». Esse comité é um comité na aceção do Regulamento (UE) n.º 182/2011.
2. Sempre que se faça referência ao presente número, é aplicável o artigo 5.º do Regulamento (UE) n.º 182/2011.
3. Sempre que se faça referência ao presente número, é aplicável o artigo 8.º do Regulamento (UE) n.º 182/2011 em conjugação com o seu artigo 5.º.

SECÇÃO 2

REVOGAÇÃO, ALTERAÇÕES E DISPOSIÇÕES TRANSITÓRIAS E FINAIS

Artigo 38.º

Revogação

O Regulamento (CE) n.º 834/2007 é revogado.

No entanto, o Regulamento (CE) n.º 834/2007 continua a ser aplicável para efeitos de conclusão do exame dos pedidos pendentes de países terceiros, conforme previsto no artigo 42.º do presente regulamento.

Artigo 39.º

Medidas transitórias relativas à conversão para a agricultura biológica

A fim de assegurar uma transição harmoniosa do antigo para o novo quadro jurídico, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, relativos a regras que prevejam uma derrogação do artigo 8.º, n.º 3, no que se refere aos períodos de conversão para os agricultores que iniciem a conversão antes da entrada em vigor do presente regulamento.

Artigo 40.º

Medidas transitórias relativas à origem do material de reprodução vegetal, dos animais para reprodução e das populações juvenis de animais de aquicultura

A fim de assegurar uma transição harmoniosa entre as regras relativas à origem biológica do material de reprodução vegetal, previstas no artigo 12.º, n.º 1, alínea i), do Regulamento (CE) n.º 834/2007, aos animais para fins de reprodução, previstas no artigo 14.º, n.º 1, alínea a), subalínea ii), do mesmo regulamento, e às populações juvenis de animais de aquicultura, previstas no artigo 15.º, n.º 1, alínea a), subalínea ii), do referido regulamento, bem como a derrogação das regras de produção adotadas pela Comissão em conformidade com o artigo 22.º do Regulamento (CE) n.º 834/2007, e as novas regras de produção aplicáveis aos vegetais e produtos vegetais, aos animais e às algas marinhas e aos animais de aquicultura, previstas no artigo 10.º, n.º 1, e no artigo 11.º, n.º 1, respetivamente, do presente regulamento, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, que prevejam derrogações, nos casos em que as derrogações sejam consideradas necessárias para garantir o acesso a material de reprodução vegetal, a animais vivos para fins de reprodução e a populações juvenis de animais de aquicultura que possam ser utilizados na produção biológica. Os atos delegados adotados ao abrigo do presente artigo deixam de ser aplicáveis em 31 de dezembro de 2021.

Artigo 41.º

Medidas transitórias relativas às autoridades de controlo e aos organismos reconhecidos nos termos do artigo 33.º, n.º 3, do Regulamento (CE) n.º 834/2007

1. O reconhecimento das autoridades de controlo e organismos de controlo concedido ao abrigo do artigo 33.º, n.º 3, do Regulamento (CE) n.º 834/2007 expira, o mais tardar, em [31 de dezembro de 2018].
2. A Comissão, por meio de um ato de execução, estabelece uma lista das autoridades de controlo e organismos de controlo reconhecidos nos termos do artigo 33.º, n.º 3, do Regulamento (CE) n.º 834/2007 e pode alterar essa lista por meio de atos de execução. Os referidos atos de execução são adotados em conformidade com o procedimento de exame referido no artigo 37.º, n.º 2.
3. A fim de assegurar a gestão da lista das autoridades de controlo e organismos de controlo a que se refere o n.º 2, a Comissão fica habilitada a adotar atos delegados,

em conformidade com o artigo 36.º, no que diz respeito às informações a enviar pelas autoridades de controlo e organismos de controlo em questão, necessárias para a supervisão do seu reconhecimento pela Comissão, bem como para o exercício dessa supervisão por parte da Comissão, nomeadamente através de exame *in loco*.

Artigo 42.º

Medidas transitórias relativas aos pedidos de países terceiros apresentados nos termos do artigo 33.º, n.º 2, do Regulamento (CE) n.º 834/2007

1. A Comissão deve concluir o exame dos pedidos de países terceiros apresentados nos termos do artigo 33.º, n.º 2, do Regulamento (CE) n.º 834/2007 que estejam pendentes na data de entrada em vigor do presente regulamento. O Regulamento (CE) n.º 834/2007 é aplicável ao exame dos pedidos em causa.
2. A fim de facilitar a conclusão do exame dos pedidos a que se refere o n.º 1, a Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 36.º, no que respeita às regras processuais necessárias para o exame, incluindo no que respeita às informações a apresentar pelos países terceiros.

Artigo 43.º

Medidas transitórias relativas às existências de produtos biológicos produzidos em conformidade com o Regulamento (CE) n.º 834/2007

Os produtos produzidos em conformidade com o Regulamento (CE) n.º 834/2007 e colocados no mercado antes de 1 de julho de 2017 podem continuar a ser comercializados depois dessa data até ao esgotamento das existências.

Artigo 44.º

Alterações do Regulamento (UE) n.º [...] [relativo aos controlos oficiais]

O Regulamento (UE) n.º XXX/XXXX (Regulamento relativo aos controlos oficiais) é alterado do seguinte modo:

1. No artigo 2.º, os pontos 38 e 39 passam a ter a seguinte redação:
«38. "Organismo delegado", um terceiro no qual as autoridades competentes tenham delegado tarefas específicas de controlo oficial ou outras atividades oficiais;
39. "Autoridade de controlo da produção biológica e da rotulagem dos produtos biológicos", uma organização administrativa pública de um Estado-Membro à qual as autoridades competentes tenham atribuído, total ou parcialmente, as suas competências relacionadas com a aplicação da legislação da União no domínio referido no artigo 1.º, n.º 2, alínea j), incluindo, se adequado, a autoridade correspondente de um país terceiro ou que opere num país terceiro;».
2. O artigo 3.º é alterado do seguinte modo:
 - a) O n.º 3 passa a ter a seguinte redação:
«3. As autoridades competentes responsáveis pela verificação do cumprimento das regras referidas no artigo 1.º, n.º 2, alínea j), podem confiar tarefas de controlo oficial

ou outras atividades oficiais a uma ou mais autoridades de controlo da produção biológica e da rotulagem dos produtos biológicos. Nesse caso, devem atribuir um número de código a cada uma dessas autoridades.»;

b) No n.º 4, a alínea c) passa a ter a seguinte redação:

«c) Autoridades de controlo da produção biológica e da rotulagem dos produtos biológicos referidas no n.º 3;».

3. O artigo 23.º passa a ter a seguinte redação:

«Artigo 23.º

Regras específicas sobre os controlos oficiais e a ação a empreender pelas autoridades competentes no que diz respeito aos produtos biológicos, às denominações de origem protegidas, às indicações geográficas protegidas e às especialidades tradicionais garantidas

1. Em relação às regras referidas no artigo 1.º, n.º 2, alínea j), as autoridades competentes devem:

a) Em caso de incumprimento que afete a integridade dos produtos biológicos em qualquer fase da produção, preparação, distribuição e exportação, em especial devido à utilização de substâncias e técnicas proibidas ou não autorizadas, ou à mistura com produtos não biológicos, assegurar que não é feita qualquer referência à produção biológica na rotulagem e na publicidade da totalidade do lote ou da produção em causa;

b) Em caso de incumprimento repetitivo ou continuado, assegurar que os operadores ou o grupo de operadores em causa, como definidos no artigo 3.º, n.ºs 6 e 7, do Regulamento (UE) n.º [produção biológica] do Parlamento Europeu e do Conselho*, além das medidas referidas no presente número, alínea a), fiquem proibidos de comercializar produtos em que seja feita referência à produção biológica, e que os respetivos certificados biológicos sejam suspensos ou retirados, conforme adequado.

2. A Comissão fica habilitada a adotar atos delegados, em conformidade com o artigo 139.º, no que diz respeito às regras para a realização de controlos oficiais e de outras atividades oficiais destinados a verificar o cumprimento das regras referidas no artigo 1.º, n.º 2, alíneas j) e k), bem como no que diz respeito às ações a empreender pelas autoridades competentes no seguimento dos referidos controlos oficiais e outras atividades oficiais.

3. No que diz respeito às regras referidas no artigo 1.º, n.º 2, alínea j), os atos delegados referidos no presente artigo, n.º 2, do devem estabelecer regras relativas aos seguintes aspetos:

a) Responsabilidades e tarefas específicas das autoridades competentes, em complemento das previstas nos artigos 4.º, 8.º, 9.º, no artigo 10.º, n.º 1, nos artigos 11.º a 13.º, no artigo 34.º, n.ºs 1 e 2, e no artigo 36.º, e em complemento do disposto nos artigos 25.º, 26.º, 28.º, 29.º, 30.º e 32.º, para a aprovação e supervisão dos organismos delegados, e nos artigos 85.º a 90.º relativos à certificação oficial;

b) Requisitos complementares aos referidos no artigo 8.º, n.º 1, para a avaliação dos riscos e para a definição da frequência dos controlos oficiais, bem como para a amostragem, conforme adequado, tendo em conta o risco de ocorrência de incumprimentos;

c) Frequência dos controlos oficiais dos operadores e casos e condições em que tais operadores ficam isentos de certos controlos oficiais;

d) Métodos e técnicas de controlo oficial complementares aos referidos no artigo 13.º e no artigo 33.º, n.ºs 1 a 5, e requisitos específicos para a realização dos controlos oficiais destinados a garantir a rastreabilidade dos produtos biológicos em todas as fases de produção, preparação e distribuição e a fornecer garantias do cumprimento das regras referidas no artigo 1.º, n.º 2, alínea j);

e) Ações e medidas complementares às previstas no artigo 134.º, n.ºs 2 e 3, em caso de suspeita de incumprimento, critérios complementares aos referidos no artigo 135.º, n.º 1, segundo parágrafo, e critérios e medidas complementares aos previstos no artigo 135.º, n.º 2, e no presente artigo, n.º 1, em caso de ocorrência de incumprimento;

f) Requisitos complementares aos previstos no artigo 4.º, n.º 1, alínea f), relativos às instalações e ao equipamento necessários para efetuar controlos oficiais e condições e obrigações específicas complementares às referidas nos artigos 25.º, 26.º, 28.º, 29.º e nos artigos 30.º a 32.º para a delegação de tarefas de controlo oficial e outras atividades oficiais nos organismos delegados;

g) Obrigações de comunicação complementares às referidas nos artigos 12.º, 28.º e 31.º respeitantes às autoridades competentes, às autoridades de controlo e aos organismos delegados responsáveis por controlos oficiais e outras atividades oficiais;

h) Critérios e condições específicos para o acionamento e o funcionamento dos mecanismos de assistência administrativa previstos no título IV, incluindo o intercâmbio de informações relativas a casos de incumprimento ou a probabilidade de incumprimento entre as autoridades competentes, autoridades de controlo e organismos delegados.

4. No que diz respeito às regras referidas no artigo 1.º, n.º 2, alínea k), os atos delegados referidos no presente artigo, n.º 3, devem estabelecer regras relativas aos seguintes aspetos:

a) Requisitos, métodos e técnicas complementares aos referidos nos artigos 11.º e 13.º para os controlos oficiais destinados a verificar o cumprimento das especificações dos produtos e dos requisitos de rotulagem;

b) Métodos e técnicas complementares aos referidos no artigo 13.º para a realização dos controlos oficiais destinados a garantir a rastreabilidade dos produtos abrangidos pelas regras referidas no artigo 1.º, n.º 2, alínea k), em todas as fases de produção, preparação e distribuição, e a fornecer garantias do cumprimento dessas regras;

c) Critérios e conteúdos específicos complementares aos previstos no artigo 108.º para a elaboração das partes relevantes do plano nacional de controlo plurianual previsto no artigo 107.º, n.º 1, e conteúdos específicos complementares do relatório previsto no artigo 112.º;

d) Critérios e condições específicos para acionar os mecanismos de assistência administrativa previstos no título IV;

e) Medidas específicas a tomar, além das referidas no artigo 135.º, n.º 2, em caso de incumprimento e de incumprimento grave ou recorrente.

5. Quando adequado, os atos delegados referidos no n.º 3 e no n.º 4 devem estabelecer derrogações às disposições do presente regulamento referidas nesses números.

* JO L ... de ..., p. ...».

4. No artigo 128.º, o n.º 1 passa a ter a seguinte redação:

«1. Nos domínios regidos pelas regras referidas no artigo 1.º, n.º 2, excluindo as alíneas d), e), g), h) e j) do artigo 1.º, n.º 2, a Comissão pode, por meio de atos de execução, reconhecer que as medidas aplicadas num país terceiro ou em regiões desse país são equivalentes aos requisitos estabelecidos nessas regras, com base:

a) Num exame exaustivo dos dados e informações fornecidos pelo país terceiro em causa de acordo com o artigo 124.º, n.º 1;

b) Sempre que adequado, no resultado satisfatório de um controlo realizado em conformidade com o artigo 119.º, n.º 1.

Os referidos atos de execução são adotados em conformidade com o procedimento de exame a que se refere o artigo 141.º, n.º 2.»

5. No artigo 141.º, o n.º 1 passa a ter a seguinte redação:

«1. A Comissão é assistida pelo Comité Permanente dos Vegetais, Animais e Alimentos para Consumo Humano e Animal instituído pelo artigo 58.º, n.º 1, do Regulamento (CE) n.º 178/2002. Esse comité é um comité na aceção do Regulamento (UE) n.º 182/2011. Para as medidas abrangidas pelo domínio a que se refere o artigo 1.º, n.º 2, alínea j), do presente regulamento, a Comissão é assistida pelo Comité da Produção Biológica instituído pelo artigo 37.º, n.º 1, do Regulamento (UE) n.º [produção biológica].»

Artigo 45.º

Entrada em vigor e aplicação

O presente regulamento entra em vigor no terceiro dia seguinte ao da sua publicação no *Jornal Oficial da União Europeia*.

O presente regulamento é aplicável a partir de 1 de julho de 2017⁵².

O presente regulamento é obrigatório em todos os seus elementos e diretamente aplicável em todos os Estados-Membros.

Feito em Bruxelas, em

Pelo Parlamento Europeu
O Presidente
[...]

Pelo Conselho
O Presidente
[...]

⁵² Pelo menos 6 meses após a sua entrada em vigor.

Ficha financeira legislativa

1. CONTEXTO DA PROPOSTA/INICIATIVA

- 1.1. Denominação da proposta/iniciativa
- 1.2. Domínio(s) de intervenção abrangido(s) segundo a estrutura ABM/ABB
- 1.3. Natureza da proposta/iniciativa
- 1.4. Objetivo(s)
- 1.5. Justificação da proposta/iniciativa
- 1.6. Duração da ação e impacto financeiro
- 1.7. Modalidade(s) de gestão prevista(s)

2. MEDIDAS DE GESTÃO

- 2.1. Disposições em matéria de acompanhamento e prestação de informações
- 2.2. Sistema de gestão e de controlo
- 2.3. Medidas de prevenção de fraudes e irregularidades

3. IMPACTO FINANCEIRO ESTIMADO DA PROPOSTA/INICIATIVA

- 3.1. Rubrica(s) do quadro financeiro plurianual e rubrica(s) orçamental(is) de despesas envolvida(s)
- 3.2. Impacto estimado nas despesas
 - 3.2.1. Síntese do impacto estimado nas despesas
 - 3.2.2. Impacto estimado nas dotações operacionais
 - 3.2.3. Impacto estimado nas dotações de natureza administrativa
 - 3.2.4. Compatibilidade com o atual quadro financeiro plurianual
 - 3.2.5. Participação de terceiros no financiamento
- 3.3. Impacto estimado nas receitas

FICHA FINANCEIRA LEGISLATIVA

1. CONTEXTO DA PROPOSTA/INICIATIVA

1.1. Denominação da proposta/iniciativa

Regulamento do Parlamento Europeu e do Conselho que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho e que revoga o Regulamento (CE) n.º 834/2007.

1.2. Domínio(s) de intervenção abrangido(s) segundo a estrutura ABM/ABB⁵³

1.3. Natureza da proposta/iniciativa

A proposta/iniciativa refere-se a **uma nova ação**

A proposta/iniciativa refere-se a **uma nova ação na sequência de um projeto-piloto/ação preparatória**⁵⁴

A proposta/iniciativa refere-se à **prorrogação de uma ação existente**

X A proposta/iniciativa refere-se a **uma ação reorientada para uma nova ação**

1.4. Objetivo(s)

1.4.1. *Objetivo(s) estratégico(s) plurianual(is) da Comissão visado(s) pela proposta/iniciativa*

A proposta visa a forma como as regras relativas à produção biológica contribuem para a concretização das prioridades políticas da estratégia Europa 2020 para um crescimento inteligente, sustentável e inclusivo, nomeadamente o estabelecimento de uma economia competitiva baseada no conhecimento e na inovação, o fomento de uma economia com níveis elevados de emprego que assegure a coesão social e territorial, bem como o apoio da transição para uma economia hipocarbónica e eficiente em termos de recursos. Objetivo(s) específico(s) e atividade(s) ABM/ABB em causa

Os objetivos específicos da proposta são:

- eliminar os obstáculos ao desenvolvimento da produção biológica na União,
- garantir condições de concorrência leal para os agricultores e os operadores e melhorar o funcionamento do mercado interno,
- manter ou aumentar a confiança dos consumidores nos produtos biológicos.

Em conformidade com o quadro comum de acompanhamento e avaliação (QCAA) da política agrícola comum (PAC) para o período de 2014-2020⁵⁵, a proposta contribui para os objetivos gerais: «Gestão sustentável dos recursos naturais e ações climáticas» fornecendo bens públicos (na sua maioria ambientais) e prosseguindo uma «adaptação às alterações climáticas e atenuação dos seus efeitos» e uma «produção alimentar viável» «correspondendo às expectativas dos consumidores» e «melhorando a competitividade do setor agrícola e aumentando a quota na cadeia alimentar», de acordo com o primeiro pilar da PAC.

⁵³ ABM: activity-based management (gestão por atividades); ABB: activity-based budgeting (orçamentação por atividades).

⁵⁴ Referidos no artigo 54.º, n.º 2, alíneas a) ou b), do Regulamento Financeiro.

⁵⁵ Artigo 110.º do Regulamento (UE) n.º 1306/2013 do Parlamento Europeu e do Conselho relativo ao financiamento, à gestão e ao acompanhamento da Política Agrícola Comum.

Além disso, a proposta contribui para o objetivo geral «gestão sustentável dos recursos naturais e ações climáticas» ao restaurar, preservar e melhorar os ecossistemas (prioridade 4), de acordo com o segundo pilar da PAC.

A proposta está relacionada com medidas apoiadas no âmbito do primeiro pilar (pagamentos diretos e mercados) e do segundo pilar da PAC.

Atividade ABB em causa: 05 04 Desenvolvimento rural (e 05 02 Intervenções nos mercados agrícolas e 05 03 Ajudas diretas).

1.4.2. *Resultados e impacto esperados*

Especificar os efeitos que a proposta/iniciativa poderá ter nos beneficiários/na população visada.

Uma perspetiva positiva do mercado, graças a uma maior confiança dos consumidores, deverá apoiar os preços dos produtos biológicos e atrair novos intervenientes.

A eliminação das derrogações às regras deverá contribuir para o desenvolvimento de fatores de produção biológicos, nomeadamente sementes.

As regras de produção mais claras e simples tornarão o setor mais atrativo.

A concorrência leal será melhorada, nomeadamente através da maior harmonização, de regras mais simples e claras, bem como da passagem da equivalência para a conformidade para o reconhecimento dos organismos de controlo em países terceiros.

A confiança dos consumidores será abordada através da harmonização das regras de produção, tendo em conta a evolução das preocupações da sociedade (bem-estar dos animais, sistema de gestão ambiental para os transformadores e comerciantes).

Espera-se que uma abordagem baseada no risco melhore a eficácia e a eficiência dos controlos e contribua, juntamente com um regime de importação mais fiável, para a prevenção de fraudes.

Especificar os indicadores que permitem acompanhar a execução da proposta/iniciativa.

Os principais indicadores de resultados do quadro comum de acompanhamento e avaliação são os seguintes:

- Quota da superfície biológica na superfície agrícola utilizada (SAU) total;
- Quota dos animais de criação biológica nos animais totais.

E os principais indicadores de realização são os seguintes:

- Superfície de terras para produção biológica (em conversão e já convertidas);
- Número de operadores biológicos certificados.

Os seguintes indicadores complementares também serão acompanhados no contexto do presente regulamento:

- Animais (número de animais de criação biológica e produtos de origem animal);
- Produção e transformação de culturas (número de operadores e valor/volume da produção por tipo de atividade económica);
- Número de derrogações utilizadas e número de derrogações suprimidas;
- Conhecimento do logótipo de produção biológica da União e confiança no mesmo (inquérito Eurobarómetro).

1.5. Justificação da proposta/iniciativa

1.5.1. *Necessidade(s) a satisfazer a curto ou a longo prazo*

O objetivo geral do quadro legislativo, que é o desenvolvimento sustentável da produção biológica, ainda não foi totalmente atingido. Desta situação decorre a perda de oportunidades para os agricultores e os operadores da União (a superfície de terrenos para produção biológica na União apenas duplicou nos últimos 10 anos, enquanto o mercado quadruplicou), o risco de limitação da expansão do mercado biológico e o risco de limitação dos benefícios ambientais associados à produção biológica.

Os principais motivadores são os seguintes: obstáculos regulamentares e não-regulamentares ao desenvolvimento da produção biológica na União; risco de erosão da confiança dos consumidores, designadamente devido às muitas derrogações que estão a diluir as regras da produção biológica e devido aos casos de fraude que surgiram ligados às debilidades do sistema de controlo e do regime de importação; concorrência desleal entre os operadores da União e de países terceiros; e problemas na conceção e aplicação das disposições legais, designadamente problemas ao nível do funcionamento do mercado interno, devido a falhas na legislação e a diferentes abordagens na implementação.

1.5.2. *Valor acrescentado da participação da UE*

A atual proposta consiste na atualização de um regime de qualidade existente, estabelecido no âmbito da política agrícola comum.

A produção e o comércio de produtos agrícolas e de géneros alimentícios no mercado interno e a garantia do funcionamento do mercado interno são matérias da competência da União Europeia. Ambas são competências partilhadas com os EM.

Um regime único à escala da União é mais eficaz do que 28 regimes diferentes e permite uma política comercial mais forte e coerente em relação aos parceiros comerciais mundiais, sobretudo através do reforço do poder de negociação da União.

O logótipo de produção biológica da União Europeia deve abranger produtos que cumpram um conjunto comum de regras aplicadas em toda a União.

Entre as áreas em que é necessária uma maior harmonização contam-se: derrogações às regras e ações para preservar a integridade da produção biológica, incluindo uma abordagem comum para fazer face à presença de resíduos de substâncias não autorizadas em produtos biológicos.

1.5.3. *Lições tiradas de experiências anteriores semelhantes*

Em 2013, foi concluída uma avaliação externa da legislação da União em matéria de agricultura biológica⁵⁶. Em especial, esta avaliação analisou a adequação das regras de produção e das regras em matéria de controlo, importação e rotulagem de produtos biológicos. A avaliação concluiu que a maioria das regras estabelecidas no quadro legislativo para a produção biológica são, de modo geral, adequadas para atingir os seus objetivos globais. Contudo, foram também identificados alguns pontos fracos, tendo sido propostas recomendações para melhoria. Essas recomendações foram devidamente consideradas na presente proposta.

⁵⁶ Sanders, J (ed.) 2013: *Evaluation of the EU legislation on organic farming*, Thünen Institute of Farm Economics http://ec.europa.eu/agriculture/evaluation/market-and-income-reports/organic-farming-2013_en.htm

O Tribunal de Contas Europeu (TCE) auditou a eficácia do sistema de controlo que rege a produção, a transformação, a distribuição e a importação de produtos biológicos, de acordo com o estabelecido no Regulamento (CE) n.º 834/2007 do Conselho. Os resultados, publicados no Relatório especial n.º 9/2012 do TCE, mostram vários pontos fracos e incluem recomendações para melhoria que foram devidamente consideradas na presente proposta.

1.5.4. Coerência e eventual sinergia com outros instrumentos relevantes

A proposta é coerente com a nova PAC, por exemplo com o novo Regulamento relativo aos pagamentos diretos⁵⁷, ao abrigo do qual as explorações biológicas beneficiam, *ipso facto*, do novo pagamento «verde», e com o novo Regulamento relativo ao desenvolvimento rural⁵⁸, que estabelece medidas específicas benéficas para a agricultura biológica, e com a nova política comum das pescas.

A proposta é também coerente com a proposta de um novo regulamento relativo aos controlos oficiais em matéria de alimentos para consumo humano e animal e com os princípios da regulamentação inteligente.

1.6. Duração da ação e impacto financeiro

Proposta/iniciativa de **duração limitada**

- Proposta/iniciativa válida entre [DD/MM]AAAA e [DD/MM]AAAA
- Impacto financeiro no período compreendido entre AAAA e AAAA

Proposta/iniciativa de **duração ilimitada**

- Aplicação com um período de arranque progressivo entre AAAA e AAAA,
- seguido de um período de aplicação a um ritmo de cruzeiro.

1.7. Modalidade(s) de gestão prevista(s)⁵⁹

Gestão direta por parte da Comissão

- nos seus serviços, incluindo pelo seu pessoal nas delegações da União;
- nas agências de execução;

Gestão partilhada com os Estados-Membros

Gestão indireta por delegação das funções de execução:

- em países terceiros ou nos organismos por estes designados;
- nas organizações internacionais e respetivas agências (a especificar);
- no BEI e no Fundo Europeu de Investimento;
- nos organismos referidos nos artigos 208.º e 209.º do Regulamento Financeiro;

⁵⁷ Regulamento (UE) n.º 1307/2013 do Parlamento Europeu e do Conselho que estabelece regras para os pagamentos diretos aos agricultores ao abrigo de regimes de apoio no âmbito da política agrícola comum e que revoga o Regulamento (CE) n.º 637/2008 do Conselho e o Regulamento (CE) n.º 73/2009 do Conselho.

⁵⁸ Regulamento (UE) n.º 1305/2013 do Parlamento Europeu e do Conselho relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) e que revoga o Regulamento (CE) n.º 1698/2005 do Conselho.

⁵⁹ As explicações sobre as modalidades de gestão e as referências ao Regulamento Financeiro estão disponíveis no sítio BudgWeb: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

- nos organismos de direito público;
- nos organismos regidos pelo direito privado com uma missão de serviço público, desde que prestem garantias financeiras adequadas;
- nos organismos regidos pelo direito privado de um Estado-Membro incumbidos da execução de uma parceria público-privada e que prestem garantias financeiras adequadas;
- nas pessoas encarregadas da execução de ações específicas no quadro da PESC por força do título V do Tratado da União Europeia, identificadas no ato de base pertinente.
- *Se for indicada mais de uma modalidade de gestão, queira especificar na secção «Observações».*

Observações

2. MEDIDAS DE GESTÃO

2.1. Disposições em matéria de acompanhamento e prestação de informações

Especificar a periodicidade e as condições.

Os Estados-Membros devem fornecer anualmente à Comissão as informações necessárias para a execução e o acompanhamento da aplicação do presente regulamento. Os Estados-Membros devem também fornecer anualmente à Comissão informações sobre os controlos realizados para assegurar o cumprimento dos requisitos relativos à produção biológica, como parte dos respetivos planos nacionais de controlo plurianuais e dos relatórios anuais referidos no regulamento relativo aos controlos oficiais.

Os países terceiros reconhecidos como equivalentes e as autoridades de controlo ou os organismos de controlo reconhecidos como conformes para a importação de produtos biológicos para a União devem apresentar à Comissão relatórios anuais com as informações necessárias para a execução dos requisitos definidos pelo presente regulamento.

2.2. Sistema de gestão e de controlo

2.2.1. *Risco(s) identificado(s)*

Os riscos gerais inerentes às regras definidas na proposta que podem ser identificados dizem respeito à eficácia da proposta e não às despesas para a UE, tendo em conta os montantes relativamente insignificantes que estão envolvidos:

As regras de produção harmonizadas que eliminam as derrogações podem, numa fase inicial, criar problemas para alguns operadores e dissuadi-los de participar no regime biológico.

O período de transição do sistema de equivalência para o sistema de conformidade, no que diz respeito às importações de produtos biológicos para a União, pode não assegurar em pleno condições equitativas de concorrência.

A substituição do controlo físico anual de todos os operadores, independentemente do respetivo perfil de risco, por uma abordagem baseada no risco relativamente aos controlos pode ser considerada inadequada por algumas partes interessadas e/ou pelos organismos ou autoridades de controlo dos Estados-Membros.

Outros riscos podem estar associados às deficiências na execução: designadamente, a implementação por parte das autoridades competentes e dos organismos ou autoridades de controlo dos Estados-Membros e dos países terceiros, e a supervisão pela Comissão.

A experiência obtida com a aplicação do Regulamento (CE) n.º 834/2007, nomeadamente através dos resultados de auditorias, da contribuição das partes interessadas no âmbito da avaliação de impacto e das recomendações de estudos externos, e a avaliação externa foram devidamente consideradas na conceção da proposta, a fim de atenuar tais riscos. Também foi dada especial atenção à atenuação dos riscos associados às possíveis debilidades na execução, através de esforços para garantir regras mais claras e mais simples de gerir e controlar.

2.2.2. *Informações sobre a criação do sistema de controlo interno*

As despesas geradas pela presente proposta devem ser executadas pela Comissão sob gestão direta, em conformidade com os princípios definidos no artigo 32.º do Regulamento (UE, Euratom) n.º 966/2012 relativo às disposições financeiras aplicáveis ao orçamento geral da União (Regulamento Financeiro).

Conforme previsto no Regulamento Financeiro, o Diretor-Geral da Agricultura e do Desenvolvimento Rural instaurou uma estrutura organizativa e processos de controlo interno adaptados à consecução dos objetivos da política e de controlo, de acordo com as normas de controlo interno adotadas pela Comissão e tendo em conta os riscos associados ao contexto em que a política é desenvolvida.

2.2.3. *Estimativa dos custos e benefícios dos controlos e avaliação do nível previsto de risco de erro*

As despesas geradas pela presente proposta não conduzirão ao aumento da taxa de erro para o Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER), tendo em conta os montantes relativamente insignificantes que estão envolvidos.

2.3. **Medidas de prevenção de fraudes e irregularidades**

Especificar as medidas de prevenção e de proteção existentes ou previstas.

A Comissão deve tomar as medidas adequadas para garantir que, quando forem executadas ações financiadas ao abrigo do presente regulamento, os interesses financeiros da União fiquem protegidos, através da aplicação de medidas preventivas contra fraude, corrupção e outras atividades ilegais, através da realização de verificações eficazes e, caso sejam detetadas irregularidades, através da recuperação dos montantes indevidamente pagos, bem como, quando apropriado, da aplicação de sanções efetivas, proporcionais e dissuasivas, de acordo com o artigo 325.º do Tratado sobre o Funcionamento da União Europeia, com o Regulamento (CE) n.º 2988/95 do Conselho relativo à proteção dos interesses financeiros das Comunidades Europeias e com o título IV do Regulamento Financeiro aplicável ao orçamento geral da União.

A Comissão ou os seus representantes e o Tribunal de Contas devem ter poderes para auditar, com base em documentos e no local, todos os contratantes e subcontratantes que tenham recebido fundos da União. O OLAF deve estar autorizado a efetuar verificações e inspeções no local junto de operadores económicos relacionados direta ou indiretamente com tais fundos, de acordo com os procedimentos previstos no Regulamento (Euratom, CE) n.º 2185/96 do Conselho, de 11 de novembro de 1996, com o intuito de comprovar a existência de fraudes. As decisões, os acordos e os contratos resultantes da implementação

do regulamento devem autorizar expressamente a Comissão, incluindo o OLAF, e o Tribunal de Contas a efetuarem tais auditorias, verificações e inspeções no local.

3. IMPACTO FINANCEIRO ESTIMADO DA PROPOSTA/INICIATIVA

3.1. Rubrica(s) do quadro financeiro plurianual e rubrica(s) orçamental(is) de despesas envolvida(s)

- Atuais rubricas orçamentais

Segundo a ordem das rubricas do quadro financeiro plurianual e das respetivas rubricas orçamentais.

Rubrica do quadro financeiro plurianual:	Rubrica orçamental	Tipo de despesa	Participação			
	Número [...]Rubrica.....]	DD/DND ⁽⁶⁰⁾	dos países EFTA ⁶¹	dos países candidatos ⁶²	de países terceiros	na aceção do artigo 21.º, n.º 2, alínea b), do Regulamento Financeiro
2	05 04 60 02 Assistência técnica operacional	DD	/NÃO	/NÃO	NÃO	NÃO

3.2. Impacto estimado nas despesas

3.2.1. Síntese do impacto estimado nas despesas

⁶⁰ DD = dotações diferenciadas/DND = dotações não diferenciadas.

⁶¹ EFTA: Associação Europeia de Comércio Livre.

⁶² Países candidatos e, se for caso disso, países candidatos potenciais dos Balcãs Ocidentais.

Rubrica do quadro financeiro plurianual	2	Crescimento sustentável: recursos naturais
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DG: AGRI			2015	2016	2017	2018	2019	2020	TOTAL
• Dotações operacionais									
05 04 60 02 Assistência técnica operacional *	Autorizações	(1)	0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Pagamentos	(2)	0,800	0,230	0,170	0,170	0,170	0,170	1,710
Dotações de natureza administrativa financiadas a partir da dotação de programas específicos ⁶³									
		(3)							
TOTAL das dotações ** para a DG AGRI	Autorizações	=1+1a+3	0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Pagamentos	=2+2a+3	0,800	0,230	0,170	0,170	0,170	0,170	1,710

* Atualmente, o controlo das importações de produtos biológicos é realizado através do sistema TRACES, que é parcialmente financiado por esta rubrica, não se esperando que a proposta venha a aumentar as necessidades para esta medida. Além da ferramenta já existente para as importações, o regulamento prevê que toda a produção biológica colocada no mercado da UE seja sujeita a uma certificação eletrónica; por conseguinte, é necessário estender a certificação eletrónica à importação para abranger os produtos dentro da União. Terá de ser desenvolvida uma ferramenta de TI no âmbito da arquitetura do sistema TRACES, avaliada em 500 000 EUR, para a certificação eletrónica da produção biológica interna prevista no artigo 23.º da proposta da Comissão, a fim de garantir que estará operacional a partir de 1.1.2016. A manutenção está avaliada em 110 000 EUR por ano.

⁶³ Assistência técnica e/ou administrativa e despesas de apoio à execução de programas e/ou ações da UE (antigas rubricas «BA»), bem como investigação direta e indireta.

* Além disso, a harmonização da base de dados de sementes biológicas está prevista no artigo 10.º da proposta. Para garantir o desenvolvimento desta base de dados de sementes separada, deve ser financiada por esta rubrica uma assistência financeira da União, avaliada em 300 000 EUR, fora do âmbito do TRACES. A manutenção está avaliada em 120 000 EUR no primeiro ano após o desenvolvimento e em 60 000 EUR nos anos subsequentes.

			2015	2016	2017	2018	2019	2020	Total
• TOTAL das dotações operacionais	Autorizações	(4)	0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Pagamentos	(5)	0,800	0,230	0,170	0,170	0,170	0,170	1,710
• TOTAL das dotações de natureza administrativa financiadas a partir da dotação de programas específicos		(6)							
TOTAL das dotações para a RUBRICA 2 do quadro financeiro plurianual	Autorizações	=4+ 6	0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Pagamentos	=5+ 6	0,800	0,230	0,170	0,170	0,170	0,170	1,710

** As ferramentas de TI serão financiadas pela assistência técnica à Comissão, de acordo com o artigo 58.º, n.º 2, do Regulamento (UE) n.º XXX/2013 do Parlamento Europeu e do Conselho relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) e que revoga o Regulamento (CE) n.º 1698/2005 do Conselho. Estes montantes já estão previstos no quadro financeiro plurianual para 2014-2020.

Rubrica do quadro financeiro plurianual	5	Administração
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Em milhões de EUR

		2015	2016	2017	2018	2019	2020	TOTAL
DG: AGRI								
• Recursos humanos		-	-	-	-	-	-	-
• Outras despesas administrativas		0,127	0,127	0,055	0,055	0,055	0,055	0,474
TOTAL DG AGRI	Dotações	0,127	0,127	0,055	0,055	0,055	0,055	0,474

TOTAL das dotações para a RUBRICA 5 do quadro financeiro plurianual	(Total das autorizações = total dos pagamentos)	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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TOTAL das dotações para a RUBRICA 5 do quadro financeiro plurianual	(Total das autorizações = total dos pagamentos)	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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Em milhões de EUR

		2015	2016	2017	2018	2019	2020	TOTAL
TOTAL das dotações no âmbito das RUBRICAS 1 a 5 do quadro financeiro plurianual	Autorizações	0,927	0,357	0,225	0,225	0,225	0,225	2,184
	Pagamentos	0,927	0,357	0,225	0,225	0,225	0,225	2,184

3.2.2. Impacto estimado nas dotações operacionais

- A proposta/iniciativa não acarreta a utilização de dotações operacionais
- A proposta/iniciativa acarreta a utilização de dotações operacionais, tal como explicitado seguidamente:

Dotações de autorização em milhões de EUR

Indicar os objetivos e as realizações			2016	2017	2018	2019	2020	TOTAL		
	REALIZAÇÕES									
	Tipo ⁶⁴	Custo médio	° Z	Custo	° Z	Custo	° Z	Custo	° Z	Custo
OBJETIVO ESPECÍFICO⁶⁵			Criar condições para a gestão sustentável dos recursos naturais, apoiando a transição para uma economia hipocarbónica e eficiente em termos de recursos							
Realização	Superfície de agricultura biológica (Número de hectares)									
Realização	Superfície em conversão (Número de hectares)									
Realização	Número de operadores biológicos certificados									
Realização	Número de produtores biológicos certificados									
CUSTO TOTAL										

⁶⁴ As realizações dizem respeito aos produtos fornecidos e serviços prestados (exemplo: número de intercâmbios de estudantes financiados, número de quilómetros de estradas construídas, etc.).

⁶⁵ Em conformidade com o quadro comum de acompanhamento e avaliação da PAC, será estabelecido um quadro comum de acompanhamento e avaliação a partir de 2014, pelo que as tabelas dos indicadores serão devidamente preenchidas numa fase posterior.

3.2.3. Impacto estimado nas dotações de natureza administrativa

3.2.3.1. Síntese

- A proposta/iniciativa não acarreta a utilização de dotações de natureza administrativa
- A proposta/iniciativa acarreta a utilização de dotações de natureza administrativa, tal como explicitado seguidamente:

Em milhões de EUR (três casas decimais)

	2015	2016	2017	2018	2019	2020	TOTAL
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RUBRICA 5 do quadro financeiro plurianual							
Recursos humanos	-	-	-	-	-	-	-
Outras despesas administrativas	0,127	0,127	0,055	0,055	0,055	0,055	0,474
Subtotal da RUBRICA 5 do quadro financeiro plurianual	0,127	0,127	0,055	0,055	0,055	0,055	0,474

Com exclusão da RUBRICA 5⁶⁶ do quadro financeiro plurianual							
Recursos humanos							
Outras despesas de natureza administrativa							
Subtotal com exclusão da RUBRICA 5 do quadro financeiro plurianual	0,127	0,127	0,055	0,055	0,055	0,055	0,474

TOTAL	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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As dotações relativas aos recursos humanos necessárias serão cobertas pelas dotações da DG já afetadas à gestão da ação e/ou reafetadas na DG e, se necessário, pelas eventuais dotações adicionais que sejam concedidas à DG gestora no âmbito do processo de afetação anual e tendo em conta as restrições orçamentais.

⁶⁶ Assistência técnica e/ou administrativa e despesas de apoio à execução de programas e/ou ações da UE (antigas rubricas «BA»), bem como investigação direta e indireta.

3.2.3.2. Necessidades estimadas de recursos humanos

- A proposta/iniciativa não acarreta a utilização de recursos humanos.
- A proposta/iniciativa acarreta a utilização de recursos humanos, tal como explicitado seguidamente:

As estimativas devem ser expressas em termos de equivalente a tempo completo

	2015	2016	2017	2018	2019	2020
XX 01 01 01 (sede e representantes da Comissão)	18	18	18	18	18	18
XX 01 01 02 (delegações)						
XX 01 05 01 (investigação indireta)						
10 01 05 01 (investigação direta)						
XX 01 02 01 (AC, PND e TT da dotação global)	3	3	3	3	3	3
XX 01 02 02 (AC, AL, PND, TT e JPD nas delegações)						
XX 01 04 aa	- na sede					
	- nas delegações					
XX 01 05 02 (AC, PND e TT relativamente à investigação indireta)						
10 01 05 02 (AC, PND e TT relativamente à investigação direta)						
Outras rubricas orçamentais (especificar)						
TOTAL (*)	21	21	21	21	21	21

XX constitui o domínio de intervenção ou título em causa.

As necessidades em recursos humanos serão cobertas pelos efetivos da DG já afetados à gestão da ação e/ou reafetados internamente a nível da DG, complementadas, caso necessário, por eventuais dotações adicionais que sejam atribuídas à DG gestora no quadro do processo anual de atribuição e no limite das disponibilidades orçamentais.

Descrição das tarefas a executar:

Funcionários e agentes temporários	Desenvolvimento da política Implementação da política Planeamento, programação, acompanhamento e supervisão Relações com os Estados-Membros e as partes interessadas Negociação, e representação da Comissão, junto de países terceiros Relações com outros organismos e instituições da União
Pessoal externo	Assistência à implementação e ao acompanhamento da política, e ao contacto com os Estados-Membros e as partes interessadas

3.2.4. *Compatibilidade com o atual quadro financeiro plurianual*

- A proposta/iniciativa é compatível com o atual quadro financeiro plurianual.
- A proposta/iniciativa requer uma reprogramação da rubrica pertinente do quadro financeiro plurianual.
- A proposta/iniciativa requer a mobilização do Instrumento de Flexibilidade ou a revisão do quadro financeiro plurianual.

3.2.5. *Participação de terceiros no financiamento*

- A proposta/iniciativa não prevê o cofinanciamento por terceiros.
- A proposta/iniciativa prevê o cofinanciamento estimado seguinte:

3.3. Impacto estimado nas receitas

- A proposta/iniciativa não tem impacto financeiro nas receitas.
- A proposta/iniciativa tem o impacto financeiro a seguir descrito:
 - nos recursos próprios
 - nas receitas diversas



Bruxelas, 24.3.2014
COM(2014) 180 final

ANNEXES 1 to 5

ANEXOS

à

Proposta de

REGULAMENTO DO PARLAMENTO EUROPEU E DO CONSELHO

que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho [Regulamento relativo aos controlos oficiais] e que revoga o Regulamento (CE) n.º 834/2007 do Conselho

{SWD(2014) 65 final}
{SWD(2014) 66 final}

ANEXO I

OUTROS PRODUTOS REFERIDOS NO ARTIGO 2.º, Nº 1

- leveduras utilizadas como géneros alimentícios ou alimentos para animais,
- cerveja,
- mate,
- extratos, essências e concentrados de café, chá ou mate e preparações à base destes produtos ou à base de café, chá ou mate; chicória torrada e outros sucedâneos torrados do café e respetivos extratos, essências e concentrados,
- néctares de frutos,
- pasta, manteiga, gordura e óleo de cacau e cacau em pó; chocolate e outras preparações alimentares que contenham cacau,
- confeitaria à base de açúcar,
- preparações à base de cereais, farinhas, amidos, féculas ou leite; produtos de pastelaria,
- sopas,
- molhos,
- refeições cozinhadas,
- sorvetes,
- iogurtes aromatizados, iogurtes adicionados de frutas, frutas de casca rija ou cacau,
- sal marinho,
- gomas e resinas naturais,
- pólen,
- cera de abelhas,
- óleos essenciais,
- bebidas espirituosas, desde que o álcool etílico utilizado na produção das bebidas espirituosas seja exclusivamente de origem agrícola.

ANEXO II

REGRAS ESPECÍFICAS DE PRODUÇÃO REFERIDAS NO CAPÍTULO III

Parte I: Regras aplicáveis à produção vegetal

Além das regras de produção estabelecidas nos artigos 7.º a 10.º, são aplicáveis à produção vegetal biológica as regras estabelecidas na presente parte.

1. Requisitos gerais

- 1.1. A produção hidropónica, que é um método de produção vegetal segundo o qual as plantas se desenvolvem com as raízes apenas numa solução de nutrientes ou num meio inerte ao qual é adicionada uma solução de nutrientes, é proibida.
- 1.2. Todas as técnicas de produção vegetal utilizadas devem impedir ou reduzir ao mínimo eventuais contribuições para a contaminação do ambiente.
- 1.3. Conversão
 - 1.3.1. Para que os vegetais e os produtos vegetais sejam considerados biológicos, as regras de produção estabelecidas no presente regulamento devem ter sido aplicadas nas parcelas durante um período de conversão de, pelo menos, dois anos antes da sementeira ou, no caso dos prados ou das forragens perenes, de, pelo menos, dois anos antes da sua utilização como alimentos biológicos para animais, ou, no caso das culturas perenes, com exceção das forragens, de, pelo menos, três anos antes da primeira colheita dos produtos biológicos.
 - 1.3.2. A autoridade competente pode decidir, nos casos em que as terras tenham sido contaminadas por produtos não autorizados na produção biológica, prorrogar o período de conversão para além do período referido no ponto 1.3.1.
 - 1.3.3. Em caso de tratamento com um produto não autorizado na produção biológica, a autoridade competente deve exigir um novo período de conversão em conformidade com o ponto 1.3.1.

Este período pode ser encurtado nos dois seguintes casos:

 - a) Tratamento com um produto não autorizado na produção biológica no âmbito de uma medida de controlo de pragas ou infestantes, incluindo organismos de quarentena ou espécies invasoras, tornada obrigatória pela autoridade competente do Estado-Membro;
 - b) Tratamento com um produto não autorizado na produção biológica no âmbito de testes científicos aprovados pela autoridade competente do Estado-Membro.
 - 1.3.4. Nos casos previstos nos pontos 1.3.2 e 1.3.3, a duração do período de conversão deve ser estabelecida tendo em conta que:
 - a) O processo de degradação do produto em questão deve garantir, no final do período de conversão, um nível de resíduos insignificante no solo e, no caso de uma cultura perene, na planta;
 - b) A colheita seguinte ao tratamento não pode ser vendida com menção da produção biológica.
 - 1.3.5. As regras específicas de conversão aplicáveis às terras associadas à produção animal biológica devem obedecer ao seguinte:

- 1.3.5.1. As regras de conversão devem ser aplicáveis a toda a área da unidade de produção em que são produzidos alimentos para animais.
- 1.3.5.2. Não obstante o ponto 1.3.5.1, o período de conversão pode ser reduzido a um ano para as pastagens e áreas ao ar livre utilizadas por espécies não herbívoras.
- 1.4. Origem dos vegetais, incluindo o material de reprodução vegetal.
- 1.4.1. Para a produção de vegetais e produtos vegetais, só pode ser utilizado material de reprodução vegetal da produção biológica. Para este efeito, o vegetal destinado à produção do material de reprodução vegetal e, se for caso disso, a planta-mãe devem ter sido produzidos em conformidade com o presente regulamento durante, pelo menos, uma geração ou, no caso das culturas perenes, durante pelo menos uma geração durante dois ciclos vegetativos.
- 1.4.2. Utilização de material de reprodução vegetal não proveniente da produção biológica
- Só pode ser utilizado material de reprodução vegetal não proveniente da produção biológica se provier de uma unidade de produção em conversão para a produção biológica ou se tal se justificar para atividades de investigação, para ensaios de campo em pequena escala ou para fins de conservação de recursos genéticos aprovados pela autoridade competente do Estado-Membro.
- 1.5. Gestão e fertilização do solo
- 1.5.1. A produção vegetal biológica deve recorrer a práticas de mobilização e de cultivo que mantenham ou aumentem a matéria orgânica dos solos, reforcem a estabilidade e a biodiversidade dos mesmos e impeçam a sua compactação e erosão.
- 1.5.2. A fertilidade e a atividade biológica dos solos devem ser mantidas e aumentadas pela rotação plurianual das culturas, incluindo leguminosas e outras culturas para sideração, e pela aplicação de estrume ou de matérias orgânicas, de preferência ambos compostados, provenientes da produção biológica.
- 1.5.3. Sempre que não seja possível satisfazer as necessidades nutricionais das plantas através das medidas previstas nos pontos 1.5.1 e 1.5.2, podem apenas ser utilizados, e só na medida do necessário, os fertilizantes e corretivos do solo autorizados para utilização na produção biológica nos termos do artigo 19.º.
- 1.5.4. A quantidade total de estrume animal, tal como definido na Diretiva 91/676/CEE do Conselho¹, aplicada na exploração agrícola não pode exceder 170 kg de azoto por ano e por hectare de superfície agrícola utilizada. Este limite é apenas aplicável a estrume, estrume seco e estrume de aves de capoeira desidratado, excrementos compostados de animais, incluindo estrume de aves de capoeira, estrume compostado e excrementos líquidos de animais.
- 1.5.5. As explorações agrícolas que praticam a produção biológica podem estabelecer acordos de cooperação escritos exclusivamente com outras explorações e empresas agrícolas que cumpram as regras da produção biológica, com vista ao espalhamento do excedente de estrume proveniente da produção biológica. O limite máximo referido no ponto 1.5.4 deve ser calculado com base no total de unidades que praticam a produção biológica abrangidas por essa cooperação.

¹ Diretiva 91/676/CEE do Conselho, de 12 de dezembro de 1991, relativa à proteção das águas contra a poluição causada por nitratos de origem agrícola (JO L 375 de 31.12.1991, p. 1).

- 1.5.6. Para melhorar o estado geral do solo ou a disponibilidade de nutrientes no solo ou nas culturas, podem ser utilizados preparados de microrganismos.
- 1.5.7. Para a ativação de compostagem podem ser utilizados preparados apropriados à base de plantas ou de microrganismos
- 1.5.8. Não podem ser utilizados fertilizantes minerais azotados.
- 1.6. Gestão das pragas e infestantes
- 1.6.1. A prevenção dos danos causados por pragas e infestantes deve assentar principalmente:
- na proteção dos predadores naturais,
 - na escolha das espécies, variedades e materiais heterogéneos,
 - na rotação das culturas,
 - nas técnicas de cultivo como a biofumigação e
 - em processos térmicos como a solarização e o tratamento superficial do solo por vaporização (até à profundidade máxima de 10 cm).
- 1.6.2. Sempre que não seja possível proteger adequadamente os vegetais das pragas através das medidas previstas no ponto 1.6.1 ou em caso de ameaça comprovada para uma cultura, podem apenas ser utilizados, e só na medida do necessário, produtos autorizados para utilização na produção biológica nos termos do artigo 19.º.
- 1.6.3. As armadilhas ou distribuidores de produtos, com exceção de feromonas, devem impedir a libertação das substâncias no ambiente e o contacto das substâncias com as culturas em cultivo. Após utilização, as armadilhas devem ser recolhidas e eliminadas em condições de segurança.
- 1.7. Produtos utilizados para a limpeza e a desinfeção
- Para a limpeza e a desinfeção só podem ser utilizados na produção vegetal produtos de limpeza e desinfeção autorizados para utilização na produção biológica nos termos do artigo 19.º.

2. Requisitos aplicáveis aos vegetais ou produtos vegetais específicos

2.1. Regras aplicáveis à produção de cogumelos

Na produção de cogumelos, podem ser utilizados substratos desde que sejam constituídos apenas pelos seguintes componentes:

- a) Estrume e excrementos de animais:
- i) provenientes de explorações agrícolas que apliquem as regras de produção biológica, ou
 - ii) referidos no ponto 1.5.3, apenas quando o produto referido na alínea i) não estiver disponível, desde que o estrume e excrementos de animais não excedam 25 % do peso do total dos componentes do substrato, excluindo as matérias de cobertura e a água adicionada, antes da compostagem;
- b) Produtos de origem agrícola, com exceção dos referidos na alínea a), provenientes de explorações agrícolas que apliquem as regras de produção biológica;

- c) Turfa sem tratamentos químicos;
- d) Madeira não tratada com produtos químicos depois do abate;
- e) Produtos minerais referidos no ponto 1.5.3, água e solo.

2.2. Regras relativas à colheita de vegetais silvestres

A colheita de vegetais silvestres, ou de partes destes, que cresçam espontaneamente em zonas naturais, florestas e zonas agrícolas é considerada produção biológica, desde que:

- a) Essas zonas não tenham sido tratadas, durante pelo menos os três anos anteriores à colheita, com produtos que não os autorizados para utilização na produção biológica nos termos do artigo 19.º;
- b) A colheita não afete a estabilidade do habitat natural nem a conservação das espécies na zona de colheita.

Parte II: Regras aplicáveis à produção animal

Além das regras de produção estabelecidas nos artigos 7.º, 8.º, 9.º e 11.º, são aplicáveis à produção animal as regras estabelecidas na presente parte.

1. Requisitos gerais

- 1.1. Se o agricultor responsável pela produção animal não gere terras agrícolas e não estabeleceu um acordo de cooperação escrito com outro agricultor, a produção animal sem terra é proibida.
- 1.2. Conversão
 - 1.2.1. O período de conversão só pode ter início a partir do momento em que o agricultor notifica as autoridades competentes da sua atividade e submete a sua exploração ao sistema de controlo em conformidade com o presente regulamento.
 - 1.2.2. Os períodos de conversão específicos do tipo de produção animal são estabelecidos no ponto 2.
 - 1.2.3. Os animais e os produtos animais produzidos durante o período de conversão não podem ser comercializados como biológicos.
 - 1.2.4. Os animais e os produtos animais podem ser considerados biológicos no final do período de conversão se a conversão for feita simultaneamente para toda a unidade de produção, incluindo animais, pastagens ou quaisquer terras utilizadas para a produção de alimentos para animais.
- 1.3. Origem dos animais
 - 1.3.1. Os animais de criação biológica devem ter nascido e ser criados em explorações agrícolas biológicas.
 - 1.3.2. Os animais presentes na exploração agrícola no início do período de conversão e os respetivos produtos podem ser considerados biológicos depois de cumprido o período de conversão aplicável referido no ponto 2.
 - 1.3.3. Quanto à reprodução dos animais de criação biológica:
 - a) A reprodução deve utilizar métodos naturais; no entanto, é autorizada a inseminação artificial;

- b) A reprodução não deve ser induzida por tratamentos com hormonas ou substâncias semelhantes, exceto como forma de tratamento terapêutico veterinário de animais individuais;
- c) Não podem ser utilizadas outras formas de reprodução artificial, como a clonagem e a transferência de embriões;
- d) Devem ser escolhidas as raças adequadas e a escolha deve contribuir para evitar o sofrimento e a necessidade de mutilar os animais.

1.3.4. Na escolha das raças ou estirpes, devem ser tidas em conta a capacidade de adaptação dos animais às condições locais, sem afetar o seu bem-estar, a sua vitalidade e a sua resistência às doenças. As raças ou estirpes de animais devem ser, além disso, selecionadas de modo a evitar doenças ou problemas de saúde específicos associados a determinadas raças ou estirpes utilizadas na produção intensiva, como a síndrome do stresse dos suínos, síndrome da carne exsudativa (PSE), morte súbita, aborto espontâneo e partos difíceis exigindo cesarianas. Deve ser dada preferência às raças e estirpes autóctones.

1.3.5. Para fins de reprodução, podem ser levados para uma exploração agrícola animais que não sejam de criação biológica quando a criação de determinadas raças estiver em risco de abandono, conforme previsto no anexo IV do Regulamento (CE) n.º 1974/2006 da Comissão², não tendo, neste caso, os animais dessas raças que ser necessariamente nulíparos.

1.4. Alimentação

1.4.1. Requisitos gerais de alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- a) Os alimentos para animais devem provir sobretudo da exploração agrícola onde os animais são mantidos ou de outras explorações biológicas da mesma região;
- b) Os animais devem ser alimentados com alimentos biológicos que satisfaçam as suas necessidades nutricionais nos vários estádios do seu desenvolvimento. A alimentação racionada não é autorizada na produção animal;
- c) É proibido manter os animais em condições ou com um regime alimentar que possam provocar anemia;
- d) As práticas de engorda devem ser reversíveis em qualquer fase do processo de criação. É proibida a alimentação forçada;
- e) Os animais, com exceção das abelhas, devem dispor de acesso permanente a pastos ou a forragens grosseiras;
- f) Não podem ser utilizados promotores de crescimento nem aminoácidos sintéticos;
- g) Na alimentação dos animais aleitados deve ser dada preferência ao leite materno por um período mínimo;

² Regulamento (CE) n.º 1974/2006 da Comissão, de 15 de dezembro de 2006, que estabelece normas de execução do Regulamento (CE) n.º 1698/2005 do Conselho relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) (JO L 368 de 23.12.2006, p. 15).

- h) Só podem ser utilizadas matérias para a alimentação animal de origem mineral, aditivos para a alimentação animal, certos produtos utilizados na nutrição animal e auxiliares tecnológicos autorizados para utilização na produção biológica nos termos do artigo 19.º.

1.4.2. Pastoreio em terrenos baldios e transumância

1.4.2.1. Os animais de criação biológica podem ser apascentados em terrenos baldios desde que:

- a) Os baldios sejam plenamente geridos em conformidade com o presente regulamento;
- b) Todos os animais de criação não biológica que utilizam o terreno em questão sejam criados num regime de produção equivalente aos descritos nos artigos 28.º e 30.º do Regulamento (UE) n.º 1305/2013³;
- c) Todos os produtos animais derivados de animais de criação biológica e que utilizem esse mesmo terreno não sejam considerados produtos da agricultura biológica, a menos que se possa provar que foram devidamente segregados de quaisquer outros animais de criação não biológica.

1.4.2.2. Os animais podem, durante o período de transumância, pastar em terrenos não biológicos quando se deslocam a pé de uma pastagem para outra. O consumo de alimentos não biológicos, sob a forma de vegetação herbácea e outra vegetação pastada pelos animais, é permitido durante, no máximo, 35 dias, cobrindo as viagens de ida e regresso.

1.4.3. Alimentos em conversão

1.4.3.1. Para as explorações agrícolas em conversão, até 15 % da quantidade total média de alimentos dados aos animais podem ser provenientes do pastoreio ou da colheita de pastagens permanentes ou de parcelas de forragens perenes ou proteaginosas, semeadas em conformidade com uma gestão biológica das terras no seu primeiro ano de conversão, desde que façam parte da própria exploração. Os alimentos para animais no seu primeiro ano de conversão não podem ser utilizados para a produção de alimentos biológicos transformados para animais. Quando sejam utilizados alimentos em conversão e alimentos de parcelas no primeiro ano de conversão, a percentagem combinada total desses alimentos não pode exceder as percentagens máximas fixadas no ponto 1.4.3.2.

1.4.3.2. Para as explorações agrícolas biológicas, até 20 %, em média, das rações alimentares podem incluir alimentos para animais em conversão, nomeadamente alimentos para animais a partir do segundo ano de conversão. Para as explorações agrícolas em conversão, quando os alimentos em conversão forem provenientes da própria exploração, essa percentagem pode ser aumentada para 100.

1.4.3.3. Os valores referidos nos pontos 1.4.3.1 e 1.4.3.2 são calculados anualmente e são expressos em percentagem de matéria seca dos alimentos de origem vegetal.

³ Regulamento (UE) n.º 1305/2013 do Parlamento Europeu e do Conselho, de 17 de dezembro de 2013, relativo ao apoio ao desenvolvimento rural pelo Fundo Europeu Agrícola de Desenvolvimento Rural (FEADER) e que revoga o Regulamento (CE) n.º 1698/2005 do Conselho (JO L 347 de 20.12.2013, p. 487).

1.4.4. Utilização de certas matérias para a alimentação animal e substâncias nos alimentos para animais

Só podem ser utilizadas na transformação dos alimentos biológicos para animais e na alimentação dos animais de criação biológica as matérias biológicas para a alimentação animal de origem animal e as matérias e aditivos para a alimentação animal autorizados para utilização na produção biológica nos termos do artigo 19.º.

1.5. Cuidados de saúde

1.5.1. Prevenção das doenças

1.5.1.1. A prevenção das doenças deve basear-se na seleção de raças e estirpes, práticas de gestão da produção animal, alimentação de elevada qualidade e exercício, encabeçamento apropriado e alojamento adequado mantido em boas condições de higiene.

1.5.1.2. É permitida a utilização de medicamentos veterinários imunológicos.

1.5.1.3. É proibida a utilização de medicamentos veterinários alopáticos de síntese química e de antibióticos nos tratamentos preventivos.

1.5.1.4. É proibida a utilização de substâncias para estimular o crescimento ou a produção (incluindo antibióticos, coccidiostáticos e outras substâncias artificiais indutoras de crescimento) e de hormonas ou substâncias similares para controlar a reprodução ou para outras finalidades (por exemplo, indução ou sincronização do cio).

1.5.1.5. No que diz respeito aos animais provenientes de unidades não biológicas, são aplicáveis medidas especiais, como testes de rastreio e períodos de quarentena, em função das circunstâncias locais.

1.5.1.6. Quanto à limpeza e desinfeção, só podem ser utilizados nos edifícios e instalações dedicados à criação animal produtos de limpeza e desinfeção autorizados para utilização na produção biológica nos termos do artigo 19.º.

1.5.1.7. Os edifícios, os compartimentos, o equipamento e os utensílios devem ser limpos e desinfetados adequadamente para evitar infeções cruzadas e o desenvolvimento de organismos patogénicos. As fezes, a urina e os alimentos não consumidos ou desperdiçados devem ser eliminados com a frequência necessária para minimizar os maus cheiros e evitar atrair insetos ou roedores. Os rodenticidas (a utilizar apenas nas armadilhas) e os produtos autorizados para utilização na produção biológica nos termos do artigo 19.º podem ser utilizados para a eliminação de insetos e outras pragas em edifícios e outras instalações em que os animais são mantidos.

1.5.2. Tratamentos veterinários

1.5.2.1. Se, apesar das medidas preventivas para assegurar a saúde dos animais, um animal ficar doente ou ferido, deve ser tratado sem demora.

1.5.2.2. Os casos de doença devem ser tratados imediatamente a fim de evitar sofrimento aos animais. Podem ser utilizados medicamentos veterinários alopáticos de síntese química, incluindo antibióticos, se necessário e em condições estritas e sob a responsabilidade de um veterinário, quando a utilização de produtos fitoterapêuticos, homeopáticos e outros não seja adequada. Devem ser definidas, nomeadamente, as restrições relativas aos tratamentos e aos prazos de segurança.

- 1.5.2.3. As matérias para a alimentação animal de origem mineral e os aditivos nutricionais autorizados para utilização na produção biológica nos termos do artigo 19.º e os produtos fitoterapêuticos e homeopáticos devem ser preferidos aos tratamentos veterinários alopáticos de síntese química, incluindo antibióticos, desde que os seus efeitos terapêuticos sejam eficazes para a espécie animal e para o problema a que o tratamento se destina.
- 1.5.2.4. Com exceção das vacinações e dos antiparasitários, assim como de planos de erradicação obrigatórios, se forem administrados a um animal ou grupo de animais mais de três tratamentos com medicamentos veterinários alopáticos de síntese química, incluindo antibióticos, no prazo de 12 meses, ou mais de um tratamento se o seu ciclo de vida produtivo for inferior a um ano, os animais em questão, ou os produtos deles derivados, não podem ser vendidos sob a designação de produtos biológicos, devendo os animais ser submetidos aos períodos de conversão referidos nos pontos 1.2 e 2.
- 1.5.2.5. O intervalo de segurança entre a última administração de um medicamento veterinário alopático a um animal em condições de utilização normais e a produção de géneros alimentícios provenientes do modo de produção biológico derivados desse animal deve ser o dobro do intervalo de segurança referido no artigo 11.º da Diretiva 2001/82/CE ou, se esse período não estiver especificado, de 48 horas.
- 1.5.2.6. São autorizados os tratamentos relacionados com a proteção da saúde humana ou animal impostos por força da legislação da União.
- 1.6. Alojamento dos animais e práticas de criação
- 1.6.1. O isolamento, o aquecimento e a ventilação do edifício devem assegurar que a circulação do ar, o nível de poeiras, a temperatura, a humidade relativa do ar e a concentração em gases se situam dentro de limites que garantam o bem-estar dos animais. Os edifícios devem permitir uma entrada de luz e uma ventilação naturais suficientes.
- 1.6.2. Não é obrigatório prever alojamento para os animais em zonas com condições climáticas adequadas que lhes permitam viver ao ar livre. Os animais devem dispor de acesso permanente a áreas ao ar livre, se possível a pastagens, sempre que as condições meteorológicas e o estado dos terrenos o permitam, a menos que, com base na legislação da União, sejam impostas restrições e obrigações relacionadas com a proteção da saúde humana ou animal. Os animais devem ter acesso a abrigos ou áreas sombreadas que lhes permitam proteger-se de condições meteorológicas adversas.
- 1.6.3. O encabeçamento dentro dos edifícios deve proporcionar conforto e bem-estar e ter em conta as necessidades específicas dos animais, que dependem nomeadamente da espécie, da raça e da idade destes. Este encabeçamento deve ter também em conta as necessidades comportamentais dos animais, que dependem designadamente da dimensão do grupo e do sexo dos animais. O encabeçamento deve assegurar o bem-estar dos animais, de forma a que disponham de espaço suficiente para poderem estar de pé naturalmente, deslocar-se, deitar-se com facilidade, virar-se, limpar-se, praticar todas as posições naturais e fazer todos os movimentos naturais como, por exemplo, esticar-se e bater as asas.

- 1.6.4. As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para as diferentes espécies e categorias de animais, são as estabelecidas nos pontos 2.1.4, 2.2.4, 2.3.4 e 2.4.5.
- 1.6.5. As áreas ao ar livre podem ser parcialmente cobertas. As varandas não são consideradas áreas ao ar livre.
- 1.6.6. O encabeçamento total não pode conduzir à superação do limite de 170 kg de azoto orgânico por ano e por hectare de superfície agrícola.
- 1.6.7. Para determinar o encabeçamento adequado referido no ponto 1.6.6, a autoridade competente deve fixar o número de cabeças normais equivalente ao limite referido no ponto 1.6.6, orientando-se pelos valores estabelecidos em cada um dos requisitos específicos por produção animal.
- 1.7. Bem-estar dos animais
- 1.7.1. Todas as pessoas que se ocupam dos animais devem possuir os conhecimentos e competências básicos necessários em matéria de saúde e bem-estar dos animais.
- 1.7.2. As práticas de criação, incluindo o encabeçamento e as condições de alojamento, devem garantir que sejam satisfeitas as necessidades de desenvolvimento dos animais, bem como as suas necessidades fisiológicas e etológicas.
- 1.7.3. Os animais devem dispor de acesso permanente a áreas ao ar livre, se possível a pastagens, sempre que as condições meteorológicas e o estado dos terrenos o permitam, a menos que, com base na legislação da União, sejam impostas restrições e obrigações relacionadas com a proteção da saúde humana ou animal.
- 1.7.4. O número de animais deve ser limitado com vista a reduzir ao mínimo o sobrepastoreio, o espezinhamento dos solos, a erosão ou a poluição causada pelos animais ou pelo espalhamento do seu estrume.
- 1.7.5. Quando forem aplicáveis o artigo 8.º, n.º 5, e a presente parte, ponto 1.4.2.2, os animais de criação biológica devem ser separados dos outros animais.
- 1.7.6. É proibido amarrar ou isolar os animais, a não ser em casos individuais durante um período limitado e na medida em que tal seja justificado por razões veterinárias. As autoridades competentes podem autorizar o amarramento do gado em microempresas se não for possível mantê-lo em grupos adequados às suas necessidades etológicas, desde que tenha acesso a pastagens durante o período de pastoreio e, pelo menos duas vezes por semana, tenha acesso a áreas ao ar livre quando o pastoreio não for possível.
- 1.7.7. A duração do transporte dos animais deve ser reduzida ao mínimo.
- 1.7.8. Qualquer sofrimento deve ser reduzido ao mínimo durante toda a vida do animal e no momento do abate.
- 1.7.9. A mutilação dos animais é proibida.
- 1.7.10. O sofrimento dos animais deve ser reduzido ao mínimo através da aplicação de anestésias e/ou analgésias adequadas e da realização das operações apenas na idade mais indicada e por pessoal qualificado.
- 1.7.11. A castração física é permitida fim de manter a qualidade dos produtos e as práticas tradicionais de produção, mas apenas sob anestesia ou analgesia adequadas, devendo a operação ser efetuada na idade mais adequada e por pessoal qualificado.

1.7.12. A carga e a descarga dos animais devem realizar-se sem recurso a qualquer tipo de estimulação elétrica para os coagir. É proibida a utilização de calmantes alopáticos antes ou durante o trajeto.

2. Requisitos aplicáveis a espécies animais concretas

2.1. Produção de bovinos, ovinos e caprinos

2.1.1. Conversão

Para que os bovinos, ovinos e caprinos e os respetivos produtos sejam considerados biológicos, as regras de produção estabelecidas no presente regulamento devem ter sido aplicadas há, pelo menos:

- a) 12 meses para os bovinos destinados à produção de carne e, em qualquer caso, pelo menos três quartos do seu tempo de vida;
- b) 6 meses para os ovinos e caprinos e para os animais destinados à produção de leite.

2.1.2. Alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- a) Os bovinos, ovinos e caprinos devem ter acesso permanente a pastagens para pastoreio sempre que as condições o permitam;
- b) Não obstante o disposto na alínea a), os bovinos machos de mais de um ano devem ter acesso a pastagens ou a áreas ao ar livre;
- c) Nos casos em que os bovinos, ovinos e caprinos tenham acesso às pastagens durante a época de pastoreio e o sistema de abrigo durante o inverno permita a liberdade de movimentos dos animais, é possível derrogar à obrigação de facultar áreas ao ar livre durante os meses de inverno;
- d) Exceto durante o período em que anualmente os animais se encontram em transumância, referido no ponto 1.4.2.2, no mínimo 90 % dos alimentos devem provir da própria exploração ou, quando tal não for possível, ser produzidos em cooperação com outras explorações que pratiquem a agricultura biológica na mesma região;
- e) No que diz respeito aos bovinos, ovinos e caprinos, os sistemas de criação devem basear-se na utilização máxima do pastoreio, de acordo com a disponibilidade em pastagens nos diferentes períodos do ano. As forragens grosseiras, frescas, secas ou ensiladas devem constituir pelo menos 60 % da matéria seca que compõe a ração diária dos bovinos, ovinos e caprinos. É permitida a redução dessa percentagem para 50 % no que diz respeito aos animais em produção leiteira, durante um período máximo de três meses, no início da lactação;
- f) No aleitamento dos bovinos, ovinos e caprinos deve ser dada preferência ao leite materno por um período mínimo de três meses no caso dos bovinos e de 45 dias no caso dos ovinos e dos caprinos.

2.1.3. Condições específicas de alojamento

No que diz respeito às condições de alojamento são aplicáveis as seguintes regras:

- a) Os pavimentos dos edifícios que alojam os bovinos, ovinos e caprinos devem ser lisos, mas não derrapantes. Pelo menos metade da superfície interior, conforme especificada no quadro do ponto 2.1.4 relativo às superfícies mínimas para os bovinos, ovinos e caprinos, deve ser sólida, isto é, não engradada nem ripada;
- b) Os edifícios devem dispor de uma área de repouso/cama confortável, limpa e seca de dimensão suficiente, consistindo numa construção sólida, não engradada. As áreas de repouso devem dispor de camas amplas e secas. As camas devem ser constituídas por palha ou outros materiais naturais adaptados. As camas podem ser saneadas e enriquecidas com qualquer dos produtos minerais autorizados como fertilizantes ou corretivos do solo para utilização na produção biológica nos termos do artigo 19.º;
- c) Não obstante o disposto no artigo 3.º, n.º 1, primeiro parágrafo, alínea a), e no artigo 3.º, n.º 1, segundo parágrafo, da Diretiva 2008/119/CEE do Conselho⁴, é proibido o alojamento em compartimentos individuais de vitelos com mais de uma semana, a não ser em casos individuais durante um período limitado e na medida em que tal seja justificado por razões veterinárias.

2.1.4. Encabeçamento

O número de bovinos, ovinos e caprinos por hectare deve respeitar os seguintes limites:

Classe ou espécie	Número máximo de animais por hectare equivalente a 170 kg N/ha/ano
Vitelos para engorda	5
Outros bovinos com menos de um ano	5
Bovinos de um a menos de dois anos, machos	3,3
Bovinos de um a menos de dois anos, fêmeas	3,3
Bovinos com dois anos ou mais, machos	2
Novilhas para reprodução	2,5
Novilhas para engorda	2,5
Vacas leiteiras	2
Vacas leiteiras de reforma	2
Outras vacas	2,5
Cabras	13,3
Ovelhas	13,3

⁴ Diretiva 2008/119/CE do Conselho, de 18 de dezembro de 2008, relativa às normas mínimas de proteção dos vitelos (JO L 10 de 15.1.2009, p. 7).

As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para os bovinos, ovinos e caprinos, são as seguintes:

	Área interior (superfície líquida disponível para os animais)		Área exterior (áreas de exercício, com exclusão de pastagens)
	Peso vivo mínimo (kg)	m ² /cabeça	m ² /cabeça
Bovinos de criação e engorda	até 100	1,5	1,1
	até 200	2,5	1,9
	até 350	4,0	3
	acima de 350	5 com um mínimo de 1 m ² /100 kg	3,7 com um mínimo de 0,75 m ² /100 kg
Vacas leiteiras		6	4,5
Touros reprodutores		10	30
Ovinos e caprinos		1,5 por ovelha/cabra	2,5
		0,35 por cordeiro/cabrito	2,5 com 0,5 por cordeiro/cabrito

2.2. Produção de equídeos

2.2.1. Conversão

Para que os equídeos e os respetivos produtos sejam considerados biológicos, as regras de produção estabelecidas no presente regulamento devem ter sido aplicadas há, pelo menos:

- 12 meses para a produção de carne e, em qualquer caso, pelo menos três quartos do seu tempo de vida;
- 6 meses para os animais destinados à produção de leite.

2.2.2. Alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- Os equídeos devem ter acesso permanente a pastagens para pastoreio sempre que as condições o permitam;
- Nos casos em que os equídeos tenham acesso às pastagens durante a época de pastoreio e o sistema de abrigo durante o inverno permita a liberdade de movimentos dos animais, é possível derrogar à obrigação de facultar áreas ao ar livre durante os meses de inverno;
- Exceto durante o período em que anualmente os animais se encontram em transumância, conforme referido no ponto 1.4.2.2, no mínimo 90 % dos alimentos devem provir da própria exploração ou, quando tal não for possível, ser produzidos em cooperação com outras explorações que pratiquem a agricultura biológica e situadas na mesma região;

- d) No que diz respeito aos equídeos, os sistemas de criação devem basear-se na utilização máxima do pastoreio, de acordo com a disponibilidade em pastagens nos diferentes períodos do ano. As forragens grosseiras, frescas, secas ou ensiladas devem constituir pelo menos 60 % da matéria seca que compõe a ração diária dos equídeos;
- e) No aleitamento dos equídeos deve ser dada preferência ao leite materno por um período mínimo de três meses.

2.2.3. Condições específicas de alojamento

No que diz respeito às condições de alojamento são aplicáveis as seguintes regras:

- a) Os pavimentos dos edifícios que alojam os equídeos devem ser lisos, mas não derrapantes. Pelo menos metade da superfície interior, conforme especificada no quadro do ponto 2.2.4 relativo às superfícies mínimas para os equídeos, deve ser sólida, isto é, não engradada nem ripada;
- b) Os edifícios devem dispor de uma área de repouso/cama confortável, limpa e seca de dimensão suficiente, consistindo numa construção sólida, não engradada. As áreas de repouso devem dispor de camas amplas e secas. As camas devem ser constituídas por palha ou outros materiais naturais adaptados. As camas podem ser saneadas e enriquecidas com qualquer dos produtos minerais autorizados como fertilizantes ou corretivos do solo para utilização na produção biológica nos termos do artigo 19.º.

2.2.4. Encabeçamento

O número de equídeos por hectare deve respeitar o seguinte limite:

Classe ou espécie	Número máximo de animais por hectare equivalente a 170 kg N/ha/ano
Equídeos com mais de seis meses	2

As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para os equídeos, são as seguintes:

	Área interior (superfície líquida disponível para os animais)		Área exterior (áreas de exercício, com exclusão de pastagens)
	Peso vivo mínimo (kg)	m ² /cabeça	m ² /cabeça
Equídeos de criação e engorda	até 100	1,5	1,1
	até 200	2,5	1,9
	até 350	4,0	3
	acima de 350	5 com um mínimo de 1 m ² /100 kg	3,7 com um mínimo de 0,75 m ² /100 kg

2.3. Produção de suínos

2.3.1. Conversão

Para que os suínos e os respetivos produtos sejam considerados biológicos, as regras de produção estabelecidas no presente regulamento devem ter sido aplicadas há, pelo menos, seis meses.

2.3.2. Alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- a) No mínimo 60 % dos alimentos devem provir da própria exploração ou, quando tal não for possível, ser produzidos na mesma região em cooperação com outras explorações biológicas ou operadores de alimentos biológicos para animais;
- b) Na alimentação dos suínos aleitados deve ser dada preferência ao leite materno por um período mínimo de 40 dias;
- c) Devem ser adicionadas à ração diária dos suínos forragens grosseiras, frescas, secas ou ensiladas.

2.3.3. Condições específicas de alojamento

No que diz respeito às condições de alojamento são aplicáveis as seguintes regras:

- a) Os pavimentos dos edifícios que alojam os suínos devem ser lisos, mas não derrapantes. Pelo menos metade da superfície interior, conforme especificada no quadro do ponto 2.3.4 relativo às superfícies mínimas para os suínos, deve ser sólida, isto é, não engradada nem ripada;
- b) Os edifícios onde os suínos são alojados devem dispor de uma área de repouso/cama confortável, limpa e seca de dimensão suficiente, consistindo numa construção sólida, não engradada. As áreas de repouso devem dispor de camas amplas e secas. As camas devem ser constituídas por palha ou outros materiais naturais adaptados. As camas podem ser saneadas e enriquecidas com qualquer dos produtos minerais autorizados como fertilizantes ou corretivos do solo para utilização na produção biológica nos termos do artigo 19.º;
- c) As porcas devem ser mantidas em grupo, exceto nas últimas fases da gestação e durante o período de aleitamento;
- d) Os leitões não devem ser mantidos em plataformas nem em gaiolas;
- e) As áreas de exercício permitem o depósito de estrume e a fossagem pelos suínos. Para este efeito, podem ser utilizados diversos substratos.

2.3.4. Encabeçamento

O número de suínos por hectare deve respeitar os seguintes limites:

Classe ou espécie	Número máximo de animais por hectare equivalente a 170 kg N/ha/ano
Leitões	74
Porcas reprodutoras	6,5
Suínos para engorda	14

Outros suínos	14
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As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para os suínos são as seguintes:

	Área interior (superfície líquida disponível para os animais)		Área exterior (áreas de exercício, com exclusão de pastagens)
	Peso vivo mínimo (kg)	m ² /cabeça	m ² /cabeça
Porcas reprodutoras com leitões até 40 dias		7,5 por porca	2,5
Suínos de engorda	até 50	0,8	0,6
	até 85	1,1	0,8
	até 110	1,3	1
Leitões	acima de 40 dias e até 30 kg	0,6	0,4
Suínos de criação		2,5 por fêmea	1,9
		6 por macho se os compartimentos forem utilizados para a cobertura natural: 10 por varrasco	8,0

2.4. Produção de aves de capoeira

2.4.1. Conversão

Para que as aves de capoeira e os respetivos produtos sejam considerados biológicos, as regras de produção estabelecidas no presente regulamento devem ter sido aplicadas há, pelo menos:

- 10 semanas para as aves de capoeira destinadas à produção de carne, introduzidas na exploração com menos de três dias;
- Seis semanas para as aves de capoeira destinadas à produção de ovos.

2.4.2. Origem das aves de capoeira

As aves de capoeira devem ser criadas até atingirem uma idade mínima ou, caso contrário, devem provir de estirpes de crescimento lento conforme definidas pela autoridade competente. Quando não forem utilizadas pelo agricultor estirpes de aves de capoeira de crescimento lento, a idade mínima de abate deve ser de:

- 81 dias para os frangos;
- 150 dias para os capões;

- c) 49 dias para os patos de Pequim;
- d) 70 dias para as patas Barbary;
- e) 84 dias para os patos Barbary;
- f) 92 dias para os patos Mallard;
- g) 94 dias para as pintadas;
- h) 140 dias para os perus e os gansos para cozinhar; e
- i) 100 dias para as peruas.

2.4.3. Alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- a) No mínimo 60 % dos alimentos devem provir da própria exploração ou, quando tal não for possível, ser produzidos na mesma região em cooperação com outras explorações biológicas ou operadores de alimentos biológicos para animais;
- b) Devem ser adicionadas à ração diária forragens grosseiras, frescas, secas ou ensiladas.

2.4.4. Condições específicas de alojamento

No que diz respeito às condições de alojamento são aplicáveis as seguintes regras:

- a) As aves de capoeira não devem ser mantidas em gaiolas;
- b) As aves aquáticas devem ter acesso a um curso de água, charco, lago ou tanque sempre que as condições meteorológicas e higiénicas o permitam, para respeitar as suas necessidades específicas e os requisitos em matéria de bem-estar dos animais; quando as condições meteorológicas não o permitirem, devem ter acesso a água onde possam mergulhar a cabeça de forma a limparem as penas;
- c) As aves de capoeira devem dispor de acesso a uma área ao ar livre durante pelo menos um terço da sua vida. As áreas ao livre destinadas às aves de capoeira devem estar maioritariamente cobertas de vegetação e dispor de equipamentos de proteção, permitindo às aves o fácil acesso a bebedouros em número adequado;
- d) Quando forem conservadas em espaços interiores devido a restrições ou obrigações impostas com base na legislação da União, as aves devem dispor de acesso permanente a quantidades suficientes de alimentos grosseiros e materiais adequados às suas necessidades etológicas;
- e) Os edifícios para aves de capoeira devem satisfazer as seguintes condições:
 - i) pelo menos um terço da superfície do solo deve ser uma construção sólida, isto é, não ripada nem engradada, e coberta de um material de cama do tipo palha, aparas de madeira, areia ou turfa,
 - ii) nos galinheiros para galinhas poedeiras, uma parte suficientemente grande da superfície do solo acessível às galinhas deve ser utilizada para a recolha dos excrementos,

- iii) devem possuir poleiros adaptados, em quantidade e dimensões, ao tamanho do grupo e dos animais, como previsto no quadro sobre as superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para a produção de aves de capoeira, estabelecidas no ponto 2.4.5,
 - iv) o limite exterior dos galinheiros, incluindo eventualmente a varanda, deve dispor de aberturas de saída/entrada com uma dimensão adequada às aves, tendo essas aberturas um comprimento total de pelo menos 4 m por 100 m² de superfície das instalações de que as aves dispõem. Quando existir uma varanda, as aberturas internas entre as instalações e a varanda devem ter um comprimento total de 2 m por 100 m² de superfície das instalações. Deve ser permitido um acesso de 24 horas à varanda,
 - v) os galinheiros devem ser construídos de forma a permitir que todas as aves disponham de acesso fácil à área ao ar livre, isto é, a distância máxima entre qualquer ponto do galinheiro e a abertura mais próxima para o exterior não deve exceder 15 m,
 - vi) os sistemas de andares múltiplos não devem ter mais do que três níveis de superfície utilizável, incluindo o piso térreo. A distância entre níveis ou áreas intermédias, tais como áreas de nidificação, não deve ser superior a 1 m. Nos andares mais elevados deve poder ser instalado um sistema automático de remoção do estrume;
- f) A luz natural pode ser complementada artificialmente para garantir um máximo de 16 horas diárias de luminosidade, com um período de repouso noturno contínuo, sem luz artificial, de pelo menos 8 horas;
- g) Os edifícios devem ser esvaziados de animais entre dois períodos de criação de aves de capoeira. Neste intervalo de tempo deve ser feita a desinfeção do edifício e dos respetivos acessórios. Além disso, no final do período de criação de cada grupo de aves de capoeira, os parques devem permanecer desocupados durante um período a estabelecer pelos Estados-Membros para permitir que a vegetação torne a crescer. Estes requisitos não se aplicam às aves de capoeira que não sejam criadas em grupos, não sejam mantidas em parques e possam andar à solta ao longo do dia.

2.4.5. Encabeçamento

O número de animais por hectare deve respeitar os seguintes limites:

Classe ou espécie	Número máximo de animais por hectare equivalente a 170 kg N/ha/ano
Frangos de carne	580
Galinhas poedeiras	230

As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para as aves da espécie *Gallus gallus*, são as seguintes:

	<i>Reprodutores/ progenitores</i>	<i>Animais jovens</i>	<i>Aves de engorda</i>	<i>Capões</i>	<i>Poedeiras</i>

Idade	Aves reprodutoras	Frangas 0-8 semanas	Frangas 9-18 semanas	Iniciação 0-21 dias	Acabamento 22-81 dias	22-150 dias	Galinhas poedeiras a partir das 19 semanas
Densidade nas instalações (aves por m ² de superfície utilizável) para as capoeiras fixas e móveis	6 aves	24 aves com um máximo de 21 kg de peso vivo/m ²	15 aves com um máximo de 21 kg de peso vivo/m ²	20 aves com um máximo de 21 kg de peso vivo/m ²	10 aves com um máximo de 21 kg de peso vivo/m ²	10 aves com um máximo de 21 kg de peso vivo/m ²	6 aves
Espaço de poleiro (cm)							18
Limites adicionais para os sistemas de andares múltiplos/m ² de piso térreo (incluindo as varandas se estiverem acessíveis 24 horas)	9 aves	36 aves excluindo a superfície da varanda	22 aves	Geralmente não aplicável			9 aves
Tamanho máximo dos bandos	3000 incluindo machos	10 000*	3 300	10 000*	4 800	2 500	3 000
Densidade nos percursos ao ar livre (m ² /ave), desde que não seja excedido o limite de 170 kg de N/ha/ano	4	1	4	1	4	4	4

* Subdivisível para a produção de lotes de 3x3000 ou 2x4800

As superfícies mínimas das áreas interiores e exteriores, bem como outras características do alojamento para as aves de espécies que não a *Gallus gallus*, são as seguintes:

	<i>Perus e peruas</i>	<i>Gansos</i>	<i>Patos</i>	<i>Pintadas</i>
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Tipo	Machos	Fêmeas	Todos	Pequim	Machos Barbary	Fêmeas Barbary	Mallard	Todos
Densidade nas instalações (aves por m ² de superfície utilizável) para as capoeiras fixas e móveis	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²	10 com um máximo de 21 kg de peso vivo/m ²
Espaço de poleiro (cm)	40	40	Geralmente não aplicável	Geralmente não aplicável	40	40	Geralmente não aplicável	20
Tamanho máximo dos bandos	2 500	2 500	2 500	4 000 fêmeas 3 200 machos	3 200	4 000	3 200	5 200
Densidade ao ar livre (m ² /ave), desde que não seja excedido o limite de 170 kg de N/ha/ano	10	10	15	4,5	4,5	4,5	4,5	4

2.4.6. Acesso às zonas ao ar livre

No que diz respeito ao acesso às zonas ao ar livre são aplicáveis as seguintes regras:

- a) As aves de capoeira devem dispor de acesso a uma área ao ar livre durante pelo menos um terço da sua vida. Em especial, o acesso contínuo ao ar livre durante o dia deve ser proporcionado desde a mais jovem idade praticável, quando as condições fisiológicas e físicas o permitirem, exceto em caso de restrições temporárias impostas com base na legislação da União;
- b) As áreas ao livre destinadas às aves de capoeira devem estar maioritariamente cobertas de vegetação composta por uma gama diversificada de plantas e dispor de equipamentos de proteção, permitindo às aves o fácil acesso a bebedouros em número adequado. A vegetação nas áreas ao ar livre deve colhida e removida a intervalos regulares a fim de reduzir o potencial excedente de nutrientes. As áreas ao ar livre não se devem prolongar para além de um raio de 150 m da abertura do galinheiro mais próxima. No entanto, é autorizada uma extensão até 350 metros da abertura do galinheiro mais próxima, desde que exista um número suficiente de abrigos e bebedouros regularmente distribuídos por todo o espaço ao ar livre, com um mínimo de quatro abrigos por hectare;
- c) Quando os alimentos disponíveis na zona de pasto forem limitados, devido, por exemplo, a cobertura por neve ou condições de aridez duradouras, podem ser incluídos na alimentação das aves de capoeira suplementos de alimentos grosseiros;

- d) Quando forem conservadas em espaços interiores devido a restrições ou obrigações impostas com base na legislação da União, as aves devem dispor de acesso permanente a quantidades suficientes de alimentos grosseiros e de materiais adequados às suas necessidades etológicas.

2.4.7. Bem-estar dos animais

A depena das aves vivas é proibida.

2.5. Apicultura

2.5.1. Conversão

Os produtos da apicultura só podem ser vendidos com menção da produção biológica se as regras da produção biológica estabelecidas no presente regulamento forem cumpridas há pelo menos um ano.

Durante o período de conversão, a cera deve ser substituída por cera proveniente da apicultura biológica.

2.5.2. Origem das abelhas

No que respeita às abelhas, deve ser dada preferência à utilização da *Apis mellifera* e dos seus ecótipos locais.

2.5.3. Alimentação

No que diz respeito à alimentação são aplicáveis as seguintes regras:

- a) No termo da estação produtiva, são deixadas nas colmeias reservas de mel e de pólen suficientes para passar o inverno;
- b) A alimentação das colónias só é autorizada quando a sobrevivência das colmeias esteja em risco devido às condições climáticas. A alimentação deve efetuar-se com mel biológico, xaropes de açúcar biológicos ou açúcar biológico.

2.5.4. Regras específicas aplicáveis à prevenção das doenças e aos tratamentos veterinários em apicultura

No que diz respeito às condições de prevenção das doenças e tratamento veterinário são aplicáveis as seguintes regras:

- a) Para efeitos de proteção dos quadros, colmeias e favos, nomeadamente contra pragas, só são permitidos os rodenticidas (e apenas em armadilhas) e os produtos adequados autorizados na produção biológica nos termos do artigo 19.º;
- b) São permitidos os tratamentos físicos de desinfeção dos apiários, como o vapor de água e a chama direta;
- c) A prática da supressão dos machos só é autorizada como meio de isolamento contra a infestação por *Varroa destructor*;
- d) Se, apesar de todas as medidas de prevenção, as colónias aparecerem doentes ou infestadas, devem ser imediatamente tratadas; se necessário, podem ser colocadas em apiários de isolamento;

- e) Os ácidos fórmico, láctico, acético e oxálico, bem como o mentol, o timol, o eucaliptol ou a cânfora, podem ser usados em caso de infestação por *Varroa destructor*;
- f) Se for aplicado um tratamento com produtos alopáticos de síntese química, as colónias tratadas devem ser colocadas, durante esse período, em apiários de isolamento, devendo toda a cera ser substituída por cera proveniente da apicultura biológica. Subsequentemente, aplica-se a essas colónias o período de conversão de um ano previsto no ponto 2.5.1;
- g) A alínea f) não é aplicável aos produtos autorizados para utilização na produção biológica nos termos do artigo 19.º.

2.5.5. Condições específicas de alojamento aplicáveis em apicultura

No que diz respeito às condições de alojamento são aplicáveis as seguintes regras:

- a) Os apiários devem ser colocados em zonas que assegurem fontes de néctar e pólen essencialmente constituídas por culturas de produção biológica ou, se for caso disso, por vegetação espontânea ou ainda florestas ou culturas geridas não biologicamente que apenas sejam tratadas com recurso a métodos de reduzido impacto ambiental;
- b) Os apiários devem ser mantidos a uma distância suficiente de fontes suscetíveis de provocar a contaminação dos produtos da apicultura ou a deterioração da saúde das abelhas;
- c) A localização dos apiários deve ser tal que, num raio de 3 km em redor do local, as fontes de néctar e de pólen sejam constituídas essencialmente por culturas de produção biológica ou vegetação espontânea ou culturas tratadas com recurso a métodos de reduzido impacto ambiental equivalentes aos previstos nos artigos 28.º e 30.º do Regulamento (UE) n.º 1305/2013, que não possam afetar a qualificação da produção apícola como biológica. Esses requisitos não são aplicáveis quando não haja floração ou as colmeias estejam em período de hibernação;
- d) As colmeias e os materiais utilizados na apicultura devem ser basicamente constituídos por matérias naturais que não apresentem qualquer risco de contaminação para o ambiente ou para os produtos da apicultura.

2.5.6. Regras específicas relativas às práticas apícolas

No que diz respeito às práticas apícolas são aplicáveis as seguintes regras:

- a) As ceras necessárias para o fabrico de novas folhas de cera devem ser provenientes de unidades de produção biológicas;
- b) No interior das colmeias só podem ser utilizados produtos naturais, tais como própolis, cera e óleos vegetais;
- c) É proibido o uso de repelentes químicos de síntese durante as operações de extração de mel;
- d) É proibida a extração de mel a partir de favos que contenham ovos ou larvas;
- e) A apicultura não pode ser considerada biológica se for praticada nas regiões ou zonas designadas pelos Estados-Membros como regiões ou zonas onde a apicultura biológica não é praticável.

2.5.7. Bem-estar dos animais

No que diz respeito ao bem-estar dos animais são aplicáveis as seguintes regras:

- a) É proibida a destruição das abelhas nos favos, como método associado à colheita dos produtos da apicultura;
- b) São proibidas as mutilações, como o corte das asas das abelhas-mestras.

Parte III: Regras aplicáveis à produção de algas marinhas e de animais de aquicultura

1. Definições

Para efeitos da presente parte, entende-se por:

- 1) «Instalação de aquicultura em circuito fechado (recirculação)»: uma instalação onde a aquicultura é realizada em meio fechado, em terra ou numa embarcação, com recirculação de água, e que depende de uma fonte permanente de energia externa para estabilizar o ambiente dos animais de aquicultura;
- 2) «Energia proveniente de fontes renováveis»: fontes de energia não fósseis renováveis, tais como energia eólica, solar, geotérmica, das ondas, das marés, hidráulica, de gases dos aterros, de gases das instalações de tratamento de águas residuais e de biogás;
- 3) «Maternidade»: local de reprodução, incubação e criação nas fases iniciais de vida dos animais de aquicultura, em particular peixes e moluscos;
- 4) «Unidade de produção de juvenis»: local onde tem lugar uma fase intermédia de produção (pré-engorda), entre as fases da maternidade e da engorda. A fase da produção de juvenis é concluída durante o primeiro terço do ciclo de produção, com exceção das espécies que passam por uma fase de smoltização;
- 5) «Poluição»: a introdução direta ou indireta no ambiente aquático de substâncias ou de energia, tal como definida na Diretiva 2000/60/CE do Parlamento Europeu e do Conselho⁵ e na Diretiva 2008/56/CE do Parlamento Europeu e do Conselho⁶, nas águas a que estas diretivas se aplicam, respetivamente;
- 6) «Policultura»: a criação de duas ou mais espécies, em geral de diferentes níveis tróficos, na mesma unidade de cultura;
- 7) «Ciclo de produção»: tempo de vida de um animal de aquicultura ou alga marinha, desde a primeira fase de vida (ovos fertilizados no caso dos animais de aquicultura) até à colheita;
- 8) «Espécie local»: uma espécie que não seja exótica nem ausente localmente na aceção do Regulamento (CE) n.º 708/2007 do Conselho⁷, bem como as espécies enumeradas no anexo IV do mesmo regulamento;

⁵ Diretiva 2000/60/CE do Parlamento Europeu e do Conselho, de 23 de outubro de 2000, que estabelece um quadro de ação comunitária no domínio da política da água (JO L 327 de 22.12.2000, p. 1).

⁶ Diretiva 2008/56/CE do Parlamento Europeu e do Conselho, de 17 de junho de 2008, que estabelece um quadro de ação comunitária no domínio da política para o meio marinho (Diretiva-Quadro Estratégia Marinha) (JO L 164 de 25.6.2008, p. 19).

⁷ Regulamento (CE) n.º 708/2007 do Conselho, de 11 de junho de 2007, relativo à utilização na aquicultura de espécies exóticas e de espécies ausentes localmente (JO L 168 de 28.6.2007, p. 1).

- 9) «Densidade de animais»: o peso vivo de animais de aquicultura por metro cúbico de água em qualquer momento durante a fase de engorda e, no caso de peixes chatos e camarões, o peso por metro quadrado de superfície.

2. Requisitos gerais

- 2.1. As operações devem situar-se em locais que não estejam sujeitos a contaminação por produtos ou substâncias não autorizados para utilização na produção biológica, ou poluentes que possam comprometer a natureza biológica dos produtos.
- 2.2. As unidades de produção biológica e não biológica devem ser adequadamente separadas e cumprir as distâncias de separação mínimas estabelecidas pelos Estados-Membros, quando tais distâncias tenham sido estabelecidas. Essas medidas de separação devem basear-se na situação natural, em sistemas de distribuição de água separados, na distância, no fluxo de marés e na localização a montante ou a jusante da unidade de produção biológica. A produção de algas marinhas não deve ser considerada biológica quando for praticada em localizações ou áreas designadas pelas autoridades do Estado-Membro como localizações ou áreas inadequadas para a aquicultura biológica ou a colheita de algas.
- 2.3. É exigida uma avaliação ambiental proporcional à unidade de produção para todos os novos empreendimentos que solicitem o estatuto de produção biológica e que produzam anualmente uma quantidade superior a 20 toneladas de produtos da aquicultura, que deverá comprovar as condições da unidade de produção e o meio ambiente imediato, assim como o impacto provável da sua atividade. O operador deve transmitir a avaliação ambiental à autoridade de controlo ou ao organismo de controlo. O conteúdo da avaliação ambiental deve basear-se no anexo IV da Diretiva 2011/92/UE do Parlamento Europeu e do Conselho⁸. Se a unidade já tiver sido objeto de uma avaliação equivalente, é autorizada a reutilizá-la para este fim.
- 2.4. O operador deve apresentar um plano de gestão sustentável proporcional à unidade de produção para a aquicultura e a colheita de algas marinhas.
- 2.5. O plano deve ser atualizado anualmente e deve apresentar de forma pormenorizada os efeitos da atividade no ambiente, a monitorização ambiental a conduzir e uma lista de medidas a adotar para minimizar os impactos negativos nos ambientes aquáticos e terrestres vizinhos, incluindo, se for caso disso, as descargas de nutrientes no ambiente por ciclo de produção ou por ano. O plano deve registar os dados relativos ao controlo e reparação do equipamento técnico.
- 2.6. Os operadores ativos na aquicultura e na produção de algas marinhas devem conceber, no quadro do plano de gestão sustentável, um plano de redução dos resíduos que deverá vigorar desde o início das operações. Sempre que possível, a utilização de calor residual deve limitar-se à energia proveniente de fontes renováveis. Em relação à colheita de algas marinhas, deve ser realizada, logo no início das atividades, uma estimativa pontual da biomassa.

3. Requisitos aplicáveis às algas marinhas

Além das regras de produção gerais estabelecidas nos artigos 7.º, 8.º, 9.º e 12.º, e, se for caso disso, na secção 2, são aplicáveis à colheita e produção de algas marinhas as

⁸ Diretiva 2011/92/UE do Parlamento Europeu e do Conselho, de 13 de dezembro de 2011, relativa à avaliação dos efeitos de determinados projetos públicos e privados no ambiente (JO L 26 de 28.1.2012, p. 1).

regras estabelecidas na presente secção 3. Essas regras aplicam-se *mutatis mutandis* à produção de todas as algas marinhas pluricelulares ou de fitoplâncton e microalgas destinados a servir de alimentos aos animais de aquicultura.

3.1. Conversão

3.1.1. O período de conversão de um local de colheita de algas marinhas deve ser de seis meses.

3.1.2. O período de conversão de uma unidade de cultura de algas marinhas deve ser de seis meses ou corresponder a um ciclo de produção completo, optando-se pelo mais longo dos períodos considerados.

3.1.3. Durante o período de conversão, a exploração aquícola pode ser dividida em unidades claramente separadas, das quais nem todas são geridas segundo as regras da produção biológica. No que se refere à produção de algas marinhas, pode dizer respeito às mesmas espécies, desde que haja uma separação adequada entre as unidades.

3.2. Regras aplicáveis à produção de algas marinhas

3.2.1. A colheita de algas marinhas selvagens, ou de partes destas, que cresçam espontaneamente no mar é considerada produção biológica, desde que:

- a) As zonas de crescimento se encontrem em estado ecológico excelente, conforme definido na Diretiva 2000/60/CE⁹, e não estejam impróprias do ponto de vista sanitário;
- b) A colheita não afete significativamente a estabilidade do ecossistema natural nem a conservação das espécies na zona de colheita.

3.2.2. Para ser considerado biológico, o cultivo de algas marinhas deve ser realizado em zonas costeiras cujas características ambientais e sanitárias sejam pelo menos equivalentes às enunciadas no ponto 3.2.1, alínea a), para serem consideradas biológicas. Aplicam-se ainda as seguintes regras de produção:

- a) Devem ser utilizadas práticas sustentáveis em todas as fases da produção, desde a colheita de algas juvenis até à colheita de algas adultas;
- b) Para assegurar a manutenção de uma grande diversidade genética, há que efetuar regularmente a colheita de algas juvenis na natureza para complementar as populações de cultura interior;
- c) Não podem ser utilizados fertilizantes, a não ser em instalações interiores e se tiverem sido autorizados para utilização na produção biológica para esse efeito.

3.3. Cultura de algas marinhas

3.3.1. A cultura de algas marinhas no mar deve utilizar exclusivamente nutrientes naturalmente presentes no ambiente ou provenientes de uma unidade de produção aquícola biológica de animais situada, de preferência, numa zona próxima, no quadro de um regime de policultura.

3.3.2. Nas instalações em terra que utilizam fontes de nutrientes externas, os níveis de concentração dos nutrientes nos efluentes devem ser comprovadamente iguais ou

⁹ Directiva 2006/113/CE do Parlamento Europeu e do Conselho, de 12 de Dezembro de 2006, relativa à qualidade exigida das águas conquícolas (JO L 376 de 27.12.2006, p. 14).

inferiores aos das águas à entrada do sistema. Apenas podem ser utilizados os nutrientes de origem vegetal ou mineral autorizados para utilização na produção biológica nos termos do artigo 19.º.

- 3.3.3. A densidade de cultura ou a intensidade operacional devem ser registadas e devem manter a integridade do meio aquático, garantindo que não seja excedida a quantidade máxima de algas marinhas que é possível cultivar sem efeitos negativos para o ambiente.
- 3.3.4. As cordas e outros equipamentos utilizados para a cultura de algas marinhas devem ser reutilizados ou reciclados sempre que possível.
- 3.4. Colheita sustentável de algas marinhas selvagens
 - 3.4.1. Deve ser realizada, no início da colheita das algas marinhas, uma estimativa pontual da biomassa.
 - 3.4.2. Deve ser mantida na unidade ou nas instalações um registo documental, a fim de permitir ao operador estabelecer e à autoridade ou organismo de controlo verificar que os operadores só forneceram algas marinhas selvagens produzidas em conformidade com o presente regulamento.
 - 3.4.3. A colheita deve ser realizada de modo a que as quantidades colhidas não causem um impacto significativo no estado do ambiente aquático. Devem ser adotadas medidas para assegurar a regeneração das algas marinhas e evitar a colheita acessória, nomeadamente em termos da técnica de colheita, do tamanho mínimo, da idade, do ciclo reprodutivo ou do tamanho das algas marinhas restantes.
 - 3.4.4. Se as algas marinhas forem colhidas numa zona de colheita partilhada ou comum, devem ser mantidas provas documentais de que a colheita total cumpre o disposto no presente regulamento.

4. Requisitos aplicáveis aos animais de aquicultura

Além das regras de produção gerais estabelecidas nos artigos 7.º, 8.º, 9.º e 12.º, as regras estabelecidas na presente secção 4 são aplicáveis às espécies de peixes, crustáceos, equinodermes e moluscos, conforme referido no ponto 4.1.5.10. Essas regras aplicam-se também *mutatis mutandis* a zooplâncton, microcrustáceos, rotíferos, anelídeos e outros animais aquáticos utilizados para alimentação animal.

- 4.1. Requisitos gerais
 - 4.1.1. Conversão
 - 4.1.1.1. Em relação aos seguintes tipos de instalações de aquicultura, incluindo os animais de aquicultura existentes, são aplicáveis os seguintes períodos de conversão para as unidades de produção biológica:
 - a) 24 meses para as instalações que não possam ser esvaziadas, limpas e desinfetadas;
 - b) 12 meses para as instalações que tenham sido esvaziadas ou sujeitas a vazio sanitário;
 - c) 6 meses para as instalações que tenham sido esvaziadas, limpas e desinfetadas;
 - d) 3 meses para as instalações em águas abertas, incluindo as utilizadas para a produção de moluscos bivalves.

4.1.1.2. Durante o período de conversão, a exploração aquícola pode ser dividida em unidades claramente separadas, das quais nem todas são geridas segundo as regras da produção biológica. No que se refere à produção de animais de aquicultura, esta pode dizer respeito às mesmas espécies, desde que haja uma separação adequada entre as unidades.

4.1.2. Origem dos animais de aquicultura

4.1.2.1. No que diz respeito à origem dos animais de aquicultura, são aplicáveis as seguintes regras:

- a) A aquicultura biológica deve basear-se na criação de populações de juvenis originárias de reprodutores biológicos e de explorações biológicas;
- b) Devem ser utilizadas espécies de origem local cuja reprodução se destinará a gerar estirpes mais adaptadas às condições de produção, que assegurem a boa sanidade e o bem-estar dos animais e que permitam uma boa utilização dos recursos alimentares. Devem ser fornecidas à autoridade ou ao organismo de controlo provas documentais da origem e do tratamento dos animais;
- c) Devem ser escolhidas espécies robustas que possam ser produzidas sem causar danos significativos às populações selvagens;
- d) Para fins de melhoramento genético, podem ser introduzidos na exploração animais selvagens capturados ou animais de aquicultura não biológica. Estes animais devem ser mantidos num regime de gestão biológica durante, pelo menos, os três meses que precedem a sua utilização para reprodução.

4.1.2.2. No que diz respeito à reprodução, são aplicáveis as seguintes regras:

- a) É proibida a utilização de hormonas e derivados de hormonas;
- b) Não podem ser utilizadas a produção artificial de estirpes monosexo, exceto por seleção manual, a indução da poliploidia, a hibridação artificial e a clonagem;
- c) Devem ser escolhidas estirpes adequadas;
- d) Quando adequado, devem ser estabelecidas condições próprias a cada espécie para a gestão dos reprodutores, a reprodução e a produção de juvenis.

4.1.3. Alimentação

4.1.3.1. No que diz respeito aos alimentos para peixes, crustáceos e equinodermes, são aplicáveis as seguintes regras:

- a) Os animais devem ser alimentados com alimentos que satisfaçam as suas necessidades nutricionais nos vários estádios do seu desenvolvimento;
- b) Os regimes alimentares devem ser concebidos de acordo com as seguintes prioridades:
 - i) saúde animal e bem-estar dos animais,
 - ii) elevada qualidade dos produtos, nomeadamente em termos de composição nutricional, que deve garantir uma elevada qualidade do produto final comestível,
 - iii) impacto ambiental reduzido;

- c) A parte vegetal da ração deve provir da produção biológica, devendo a parte dos alimentos derivada de animais aquáticos provir da aquicultura biológica ou da exploração sustentável dos recursos haliêuticos;
 - d) Só podem ser utilizadas matérias não biológicas para a alimentação animal de origem vegetal, matérias para a alimentação animal de origem animal e mineral, aditivos para a alimentação animal, certos produtos utilizados na nutrição animal e auxiliares tecnológicos autorizados para utilização na produção biológica nos termos do presente regulamento;
 - e) Não podem ser utilizados promotores de crescimento nem aminoácidos sintéticos;
 - f) Só podem ser utilizadas na aquicultura biológica matérias para a alimentação animal de origem mineral autorizadas para utilização na produção biológica nos termos do artigo 19.º;
 - g) Só podem ser utilizados na aquicultura biológica aditivos para a alimentação animal, certos produtos utilizados na nutrição animal e auxiliares tecnológicos referidos na parte II, ponto 1.4.4.
- 4.1.3.2. No que diz respeito aos moluscos bivalves e outras espécies que não são alimentadas pelo homem mas que se alimentam de plâncton natural, são aplicáveis as seguintes regras:
- a) Estes animais filtrantes devem satisfazer todas as suas necessidades nutricionais na natureza, exceto no caso de juvenis criados em maternidades e unidades de produção de juvenis;
 - b) As zonas de crescimento devem encontrar-se em estado ecológico excelente, conforme definido na Diretiva 2000/60/CE.
- 4.1.3.3. Regras específicas relativas aos alimentos para animais carnívoros de aquicultura
- Os alimentos para os animais carnívoros de aquicultura devem ser obtidos de acordo com as seguintes prioridades:
- a) Alimentos biológicos de origem aquícola;
 - b) Farinha de peixe e óleo de peixe provenientes de aparas de peixe, crustáceos ou moluscos provenientes da aquicultura biológica;
 - c) Farinha e óleo de peixe e ingredientes derivados de aparas de peixe, crustáceos ou moluscos já capturados para o consumo humano numa pesca sustentável;
 - d) Farinha e óleo de peixe e ingredientes derivados de aparas de peixe, crustáceos ou moluscos inteiros capturados na pesca sustentável e não utilizados para o consumo humano;
 - e) Materiais biológicos para a alimentação animal de origem vegetal ou animal. Os materiais vegetais não podem exceder 60 % dos ingredientes totais.
- 4.1.3.4. Regras específicas relativas aos alimentos para certos animais de aquicultura
- Os peixes das águas interiores, os camarões-peneaeídeos, os camarões-d'água-doce e os peixes tropicais de água doce devem ser alimentados do seguinte modo:
- a) Devem ser alimentados com alimentos naturais disponíveis nas lagoas e lagos;

- b) Caso não se encontrem disponíveis em quantidades suficientes alimentos naturais para animais, conforme referidos na alínea a), podem ser utilizados alimentos biológicos de origem vegetal, de preferência produzidos na própria exploração, ou algas marinhas. Os operadores devem manter provas documentais da necessidade de utilizar alimentos para animais adicionais;
- c) Se os alimentos naturais para animais forem suplementados em conformidade com a alínea b), os alimentos das espécies referidas no ponto 4.1.5.10, alínea g), e dos pangásius (*Pangasius* spp.) podem incluir um máximo de 10 % de farinha de peixe ou óleo de peixe provenientes da pesca sustentável.

4.1.4. Cuidados de saúde

4.1.4.1. Prevenção das doenças

No que diz respeito à prevenção das doenças, são aplicáveis as seguintes regras:

- a) A prevenção das doenças deve basear-se na manutenção dos animais em condições ótimas mediante uma localização adequada, tendo em conta, *inter alia*, as exigências da espécie quanto à boa qualidade, fluxo e renovação das águas e uma conceção ótima das explorações, a aplicação de boas práticas de criação e de gestão, incluindo a limpeza e desinfeção regulares das instalações, uma alimentação de elevada qualidade, uma densidade de animais apropriada e a seleção de raças e estirpes;
- b) É permitida a utilização de medicamentos veterinários imunológicos;
- c) O plano de gestão zoossanitário deve especificar as práticas em matéria de biossegurança e de prevenção de doenças, incluindo um acordo escrito de aconselhamento sanitário, proporcional à unidade de produção, celebrado com serviços competentes em matéria de saúde dos animais de aquicultura que visitarão as explorações com uma frequência não inferior a uma vez por ano e não inferior a uma vez de dois em dois anos no caso dos moluscos bivalves;
- d) Os sistemas, equipamento e utensílios da exploração devem ser devidamente limpos e desinfetados;
- e) Os bioincrustantes são retirados unicamente manualmente ou por outros meios físicos adequados e, quando apropriado, devolvidos ao mar num local distante da exploração aquícola;
- f) Apenas podem ser utilizadas substâncias para a limpeza e a desinfeção dos equipamentos e instalações autorizados para utilização na produção biológica nos termos do artigo 19.º;
- g) No que diz respeito ao vazio sanitário, são aplicáveis as seguintes regras:
 - i) a autoridade competente deve estipular se é necessário um período de vazio sanitário, bem como a sua duração adequada, que deve ser aplicado e documentado após cada ciclo de produção nos sistemas de produção em águas abertas, no mar,
 - ii) o vazio não é obrigatório na cultura de moluscos bivalves,
 - iii) durante o período de vazio sanitário, a jaula ou qualquer estrutura utilizada na produção de animais de aquicultura deve ser esvaziada, desinfetada e mantida vazia antes de voltar a ser utilizada;

- h) Sempre que seja adequado, os alimentos para peixes não consumidos, as fezes e os animais mortos devem ser removidos rapidamente para evitar quaisquer danos significativos para o ambiente no que diz respeito ao nível de qualidade da água, bem como para minimizar os riscos de doenças e evitar atrair insetos ou roedores;
- i) A luz ultravioleta e o ozono apenas podem ser utilizados em maternidades e unidades de produção de juvenis;
- j) No controlo biológico dos ectoparasitas, deve ser dada preferência à utilização de peixes limpadores.

4.1.4.2. Tratamentos veterinários

No que diz respeito aos tratamentos veterinários, são aplicáveis as seguintes regras:

- a) Os casos de doença devem ser tratados imediatamente a fim de evitar sofrimento aos animais. Podem ser utilizados medicamentos veterinários alopáticos de síntese química, incluindo antibióticos, se necessário, em condições estritas e sob a responsabilidade de um veterinário, quando a utilização de produtos fitoterapêuticos, homeopáticos e outros não seja adequada. Sempre que adequado, devem ser definidas as restrições relativas aos tratamentos e aos intervalos de segurança;
- b) São autorizados os tratamentos relacionados com a proteção da saúde humana ou animal impostos por força da legislação da União;
- c) Se surgir um problema sanitário, apesar das medidas preventivas para assegurar a saúde dos animais em conformidade com o ponto 4.1.4.1, podem ser utilizados tratamentos veterinários pela seguinte ordem de preferência:
 - i) substâncias de origem vegetal, animal ou mineral, numa diluição homeopática,
 - ii) vegetais e extratos de vegetais que não tenham efeitos anestésicos, e
 - iii) substâncias como oligoelementos, metais, estimulantes naturais do sistema imunitário ou probióticos autorizados;
- d) A utilização de tratamentos alopáticos deve ser limitada a dois tratamentos por ano, com exceção das vacinações e dos planos de erradicação obrigatórios. Contudo, nos casos de ciclos de produção inferiores a um ano, aplica-se o limite de um tratamento alopático. Se os limites indicados para os tratamentos alopáticos forem excedidos, os animais de aquicultura em questão não podem ser vendidos como produtos biológicos;
- e) A utilização de tratamentos antiparasitários, não incluindo os regimes de controlo obrigatórios implementados pelos Estados-Membros, deve ser limitada a duas vezes por ano ou uma vez por ano se o ciclo de produção for inferior a 18 meses;
- f) O intervalo de segurança entre os tratamentos veterinários alopáticos e os tratamentos antiparasitários em conformidade com a alínea d), incluindo os tratamentos ao abrigo de regimes obrigatórios de controlo e erradicação, deve ser o dobro do intervalo de segurança referido no artigo 11.º da Diretiva 2001/82/CE ou, se esse período não estiver especificado, de 48 horas;

- g) Sempre que sejam utilizados medicamentos veterinários, tal utilização deve ser comunicada à autoridade ou ao organismo de controlo antes de os animais serem comercializados como biológicos. Os animais tratados devem ser claramente identificados.

4.1.5. Alojamento dos animais e práticas de criação

4.1.5.1. São proibidas as instalações aquícolas de produção de animais com sistema de recirculação em circuito fechado, com exceção das maternidades e das unidades de produção de juvenis ou das instalações destinadas à produção de espécies utilizadas na alimentação biológica dos animais.

4.1.5.2. A utilização de sistemas artificiais de aquecimento ou de arrefecimento da água só é permitida nas maternidades e nas unidades de produção de juvenis. Em todas as fases de produção, pode ser utilizada para esse fim água proveniente de furos naturais.

4.1.5.3. O ambiente propício à criação dos animais de aquicultura deve ser concebido de modo que, em função das necessidades da espécie, os animais de aquicultura:

- a) Disponham de espaço suficiente para o seu bem-estar e, se for caso disso, de uma densidade de animais mínima;
- b) Sejam mantidos em água de boa qualidade com, *inter alia*, fluxo e taxa de renovação adequados, níveis de oxigénio suficientes e com um baixo nível de metabolitos;
- c) Sejam mantidos em condições de temperatura e de iluminação em função das necessidades da espécie e tendo em conta a localização geográfica.

No caso dos peixes de água doce, o tipo de fundo deve aproximar-se tanto quanto possível das condições naturais.

No caso das carpas, o fundo deve ser de terra natural.

4.1.5.4. A conceção e a construção dos sistemas de produção aquáticos devem proporcionar caudais e parâmetros físico-químicos suscetíveis de proteger a saúde e o bem-estar dos animais, bem como de satisfazer as suas necessidades etológicas.

4.1.5.5. As unidades de produção em terra devem cumprir os seguintes requisitos:

- a) Nos sistemas em circuito aberto, deve ser possível monitorizar e controlar o débito e a qualidade da água à entrada e à saída;
- b) Pelo menos 5 % da superfície do perímetro («interface terra-água») deve conter vegetação natural.

4.1.5.6. Os sistemas de produção no mar devem satisfazer as seguintes condições:

- a) Devem estar situados em locais em que o fluxo, a profundidade e a renovação da massa de água sejam adequados para minimizar o seu impacto no fundo do mar e na massa de água circundante;
- b) Devem dispor de jaulas concebidas, construídas e mantidas de maneira adequada à exposição ao ambiente operacional.

4.1.5.7. Os sistemas de produção devem ser concebidos, localizados e geridos de modo a minimizar os riscos ligados à fuga dos animais.

4.1.5.8. Caso se verifique a fuga de peixes ou crustáceos, devem ser tomadas medidas adequadas para reduzir o impacto no ecossistema local, incluindo a sua recaptura, se for caso disso. Devem ser mantidas provas documentais a esse respeito.

4.1.5.9. No respeitante à produção aquícola de animais em lagoas, tanques e (sistemas de) canais, as explorações devem ser dotadas de camadas de filtros naturais, de tanques de decantação ou de filtros biológicos ou mecânicos para recolher os nutrientes residuais ou utilizar algas marinhas ou animais (bivalves e algas) que contribuam para melhorar a qualidade dos efluentes. Sempre que seja adequado, os efluentes devem ser controlados a intervalos regulares.

4.1.5.10. Densidade de animais

Ao considerar os efeitos da densidade de animais no bem-estar dos peixes de cultura, deve controlar-se o estado dos peixes (como, por exemplo, os danos nas barbatanas, outros ferimentos, o ritmo de crescimento, o comportamento e a sua saúde geral) e a qualidade da água.

A densidade de animais deve ser a estabelecida por espécie ou grupo de espécies:

a) Produção biológica de salmonídeos em água doce:

Espécies abrangidas: truta-marisca (*Salmo trutta*) – truta-arco-íris (*Oncorhynchus mykiss*) – truta-das-fontes-norte-americana (*Salvelinus fontinalis*) – salmão (*Salmo salar*) – salvelino (*Salvelinus alpinus*) – peixe-sombra (*Thymallus thymallus*) – truta-do-lago-norte-americana (*Salvelinus namaycush*) – salmão-do-danúbio (*Hucho hucho*)

Sistema de produção	Os sistemas de crescimento em exploração devem ser alimentados por sistemas abertos. O nível de fluxo deve garantir um mínimo de saturação de oxigénio de 60 % para a população, bem como o seu conforto e a eliminação do efluente da produção.
Densidade máxima de animais	Espécies de salmonídeos não indicados abaixo: 15 kg/m ³ Salmão: 20 kg/m ³ Truta marisca e truta-arco-íris: 25 kg/m ³ Salvelino: 20 kg/m ³

b) Produção biológica de salmonídeos em água do mar:

Espécies abrangidas: salmão (*Salmo salar*), truta-marisca (*Salmo trutta*), truta-arco-íris (*Oncorhynchus mykiss*)

Densidade máxima de animais	10 kg/m ³ em gaiolas de rede
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c) Produção biológica de bacalhau (*Gadus morhua*) e outros peixes da Família Gadidae, robalos (*Dicentrarchus labrax*), dourada (*Sparus aurata*), corvina (*Argyrosomus regius*), pregado (*Psetta maxima* [= *Scophthalmus maximus*]), pargo-vermelho (*Pagrus pagrus* [= *Sparus pagrus*]), corvinão-de-pintas (*Sciaenops ocellatus*) e outros esparídeos (*Sparidae*), e macuas (*Siganus spp.*):

Sistema de produção	Em sistemas de produção abertos (jaulas/gaiolas de rede), com uma velocidade de corrente marinha mínima, de forma
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	a garantir o bem-estar dos peixes, ou em sistemas abertos em terra.
Densidade máxima de animais	Peixes, com exceção do pregado: 15 kg/m ³ Pregado: 25 kg/m ²

- d) Produção biológica de robalo, dourada, corvina, tainha (*Liza*, *Mugil*) e enguia (*Anguila* spp.) em tanques de terra sob influência das marés e em lagunas costeiras:

Tipo de estabelecimentos de produção	Tanques de salinas tradicionais transformadas em unidades de produção aquícola, e tanques de terra semelhantes em áreas sob influência das marés.
Sistema de produção	A renovação da água deve ser adequada para garantir o bem-estar das espécies. Pelo menos 50 % dos diques deve ter um coberto vegetal. Utilização obrigatória de tanques de depuração baseados em zonas húmidas.
Densidade máxima de animais	4 kg/m ³

- e) Produção biológica de esturjão em água doce:
Espécies abrangidas: Família dos esturjões (*Acipenseridae*)

Sistema de produção	O caudal em cada unidade de criação deve ser suficiente para garantir o bem-estar dos animais. Os efluentes líquidos devem ter uma qualidade equivalente às águas de entrada.
Densidade máxima de animais	30 kg/m ³

- f) Produção biológica de peixes em águas interiores:
Espécies abrangidas: Família das carpas (*Cyprinidae*) e outras espécies associadas no contexto da policultura, incluindo perca, lúcio, peixe-lobo-riscado, coregonídeos, esturjão

Sistema de produção	Em tanques que devem ser periodicamente e completamente drenadas e em lagos. Os lagos devem ser exclusivamente dedicados à produção biológica, incluindo as culturas desenvolvidas em áreas secas. A zona de captura do peixe deve estar equipada com uma entrada de água limpa e ter uma dimensão suficiente para otimizar o bem-estar dos peixes. Os peixes devem ser armazenados em água limpa após a colheita.
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	<p>A fertilização biológica e mineral das lagoas e lagos deve ser realizada apenas com fertilizantes e corretivos dos solos autorizados para utilização na produção biológica nos termos do artigo 19.º, com uma aplicação máxima de 20 kg de azoto/ha.</p> <p>São proibidos tratamentos que envolvam produtos químicos sintéticos para o controlo de plantas hidrófitas e da cobertura vegetal presente nas águas de produção.</p> <p>Devem ser mantidas zonas de vegetação natural em torno das unidades de águas interiores, como zona-tampão para as áreas de terra exteriores que não sejam utilizadas na atividade de produção em conformidade com as regras de aquicultura biológica.</p> <p>A «policultura» de engorda é utilizada desde que se respeitem devidamente os critérios estabelecidos nas presentes especificações aplicáveis a outras espécies de peixes lacustres.</p>
Rendimento da produção	A produção total de espécies está limitada a 1 500 kg de peixe por hectare e por ano.

g) Produção biológica de camarões penaeídeos e de camarões-d'água-doce (*Macrobrachium* spp.):

Estabelecimento da(s) unidade(s) de produção	As unidades devem estar localizadas em zonas argilosas estéreis, a fim de minimizar o impacto ambiental da construção das lagoas, que devem ser construídas com a argila natural existente. Não é permitida a destruição de mangais.
Período de conversão	Seis meses por lagoa, correspondendo ao tempo de vida normal de um camarão de piscicultura.
Origem dos reprodutores	Pelo menos metade dos reprodutores deve ser domesticada após três anos de atividade. O restante deve ser constituído por reprodutores selvagens isentos de organismos patogénicos e provenientes de uma pesca sustentável. É obrigatória a realização de um rastreio na primeira e segunda geração, antes da introdução dos animais na exploração aquícola.
Ablação do pedúnculo ocular	Proibida.
Densidade máxima na exploração e limites de produção	Sementeira: no máximo, 22 indivíduos em estágio pós-larvar/m ² Biomassa instantânea máxima: 240 g/m ²

h) Moluscos e equinodermes:

Sistemas de produção	<p>Palangres, jangadas, cultura de fundo, sacos de rede, jaulas, tabuleiros, redes em forma de campânula (lanternas), estacaria e outros sistemas de produção.</p> <p>Para a cultura de mexilhão em jangadas, o número de cordas não deve exceder uma por metro quadrado de superfície. O comprimento máximo de corda suspensa não deve exceder 20 m. Durante o ciclo de produção, não deve proceder-se ao desbaste das cordas/cabos; no entanto, a subdivisão das cordas/cabos deve ser permitida desde que não haja aumento da densidade de animais.</p>
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- i) Peixe tropical de água doce: peixe-leite (*Chanos chanos*), tilápias (*Oreochromis spp.*), pangásius (*Pangasius spp.*):

Sistemas de produção	Lagoas e gaiolas de rede
Densidade máxima de animais	<p>Pangásius: 10 kg/m³</p> <p><i>Oreochromis</i>: 20 kg/m³</p>

4.1.6. Bem-estar dos animais

4.1.6.1. As pessoas que se ocupam dos animais de aquicultura devem possuir os conhecimentos e competências básicos necessários em matéria de saúde e bem-estar dos animais.

4.1.6.2. O manuseamento dos animais de aquicultura deve ser reduzido ao mínimo, realizado com o maior cuidado e com equipamento adequado e na observância de protocolos destinados a evitar o stresse e os danos físicos associados a tais procedimentos. Os reprodutores devem ser manuseados de modo a minimizar os danos físicos e o stresse, devendo recorrer-se a anestesia sempre que seja adequado. As operações de calibragem devem ser tão limitadas quanto possível e compatíveis com o bem-estar dos peixes.

4.1.6.3. A utilização de luz artificial está sujeita às seguintes restrições:

- O prolongamento da luz natural do dia não deve exceder um limite máximo que respeite as necessidades etológicas, as condições geográficas e a saúde geral dos animais de criação, ou seja, um máximo de 16 horas diárias de luminosidade, exceto para fins de reprodução;
- As alterações bruscas de intensidade luminosa devem ser evitadas no período de transição mediante a utilização de luzes de intensidade regulável ou de iluminação indireta.

4.1.6.4. O arejamento é permitido para garantir o bem-estar e a saúde dos animais, desde que os agitadores mecânicos sejam alimentados, de preferência, a partir de fontes de energia renováveis.

4.1.6.5. O recurso ao oxigénio só é autorizado para utilizações relacionadas com requisitos zoossanitários e de bem-estar e períodos críticos de produção ou transporte, nos seguintes casos:

- Casos excepcionais de aumento da temperatura, descida da pressão atmosférica ou poluição accidental;

- b) Procedimentos pontuais relacionados com a gestão dos animais, tais como a colheita de amostras e a triagem;
 - c) Para garantir a sobrevivência dos animais da exploração.
- 4.1.6.6. Devem ser tomadas medidas adequadas para minimizar a duração do transporte dos animais de aquicultura.
- 4.1.6.7. Qualquer sofrimento deve ser reduzido ao mínimo durante a vida toda do animal e no momento do abate.
- 4.1.6.8. As técnicas de abate devem deixar os peixes imediatamente inconscientes e insensíveis à dor. O manuseamento antes do abate deve evitar ferimentos e minimizar o sofrimento e o stresse. Ao considerar os melhores métodos de abate, devem ser tidas em conta as diferenças entre os tamanhos para colheita, as espécies e os locais de produção.

4.2. Regras específicas para os moluscos

4.2.1. Origem das sementes

No que diz respeito à origem das sementes, são aplicáveis as seguintes regras:

- a) Pode utilizar-se semente selvagem proveniente do exterior dos limites da unidade de produção no caso dos moluscos bivalves, desde que não se registem danos significativos no ambiente, que a legislação local o permita e que a semente selvagem provenha de:
 - i) bancos naturais de populações com poucas probabilidades de sobreviver ao frio invernal ou que sejam excedentários em relação às necessidades ou
 - ii) aglomerações naturais de sementes de moluscos instaladas nos coletores;
- b) No caso da ostra-gigante, *Crassostrea gigas*, deve dar-se preferência a populações criadas seletivamente para reduzir a desova no meio selvagem;
- c) Devem ser mantidos registos relativos ao processo, ao local e à data em que foi recolhida a semente selvagem, a fim de assegurar a rastreabilidade da zona de colheita.

4.2.2. Alojamento dos animais e práticas de criação

No que diz respeito às condições de alojamento e às práticas de criação, são aplicáveis as seguintes regras:

- a) A produção pode ser efetuada na mesma zona de produção aquícola que a criação biológica de peixes e de algas marinhas, segundo um processo de policultura documentado no plano de gestão sustentável. Os moluscos bivalves podem também ser criados em regime de policultura juntamente com moluscos gastrópodes, tais como os burriés;
- b) A produção biológica de moluscos bivalves deve ser realizada em zonas demarcadas por estacas, flutuadores ou outros marcadores visíveis e, se for caso disso, delimitada por sacos de rede, jaulas ou outros meios fabricados pelo homem;

- c) As explorações de produção biológica de moluscos devem minimizar os riscos para as espécies que apresentam um interesse de conservação. Se forem utilizadas redes contra predadores, estas devem ser concebidas de modo a não causarem danos às aves mergulhadoras.

4.2.3. Cultura

No que diz respeito à cultura, são aplicáveis as seguintes regras:

- a) A cultura de mexilhão em cordas e por outros métodos enumerados no ponto 4.1.5.10, alínea h), pode ser elegível como produção biológica;
- b) A cultura de moluscos no fundo só é autorizada se não tiver um impacto ambiental significativo nos locais de colheita e de produção. A comprovação de um impacto ambiental mínimo deve ser fundamentada por um estudo e um relatório sobre a zona de exploração que o operador deverá facultar à autoridade ou ao organismo de controlo. O relatório deve ser anexado ao plano de gestão sustentável, num capítulo separado.

4.2.4. Gestão

No que diz respeito à gestão, são aplicáveis as seguintes regras:

- a) Na produção, é utilizada uma densidade de animais que não exceda a utilizada no caso dos moluscos de produção não biológica presentes no local. Os ajustamentos em matéria de triagem, de desbaste e de densidade devem ser realizados em função da biomassa, com vista a garantir o bem-estar dos animais e um produto de elevada qualidade;
- b) Os bioincrustantes devem ser retirados manualmente ou por outros meios físicos adequados e devolvidos ao mar num local distante das explorações de moluscos. Os moluscos podem ser tratados uma vez durante o ciclo de produção com uma solução de cal para controlar os incrustantes concorrentes.

4.2.5. Regras específicas aplicáveis à ostreicultura

É autorizada a cultura em sacos em mesas sobrelevadas. Estas estruturas onde as ostras são colocadas, ou outras, devem ser dispostas de modo a evitar a formação de uma barreira total ao longo do cordão litoral. Para otimizar a produção, as ostras devem ser cuidadosamente colocadas nas zonas intertidais no sentido do fluxo das marés. A produção deve satisfazer os requisitos estabelecidos no ponto 4.1.5.10, alínea h).

Parte IV: Regras aplicáveis à produção de géneros alimentícios transformados e de alimentos transformados para animais

Além das regras de produção gerais estabelecidas nos artigos 7.º, 9.º e 13.º, são aplicáveis aos géneros alimentícios transformados e aos alimentos transformados para animais as regras estabelecidas na presente parte.

1. Requisitos gerais para a produção de géneros alimentícios transformados e de alimentos transformados para animais

- 1.1. Os aditivos, auxiliares tecnológicos e outras substâncias e ingredientes utilizados para a transformação de géneros alimentícios ou de alimentos para animais e todos os processos de transformação aplicados, tal como a fumagem, devem respeitar os princípios de boas práticas de fabrico¹⁰.
- 1.2. Os operadores que produzem géneros alimentícios transformados ou alimentos transformados para animais devem estabelecer e atualizar procedimentos adequados, baseados numa identificação sistemática das fases críticas de transformação.
- 1.3. A aplicação dos procedimentos referidos no ponto 1.2 deve garantir em qualquer momento que os produtos transformados produzidos obedecem ao presente regulamento.
- 1.4. Os operadores devem cumprir e aplicar os procedimentos referidos no ponto 1.2, devendo nomeadamente:
 - a) Tomar medidas preventivas para evitar os riscos de contaminação por substâncias ou produtos não autorizados;
 - b) Aplicar medidas de limpeza adequadas, controlar a sua eficácia e registar estas operações;
 - c) Assegurar que os produtos não biológicos não sejam colocados no mercado com uma indicação referente à produção biológica.
- 1.5. A preparação de produtos biológicos transformados deve ser separada, no tempo ou no espaço, da preparação de produtos não biológicos. Quando, na unidade de preparação em causa, são igualmente preparados ou armazenados produtos não biológicos, o operador deve:
 - a) Informar a autoridade de controlo ou organismo de controlo em conformidade;
 - b) Efetuar as operações por série completa e de forma a que as mesmas sejam física ou cronologicamente separadas de operações semelhantes sobre produtos não biológicos;
 - c) Armazenar os produtos biológicos, antes e depois das operações, separadamente, física ou cronologicamente, dos produtos não biológicos;
 - d) Manter disponível um registo atualizado de todas as operações e quantidades transformadas;
 - e) Tomar as medidas necessárias para garantir a identificação dos lotes e evitar misturas ou trocas com produtos não biológicos;
 - f) Efetuar as operações relativas a produtos biológicos apenas após a limpeza adequada do equipamento de produção.
- 1.6. Não devem ser utilizados produtos, substâncias e técnicas destinados a reconstituir propriedades que tenham sido perdidas durante a transformação e a armazenagem de géneros alimentícios biológicos, que corrijam os resultados de negligências na transformação de géneros alimentícios biológicos ou que de outro modo possam induzir em erro no que respeita à verdadeira natureza dos produtos que se destinem a ser comercializados como géneros alimentícios biológicos.

¹⁰ Boas práticas de fabrico (BPF), conforme definidas no artigo 3.º, alínea a), do Regulamento (CE) n.º 2023/2006 da Comissão, de 22 de dezembro de 2006, relativo às boas práticas de fabrico de materiais e objetos destinados a entrar em contacto com os alimentos (JO L 384 de 29.12.2006, p. 75).

2. Requisitos para a produção de géneros alimentícios transformados

2.1. À composição dos géneros alimentícios biológicos transformados, são aplicáveis as seguintes condições:

- a) O produto deve ser obtido principalmente a partir de ingredientes agrícolas; para determinar se um produto é obtido principalmente a partir de ingredientes agrícolas, não deve ser tida em conta a adição de água nem de sal;
- b) Nos géneros alimentícios destinados a uma alimentação especial, só podem ser utilizados aditivos alimentares, auxiliares tecnológicos, aromas, água, sal, preparados de microrganismos e enzimas alimentares, minerais, oligoelementos, vitaminas, bem como aminoácidos e outros micronutrientes, autorizados para utilização na produção biológica nos termos do artigo 19.º;
- c) Um ingrediente biológico não pode estar presente juntamente com um ingrediente idêntico em conversão ou em forma não biológica;
- d) Os géneros alimentícios produzidos a partir de culturas em conversão devem conter apenas um ingrediente vegetal de origem agrícola.

2.2. Utilização de determinados produtos e substâncias na transformação dos géneros alimentícios

2.2.1. Na transformação de géneros alimentícios, com exceção dos produtos e substâncias do setor vitivinícola, aos quais se aplica a parte V, ponto 2, e das leveduras, às quais se aplica a parte VI, ponto 1.3, só podem ser utilizados os produtos e substâncias referidos no ponto 2.1, alínea b), bem como os produtos e substâncias referidos nos pontos 2.2.2, 2.2.4 e 2.2.5.

2.2.2. Na transformação dos géneros alimentícios, é autorizada a utilização dos seguintes produtos e substâncias:

- a) Preparados de microrganismos e enzimas alimentares normalmente utilizados na transformação dos géneros alimentícios; no entanto, as enzimas alimentares para utilização como aditivos alimentares têm de ser autorizadas para a utilização na produção biológica nos termos do artigo 19.º;
- b) Substâncias e produtos conforme definidos no artigo 3.º, n.º 2, alíneas b) e d), do Regulamento (CE) n.º 1334/2008 do Parlamento Europeu e do Conselho¹¹ rotulados como substâncias aromatizantes naturais ou preparações aromatizantes naturais, em conformidade com o artigo 15.º, n.º 1, alínea e), e com o artigo 16.º desse regulamento;
- c) Corantes para carimbar as carnes e as cascas dos ovos em conformidade com o artigo 17.º do Regulamento (CE) n.º 1333/2008 do Parlamento Europeu e do Conselho¹²;

¹¹ Regulamento (CE) n.º 1334/2008 do Parlamento Europeu e do Conselho, de 16 de dezembro de 2008, relativo aos aromas e a determinados ingredientes alimentares com propriedades aromatizantes utilizados nos e sobre os géneros alimentícios e que altera o Regulamento (CEE) n.º 1601/91 do Conselho, os Regulamentos (CE) n.º 2232/96 e (CE) n.º 110/2008 e a Diretiva 2000/13/CE (JO L 354 de 31.12.2008, p. 34).

¹² Regulamento (CE) n.º 1333/2008 do Parlamento Europeu e do Conselho, de 16 de dezembro de 2008, relativo aos aditivos alimentares (JO L 354 de 31.12.2008, p. 16).

- d) Água potável e sais (com cloreto de sódio ou cloreto de potássio como componentes de base) geralmente utilizados na transformação dos alimentos;
- e) Minerais (incluindo oligoelementos), vitaminas, aminoácidos e micronutrientes, unicamente autorizados na medida em que a sua utilização seja legalmente exigida nos géneros alimentícios em que são incorporados.

2.2.3. Para efeitos do cálculo referido no artigo 21.º, n.º 3, são aplicáveis as seguintes regras:

- a) Certos aditivos alimentares autorizados para utilização na produção biológica nos termos do artigo 19.º devem ser calculados como ingredientes agrícolas;
- b) As preparações e substâncias referidas no ponto 2.2.2 não devem ser calculadas como ingredientes agrícolas;
- c) As leveduras e os produtos à base de leveduras devem ser calculados como ingredientes agrícolas.

2.2.4. Os seguintes ingredientes agrícolas não biológicos podem ser utilizados na transformação dos géneros alimentícios biológicos:

- a) Produtos de origem animal:
 - i) organismos aquáticos, não provenientes da aquicultura, autorizados na preparação de géneros alimentícios não biológicos,
 - ii) gelatina,
 - iii) tripas;
- b) Produtos vegetais não transformados e produtos deles derivados por transformação:
 - i) frutos, frutos de casca rija e sementes comestíveis:
 - nozes de cola *Cola acuminata*
 - ii) especiarias e ervas comestíveis:
 - sementes de rábano silvestre *Armoracia rusticana*
 - flores de cártamo *Carthamus tinctorius*
 - agrião *Nasturtium officinale*
 - iii) diversos:
 - algas, incluindo algas marinhas
- c) Produtos vegetais transformados:
 - i) açúcares, amidos e féculas e outros produtos derivados de cereais e tubérculos:
 - folha de papel de arroz
 - amido de arroz e de milho ceroso, não modificado quimicamente
 - ii) diversos:
 - rum, exclusivamente obtido do suco da cana-de-açúcar

2.2.5. As gorduras e óleos, refinados ou não, mas não modificados quimicamente, podem ser utilizados na sua forma não biológica se forem derivados de plantas com exceção de:

– Cacau	<i>Theobroma cacao</i>
– Coco	<i>Cocos nucifera</i>
– Azeitona	<i>Olea europaea</i>
– Girassol	<i>Helianthus annuus</i>
– Palma	<i>Elaeis guineensis</i>
– Colza	<i>Brassica napus, rapa</i>
– Cártamo	<i>Carthamus tinctorius</i>
– Sésamo	<i>Sesamum indicum</i>
– Soja	<i>Glycine max</i>

3. Requisitos para a produção de géneros alimentícios transformados

- 3.1. As matérias biológicas para a alimentação animal ou as matérias para a alimentação animal em conversão não devem entrar simultaneamente com matérias para a alimentação animal idênticas produzidas por meios não biológicos na composição dos alimentos biológicos para animais.
- 3.2. As matérias para a alimentação animal utilizadas ou transformadas na produção biológica não podem ter sido transformadas com o recurso a solventes de síntese química.

Parte V: Vinho

1. Âmbito de aplicação

- 1.1. Além das regras de produção gerais estabelecidas nos artigos 7.º, 8.º, 9.º e 14.º, as regras estabelecidas na presente parte são aplicáveis à produção biológica dos produtos do setor vitivinícola, conforme referido no artigo 1.º, n.º 2, alínea l), do Regulamento (UE) n.º 1308/2013.
- 1.2. Salvo disposição explícita em contrário da presente parte, são aplicáveis os Regulamentos (CE) n.º 606/2009¹³ e (CE) n.º 607/2009¹⁴ da Comissão.

2. Utilização de certos produtos e substâncias

- 2.1. Os produtos do setor vitivinícola devem ser produzidos a partir de matérias-primas biológicas.
- 2.2. Só podem ser utilizados na produção de produtos do setor vitivinícola, nomeadamente durante os processos e práticas enológicas, os produtos e substâncias autorizados na produção biológica nos termos do artigo 19.º, sujeitos às condições e

¹³ Regulamento (CE) n.º 606/2009 da Comissão, de 10 de julho de 2009, que estabelece regras de execução do Regulamento (CE) n.º 479/2008 do Conselho no que respeita às categorias de produtos vitivinícolas, às práticas enológicas e às restrições que lhes são aplicáveis (JO L 193 de 24.7.2009, p. 1).

¹⁴ Regulamento (CE) n.º 607/2009 da Comissão, de 14 de julho de 2009, que estabelece normas de execução do Regulamento (CE) n.º 479/2008 do Conselho no que respeita às denominações de origem protegidas e indicações geográficas protegidas, às menções tradicionais, à rotulagem e à apresentação de determinados produtos vitivinícolas (JO L 193 de 24.7.2009, p. 60).

restrições estabelecidas no Regulamento (UE) n.º 1308/2013 e no Regulamento (CE) n.º 606/2009 e, em especial, no anexo I A deste regulamento.

3. Práticas enológicas e restrições

- 3.1. Sem prejuízo das secções 1 e 2 e das restrições e proibições específicas previstas nos pontos 3.2 a 3.5, só são permitidas as práticas, processos e tratamentos enológicos, incluindo as restrições previstas no artigo 80.º e no artigo 83.º, n.º 2, do Regulamento (UE) n.º 1308/2013 e no artigo 3.º, artigos 5.º a 9.º e artigos 11.º a 14.º do Regulamento (CE) n.º 606/2009 e nos anexos desses regulamentos, utilizados antes de 1 de agosto de 2010.
- 3.2. É proibida a utilização das seguintes práticas, processos e tratamentos enológicos:
- a) Concentração parcial por arrefecimento em conformidade com o anexo VIII, parte I, secção B, ponto 1, alínea c), do Regulamento (CE) n.º 1308/2013;
 - b) Eliminação do dióxido de enxofre por processos físicos em conformidade com o anexo I A, ponto 8, do Regulamento (CE) n.º 606/2009;
 - c) Tratamento por eletrodialise para estabilização tartárica do vinho em conformidade com o anexo I A, ponto 36, do Regulamento (CE) n.º 606/2009;
 - d) Desalcoolização parcial de vinhos em conformidade com o anexo I A, ponto 40, do Regulamento (CE) n.º 606/2009;
 - e) Tratamento de permuta catiónica para a estabilização tartárica do vinho em conformidade com o anexo I A, ponto 43, do Regulamento (CE) n.º 606/2009.
- 3.3. É permitida a utilização das seguintes práticas, processos e tratamentos enológicos, nas condições referidas:
- a) Tratamentos térmicos em conformidade com o anexo I A, ponto 2, do Regulamento (CE) n.º 606/2009, se a temperatura não exceder 70 °C;
 - b) Centrifugação e filtração com ou sem adjuvante de filtração inerte em conformidade com o anexo I A, ponto 3, do Regulamento (CE) n.º 606/2009, se a dimensão dos poros não for inferior a 0,2 micrómetros.
- 3.4. O recurso às seguintes práticas, processos e tratamentos enológicos será reexaminado pela Comissão antes de 1 de agosto de 2015, com vista à sua eliminação progressiva ou restrição:
- a) Tratamentos térmicos conforme referidos no anexo I A, ponto 2, do Regulamento (CE) n.º 606/2009;
 - b) Utilização de resinas de permuta iónica conforme referido no anexo I A, ponto 20, do Regulamento (CE) n.º 606/2009;
 - c) Osmose inversa em conformidade com o anexo VIII, parte I, secção B, ponto 1, alínea b), do Regulamento (CE) n.º 1308/2013.
- 3.5. As alterações efetuadas após 1 de agosto de 2010 no que respeita às práticas, processos e tratamentos enológicos previstos no Regulamento (CE) n.º 1234/2007 ou no Regulamento (CE) n.º 606/2009 só são aplicáveis à produção biológica de vinho após a adoção das medidas necessárias para aplicar as regras de produção previstas na presente secção 3 e, se necessário, na sequência de um processo de avaliação nos termos do artigo 19.º do presente regulamento.

Parte VI: Leveduras utilizadas como géneros alimentícios ou alimentos para animais

Além das regras de produção gerais estabelecidas nos artigos 7.º, 9.º e 15.º, as regras estabelecidas na presente parte são aplicáveis às leveduras biológicas utilizadas como géneros alimentícios ou alimentos para animais.

1. Requisitos gerais

- 1.1. Para a produção de leveduras biológicas, só podem ser utilizados substratos obtidos biologicamente.
- 1.2. Os géneros alimentícios e os alimentos biológicos para animais não podem conter simultaneamente leveduras biológicas e leveduras não biológicas.
- 1.3. Na produção, preparação e formulação de leveduras biológicas podem ser utilizadas as seguintes substâncias:
 - a) Auxiliares tecnológicos autorizados para utilização na produção biológica nos termos do artigo 19.º;
 - b) Produtos e substâncias referidos na parte IV, ponto 2.2.2, alíneas a) e d).

ANEXO III

RECOLHA, ACONDICIONAMENTO, TRANSPORTE E ARMAZENAGEM DOS PRODUTOS

1. Recolha de produtos e transporte para as unidades de preparação

Os operadores só podem efetuar a recolha simultânea de produtos biológicos e não biológicos se forem tomadas medidas adequadas para impedir qualquer mistura ou troca possível com produtos não biológicos e para garantir a identificação dos produtos biológicos. O operador deve manter à disposição da autoridade ou organismo de controlo os dados relativos aos dias, horas e circuito de recolha, e à data e hora de receção dos produtos.

2. Acondicionamento e transporte de produtos para outros operadores ou unidades

2.1. Os operadores devem assegurar que os produtos biológicos só sejam transportados para outros operadores ou unidades, incluindo grossistas e retalhistas, em embalagens, contentores ou veículos apropriados, fechados de modo a que o seu conteúdo não possa ser substituído sem manipulação ou danificação do selo e munidos de um rótulo que mencione, sem prejuízo de outras indicações eventualmente previstas por disposições regulamentares da União:

- a) O nome e endereço do operador e, se não for o mesmo, do proprietário ou do vendedor do produto;
- b) O nome do produto ou uma descrição do alimento composto para animais, acompanhado de uma referência à produção biológica;
- c) O nome ou número de código da autoridade de controlo ou organismo de controlo a que está submetido o operador, e
- d) Se for caso disso, a marca de identificação do lote, em conformidade com um sistema de marcação aprovado a nível nacional ou acordado com a autoridade ou organismo de controlo, que permita relacionar o lote com os registos referidos no artigo 24.º.

As informações referidas nas alíneas a) a d) podem também ser apresentadas num documento de acompanhamento, caso este possa ser incontestavelmente relacionado com a embalagem, contentor ou veículo que transporta o produto. O referido documento deve conter também informações relativas ao fornecedor ou ao transportador.

2.2. Não é necessário fechar as embalagens, contentores ou veículos, se:

- a) Os produtos forem transportados diretamente de um operador a outro operador que estejam submetidos ao sistema de controlo biológico;
- b) Os produtos forem acompanhados de um documento que contenha as informações exigidas no ponto 2.1, e
- c) O operador expedidor e o operador destinatário mantiverem registos documentais dessas operações de transporte à disposição da autoridade ou organismo de controlo.

3. Regras especiais aplicáveis ao transporte de alimentos para animais para outras unidades de produção ou preparação ou para instalações de armazenagem

Aquando do transporte de alimentos para animais para outras unidades de produção ou preparação ou para instalações de armazenagem, os operadores devem assegurar a observância das seguintes condições:

- a) Durante o transporte, os alimentos biológicos para animais, os alimentos em conversão para animais e os alimentos não biológicos para animais devem ser objeto de separação física eficaz;
- b) Os veículos ou os contentores que tenham transportado produtos não biológicos só podem ser utilizados para o transporte de produtos biológicos se:
 - i) tiver sido efetuada, antes de iniciar o transporte dos produtos biológicos, uma limpeza adequada cuja eficácia tenha sido controlada e os operadores documentarem estas operações,
 - ii) forem aplicadas todas as medidas adequadas, em função dos riscos avaliados de acordo com o regime de controlo, e, sempre que necessário, o operador assegure que os produtos não biológicos não possam ser colocados no mercado com uma indicação referente à produção biológica,
 - iii) o operador mantiver registos documentais dessas operações de transporte à disposição da autoridade ou organismo de controlo;
- c) O transporte dos alimentos biológicos acabados para animais deve ser separado fisicamente ou no tempo do transporte de outros produtos acabados;
- d) Aquando do transporte, deve proceder-se ao registo da quantidade de produtos à partida, bem como das quantidades de cada entrega durante o circuito.

4. Transporte de peixes vivos

- 4.1. Os peixes vivos devem ser transportados em contentores adequados, com água limpa que satisfaça as suas necessidades fisiológicas em termos de temperatura e de oxigénio dissolvido.
- 4.2. Antes do transporte de peixes e de produtos de peixe biológicos, os contentores devem ser devidamente limpos, desinfetados e enxaguados.
- 4.3. Devem ser tomadas precauções para reduzir o stresse dos animais. Durante o transporte, a densidade não deve atingir um nível que seja prejudicial para a espécie.
- 4.4. Devem ser conservadas provas documentais das operações referidas nos pontos 4.1, 4.2 e 4.3.

5. Receção de produtos de outros operadores ou unidades

Aquando da receção de um produto biológico, o operador deve verificar o fecho da embalagem ou do contentor, sempre que tal seja exigido, bem como a presença das indicações previstas na secção 2.

O operador deve confrontar as informações constantes do rótulo referido na secção 2 com as informações constantes dos documentos de acompanhamento. O resultado destas verificações deve ser explicitamente mencionado nos registos referidos no artigo 24.º.

6. Regras especiais aplicáveis à receção de produtos provenientes de países terceiros

Quando forem importados de países terceiros, os produtos biológicos devem ser transportados em embalagens ou contentores apropriados, fechados de modo a impedir a substituição do seu conteúdo e munidos da identificação do exportador e de quaisquer outras marcações e números necessários para identificar o lote, bem como do certificado de inspeção para importação de países terceiros, se for caso disso.

Aquando da receção de um produto biológico importado de um país terceiro, a pessoa singular ou coletiva a quem a remessa importada é entregue e que a recebe para subsequente preparação ou comercialização, deve verificar que a embalagem ou o contentor se encontra fechado e, no caso dos produtos importados em conformidade com o artigo 28.º, n.º 1, alínea b), subalínea ii), que o certificado de inspeção referido nesse artigo cobre o tipo de produto contido na remessa. O resultado desta verificação deve ser explicitamente mencionado nos registos referidos no artigo 24.º.

7. Armazenagem dos produtos

- 7.1. As áreas de armazenagem dos produtos devem ser geridas de forma a garantir a identificação dos lotes e evitar qualquer mistura ou contaminação com produtos ou substâncias não conformes às regras da produção biológica. Os produtos biológicos devem ser claramente identificáveis em qualquer momento.
- 7.2. No caso das unidades de produção vegetal e animal biológica, é proibida a armazenagem na unidade de produção de matérias-primas que não as autorizadas para utilização na produção biológica nos termos do artigo 19.º.
- 7.3. É permitida a armazenagem de medicamentos veterinários alopáticos e de antibióticos nas explorações agrícolas e aquícolas desde que tenham sido receitados por um veterinário no âmbito dos tratamentos previstos na parte II, ponto 1.5.2.2, e parte III, ponto 4.1.4.2, alínea a), estejam armazenados num local vigiado e sejam inscritos no registo pecuário a que se refere o artigo 24.º.
- 7.4. Quando os operadores manuseiem produtos não biológicos e produtos biológicos e estes últimos sejam armazenados em instalações de armazenagem em que sejam também armazenados outros produtos agrícolas ou géneros alimentícios:
 - a) Os produtos biológicos devem estar separados dos outros produtos agrícolas ou géneros alimentícios;
 - b) Devem ser tomadas as medidas necessárias para garantir a identificação dos lotes e evitar misturas ou trocas com produtos não biológicos;
 - c) Antes da armazenagem dos produtos biológicos, deve ter sido efetuada uma limpeza adequada cuja eficácia foi controlada e essas ações devem ser registadas pelos operadores.

ANEXO IV

MENCÕES REFERIDAS NO ARTIGO 21.º

BG: биологичен.

ES: ecológico, biológico.

CS: ekologické, biologické.

DA: økologisk.

DE: ökologisch, biologisch.

ET: mahe, ökoloogiline.

EL: βιολογικό.

EN: organic.

FR: biologique.

GA: orgánach.

HR: ekološki.

IT: biologico.

LV: bioloģisks, ekoloģisks.

LT: ekologiškas.

LU: biologesch.

HU: ökológiai.

MT: organiku.

NL: biologisch.

PL: ekologiczne.

PT: biológico.

RO: ecologic.

SK: ekologické, biologické.

SL: ekološki.

FI: luonnonmukainen.

SV: ekologisk.

ANEXO V

LOGÓTIPO DE PRODUÇÃO BIOLÓGICA DA UNIÃO EUROPEIA E NÚMEROS DE CÓDIGO

1. Logótipo

- 1.1. O logótipo de produção biológica da União Europeia deve respeitar o modelo seguinte:

Inserir LOGÓTIPO

- 1.2. A cor de referência em Pantone deve ser Green Pantone n.º 376 e Green (50 % Cyan + 100 % Yellow) sempre que seja utilizada quadricromia.

- 1.3. O logótipo de produção biológica da União Europeia pode também ser utilizado a preto e branco, como ilustrado, unicamente quando não seja praticável aplicá-lo a cores:

Inserir LOGÓTIPO

- 1.4. Se a cor de fundo da embalagem ou do rótulo for escura, os símbolos podem ser utilizados em negativo, na mesma cor de fundo empregue para a embalagem ou rótulo.

- 1.5. Se um logótipo de cor for utilizado num fundo de cor que torne a sua visão difícil, pode ser isolado por uma linha exterior de delimitação, a fim de contrastar melhor com a cor de fundo.

- 1.6. Em certas situações específicas em que haja indicações numa cor única na embalagem, o logótipo de produção biológica da União Europeia pode ser utilizado na mesma cor.

- 1.7. O logótipo de produção biológica da União Europeia deve ter uma altura mínima de 9 mm e uma largura mínima de 13,5 mm; a proporção entre a altura e a largura deve ser sempre de 1:1,5. Excepcionalmente, o tamanho mínimo pode ser reduzido para uma altura de 6mm no caso das embalagens muito pequenas.

- 1.8. O logótipo de produção biológica da União Europeia pode ser associado a elementos gráficos ou textuais que refiram a produção biológica, desde que não alterem ou modifiquem a natureza do logótipo de produção biológica da União Europeia ou qualquer das indicações definidas em conformidade com o artigo 22.º. Quando estiver associado a logótipos nacionais ou privados que utilizem uma cor verde diferente da cor de referência mencionada no ponto 2, o logótipo de produção biológica da União Europeia pode ser utilizado na referida cor diferente da de referência.

2. Números de código

O formato geral dos números de códigos é o seguinte:

AB-CDE-999

em que:

- a) «AB» é o código ISO do país em que são realizados os controlos;
- b) «CDE» é um termo, indicado em três letras a decidir pela Comissão ou por cada Estado-Membro, como «bio» ou «öko» ou «org» ou «eko», que estabelece uma ligação com a produção biológica, e

- c) «999» é o número de referência, indicado em três dígitos, no máximo, a atribuir:
- i) Pela autoridade competente de cada Estado-Membro às autoridades de controlo ou organismos de controlo aos quais tenham delegado as tarefas de controlo;
 - ii) Pela Comissão:
 - às autoridades de controlo e organismos de controlo reconhecidos pela Comissão nos termos do artigo 29.º;
 - às autoridades competentes de países terceiros reconhecidas pela Comissão nos termos do artigo 31.º.



Brussels, 24.3.2014
SWD(2014) 65 final

PART 1/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on organic production and labelling of organic products, amending Regulation (EU)
No XXX/XXX of the European Parliament and of the Council [Official controls
Regulation] and repealing Council Regulation (EC) No 834/2007**

{COM(2014) 180 final}
{SWD(2014) 66 final}

TABLE OF CONTENTS

1.	PROCEDURAL ISSUES AND RESULTS FROM CONSULTATION OF INTERESTED PARTIES.....	1
2.	POLICY CONTEXT, PROBLEM DEFINITION, AND SUBSIDIARITY.....	5
2.1.	CAP and CFP post 2013.....	5
2.2.	Legislation on organic farming.....	6
2.3.	Focus on the control system.....	7
2.4.	Consistency with other policies.....	8
2.5.	Problem definition.....	9
2.5.1.	General problem.....	9
2.5.2.	Problem tree.....	10
2.5.3.	Specific problems and problem drivers.....	11
2.5.3.1.	Supply and demand for organic products in the EU	11
2.5.3.2.	Obstacles to the development of domestic supplies	14
2.5.3.3.	Risk of loss of consumer confidence	17
2.5.3.4.	Fair competition among producers not guaranteed and risks for the functioning of the internal market	24
2.5.4.	Who is affected by the problem, in what ways and to what extent?.....	29
2.6.	How would the problem evolve without a change in policy?.....	30
2.6.1.	Supply.....	30
2.6.2.	Consumer confidence, issues for the internal market.....	31
2.6.3.	Socio-economic impacts of the current legislation.....	33
2.6.4.	Environmental impacts.....	34
2.7.	Does the EU have the right to act?.....	34
3.	OBJECTIVES.....	35
3.1.	General objectives and consistency with new CAP objectives.....	35
3.2.	Specific and operational objectives.....	36
4.	POLICY OPTIONS.....	38
4.1.	Policy option 1: improved status quo.....	38
4.2.	Policy option 2: market-driven option.....	40
4.3.	Policy option 3: principle-driven option.....	41
4.4.	Options discarded at an early stage.....	44
5.	IMPACT ANALYSIS.....	46

5.1.	Option 1	46
5.2.	Option 1A	47
5.3.	Option 2	48
5.4.	Option 2.A	50
5.5.	Option 3	51
5.6.	Option 3.A	53
5.1.	Option 3.B	54
5.2.	Simplification and administrative costs.....	56
5.2.1.	Simplification associated with the options	56
5.2.2.	Assessment of administrative costs	56
5.3.	Conclusions on topics on which the Council had asked a report to the Commission.....	58
6.	COMPARING THE OPTIONS – PREFERRED OPTION	58
7.	MONITORING AND EVALUATION.....	62

Executive Summary Sheet

Impact assessment on Proposal for a Regulation of the European Parliament and of the Council on organic production and labelling of organic products

A. Need for action

Why? What is the problem being addressed?

The overall objective of the EU political and legislative framework is the sustainable development of organic production. But, while organic farming in the EU is expected to develop in line with market developments, the EU organic land area has only doubled in the last 10 years, while the market has increased fourfold. There is a risk of limitation to the organic market expansion and a risk of limitation to the environmental benefits associated with organic farming. The main drivers are:

- regulatory and non-regulatory obstacles to the development of organic farming in the EU;
- a risk of erosion of consumer confidence, notably because organic production rules are watered down and fraud cases are developing, in connection with shortcomings in the control system and in the trade regime,
- unfair competition among producers and risks for the functioning of the internal market, because of gaps in the legislation and implementation and enforcement failures.

What is this initiative expected to achieve?

In the context of the 2020 CAP reform, the proposal aims at:

- removing obstacles to the development of organic production in the EU,
- improving the legislation in order to guarantee fair competition for farmers and producers and to improve the functioning of the internal market,
- maintaining or improving consumer confidence in organic products.

In addition, the initiative is part of the Commission's Regulatory Fitness and Performance Programme and aims at simplifying rules and their implementation and at reducing administrative costs for administrations and operators.

What is the value added of action at the EU level?

The current exercise is an updating of an existing scheme set within the CAP. Production and trade of agricultural products and foodstuffs on the internal market and ensuring the integrity of the internal market are matters of EU competence. Both are EU shared competences with MS. An EU-wide scheme is more efficient than 28 different schemes and allows for a stronger and more consistent trade policy vis-à-vis global trading partners, most notably by enhancing its bargaining power. Areas where further harmonisation is needed: exceptions to the rules, procedures in case of presence of non-authorized substance residues in organic products and cases of non-compliances where products lose their organic status are addressed.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

A wide range of options, including the 'no policy option', have been considered. Three policy options have been assessed in depth. The *improved status quo option* notably includes clarifications in the scope of the legislation, simplifications in the labelling rules and addresses some gaps in the legislation. The *market-driven option* aims at providing the conditions to respond dynamically to further market developments thanks to a more product-oriented scheme with flexible production rules. The *principle-driven option* aims at re-focussing organic farming on its principles. Production rules are strengthened; the control system is fully risk-based; import rules are overhauled. The preferred option is the *principle-driven option* including sub-options to introduce group certification for small farmers and the obligation for organic processors and traders to run an environmental management system (EMS). The three options include a legislative proposal. The *market-driven* and the *principle-driven* options include an EU Action Plan.

Who supports which option?

In May 2013 the Council called for a review of the EU organic farming legislation and of the 2004 Action Plan. The public consultation has shown that citizens would like to see organic production rules further harmonised and strengthened. The stakeholders of the organic sector, notably IFOAM EU (European branch of the International

Federation of Organic Agriculture Movements) and COPA COGECA consider that the EU organic legislation should remain close to the principles and values of the sector; both started by cautiously supporting the *improved status quo* but have made steps towards the *principle-driven option*. The principle-driven option is supported by other organisations (the European Coordination Via Campesina, animal welfare organisations, etc). The *market-driven option* is supported notably by Eurocommerce.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The preferred option is expected to remove obstacles to the development of organic farming in the EU thanks to clearer and simpler production rules. The removal of exceptions will lead to the development of organic inputs, notably seeds. The implementation of the action plan will bring more synergies with other EU policies, help addressing specific needs of the organic sector and improve access to third country markets. Fair competition will be improved notably thanks to simpler and clearer rules and to the move from equivalence to compliance for CBs in third countries. Consumer confidence will be addressed with stricter production rules taking into account evolving societal concerns (animal welfare, EMS for processors and traders). Fraud prevention will be higher, thanks to a more efficient control system, based on risk-assessment, and a more reliable import regime. Because of incomplete data notably on the economics of organic farms and operators, on prices, on the market size and on trade flows, impacts mentioned in the report are only qualitative.

What are the costs of the preferred option (if any, otherwise main ones)?

Some producers will have to leave the sector because they want to keep a part of conventional production on their holding, or because their system depends on exceptions. Production costs could be higher because of stricter rules. Stricter rules can be seen as a barrier to conversion, notably because insufficient availability of inputs such as seeds in their organic form when stricter rules are implemented. Higher production costs could lead in the short term to a market contraction because of higher consumer prices, but this should not continue in the medium and long term, since the development of inputs in their organic form, more adapted to organic production, should boost organic yields. The introduction of an EMS entails additional costs for operators the first year it is implemented, but they should be compensated by energy savings afterwards. Because of incomplete data notably on the economics of organic farms and operators, on prices, on the market size and on trade flows, impacts mentioned in the report are only qualitative.

How will businesses, SMEs and micro-enterprises be affected?

Micro-enterprises will be exempted from the requirement to apply an EMS system.

Small farms are under-represented in the organic sector. While 69% of all agricultural holdings have less than 5 ha, only 18,7% of organic holdings have less than 5 ha. The requirements for small farms, including those with processing activities, will be simplified if they apply group certification which will be introduced in the preferred option. The option will bring more legal clarity. The preferred option also entails much simplification and a reduction in the administrative costs. The number of information obligations for operators will be reduced by 17 out of the existing 80.

Will there be significant impacts on national budgets and administrations?

The preferred option entails much simplification and a reduction in the administrative costs. The number of information obligations will be reduced by 20 out of the existing 41.

Will there be other significant impacts?

Third countries and international relations: stricter rules in the preferred option involve a review of existing equivalence arrangements. Issues for developing country producers are addressed through the introduction of group certification.

Social impacts: there are indications that organic agriculture is more labour intensive than conventional agriculture, therefore its development should facilitate new job creation.

Environmental impacts: positive on biodiversity, water quality, soil health and quality. Energy savings with EMS imposed for processors and traders. Animal welfare conditions improved.

D. Follow up

When will the policy be reviewed?

The policy review is included in the 2014 CWP. After that, the policy will be reviewed according to a regular cycle.

LIST OF ACRONYMS

AGOF	Advisory Group on organic Farming
CA	Competent Authority
CAP	Common Agricultural Policy
CB	Control body or control authority
CERTCOST Farming	Economic Analysis of Certification Systems in Organic Food and
CFP	Common Fisheries Policy
COPA-COGECA	Committee of Professional Agricultural Organisations and General Confederation of Agricultural Cooperatives in the European Union
DG	Directorate-General
DG AGRI	Directorate-General for Agriculture and Rural Development
ECA	European Court of Auditors
EGTOP	Expert Group for Technical advice on Organic Production
EU	European Union
BEUC	European Consumer Organisation
EMAS	Eco-Management and Audit Scheme
EMS	Environmental management System
EOCC	European Organic Certifiers Council
EIP	European Innovation Partnership
FADN	Farm Accountancy Data Network
FVO	Food and Veterinary Office
GMO	Genetically Modified Organisms
IAB	Impact Assessment Board
IFOAM	International Federation of Organic Agriculture Movements
IO	Information Obligation
ISSG	Inter-Service Steering Group
JRC	Joint Research Centre
MRL	Maximum Residue Limit
MS	Member State
NGO	Non Governmental Organisation
OFFC	Official Food and Feed Controls
OFIS	Organic farming Information System
RD	Rural Development
UAA	Utilised Agricultural Area
WTO	World Trade Organisation

1. PROCEDURAL ISSUES AND RESULTS FROM CONSULTATION OF INTERESTED PARTIES

The impact assessment has focused on:

- **Legislative tools, in particular Council Regulation (EC) 834/2007¹ on organic production and labelling of organic products**, applicable since January 2009, which provides for the scope, principles, objectives and general rules for organic farming. Detailed rules for the production, labelling and controls of organic products are provided in Commission Regulation No 889/2008². Detailed rules on imports are provided in Commission Regulation No 1235/2008³. The report intends to analyse the impacts of a new basic legislative Act as well as the necessary implementation measures.
- The relevance of a new strategy for organic farming in the EU. The **European Action Plan for Organic Food and Farming⁴** adopted by the Commission in 2004 provided a basis for the policy development over the past years. All the actions have by now been completed or have become obsolete.

The review of the Organic Farming legislation is part of the Commission's Regulatory Fitness and Performance Programme (REFIT)⁵ which aims at identifying inconsistencies, gaps and ineffective measures, in order to simplify rules and their implementation and/or reduce regulatory costs for businesses and citizens without compromising public policy objectives.

Work on the impact assessment for the review of the organic farming policy⁶ was carried out by a **European Commission ISSG** set up by DG AGRI in June 2012. The first meeting of the ISSG took place on 12 July 2012.

All Directorates General (DGs) of the European Commission were invited to participate in the work of the ISSG, and in addition to DG AGRI, the following DGs were actively

¹ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1)

² Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.09.2008, p. 1)

³ Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334, 12.12.2008, p. 25)

⁴ European Action Plan for Organic Food and Farming Com (2004) 415 final of 10.06.2004.

⁵ Commission Communication on EU Regulatory Fitness of 12 December 2012 – COM(2012)746

⁶ The **Roadmap** on "Regulation of the European Parliament and of the Council on organic production and labelling of organic products – Review of EU political and legal framework for organic production" was adopted in September 2012

http://ec.europa.eu/governance/impact/planned_ia/docs/2012_agri_014_organic_farming_en.pdf

involved in the exercise: the Secretariat-General, the Legal Service, SANCO, ENTR, ENV, DEVCO, ESTAT, TAXUD, RTD, JRC, MARE, TRADE and CLIMA⁷.

The work on the impact assessment was carried out between June 2012 and September 2013, during which the ISSG held monthly meetings. The situation was analysed in depth thanks to **stakeholder hearings**, in which the ISSG listened to **72 stakeholders**: experts, academics and representatives of consumers, producers, retailers, operators, processors, third countries and associations representing third countries, traders, laboratories and researchers, animal welfare organisation. The hearings took place in the fall of 2012. The agendas of the meetings with stakeholders and their presentations can be consulted on the Commission web-site⁸.

Two AGOF meetings enlarged to the participants in the hearings were dedicated to the review. A final consultation meeting with the AGOF took place on 26 June.

MS, as competent authorities in charge of implementing the legislation, were kept informed and were consulted on technical aspects of the review. In addition, replies to a questionnaire addressed by the Irish presidency to the MS on the EU organic farming policy have been used (MS who transmitted their reply to the Commission).

A wide public consultation

A **public consultation through an on-line questionnaire** was launched from 15 January 2013 to 10 April 2013. It attracted high interest and almost 45.000 replies were submitted to the on-line questionnaire. In addition, about 1.350 additional contributions were received by the Commission.

The majority (96%) of responses to the on-line questionnaire were submitted by EU citizens, while 4% were sent by stakeholders, the majority of which were companies (57%) and industry associations and NGOs (18%). The main interests represented by the 1 827 stakeholders who replied to the questionnaire were those of farmers (48%); consumers⁹ (10%); processors (9%); advisory services (5%); researchers (4%); national associations (3%); traders (3%); public competent authorities/public control authorities/accreditation bodies (3%); retailers (3%); private CBs (2%); public authorities in non-EU countries (0.3%).

Citizens who replied to the questionnaire can be characterised by a relative high awareness of organic production: 83% of them declared to be regular consumers and 15% occasional consumers. The knowledge of the EU organic logo appeared to be high, with 79% knowing the EU organic logo (compared to 24% following the 2012 Eurobarometer's survey).

⁷ DG SANCO (Health and Consumers), ENTR (Enterprise and Industry), ENV (Environment), DEVCO (EuropeAid Development and Cooperation), ESTAT (EUROSTAT), TAXUD (Taxation and Customs Union), RTD (Research and Innovation), JRC (Joint Research Center), MARE (Maritime Affairs and Fisheries), TRADE (Trade) and CLIMA (Climate Action)

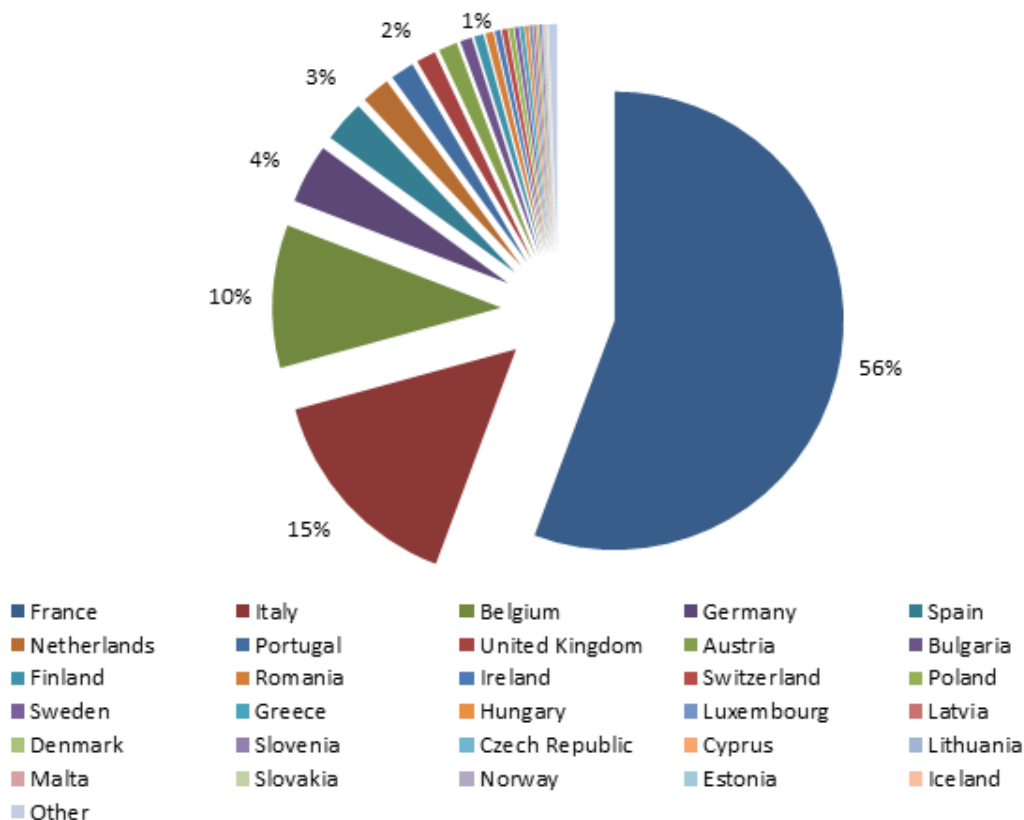
⁸ http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en

⁹ The persons who replied on behalf of a consumer organisation are considered as consumers, while the ones who replied on personal behalf are considered as citizens.

The respondents were asked to indicate drives for purchasing and consuming organic products. Over 80% of all questioned citizens claimed that the most important rationales behind organic products consumption were concerns about the environment (83%) as well as purity of these products with regard to GMOs (81%) and pesticide and other chemical substances residues. A considerable number of citizens' respondents also emphasized that they purchased organic products because of belief in and support for seasonal and local products (78%) as well as strong conviction that organic farming system is more sustainable than conventional (74%). Approximately 63% of the respondents considered organic foodstuffs as healthier than their conventional counterparts. About half of them underlined that they are motivated to buy organic products because organic production respect animal welfare. Besides, important reasons that encouraged almost half of the questioned consumers to consume organic products are beliefs that these goods are of higher quality (47%) and better taste (43%). In addition, 10% of private consumers, who responded to the questionnaire, consume organic products for other beliefs than those stated above.

From a geographical point of view, France was overrepresented¹⁰, with 56% of the replies, followed by Italy (15%) and Belgium (10%) (see graph 1).

Figure 1: Percentage share of replies to the public consultations' questionnaire by country



A report presenting a detailed analysis of the results as well as an executive summary can be consulted on the Commission web-site¹¹.

¹⁰ To check whether some particular sub-classes (by country, capacity, attitude, orientation etc.) could introduce bias on average results from the sample, analyses based on groups were carried out: by selecting most relevant classes no distortive effect was proved.

Annex 2 to this report presents a synthesis of the results of the consultations carried out for the review.

¹¹ http://ec.europa.eu/agriculture/consultations/organic/contributions_en.htm.

Scrutiny by the Commission IAB

The IAB assessed a draft version of the present impact assessment and issued a positive opinion on 20 December 2013. The report was amended in line with the recommendations from the IAB, as follows:

(1) Further improve the problem definition: An effort was made to demonstrate the relative importance and impact and demand for organic products in the EU of the problem drivers presented in the report, despite the lack of data. The problems are presented in a more neutral manner and it is clarified that the development of organic production in the EU is lower than what can be expected from market developments.

(2) Better describe the options: for each envisaged options, addressed problem drivers are indicated. It is clarified that the impact assessment covers measures envisaged under the basic Act and its implementing measures. The envisaged changes to the objectives and principles of organic farming are explained. The report better explains the link between the envisaged export certificate and export issues, and how measuring of environmental performance when processors and traders deal with both organic and conventional products, assessing the risk of non compliance of retailers, setting transitional periods for organic inputs and defining transitional measures for control bodies will work in practice.

(3) Further develop the assessment and comparison of impacts:the report further discuss the possibility that the expected increase in consumer confidence would not sufficiently compensate potentially higher prices under the preferred option. Greater efforts have been made to indicate which product categories, MS and third countries are likely to be most impacted.

(4) Better present stakeholders views: the analysis is corroborated with the views of key stakeholders groups, where available. It presents the overall summary of both public and targeted consultations in Annex 2.

Procedure and presentation: the report has been substantially shortened by streamlining the problem definition, shortening the discussion on general objectives, avoiding duplication in assessing the effectiveness of options and re-focussing the monitoring and evaluation arrangements on specific rather than operational objectives.

2. POLICY CONTEXT, PROBLEM DEFINITION, AND SUBSIDIARITY

2.1. CAP and CFP post 2013

The new CAP adopted in 2013, provides for the overall framework for the development of agriculture in the EU for the period 2014-2020. The **overarching objective for the CAP post 2013** was the sustainable competitiveness to achieve an economically viable food production sector, in tandem with sustainable management of the EU's natural land-based resources .An emblematic measure of the new CAP is the introduction of a strong greening component (30%) in the direct payments received by farmers, which can be received if they go beyond the basic requirements and deliver environmental and climate benefits. Given the recognised environmental benefits of the organic farming systems, **organic farms will benefit from this "greening" payment.** For details on the instruments supporting the organic farming policy see Annex 3.

The **RD measures will more widely address organic farming** during the programming period 2014-2020. Besides the new measure for supporting organic farming through compensating for additional costs or income foregone resulting from organic conversion or management, other relevant measures will be proposed, such as the development of **innovative products**, processes, practices, technologies and **cooperation** approaches among actors of the food chain.

It is necessary to ensure that **the legislation on organic farming is still consistent with the new CAP**.

CFP post 2013

The revised CFP for the next ten years was adopted in 2013¹². Organic aquaculture is viewed as a promising sector, where further growth is anticipated in the coming years for various species of fish, shellfish and seaweed. As the EU implementing rules have only applied to aquaculture since 1 July 2010, organic aquaculture is still a young sector compared to organic farming.

2.2. Legislation on organic farming

The first EU legislation on organic farming was adopted in 1991. Council Regulation (EEC) No 2092/91 provided a legal definition of organic farming through production rules, defined control and labelling requirements and rules for importing organic products. This provided a basis to protect consumers and organic farmers against false and misleading organic claims.

The legislation was substantially revised with the adoption of Council Regulation No (EC) 834/2007 in June 2007. which notably:

- defined organic farming more accurately by describing its **objectives and principles**,
- further **harmonised** organic production rules within the EU, by putting an end to national rules for animal products,
- introduced the **possibility of exceptions to the rules** under the responsibility of MS, with the objective to limit them to the strict necessary and for a limited period of time,
- linked the organic control system to the OFFC provided in Regulation (EC) No 882/2004¹³ and made obligatory the **accreditation** of private CBs,
- **restructured the import regime**: in addition to the recognition of third countries for the purpose of equivalence, the EU is now able to recognise directly CBs active in third countries for the purpose of equivalence or compliance. The system of individual authorisations granted by MS consignment by consignment is being phased out (till 2014).

¹² Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC, (OJ L 354, 28.12.2013, p. 22–61)

¹³ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1–141)

While most of the provisions were simply transferred from Council Regulation (EC) No 2092/91, the new elements have been implemented from 2009 onwards. However, the new import system through recognised CBs for the purpose of equivalence¹⁴ applied from July 2012.

When adopting Council Regulation (EC) No 834/2007, **the Council earmarked a series of issues**, regarding, in particular, the scope of the legislation, the prohibition of the use of GMOs and the functioning of the internal market and control system, on which the Commission was required to submit a report to the European Parliament and the Council, after having reviewed the experience gained from the application of Regulation 834/2007.

The Commission adopted the report¹⁵ in May 2012. It was a factual report which included in particular the results of a MS-survey on organic food prepared by caterers. In order to be better prepared for the review, the Commission ordered **an external evaluation** in September 2012, parts of which have been used for this impact assessment.

The Council adopted conclusions on the report at its meeting on Agriculture and Fisheries of 13-14 May 2013¹⁶ on the basis of the Commission report. Among others, it called to develop the organic farming sector **at an ambitious level** by reviewing the current legal framework, with a view to improving its usability **while providing for a period of stability and certainty**, and aiming at further clarification and simplification and addressing the current outstanding issues requiring further development.

2.3. Focus on the control system

The **ECA audited the effectiveness of the control system** governing the production, processing, distribution and imports of organic products in 2010 and 2011. The results, published in the ECA Special Report No 9/2012¹⁷, show a number of **weaknesses** and include recommendations for improvement. Annex 9 provides a detailed description of the control system and of the most relevant findings of the ECA.

The Commission addressed the ECA' more pressing recommendations with the adoption of Commission Regulation (EU) No 392/2013¹⁸ amending the implementing rules on the organic control system **in April 2013**. The Regulation, applicable as from 1 January 2014, enhances the exchange of information along the chain, harmonises and strengthens the risk-based approach and calls on MS to increase supervision of CBs, to develop a catalogue of sanctions and to improve the quality of their reporting to the Commission on the control activities carried out.

¹⁴ Commission Implementing Regulation 1267/2011 of 6 December 2011 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

¹⁵ COM (2012) 212 final of 11 May 2012 Report from the Commission to the European Parliament and to the Council on the application of Council regulation (EC) No 834/2007 on organic production and labelling of organic products

¹⁶ 8906/13 AGRILEG 56 – Organic Farming: Application of the regulatory framework and development of the sector

¹⁷ Special Report of the ECA no 9/2012 on "The audit of the control system governing the production, processing, distribution and imports of organic products" published on 26 June 2012

¹⁸ Commission Implementing Regulation (EU) No 392/2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production (OJ L 118, 30.4.2013, p. 5-14)

In May 2013, the Commission adopted a **proposal¹⁹ to review the OFFC Regulation**. The proposal aims at improving the existing situation in respect of overlaps, gaps and grey areas due to the presence of control requirements in different pieces of legislation. It explicitly refers to organic as part of the scope of official controls, thereby removing a number of previous uncertainties. Coordination will be needed when defining specific or additional measures for organic controls, such as on control responsibilities and tasks, minimum control frequency, measures for non-compliance, specific reporting obligations and derogations as appropriate.

2.4. Consistency with other policies

The review will have to take into account other policies such as **quality schemes** developed under the CAP²⁰, (with discussions on new optional quality terms), the ongoing review of the **promotion and information policy for EU agricultural products** (for more details see Annex 4) and other initiatives such as "**Unlocking the Single Market for Green Products**" and the "**Sustainable Food initiative**". The present review is also an opportunity to progress on the debate about the possible **extension of the Ecolabel²¹²² to the food and feed sector**, which has been previously envisaged. A study²³ published in October 2011 evaluated in particular the option of limiting the scope of the EU Ecolabel for food, feed and drink products to organically certified products only and underlined the confusion that could result for the consumer from such an extension.

Consistency with the EU Health and Consumer policy and in particular with the horizontal rules on food and feed safety and labelling is essential to ensure the coherence of the EU approach in the food and feed sector thus offering consumers the same public health guarantees throughout the EU, including for imported products. In this area, the Commission is also working on measures on animal cloning for food production in the EU. The legislation on organic production will need adaptations in order to clarify the exclusion of such techniques in organic production, taking into account the organic farming principles.

¹⁹ COM(2013) 265 final of 6.5.2013: Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...]2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

²⁰ Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs. OJ L 343 of 14.12.2012, p. 1

²¹ Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel - OJ L 27, 30.1.2010, p. 1.

²² Article 36 of Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products requires the Commission to submit, by 1 January 2015, a feasibility report on options for an Ecolabel scheme for fisheries and aquaculture products.

²³ EU Ecolabel for food and feed products – feasibility study (ENV.C.1/ETU/2010/0025) – Oakdene Hollins Research and Consulting

On the international side, consistency with the international agreements and with the EU Development Policy needs to be maintained.

2.5. Problem definition

2.5.1. General problem

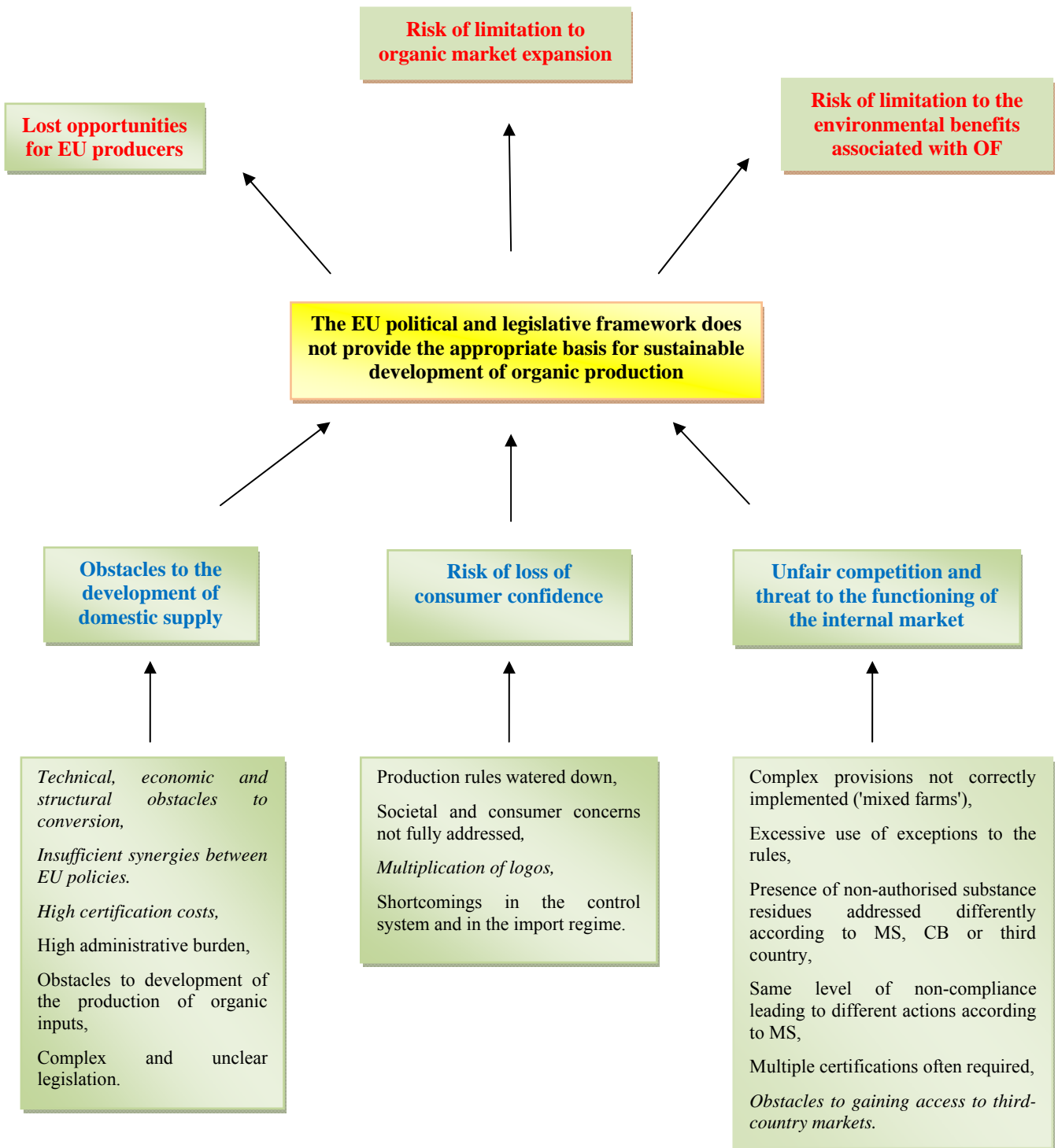
The overall objective of the current EU political and legislative framework, which is the **sustainable development of organic production**, is not met. Although the organic farming sector develops in the EU, **the progression is not in line with market developments**, while studies indicate organic farms tend to require more labour and to achieve higher margins per unit of production than conventional ones²⁴. **Therefore the economic growth and the delivered level of employment in the EU organic sector are below what could be expected from the market development, which means lost opportunities for EU producers.**

There is also a risk of limitation to the organic market expansion. The organic market has built on consumer confidence. Research results show that consumer confidence is higher with strict production rules and reliable control procedures. But with the current legislation, the organic production rules are being watered down notably by an excessive use of exceptions. In addition, deficiencies in the control system and in the import regime lead to negative reports in the media because of fraud cases. **Therefore there is a risk of erosion of consumer confidence which entails a risk of limitation to the organic market expansion.**

There is evidence that organic farming practices, when compared to conventional agriculture, have positive effects on the environment, notably on biodiversity, soil and water. This is further analysed in Annex 13. But **the current legislative framework hinders these positive effects** by limiting the surfaces managed according to the organic farming principles in the EU because of lost opportunities for EU organic producers and by watering down the organic production rules. It results in a **risk of limitation to the environmental benefits associated with organic farming.**

²⁴ Organic versus conventional farming, which performs better financially? An overview of organic field crop and milk production in selected MS. Farm Economics Briefs, No 4, November 2013, European Commission, DG Agriculture and Rural Development. http://ec.europa.eu/agriculture/rca/publications_en.cfm#BR2011

2.5.2. Problem tree



Non-regulatory drivers are in italics.

2.5.3. *Specific problems and problem drivers*

This part analyses first the development of demand and supply for organic products in the EU and then the specific problems and the problem drivers.

2.1.1.1. Supply and demand for organic products in the EU

Demand side: organic market outlook

In recent years the organic market in the EU and worldwide has been characterized by an unprecedented development.

The global market for organic food has expanded fourfold since 1999. Its value was estimated at 63 billion US dollars in 2011²⁵. Although growth has slowed since the financial crisis started in 2008, sales have continued to increase. Demand for organic products is concentrated in two regions: North America and Europe represent around 45% each of global revenues.

In the EU, the total value of the organic market was estimated at **around 20 billion Euro in 2011**²⁶. This figure represents approximately 2% of the turn-over of the EU food and drink industry in the EU which is estimated at 1,017 billion Euro for 2011²⁷, a share that has doubled since 2004. Since 2008, the growth is around 7-8% per year and was estimated at **9% in 2011**. Market growth rates are expected to recover as the European economy strengthens. Some analysts project the European organic market to continue to increase by around 7% per year, with revenues reaching 30.5 billion Euro in 2016²⁸.

The by far largest organic market in the EU was Germany with 6.6 billion Euro in 2011. France held the second place with 3.8 billion Euro. This market showed one of the most dynamic growth rates in the past couple of years. The UK organic market is estimated at 1.9 billion Euro, while in Italy it is 1.7 billion Euro. The organic sector is described in Annex 1, with some more indications on the consumption of organic products.

The organic market is developing not only from a quantitative point of view, but also from a qualitative point of view. The **range of organic products** offered to consumers is widening with in particular more and more varieties of organic processed products available. The **distribution** has evolved. Retail, supermarkets and internet traders are now significant players together with direct sales, local markets and specialised shops.

The **economic crisis** has had two types of impacts on the organic market. In some MS, it has caused a reduction in consumption because organic products are more expensive than conventional food. On the other hand, the crisis has triggered some consumers to look for more responsible and sustainable products leading to an increase in organic sales²⁹. Overall, the market has continued to grow at a healthy pace.

²⁵ Source: Organic Monitor

²⁶ The World of Organic Agriculture: Statistics and Emerging Trends 2013 - FiBL and IFOAM

²⁷ FoodDrink Europe, Data and Trends of the European Food and Drink Industry 2012

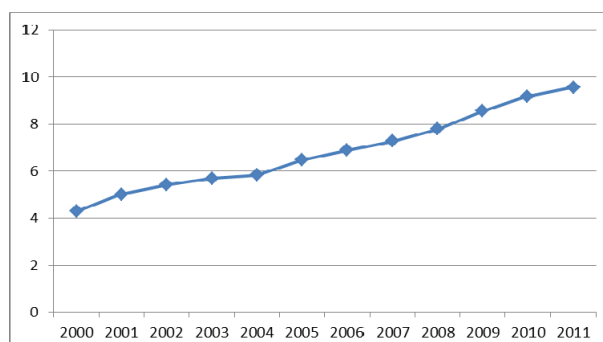
²⁸ Estimates of the size of the organic market are from private sources

²⁹ IFOAM – FRESHFEL, BEUC September hearing

Supply side

Available data³⁰ shows a rapid development of the organic farming sector in the EU during the last decade:

Graph 2.5.2.2: Evolution of the area under organic cultivation in the EU (million ha) between 2000 and 2011



Source: Eurostat annual survey

A thorough analysis of the adequation of the supply to the demand in the EU cannot be provided, since data on organic production is incomplete.

Incomplete data on organic production

The EU organic production legislation currently defines identification and collection of statistical data within the context of the EU Statistical Programme. On this basis, it provides for the collection by MS of data related to: surfaces (in conversion and fully converted), operators (by type of activity), livestock (organic animals and products of animal origin), crop production and processing (operators and value/volume of production by type of economic activity). According to Eurostat analysis (Task Force "Organic farming statistics" 7-8 March 2011), data are substantially incomplete with regard to specific crop production, products of animal origin and processed products.

The land area converted to organic farming in the EU is growing at a slower pace than the organic market. Starting in 1993, the share of UAA devoted to organic farming has grown from 0.6% in the EU-15 to 5.4% in the EU-27 in 2011 where it covered 9.6 million ha of land. The **organic area has approximately doubled** in the decade 2000 - 2010, with varying situations according to MS. This has to be put in perspective with a **four-fold growth of the global organic market** between 1999 and 2011, during almost the same period.

In the organic sector, the obligation to undergo a conversion period of usually up to two years allows only a medium-term response of the supply-side to changes in the demand side. This leads to a certain degree of imbalance between domestic supply and demand in the organic market. However, this is not sufficient to explain the gap between supply and demand in the EU.

³⁰ See in particular "Facts and figures on organic agriculture in the European Union" – Commission report, November 2013. http://ec.europa.eu/agriculture/markets-and-prices/more-reports/pdf/organic-2013_en.pdf

There is evidence of lost opportunities for EU producers, notably the fact that the organic production in the EU does not cover the demand:

- stakeholders³¹ have reported that the demand is far from being covered by the production in the EU, notably for **fruit and vegetables and crop products, including protein-rich crops for feed,**
- an **inadequate level of production of organic inputs, such as seeds and young animals,** is attested by a wide use by MS CA of the possibility to authorise the use of conventional inputs if they are not available on the market in their organic form,
- the external evaluation has quoted one study reporting an oversupply in certain sectors of the EU organic food industry since the demand is not keeping pace with supply. It has proved to have occurred in the organic milk sector only, according to the information received by DG AGRI during the stakeholder consultation.

The difference between EU production and demand is covered by growing imports.

Because of the lack of data on sales and trade, this cannot be corroborated by a thorough statistical analysis, but it is confirmed by:

- a comprehensive study³² on imports of organic products into Germany showing that the share of imported organic products that could also be produced in the country varies from 2 to 95 %;
- the share of organic imported products on the French organic market estimated at 25 % in 2013 by the 'Agence Bio'.

Both sources do not differentiate imports from third countries and products bought in other MS.

More specifically, the increase in imports from third countries is demonstrated by:

- **data on exports from third countries:** for instance from India. The EU is the main destination for organic products exported from India (47% in volume, 58% in value in 2012). In the marketing year 2010-11, India³³ exported a total volume of almost 70.000 tonnes, including about 33.000 tonnes to the EU. This compares with a total volume of less than 4.200 tonnes exported by India in 2002-2003. Exports from India into the EU have regularly increased during the last decade;

³¹ UNADIS (Union Professionnelle Belge des Détaillants Spécialisés en produits Bio et compléments alimentaires) reported that demand is higher than supplies. Freshfel (European Fresh Produce Association) noted that the contrast between availability of organic production and drive towards green public procurement - discrepancies between political willingness and operational possibilities.

³² Analyse der Entwicklung des ausländischen Angebots bei Bioprodukten mit Relevanz für den deutschen Biomarkt – BÖLN

³³ Source: APEDA - http://www.apeda.gov.in/apedawebsite/organic/Organic_Products.htm

- an analysis by a private consulting³⁴, according to which "*large volumes of organic **beans, seeds, grains and ingredients such as cocoa and vanilla** are imported into Europe*"; good market opportunities are mentioned in the **meat sector**, and high growth in the **organic seafood market** more import reliant; "*many products, such as organic tea and coffee are imported. Imports are also important for **organic juices, wine and some soft drinks***";
- the USDA Foreign Agricultural Service³⁵, which published in February 2013 an analysis of the export opportunities for U.S. organic products in the EU market. The potential market for U.S. organics on the EU market is estimated at almost USD 50 million with opportunities to be found in vegetables, fresh fruit, dried fruit and nuts, specialty grains and processed products.

2.1.1.2. Obstacles to the development of domestic supplies

Obstacles to the development of organic farming in the EU

(a) Technical, economic and structural obstacles to conversion

The conversion of a holding to organic farming is a complex process which involves fundamental changes.

Obstacles to conversion can be:

- **Technical issues:** for instance, farmers have to better **integrate natural systems and cycles in their production method** and to use them in order to improve soil fertility and to protect plants against pests and diseases. Appropriate technical advice is not always available.
- **Structural aspects:** there is a general trend towards intensification and specialisation of agriculture, while diversification is crucial in organic farming. In particular, the number of mixed farms with crop and livestock production is declining in the EU.
- **Economic aspects:** because they can expect lower and more irregular yields with organic farming, farmers can be reluctant to convert to organic farming. In addition, the land has to undergo a **conversion period** (2 or 3 years depending on the crops) during which the products cannot be sold as organic.

The organic sector needs on specific technical and financial support could notably be addressed in RD programmes under the new programming period 2014- 2020. This is a non-regulatory driver which could be addressed in an action plan.

Research and innovation policies could adress technical issues and, to a certain extent, structural aspects. It has to be noted that the answer from research and innovation policies to the organic sector development needs has been partial. This could be due to an insufficient uptake or dissemination of research results (organic, low input agriculture

³⁴ Organic Monitor, the Global Market for Organic Food and Drink: Business Opportunities and Future Outlook (3rd Edition)

³⁵ Export opportunities for U.S. organics in the EU market - Gain Report Number: NL3003- 2/11/2013 The Hague

and conventional agriculture), and by a weak identification of the sector's development needs³⁶.

This is a non-regulatory driver which could be addressed in an action plan, through existing instruments under the EIP and Horizon 2020 research policy. Annex 5 provides background information on the possibilities offered by these instruments.

The EGTOP has a valuable contribution for the evaluation of new substances and techniques that can be considered compatible with the objectives and principles of organic farming; however this system faces challenges, as shown in details in Annex 7. This is a regulatory driver that can be addressed with this initiative.

Insufficient conversion to organic farming affects negatively the supply of organic products in the EU. An improved legislative framework could probably contribute to ease conversions, but it would be useful to understand what makes the organic sector attractive or not for producers. A specific study could be proposed in an action plan.

(b) Insufficient synergies between EU policies

Organic production delivers also in the new policy framework and EU 2020 strategy: protection of biodiversity and soil, animal welfare, development of rural areas and local food chains, multifunctional agriculture, long term food security. Complexity of EU instruments requires further efforts in order to ensure coherence and synergies between EU policies.

This is a non-regulatory driver which could be addressed in an action plan.

(c) High certification costs

According to the CERTCOST³⁷ project the inspection fee is the most relevant monetary expenditure for organic operators with respect to the certification costs. The median of the inspection fee amounts to 500 Euro per farm, ranging from 318 Euro in the Czech Republic to 647 Euro in the United Kingdom. The calculation of the fee can be quite sophisticated, including a basic fee and a variable fee according to the area, the type of crop, the number and type of animals. Concrete examples are provided in Annex 10.

This level of inspection and certification cost is in some cases not proportionate with the economic dimension of small agricultural holdings. According to Eurostat data, **73% of EU agricultural holdings have an output lower than 8 000 euros.**

In other respects, the current control rules that require annual inspection of all operators (articles 27(3) and 28 of Council Regulation (EC) No 834/2007) do not allow group certification that is accepted for the import of organic products produced by small producers in Third Countries as a measure of equivalent control effectiveness. Group certification is defined by IFOAM as "the certification of an organized group of small-scale producers with similar farming and production systems. The requirements for group certification apply only to such groups when the certification applies to the group as a

³⁶ Since 2000, the EU has funded 49 research projects on organic farming and low input agriculture.

³⁷ The full set of reports from the CERTCOST projects is available at www.certcost.org

whole and when special inspection arrangements have been applied". Further information and review of existing group certification schemes is provided in Annex 15.

This is a non-regulatory driver; however, it can be addressed through some legislative provisions which impact the efficiency of the control system.

(d) A high level of administrative burden for the organic operators

The most burdensome obligations are to keep documentary evidence of the need to use (authorised) plant protection products and fertilisers, the control arrangements and undertaking necessary to enter the organic scheme, to keep specific register of livestock records and to keep documentary evidence in relation to coexistence of organic and conventional production (see paragraph 5.5).

The obligation of detailed record keeping has been mentioned as particularly difficult in the case of small organic holdings. This issue, combined with disproportionate inspection fees (see below), leads to small agricultural holdings to be under-represented in the organic sector. **While 69% of all agricultural holdings have less than 5 ha, only 18,7% of organic holdings have less than 5 ha.**

The administrative burden is a regulatory driver that can be addressed with this initiative, by improving the legislation.

(e) Obstacles to the development of the production of 'organic inputs'

Some exceptions can be granted by MS CA where they are necessary to ensure access to inputs which are not available in organic form on the market, notably young animals, seeds or protein feed. Their existence has had the unintended consequence to **limit the development of the production of the inputs in their organic form.**

The external evaluation has demonstrated this issue:

- In the case of the exception allowing the use of non-organic pullets: in Denmark, the use of conventional young poultry has been prohibited for many years which fostered the development of a market for young organic poultry. As a consequence, the supply in young organic poultry is adequate. But in other countries which grant easily exceptions to use non-organic pullets, the supply of non-organic pullets is not adequate. In countries studied by the external evaluation, authorities and/or operators said that a 100 % organic supply would be possible if there were no market perturbation like the possibility provided by the exceptional rule. Experts from Austria, Denmark, France and the Netherlands reported that there was no need for exceptional rules for young poultry, while experts from the Czech Republic, Estonia, Italy, Poland and Slovenia stressed that there is no or only a limited supply of organic young poultry in their countries. To postpone the ending date hampers the development of supplies and is considered not fair for sectors that have started to adapt to the end of the exception.
- In the case of the use of non-organic seeds, the analysis of specific data and of the information on the use of the seed management database has shown an extensive and increasing use of the exceptional rule system at EU level. Providing access to the conventional seed market through the exceptional rule plays against the development of the organic seed sector. Data provided in 8 MS annual reports for 3 crops (wheat, maize and potatoes) show a variable share of organic land area

sown with non-treated conventional seeds. The highest rate of use of non-organic seeds, around 100%, was found in Italy. A general use of non-organic seeds was also observed in Denmark and Estonia, because of general exceptions, leading farmers to favour cheaper non-organic seeds, even when adequate organic supply is available for specific varieties. In contrast, high levels of organic supply for soft wheat seeds have been achieved in Austria and the UK. For maize, the share of organic areas cultivated from organic seed is close to 100 % in the Netherlands, Austria and Spain. Organic supply for seed potatoes is quite high in Austria, Bulgaria, Denmark, the Netherlands and the United Kingdom, with non-organic seeds used on less than 30% of the organic areas. The European Consortium for Organic Plant Breeding reported in its 7th workshop in October 2013 that the important development of the organic market was not accompanied by a corresponding development in the use of organic seeds. **The consortium would strongly support the end of exceptions to the rule.**

The issue of organic inputs is crucial. For instance, in the case of seeds, growing organic seeds is better for the environment. In addition, organic seeds are better suited for organic growing conditions. Therefore, the development of organic seeds is a condition for the sustainable development of organic farming. The issue was summarised by the representative of Belgium in the Council: "*... Organic agriculture needs new varieties of plants in order to further develop. The use of organic propagating material is a fundamental part of the closed production cycles, which are promoted as a feature of organic agriculture. The current regulations (...) provide mandatory use of organic propagating material but on the other hand allows many derogations for the use of conventional propagating material. Whereas research has shown that plant varieties specifically selected in and for organic agriculture have essential importance in the development of the organic crop production, it is not very attractive for the seed producers to make investments in this small scale market. Many companies prefer selling conventional not treated (...) varieties, despite the fact that those varieties have not been selected for organic agriculture.*"

The issue of exceptions is a regulatory driver that can be addressed with this initiative, by amending the legislation.

(f) *Complex and unclear legislation on organic production*

Some provisions of the EU legislation are complex or unclear, which may discourage producers who wish to join or to develop their activities in the organic sector.

One example is the scope of Council Regulation No 834/2007, which does not refer to a precise list of agricultural and processed products. MS CA and companies consult regularly the Commission to clarify whether or not certain products are included. As a result, producers might prefer not starting producing organic production if they are not certain to be able to sell their products as organic.

This is a regulatory driver which can be addressed with this initiative.

2.1.1.3. Risk of loss of consumer confidence

This part addresses the objective of ensuring consumer confidence and protecting consumer interests as stated in Article 1 of Council Regulation (EC) No 834/2007.

The organic market has built on consumer confidence. Research results which show that consumer confidence is higher with strict production rules and control procedures are summarised in part 4 of Annex 1.

Why do consumers choose organic products?

According to BEUC, consumers choose organic products because they perceive them as healthy and environmentally-friendly. In addition, they meet other concerns such as animal welfare and use of additives.

The major barriers for consumers to choose organic products would be their perceived too high price and their insufficient accessibility. Consumers wish organic products to be available in supermarkets, including discounts. They also appreciate box schemes, like boxes of organic fruit and vegetables delivered at home.

Consumer expectations depend on their knowledge, but they usually expect more than what is required under Regulation (EC) No 834/2007. In particular, they want residue-free products.

The risk of loss of consumer confidence is due to conflicts between consumer expectations and reality. However, consumer knowledge on quality schemes is usually low.

(a) Production rules watered down

The results of the public consultation show that **the majority of citizens (62%) and stakeholders representing consumers (63%) did not approve the possibility for farmers and other operators to be exempted from production rules and still have their produce certified organic.**

In addition, the largest part of respondents (77%) agreed that **exemptions from production rules granted to farmers and other operators should always be limited in time.**

-

(b) Societal and consumer concerns not fully addressed

The sustainable use of energy and the management of environmental impacts are increasing concerns which are not fully reflected in the EU legislation. While organic farmers and operators producing seaweed and aquaculture products have to respect strict principles benefiting the environment, there is no obligation for other organic operators regarding environmental impacts related to food and feed processing, packaging, transport and distribution of organic products, despite the expectations of consumers.

Concerns regarding the need to consider the whole lifecycle of food and feed products could be addressed by applying the **EU Ecolabel to food and feed products**, including organic ones. In this respect, the recently revised Ecolabel Regulation (66/2010)³⁸ required the Commission to carry out a study on the feasibility of developing Ecolabel

38 Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27 of 30.1.2010, p.1

criteria for food and feed products, with a special attention to organic products. This study³⁹, completed in October 2011, underlined in particular the confusion that could result for the consumer between the Ecolabel and the organic logo. As an alternative to placing the Ecolabel on organic products, it was suggested "to amend the Organic certification [...] to cover the full life cycle of food products, including the processing and packaging and [called] on the European Commission to give due consideration to this option, to improve the performance of the existing Organic Regulation."

During the hearings, BEUC declared that consumers would not support the introduction of Ecolabel for food and drink, because it would entail confusion. In the Council, some MS mentioned "incompatibilities between the EU regulatory framework on organic farming and Regulation (EC) No 66/2010 (...) on Eco-Label" and even stated that "it was not appropriate to extend (...) its scope to food and drinks, although it has not been applied yet".

IFOAM EU, supported by other stakeholders, suggested to have operators downstream of primary production, i.e processors and traders, manage their environmental performance via an EMS (e.g. ISO 14001 or EMAS). An EMS is a tool that provides organisations with a method to systematically manage and improve the environmental impacts of their production processes. It helps organisations to achieve their environmental obligations and performance goals. In addition to EMAS and EN ISO 14001, non-formal EMS exist in the EU. Many of them have been adopted by both private and public organisations. These EMS are mostly designed to cover organisations with a specific size (e.g. SMEs) and organisations coming from specific areas or specific sectors of activities.

In the public consultation, a majority (61%) was in favour of an obligation for producers and traders to implement an EMS to improve their environmental performance.

Such societal concerns are non-regulatory drivers that can be addressed through regulatory measures.

Animal welfare is an increasing societal concern, which was raised in the public consultation. 34% of respondents underlined that organic farming producers should be obliged to comply with specific rules for animal welfare. In addition, around one quarter of respondents considered animal welfare standards in organic farming should systematically be higher than in conventional farming. Only 9% declared that current rules for animal welfare in organic farming are sufficient.

The organisations Eurogroup for Animals and Compassion in World Farming have been heard in the hearings and have transmitted detailed proposals to improve animal welfare in organic farming, presented in detail in Annex 14. Organisations have underlined that current practices are not always consistent with organic principles, for instance the mutilations authorised as "specific operations essential to certain types of production and for the sake of security for animals and human beings, permitted under restricted conditions", while the general rule provides that "mutilations which lead to stress, harm, disease or the suffering of animals should be banned".

The present initiative is an opportunity to address this regulatory issue, notably to re-focus the animal welfare provisions on the organic farming principles.

39 http://ec.europa.eu/environment/ecolabel/documents/Ecolabel_for_food_final_report.pdf

The issue of presence of non-authorised substance residues in organic products is crucial for consumers. In the public consultation, 85% of the citizens declared they buy organic products because they want to avoid food containing pesticide residues. 62% of them would support the testing of all organic products for pesticide residues, even it would increase costs and make them dearer for consumers. Three quarters of the respondents agree that no pesticide should be allowed in organic farming; only 11% support the authorisation of some pesticides under very strict procedures. These high expectations sometimes conflict with reality. The issue is further developed in paragraph 2.5.3.4 (d).

(c) Multiplication of logos

The multiplication of logos is one of the main drivers for consumer confusion and risk of being misled. The EU organic policy provides a set of rules to be applied all over the EU and the use of the EU logo guarantees that they are respected. The use of other "organic" logos can be seen as a sign that the EU rules/logo does not inspire sufficient confidence to consumers. There are many private organic logos and other scheme logos on the market. A recent study mentioned a total of 901 quality schemes in the EU, among which 234 were related to organic farming⁴⁰.

In 2010, the Commission published best practice guidelines for voluntary certification schemes⁴¹, one of the purposes of which was to avoid consumer confusion and increase the transparency and clarity of the schemes requirements. However, according to the above-mentioned study, the awareness of these guidelines among operators is currently insufficient. The study also highlighted that the public usually knows a limited number of schemes and stated that some confusion exists about logos and symbols used.

The use of the EU organic farming logo became obligatory on the packaging of EU organic products in 2010. According to Eurobarometer⁴², in July 2012 on average over all 27 EU MS, 24 % of the respondents indicated to know the EU organic logo on organic farming. This share was higher in Denmark (39 %), France (38 %), Luxembourg (37 %) and Austria (36 %). The lowest share of respondents knowing the EU logo was found in Romania (10 %), Poland (12 %), Bulgaria (13 %) and Spain (14 %).

However, a comparative analysis of the EU organic logo and other organic and non-organic food logos conducted for the external evaluation in six case study countries (Estonia, France, Germany, Italy, Poland and the United Kingdom) has shown that, in all countries other organic logos exist in the market place, which were better known than the EU organic logo.

The issue of logos is both a regulatory and non-regulatory driver. It can be addressed indirectly with this review by reinforcing the EU organic scheme in order to avoid the development of new schemes and logos.

⁴⁰ **Consumer market study on the functioning of voluntary food labelling scheme for consumers in the EU.** Draft final report by Ipsos and London Economics Consortium, September 2013

⁴¹ Commission Communication — EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs. EU OJ 2010/C 341/04, 16.12.2010, p. 5.

⁴² **Eurobarometer report n° 389** (What Europeans think of food security, food quality and the relation between agriculture & the countryside - July 2012)

(d) Shortcomings in the control system and in the import regime

The EU organic control system covers the activities performed by operators at all stages of the production, preparation and distribution chain: from farm to fork.

Any operator who produces, prepares, stores, imports or places on the market organic products shall notify his activity to the MS CA and shall submit his undertaking to the control system (article 28(1) of Regulation No 834/2007).

Organic products are "credence goods": their organic attributes or nature results from the production process and cannot be reliably assessed by consumers, neither before nor after purchase⁴³. Consumers willing to buy organic products therefore have to rely on the organic labelling, enforced by the control system.

Fraud cases in the media

Recent fraud cases in the EU organic sector have been revealed which, for their scope and duration, seem linked to systemic control weaknesses rather than isolated instances. They have had very wide press coverage, beyond the organic specialised sector, and led to a wave of concerns and doubts on whether the organic system can really be trusted. For instance, in **December 2011** a large fraud case concerning organic products, "Gatto con gli stivali", was revealed by the Italian tax investigation authorities. It has been used as a case study by the external evaluation.

A non-exhaustive selection of articles from the following newspapers: Politika (Warsaw), die Welt (Berlin) and die Tageszeitung (Berlin), translated and available on-line by PressEurop, is shown in Annex 9.

Until now, the fraud cases do not seem to have significantly harmed the confidence of citizens. Nearly three quarters of the respondents to the public consultation (71%) acknowledged that they have full confidence in organic products. Nonetheless, almost one out of five of the interviewees, i.e. 18% did not trust the organic integrity of products. In addition, 11% of respondents abstained from answering to this question.

More than half (58%) of the citizens required improvement of the European control system for organic products even if this entails an increase in prices. 22% repliers to the questionnaire stated that improvements are not needed, especially if these lead to a rise of organic products' prices. 20% of the respondents did not express any opinion on this.

What remains to be done to improve the control system?

Some shortcomings signalled by the ECA have been only partly addressed, notably the followings:

ECA Special Report No 9, 2012

"MS CA encounter difficulties in ensuring the traceability of the organic products within the territory for which they have authority. Traceability is even more difficult to achieve for products crossing borders"

"Controls should be strengthened to ensure that operators fulfill the regulatory requirements regarding traceability, in this regard, the Commission should clarify the roles and responsibilities of the different actors. "

DECISIONS IN ORGANIC FOOD PRODUCT MARKETS

The control system and the import regime have been subject to specific questions as part of the **external evaluation**. However, the external evaluation scope was limited to the adequacy of the legal provisions, defined as being sufficient in relation to the intervention's objectives, while the impact assessment has to consider also their effectiveness and efficiency in line with the principle of sound financial management. This explains why the external evaluation concluded that the overall control system of organic farming is largely adequate in terms of achieving the global objectives of the Regulation, but with shortcomings in its implementation and recommended a more risk-based approach.

The main issues remaining to be addressed after the initiatives described in paragraph 2.3 are the following:

- a) Incomplete coverage of the control system: retailers may be exempted by MS. The status of exporters and subcontractors is also unclear. Wholesalers dealing only with prepackaged products currently benefit from an exemption to the annual inspection, while such operators have been involved in fraud cases.
- b) Follow up of irregularities and sanctions: please see paragraph 2.5.3.4 (e)
- c) Insufficient market control and traceability of organic products.

The difficulties are notably due to the insufficient implementation of risk based controls and to the use of outdated tools. For instance, the documentary evidence for EU organic operators and inspection certificates for imported organic products do not sufficiently ensure traceability and are vulnerable to fraudulent use. So far, the most important fraud cases in the sector involved traders selling conventional products as organic, often through falsification of documentary accounts including organic certificates. Fraud cases can also occur at a much earlier stage, when producers put on the market such products with falsified certificates.

1. Insufficient implementation of the risk-based approach

As a general rule, all operators shall be subject to verification of compliance **at least once per year**⁴⁴. The implementing rules regulation qualifies this annual verification of compliance as a **physical inspection**⁴⁵. Regulation (EC) No 834/2007, while maintaining in any event the obligation of an annual verification of compliance for all operators, introduces a risk-based approach to controls. Namely, it sets out that the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements. Commission Regulation (EC) No 889/2008 clarifies that, in addition to the annual inspections, CBs shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules. Three risk factors shall be taken

⁴⁴ Article 27 of Regulation No 834/2007

⁴⁵ Article 65 of Regulation No 889/2008

into account for the risk evaluation: the results of previous controls, the quantity of products concerned and the risk of exchange of products. As from 1 January 2014, the risk analysis has to provide the basis for the intensity of the unannounced or announced control visits; random visits in addition to the annual inspection have to be carried out on at least 10% of operators in accordance with the risk category; and at least 10% of the total annual inspections and additional random visits have to be unannounced.

A full implementation of the risk-based approach would require MS to focus resources where the risk of non-compliance with the rules – including intentional non-compliance that constitutes fraud – is greatest. But the current system requiring annual mandatory physical inspections of all operators, does not allow an efficient use of resources. Operators with a consistently clean record could be inspected with less frequency than once per year, in order to save resources which could be used to target controls to riskier operators. So far, the major fraud cases in the organic sector (Gatto con gli stivali, Italy, 2011) did not affect the yearly inspected producers but traders selling conventional products as organic with import certificates: control visits to address effectively such cases are more difficult and time-consuming.

The external evaluation mentioned that "In contrast to the annual visit of each organic operators, other areas work with considerably lower control frequencies. For example, the EU legal framework for the RD programmes requires annual on-the-spot checks of 5 % of all beneficiaries". A risk-based approach was recommended: "this would allow for identifying low-risk operators and high-risk operators and thus allow a more targeted and dynamic approach to the control process... such a dynamic approach is not compatible with the static approach of the mandatory annual control visit as currently implemented...".

Results of the public consultation show diverse opinions on the issue of control frequency. While the majority of respondents (57%) disapproved the idea of lowering the number of inspections for organic operators with a proven track record of abiding to the rules, a percentage of approximately 36% of the respondents approved it, which is significant for what can be considered as a radical change. The majority of stakeholders representing all categories without exceptions were against the risk-based frequency of inspections of organic operators. The strongest opponents to the idea to lower the number of inspection for trusted organic operators are the following stakeholders in descending order: private CBs (83%), retailers (70%), public CA, public control authorities, accreditation bodies (68%), processors (63%) as well as advisory services (60%) and non-EU public authorities (60%).

However, several MS in the Council argued in favour of a move towards a more risk-based approach (Germany, Italy, Finland, Sweden, the Netherlands), while few of them (Greece) stated explicitly their preference for the mandatory annual inspection. In the stakeholders' consultation, the ones in favour of a risk-based control system were FIBL (Research Institute for Organic Agriculture), Dakks (National Accreditation Body for Germany) and the Finnish Food Safety Authority (Evira). Stakeholders in favour of maintaining the annual inspection are the European Poultry Association, the Soil Association, Bio-Austria, the FNSEA and Synalaf.

The resistance to move to a fully risk-based control system can be explained by:

- the need to re-think the control system, which can be seen as challenging (national CA, accreditation bodies),

- the risk of losing individual advice from CBs, actually resulting from a confusion of roles (farmers); it is also a way for CBs to justify quite high inspection fees (CBs);
- the risk of losing an argument to sell organic products, as suggested by the external evaluation. However, 50% of the respondents to the public consultation didn't know that there is an obligation of annual inspection, despite a relatively high familiarity with the organic farming system (mostly regular consumers with high knowledge of the logo).]

2. Supervision of controls in third countries

The reliability of controls on imported organic products has been questioned during the consultation process. In the public consultation, citizens have been asked to choose proposals to improve the control system in general. **The vast majority of respondents (73%) requested to improve controls on imported organic products.** The issue has been corroborated by stakeholders in the consultation process (see Annex 2).

The recognition of third countries for the purpose of equivalence is considered as a reliable system by the Commission for the control of imported organic products, since it relies on a national CA to supervise controls. The details of the system are presented in Annex 12. The ECA in its report raised the issue of supervision of these recognised countries, currently being addressed with audits by the FVO. In other respects, the ECA also noted a significant backlog in assessing applications for equivalence from third countries, linked to the burdensome assessment procedure.

The obligation to have a control system as effective as the EU one is a limiting factor for the recognition of equivalence of third countries (only 11 countries are currently recognised). Therefore the system of recognition of private CBs is crucial to continue to import organic products from non recognised countries.

The EU is the first country in the world to implement a system of recognition of CBs based on equivalence. Other countries like the US, Canada and Japan, run systems based on compliance to their rules. The EU is supposed to implement both systems in parallel, but the implementation of compliance has been postponed to October 2014. A table providing a comparison between both systems and a comparison of the workload for the implementation of compliance and equivalence are in Annex 12. They show an advantage for the compliance regime.

The issues related to the control system and to the trade regime are regulatory drivers which can be addressed with this initiative.

2.1.1.4. Fair competition among producers not guaranteed and risks for the functioning of the internal market

This part addresses the objective of guaranteeing fair competition as stated in Article 1 of Council Regulation (EC) No 834/2007.

(a) Complex provisions not correctly implemented

The legislation on organic farming includes diluted provisions which are difficult to apply. This is because the legislation was designed for a small sector and intended to take into account any specific case.

An example is the case of "mixed farms" (meaning with organic and conventional production). Article 11 of Regulation No 834/2007 in its first paragraph prohibits conventional production on organic farms. This is motivated notably by the risky nature⁴⁶ of such operators: it can be difficult to control that a farmer has not used non-allowed substances on the organic products, if they are present on the farm. But the second paragraph of Article 11 considerably weakens this provision by introducing circumstances under which "parallel" conventional production is authorized. MS CAs and CBs in third countries face difficulties in applying this confusing provision.

Examples of findings - FVO audits

Presence of conventional production on organic farms, not respecting the EU rules – for instance the same crop varieties were cultivated in their conventional and organic forms on a farm, and therefore the organic production could not be easily differentiated. This was not treated as non-compliances in some MS.

This leads to unfair competition between producers in MS where the rules are respected and the ones in MS where the rules are not respected. In the first case, some producers will not join the organic sector, while in the second case, producers in the same conditions will be able to join the organic sector and to sell products as organic. The issue has been raised during the hearings, for instance by the Bund Ökologische Lebensmittelwirtschaft which recommended the mandatory conversion of the whole farm. No evidence could demonstrate the extent of possible unfair competition entailed by such implementation failures.

It is a regulatory driver that can be addressed with this initiative.

(b) Excessive use of exceptions to the rules

Unfair competition entailed by the use of exceptions to the rules by MS has been demonstrated by the findings of the audits carried out by the FVO in MS in 2012 and in 2013. It usually results from an improper application of EU rules by MS. The main reason for that is the insufficient resources dedicated to the management of the exceptions, which entails a high level of administrative burden.

Examples of findings - FVO audits

- **Retroactive recognition of a conversion period** without adequate justification by some MS competent authorities which leads to unfair competition to producers in other MS who have to bear the full conversion cost;
- **Use of non-organic feed**: exceptions granted to the whole territory of a region or a country without identifying individual operators: this lead to unfair competition for producers in other MS who could not benefit from such derogations;
- **Non respect of animal welfare rules**: dehorning or mutilation such as castration of piglets allowed without prior authorisation, contrary to the EU legislation. Such practices provide an economic advantage to the producers of these MS, compared with producers in MS fully applying the rules.

⁴⁶ This is confirmed by the fact that "mixed farms" are usually tagged in the most risky category by CBs when doing their risk analysis

The issue was also mentioned by MS, for instance Denmark, according to which "there are large differences among MS in the way organic seeds derogations are handled and the way derogation data is reported."

Similar issues have been shown with CBs operating in third countries. The first list of CBs have been recognised for a 3-year period starting from July 2012. Once the CB is recognised, the fact that it applies its own production standard and control measures rather than the EU ones generates a risk of non-equivalent production rules or control measures being applied while remaining undetected. This is shown by the analysis on the CB equivalence regime in Annex 12, which shows that CBs can be tempted to compete on the possibility to decide on exceptions to the rules. In practice, the system is fuelling an unfair competition among CBs, based on lowering standards, as it was reported by stakeholders (see Annex 2). The extent of the problem is linked to the number of CBs recognised under the equivalence regime (currently 60), each one with its own standard with rules as detailed as the EU organic production rules.

The magnitude of the highlighted problem could not be precisely estimated. It is a regulatory driver that can be addressed with this initiative.

(c) *Presence of non-authorised substance residues addressed differently according to MS, CB or third country*

The taking of product sample for the detection of products not authorised in organic farming is already a widely used tool for control purpose. The results of the analysis show in some cases the presence of non-authorised substance-residues in products intended to be sold as organic. It can result either from the illegal use of these substances or from accidental or technically unavoidable presence; more often such substances are found in organic products due to spray-drifts originating from neighbouring non organic production fields, mixing during the transport and storage or other factors, because of coexistence between organic and conventional crop production.

According to the 2010 EU Report on Pesticide Residues in Food⁴⁷, non-authorised substance residues were found in a non-negligible share of organic products:

- 21.4% of organic animal products,
- 9.8% of organic baby-food,
- 11.8% of organic fruit, vegetable and other plant products,
- 8.1% of organic cereals.

These figures include samples with presence of non-authorised substance residues below, at, or above the MRL. **The level of residues found in organic products is rarely above the MRL.** In addition, the share of products with presence of non-authorised substance residues is on average lower in organic than in conventional products.

The legislation on organic production is silent about the possible presence of non-authorised substance residues in organic products. It does not state if the products can still be sold as organic, under which conditions and which procedure has to be followed by CBs and MS CAs, and notably if an investigation is always necessary. The problem

⁴⁷ <http://www.efsa.europa.eu/en/efsajournal/doc/3130.pdf>

also relates to the level of presence of substances found, especially since the sensitivity of analysis is ever increasing.

In the absence of specific provisions in the EU legislation, different approaches have already been adopted by MS or by stakeholders, as described in Annex 11. Italy and Belgium have developed national legislation and the Czech Republic is developing rules. This leads to different treatments of products where contamination is found. Guidelines have also been developed by the main stakeholders IFOAM and EOCC and by associations such as the Bundesverband Naturkost Naturwaren (BNN) in Germany, with different rules and threshold levels, which add to confusion.

As a consequence, products with the same contamination level can be marketed as 'organic' in some MS, in others not, which creates distortions on the market, both in the EU and with Third Countries.

This extent of the issue could not be precisely estimated, but the development of the cases of non-compliances shows its increasing significance. The following table shows the evolution of the number of non-compliance cases on products traded between the EU MS⁴⁸. The vast majority of the cases relate to the presence of non-authorized pesticide residues:

Year	Number of cases	Including cases involving products imported from third countries
2008	58	5
2009	39	6
2010	62	6
2011	58	11
2012	97	25
2013 up to 12 Nov 2013	101	26

The following table shows the evolution of the number of non-compliance cases on products imported from third countries:

Year	Number of cases	Still unsolved cases
2011	34	3
2012	67	9
2013 up to 12 Nov 2013	90	66

This is a regulatory issue which can be addressed by introducing in the legislation measures defining the conditions under which a product with presence of non authorized substances residues can be sold as organic.

⁴⁸ Non-compliances cases on organic products sold in the MS where they were produced are not included

(d) Same non-compliance leading to different actions according to MS

The legal provisions on non-compliances to the legislation on organic production and on sanctions are recalled in Annex 9, part 7.

The ECA concluded in its special report 9/2012 that in several MS the CA have not defined detailed categories of non-compliance and corresponding sanctions, as required by the legislation. Namely, this was the case for 3 out of the 6 audited MS (Germany, France and the United Kingdom). As a consequence, each CB defines the non-compliance and applies sanctions in a different way, with considerable differences in control results. This situation leads to operators being sanctioned differently, across MS and even within the same MS, for the same case of non-compliance.

On-the-spot audits carried out by the FVO in 2012 confirmed weaknesses in some MS' follow up to cases of non-compliance. They did not always ensure that irregularities were followed-up and sanctions were imposed in a systematic and timely manner.

Several MS have mentioned their concerns that the same non-compliances are not followed by the same measures in different MS (Germany, France, Spain, Belgium).

The issue can be only partly addressed in the EU legislation on organic production, since the definition of sanctions is a competence of MS.

(e) Multiple certifications needed to have access to certain markets

The fact that production rules are considered too flexible leads some producers to create private schemes with more stringent rules. While some long standing private organic standards have peculiarities which consumers look for, there are examples of new organic schemes created to valorise stricter rules. There has been experience in 2009 after MS had to apply harmonised rules on organic animal production, which led in some MS to less strict rules. In France some producers reacted and decided to identify their products with the creation of a new label *Bio-Cohérence*⁴⁹.

In other respects, the retail sector often requires a second certification, according to a private standard.

Stakeholders have reported concrete difficulties. A dairy company exporting organic products in Europe and all over the world reported difficulties to export to the German market, because the retail sector is dominated by a private scheme. A MS reported that "some suppliers of other MS demand from certain operators that their products be certified by a CB of the MS in question; in addition to the certification (of the MS of origin) where the operator is registered".

It is both a regulatory (when MS themselves impose an additional certification) and a non-regulatory driver. It can be addressed with this initiative by reinforcing the EU organic scheme in order to reduce the development of new schemes and requirements for multiple certifications.

⁴⁹ <http://www.biocoherence.fr/>

(f) *Obstacles to access to third country markets*

EU organic producers are well advanced in the production of processed products, like baby-food or organic wine, for which the demand is growing world-wide. But stakeholders have reported **recurrent export issues**, for examples:

- requirements for CB to be approved by the national CA, before products it controls can be exported as organic to the third country. The process can include bureaucratic, complicated and sometimes insurmountable constraints like a test for the CB inspectors in the language of the country;
- disproportionate requirements such as the obligation that each raw material producer for each cycle of production be inspected by the third country national inspectors before the import of organic processed products can be authorised;
- need for EU CBs to be approved by the national CA to export to a third country, while there was a mutual recognition arrangement;
- use of the national organic logo of a third country obligatory to have access to its domestic market, but only permitted if the product was controlled by a CB recognised by the national CA, while there was a mutual recognition arrangement.

All these issues lead to **increased administrative burden and costs** to the EU operators and **they face an economic disadvantage on many third country markets**.

The extent of the issue is difficult to assess. It would require detailed investigations on the import regimes for organic products put in place in third countries and the way they implement them.

The Commission has started in recent years to develop mutual equivalence arrangements with third countries, notably with the U.S., Canada, Switzerland and Japan, which solve (at least partly) the issues with these countries. However, Council Regulation (EC) No 834/2007 does not include any specific provisions on exports. There is no tool in place to support the export of EU organic products.

The export issue is both a regulatory and a non-regulatory driver, which can be addressed through other tools, notably the action plan.

2.5.4. *Who is affected by the problem, in what ways and to what extent?*

The problem affects not only the organic sector, but also consumers, small farms, national administrations, society and third countries.

Consumers, because there are conflict between their expectations and the reality of organic production; in addition, because of shortcomings in the control system and in the trade regime, some products sold as organic do not fulfil the requirements of the EU legislation,

The organic sector:

- **Producers** respecting the rules of organic farming face **unfair competition** inside and outside the EU,

- The development of the sector is affected by identified lost market opportunities, both on the domestic market and on the export side. The **development of the production of organic inputs** (notably seeds) is hindered by the use of existing exceptions,
- The **competitiveness of producers, processors and importers** is affected by heavy and out-dated procedures,

The smallest farms in the EU which are not joining the organic sector under the current system,

National competent authorities: they face increasing administrative burden mostly due to the management of the control system and of the exceptional rules. Their responsibility in controlling the products on the market, including of imported products, is more and more significant, because of the development of the market,

Society is affected because the sustainable development of organic production in the EU is not ensured.

Third countries, because their producers can face unfair competition. In other respects, some of them have applied for equivalence recognition for several years without a reply.

2.6. How would the problem evolve without a change in policy?

The baseline scenario seeks to provide an outlook for 2025 of the evolution of the main identified problem drivers.

2.6.1. Supply

(a) Obstacles to the development of the sector

Technical and structural obstacles to the conversion to organic farming will persist.

The **issue of certification cost is likely to deteriorate**, because CBs are likely to increase their tariffs, arguing notably on the obligatory annual inspection of all operators. Combined with the effects of the administrative burden, this will maintain the exclusion of the smallest farms in the EU (with less than 5 ha). According to evidence collected during the consultation, even bigger farms will be excluded or forced to leave the sector. The complexity and unclarity of the rules will also discourage new producers to join the organic sector. Therefore **the increase in the number of organic farms is likely to slow down**.

(b) Exception to the rules and complex provisions

Regarding the exceptions to the rules, two of them will expire on 31 December 2014:

- the one authorizing the bringing of non-organically reared pullets for egg production of not more than 18 weeks into an organic livestock unit when organically reared pullets are not available,
- the one authorizing the use of maximum 5% non-organic protein feed of plant and animal origin for porcine and poultry species.

As shown by the external evaluation on the example of Denmark (see Annex 6), the end of the exception to use non-organic pullets should lead to a 100 % organic supply. Even if it leads to a difference of cost, **the production of organic pullets** will be boosted.

The end of the possibility to use non-organic protein feed will probably entail changes in the production of pig and poultry meat. Currently, the majority of organic pig and poultry producers can use strains with a high genetic yield capacity, which need optimal feed rations. Because of the shortage of protein rich organic feed, they rely on the exceptions of the 5 % non-organic feed rule to compensate the organic rations, which usually do not contain enough proteins and they use conventional soy-products, corn gluten or potato protein. The end of the exception could lead to **a des-intensification in the production of pigs and poultry, with more use of slow growing strains or robust breeds**. It could also **boost the production of protein rich organic feed**, notably soya, which would permit to maintain a more intensive breeding system. New techniques are considered by interviewed experts as promising alternatives, but are not entirely ready for a broad practical use yet, such as methods to produce methionine via enzymatic fermentation based on organic raw materials or the use of insect larvae or algae as a protein source for feed.

The sector is preparing for this move. **COPA-COGECA declared that it fully supports the end of this derogation in an AGOF meeting on 21 November 2013.**

However, **two of the main exceptions authorising the use of non-organic inputs will remain:**

- the one authorizing to bring non-organic chicks into an organic poultry production unit,
- the one authorising the use of seed or vegetative propagating material not obtained by the organic production method.

The maintenance of these exceptions will **hamper the development of the sectors of organic chicks and organic seeds and reproducing vegetative material.**

MS will face increasing difficulties to correctly apply complex provisions and exceptions to the rules in a context of limitation of resources. General derogations are likely to continue to be applied instead of individual exceptions.

2.6.2. *Consumer confidence, issues for the internal market*

(a) *Societal and consumer concerns: animal welfare, environmental management systems, pesticides*

In addition, some practices **ignoring animal welfare concerns** will continue to be authorised, either as exceptions to the rules, or as specific cases directly provided in the legislation.

With regard to the environment and the responsible use of energy, the absence of provisions at EU level for organic processors and traders **could undermine consumer confidence**. Few data is available on the use of EMS by food processing, wholesale agribusiness and retail agribusiness companies. The use of EMAS is not much developed in such sector. Some detailed data are provided in Annex 13. Stakeholders have reported that simplified systems are used in the food sector in Germany. Two of them applied in

Lower Saxony are presented in Annex 13. In France, the association of organic processors SYNABIO has launched an initiative "bio-entreprise-durable", allegedly based on the principles of ISO 26000 standard, with a wider scope: sustainability, social and environmental responsibility, authenticity of products, territorial development, etc.

(b) Presence of non-authorised substance residues

The presence of non-authorised substance residues in organic products will become an increasing issue, because the detection level is getting lower and lower thanks to evolving methods of analysis and the detection rate will become higher. Therefore, the share of organic products where non-authorised substance residues are found is likely to increase, while consumer sensitivity, notably on pesticide residues, is already high.

(c) Co-existence of other logos with the EU logo

Because of watered down organic production rules, **new logos are likely to develop and to increase consumer confusion**, notably production rules are considered too flexible, which leads some producers to create private schemes with more stringent rules. Other new schemes can result from societal concerns not sufficiently taken into account in the EU organic scheme.

The proliferation of logos (see examples in Annex 8) leads to consumer confusion and can lead to costly multiple certification requirements. In some cases it disrupts trade between MS, which is an obstacle to the development of organic farming in some MS, where there are still few processors and traders.

If nothing changes, after 31 December 2014 the case of private and national organic logos will fall under the provisions on food information to consumers⁵⁰, according to which "food information shall not be misleading, particularly by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics...". At the same time, Article 34 of Council Regulation (EC) No 834/2007 prohibits any restriction to the marketing of organic products produced and controlled in another MS, in so far as those products meet the requirement of the Regulation.

(d) Control system

Fraud cases will continue to develop because of the shortcomings in the control system and in the import regime. At the time of writing this report, the Commission was informed about new fraud cases in the poultry sector. However, there will be a number of improvements as from 1.1.2014 through the application of Commission Regulation (EC) No 392/2013 and, when approved, through the new OFFC Regulation.

⁵⁰ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 – OJ L 304, 22.11.2011, p. 18.

(e) *Import regime*

The import regime will become even more complex and burdensome. From 2014, the Commission will have to implement the second regime of recognition of CBs based on compliance, according to Article 32 of Council Regulation (EC) No 834/2007, but there are obstacles: notably the existence of provisions, notably the exceptions, where MS can decide, and the fact that group certification is not authorised in the EU. Therefore the Commission will have to propose a set of production rules to apply compliance. In addition, Council Regulation (EC) No 834/2007 does not give the basis to require the information in order to ensure the traceability on the whole food chain of imported organic products under the compliance regime (it is provided with the inspection certificate under the equivalence regime). Therefore the implementation of the compliance regime under the current legislation will be weakened. In addition, the interest to have two systems in parallel is limited.

On the other hand, the wide possibilities offered to third countries to export organic products to the EU thanks to the CB equivalence regime **has already lowered the pressure from third countries to be recognised for the purpose of equivalence.** No new request has been submitted to the Commission since the application of the new CB regime.

(f) *Issue of presence of non-authorised substance residues*

More and more MS and private initiatives to address the issue will be taken, leading to different requirements (some may do not require any investigations for instance) and different thresholds. It will lead to more and more unfair competition and to dysfunctionings of the internal market, notably because importers will be inclined to choose to import organic products from third countries through the MS with the lowest requirements.

2.6.3. *Socio-economic impacts of the current legislation*

Organic farming is developing at the expenses of conventional agriculture. However, organic farming would be **more profitable per unit of production** (ha or cow) than conventional agriculture, according to the results of an analysis of FADN data on selected MS⁵¹. In addition, they are **more labour intensive** than conventional ones. This is confirmed by data from the Agence Bio, according to which organic farms represented 3.8% of the UAA and 4.7% of the farms, but 7% of the agricultural employment in France at the end of 2012. Therefore, in this impact analysis it is considered that conversions to organic farming have global positive socio-economic impacts, both on farm income and on employment.

In the baseline scenario, the current average annual increase of 500 000 ha in the organic land area will be difficult to maintain. The increase in the number of organic farms is likely to slow down as well as the associated employment.

The evolution of the income of organic farmers is difficult to forecast, because it depends on multiple factors, notably:

⁵¹ **Organic versus conventional farming, which performs better financially?** Farm Economic Brief No 4, November 2013, European Commission.

- on the price paid for the agricultural products, which is higher for organic than for conventional products. But the competition (sometimes unfair competition) with imported products is likely to push prices down,
- on input costs, which are likely to stay lower in organic than in conventional agriculture,
- on public support, whose evolution will depend on the way MS decide to apply the new CAP instruments benefiting to organic farming: greening, specific and general RD measures.

2.6.4. *Environmental impacts*

Organic farming has positive environmental effects:

- positive impacts on biodiversity derived from general organic production practices resulting in increasing abundance of plants, birds and predatory insects,
- positive impacts on water quality thanks to positive direct and indirect effects of the production rules, even if there is no direct requirement regarding water use.
- positive impacts on soil health and quality, which are enhanced through the obligation to use organic fertilisers and manure, and to practise crop rotation.

In the baseline scenario, these positive environmental effects are limited because of the limitation to the expansion of the organic land area.

2.7. **Does the EU have the right to act?**

The basis for the CAP is formulated in the Treaty on the Functioning of the EU, where article 38 stipulates that “The Union shall define and implement a common agriculture and fisheries policy” with objectives set out in article 39 and detailed provisions in articles 40-44. The Lisbon Treaty has confirmed the relevance of CAP objectives of increasing agricultural productivity, ensuring a fair standard of living for the agricultural community, stabilising markets, assuring the availability of supplies and ensuring that supplies reach consumers at reasonable prices.

The current exercise is an updating of an existing scheme set within the CAP. The first Regulation on Organic Farming was introduced in 1991 in the context of the reorientation of the CAP to encourage diversification of agricultural production and more environmentally friendly production methods. The development of specific products was to benefit the rural economy, particularly in less-favoured or remote areas, both by improving the income of farmers and by retaining the rural population in these areas.

Production and trade of agricultural products and foodstuffs on the internal market and ensuring the integrity of the internal market are matters of EU competence. Both are EU shared competences with MS.

An EU-wide scheme is more efficient than 28 different schemes in view of the smooth development of the single market. In addition, it allows for a stronger and more

consistent trade policy vis-à-vis global trading partners, most notably by enhancing its bargaining power.

Council Regulation (EC) No 834/2007 provides that MS can grant exceptions to the rules in precised framework defined in Article 22. The experience, illustrated in chapter 2.5, has shown that this leads to unfair competition among producers in different MS, risk of loss of consumer confidence, complexity in the legislation and trade issues (difficulties to implement compliance). Further harmonisation at EU level would therefore be appropriate in this area.

The fact that the same non-compliance to EU organic legislation can lead to different actions according to MS is an issue leading to unfair competition and ineffective functioning of the single market. While the definition of sanctions is under MS competence, it would be appropriate to define at EU level broad categories of non-compliances that would require adequate levels of intervention, in particular, the cases where products cannot keep their organic status. This has to be consistent with the review of the OFFC Regulation mentioned in chapter 2.3.

3. OBJECTIVES

3.1. General objectives and consistency with new CAP objectives

The overarching objective of Council Regulation (EC) No 834/2007 is the basis for the sustainable development of organic farming. According to this objective, the development of organic farming is expected to deliver at three levels which correspond to key objectives of sustainable development⁵²:

- **economical**; according to whereas (3), *"the Community legal framework governing the sector of agricultural production... should further aim at providing conditions under which this sector can progress in line with production and market developments"*;
- **environmental**; this is stated in whereas (1): *"the organic production method... delivers public goods contributing to the protection of the environment and animal welfare..."*;
- **social**, by responding to consumer's qualitative and quantitative demand for organic products, and to society's demand for more environmental-friendly production methods; whereas (1) mentions the *"preference for certain consumers for products produced using natural substances and processes"* and *"the organic production method... provides for a specific market responding to a consumer demand for organic products..."*.

While the new CAP represents a further step towards greener practices in agriculture, the existence of an organic farming scheme at EU level is still fully justified, notably because of the gap between the requirements for farmers to benefit from the greening payments and what is required under the EU organic farming legislation. Organic farming is a holistic approach which encompasses economic, social and environmental aspects of

⁵² See notably Commission Communication "Draft Declaration on Guiding Principles for Sustainable Development", COM (2005)218 final, 25.5.2005.

agriculture. The development of organic production is based on the organic market development and includes the whole food chain. Organic products are identified on the market notably through the EU organic logo.

In accordance with the 2014-2020 Common Monitoring and Evaluation Framework for the CAP, the organic scheme contributes to the following general objectives under Pillar I of the CAP:

- "Sustainable management of natural resources and climate action" by providing public goods (mostly environmental) and by pursuing "climate change mitigation and adaptation",
- "Viable food production" by "meeting consumers expectations" and by "improving the competitiveness of the agricultural sector and enhancing the share in the food-chain".

In addition, it contributes to the general objective "sustainable management of natural resources and climate action" by restoring, preserving and enhancing ecosystems under Pillar II of the CAP.

The three following objectives of Council Regulation (EC) No 834/2007 participate to the overall objective of sustainable development:

- (1) ensuring the effective functioning of the internal market,,
- (2) guaranteeing fair competition,
- (3) ensuring consumer confidence and protecting consumer interests.

The external evaluation has made some recommendations to further clarify the legal status of the objectives⁵³ (Article 1) and principles of organic production (Article 3 to 7). A thorough examination of the nature of the objectives and principles of organic farming has shown that both categories could be merged under a single heading: "principles", which should be reflected in the new basic Act.

3.2. Specific and operational objectives

The above problem definition and its drivers lead to the setting of the following objectives:

Specific objectives

1. to remove obstacles to the development of organic production in the EU,
2. to improve the legislation in order to guarantee fair competition for producers and to improve the functioning of the internal market,
3. to maintain or to improve consumer confidence in organic products.

⁵³ Similarly, Regulation (EC) No 178/2002⁵³ ("food law") provides for the policy objectives in its Article 1 (aim and scope) and for principles and objectives in its Articles 5 to 10.

In addition, given the high administrative burden entailed by the EU legislation, the objective of simplification has been considered as a fourth specific objective for the review.

Operational objectives

(1) to define clear and unambiguous production rules

to improve fair competition, to improve consumer confidence and to simplify the legislation. The end of the exceptions to the rules will remove an obstacle to the implementation of compliance to the EU rules in third countries,

(2) to implement a risk-based control system

to improve the efficiency of the control system, to address remaining issues regarding the coverage of the control system. This will allow a better control of riskier operators, thus limiting the fraud cases and contributing to consumers' confidence. It should also lead to lower certification costs, thus reducing an obstacle to join the organic sector. It contributes to all specific objectives,

(3) to harmonise the approach in case of presence of non-authorised substance residues in organic products

to make sure that similar situations do not lead to different actions. It will improve fair competition,

(4) to simplify the administrative requirements in particular for small farmers in the EU

to remove obstacles for small farmers to join the EU organic sector,

(5) to implement a single and reliable system of recognition of CBs in third countries

to ensure a proper supervision of CBs in TCs, to ensure that the controls are effective, to ensure a level playing field for EU producers. It corresponds to the objectives of improving consumer confidence and guaranteeing fair competition. The limitation to one system only will simplify the implementation for the Commission, CBs, operators in third countries and EU importers.

(6) to establish a balanced trade regime

to ensure that EU organic producers have the best possible access to third country markets, thus reducing an obstacle to the development of organic production in the EU.

(7) to clarify labelling rules

to lower the burden of producers, to avoid consumer confusion.

(8) to integrate evolving societal concerns

to address management of environmental performance by processors and traders of organic products and animal welfare concerns. It will make schemes competing with the EU organic scheme less attractive, thus contributing to limit the obligation for producers to be certified according to several schemes to get access to different markets.

(9) to improve transparency and information on the sector and on organic trade

for producers (tools), decision takers (statistics)

4. POLICY OPTIONS

The impacts of three broad coherent policy options have been analysed in details. They are based on three possible solutions to address the identified problem, according to suggestions heard in the hearings and the consultations. They are also based on three different long-term visions of the organic sector. The improved status quo option is based on the approach that has been followed in the last twenty years. The market-driven option aims at providing the conditions to respond dynamically to further market developments. The principle-driven option aims at re-focussing organic farming on its principles.

On the question of exceptions to the rules, option 2 proposes the integration of exceptions as permanent rules in the legislation, while option 3 proposes to remove exceptions. Alternative intermediate options which would remove only part of the exceptions have not been considered for the analysis, because all exceptions are granted for economical reasons (if producers cannot fulfil the requirements for organic production, the products can be sold as conventional at lower price). It is therefore difficult to consider some of them as essential and others as superfluous. But keeping or removing the exceptions correspond to different orientations for the organic sector.

Measures that are not essential for the consistency of the options are presented as sub-options.

4.1. Policy option 1: improved status quo

Option 1 proposes improvements and better enforcement of the current legislation, considered as a minimum to address the identified issues. It does not propose any significant change in the policy orientations. For instance, the current system of exceptions is kept. Therefore, there is no need for an action plan to accompany the sector to adapt.

Option 1 addresses the following issues:

- complex and unclear provisions on production and labelling rules,
- shortcomings in the control system, notably on the following issues: traceability and the presence of non-authorized substance residues,
- obstacles to conversion to organic farming, since a clearer legislation would be more attractive.

In addition, option 1.A addresses the issue of uncomplete coverage of the control system.

During the consultation process, option 1 was supported by the main stakeholders IFOAM EU and COPA-COGECA. However, both have moved since then towards a more principle-driven approach (see Annex 2).

EOCC supported option 1, because of the expected better application of the production rules, better controls and better supervision, as well as the advantages of electronic

certification. Keeping the obligatory annual inspection seems an essential point for EOCC: "the installation of an efficient and meaningful risk-based inspection system does not forcibly need to include the abandon of the annual inspection for each operator".

The instruments proposed are the following:

A Regulation of the European Parliament and the Council to replace Council Regulation (EC) No 834/2007:

- to clarify the status of objectives and principles of organic farming,
- to **clarify the scope** of the legislation by listing precisely processed agricultural products intended for food and not included in Annex I to the Treaty, which can be labelled as "organic", for instance cooked meals or essential oils. The details of the measures are in Annex 6.
- to **clarify production and controls rules** to avoid ambiguities, to fill gaps and to remove legal uncertainty.
- to clarify the **labelling rules**, notably by expanding the limit of 2% for ingredients of agriculture origin not coming from the mentioned area to 5% for the "EU" or "non-EU" indication. The detailed of the measures on labelling are in Annex 8.
- to remove the possibility of recognition of CBs for the purpose of **compliance**. The system of recognition of CBs in place, based on equivalence, is kept. Because exceptions to the rules are not removed, the MS decision level is kept, which is hardly compatible with the implementation of the compliance system.

Measures to reinforce the control system

- the general rules for the accreditation of CBs will be clarified by indicating the standards and specifications against which they should be accredited and the conditions to be fulfilled by accreditation bodies.
- the issue of presence of non-authorized substances or products will be addressed by requiring investigations in case of presence of such residues in organic products and defining a level above which the product may not be labelled as organic. While the principle will be introduced in the basic act, the details will be defined in a delegated act. The experience of existing initiatives, notably in the MS which have defined such rules, will be taken into account. As shown in Annex 11, the "baby-food limit" would be the best adapted level.
- implementation of a system of electronic certification to enhance traceability and control and at the same time to reduce the administrative burden for operators, CBs, and public administration. It will exploit the synergies with the Commission's information management system for official controls to be set out according to the proposal for a new Regulation on official controls. This system will integrate and/or provide the appropriate linkages to the existing computerised systems managed by the Commission (namely TRACES: Trade control and expert system, and OFIS).

Possible sub-option 1.A:

- end of the possible exemption for retailers from the control system. Retailers will be submitted to the same control requirements as other operators and will be subject to a risk analysis, taking into account the results of previous controls if available, the quantity of products sold and the risk of exchange of products.

4.2. Policy option 2: market-driven option

Less stringent production rules allow producers benefitting from current exceptions to continue to produce organically, and newcomers to join more easily thanks to the integration of exceptions as normal rules in the legislation. The control system is amended as in option 1. The import regime is unchanged. A sub-option imposing an obligation of results on all organic operators, regarding the absence of non-authorised substance-residues in organic products is proposed.

Option 2 addresses the following issues:

- complex legislation, difficult to implement,
- risk of unfair competition due to excessive use of exceptions,
- shortcomings in the control system (the rules become easier to control),
- high administrative burden linked to the management of exceptions.

However, the option will lower the standard, with a renewed risk of multiplication of logos.

Option 2.A addresses the main consumer concerns, who wish products without residues. It corresponds to a conception of organic farming less production process oriented, but with an obligation of result at the end.

Option 2 was supported by several stakeholders during the consultation (see Annex 2), notably **Eurocommerce**, which considers that the EU rules are only the baseline to market products as organic and that the Regulation should be permanent on the lowest common denominator. In particular, an increase in the volume of organic processed products is seen as essential for the further development of the sector. Eurocommerce is against ending possible exceptions for retailers to be covered by the organic control system.

The instruments proposed are the following:

An Action Plan defining a strategy for organic farming in the EU, putting forward an adequate use of existing tools and an appropriate coordination with other EU policies in order for the organic sector to develop as required by the market. It includes appropriate instruments to increase information on the sector in the EU (market, production, added value, trade) and accompanying measures to improve and increase controls on final products.

The main stakeholders IFOAM EU and COPA COGECA call for a new action plan.

A Regulation of the European Parliament and the Council to replace Council Regulation (EC) No 834/2007:

- to amend the objectives and principles of organic farming and to clarify their status,
- to **integrate as provisions of the EU Regulation current long-lasting exceptional rules** granted by MS as provisions in the EU Regulation; to re-introduce exceptional rules expiring end 2013 and end 2014; to clarify diluted or complex provisions by making more transparent the permitted flexibility,
- to draft production rules in a stand-alone document addressing the issue of readability and making imports possible under a compliance regime,
- to include legislative measures presented in option 1,

Measures to reinforce the control system (as in option 1: accreditation and electronic certification)

Authorisation of substances and practices for organic farming under the responsibility of the sector.

Electronic certification as in option 1.

Possible sub-option 2.A:

- Introduction of specific maximum thresholds (below MRL) for the accidental presence of non-authorised substance residues in organic products.

Sub-option 2.A would entail systematic analysis of organic products and differs from the measures proposed as improvements in option 1 where analysis remain a control tool conducted on a sample of products according to a risk-analysis.

While it corresponds to consumer demand, the main stakeholders, in particular IFOAM EU, are against such approach: "*organic farming is defined from the beginning by a process approach (...) most of the criteria cannot be verified by analytical methods (...) if the sector is trained to verify the organic integrity of a product by analytical methods, based on thresholds, market access will be established by those findings and not by compliance with process criteria of the organic Regulation. This would turn the organic process quality approach into the direction of an (end) product approach*".

4.3. Policy option 3: principle-driven option

Production rules are strengthened by removing any flexibility, considering that flexibility had been introduced to make easier the conversion of holdings when the organic sector was embryonic, but that it is not justified any more in the light of the development of the sector. The control system is amended to reinforce the risk-based approach and to further enhance enforcement. On the import side, the equivalence regime is replaced by compliance, since the strengthening of production rules involves changes in the import regime in order to be consistent. A regime of equivalence with third countries remains. One sub-option proposes the introduction of an obligation for processors and traders to improve their environmental performance, and a second one the introduction of specific measures for small farmers.

Option 3 addresses the following issues:

- complex legislation, difficult to implement,
- risk of unfair competition due to excessive use of exceptions,
- shortcomings in the control system (risk-based approach, harmonisation of actions to address instances of non-compliances),
- shortcomings in the import regime, with the move from equivalence to compliance for CBs,
- societal concerns with improved animal welfare conditions in organic farming,
- consumer concerns and risk of multiplication of logos, with strengthened rules,
- high administrative burden linked to the management of exceptions.

The main stakeholders, IFOAM EU and COPA-COGECA, have shown interest in option 3 during the consultation process but without supporting it. However their position has progressively changed. IFOAM EU has acknowledged that this option is close to the movement's objectives, according to which *"the process approach to organic quality definition and certification should be maintained and strengthened and the EU organic Regulation further developed with regard to quality and integrity, so that it can be an effective tool to move all organic practice close to its aims and principles"*.

Option 3 was supported by several organisations, notably animal welfare organisations. (see Annex 2).

If combined with the first sub-option, option 3 addresses concerns about environmental issues, which should improve consumer confidence.

If combined with the second sub-option, option 3 will remove some obstacles for small producers to join the organic sector.

The instruments proposed are the following:

An Action Plan defining a strategy for organic farming in the EU, putting forward an adequate use of existing tools and an appropriate coordination with other EU policies in order for the organic sector to develop while remaining close to its values and principles. It includes:

- appropriate instruments to increase information on the sector in the EU (market, production, added value, trade),
- because of the end of exceptions, it will in particular call for measures to further address technical constraints for producers, by finding synergies with EIP⁵⁴ and Horizon 2020 instruments (uptake and dissemination of research results; better identification of research and innovation needs of farmers and producers),

⁵⁴ EIP on agricultural productivity and sustainability

- creation of a permanent expert group for the examination of new techniques and substances to be considered in organic farming and finally prioritising examination of new techniques and substances,
- a specific export policy, for which the Commission will ask a mandate to the Council.

Most MS have mentioned the need for reciprocity in future arrangements with third countries, in addition to stakeholders like COPA COGECA: "*the Commission must pay greater attention to rules of mutual recognition as part of agreements with third countries*".

A Regulation of the European Parliament and the Council to replace Council Regulation (EC) No 834/2007:

- to remove exceptional rules from the Regulation but possible temporary measures to allow organic production to continue or recommence in the case of catastrophic circumstances will remain, as well as the possible exception allowing the tethering of animals in micro-enterprises. Exceptions will be phased out with transitional periods, shorter in cases where farmers only have to amend the management of the farm, but longer in cases where the change does not depend on the farmer (e.g. availability of organic seeds on the market – in this case a transitional period until 2021 will be proposed). IFOAM EU acknowledged that some current exceptions (the use of non-organic animals, the use of non-organic feed and the addition of non-organic yeast extract) could be deleted or converted to transitional rules. However, some of them should be converted to permanent rules, like tethering of animals in small holdings. In the case of organic seeds, the organisation said the immediate deletion of exceptions could have a strong impact on the sector, but the current revision process should be used to make further progress in this area.
- to oblige organic holdings to be entirely managed in compliance with the requirements applicable to organic production,
- to put an end to the retrospective acknowledgement of conversion,
- to draft production rules in a stand-alone document addressing the issue of readability and making imports possible under a compliance regime,
- to include provisions on exports of organic products. The possibility to establish an export certificate will be included in the basic Act and the details will be provided in implementing rules. The export certificate will be a standardised document that could be used by EU organic exporters as a tool to prove that the product has been produced according to the EU organic standard and that it has been controlled according to the EU control system. The intention is to implement an electronic certificate in coordination with existing documents, notably the SAD (single administrative document – documentary basis for customs declaration) in order to avoid the duplication of request of information and to make the system as smooth as possible. Once the tool will be in place, the Commission will be able to use it when negotiating with third countries. It should facilitate the conclusion of reciprocal agreements, since the third country will not have to implement an organic import system; EU organic products will be easily identified.

- to remove the possibility of recognition of CBs for the purpose of equivalence (Article 33 (3)), with appropriate transitional measures to avoid market disruption and to give CBs time enough to be prepared to move from an equivalence to a compliance regime. In practice, the transition between equivalence and compliance is already starting through adaptations of Commission Regulation (EC) No 1235/2008 to apply compliance. For their next 3-year recognition period, which coincides with their accreditation cycle, CBs will have the possibility to apply compliance. The new basic Act will provide that the recognition of CBs for equivalence shall expire on 31 December 2018 at the latest.
- to adapt the system of **recognition of CBs for the purpose of compliance** (Article 32), notably by including in the basic Act provisions requiring sufficient information to ensure the full traceability of imported organic products.
- to include legislative measures presented in option 1, except removal of Article 32 on import of compliant products.

Measures to reinforce the control system:

- to reinforce the risk-based approach by adapting the control frequency so that organic operators with a proven clean record can be physically inspected less than annually and/or be subject to a reduced annual physical inspection where feasible. This would free resources that would be concentrated on those areas and operators presenting the highest risks.
- to clarify the existing provisions on irregularities and infringements by defining categories of non-compliance that, by affecting the organic status of products, require the application of a uniform level of measures by the competent authorities across MS – independently from the penalties and sanctions that each MS will lay down.
- to introduce electronic certification as in option 1.

Possible sub-options:

- 3.A: Introduction of an obligation of improving environmental performance for organic processors and traders, with the exception of micro-enterprises. In case they deal with both organic and conventional products, such operators will have to run an EMS system for all production units where organic products are processed, packaged or stored.
- 3.B: Simplified requirements for small farmers and introduction of group certification.

The details for the measures proposed as sub-options will be provided in delegated and/or implementing Acts.

4.4. Options discarded at an early stage

Options defined by the use of alternative legal instruments have been considered but have been discarded at an early stage:

- The use of a framework directive would not meet the objective of more simplification. Unfair competition issues could arise because of the absence of harmonised rules. Equivalence arrangements with third countries would probably be put into question.
- The introduction of "organic farming" as an optional reserved term under Council Regulation (EU) No 1151/2012⁵⁵ on quality schemes for agricultural products and foodstuffs would not acknowledge the holistic approach of organic farming which is not only a quality scheme but also a specific way of farming.

These options got no support among stakeholders and MS.

The harmonisation of organic production rules for textiles and cosmetics was considered but discarded because the need for EU action is not demonstrated. The external evaluation recommended not to extend the scope to these products. Few MS (Italy) supported this suggestion. Some of them recommended to explore this possibility (Sweden, Romania, Estonia). Spain called for the introduction in the scope of the legislation of certain textile products. But most MS were against. Germany stated that "it should be noted that including textiles and cosmetics would enormously expand the legal framework and render it much more complex." IFOAM EU stated that "European standards for textiles, cosmetics and other products which use the term "organic" must be established so as not to undermine consumers' confidence in organic farming products."

The co-Regulation and self-Regulation options could result in difficulties for the sector to develop high and harmonised EU production rules accepted by society all over the EU. They could also undermine consumer confidence, since the EU Regulation and the official control system are important reasons for consumers to trust organic products. They got no support among stakeholders and MS.

The no-EU action option would bring the EU organic sector in a weak position on the global market, where there is a general trend towards more harmonisation in production rules. The use of the international standard included in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced foods⁵⁶ would lead to a similar situation, since MS could decide on national legislations. The standard is not designed to be directly applied in WTO Member countries. In particular, the decision-making process is heavy and long and would not be appropriate to decide on implementing rules. It was not supported by stakeholders.

The inclusion of catering in the scope of the legislation, was also discarded because the added-value at EU level has not been proved. The external evaluation has recommended not to extend the scope of the EU legislation to catering. MS have adopted measures which do not pose any problem to the functioning of the single market. These national schemes for organic catering are regularly notified to the Commission and to other MS as technical standards. Several MS are opposed to the introduction of catering in the scope of the legislation on organic production (Poland, Latvia, Estonia, Bulgaria, Ireland, UK, Belgium, Denmark, Czech Republic). The rationale for that vary. Most of MS want to avoid to receive a new resource-demanding competence, others, like Denmark, are

⁵⁵ Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs - OJ L 343, 14.12.2012, p. 1.

⁵⁶ GL 32-1999

strictly opposed because they have implemented a successful national system. Other MS (Italy, Germany, Luxembourg, Slovenia, Greece, Sweden, Cyprus, Spain, Romania) were in favour of the introduction of catering in the scope, at least partial.

According to IFOAM EU, "*catering should only use the word organic according to national rules as there is little cross-boarder market for catering, consequently a common EU standard is not required*".

5. IMPACT ANALYSIS

The period considered for the impact analysis is 2016-2025, with 2016 considered the first year when the reviewed policy applies. Between 2011 and 2016, the baseline applies. This part analyses how the options presented in chapter 4 can impact the market of organic products (supply and demand). Socio-economic and environmental impacts, including animal welfare conditions, have been examined, as well as possible international impacts.

The development of organic production in the EU is accompanied by a corresponding reduction of conventional agriculture, since the lands converted to organic agriculture is usually taken from the conventional sector. Therefore, since all options are expected to entail an increase in the organic land area, a corresponding decrease is expected in the conventional sector. Where relevant, other possible impacts of the options on conventional agriculture are indicated.

5.1. Option 1

Supply

Positive factors: unfair competition is reduced on the EU market by addressing the issue of presence of non-authorized substance residues, which also improves the functioning of the internal market. Unfair competition with third country producers entailed by the CBs equivalence regime is slightly reduced, thanks to the harmonisation of the accreditation system both in the EU and in third countries.

Negative factors: technical, economic and structural obstacles to the development of organic production in the EU are not reduced. The exceptions hinder the development of the sectors of organic chicks and seeds. High administrative burden and certification costs remain. Small producers continue to be excluded.

The option is not likely to have significant effects on the volumes of organic products on the market and on prices.

Demand

Positive factors: labelling improvements are seen by IFOAM EU as positive. "They will minimise confusion of consumers". The risk of fraud is slightly reduced thanks to the introduction of electronic certification.

Negative factors: production rules are still watered down. Private schemes and logos continue to multiply, since evolving and societal consumer concerns are not met and the production rules remain quite weak.

The market expansion is expected to slow down at the end of the period because consumer confidence is not significantly improved.

Socio-economic impacts

The organic land area, the number of farms and the employment are expected to continue to increase, with a less pronounced slow-down compared with the baseline scenario. No significant change is expected in the income of organic farms.

Processors and traders benefit from clearer and simpler rules on scope and labelling, as stated by IFOAM EU "*reducing the complexity has a positive impact on social and economic performance*".

The harmonisation of measures applying in case of presence of non-authorised substance residues in organic products improves the level playing field, notably to the benefit of SMEs of the sector.

Environmental impacts

The increase in the organic land area is higher than in the baseline scenario and the organic production rules applied to farming are identical to the baseline scenario. Therefore, the environmental impact of option 1 is slightly positive.

Animal welfare

This option does not improve animal welfare conditions in organic farming.

International impacts

This option has the same impact on third countries as the baseline scenario. However, the introduction of electronic certification and the marginal improvements in the labelling rules contribute to reduce paper-based procedures and then to **slightly ease organic imports**.

5.2. Option 1A

Supply

As in option 1

Demand

Positive factor: a further reduction in the risk of fraud is expected.

Socio-economic impacts

There is no official data on the number of retailers selling organic products in the EU, but the change will have an impact on almost all retailers in the EU, according to Eurocommerce.

Retailers are supposed to face general inspection requirements under the food law and the specific requirements as organic operators are not expected to generate much additional burden. However, Eurocommerce has underlined that it could entail some costs, but without precise figures: *"Including retailers in the specific organic control system will increase the costs for retailers and of organic products, without adding any value for the consumers. In some MS private certifiers have already developed inspections of retailers to enable them to sell un-packed fresh products. For retailers selling only packed organic products, additional inspections do not have any benefit. This additional cost linked to the controls would make the organic products less competitive, and the consumers less interested"*. Therefore Eurocommerce is against this option.

The most impacted MS will be the ones with the highest share of the market: Germany, France, the United Kingdom.

Environmental impacts

As in option 1.

Animal welfare

As in option 1.

International impacts

As in option 1.

5.3. Option 2

Supply

Positive factors: the integration of exceptional rules as permanent rules in the legislation leads to more flexible rules; more conversions are expected at the beginning of the period, leading to more volumes on the market.

Negative factors: flexible rules fuel competition with imported products and prices paid to the producers decline. The sector becomes progressively less attractive. Some organic producers fully applying organic principles (not using exceptions) leave progressively the sector to join or to create private quality schemes.

The development of the production of "organic inputs", notably organic chicks and organic seeds reduces, because rules provide flexibility to use non-organic ones. According to IFOAM EU: *"investments and efforts of operators willing to overcome these exceptional rules would be frustrated if all exceptions were made permanent."*

The situation for small farms does not improve.

Demand

Positive factors: the volume of organic products on the market is likely to increase and prices to decline, depending on how the variations of price are transmitted along the food chain.

Negative factors: watered down rules which do not integrate societal and consumer concerns, as mentioned by IFOAM EU: "*including all current long lasting exceptional rules would have a negative impact at consumers' perception level.*"

New schemes and logos are likely to multiply, fuelling consumer confusion.

This will lead to some erosion of consumer confidence. It is difficult to estimate if lower prices can compensate for the loss of confidence.

Socio-economic impacts

An increase in the number of conventional farms converting to organic is expected at the beginning of the period. Therefore, the number of farms and the employment in organic farms increases at the beginning of the period, but slows down at the end.

The gross-margins and income should decrease at the end of the period because of lower prices paid to producers, under the pressure of imports.

Organic processors are supported by lower prices of raw materials, but they are affected by the market deterioration at the end of the period.

Organic seeds and vegetative propagating material and organic chicks producers will be negatively impacted in this option. Producers in MS which have developed national rules for organic chicks (e.g. Denmark) will face unfair competition.

Environmental impacts

The option is expected to be slightly positive in comparison with the baseline scenario. The integration of exceptions leads to less environmentally friendly practices. For instance, the proportion of use of non-organic seeds is likely to increase and the benefits associated with the cultivation of these organic seeds will be lost. But it is compensated by a further increase in the land area.

Animal welfare

The integration in the legislation of exceptional rules allowing for dehorning, tethering of animals in small holdings, indoors final fattening phase of adult bovines for meat production leads to the deterioration of animal welfare conditions. Producers will have some flexibility to apply such derogations without individual or collective exemption.

International impacts

An easing in imports, but obstacles on the export side, is expected. Since production rules are less stringent, **third countries are more reluctant to recognise the EU as equivalent**. Some concluded agreements/arrangements with third countries can be questioned.

Example: equivalence arrangement between the EU and the U.S.

The EU and US have recognised each other's organic production rules and control systems as equivalent under their respective rules. This equivalence arrangement took effect on 1 June 2012.

The arrangement was concluded in the form of an exchange of letters between both administrations. According to these letters, the European Commission must notify the US administration in a timely manner of any proposed EU legislation that would modify any of the EU regulations referred to in the arrangement. A new assessment of the equivalence of the new EU legislation with the US legislation should be carried out jointly by both administrations.

The discussions and decisions on the assessment of the equivalence would take place in the framework of the EU-US Organics Working Group that was set up by the arrangement. The group consists of

Organic producers in non-recognised third countries continue to benefit from flexible rules under equivalence, which should allow a continuous export flow to the EU.

5.4. Option 2.A

Supply

Negative factors: a share of the products produced on organic farms cannot be marketed as organic because of presence of non-authorized substance residues above the defined threshold. Depending on the threshold, up to 21.4% of organic animal products, 9.8% of organic baby-food, 11.8% of organic fruit, vegetable and other plant products and 8.1% of organic cereals could be declassified (according to EFSA figures – see 2.5.2.3). Extra-costs linked to the analysis lead to further obstacles for small farms to join.

Demand

Positive factors: This option would have positive impacts on consumer confidence. The organic sector could communicate on the absence of non-authorized substance residues, thus addressing the main consumer concern.

Negative factors: according to IFOAM EU, "*introducing a threshold that determines the organic status would upset the basic concept of organic farming and principles*". This could lead to some confusion. In addition, the systematic sampling and testing of organic products, and the interpretation of results, could lead to an increase in the price of organic products.

Socio-economic impacts

The obligation to test a sample of all organic products lots would have an impact on costs for all operators which could be significant. The lower the threshold, the higher the cost. There is a risk that the costs of sampling, testing and analysing the results become disproportionate in relation to the economic dimension of organic operators. In addition, it would result in products produced on organic farms and/or processed in respect with the rules, not to be sold as organic because of an accidental and unintentional contamination with non-authorized substances. Depending on the threshold, the share of the production that would have to be declassified and sold as conventional would vary between 0.44 and 21% for animal products, 0.67 and 9.09% for baby-food, 1 and 10.8% for fruit, vegetable and other plant products and 0.36 and 7.76% for cereal products (according to EFSA data presented in Annex 11).

Environmental impacts

Like in option 2.

Animal welfare

Like in option 2.

International impacts

The systematic testing of samples for non authorised substance residues could entail disproportionate costs for producers in developing countries.

Impact on conventional agriculture

Products from conventional agriculture, by contrast, could be seen as the ones "with pesticides", which could entail a loss of consumer confidence in conventional products.

5.5. Option 3

Supply

Positive factors: new stricter rules reinforce farmers' confidence in the organic scheme. Organic farmers fully applying organic principles (not using derogations) are more inclined to remain in the sector.

The end of the exceptional rules boosts the sectors of organic inputs, notably organic chicks and seeds.

The action plan will contribute to reduce technical obstacles to the development of organic production. On the export side, a better access to third country markets is expected thanks to negotiations with third countries interested in mutual recognition agreements with the EU. The negotiations will take advantage of tools like the export certificate, which will permit the identification and traceability of EU organic products.

Negative factors: some producers have to leave the sector because they want to keep a part of conventional production on their holding. IFOAM EU considers that "the conversion of the entire farm is the aim and this provides the basis for fulfilling the organic principles in the best way". Nevertheless, both IFOAM EU and COPA COGECA point out practical or economical reasons for farmers not to be able to convert their farms at once. Other producers have to leave because their system depends on exceptions, as mentioned by IFOAM EU: "remove all exceptions to the rules today would mean exclude many operators, in particular in new MS and in disadvantageous areas". No data has been provided to corroborate this statement.

Stricter rules can be seen as a barrier to conversion, notably because of insufficient availability of inputs such as seeds in their organic form. As a result the price of organic inputs could increase and weigh on production costs. This could be the case in MS where organic farming is less developed. But the transitional period until 2021 allows for a progressive development of certain organic inputs. Their development on the medium or long term should lead to cheaper and more adapted inputs, and to an improved productivity in the organic sector. Notably, the increase in the size of the market of

organic seeds should allow companies of the sector to invest in new varieties adapted to organic growing conditions, with expected yield increases.

Stricter import rules restrain imported flows and result in less competition.

Demand

Positive factors: the market should expand more securely thanks to improved consumer confidence, which is likely to progressively lead to less competing private organic schemes and logos. The potential for organic national logos to differentiate from the EU one should reduce. Their use could be progressively abandoned, which would subsequently improve the functioning of the internal market for organic products.

Negative factors: the volume of organic products on the market at the beginning of the period could be lower than in the baseline scenario, thus leading prices to increase. Depending on the transmission of prices effects along the food chain, higher production costs could result in increased consumer prices for organic products. The public consultation has shown that the majority of citizens is ready to pay more for organic products, provided that the price difference remains reasonable (see Annex 2). Too high prices would make organic products less attainable for lower income consumers. Therefore option 3 could lead to a contraction of the market instead of an expansion at the beginning of the period. However, expected lower production costs in the medium and long term (see above) should be accompanied by lower consumer prices, thus reducing the probability for such a market contraction, if any, to continue over the short term.

Socio-economic impacts

According to the most probable scenario described before, the **organic land area** and the **number of farms** are likely to increase slightly at the beginning of the period, more significantly after, as well as the employment on organic farms.

There is no precise data on the share of organic farms with parallel conventional production. It is estimated at a few percents of the total organic holdings in the EU. These farms could choose to fully convert to organic production, if a sufficient transition period is allowed, because of the positive market outlook in the sector. This cannot be corroborated by their views because no specific consultation to such farmers could be done.

Prices paid to producers should increase. However, because of the end of exceptional rules, production costs will also be higher (ex: crops and vegetable growers to use 100% organic seeds). Production costs are likely to decrease gradually with the development of the production of inputs in their organic form. In other respects, some organic farms will need important investments to adapt buildings to animal welfare requirements.

Environmental impacts

The effect on the environment depends on the evolution of organic production in the EU, linked to the organic market. The removal of exceptions to the rules stresses organic farming positive impacts on environment. For instance, the generalisation of the use of organic seeds leads to a significant increase in the organically managed land area for the production of such seeds, with positive associated effects.

Animal welfare

The end of exceptions to the rules leads to better animal welfare conditions. Mutilations and indoors final fattening phase of adult bovines for meat production are not allowed any more.

International impacts

Existing equivalence arrangements with recognised countries have to be reviewed in order to maintain a level playing field for EU producers.

The move to a CB compliance regime will renew the interest from third countries to be recognised as equivalent, in order for their producers to be able to produce according to their national rules instead of the EU rules.

Imports from developing countries

Non recognised third country producers will have to comply with EU rules which will have an impact on producers in developing countries. According to IFOAM EU: "*compliance is in most third countries not appropriate because climatic, social and cultural differences to EU countries(...) this option would lead to negative, social, environmental and economic impact.*"

DG AGRI has analysed the production rules applied by CBs in developing countries within the current regime of equivalence. The analysis is presented in Annex 12. It comes to the following conclusion:

- most provisions included in the CB production rules are identical to EU production rules,
- cases where the provisions are different mostly refer to provisions of the EU Regulation on which MS have to decide, notably on the exceptions. In such cases, some CBs apply the lowest possible standard, while other ones apply strict rules.

The most important products imported from developing countries in terms of volume are bananas, coffee, citrus fruit and cocoa. Animal products are hardly imported. No case of impossibility to apply the EU organic production rules because of local geographical or climatic reason was found. Most of the products are produced by grower groups⁵⁷ certified according to group certification requirements, which are considered equivalent to EU control measures, but not authorised in the EU. Therefore, a move to the compliance regime without group certification being authorised in the EU would result in the obligation to apply individual certification, which would **entail disproportionate burden and costs for most producers currently in recognised grower groups.**

5.6. Option 3.A

Supply

As in option 3.

⁵⁷ Louis Bolk Insitute and FIBL, hearing

Demand

Positive factors: in addition to option 3, consumer confidence is expected to improve, because it addresses a developing concern.

Socio-economic impacts

Processors and traders of organic products, with the exception of micro-enterprises, have to apply an environmental management system. The most impacted MS will be the ones with the highest production of organic processed products: Germany, France and Italy. It will entail increased efficiency and energy savings, which are likely to more than compensate the additional costs, as shown by the results of a study on the costs and benefits of EMAS to the registered organisations⁵⁸ carried out in 2009. Potential annual efficiency savings for small enterprises amounted to 20.000 to 40.000 Euro, with an annual cost to run the system at 22.000 Euro. For medium enterprises, the savings exceeded 100.000 Euro, while the annual cost was 17.000 Euro. However, the implementation cost in the first year is higher than the savings. For micro-enterprises, the savings do not compensate for the additional costs, but they are not covered by the proposed measure. The details are presented in Annex 13.

Environmental impacts

This sub-option is more positive for the environment, because processors and traders will adopt more environmentally-friendly practices.

Animal welfare

As in option 3.

International impacts

Processors and traders in third countries (except micro-enterprises) will have to implement an EMS.

5.1. Option 3.B

Supply

Positive factors: the implementation of group certification in the EU will reduce certification costs for group members after a few years of implementation. In addition, it will mitigate the burden of administrative requirements, thus reducing obstacles to conversion to organic for small farmers. It should benefit to MS with the highest share of small farms: notably Romania, Bulgaria, Hungary, Poland, Portugal, Greece, Italy and the Baltic States. Potentially all categories of products would be concerned. It could give a boost to organic fruit and vegetable production, which is usually more labour intensive.

⁵⁸ Study on the costs and benefits of EMAS to registered organisations (2009). Milieu Ltd and Risk and Policy Analysis Ltd for DG Environment of the European Commission.

http://ec.europa.eu/environment/emas/pdf/news/costs_and_benefits_of_emas.pdf

A pilot project⁵⁹ on Group Certification in Turkey, France, Italy and Spain, showed that group certification costs were higher than individual certification in the first two years but became cheaper in the subsequent years. It also showed that an internal control system (ICS) does not only serve organic certification but also has other benefits, such as farmer-to-farmer advice, quality improvement, joint marketing or promoting a specific agricultural region.

Demand

Positive factors: products produced on small farms are positively perceived by some consumers.

Negative factors: the implementation of group certification in the EU could undermine consumer confidence because controls could be suspected to be less effective. However, even if the objective is to reduce controls from CBs of individual members of the group, the system involves an ICS which has to comply with precise requirements.

In the public consultation, 70% of the citizens agreed that group certification should be allowed in the EU. Stakeholders who supported the proposal were: non-EU public authorities (80%), consumers (74%), researchers (71%), citizens (71%), advisory services (70%) and others (67%). The most significant opponents were private CBs (44%), national associations (37%), farmers (36%) and retailers (31%).

Socio-economic impacts

Group certification is a way to address small farms' concerns, which proved to be effective in developing countries. The potential to develop in the EU depends on farm structures in the different MS. MS with many small-scale farms are Bulgaria, Romania, Poland, Hungary, Italy, Greece and Portugal.

It is expected to lead to further increase in the number of organic farms and in the organic land area.

Environmental impacts

The option is positive for the environment because of the increase in the land area.

Animal welfare

As in option 3

International impacts

Sub-option 3.B allows a smooth move to compliance for the CB import regime. Developing country producers, including those in recognised grower groups, will be able to apply compliance with the EU rules.

⁵⁹ Pilot Project Group certification in Europe, end report, Agro Eco, Ferko Bodnár, May 2008. The pilot project was funded through the "IFOAM-Growing Organic" programme and the "Fund for Sustainable Biodiversity Management" of the Dutch government.

5.2. Simplification and administrative costs

5.2.1. Simplification associated with the options

All options are expected to remove ambiguities and make the legislation more user-friendly, thanks to clearer provisions. Gaps on the scope, on production rules and on controls will be addressed. **Many ineffective provisions are removed** in the three options, but more in option 3 (end of mixed farms, reinforcement of the risk-based approach on controls, etc). More details on simplification areas brought by the different options are provided in paragraph 6, notably in table 6.2.

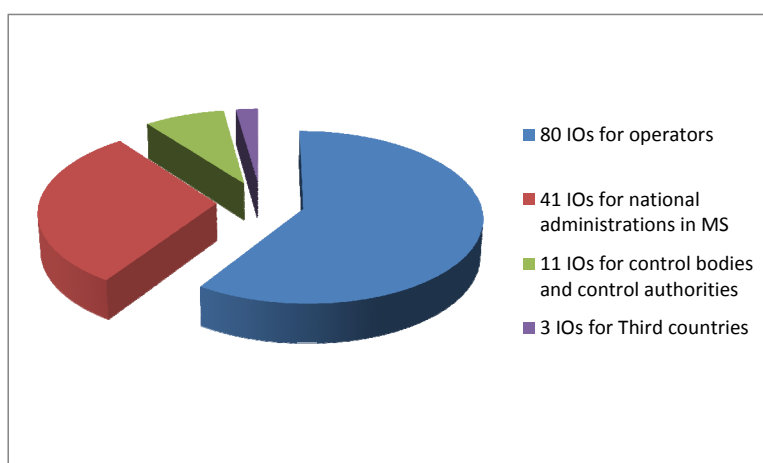
Simplification for small producers has been considered in the course of the impact assessment. By nature an exemption of controls is not compatible with the requirements of product certification. However, a major simplification for the smallest farms is brought by **group certification** (sub-option 3.C), which allows for more proportionate inspection and register-keeping requirements. More details are provided in Annex 15.

These elements, as well as the investigation on administrative costs, have been used to compare the options in terms of efficiency (see table 6.2).

5.2.2. Assessment of administrative costs

Particular attention has been paid to the administrative costs that the legislation imposes on national administrations, operators and CBs. In table 1 of Annex 16, a complete list of **135 IOs** which are imposed by the EU organic legislation and could potentially involve administrative costs was compiled. MS and stakeholders (in AGOF) were consulted on the completeness of the mapping and, at the same time, they were asked to identify and quantify IOs which are the most burdensome for them. IOs relating to provisions which are currently being phased out have not been considered, since they are not part of the baseline scenario. They relate to exceptions (to use of up to 5% organic feed for pigs and poultry, to bring non-organically reared pullets for egg production to organic livestock unit and colouring of eggs) and to the possibility for MS to grant import authorisations.

Graph 5.2.2.1: Number of information obligations



While **80 IOs are imposed on operators**, the total number of IOs imposed on a particular operator largely depends on the type of operations: plant production, animal production, aquaculture, processing, etc. the operator is running. For instance, 10 out of the 80 IOs concern only operators with aquaculture production. The most burdensome IOs are to keep documentary evidence of the need to use (authorised) plant protection

products and fertilisers, the control arrangements and undertaking necessary to enter the organic scheme, to keep specific register of livestock records and to keep documentary evidence in relation to coexistence of organic and conventional production.

Out of **41 IOs imposed on MS**, the most burdensome are, in descending order, to provide statistical data on the organic production in their country, to publish up-to-date lists of operators and to provide a summary report on authorisations of non-organic seeds.

Out of 11 IOs imposed on CBs, the most burdensome are to grant derogations to operators for use of non-organic seeds, to request inclusion in the EU equivalent recognised Third countries CBs list (the first inclusion has been granted for 3 years), to provide an annual report on their activity and to verify the indication of the CB's code number in the label of organic products, which, in practice, has to be checked each time an operator introduces a new product on the market.

IOs related to the obligation to use organic seeds whenever available, i.e. operating the seed database, granting of derogations for non-organic seeds (more than 150.000 derogations granted in the EU annually) and related reporting were highlighted as particularly burdensome by several actors. This authorisation and reporting system is proposed to be removed under options 2, 2.A, 3, 3.A and 3.B.

Details regarding the assessment of administrative costs, including a description of the methodology used and the results obtained is included in Annex 16. It has not been possible to monetarise the administrative costs and the expected savings under the preferred option, because of the large number of IOs involved and incomplete data.

– **Option 1 and 1A**

These policy options do not entail savings in terms of reduction of administrative costs. It is estimated that the level of costs would remain the same.

– **Option 2 and 2A**

Important administrative savings are expected through a reduction of 34 IOs. This is due to the fact that the new proposed legislation and production rules would require less record keeping and reporting and because of the ending of a number of derogations and exceptions which are possible under the present legislation.

– **Option 3, 3A and 3B**

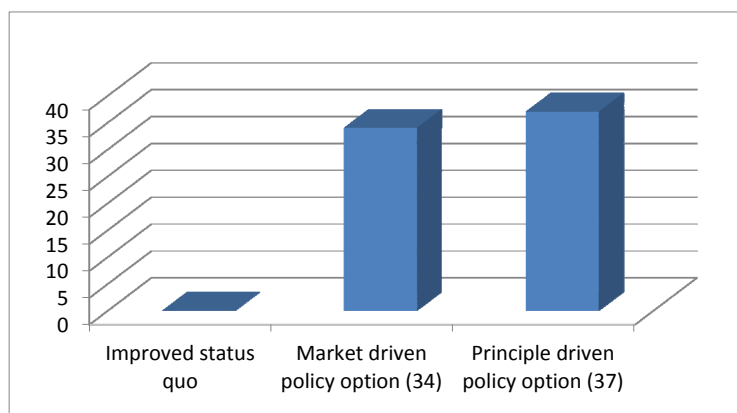
These options are the most favourable in terms of reduction of number of IOs: 37 IOs would be removed. The reduction is mostly achieved by putting an end to various derogations and exceptions which are possible under the present legislation.

A cautious approach has been taken as regard the removal of the mandatory annual inspection. The main objective of the implementation of the risk-based control system is to increase the control frequency on risk-operators; therefore it has been considered that it will entail no savings for the national administrations and CBs.

Option 3.A includes the introduction of an environmental management system which will create an additional administrative burden on processors and traders, since it will be based on an ad-hoc certification system. As mentioned in the impact analysis, this will be

compensated by the increased efficiency and the energy savings, and reduction in burden after the implementation of the system.

Graph 5.2.2.2: Number of IOs removed under the three main policy options



5.3. Conclusions on topics on which the Council had asked a report to the Commission

It can be concluded the following:

- a) On the scope of the Regulation, there would be no EU added value in including organic food prepared by caterers,
- b) The provisions on GMOs should be kept unchanged, since they correspond to a balance between benefits and costs. In particular, a specific tolerance threshold does not appear realistic in view of the costs of analysis. The details are provided in Annex 6.
- c) Issues relating to the functioning of the internal market have been identified:
 - absence of harmonised approach in case of presence of non-authorized substance residues in organic products: it is addressed in all options,
 - use of exceptions to the rules by MS; it is addressed in options 2, 2A, 3, 3A and 3B,
 - same non-compliances leading to different actions in different MS. It is addressed in options 3, 3A and 3B.

6. COMPARING THE OPTIONS – PREFERRED OPTION

The three policy options have been assessed:

- (1) against their potential to achieve the specific objectives and the operational objectives of the review. The results are presented in table 6.1.
- (2) in terms of effectiveness, efficiency and coherence with over-arching objectives. The results are presented in table 6.2.

The **specific policy objectives** are better ensured through option 3.B or 3.A, followed by 3, 2.A and 2, because:

- more **obstacles to the development of organic farming** in the EU are removed with options 3.A and 3.B, thanks to clearer production rules, the removal of exceptions to the rules which lead to the development of organic inputs and to the implementation of the action plan. In addition, option 3.B addresses the case of small producers. However, options 3, 3.A or 3.B could lead some producers to leave the sector at the beginning of the period because of the end of exceptions to the rules,
- **fair competition and the functioning of the internal market** are slightly improved in option 1, notably because it tackles the issue of presence of non-authorised substances. Option 2 goes further, because the exceptions are integrated in the production rules, thus providing a level-playing field among the EU. Option 3 performs better thanks to provisions to harmonise the cases of non-compliances which lead products to lose their organic status and to the move from equivalence to compliance for CBs in third countries, which improves the level-playing field with producers in third countries,
- **consumer confidence** is better addressed in options 3, 3.A and 3.B by addressing several societal concerns and improving the production rules, the control system and the import regime. Consumer confidence is improved to a lower extent in option 2, while 2.A is interesting with the systematic tests for pesticide residues.

The **operational objectives** are better achieved through option 3.B followed by 3.A, 3, 2.A and 2, because:

- In options 2, 2.A, 3, 3.A, 3.B, the removal of exceptions and the reduction in the MS decision level leads to clearer rules, which can be drafted in a single and stand-alone document,
- The implementation of a risk-based control system is better achieved in option 3, 3.A and 3.B, with the removal of the mandatory annual inspection,
- The harmonisation of the approach in case of presence of non-authorised substance residues is addressed equally in all options. Option 2.A performs better with systematic samples and analysis,
- The administrative requirements are simplified in options 2, 2.A, 3, 3.A and 3.B with the end of exceptions to the rules; option 3.B addresses the specific needs of small producers with group certification,
- The single and reliable CB import regime is obtained in options 3, 3.A and 3.B thanks to the move to compliance,
- Options 3, 3.A and 3.B allow a more balanced trade regime thanks to the specific export policy; thanks to stricter rules, the EU will be able to negotiate better with third countries; option 3.B with group certification fits better with a compliance system, since group certification is widely used in third countries,
- The clarification of labelling rules is equally addressed in all options,

- Consideration of societal concerns is not improved in options 1, 1.a and 2, but in 2.B, 3, 3.A and 3.B,
- The transparency and information on the sector are better ensured in options 2, 2.A, 3, 3.A and 3.B with the implementation of action plans,

Table 6.1: summary table – comparison of options in terms of achieving the objectives of the review

	Options	1	1.A	2	2.A	3	3.A	3.B
Specific policy objectives	to remove obstacles to the development of organic production in the EU	0	0	+	+	++	++	+++
	to improve the legislation in order to guarantee fair competition for producers and to improve the functioning of the internal market	+	+	++	++	+++	+++	+++
	to maintain or to improve consumer confidence in organic products	+	+	++	+++	+++	+++	+++
Operational objectives	to define clear and unambiguous production rules	0	0	+	+	+	+	+
	to implement a risk-based control system	-	0	0	0	++	++	++
	to harmonise the approach in case of presence of non-authorised substance residues in organic products	+	+	+	+++	+	+	+
	to simplify the administrative requirements in particular for small producers in the EU	0	0	+	+	+	+	+++
	to implement a single and reliable system of recognition of control bodies in third countries	0	0	0	0	+	+	++
	to establish a balanced trade regime	0	0	0	0	+	+	+
	to simplify labelling rules	+	+	+	+	+	+	+
	to integrate evolving societal concerns	--	--	0	++	++	+++	++
	to improve transparency and information on the sector and on organic trade	+	+	++	++	++	++	++

Table 6.2: summary table – comparison of options in terms of effectiveness, efficiency and coherence with overarching EU objectives

	Effectiveness	Efficiency	Coherence with EU objectives
Option 1	Most of the obstacles to the development of organic production remain. Functioning of single market slightly improved. Level playing field for producers not achieved. Consumer confidence improved but short term only.	Administrative burden for national administrations and operators due to the system of exceptions remains. Efficiency of control system not optimized (annual inspections). High resources needed for CB equivalence regime.	Coherence with general CAP objectives good but not improved in this option. Limited simplification. Evolving societal concerns (animal welfare, etc). not reflected.
Option 1.A	Like option 1, with higher positive effect on consumer confidence.	Retailers have to comply with administrative requirements to be covered by the control system.	Like option 1.
Option 2	Few obstacles to the development of organic production removed. Improved fair competition with the integration of possible exceptions as permanent rules. However possible unfair competition with imported products remain. Consumer confidence likely to erode.	Decrease in the costs of inputs. Lighter administrative burden for national administrations and operators thanks to the integration of possible exceptions in the rules. Efficiency of control system not optimized (annual inspections). High resources needed for CB equivalence regime.	Coherence with general CAP objectives improved, notably as far as market-orientation is concerned. Important simplification effect. Societal concerns not deeply addressed.
Option 2.A	Like option 2, but consumer confidence improved thanks to systematic tests on organic products.	Costly analysis required to the operators. Test analysis and litigious cases increase the administrative burden on CBs and national administrations.	Like option 2, with the main consumer concern (no pesticides in organic products) extensively addressed.
Option 3	Many obstacles to the development of organic production removed. Improved fair competition because no more exceptions to the rules and imported products have to comply with EU rules. Consumer confidence improved thanks to stricter rules.	Some farms have to leave the sector or to invest to adapt. Increase in costs of inputs at the beginning of the period. Less administrative burden on administrations and operators, because exceptions are removed. Control system fully risk-based becomes more efficient. Compliance system for CBs entails less administrative burden. Need to re-assess existing equivalence arrangements.	Coherent with CAP objectives improved notably in terms of sustainable management of natural resources. Many societal concerns addressed. Important simplification effect.
Option 3.A	Like option 3, with consumer confidence better improved because the environmental impacts of the whole organic food chain are taken into account.	Like option 3, but with additional administrative requirements on processors and traders to run an environmental management system .	Like option 3. Best option for the sustainable management of natural resources.
Option 3.B	Like option 3, with additional obstacles to the development of organic production in the EU removed.	Like option 3, with less administrative burden on small-scale producers.	Like option 3. In addition, group certification might participate to a more balanced territorial development.

In view of the result of the comparison of options, the preferred option is option 3, including measures proposed in option 1 and in sub-options 1.A, 3.A and 3. B.

7. MONITORING AND EVALUATION

The Commission will monitor the development of organic production in the EU through data collected by Eurostat (see paragraph 2.5.2.1) in the EU. MS are required to provide the Commission annually with the necessary information. The main result indicators in the Common Monitoring and Evaluation Framework of the CAP are:

- Share of organic area in total UAA,
- Share of organic livestock in total livestock.

And the main output indicators are:

- Organic land area (in conversion and fully converted),
- Number of certified organic operators.

The following complementary indicators will be monitored within the context of this Regulation:

- Livestock (number of organic animals and products of animal origin),
- Crop production and processing (number of operators and value/volume of production by type of economic activity),
- Number of exceptions used and number of exceptions removed,
- Knowledge of, and confidence in the Union organic logo (Eurobarometer survey).

As soon as electronic certification for imported products will be operational, the Commission will also be able to monitor the evolution of imports of organic products. This will allow the evaluation of the impact of the new legislation on countries beneficiaries of EU-cooperation.

The external evaluation has underlined that "the availability of comparable data on costs of production or intra-EU trade, which would be required to assess the quantitative impact of various rules on potential distortion of competition, is very limited" and has recommended "to explore possibilities to establish a monitoring system of the national implementation of the Regulation". It further recommended to take a consistent EU-wide approach in the definition, collection and publication of market data (including costs of production) for the organic sector. Knowing the difficulties to collect data on organic production in the EU, it would appear disproportionate to require the collection of public market data. However, the new European research project "OrganicDataNetwork" started in January 2012 is expected to be a significant step in view of improving market knowledge. The project aims to increase the transparency of the European organic food market through better availability of market information about the sector, thus meeting the needs of policy makers and actors involved in organic markets. The partnership will act as coordinating centre between stakeholders, and will result in a proposal for the establishment of a permanent network to achieve collaboration on statistical issues regarding organic market data.



Brussels, 24.3.2014
SWD(2014) 65 final

PART 2/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on organic production and labelling of organic products, amending Regulation (EU)
No XXX/XXX of the European Parliament and of the Council [Official controls
Regulation] and repealing Council Regulation (EC) No 834/2007**

{COM(2014) 180 final}
{SWD(2014) 66 final}

ANNEXES 1 to 8

TABLE OF CONTENTS

Contents

ANNEX 1: THE ORGANIC SECTOR IN THE EUROPEAN UNION	4
1. STRUCTURAL INDICATORS ON THE ORGANIC SECTOR	5
1.1. Area	5
1.1.1. Utilised Agricultural Area (UAA)	5
1.1.2. Share of organic area	6
1.1.3. Size of organic crop area	9
1.2. Organic holdings	10
1.2.1. Number of organic holdings	10
1.2.2. Share of organic holdings	11
1.3. Organic operators	12
1.3.1. Registered processors	12
1.3.2. Registered importers	13
2. ORGANIC AQUACULTURE	13
3. THE EU ORGANIC MARKET	14
3.1. General aspects	14
3.2. Consumer behaviour	15
ANNEX 2: SYNTHESIS OF THE PUBLIC CONSULTATION AND OF TARGETTED STAKEHOLDERS' CONSULTATIONS	17
1. CONSULTATION PROCESS	17
2. MAIN RESULTS BY TOPIC	19
2.1. Relevance of a review of the legislation on organic farming and policy options	19
2.2. Organic standard	20
2.3. Exceptions and derogations	21
2.4. Authorisation of substances in organic production	23
2.5. Sustainable use of energy and management of environmental impacts	23
2.6. Animal welfare	24
2.7. GMOs	25
2.8. Labelling, organic logo, confusion with other logos and Eco-label	25
2.9. Improvements in the control system	26
2.10. Move towards a risk based approach in the control system	27
2.11. Trade with third countries	28
2.12. Controls of imported products: equivalence vs compliance and risk of unfair competition	30
2.13. Presence of non-authorized substance residues in organic products	31
2.14. Small farms' issues and group certification	32

2.15. Information and promotion	34
2.16. Research and innovation	35
3. PRESENTATION OF THE MAIN STAKEHOLDERS	35
ANNEX 3: MAIN INSTRUMENTS OF THE COMMON AGRICULTURAL POLICY (CAP) SUPPORTING THE ORGANIC FARMING POLICY	38
1. THE CURRENT CAP IN A NUTSHELL.....	38
2. ORGANIC FARMING IN THE CONTEXT OF THE CAP.....	38
3. SUPPORT MEASURES ADDRESSING ORGANIC FARMING UNDER THE CURRENT CAP	39
3.1. Rural Development Policy	39
3.1.1. Support under Axis 1: Improving the competitiveness of the agricultural and forestry sector	39
3.1.2. Support under Axis 2: Improving the environment and the countryside	40
3.1.3. Support under Axis 3: Improving the quality of life in rural areas and encouraging diversification of the rural economy	42
3.2. Market and income policy.....	42
4. OTHER NATIONAL OR REGIONAL ORGANIC SUPPORT MEASURES	43
5. ORGANIC ACTION PLANS.....	44
6. SUPPORT MEASURES ADDRESSING ORGANIC FARMING IN THE FUTURE CAP	46
6.1. Rural development policy	47
6.2. Market and income policy.....	47
ANNEX 4: INFORMATION AND PROMOTION ON ORGANIC FARMING AT EU LEVEL.....	49
1. COFINANCED INFORMATION AND PROMOTION CAMPAIGNS.....	49
2. INFORMATION AND PROMOTION ACTIONS DIRECTLY MANAGED BY DG AGRI.....	50
2.1. Own DG AGRI campaigns through the Council Regulation (EC) n°3/2008 on information provision and promotion measures for agricultural products on internal market and in third countries	50
2.2. Via the Council Regulation (EC) n°814/2000 on information measures relating to the CAP.....	51
ANNEX 5: RESEARCH AND INNOVATION IN ORGANIC FARMING.....	52
1. EU RESEARCH FRAMEWORK PROGRAMME.....	52
2. EUROPEAN INNOVATION PARTNERSHIP 'AGRICULTURAL PRODUCTIVITY AND SUSTAINABILITY' (EIP).....	53
3. RESULTS OF THE ON-LINE CONSULTATION CONCERNING THE NEED FOR RESEARCH AND INNOVATION	54
ANNEX 6: THE EU ORGANIC PRODUCTION RULES.....	56
1. THE EU ORGANIC PRODUCTION RULES.....	57

1.1.	Definition of organic farming	57
1.2.	Scope of the legislation	57
1.2.1.	Commission report	57
1.2.2.	Identified problems	58
1.3.	General production rules	59
1.4.	Current situation regarding GMOS	60
1.4.1.	Coexistence	61
1.4.2.	Facts, figures and recommendations resulting from the autumn 2012 hearings	62
1.4.3.	Results of the public consultation	62
1.4.4.	GMO Identified issues relate to:	63
1.4.5.	Analysis of options.....	63
2.	POSSIBLE EXCEPTIONAL RULES UNDER ART 22 OF REGULATION 834/2007	65
2.1.	Overview	65
2.2.	Exceptional rules for using non-organic young poultry.....	66
2.2.1.	Legal provisions	66
2.2.2.	Issues	67
2.3.	Exceptional rules for using non-organic feed	68
2.3.1.	Legal provisions	68
2.3.2.	Issues	68
2.3.3.	Results of the public consultation	70
2.4.	The use of seed or vegetative propagating material not obtained by the organic production method	70
2.4.1.	Legal provisions	70
2.4.2.	Issues	73
2.5.	Issues with the exceptional rules allowing the use of non-organic inputs	76
2.6.	Transitional measures concerning animal housing	77
2.6.1.	Legal provisions	77
2.6.2.	View of stakeholders.....	77
3.	CONCLUSIONS.....	78
3.1.	Scope.....	78
3.2.	GMOs.....	78
3.3.	Exceptional rules.....	79
	ANNEX 7: AUTHORISATION OF SUBSTANCES AND TECHNIQUES IN ORGANIC FARMING	81
1.	CURRENT SITUATION AND LEGAL FRAMEWORK.....	81
2.	THE PROCESS OF EVALUATION OF SUBSTANCES AND TECHNIQUES ...	83
3.	ISSUES	84
4.	CONCLUSIONS AND OPTIONS	84
	ANNEX 8: LOGO AND LABELLING	86

1.	GENERAL RULES ON LABELLING OF ORGANIC PRODUCTS.....	86
2.	AWARENESS OF THE EU LOGO, CONFUSION ASSOCIATED WITH MULTIPLE LOGOS	88
3.	INDICATION OF THE PLACE OF FARMING: COMPLEX BUT IMPORTANT FOR CONSUMERS	92
4.	THE ISSUE OF DOUBLE LABELLING OF COUNTRY OF ORIGIN	92
5.	COMPLEXITY OF THE LABELLING OF ORGANIC PROCESSED PRODUCTS	93
6.	POLICY OPTIONS	93

ANNEX 1: THE ORGANIC SECTOR IN THE EUROPEAN UNION

This Annex aims at describing the most important indicators on the organic farming sector, notably the land area under organic cultivation and the number of operators (holdings, processors and importers). A short description of the EU organic market is also presented. When possible the available data is presented on a 10-year period, from 2000 to 2010 (or 2011 when available).

The source for the data is mostly Eurostat (annual survey and farm structure survey). The market analysis is based on data from "The world of organic agriculture statistics and emerging trends 2013" (FIBL and IFOAM) and on a study from the Organic Monitor¹. The source of the data on aquaculture is mostly from the study on "The current status and future perspectives of European Organic Aquaculture"².

In 2011, more than 9.6 million ha³ were managed organically by more than 235 000 organic producers in the EU⁴. Every year the organic land area has increased by 500 000 ha on average since 2000. In 2011, the organic land area in the EU represented 5.4 % of the total agricultural area.

The total value of the EU organic market was approximately 19.7 billion euro in 2011 with Germany being the biggest market in the EU followed by France, the United Kingdom and Italy.

¹ Organic Monitor: the Global Market for Organic Food and Drink: business opportunities and future outlook (3rd edition, 2010, www.organicmonitor.com)

² Zubiaurre C, 2013, The current status and future perspectives of European Organic Aquaculture. *Aquaculture Europe* 38 (2), pp14-21 (Based on MSc study University of Barcelona in conjunction with the European Aquaculture Society).

³ Estimation based on Official Eurostat data, the 2011 figures were missing for IE, CY, LU, thus their available data was used from 2010.

⁴ Estimation based on Official Eurostat data, the 2011 figures were missing for IE, CY, LT, LU, and UK, thus their available data was used from the previous year.

1. STRUCTURAL INDICATORS ON THE ORGANIC SECTOR

1.1. Area

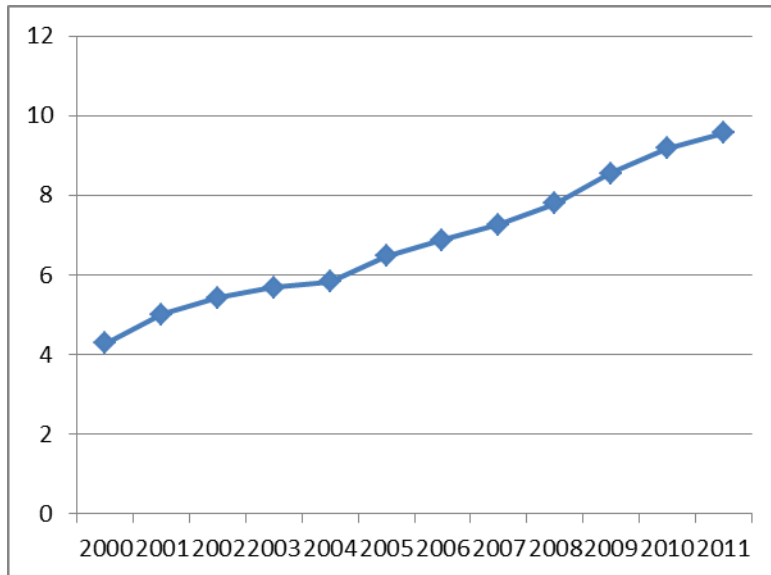
1.1.1. Utilised Agricultural Area (UAA)

The area under organic agriculture has increased significantly in the last years. In the period 2000-2011, the total organic area has increased from 4.3 to an estimated 9.6 million ha (6.7% yearly growth on average).

In absolute terms, the MS with the largest areas in 2011 were Spain (1.8 million ha), Italy (1.09 million ha), Germany (1.01 million ha), France (977 000 ha) and the United Kingdom (638 000 ha). These countries together represent 57% of the EU organic area.

Graph 1 shows the regular increase in the total EU organic land area between 2000 and 2011⁵.

Graph 1. Area under organic cultivation in the EU (million ha) between 2000 and 2011

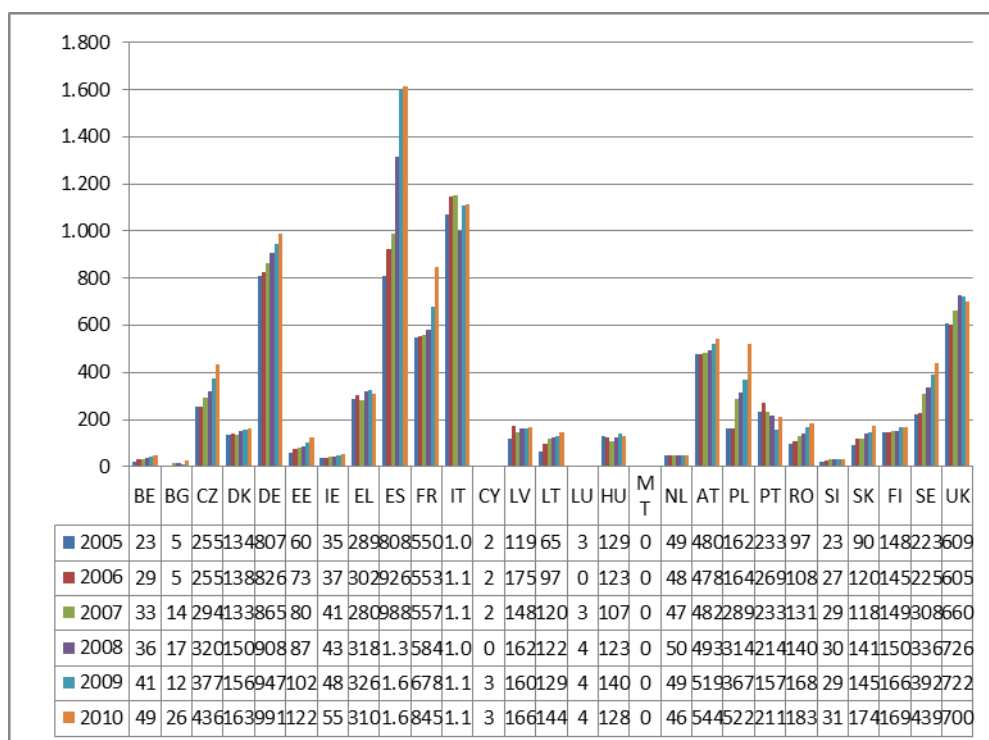


Source: Eurostat

Graph 2 shows the evolution of the organic area at MS level over the period from 2005 to 2010. Most MS and in particular the Czech Republic, Germany, Spain, Poland, France and Sweden, have shown a strong growth in the area of organic farming, while in others like Denmark, Estonia, Lithuania the organic farming area has grown to a lesser extent. Only a few countries did not experience any growth on the same period.

⁵ Total organic land area (ha) (certified and in-conversion area) - total area, including Arable land crops, Permanent grassland (pastures and meadows), Permanent crops, Fallow land as part of crop rotation

Graph 2. Evolution of the organic area (certified organic + in-conversion) in the MS in thousand ha from 2005-2010

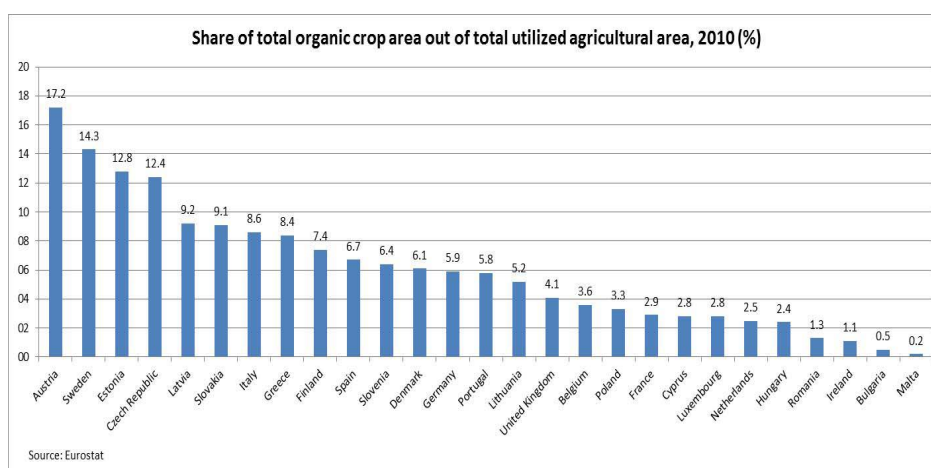


Source: Eurostat (no data for Malta)

1.1.2. Share of organic area

Graph 3 shows that in 2010, Austria with 17.2% was the MS with the highest share of organic land in the total UAA. Sweden followed with 14.3%. Estonia and the Czech Republic had 12.8% and 12.4% respectively. In 13 MS the share was below the EU average (5.4%).

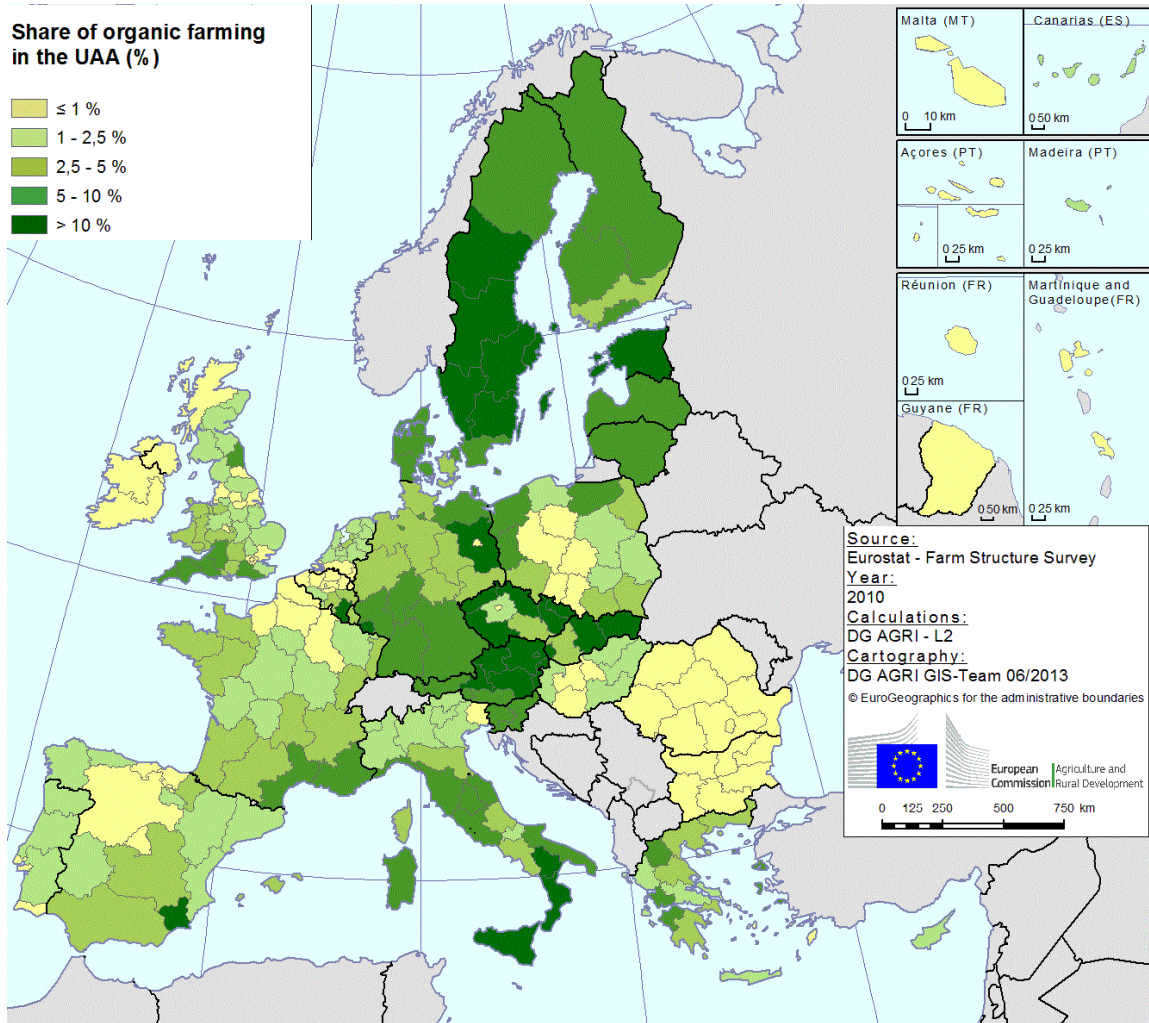
Graph 3. Share of the organic area in the UAA in the EU in 2010 (%)



Source: Eurostat

Graph 4 shows the share of organic agricultural area in the total utilised agricultural area (UAA) at regional level. The highest shares in 2010 were recorded in regions of Austria, Sweden, Estonia and the Czech Republic, which is consistent with the results at national level.

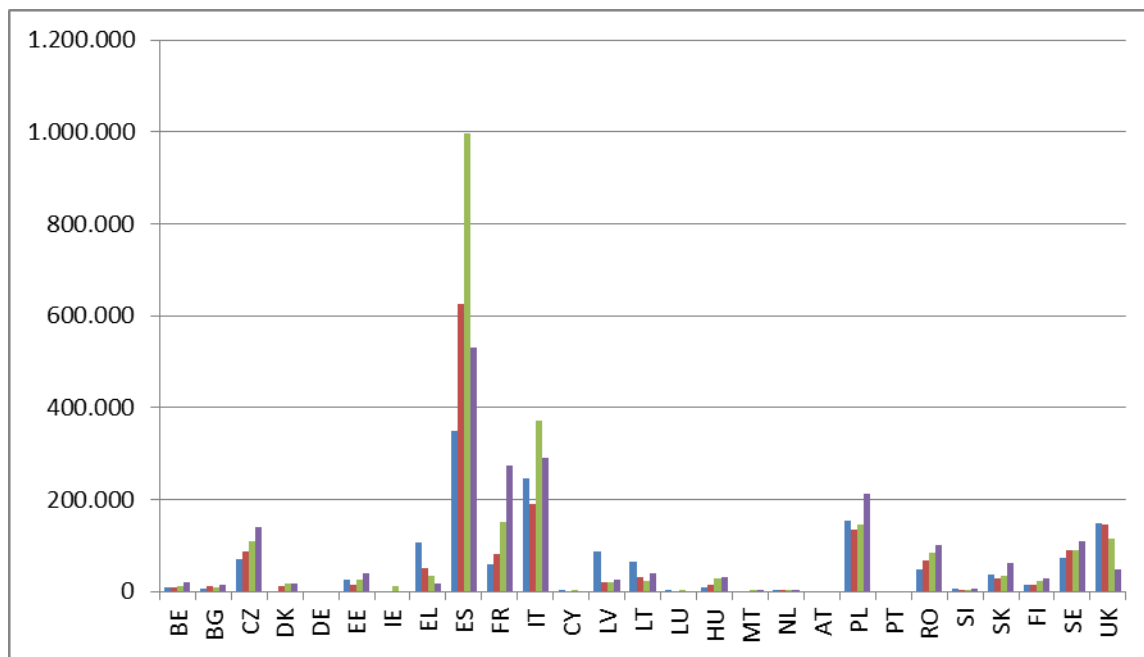
Graph 4. Share of the organic area in the UAA in the EU at regional level, 2010 (%)



Source: Eurostat – Farm Structure Survey

Graph 5 shows the dynamics of the development of the sector with estimates of the area which enters annually the in-conversion process in the organic farming sector⁶. The MS with the highest land share converted to organic was Spain followed by Italy, France and Poland. Over the period 2007-2010 the area entering the sector each year increased, with a notable acceleration in 2008.

Graph 5. Estimated annual area entering the in-conversion process in the EU (ha) between 2007 and 2010



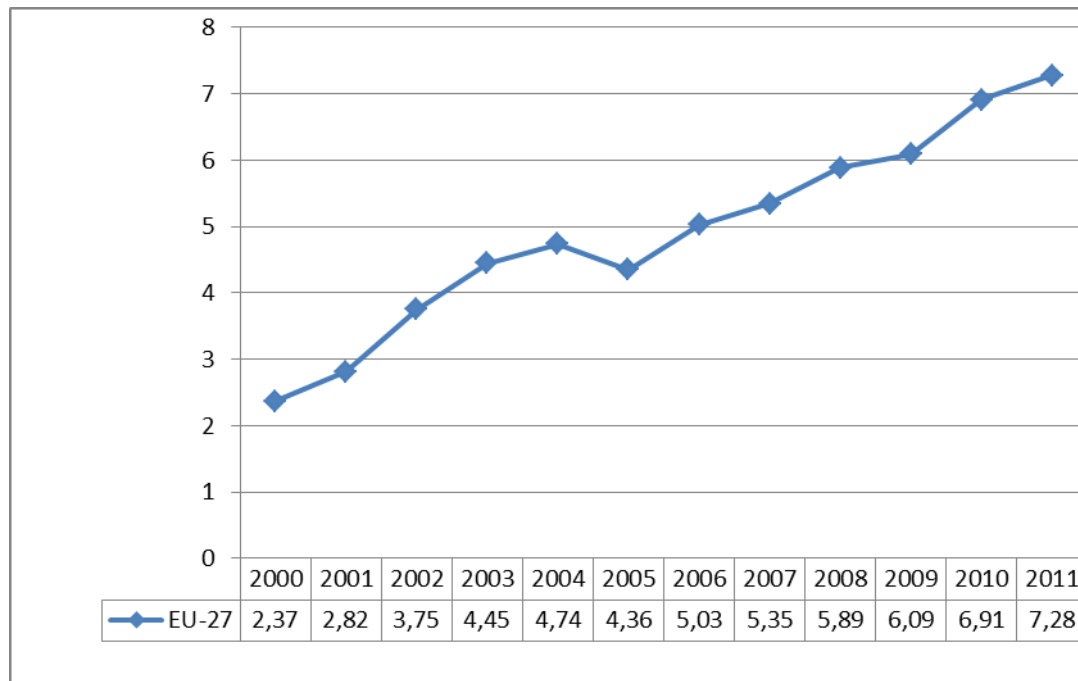
Source: Eurostat

⁶ Conversion means the transition from non-organic to organic farming within a given period of time, during which the provisions concerning the organic production have been applied (Article 2 of Council Regulation (EC) No 834/2007)

1.1.3. Size of organic crop area

Graph 6 shows that since 2000 the organic crop area⁷ has been growing rapidly, it increased from 2.3 million ha in 2000 to 7.2 million ha in 2011. Despite the drop in 2005, the overall growth was higher than the growth of total land under organic cultivation (see Graph 1). The missing data of France for 2005 has caused the drop in the territory of certified organic crop. The missing figure for France is close to 0.5 million ha.

Graph 6. Certified organic crop area in the EU in million ha



Source: Eurostat

⁷ Crops are arable crops (cereals, protein crops, root crops, industrial crops, fresh vegetables, forage plants and other arable land crops) and permanent crops (fruit, berries, citrus fruit, olives, vineyards and other permanent crops).

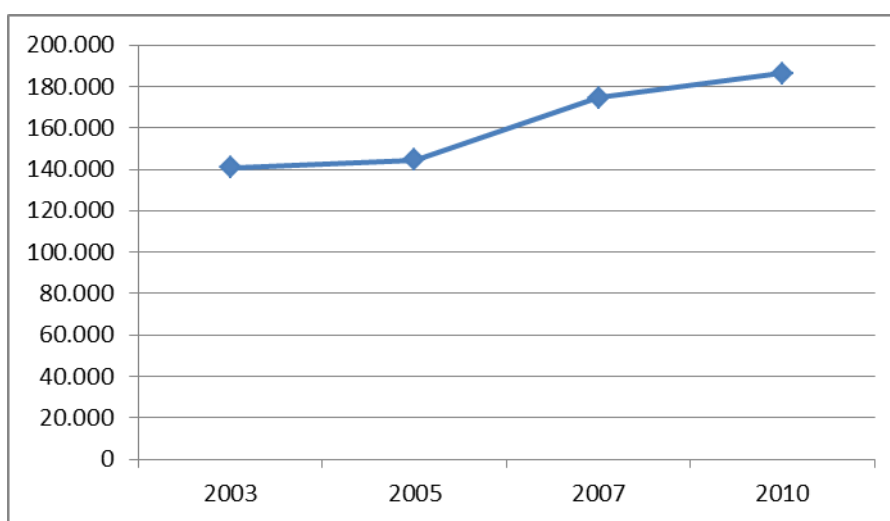
1.2. Organic holdings

1.2.1. Number of organic holdings

The number of organic holdings was estimated at almost 200 000 holdings in 2010 in the EU, which represented 1.55% of the total number of farms. At MS level, the share varied between 0.3% in Romania and 14.4 % in Austria. The share of organic holdings has increased in most MS since 2003⁸.

Graph 7 shows the steady growth in the total number of organic holdings since 2003. It has increased from 140 900 to 186 250 from 2003 to 2010.

Graph 7. Total number of organic holdings in the EU including in-conversion farms (2003, 2005, 2007 and 2010)



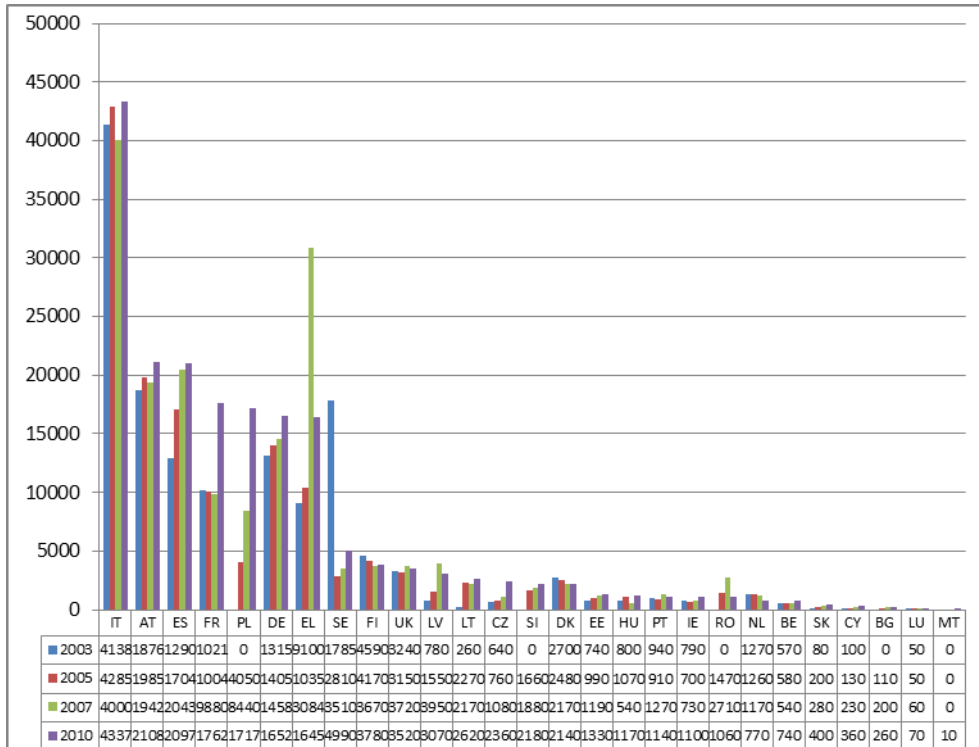
Source: Eurostat

The highest number of organic holdings is to be found in Italy (43 370) followed by Austria (21 080), Spain (20 970) and France (17 620).

Graph 8 shows the evolution of the number of agricultural holdings in the MS between 2003 and 2010. Poland experienced higher growth than any other MS in absolute number between 2007 and 2010, with 8 730 new organic holdings. The evolution of the sector can be linked to different factors, one of them is the support measures provided to the sector, which explains the number of organic holdings has grown exponentially. Due to the benefits of the support measures higher number of farmers started their organic operation than before. Such is the case in Greece for example: organic holdings have trippled between 2005 and 2007, but later halved in 2010. Another factor that explains the evolution is the better environment offering services, vocational training and research. Such is the case in Austria and Germany where steady growth of the number of organic holdings was registered. In parallel, the share of organic holdings in the total number of agricultural holdings increased from less than 1% in 2003 to 1.55% in 2010 (see Graph 9).

⁸ An analysis of the EU organic sector, June 2010 European Commission, DG for Agriculture and Rural Development

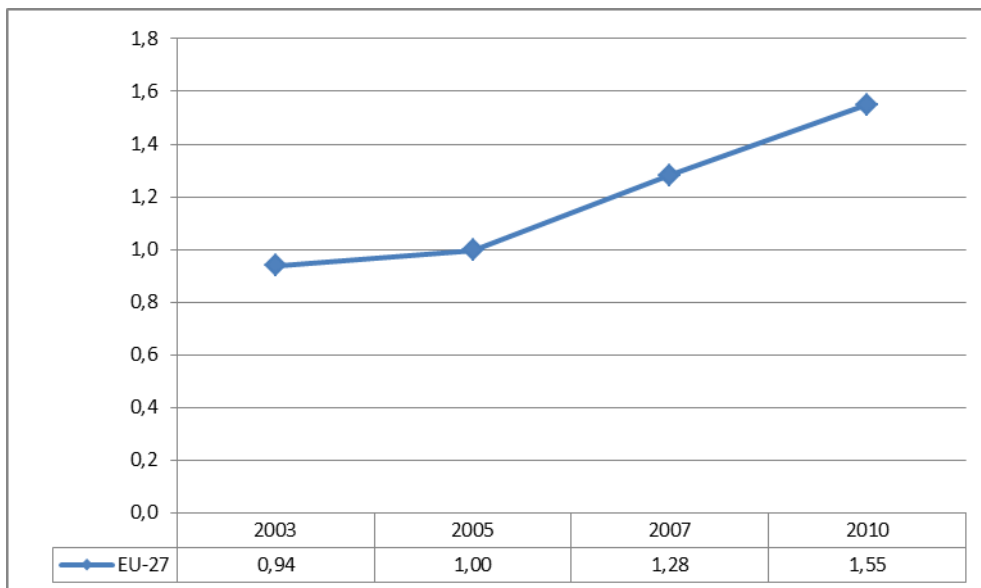
Graph 8. Evolution of the number of organic holdings in the MS (2003, 2005, 2007, 2010)



Source Eurostat. Data is not available for some countries for some years

1.2.2. Share of organic holdings

Graph 9. Evolution of the share of organic holdings in total agricultural holdings in percentage



Source: Eurostat

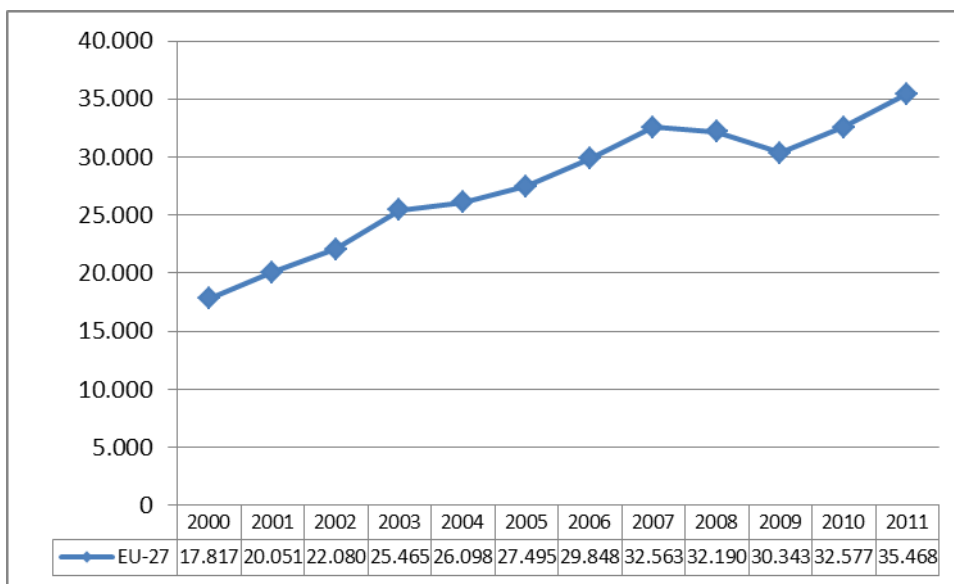
1.3. Organic operators

1.3.1. Registered processors

The number of organic processors in the EU almost doubled in the last decade, from less than 18 000 in 2000 to around 35 500 in 2011 (data are not available for all MS). The number has been growing steadily with a slight drop in 2008 and in 2009 (see Graph 10). The reason might be the slowdown of the world economy or simply a lack of sufficient data for certain countries such as France and Austria.

The number of processors has increased significantly in some MS, like Germany (from 5 571 in 2003 to 8 905 in 2011) or the Czech Republic (from 109 in 2003 to 422 in 2011).

Graph 10. Evolution of the number of processors of organic products between 2000 and 2011 in the EU

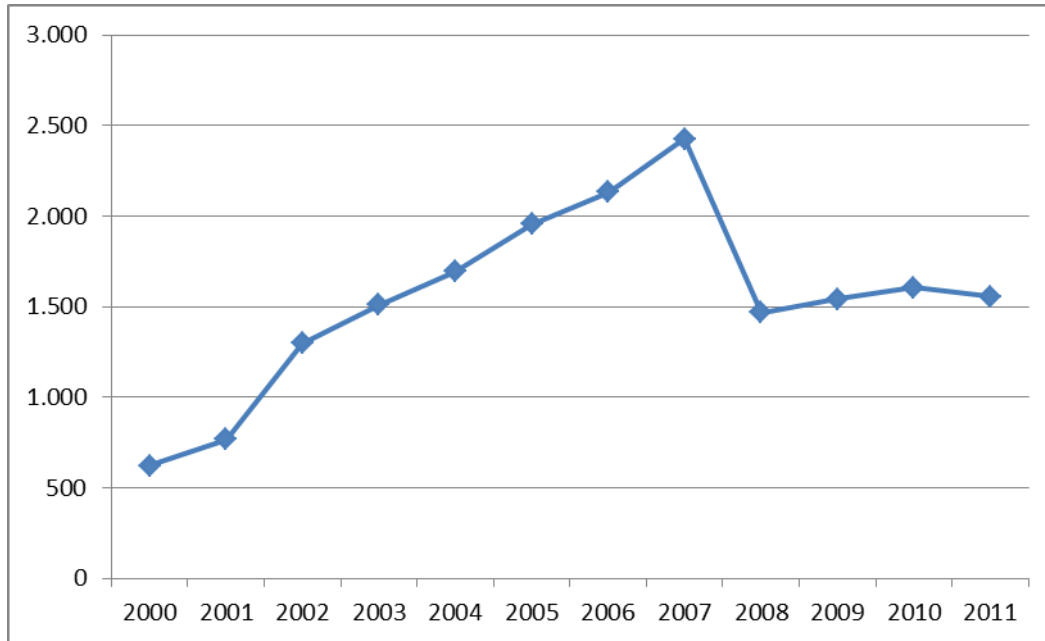


Source: Eurostat (for some years the figures for previous year were applied)

1.3.2. Registered importers

Almost 1.600 organic importers were registered in the EU at the end of 2011 compared to 623 in 2000. Their number increased steadily until 2007 (2.427), but then sharply decreased in 2008 (1.466), as shown by Graph 11. However the data is difficult to analyse because it is incomplete. Similarly to the case of processors, the data of registered importers was missing entirely for some relevant importers such as Austria and France. For Germany the number of importers has sharply fallen from 826 to 242 from 2007 to 2008.

Graph 11. Evolution of the number importers of organic products between 2000 and 2011 in the EU



Source: Eurostat

2. ORGANIC AQUACULTURE

Organic aquaculture is a relatively new sector and EU implementing rules have only applied since 1 July 2010. Data available from Eurostat is quite limited; with 12 MS providing replies in 2010 and 10 in 2011. Most replies relate only to the total number of production units, which averaged 75 in total over this two year period. Salmon and trout are the largest sectors at present and EU production of organic salmon was an estimated 12.540 tonnes in 2012, which was 7.8% of total production. Ireland is the largest producer of organic salmon (9.600 tonnes) followed by the UK (2.940 tonnes). EU production of organic rainbow trout was an estimated 1.717 tonnes in 2012 (in France, Denmark, Ireland and Poland), which was 0.9% of total. Combined organic seabass and seabream production in the EU and Croatia in 2012 (Greece, France and Croatia) was an estimated 1.614 tonnes, an estimated 0.9% of total. Data for organic carp production is not available. Organic shellfish production had commenced since the EU rules were introduced in France, Ireland and the Netherlands. Ireland produced 5.200 tonnes of organic mussels in 2012. France has an estimated 18 organic shellfish units and nine organic seaweed units. There are significant imports of organic aquaculture products from outside the EU.

3. THE EU ORGANIC MARKET

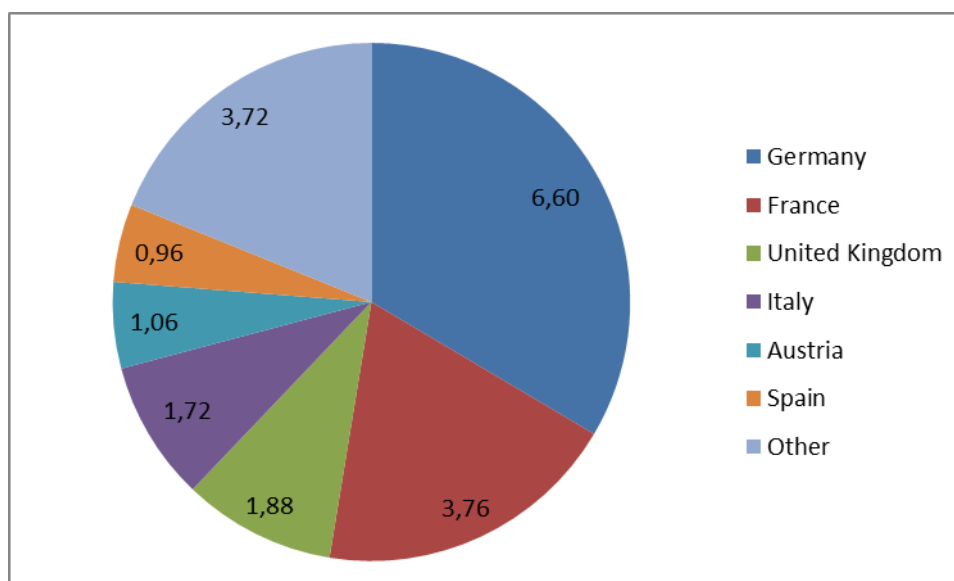
3.1. General aspects

The EU market for organic food products was valued at 19.7 billion euro with a 9% growth rate in 2011. The EU market is the second largest in the world behind the US, home to some of the leading organic food companies.

The financial crisis had a negative impact on many European economies, reducing consumer purchasing power and raising unemployment. After reporting healthy growth rates for several years, revenue growth slowed to 3.5 % in 2009. The German organic market reported a slight contraction, mainly because of lower prices of organic products. Other organic food and drink markets, especially those in France, Sweden and the Netherlands, showed double-digit growth in 2009. The UK market for organic food experienced a 14% contraction in 2009 as consumers curtailed expenditure and retailers rationalised their organic product ranges. The above figures of 2011 prove that the market has regained its healthy growth.

The by far largest organic market in the EU was Germany with 6.6 billion euro in 2011. France held the second place with 3.8 billion euro. This market showed one of the most dynamic growth rates in the past couple of years. The UK organic market is estimated at 1.9 billion euro, while in Italy it is 1.7 billion euro.

Graph 12. The largest organic food markets in the European Union in billion euros



Source: Eurostat and FiBL

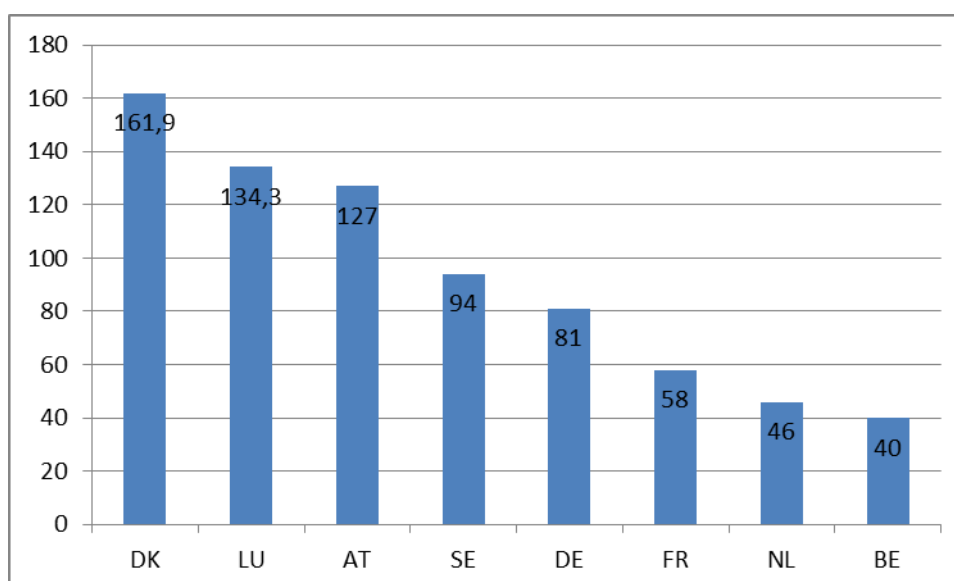
The current organic supply and demand situation in EU MS is also reflected in the numbers of processors and importers, which are mainly located either in countries characterised by a large organic market, a large organic area or both.

The market growth rates are expected to recover as the European economy strengthens. The European organic market is projected to post 7.2% compound annual growth rate, with revenues reaching 30.5 billion euro in 2016⁹.

3.2. Consumer behaviour

Consumer behaviour can provide indication on the outlook of the market for organic farming products. Sales per capita in the MS were particularly high in Denmark (162 euro), Luxembourg (134 euro), Austria (127 euro), Sweden (94 euro) and Germany (84 euro). Domestic sales are low in Poland, Romania and Hungary despite the fact that these MS are important producers of organic crops, therefore the production is not intended for domestic consumption.

Graph 13. The 8 highest consumption of organic products per capita (annual per capita consumption in euro)



Source: FiBL

In terms of consumer behaviour, a common characteristic in many European countries is that a small consumer base is responsible for most organic food purchases. In Germany and the UK, researchers found that less than 10% of consumers comprise the bulk of organic food sales. Similar observations are made in other countries like France, Italy, Belgium and Finland¹⁰.

4. CONSUMER CONFIDENCE IN ORGANIC PRODUCTS

The organic market has built on consumer confidence. This part summarises research results on consumer confidence in organic products, which show that consumer confidence is higher with strict production rules and control procedures:

- The CERTCOST¹¹ project highlighted that "consumer trust is a crucial issue in the market for organic food, since consumers are not able to verify whether a product is an organic product,

⁹ The Organic Monitor 2010

¹⁰ Ibid

¹¹ The full set of reports from the CERTCOST projects is available at www.certcost.org

not even after consumption. An instrument to gain consumer trust is third-party certification of the supply-side".

- According to Jahn et al.¹², "under asymmetric information, process-oriented quality characteristics such organic farming, animal welfare, or fair trade raise the question of mislabelling. In the long run, only a reliable control procedure can reduce the risk of food scandal" and "not fully credible standards jeopardize public confidence and lead to market failure on a higher level".
- A study¹³ on a consumer survey conducted as part of the "QualityLowInputFood"¹⁴ (QLIF) research project showed that communicating specific quality attributes represents a promising marketing tool of product differentiation. In addition, a study¹⁵ conducted in five European countries concluded that defining stricter production standards could be a promising strategy for existing certification schemes to differentiate themselves from the mandatory EU logo, which indicates the pertinence of defining stricter production rules in order to raise consumer confidence.
- A study¹⁶ on the State and consumer confidence in eco-labelling conducted in Denmark, Sweden, the UK and the US suggests that public authorities should themselves engage heavily in eco-labelling, because substantial State involvement increases consumer confidence. Consumers would be more likely to trust labelling schemes where the State plays an active and visible role.

¹² The Reliability of Certification: Quality Labels as a Consumer Policy Tool – Jahn et al. *Journal of Consumer policy* (2005) 28: 53-73.

¹³ Consumer attitudes towards organic versus conventional food with specific quality attributes – Stolz et al, *NJAS – Wageningen Journal of Life Sciences* 58(2011) 67- 72.

¹⁴ <http://www.qlif.org>

¹⁵ Consumer perception of different organic certification schemes in five European countries - Janssen, M. and Hamm, U. (2011). *Organic Agriculture* 1(1):31-43.

¹⁶ The state and consumer confidence in eco-labelling: organic labeling in Denmark, Sweden, The UK and the US – Kim Mannemar Sønderkov - Carsten Daugbjerg. Department of Political Science, Aarhus University, Denmark. *Agric Hum Values* (2001) 28:507-517.

ANNEX 2: SYNTHESIS OF THE PUBLIC CONSULTATION AND OF TARGETTED STAKEHOLDERS' CONSULTATIONS

This Annex presents a synthesis of the consultations conducted for the review of the EU organic farming policy (Regulation and Action Plan).

1. CONSULTATION PROCESS

Public consultation:

The public consultation ran from 15 January 2013 to 10 April 2013 through an on-line questionnaire. Almost 45.000 replies were submitted to the on-line questionnaire. In addition, about 1.350 additional contributions have been received by the Commission.

The majority (96%) of responses to the on-line questionnaire were submitted by EU citizens, while 4% were sent by stakeholders, the majority of which were companies (57%) and industry associations and NGOs (18%). The main interests represented by the 1 827 stakeholders who replied to the questionnaire were those of farmers (48%); consumers¹⁷ (10%); processors (9%); advisory services (5%); researchers (4%); national associations (3%); traders (3%); public competent authorities/public control authorities/accreditation bodies (3%); retailers (3%); private CBs (2%); public authorities in non-EU countries (0.3%).

Citizens who replied to the questionnaire can be characterised by a relative high awareness of organic production: 83% of them declared to be regular consumers and 15% occasional consumers. The knowledge of the EU organic logo appeared to be high, with 79% knowing the EU organic logo (compared to 24% following 2012 the Eurobarometer's survey).

The respondents were asked to indicate drives for purchasing and consuming organic products. Over 80% of all questioned citizens claimed that the most important rationales behind organic products consumption were concerns about the environment (83%) as well as purity of these products with regard to GMOs (81%) and pesticide and other chemical substances residues. A considerable number of citizens' respondents also emphasized that they purchased organic products because of belief in and support for seasonal and local products (78%) as well as strong conviction that organic farming system is more sustainable than conventional (74%). Approximately 63% of the respondents considered organic foodstuffs as healthier than their conventional counterparts. About half of them underlined that they are motivated to buy organic products because organic production respect animal welfare. Besides, important reasons that encouraged almost half of the questioned consumers to consume organic products are beliefs that these goods are of higher quality (47%) and better taste (43%). In addition, 10% of private consumers, who responded to the questionnaire, consume organic products for other beliefs than these stated above.

The majority of interviewees (78%) indicated that they were prepared to pay more for organic goods. Most consumers also consider that the price premium should not be higher than 10-25 %.

¹⁷ The persons who replied on behalf of a consumer organisation are considered as consumers, while the ones who replied on personal behalf are considered as citizens.

From a geographical point of view, France was overrepresented¹⁸, with 56% of the replies, followed by Italy (15%) and Belgium (10%) (see graph 1).

The full analysis of the public consultation is published on the EUROPA website¹⁹.

In addition to the public consultation, stakeholders have been consulted in various occasions:

Hearings:

The Commission inter-service steering group has listened to 72 stakeholders in 3 hearings: experts, academics and representatives of consumers, producers, retailers, operators, processors, third countries and associations representing third countries, traders, laboratories and researchers, animal welfare organisation, presented their views and were interviewed by the Commission services. They were organised around 3 main topics:

- The EU organic market – internal market and standards - 27 and 28 September 2012.
- Organic production - Controls and Enforcement - in the EU and in third countries - 25 and 26 October 2012.
- External trade in organic products and global issues - 20 and 21 November 2012.

AGOF meetings, some of them enlarged to experts who participated to the hearings:

- 10 December 2012: presentation of the results of the hearings,
- 11 April 2013: Impact assessment analysis on the organic farming review:
 - o Presentation of the preliminary results of the public consultation on the organic farming review.
 - o Analysis of the problem and the objectives of the policy.
 - o Issues related to small farms.
 - o Consultation on policy options.
- 26 June 2013:
 - o Review of EU policy on organic farming (legislation and action plan) : information and discussion on the state of play and next steps
 - o Administrative burden and costs
 - o Consultation on the impacts of the options presented at the AGOF meeting of 11 April.

Special meeting on small farms – 26 June 2013

Issues related to small farms were on the agenda of the AGOF meeting, but the discussion proved to be limited. The Commission Services concluded that a technical meeting with experts

¹⁸ To check whether some particular sub-classes (by country, capacity, attitude, orientation etc.) could introduce bias on average results from the sample, analyses based on groups were carried out: by selecting most relevant classes no distortive effect was proved

¹⁹ http://ec.europa.eu/agriculture/organic/news_en

needed to take place in order to examine further the difficulties faced by small farms to join the organic sector.

The following experts were invited:

- Ms Diane BOWEN – IFOAM International
- Mr Edouard ROUSSEAU - COPA-COGECA
- Ms Ute EISENLOHR – IMO-Institute for Market Ecology (Switzerland)
- Mr Andrea FERRANTE – AIAB-Associazione Italiana per l'Agricoltura Biologica
- Mr Dominique MARION - FNAB-Fédération Nationale d'Agriculture Biologique des régions de France)
- Mr Michel REYNAUD – ECOCERT- Organisme de contrôle et de certification
- Mr Nabs SUMA – Fair Organics Solutions Ltd (apologies, but provided background information)
- Mr Bo van ELZAKKER - AgroEco / Luis Bolk Institute- Advice and development services for sustainable agriculture – (apologies, but sent contribution)

MS consultation

- The Irish presidency sent a questionnaire to MS in January 2013. The replies have been used for this review. In addition, MS have been kept informed on the developments of the impact assessment process and have been asked to contribute, notably on administrative costs, in SCOF meetings. They were also invited to contribute to the public consultation.

In addition, the Commission staff participated to several meetings where the review was discussed, notably to the IFOAM congress in Vilnius in June 2013.

2. MAIN RESULTS BY TOPIC

2.1. Relevance of a review of the legislation on organic farming and policy options

When the consultation process started, the main stakeholders (notably IFOAM EU and COPA COGECA) disapproved the revision process, arguing the recent adoption of the current legislation (2007) and that fundamental legislative changes could have strong negative impacts on the sector. When the discussions on options started, they supported the improved status quo option. However, progressively, most stakeholders have agreed with the need for a more ambitious review. Notably, in a letter sent on 30 December to the Commission, IFOAM EU declared that it "*clearly supports a principle driven development of the organic regulation, but emphasises that the development must ensure both increasing consumers trust and feasibility for the sector to comply with strengthened standards.*"

At the time of the public consultation, several stakeholders expressed their opposition to the review, notably the association Bio Austria.

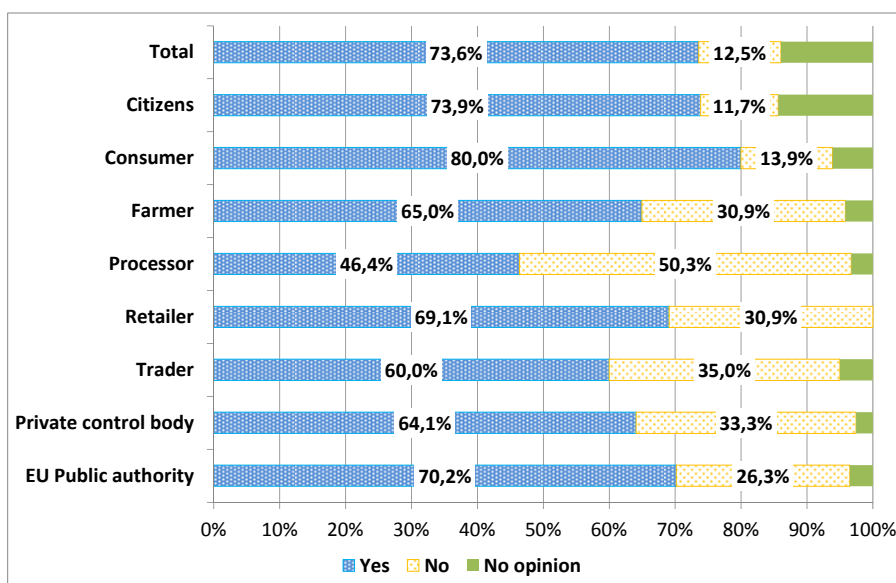
Some stakeholders supported specific options for special reasons. The market-driven option was supported by Eurocommerce and FEFAC²⁰, because feed manufacturers would like the use of 5% non-organic feed in the ratio of pigs and poultry to be permanently authorised. The association highlights that a balanced ratio contributes to animal welfare. The principle-driven option was supported by FNAB and Via Campesina, for its likely positive impact on rural development and on small farms.

2.2. Organic standard

The public consultation showed the wish for harmonised rules at EU level: 74 % of all respondents requested that the European organic standard be strengthened. Around 40% of respondents stated that this should be done by making the rules stricter and/or introducing sanctions (penalties). 22% of interviewees stated that, to make the current European standard more robust, all flexibility should be removed.

The majority of respondents (86%), from most of the countries and representing all categories of stakeholders wished to have uniformity of organic rules in all EU countries for European farmers and other operators.

Online questionnaire: should the European organic production rules be strengthened?



Several stakeholders called for further harmonisation of the legislation on organic production, in several areas notably organic poultry production and organic glasshouse production (COPA, IFOAM EU, Freshfel, Grodan, Danish Agriculture and Food Council, SYVOFA, Bio Austria).

Conversely, a few of them were of the opinion that some flexibility is needed, like Organic Denmark and Interfel. They argued that some regulatory differences can be accepted to take into account the variability of soil and climatic conditions, as well as consumer sensitivity in different MS.

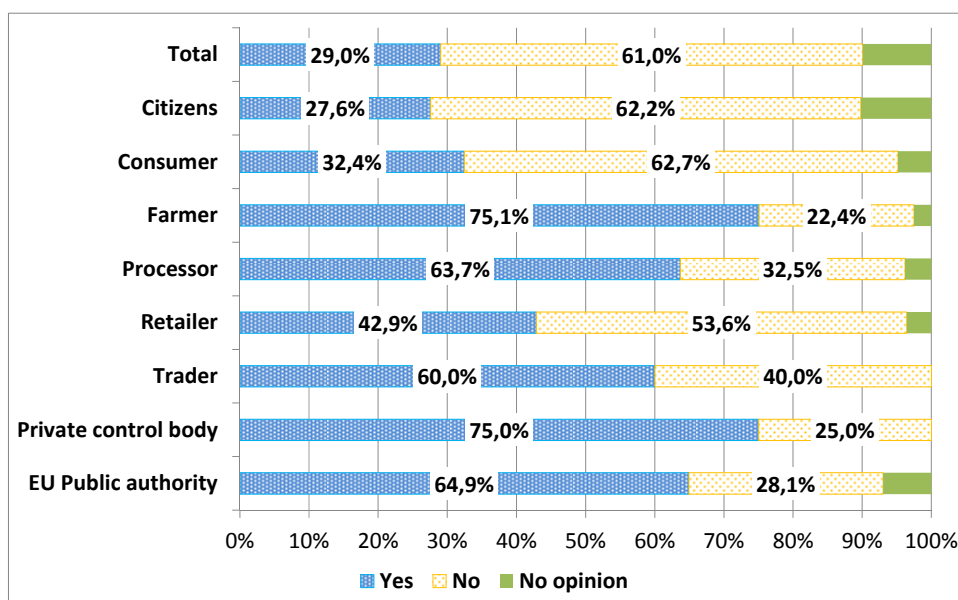
The issue of feed was addressed in the consultation. 49% of respondents stated that organic livestock should be fed with 100% feed from the farm or region. 27% of respondents opted for setting a minimum percentage of feed for organic livestock that should be from the farm or region. 16% of respondents considered that as long as feed is of organic quality, it could come from any location.

The majority of the respondents (66%) indicated that the effective solution for addressing the shortage of organic protein-rich feed in Europe is to introduce in the EU legislation, initiatives to boost European production of organic protein crops. In addition, 61% found that a specific organic protein-crop production strategy should be developed.

2.3. Exceptions and derogations

Most of the respondents (61%) were against keeping exemptions from production rules under specific conditions while allowing the certification of such products as organic. 29% of respondents were of the opposite opinion.

Online questionnaire: should the exemptions to production rules continue?



COPA COGECA was of the opinion that the conditions to grant exceptions must be strengthened and restricted, and must be limited in time. At the final stage, climatic events should be the only ground for derogations. The scheduled end of the derogations must be realistic and the timeframe must be agreed on in advance with the organic farming sector, in order to adapt. ERPA illustrated this issue with the example of poultry and eggs production, where producers invest for 15 to 20 years. Installation of young farmers or the construction of a new poultry building can be envisaged only if the farmer has assurance that the organic rules will not change.

IFOAM EU recommended limiting exceptional rules only to those linked to catastrophic circumstances by phasing out and/or converting them in transitional rules or transparent permanent rules in the new organic regulation. The movement indicated that on many issues, such as seeds & propagation material or protein feed, the regulation alone cannot deliver complete and effective solutions. The support of horizontal policies, further investments and provision of resources and the efforts of organic producers would be needed to ensure real

progress. A new Organic Action Plan could include measures supporting research and investments in the organic sector. According to IFOAM EU, exceptions can be classified under:

1) Current exceptions to be deleted or converted to transitional rules:

- **Use on non-organic animals**
- **Use of non-organic protein feed** of plant and animal origin for livestock (request to prolong status quo until 2018, then review; to limit the exceptions to piglets up to 35 kg, young pullets and chicks; 100% organic feed remains the final aim)
- **Addition of non-organic yeast extract** (not necessary any more)

2) Current exception to be converted to permanent rules in the future Organic Regulation

- **Tethering of animals** (The largest part of tethering systems will disappear in organic farming due to the end of the transitional rules referred to in Art. 95(1) of Regulation (EC) No 889/2008. IFOAM EU recommends to keep and convert into a permanent rule the exemption laid down in Article 39 Regulation (EC) No 889/2008 for small operations. Progress is possible in the major part of organic production whereas some small traditional structures could not be able to move towards a new system since e.g. the stables are in mountainous locations where structural modifications are not possible).
- **Parallel Production** (exceptions for research and educational aims, for production of seeds, propagating material and transplants and for grazing grassland are considered still meaningful and concern only specific production areas).
- **Management of beekeeping units** for the purpose of pollination and use of non-organic beeswax (these two exceptions are considered still critical for the honey production sector. Pollination is in fact a specific and essential practice of beekeeping and the exception is still needed. The use of non-organic beeswax exclusively for the conversion period should stay provided that the possibility to use non-organic beeswax is linked to very restrictive conditions.)
- **Specific management problems in organic livestock** (exception regarding the final fattening period exclusively for bovines is connected to the climatic conditions in many European regions and should be integrated).

3) The specific case of seeds and vegetative propagation material

- The deletion of possible exceptions to use non-organic seeds or propagating material could have an immediate negative impact on the sector, because the availability of sufficient amount of organic seed and vegetative propagating material cannot be ensured in the near future. **However, the organisation recommended using the current revision process to make further progress** in order to reduce the number of authorisations granted by MS, notably by exploring the feasibility of national lists of varieties for which exceptions are not possible. A new Action Plan is seen as essential to provide tools to encourage "organic breeding and multiplication activities as well as research for this purpose".

Possible inconsistencies with other policies, notably CAP cross compliance, were mentioned.

WECF would like to see a limited number of derogations, where it is about a living organism the supply of which is not sufficient in organic form (seeds).

According to Euro Coop, organic farming should mainly make use of organic seeds and traditional varieties of seeds developed in specific local conditions. Considering that during the last century, 75% of genetically diverse seeds have been lost (according to FAO), Euro Coop favours seed security and the exchange of seeds among local farmers. The promotion of seeds diversification enhances food security and preserves traditional practices.

2.4. Authorisation of substances in organic production

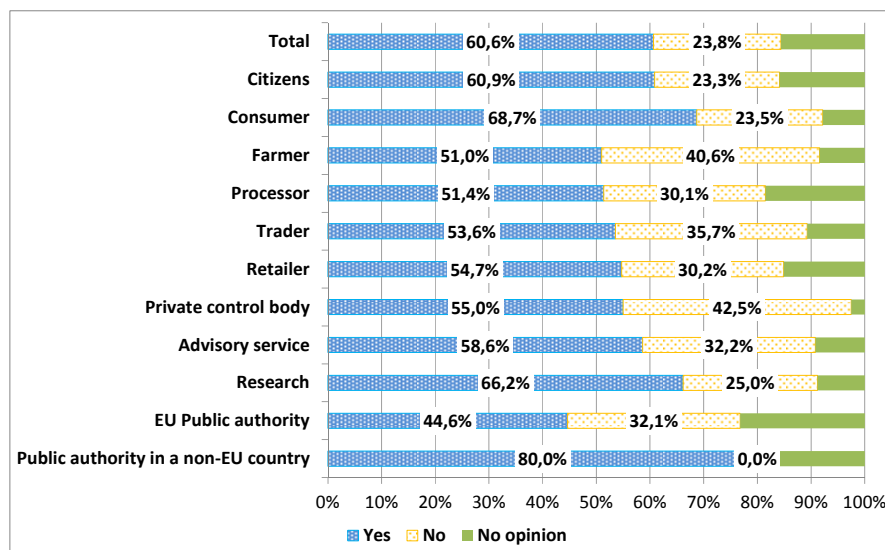
The results of the public consultation show that citizens would like strict rules to be applied in terms of authorisation of pesticides and additives in organic farming. In fact, a majority of them (respectively 73% and 67%) requested that such categories of substances should not be allowed at all in organic production. With regards to fertilizers, feed materials, processing aids and products for cleaning and disinfection, the public demanded that they are evaluated according to strict criteria.

Some organisations showed concerns on the approval of substances (Freshfel, WECF). Freshfel called attention to the lack of harmonisation at EU level in the substance authorisation process, which put at risk the functioning of the single market and the confidence of operators and consumers. A strict procedure for authorising substances (regardless of the substance, from fertilisers to processing aids) is recommended, with rules equally applicable across Europe. Interfel suggested the authorisation process to be fully part of the legislation on organic farming.

2.5. Sustainable use of energy and management of environmental impacts

With regard to environmental performance, a large number of respondents (61%) to the public consultation requested the enforcement of an obligation for processors and traders to implement an EMS to measure and evaluate their environmental performance and impacts in addition to other European requirements.

Online questionnaire: do you think that producers and traders should be required to implement an EMS to measure and evaluate their environmental performance and impacts?



IFOAM EU recommended obliging processing and trade companies to implement an EMS. Farms and possibly small operators should be exempted. In a first step a primary simple EMS should be put in place by operators involved in processing and trading activities, based on the EMAS structure. IFOAM EU clarified that consumer expectation was not the only driver for this proposal, since one objective was also to avoid that the Eco-Label extends its scope to the food and drink sector.

This proposal was supported by several stakeholders, like the Bund Ökologische Lebensmittelwirtschaft, according to which *"consumers expect that the production of organic food is sustainable at its whole. Therefore organic food processing could not only be defined by ingredients and processing methods. Operators have to improve their environmental performance too."* BEUC indicated its support for the inclusion *"of more sustainability and environmental criteria (climate, packaging, transportation etc.) in the criteria for organic production, so that organic products with no doubt is the most environment-friendly choice"*.

Other organisations called for a cautious approach in the implementation of an EMS, notably ERPA, according to which implementing an EMS would be very difficult for small organic farmers and it would provide dissuasive administrative burden. It considered environmental performance as the result of organic production standards. WECF agreed with the introduction of EMS, if the application is balanced and realistic.

2.6. Animal welfare

In the public consultation, more than 60% of respondents strongly insisted on strengthening animal welfare standards for all types of agricultural production systems. A third of respondents (34%) underlined that organic farmers should be obliged to comply with specific rules for animal welfare and 23% considered that animal welfare standards in organic farming should systematically be higher than in conventional farming.

IFOAM EU agreed there is still room for improvement in certain kind of organic livestock production. COPA COGECA was the opinion that more harmonisation in the way animal

welfare standards are interpreted in MS is necessary in order to avoid unfair competition among producers, notably in the organic poultry meat production sector.

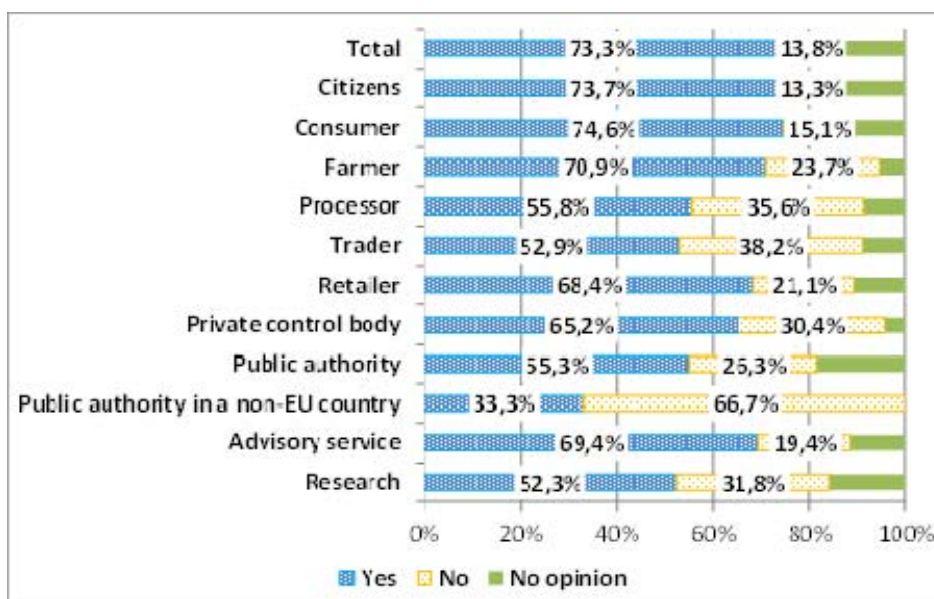
Detailed requests and opinions of animal welfare organisations are presented in Annex 14.

2.7. GMOs

More than 90% of the respondents to the online consultation, from almost all countries, representing all groups of stakeholders as well as regular and occasional organic goods' consumers stated that 'organic', by definition, means 'GMO-free' and is a critical reason for purchasing these products. This was corroborated by a high number of free contributions from EU citizens.

The majority of respondents (68%), from all represented countries and also all types of consumers irrespective of the regularity of their consumption of organic products (70-80%), supported having the same labelling rules for organic products as for conventional products with regards to GMOs.

Online questionnaire: should the labelling threshold for accidental presence of GMOs be lower than for conventional products?



While recalling that organic farming does not allow the use of GMOs, COPA COGECA stated that an accidental GMO contamination in organic products can never be completely ruled out. The threshold of the adventitious presence of GMOs set out in horizontal legislation was determined based on an analysis of potential risk and an economic analysis. The producers do not see a justification to establish different thresholds for different production systems. IFOAM EU stated that, while such a threshold would not solve the problem, it would imply even higher costs for testing and certification on organic producers, while not significantly changing the situation for consumers. These views were confirmed by the contribution from the European Plant Science Organisation (EPSO). Euro Coop pointed out that the risk of contamination of organic products by GMOs is only significant in countries whose government has authorised the cultivation of GM crops on a commercial scale. In such countries, organic farmers run the risk of having their crops contaminated through cross-pollination, with possible heavy economic consequences.

Some organisations requested a lower GMO threshold for organic products: Interfel, WECF (but for all products including conventional), SYNABIO (a lower threshold for organic products for food (0.1%) while keeping the current threshold (0.9%) for organic feed products).

EUROPABIO had opposite views and stated that the incompatibility of GM and organics is unfounded. Provisions included in Council regulation (EC) No 834/2007 were qualified as "ideological statement". Certain GM crops would be able to fulfil the organic requirements very well, like the insect resistant GM crops which require less insecticide spraying.

2.8. Labelling, organic logo, confusion with other logos and Eco-label

The European organic logo was well-known by the public that took part in the public consultation (79%), irrespective of the country of origin or category of stakeholders. The majority of all respondents regardless of the regularity of their consumption of organic products indicated that the two main ways to recognise an organic product was the presence of the national organic logo (66%) and of the European organic logo (66%). In addition, a large number of respondents claimed that they purchase organic products directly from an organic producer without any kind of packaging or labels or by finding the word "organic" on the label.

The issue of confusion of logos, first of all with national and private organic logos, was highlighted by several stakeholders. According to BEUC, *"the ideal would be to have ONE label = the EU Label, and we should work towards that. But for the present market situation, trust in national organic labels is so high that we need them as well for the coming years."*

FRESHFEL also warned against the confusion of labels and pointed out the proliferation of "quality" logos, besides the already large range of private brand logos available on the market and informing consumers (PGI, PDO, Fair Trade or even in the future possible logos for European promotion schemes or for "local" products). According to FRESHFEL, *"a proliferation of logos is bringing more confusion to consumers or dilutes the efficiency of the message. A clear logo and the indication of the word organic work best for the identification of organic produce on the market despite that at retail level, organic fresh produce are often confined in a specific section of the supermarket shelf. Some of our members call for a simplification of the logo obligation and one should avoid a double labelling obligation."*

MS representatives in the Council showed deep concerns about the confusion of the organic scheme with other labels, **notably with the Eco-Label**. Spain declared: *"We detected incompatibilities between the EU regulatory framework on organic farming and Regulation (EC) No 66/2010 (...) on Eco-Label. We consider it was not appropriate to extend (...) its scope to food and drinks, although it has not been applied yet. The main reason is that we consider this term incompatible with the term reserved to organic farming..."* and Ireland: *"The organic label based on a robust control system is the core basis of consumer guarantees and confidence in the system. It is important that the labelling of organic products is unambiguous and such that it is not confused with other labels e.g. Eco-Label (...) The premium price of organic products attracts unscrupulous operators whose fraudulent activities completely undermine the sector."*

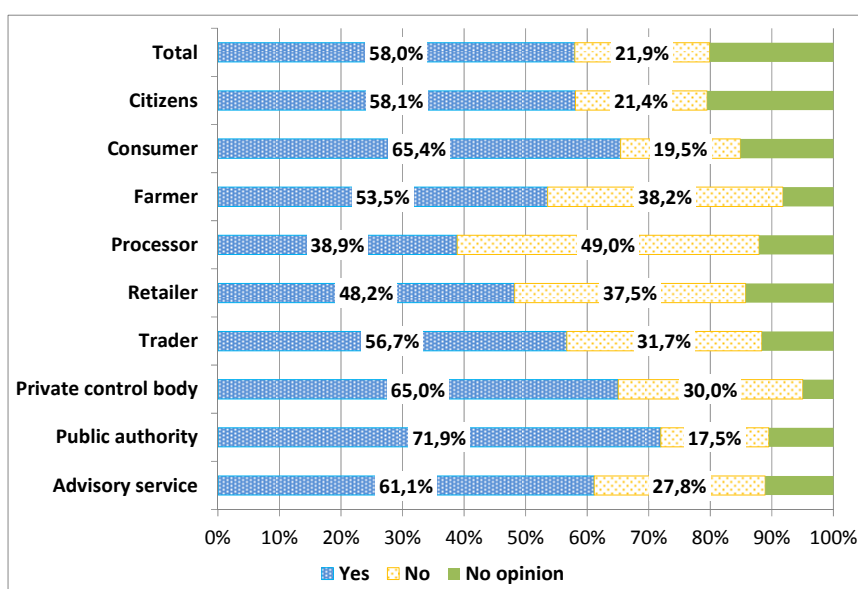
According to IFOAM EU, the use of the Eco-Label on the labelling of organic products would lead to food products labelled with EU organic leaf and/or Eco-label logo and would lead consumers into confusion and to the idea that organic is not environmental-friendly. This was supported by the Bund Ökologische Lebensmittelwirtschaft, which recommended *"defending organic labeling as a labeling of an integrated sustainable system against consumer misleading labels as Eco-label, Animal Welfare, Origin Labeling"*.

2.9. Improvements in the control system

Consumers trust organic products and insist on efficient controls: 71 % of all respondents to the online consultation, from almost all countries, and representing almost all categories of stakeholders as well as regular and occasional consumers of organic products indicated that they trust organic products.

However, more than half of the interviewees (58%), from almost all countries strongly required to improve the European control system for organic products even if it means an increase in prices. The vast majority of respondents (more than 70%), opted for two improvements, namely better controls on imported organic products and at all levels of the production chain. 50% of the respondents are in favour of the creation of a European database listing all certified organic operators in Europe. More than one third (i.e. 37% of the respondents) were in favour of the development of electronic means to ensure traceability.

Online questionnaire: should the control system of organic products sold in Europe be improved?



The most consensual suggested improvements to the control system in the free contributions from stakeholders were: better exchange of information on cases of non-compliance, more harmonisation among MS, more supervision by the Commission (regular audits), implementation of electronic certification (at least for imports), a harmonised system of sanctions and adequate controls on imported products.

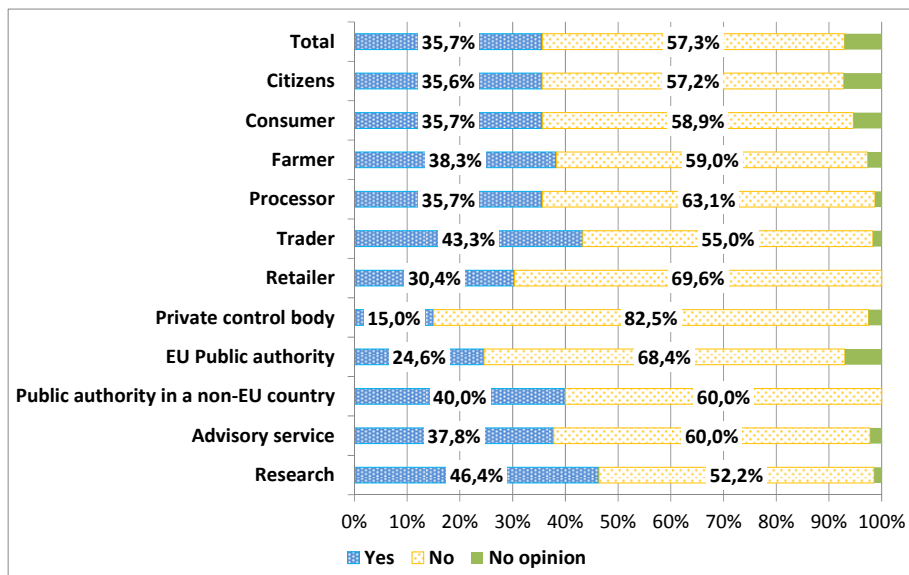
2.10. Move towards a risk based approach in the control system

In the public consultation, half (22269) of the respondents knew, but the second half (22577) did not know that organic operators are controlled at least once a year. There was a similar level of awareness among consumers, irrespective of the regularity of their consumption of organic products.

The majority of respondents (57%) disapproved the idea of lowering the number of inspections for organic operators with a proven track record of abiding to the rules. To the contrary, a

significant percentage (36%) of the respondents was in favour of a risk-based regularity of organic operators' inspections.

Online questionnaire: would you agree that organic operators with a proven track record of abiding by the rules could be inspected less often, for instance every 2 or 3 years?



Several MS declarations in the Council were in favour of a move towards a risk-based control system: *"In the process, it should be possible to implement the risk-orientation of controls more clearly."* (Germany); *"The frequency of inspections (...) may be reduced to less than one year in special circumstances."* (Italy); *"Details on the risk-based inspection should not be regulated at EU level, as the conditions and the risks accordingly vary from state to state and according to the type of operators and their produce (...) To achieve efficiency in the control system, the requirements for the annual physical inspection should be waived. This would give possibility to allocate resources for more controls among operators and products of high risks and cross-inspections."* (Finland); *"With a fully risk-based approach, the requirement for one physical inspection yearly could be deleted."* (Sweden).

The stakeholders in favour of more risk-based approach in the control system were FiBL (Research Institute for Organic Agriculture), according to which the focus should be put on 10 % of operators with risk of irregularities; the burden for compliant operators should be reduced by removing the obligation for a mandatory annual inspection. DakkS (National Accreditation Body for Germany) pointed out the need to intensify risk-oriented controls, in particular in third countries. The Finnish Food Safety Authority (Evira) considered that lowered inspection frequency should be an option for the future; additional inspections should focus on higher risk operators.

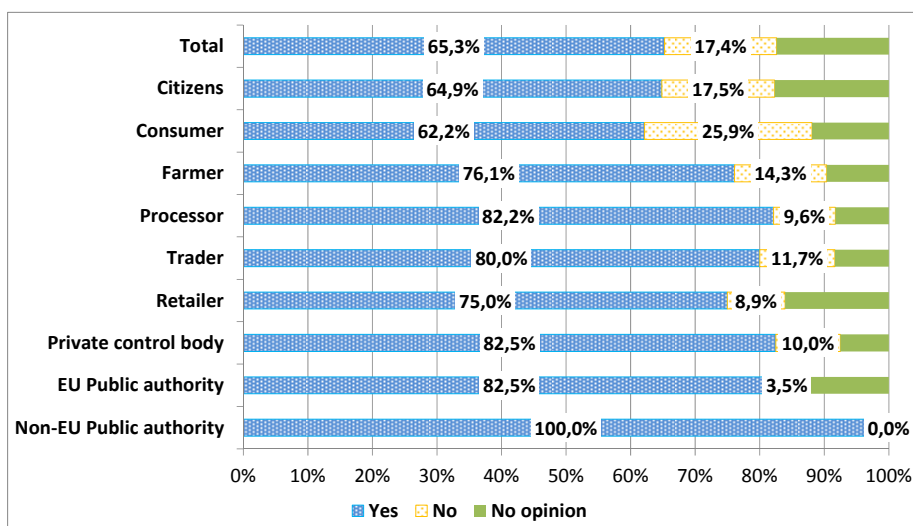
Several stakeholders expressed they would like the obligatory annual inspection to be maintained, notably ERPA, SYNALAF.

2.11. Trade with third countries

The majority of respondents (65%) to the online consultation, from all countries, representing all capacities and categories of stakeholders and irrespective of the regularity of their consumption of organic products, favoured the opening of the non-EU markets to EU organic products.

According to 72% of the respondents, the most relevant objective for the EU negotiations trade agreements for organic products was to support the development of more sustainable and eco-friendly agricultural practices in other countries. The second objective of great significance to respondents was to encourage organic farmers and other operators from developing countries to expand their production and exports of organic products (52 %).

Online questionnaire: do you agree that non-EU countries exporting to the EU should open their market to organic products produced in EU countries?



COPA has underlined that the consumption of organic products from the EU currently outstrips EU production of organic products, and today some demand is covered by imports. COPA considers important that the EU equips itself with instruments which will guarantee the development of organic production in the EU in order to meet EU consumers' demand. COPA also calls for a strategy to reach a balance between the EU and its trade partners, in order to develop export capacity of high added value EU organic products. There is a need to identify the most promising markets. Promotion campaigns would be considered an asset. IFOAM EU also mentioned that many MS are major exporters of organic processed food and feed and are interested in the new growing market. Freshfel underlined the EU has a great role to play in international organic trade, as matching demand on some markets implies trade (e.g. organic bananas on the German market are 100% imported from third countries) and indicated its support to the Commission efforts towards mutual recognition with third countries, provided trade is sustained behind the agreement on such recognition. It noted in the case of the EU-USA deal on mutual recognition that EU organic apples and pears cannot be shipped, given the lack of plant health protocols accepted by the USA. The same can be observed with New Zealand, Israel etc. where trade flows remain hindered by SPS matters preventing the export of EU fresh produce, being either conventional, IPM or organic.

Several organisations (Freshfel, FRUCOM) considered that the system of recognition of control bodies for the purpose of equivalence is a positive move towards simplification and less bureaucracy to import organic products. But "the framework needs to be matching operational perspectives and provide trust for operators". Therefore, there were calls to extend the lists of recognised third countries and recognised control bodies.

Some contributions highlighted that control costs are lower for local products than for imported products and suggested to support local products on this ground (WECF).

2.12. Controls of imported products: equivalence vs compliance and risk of unfair competition

According to several stakeholders, an effort is needed on controls on imported products. COPA COGECA stated the controls on organic products produced in third countries should be at least as rigorous as those in the EU, in order to ensure fair competition against products from third countries and to secure consumer confidence, even if that would lead to an increase in their price. It recommended paying *"greater attention to the rules on mutual recognition set out in agreements with third countries where standards are recognised as equivalent in order to guarantee that imported products adhere to production and control standards which are a strict as those for EU organic products. Greater vigilance is also essential regarding the equivalence system for control bodies for imports from non-recognised third countries where we consider that the supervision guarantees made by the European Commission are lacking."* Freshfel mentioned the need for a clear environment to create a level playing field among operators and confidence and indicated some loopholes which needed to be clarified to enhance trade opportunities (notably the aspects of cross contamination and of share of responsibilities between the Commission, MS and CBs).

Issues with imported products were reported by a representative from an informal group of importing MS, who participated in the hearings. This informal group has accumulated experience in dealing with import authorisations and has closely followed the implementation of the CB recognition system. The representative mentioned concerns over non-compliance product cases not being dealt with, problematic cases of products certified by different CBs from a non-equivalent country, cases where the correct assessment was in doubt (in one case, an inspection of a 30.000 ha operation took only two days). He also mentioned the following issues: *"Imports that arrive via a complex route under equivalent CB cause problems"/ "Multiple operators on one certificate, a lack of control over the chain of provenance, and more than one CB for one operator with little communication between them, lack of risk-based inspections at operators are major concerns."* *"Reduced conversion period is a major concern; this allows operators to move in and out of the system or to use natural forest areas without proper control, CBs wish to offer these in order to obtain customers."* *"Major operators have greater power than the CBs"*. It was recommended to concentrate on problem products such as grain, oilseeds, bananas, soya, other animal feed and other bulk products,

A trader in organic products reported in the hearings, *"Integrity of imported organic products is easily questioned and control is difficult"*. *"Residue testing is now a major identifier for the integrity of organic produce, but the results are never black and white and widely interpretable"*.

According to the French processing industry association SYNABIO, *"for processed products,.. the risk of distortion of competition is objective. It is notably linked to additive and processing aid lists, to the use of aroma ... differently handled in different standards"*.

Cases of unfair competition have been directly reported to the Commission, for instance the following reported by a CB applying the equivalence regime in third countries:

"While Regulation (EC) 889/2008, Art 36(2) (b) determines that periods prior to officially starting the conversion period may be retroactively recognised only if the respective fields "were not treated with products not authorised for organic production", and competent authorities in the EU agree that this includes the use of chemically treated seeds, the equivalent standard developed by the CB X does not require a field to undergo a new conversion period after sowing chemically treated seeds." ; "it is obvious that a farmer in the EU who has to undergo a three

year conversion period is subject to very significant economic disadvantages compared to farmers in third countries who have to undergo only a one year conversion period". "...each certification body is under continuous pressure to downgrade its "equivalent" standard, in order to avoid losing clients".

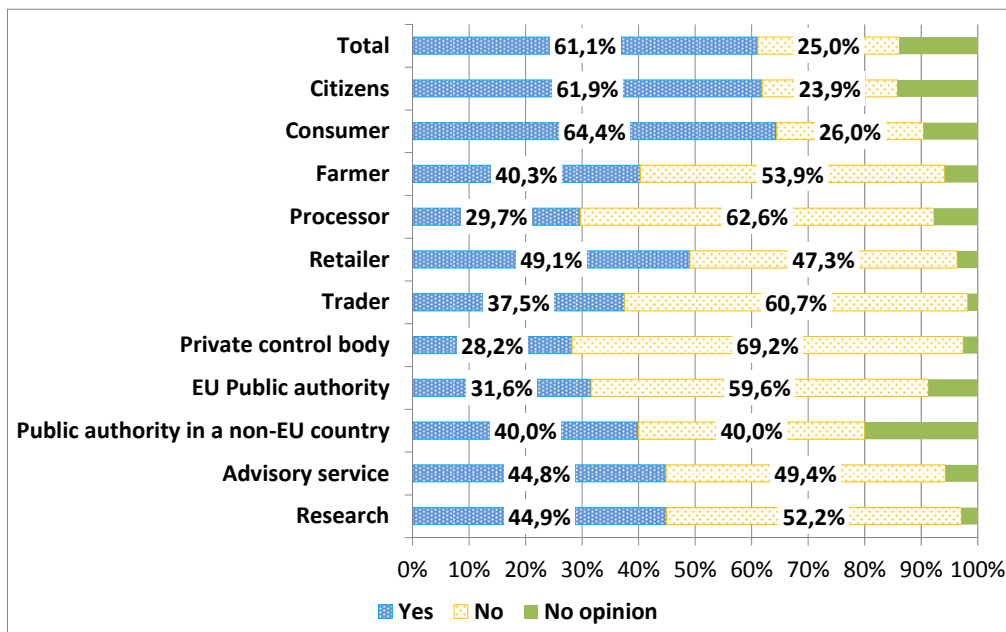
But some stakeholders like Euro Coop or FRUCOM consider the supply of organic food products not sufficient. It prevents the growth of the organic sector and increases the final price of organic products. They would like to see imports of organic products to be facilitated, and therefore recommend the EU to continue to favour equivalence against compliance.

2.13. Presence of non-authorized substance residues in organic products

Proposition of systematic testing

In the public consultation, 61% of the respondents wished for all organic products to be tested for pesticide residues. 25 % of the respondents were against.

Online questionnaire: should testing organic products for pesticide residues be made compulsory?



According to COPA and other stakeholders, the risk of adventitious contamination of organic products by non-authorized substances, mainly pesticides, can never be completely ruled out, despite the precautionary measures taken by organic producers. However the lower level of contamination of organic products, compared with conventional products has been underlined several times. A systematic testing for pesticide residues in all organic products was deemed inappropriate by many organisations: COPA, IFOAM EU, FRESHFEL, ERPA, SYNALAF, Soil Association. There was a consensus among producer organisations on the fact that testing for pesticide residues should remain one of the possible instruments to control organic products, which can be combined with other investigation tools. One stakeholder pointed out that the parameters for testing all products would be difficult to define (would it be applied just at the farm level, at each processing step, for each consignment, and with what quantity limit and for which pesticides?).

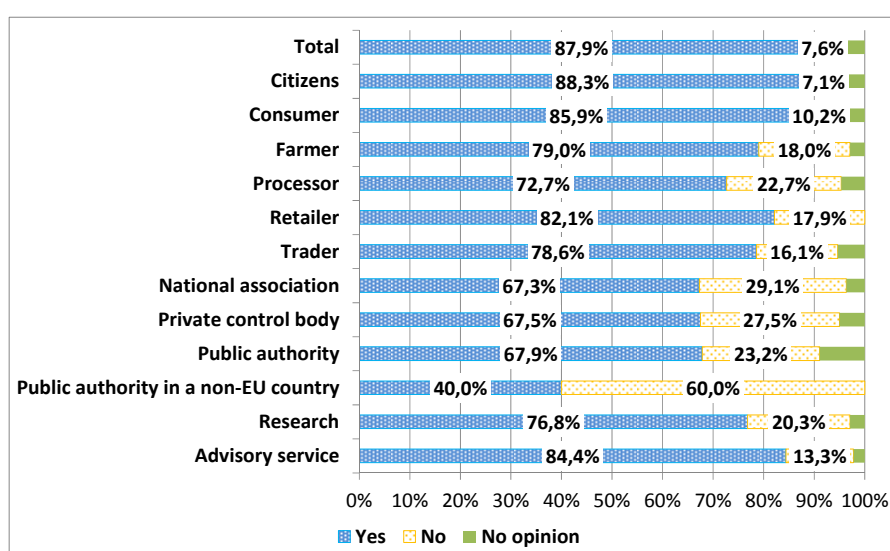
Issue of presence of pesticide residues in organic products tackled differently according to MS

The issue has been brought in the Council debates by several MS representative, like Sweden: *"MS tackle findings of residues differently. This creates unfair competition."* Or Italy: *"The application in the MS of different (non-authorized substances) residue levels, beyond which the product cannot keep its organic status, can create barriers to trade."*

The issue has also been mentioned by several stakeholders as one ground for unfair competition. FRESHFEL mentioned possible distortion of competition and uncertainties which are notably detrimental for perishable products: *"FRUCOM believes that the European Commission should harmonise at EU level the way MS deal with cases of cross-contamination in order to prevent trade distortion amongst MS"*.

Threshold for organic products:

Online questionnaire: should the level of pesticide residues for organic products be set at a lower level than for conventional products?



The stakeholders were shared between the ones who could accept a lower threshold for organic products and the ones who don't see the justification for that. The level based on the Baby food-law seems the most appropriate to several stakeholders (notably IFOAM EU, FRESHFEL).

2.14. Small farms' issues and group certification

Issues faced by small-scale farmers have been shown in several free contributions to the public consultation, notably on certification costs: *"I am a small scale (4 hectare) organic grower, mainly old varieties of apple, soft fruit and some vegetables. The annual fee charged by ... for inspection is £560. This is sometimes more than my profit for the year... If I had 4,000 hectares, the certification cost would be £900!! We, along with many other small scale organic producers will be forced out of organic production in the next 2 or 3 years. ... a typical annual inspection takes about 45 minutes."/* *"There should be help for small farms to be able to certify their farms as organic, as now very small farms cannot afford it."/* *"There are too many small farms, which cannot afford the control costs."/* *"Costs of certification should be lowered to promote small organic farming concepts."*

Excessive administrative burden was also highlighted: *"Primarily, the review should prioritise small-scale and local production as opposed to large-scale and intensive production. This includes minimising the burden on farmers in terms of paper-work...There should be incentives for switching to organic production focused on the education of the next generation of farmers in organic methods. This includes providing investment in training at school, college and life-long learning in how small-scale and local production is the only realistic long-term prospect for agriculture."/* *"Our holding is 70ha. Small farmers are disproportionately burdened with paperwork and form filling in relation to their financial turnover. The EU must address this problem as it is a real disincentive to farm on a small scale and it is at that level that the best wildlife, community and environmental benefits can be gained. You need to move to a far more flexible system of regulation that respects the value of small producers."*

In the meeting with experts, the following topics were discussed: definition of small farms, possible simplified requirements for small farms and group certification (including experiences in third countries).

The issue of definition appeared complex and opinions on what a small farm is varied. Several criteria were discussed, which could be combined: income, labour, size (possibly linked to the type of production). The situation can vary according to MS (and third countries) because of different levels of development. Some experts thought the definition should be left to MS or regions; others believed there should be one single definition for the whole EU. The advantages and drawbacks of a definition based on the relationship between turnover and certification cost, often used in third countries, were discussed. This can be an incentive for certifiers to adjust their fees according to specific situations.

Simplification: participants agreed that the administrative burden is too high. A suggestion was made to have a single administrative document giving a full description of the farm and to be updated once a year.

Group certification: one expert was of the opinion that the current control system has reached its limits and is not able to deal with high numbers of farms. Today the implementation of the system is not able to offer the required guarantees on the products. One example, the control before harvest is not carried out (too many farms should be visited in a few days). It would be useful to introduce social control. It could be achieved while taking into account social relations, rural communities and rural development. Integration of a group by a private operator is not necessarily the right solution.

Another expert highlighted the territorial dimension of group certification. Facilitating the conversion of small farms to the organic farming scheme could benefit to entire regions. For instance, in mountain areas, hundreds of farms apply farming practices close to organic farming but they are not in the system because of cost and administrative issues. Group certification can be an answer.

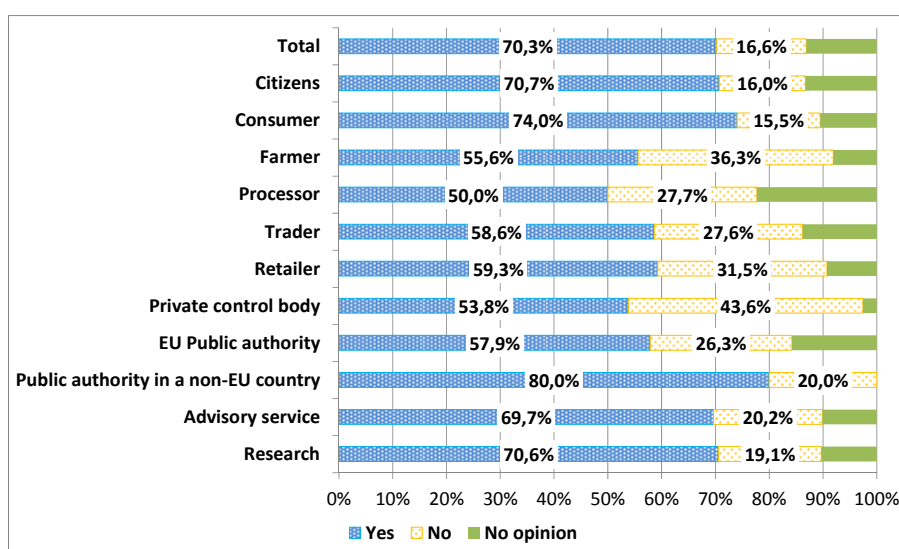
Some experts suggested to use RD funds for the set-up of internal control system needed that groups have to apply. A link could be made between RD and organic farming for this particular question.

One expert was of the opinion that group certification is not always cheaper than individual certification and suggested that the best answer to the problem may be to provide small farms with access to subsidies to cover the cost of certification. The internal control system has to be managed and cannot replace the external control system.

Experience in third countries: Group certification is not limited to developing countries. Canada and Korea have adopted such system. In Canada there is no limit in size and group certification is allowed for retailers but not for processors. In developing countries, group certification is generally cheaper than individual certification in particular because of lower labour costs of local staff managing the internal control system. The effects of group certification go beyond economic benefits and include improvements in the fields of training, education, poverty alleviation, etc. There are not always quantitative criteria to define small farmers in third countries.

In the public consultation, 70% of the respondents favoured the idea of permitting group certification in the EU, which is allowed for organic farmers in some non-EU countries. There were only 17% of responses against group certification.

Online questionnaire: do you think that group certification should be allowed in the EU?



COPA was against group certification: "Group certification is not compatible with the current mandatory annual on-site inspections. As a result, it should not be authorised in the EU."

According to Euro Coop, an effective way to encourage European organic production would be to offer a public and free of charge certificate for small farmers (possibly financed by RD funds), considering that they are also those contributing to the development of rural communities. The association Italia Nostra suggested that small producers, while being controlled, could be exempted from the obligation of labelling their products as organic, for the sake of simplification.

Other organisations were in favour of group certification: Slow Food, Soil Association, WECF (but only in specific cases: in peri-urban areas, mountains, picking).

2.15. Information and promotion

A vast majority of respondents (94%) to the online questionnaire required more information on organic products. The need for more information on organic products was expressed by respondents from every single country, category of stakeholders as well as consumers. A large number of respondents (59%) stated that they did not know about existence of such the EU's organic farming web-site.

2.16. Research and innovation

The respondents to the online questionnaire identified four areas which should benefit from more research and innovation into the organic food and farming sector, namely "Economic and social dimension of organic farming" (58%), "Seeds and plant propagating material adapted to low-input agriculture" (52%), "Local production of protein in-rich crops" (48%) and "Waste management".

Soil association: Research should be directed at improving the sustainability and self-sufficiency of organic production, and at addressing the limiting factors to better and more organic farming. There is no need for research into GMO co-existence – what is required is a proper and strict regime that ensures a similar level of control, traceability and accountability as the organic system already imposes, so that GMOs do not escape and contaminate non-GM production and the perpetrators can be identified. The specified areas for research rightly focus on applied research to deliver short and medium term benefits to farmers and growers, which will build increased resilience and security into food production. Nonetheless, there is also a need for more fundamental research and within the unspecified 'other areas' should be improved understanding of pests and diseases. Organic farming is the leading edge of agriculture (e.g. energy efficiency, carbon sequestration, soil stabilisation, animal welfare, nutrient recycling, pest and disease management) and has strategic importance in delivering the objectives of the Common Agricultural Policy. Knowledge, techniques and innovations developed through research into organic systems can also have a significant positive impact on all systems of farming. Therefore, there should be a specific organic research budget and it should be several times more than would be indicated by the proportion of organic land, for the above reasons. Adoption of ecological principles into organic farming means adaptation to local environmental conditions. The distribution of research budgets should reflect this systems diversity, the understanding of which is fundamental to building resilience into food production.

3. PRESENTATION OF THE MAIN STAKEHOLDERS

This chapter presents the stakeholders (interest groups, civil society organizations) represented in AGOF.

IFOAM EU Group is a European umbrella organisation, which advocates for the development and integrity of European organic food and farming. It has more than 160 member organisations that cover the organic food chain and beyond: from farmers and processors, retailers, certifiers, consultants, traders and researchers to environmental and consumer advocacy bodies. IFOAM has chaired the AGOF for the last two years.

EOOC, the European Organic Certifiers Council comprises control bodies for organic production, which are interested in cooperation and exchange of information.

Producers

COPA-COGECA is the union of COPA, the Committee of Professional Agricultural Organisations, historical European representative organisation for farmers established in 1958, and COGECA, European umbrella organisation of the agricultural cooperatives of the European Community created in 1959.

CEJA is the European Council of Young Farmers representing the interests of Europe's young farmers.

ECVC, the European Coordination Via Campesina includes organisations that formerly gathered in the European Farmers Coordination (CPE 1986-2008) and other farmers' and agricultural workers' organisations of several European states. The principal objective of ECVC is to shape food and agricultural policies based on more legitimacy, fairness, solidarity and sustainability.

ERPA, the European Rural Poultry Association defends, supports and develops the production of rural poultry in the European Union.

Trade

CELCAA, the European Liaison Committee for Agricultural and Agri-Food Trade is an umbrella organisation representing at European level associations and companies active in the sector of agricultural and agri-food trading.

EUROCOMMERCE represents six million retailers, wholesalers and other trading companies. Its members include national commerce federations in 31 countries, Europe's 27 leading retail and wholesale companies as well as federations representing specific sectors of commerce.

Fair Trade Advocacy Office strives for fair trade and trade justice with the aim to improve trading conditions for the benefit of small and marginalised producers and poor workers in developing countries.

Industry:

FoodDrinkEurope facilitates development of the environment for the European food and drink companies. It represents its members that are national federations, sector associations, as well as food and drink companies in the European Union.

Consumers

BEUC, the European Consumer Organisation is an umbrella organisation of 41 independent national consumer organisations from 31 European countries.

Euro Coop is the European Community of Consumer Co-operatives, whose members are the national organisations of consumer co-operatives in 18 European countries and 1 non-European member.

Environmental organisations

EEB/BEE (European Environmental Bureau) works on environmental questions at the European level.

WWF-EPO (the World Wide Fund European Policy Office) is the political advocacy center of WWF at the European Union level.

BIRDLIFE is a global partnership of conservation organizations that strives to conserve birds, their habitats and global biodiversity.

LE FORUM EUROPEEN POUR LE PASTORALISME ET LA CONSERVATION DE LA NATURE (European Forum on Nature Conservation and Pastoralism (EFNCP)) was

established in 1988 as a Europe-wide network which raises awareness of the importance of low-intensity farming for nature conservation.

Animal welfare organisations

Eurogroup for Animals is a leading organization advocating for better animal welfare conditions at European Union level.

Compassion in World Farming is a campaign based organisation to fight for better conditions for animals.

3.1.

ANNEX 3: MAIN INSTRUMENTS OF THE COMMON AGRICULTURAL POLICY (CAP) SUPPORTING THE ORGANIC FARMING POLICY

1. THE CURRENT CAP IN A NUTSHELL

Over the last two decades, the CAP has undergone a substantial reform process, which reflects the changing societal concerns related notably to the environment, food quality and safety, territorial balance, as well as to the evolving needs of the EU economy. As a result of this process, the CAP provides today the general framework to address competitiveness and sustainability challenges of agriculture and rural areas across the EU territory. This framework takes the form of two complementary pillars.

Pillar I – market and income policy – includes instruments related to the functioning of agricultural markets and the food supply chain and to direct payments conditional upon statutory management requirements and good agricultural and environmental conditions. Combined, these measures provide a fundamental layer of support to EU farmers, creating the basis for keeping sustainable farming in place throughout the EU. Pillar I measures are mandatory for MS and, apart from very few exceptions, there is no co-financing.

Pillar II – rural development policy – includes measures that aim at improving the competitiveness of the agriculture sector, delivering specific environmental public goods and promoting the diversification of economic activity and quality of life in rural areas. These measures are largely voluntary, contractual in nature, co-financed and delivered within a strategic framework which links policy action to European, national, regional and local needs.

2. ORGANIC FARMING IN THE CONTEXT OF THE CAP

For more than 20 years, European policies for organic farming have been developed on a number of levels. The first scheme specifically targeted at organic farming was introduced in Denmark in 1987, shortly followed by other countries. As part of the MacSharry reform of the CAP in 1992, the introduction of agri-environment programmes provided a unified framework for supporting conversion to and maintenance of organic production across the EU. Today there are a wide range of different policy measures in EU MS that are financed by different funding sources and that address organic farming in different ways: with specific provisions (e.g. higher payment rates for organic farming), with partly specific provisions (e.g. higher payment rates for organic and other specified types of farming) or where organic farming is at least mentioned specifically (e.g. as one of a number of target groups) but without any specific provisions. In the following, based on the results of a previous study (Sanders *et al.*, 2011), the support measures applied to organic farming are briefly described. There is also a description of the measures proposed in the framework of the upcoming CAP reform.

3. SUPPORT MEASURES ADDRESSING ORGANIC FARMING UNDER THE CURRENT CAP

3.1. Rural Development Policy

According to the Community Strategic Guidelines for Rural Development, MS are encouraged to make use of the contribution of organic farming to the environmental and animal welfare objectives of the CAP. Most EU countries have followed this recommendation and provide specific area payments for organic farming under Axis 2 (Improving the environment and the countryside) of their rural development programmes. In addition, some MS have, to a varying degree, also implemented policy measures addressing organic farming under Axis 1 (Improving the competitiveness of the agricultural and forestry sector) and Axis 3 (Improving the quality of life in rural areas and encouraging diversification of the rural economy).

3.1.1. Support under Axis 1: Improving the competitiveness of the agricultural and forestry sector

In 22 MS or their regions, organic farming was addressed in one or several of the following 6 RDP measures under Axis 1 in the period 2007-2011.

- **Setting up of young farmers** (Measure 112): In the Czech Republic, applications are selected on the basis of a point system, where organic farmers receive extra points. In three Spanish and two Italian regions, organic farmers receive higher payment rates than conventional farmers. Furthermore, in some regions in Italy and Spain organic farming is mentioned as a reason for intervention or as one of several target groups.
- **Modernisation of agricultural holdings** (Measure 121): In Flanders (Belgium), Madeira (Portugal) and North Rhine-Westphalia (Germany) higher grants are given to organic farmers investing in agricultural holdings to improve the overall performance of the farm; in Austria this is limited to organic livestock farmers investing in farm buildings. Organic livestock farmers along with other groups of (non-organic) farmers receive higher investment grants in Mecklenburg-Western Pomerania and Bavaria (Germany). In Bulgaria, organic farmers receive the same level of support as non-organic farmers; however a minimum of 5 % of the Measure 214 funds is reserved for investments required for conversion to organic farming. Higher evaluation scores are given for applications related to organic farming in Cyprus, Czech Republic, Latvia and Slovakia. Furthermore, various countries have mentioned organic farming as one of several target groups, but it is not clear what direct advantage for organic farmers this implies.
- **Adding value to agricultural and forestry products** (Measure 123): In Bavaria (Germany) and Slovenia, projects related to organic food production, processing or marketing receive higher support rates. In Estonia, a sub-scheme specifically targets organic farming as well as conventional dairy farmers referring to specific circumstances of the organic and dairy sectors. Rather than higher grants, a higher priority is given to projects related to organic farming under the selection schemes in Cyprus, the Czech Republic, Latvia and Slovakia. A tiered support scheme is used in Austria and in two regions in Spain to determine the level of support within which organic farming is one criterion among others to be eligible to receive a top-up grant. In Bulgaria, Denmark, Hungary, Malta, Romania and some regions of Spain,

organic farming has been defined as a (particular) target group or reason for intervention, but no special provisions are made for organic farming.

- **Participation of farmers in food quality schemes** (Measure 132): MS have adopted different approaches to refund certification and inspection costs of organic farmers. Several countries/regions use Measure 132 to cover parts of the certification and inspection cost incurred by farmers (Austria, Belgium, Cyprus, Estonia, Greece, Malta, the Netherlands, Poland, Portugal, Slovenia, most regions of Italy and Spain as well as parts of the UK). Flanders and Wallonia (Belgium) as well as Greece introduced support schemes for organic farmers in 2011. These schemes are usually also open to farmers participating in other approved quality schemes.
- **Information and promotion activities** (Measure 133): In some MS, Measure 132 is combined with Measure 133, which supports information and promotional activities for products or foodstuffs covered by approved quality schemes. In Malta and Estonia, only organic producers may receive support through Measure 133. Other countries offer no special provisions for organic producers.
- **Setting up of producer groups** (Measure 142): In Slovenia, financial support is given to organic farmers who set up producer groups and therewith strengthen the institutional structure of the primary sector. This measure is however not exclusively targeted at organic. Farmers producing other special agricultural products (e.g. food labelled as Protected Designation of Origin (PGO) or Protected Geographical Indication (PGI)) are also eligible for aid.
- In addition to the measures described above, many MS have implemented specific training courses or advice for organic farming under Measure 111 (Vocational training and information actions) and/or Measure 114 (Use of advisory services). Since both activities are also relevant for conventional farmers, organic farming is, in most cases, neither addressed nor mentioned under these measures. Similarly, Wales uses Measure 124 (Cooperation for development of new products, processes and technologies in the agriculture and food sector and in the forestry sector) to improve supply-chain links. Whilst the measure itself does not address organic farming, it is used to finance a project which is highly relevant for organic sector development in Wales.

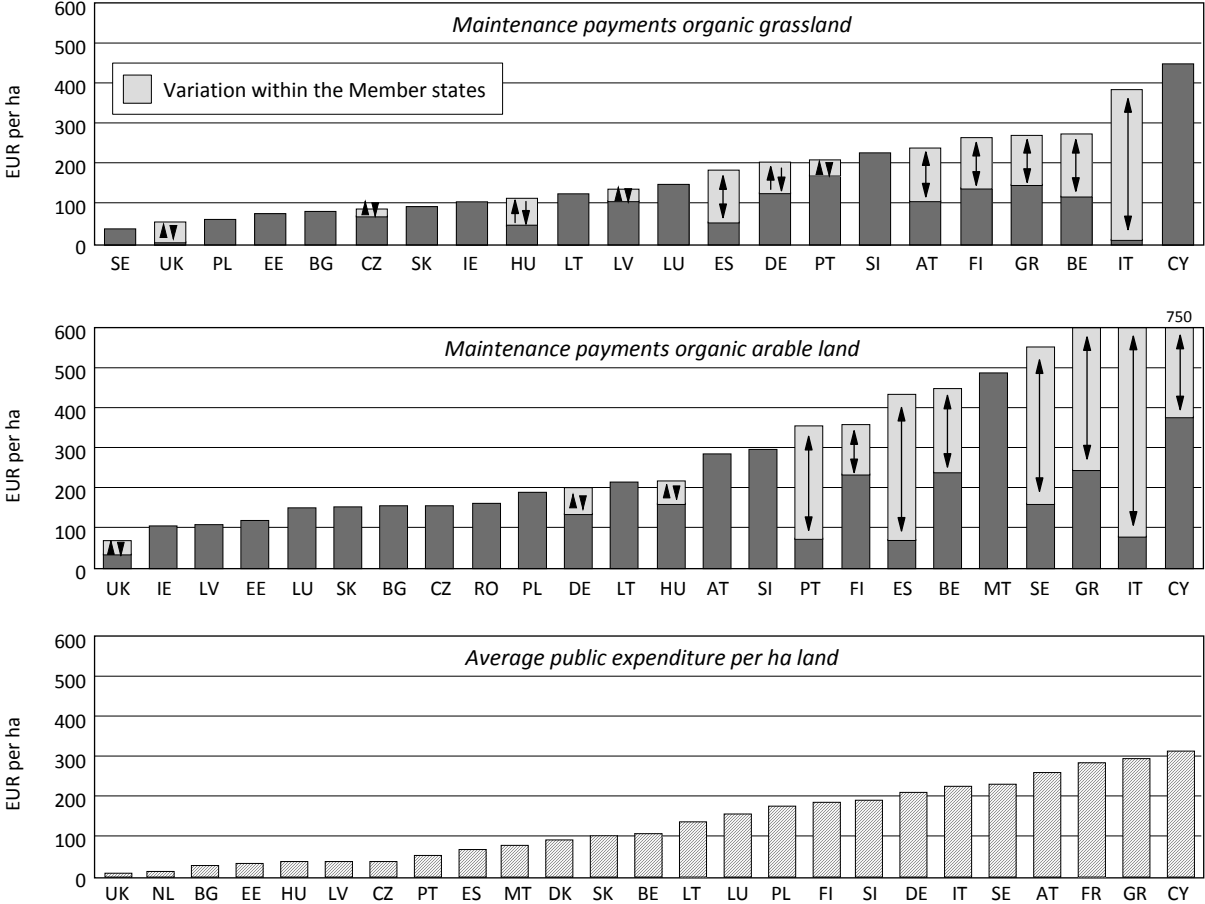
3.1.2. Support under Axis 2: Improving the environment and the countryside

In 25 MS or their regions, organic farming is addressed in one or both of the following two RDP measures under Axis 2 in the period 2007-2011.

- **Agri-environment payments** (Measure 214): For organic farming agri-environment payments are undoubtedly the most important support measure of the rural development programmes. With the exception of the Netherlands and France, all MS have implemented specific area payments for organic farming in the framework of national/regional agri-environmental schemes (Measure 214) to compensate for additional costs and/or income foregone resulting from organic management. Differentiation of seven land types is used including arable land, grassland, vegetables and herbs, greenhouse crops, perennials and orchards, vineyards, and olive trees. There are large variations in the payment rates for the same land type across countries. For example, maintenance payment rates per hectare for grassland varied between EUR 39 and EUR 450 across the EU (Figure 1). Even greater variations were observed for conversion payments. Differences in payment rates are the result

of a number of factors including different payment differentiations within the broader land types (e.g. a specific cereal payment is likely to lead to a higher payment rate than an average arable payment), different economic assumptions and different cost and income foregone components in payment calculations.²¹ Policy priorities, budget allocations and constraints, consideration of different bio-physical land characteristics and the inclusion of (area-based) livestock payment components are also factors.

Figure 1: Maintenance payments in 2011 and average public expenditure per ha in 2008-2009 in EU MS



Source: Sanders et al. (2011)

High payment rates do not necessarily guarantee a high level of support for organic farms. Scheme access problems, as reported from several MS, can reduce the positive impacts of high support payments. Average public expenditure for organic support payments under the agri-environmental measure per certified organic hectare varied between EUR 7 and EUR 314 for the period 2008 to 2009. On average, public expenditure amounted to EUR 163 per hectare for the

²¹ According to Reg. (EC) 1698/2005 payment rates shall cover additional costs or income foregone resulting from organic management (i.e. only those commitments going beyond the relevant mandatory requirements established by EU or national legislation). The level of payments is defined by Member States based on the following parameters: differences in yield, production costs, prices and transaction costs. Usually Member States define a typical regional organic farm and a conventional reference farm to calculate the additional costs. As reported by Sanders et al. (2011) not all countries/regions compensate 100 % of the additional costs. In most countries which do not compensate 100 % of the additional costs, there are large variations between individual crops or land use types. Since additional costs are calculated on the basis of a typical farm, low compensation levels do not necessarily mean that all farmers are only partially compensated. The real implications of compensation levels depend very much on the selected organic and conventional reference farms.

EU-27 (excluding Ireland, Romania and England). Substantial differences between the MS also exist in the design and application of eligibility criteria and requirements such as payment limits, stocking rates and additional scheme requirements beyond organic standards which are not necessarily reflected in the payment rates.

It is important to note that a wide range of options for combining organic with agri-environmental payments exists across most MS covering nearly all the key agri-environmental themes. “Topping up” organic support payments through other agri-environmental payments utilises the comparative advantages of organic farms in providing environmental benefits and public goods, and grants additional financial support to organic farms.

- **Animal welfare** (Measure 215): Cataluña (Spain) provides additional support for organic livestock farmers under Measure 215 aiming to cover additional costs or income foregone due to commitments regarding feeding facilities or free outdoor access. In some other countries, specific organic livestock payments are integrated in Measure 214.

3.1.3. Support under Axis 3: Improving the quality of life in rural areas and encouraging diversification of the rural economy

In the Czech Republic, organic farming was addressed in two RDP measures under Axis 3 in the period 2007-2011:

- **Diversification into non-agricultural activities** (Measure 311)
- **Encouragement of tourism activities** (Measure 313).

Both measures aim to diversify the rural economy through grants for the introduction or expansion of activities related to local services, products, trade and tourism. Similar to provisions made for Axis 1 measures, projects related to organic farming are awarded higher points in the Czech Republic which may increase the likelihood to receive support. References to organic farming are also made in Hungary under RDP measure 313.

3.2. Market and income policy

Besides rural development programmes, some EU MS provide financial support for organic farmers in the framework of Article 68 of Regulation (EC) 73/2009 as well as top-ups in the Common Market Organisation for fruit and vegetables.

The EU rules for direct support schemes under the CAP Pillar 1²² allow MS to support specific types of farming and quality (so-called 'Article 68 measure'). France is using this measure – instead of RDP Measure 214 (agri-environment schemes)²³ – for conversion and maintenance payments for organic farming. Romania is following a dual approach: while maintenance payments are paid under RDP Measure 214, Article 68 is used to finance conversion payments. In Denmark, the current RDP extensification scheme under Measure 214, which provides area payments for organic farmers, is stepwise replaced by a similar Article 68 measure. In addition Greece, Italy, Spain and Sweden have also implemented specific support to farmers for

²² Schemes are based on Council Regulation (EC) 73/2009 establishing common rules for direct support schemes for farmers.

²³ For the contracts concluded by 2010/11 France implements maintenance and conversion payments for organic farming under Axis 2 of its rural development programmes through agri-environment payments (Measure 214). These payments will continue to be carried out until the end of the contracts, having a duration of 5-7 years.

improving the quality of agricultural products. These schemes are targeted not only at organic farmers, but also at farmers participating in other food quality schemes.

The Fruit and Vegetables Regime of CAP Pillar 1 aims to increase the use of environmentally-friendly cultivation and production techniques. To receive a grant, producer organisations have to prepare an operational programme in which they describe how their activities contribute to the specific national goals defined in the national strategies for sustainable operational programmes. Specific provisions are made for organic producer organisations. The Community co-financing rate for organic production in the operational programmes is 60 % of the eligible costs (usually 50 %) with a maximum financial contribution of 4.1 % of the total value of marketed produce. In general, support for the environmental actions covers additional costs and income foregone resulting from that action. Several MS have, however, made country-specific provisions regarding the type of eligible costs related to organic farming. In Belgium, Ireland, the Netherlands and Sweden, only expenditure for specific equipment or means of production is eligible for aid (e.g. for packing and storing of organic products, use of organic dung and compost, etc.). Support for training and advisory costs are granted in Germany and Austria. The Czech Republic provides support for planting new organic orchards. In Spain, financial support is either given as a per-hectare payment or is based on invoices for specific cost items.

4. OTHER NATIONAL OR REGIONAL ORGANIC SUPPORT MEASURES

MS and regions have also introduced a wide range of other national and/or regional policy instruments not (co-)financed by the EU (see Figure 2). Examples include financial support for producing, processing and marketing organic products, a range of communication policies as well as support for research projects related to organic farming. In many cases, the identified measures have some similarities to those implemented under rural development programmes. This is particularly the case for investment aids, marketing aids and support for training programmes and advisory services. Some of them could probably also be financed under the RDP Measures 111, 114, 121 and 123. Clearly, some MS forgo the opportunity of co-financing these measures through the EU in order to retain greater flexibility in programme planning and implementation or to avoid reporting duties.

Figure 2: Overview of identified national or regional public measures addressing organic farming which are not (co-) funded by the EAFRD or EAGF in 2007-2011

	Farm investment	Marketing & Processing	Certification & Regulation	Training & Advice	Information & Education	Public procurement	Promotion campaigns & events	Institutional support	Research	Others
AT					■		■	■	■	
BE		■	■	■			■	■	■	
BG										
CY										
CZ				■	■	■	■	■	■	■
DK			■					■	■	
EE		■	■		■		■		■	
FI		■		■					■	■
FR									■	■
DE		■		■	■	■	■	■	■	■
GR										
HU										
IE	■	■	■	■	■		■			
IT		■	■	■	■	■	■	■	■	■
LV		■			■		■	■	■	
LT		■							■	
LU				■	■	■	■	■	■	■
MT										
NL		■		■			■	■	■	■
PL			■	■	■		■		■	
PT										
RO		■	■				■			■
SK								■	■	
SI				■	■			■	■	■
ES		■		■	■	■	■	■	■	■
SE							■		■	
UK		■		■	■			■	■	■

■ Public support measures not (co-) financed by EAFRD or EAGF available in the whole country
 ■ Public support measures not (co-) financed by EAFRD or EAGF available only in certain regions

Source: Sanders et al. (2011)

5. ORGANIC ACTION PLANS

National or regional organic action plans provide a strategic instrument to coordinate different supply-push and demand-pull instruments tailored to local conditions. In total, 17 national and 10 regional action plans or similar support schemes that have been implemented since 2007 were identified in EU MS (Table 1). In many cases, action plans bundle CAP measures and complementary national/regional measures not (co-) funded by the EU. The action plans differ substantially with respect to policy targets, running period, types of actions specified, financial resources, number of previous action plans, and initial year of implementation reflecting different support strategies and developmental stages of the EU's national/regional organic sectors.

Table 1: Overview of organic action plans or similar support schemes in EU MS implemented in 2007-2011

EU Member States	Running period	Number of previous actions plans	Year of implementation of the first action plan	Quantitative targets		Target year
				Share of organic land area in the total UAA	Share of organic food in the total food market	
AT Austria	2011 - 2013	4	2001	20 %	-	2013
BE Flandern	2008 - 2012	2	2000	-	-	-
BG Bulgaria	2007 - 2013	0	2007	8 %	-	2013
CY Cyprus	-	-	-	-	-	-
CZ Czech Republic	2011 - 2015	1	2004	15 %	3 %	-
DK Denmark	2011 – 2013/15	2	1995	14 %	-	2020
EE Estonia	2007 - 2013	0	2007	ca. 3 %	3 %	-
FI Finland	2007 - 2015	-	2007	-	-	-
FR France	2011 - 2013	1	2008	6 %	-	2012
DE Germany	since 2002	cont.	2002	-	-	-
GR Greece	-	-	-	-	-	-
HU Hungary	-	-	-	-	-	-
IE Ireland	2008 - 2012	0	2008	5 %	-	2012
IT Italy	-	-	-	-	-	-
LV Latvia	2007 - 2013	1	2007	10 %	-	2013
LT Lithuania	-	-	-	-	-	-
LU Luxembourg	2009 - 2011	0	2009	ca. 5 %	-	-
MT Malta	-	-	-	-	-	-
NL Netherlands	2008 - 2011	2	2001	-	-	-
PL Poland	2011 - 2014	1	2007	ca. 4%	-	2014
PT Portugal	-	-	-	-	-	-
RO Romania	-	-	-	-	-	-
SK Slovakia	2001 - 2013	1	2006	5 %	-	-
SI Slovenia	2005 - 2015	1	2007	20 %	10 %	2015
ES Spain	2007 - 2010/11	0	2007	-	-	-
SE Sweden	since 2007	-	-	20 %	-	2010
UK Scotland	2011 - 2017	1	2007	-	-	-
Wales	2005 - 2010	-	-	-	-	-

Source: Sanders et al. (2011)

6. SUPPORT MEASURES ADDRESSING ORGANIC FARMING IN THE FUTURE CAP

The CAP framework explained under section 1 above responded to the challenges EU agriculture faced during the past two decades. However, for the policy to remain relevant, the framework under which it functions has to prove itself capable also to address the evolution which EU agriculture is expected to face in the current decade: economic, environmental and climate change pressures as well as the territorial aspects of the policy.

In this context, the Commission adopted in November 2011 legal proposals to reform the CAP for the period 2014-2020. They aimed to fulfil the three broad objectives of the future CAP, i.e. "Viable food production", "Sustainable management of natural resources" and "Balanced territorial development".

It was proposed to adapt the current CAP framework along the following lines:

- Gearing the CAP measures towards increasing the productivity and the competitiveness of the agricultural sector by:
 - improving the functioning of the advisory system and creating networks (of farmers, advisors, researchers, food operators, consumers etc.) for knowledge creation and transfer and favouring innovative approaches in granting funding for projects for rural development measures
 - encouraging pro-competitive joint action among farmers in order to foster efficient use of resources, product development and marketing
 - provide incentives to use risk management instruments and active prevention strategies
- Improving the environmental and climate change performance of the CAP by:
 - increasing the number of agricultural areas which are under agricultural practices providing environmental and climate action benefits and encouraging the take-up of more advanced agri-environmental measures by MS and farmers;
- Enhancing the effectiveness and efficiency of the policy by:
 - rebalancing the direct payment support to better reflect income support objective and environmental performance
 - reducing the disparities in direct payment support levels between MS and farmers.

After almost two years of negotiations between the Commission, the European Parliament and the Council, a political agreement on the reform of the CAP was reached on 26 June 2013²⁴. A number of instruments agreed for the next programming period have a significant potential to increase the development and visibility of the organic farming sector.

²⁴ http://europa.eu/rapid/press-release_MEMO-13-621_en.htm

6.1. Rural development policy

In the context of the RD policy for the period 2014-2020 as agreed among the institutions, a farmer engaging in organic production will be able to receive support through a number of measures, among which the following ones:

- knowledge transfer and information actions (article 15), covering participation in training activities,
- advisory services, farm management and farm relief services (article 16), for the use of advisory services,
- quality schemes for agricultural products and foodstuffs (article 17), covering certification costs for new participation in organic food quality schemes,
- investments in physical assets (article 18),
- farm and business development (article 20), granting business start-up aid for the development of small farms,
- agri-environment-climate (article 29), when an organic farmer undertakes an environmental or climate commitment not supported under article 30,
- organic farming²⁵ (article 30), compensating for additional costs, income foregone and transaction costs when converting to and/or maintaining organic farming practices in line with Council Regulation 834/2007,
- animal welfare (article 34), for commitments going beyond mandatory standards and not already covered by article 30,
- cooperation (article 36), which supports the development of innovative products, processes, practices, technologies, and cooperation approaches among actors of the food chain.

It will be up to the MS or regions to include in their RD programmes the measures they consider relevant for supporting organic farming and to set out how these measures can be combined with one another in order to avoid double funding and to ensure complementarity/synergy between them.

6.2. Market and income policy

For the period 2014-2020, besides maintaining a basic direct payment for farmers (including organic farmers), the EU institutions have agreed to introduce a **strong greening component** into the first pillar to ensure that all EU farmers in receipt of support go beyond the requirements of cross-compliance and deliver environmental and climate benefits as part of their everyday activities. Thirty percent of direct payments will be tied to the 3 compulsory greening practices (i.e. crop diversification, establishment of ecological focus areas, maintenance of permanent grassland).

In order to avoid penalising farmers that already address environmental and sustainability issues, the agreement foresees a "Greening equivalency" system whereby the application of

²⁵ During the 2007-2013 programming period, support for organic farming was part of the compulsory agri-environmental measure. For the programming period 2014-2020, it has been proposed to establish a specific voluntary Organic farming measure. This is to recognise the importance of organic farming in contributing to various rural development objectives and priorities.

environmentally beneficial practices already in place are considered to replace the basic requirements. For example, **organic producers will have no additional requirements** as their practices are shown to provide a clear ecological benefit. For others, agri-environment schemes may incorporate measures that are considered equivalent. The new regulation contains a list of such equivalent measures. To avoid "double funding" of such measures, the payments through rural development programmes must take into account the basic greening requirements.

The current "article 68" measure is not prolonged in the next programming period.

In receiving support from several of the measures outlined above, a farmer will be able to achieve more easily the objectives of the organic farming regulation, i.e. establish a sustainable management system for agriculture, produce products of high quality and respond to consumers demands for goods produced using processes that do not harm the environment, human health, plant health or animal health and welfare.

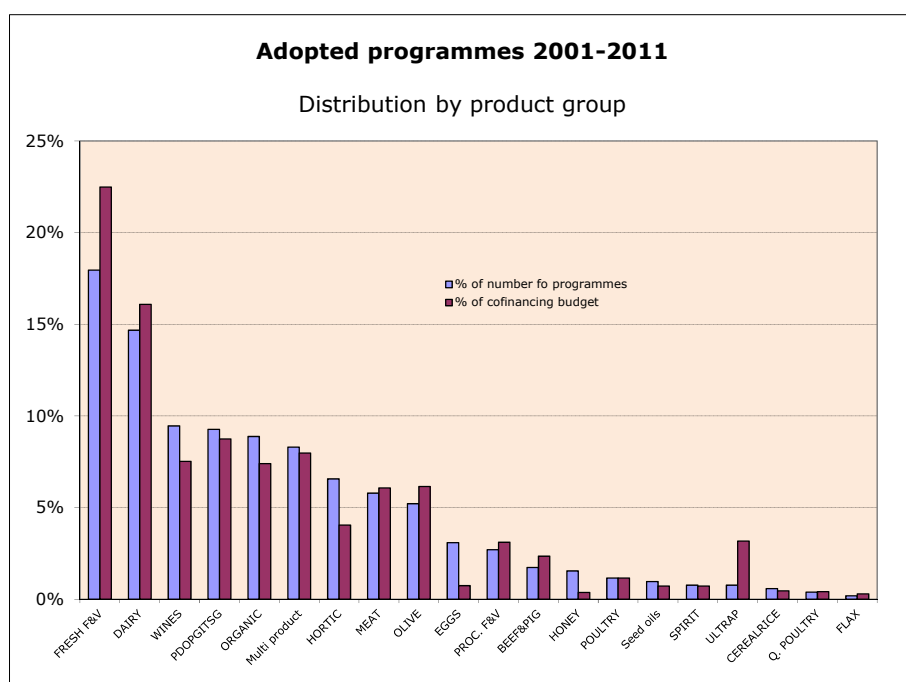
ANNEX 4: INFORMATION AND PROMOTION ON ORGANIC FARMING AT EU LEVEL

The possibilities of financing information, communication or promotion actions in the organic sector are listed below:

1. COFINANCED INFORMATION AND PROMOTION CAMPAIGNS

Through the Council Regulation (EC) n°3/2008 on information provision and promotion measures for agricultural products on internal market and in third countries, the organic sector is eligible to the EU promotion scheme on internal market and in third countries. It is a horizontal policy covering almost all agricultural sectors and emphasising the general characteristics and added value of the CAP such as quality, safety, health, labelling, specific production methods, respect for the environment, animal welfare. The assistance is normally given to professional producer organisations, for example associations representing specific agricultural products, or associations promoting particular approaches to agriculture, such as organic farming. The European Commission allocates **roughly €50 million annually** in financial support.

Between 2006-2010, a total amount of 35.7m€ was spent in promotion activities in the organic sector (17.9m€ under EU co-financing), spread in 15 programmes representing 7.18% of the total programmes. This % is comparable to the amount spent on programmes for the promotion of other products under EU quality schemes (Protected Designations of Origin, Protected Geographical Indications and Traditional Specialities Guaranteed).



Source: DG AGRI, Unit D4

2. INFORMATION AND PROMOTION ACTIONS DIRECTLY MANAGED BY DG AGRI

2.1. Own DG AGRI campaigns through the Council Regulation (EC) n°3/2008 on information provision and promotion measures for agricultural products on internal market and in third countries

In 2004, the European Action Plan for Organic Food and Farming set out 21 initiatives to achieve the objectives of developing the market for organic food and improving standards by increasing efficacy, transparency and consumer confidence. **Action 1 referred to the promotion of the organic sector:**

"Introduce amendments in Council Regulation (EC) No 2826/2000 (internal market promotion) which would give the Commission greater possibilities for direct action in order to organise information and promotion campaigns on organic farming. Launch a multi-annual EU-wide information and promotion campaign over several years to inform consumers, public institutions canteens, schools and other key actors in the food chain about the merits of organic farming, especially its environmental benefits, and to increase consumer awareness and recognition of organic products, including recognition of the EU logo. Launch tailored information and promotion campaigns to well-defined types of consumers such as the occasional consumer and public canteens. Increase Commission cooperation efforts with MS and professional organisations in order to develop a strategy for the campaigns."

As follow up of Action 1 of Action Plan a **promotion campaign on organic food and farming was launched in 2008, with a budget of € 3 million (over 3 years)** and covering all 27 MS. Its results were very positive because albeit its limited budget, simple and effective marketing and information tools were offered to a number of different target groups (see detailed report COM(2010) 692 final). Within the campaign, a **multilingual website www.organic-farming.europa.eu** was developed in 22 languages, offering a wide range of information on organic farming to different target groups, including organic and conventional farmers, stakeholders' organisations, final consumers and their associations, students, and children. The website is also used as a **platform for distributing promotional material** from a "toolbox" available free of charge in 22 languages to anyone wishing to promote organic food and farming in the EU.

The website provides information on organic farming in general, EU policy in the fields of environment, animal welfare, consumer confidence, and relevant institutions in the field of organic farming. After the launch of the website, the focus was shifted to the promotion of this campaign all over Europe to stakeholders, which were the primary target group of the campaign. In this perspective, **the campaign was introduced at 17 promotional events all over Europe.**

The development of the promotional campaign has been closely monitored by an expert group (made up of both governmental and private members) for the promotion of organic farming. National experts followed the development of the content of the website and the toolbox and helped with the revision of texts made available to the public on those supports.

Evaluation has shown that the tools are accepted and used by the target groups, especially in countries where the sector is less developed and there are fewer initiatives at national level. Various co-financed programmes for the promotion of organic products have made use of this new material developed within the campaign. This allowed the programmes to be run with a

smaller budget than would have been possible otherwise, as they did not have to bear the cost of financing the development of new promotional material.

The statistical data on website traffic were also very positive. The website during that period was the most visited of all DG AGRI sub-sites on Europa, with on average 70-80 000 visits per month and 15 000-30 000 downloads of material. During 2009, the website was visited 1 070 000 times (this figure represents 63 % of the total visits to the whole of DG AGRI's site). By scoring high on major search engines, the website has become a point of reference for all those looking for information on organic food and farming.

Current review of the existing EU information and promotion policy of agricultural products

The organic sector will benefit from the current revamp of the information and promotion policy of agricultural products, not only thanks to a budget increase compared to the € 60 million dedicated in 2013 but also because organics have been identified as one of the key themes of interest for the European Union for which information actions are needed. Moreover new elements of the promotion policy to be put in place such as the highlight of the European dimension (through the encouragement of multi-country and multi-product initiatives) as well as the introduction of a European strategy to better target the promotion programmes to specific markets, populations, themes, products or sectors will contribute to various synergies of the organic sector stakeholders at European level.

2.2. Via the Council Regulation (EC) n°814/2000 on information measures relating to the CAP

One project submitted by IFOAM EU was financed in 2011. Its total budget amounted to 139.549€ (50% of eligible costs and 10.000€ for staff costs).

Various issues relate to the organic logo, which is dealt with on a separate fiche. Nevertheless, problems linked to the logo have been included in the present paper (Promotion and information fiche), the logo being the backbone of a promotion policy of organic products.

ANNEX 5: RESEARCH AND INNOVATION IN ORGANIC FARMING

1. EU RESEARCH FRAMEWORK PROGRAMME

During the past 12 years, the European Commission contributed over €150 million to almost fifty research projects on low-input and organic agriculture.

Close interaction between various actors in the organic sector, specifically within the Technology Platform Organics²⁶, resulted in development of a highly relevant research agenda. In acknowledgment of its important role, in July 2013, TP Organics was considered by the European Commission services to fulfil the criteria for recognition as a European Technology Platform (ETP), and is therefore included in the publicly available list of recognised ETPs on the European Commission website²⁷.

The completed and on-going research projects within the low-input and organic subject area have significantly contributed to the development of this sector by, for instance, improvement of organic regulation (e.g. ORWINE²⁸), provision of a wide range of methods for markets' assessments (e.g. OrganicDataNetwork²⁹) as well as enhancement of the productivity by creation and implementation of innovative production methods (e.g. QualityLowInputFood – QLIF³⁰ or LowInputBreeds³¹).

Horizon 2020³² is a financial instrument implementing the Innovation Union³³, a Europe 2020^{34,35} – flagship initiative aimed at securing Europe's global competitiveness. Running from 2014 to 2020, the EU's new programme for research and innovation is part of the drive to create new growth and jobs in Europe. Horizon 2020 reflects the policy priorities of the Europe 2020 strategy and addresses major concerns shared by citizens in Europe and elsewhere. It covers activities from research to market with a new focus on innovation-related activities and will include establishment of links with the activities of the European Innovation Partnerships. To address the challenges of the present and future, funding will be focused *inter alia* on the following Societal Challenges, which are of great relevance for organic farming, namely:

²⁶ <http://www.tporganics.eu/>

²⁷ http://cordis.europa.eu/technology-platforms/individual_en.html

²⁸ Organic viticulture and wine-making: development of environment and consumer friendly technologies for organic wine quality improvement and scientifically based legislative framework, STREP (Specific Targeted Research or Innovation Project) Contract no.:022769, Sixth EU Framework Programme, Priority 8.1 - Policy-oriented Research (SSP), Area 1.2, - Task 1: Organic viticulture and wine processing, Project Coordinator: AIAB

²⁹ http://ec.europa.eu/research/bioeconomy/agriculture/projects/organicdatanetwork_en.htm

³⁰ http://ec.europa.eu/research/research-for-europe/agriculture-quality-low-input-food_en.html

³¹ http://ec.europa.eu/research/bioeconomy/agriculture/projects/lowinputbreeds_en.htm

³² http://ec.europa.eu/research/horizon2020/index_en.cfm

³³ http://ec.europa.eu/research/innovation-union/index_en.cfm

³⁴ http://ec.europa.eu/europe2020/index_en.htm

³⁵ Communication from the Commission - Europe 2020 - A strategy for smart, sustainable and inclusive growth - COM(2010) 2020 of 3 March 2010

- Food security, sustainable agriculture, marine and maritime research and the bio-economy.

The research agenda for the next 7 years is under preparation. The Societal Challenges and the way to address them are of utmost importance in this exercise, which among others encompasses the identification of research and innovation goals that will leverage the organic sector's contribution to healthy planet and healthy food production and enhancement of sustainability in the wider agricultural field.

2. EUROPEAN INNOVATION PARTNERSHIP 'AGRICULTURAL PRODUCTIVITY AND SUSTAINABILITY' (EIP)

Knowledge management and exchange is of primary importance to low-input and organic systems. The diverse nature of organic farming makes it difficult to exchange knowledge between researchers, producers and other stakeholders. The newly developed European Innovation Partnership for 'Agricultural Productivity and Sustainability' will provide a vast array of opportunities to address this issue and boost multidimensional cooperation between the research community and farming practice.

Given that the aim of the EIP is to foster a competitive and sustainable agriculture and forestry that "achieves more from less" and works in harmony with the environment, organic farming can easily find its place in the EIP set up and take a great advantage of it.

The innovation model under the agricultural EIP goes far beyond speeding up transfer from laboratory to practice through diffusion of new scientific knowledge (referred to as a "linear innovation model"). The EIP adheres to the "interactive innovation model" which focuses on forming partnerships - using bottom-up approaches and linking farmers, advisors, researchers, businesses, and other actors within so-called Operational Groups. This will generate new insights and ideas and mould existing tacit knowledge into focused solutions. Such an approach will stimulate innovation from all sides and will help to target the research agenda.

For funding concrete innovative actions, the agricultural EIP will be implemented through actions that are mainly supported by two European Union policies:

- Rural Development Policy provides co-funding for innovative actions of "Operational Groups". The key measures include 'cooperation', 'knowledge transfer and information actions', 'advisory services', 'investment in physical assets' and 'farm and business development'. In addition, the Rural Development Policy will provide the means for setting up an EIP network facility at EU level.
- EU Research and Innovation Policy (Horizon 2020) plays its key role in providing the knowledge base for innovative actions on the ground. Key actions feeding into the EIP include 'applied research projects', 'cross-border initiatives', 'thematic networks', 'multi-actor approaches', 'pilot or demonstration projects', as well as supporting 'innovation brokers' and 'innovation centres'.

As a key instrument of the EIP, the network facility (or Service Point), in place since mid-April 2013, will act as a mediator for enhancing communication between science and practice and fostering their cooperation. It will encourage the formation of "Operational Groups" and support their work through focus groups, seminars and workshops, the establishment and maintenance of

databases with *inter alia* relevant research results and good practice examples, support for partnering, and helpdesk functions.

In this respect, the first three focus groups under the EIP are ready to start their activities. They will work on the following issues directly or indirectly advantageous for the organic sector:

- Organic farming (optimizing arable yields): Why do yields vary so much between organic farms; how can this yield gap be minimized?
- Protein crops: What does the feed sector need in terms of protein? Why is EU farming not able to deliver? Why is EU farming in protein crops not competitive? How can this be remedied?
- Animal husbandry: How can we reduce the use of antibiotic treatments in the pig sector?

Each focus group will bring together up to 20 experts that have practical experience in the relevant field and that are able and willing to share their expertise with others. Experts will be chosen according to their competences based on proven expertise for supporting the progress of the focus group. Attention will be paid to covering a reasonable balance of expertise and represented interest (e.g. scientists, farmers, advisors, representatives from industries, environmental NGOs, consumer groups, etc.).

3. RESULTS OF THE ON-LINE CONSULTATION CONCERNING THE NEED FOR RESEARCH AND INNOVATION

An overwhelming majority of the questioned citizens (i.e. 81%, 33411) during the on-line public consultation expressed the opinion that the organic sector should benefit from a public budget reserved only for research.

In addition, the respondents clearly identified four areas which should benefit from more research and innovation in organic food and farming sector:

- economic and social dimension of organic farming (58%, 26165),
- seeds and plant propagating material adapted to low-input agriculture (52%, 23519),
- local production of protein in-rich crops (48%, 21542) and
- waste management (45%, 20371) followed each other in the ranking set up by the respondents with only few percentage point of difference.

Two areas were selected as areas which would need more research and innovation but with a percentage much lower than the four above listed, namely "low-growth strains of animals" (15%, 6534) and "co-existence of organic farming with conventional farming and GMOs" (12%, 5532).

A significant number of respondents sent also by e-mail a range of other suggestions for research projects that are currently needed in organic farming sector such as: Innovations in organic farming are needed especially in the areas of plant breeding and the regional production of protein crops; Research comprising the comparison of the real production costs of agricultural /food products from organic and conventional farming systems; Research on environmental and health benefits of organic farming system; Research on innovative, renewable (=recyclable) and non-renewable (=non-recyclable) fertilizers and pesticides; etc.

Conclusion:

All the above-mentioned issues (research needs, funding for research and innovation, exchange of knowledge) have their rightful place in the new Action Plan for organic food and farming that will accompany the proposal for a future organic farming legislation.

ANNEX 6: THE EU ORGANIC PRODUCTION RULES

For many decades, the European organic sector was characterised by a system of private standards, with third party inspection and certification. **National legislations on organic farming were introduced in the 1980s.** France was the first country introducing such a legal framework in 1980, followed by Austria in 1983 and Denmark in 1987. The aims of these national legislations were to protect consumers from misleading claims and creating a level playing field for organic producers.

Council Regulation (EEC) 2092/91³⁶ introduced for the first time an EU-wide definition of organic farming and set out rules for organic crop production and indications referring thereto on agricultural products and foodstuffs. Rules on organic livestock and processed products were introduced eight years later with Council Regulation (EC) 1804/1999³⁷, supplementing the existing Regulation.

In the European Action Plan for Organic Food and Farming (EOAP)³⁸ of 2004, the European Commission proposed **to improve and reinforce the Community's organic farming production rules** as well as import and inspection requirements, and specified a number of actions with respect to production rules and inspection.

The legislation was substantially revised with the adoption of Council Regulation (EC) 834/2007 in June 2007, which notably:

- defined organic farming more accurately by describing its **objectives and principles**,
- improved the **harmonisation** of the organic production rules within the EU, by putting an end to national production rules for animal products,
- introduced the **possibility of exceptions to the rules** under the responsibility of MS, intended to replace a multitude of former derogations.

The aspects related to the labelling of organic products, to the control system and to the trade regime are dealt with in separate Annexes.

The new legislation was implemented from 2009 onwards. Since then, the legislation has been extended notably to **organic aquaculture** in 2009 (Commission Regulation (EC) No 710/2009³⁹) and to **organic wine making** in 2012 (Commission Regulation (EC) No 203/2012⁴⁰).

³⁶ Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs – UE OJ L 198, 22.7.1991, p. 1.

³⁷ Council Regulation (EC) No 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production – UE OJ L 222, 24.8.1999, p. 1.

³⁸ European Action Plan for Organic Food and Farming Com (2004) 415 final of 10.06.2004.

³⁹ Commission Regulation (EC) No 710/2009 of 5 August 2009 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production, UE OJ L 204, 6.8.2009, p. 15.

⁴⁰ Commission Implementing Regulation (EU) No 203/2012 of 8 March 2012 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards detailed rules on organic wine, UE OJ L 71, 9.3.2012, p. 42.

At international level, the EU plays an active role in the definition of Codex Guidelines GL-32-1999 for the Production, Processing, Labelling and Marketing of Organically produced Foods and contributes to the up-dates, like the current work for the inclusion of organic aquaculture.

1. THE EU ORGANIC PRODUCTION RULES

1.1. Definition of organic farming

The EU legislation actually defines organic farming. Articles 3 to 7 of Council Regulation (EC) No 834/2007 provide for detailed objectives and principles of organic farming translated into rules (in Regulations 834/2007 and 889/2008).

1.2. Scope of the legislation

Council Regulation (EC) No 834/2007 is limited in scope as it applies to products originating from agriculture, including aquaculture, where such products are placed on the market or intended to be placed on the market:

- agricultural products (live or unprocessed),
- processed agricultural products intended for food,
- feed,
- vegetative propagating material and seeds for cultivation,
- yeast used for food or feed.

The legislation covers all stages of production, preparation and distribution of organic products. However, mass catering operations are specifically excluded from the scope of this Regulation. MS may apply national rules or, in the absence thereof, private standards, on labelling and control of products originating from mass catering operations, as long as these rules comply with EU law.

In Article 41 of Council Regulation (EC) No 834/2007, the Council asked the Commission to submit a report on different subjects including the scope of the Regulation and mass catering which is specifically excluded from the rules.

1.2.1. Commission report

The Commission produced a report in May 2012⁴¹ which was forwarded to the European Parliament and to the Council.

1.2.1.1. Mass catering

The report analyses the experience with mass caterers. This sector is already subject to EU horizontal rules on hygiene and food labelling.

Currently, seven MS have introduced national rules for organic mass catering, while private standards are applied in ten other MS. These rules provide certification of ingredients, dishes, menus or complete catering operations. Following a survey carried out with the MS authorities in charge of organic production, most of them were of the opinion that mass catering operations

⁴¹ COM (2012) 212 final of 11.5.2012 Report from the Commission to the European Parliament and to the Council on the application of Regulation (EC) No 834/2007 on organic production and labelling of organic products

should not be subject to EU Regulation on organic production in the short term, not only because of possible increased complexity, but also because of the limited impact on trade due to their local character. The report concluded that there was currently no need to include mass catering operations in the Regulation but that the Commission would closely follow developments in this sector.

1.2.1.2. Textiles and cosmetics

There has been significant market growth for textiles and cosmetics bearing reference to organic production. Those two product categories are not included in the scope of the EU organic legal framework, which is limited to non processed agricultural products or processed agricultural products for use as food or feed. A debate has started on the question of the reference to "organic" for agricultural products outside the scope of the current Regulation and the possible risk for the credibility of the term "organic".

The European Union's general legislation on textiles deals with fibre names and labelling rather than production methods. Within the voluntary EU Ecolabel scheme, criteria have been established for textile products. In the case of cotton, if 95 % of the product is made of organic cotton, the denomination "organic cotton" is allowed under this scheme.

Agricultural raw materials, such as plant oils and plant extracts, are present in many cosmetics. The Union's legislation on cosmetics regulates the use of claims on cosmetic products.

The report concluded that it may be worth exploring the opportunities offered by the Union's legislation to extend the protection of the use of the word "organic" to textiles and cosmetics.

1.2.1.3. Other

The status of certain products outside Annex I of the Treaty but which are closely linked to Annex I products or to rural economy, such as beeswax, essential oils, or maté was not examined in detail in the report but it was underlined that the Commission recognises a need for clarification regarding such products.

1.2.2. Identified problems

- ***Should mass catering be included in the scope of the framework?***

Mass catering represents an additional outlet for organic products. The question is whether the introduction of EU harmonised rules is necessary or not. It has been put to the Commission and must be answered in the context of this review.

In the first hearing it was concluded by the experts that there is no need to extend the scope of EU implementing rules to mass catering, the preference is to keep this under the national rules.

- ***Should textiles and cosmetics be included in the scope of the framework?***

Organic textiles and cosmetics constitute a valuable outlet for organically produced raw materials. Currently, as they are not included in the scope of the legislation, it could be considered that they are posing a risk to the integrity of the term "organic" in the EU because their organic nature is not regulated in the same way as for food and feedstuffs i.e. in accordance with a production process. To include these categories of products, the legal basis of the EU organic legislation would have to be reviewed.

In the first hearing on the future of organic farming, when this subject was discussed, it was concluded that if textiles were to be included in the scope of the EU organic legislation, the organic standard would have to be a global standard to cover the whole world because natural fibre is mainly produced and also processed outside the EU (cotton is no° 1 fibre in the world).

- *Should the scope be extended to other/new products?*

There was a general agreement on the following. Whatever choice is made regarding a possible extension for the scope, considering that the objectives of the policy are to achieve a level playing field and consumer trust, clear and simple rules are preferable in all cases. The current legislation requires repeated interpretation.

If changes are brought to the scope, this could have an impact on existing international arrangements.

Extension of the scope would add an extra burden in terms of controls (for MS) and compliance and possibly also increase costs for the concerned operators for instance if there was a change from national to EU rules for mass catering.

On the basis of the above mentioned Commission's report, the Council drew conclusions in May 2013. As regards these particular issues, there was a call for "clarifying the situation regarding protection of the use of the term 'organic' for non Annex I products" and "providing guidance on the organic claims associated with the preparation of organic products in mass catering operations."

1.3. General production rules

The **EU organic production rules** are described in Title III of Council Regulation 834/2007 and in Commission Regulation 889/2008.

The starting point for organic plant production is the soil. Prescribed practices aim at maintaining or increasing the soil organic matter and enhancing soil stability and soil biodiversity. The fertility and the biological activity of the soil are essentially ensured by using **multiannual crop rotation including legumes and other green manure crops** and by the application of livestock manure or organic material.

The use of inputs is strictly limited. Annexes I and II to Commission Regulation 889/2008 provide for positive lists of authorised substances (fertilizers, plant protection products, etc).

The **organic livestock production rules** are characterized by **high animal welfare requirements** which aim at meeting animals' species-specific behavioural needs. In particular, a permanent access for livestock to open air areas is required and minimum surface areas indoors and outdoors are set for each species. Animals shall be fed with organic feed preferably produced on the farm or in the region.

Annexes III to VII to Commission Regulation 889/2008 provides notably for positive lists of feed materials authorised, feed additives used in animal nutrition and products for cleaning and disinfection of buildings for livestock production.

Production rules for organic processed food or feed require that the production of processed organic food or feed is separated in time or space from non-organic feed or food. Organic ingredients shall be used but exceptions are possible.

Annex VIII to Commission Regulation 889/2008 provides for positive lists of food additives and processing aids which might be used in organic processed products. Products and substances for use or addition in organic wine are listed in Annex VIIIa. Annex IX provides for a list of ingredients which can be used in their non-organic form in processed organic products.

In addition, MS have the possibility to authorize the use of ingredients in their non-organic form on a temporary basis according to Article 29 of Regulation 889/2008. Before granting such authorization, a MS shall verify that the operator has undertaken the necessary contacts with suppliers in the EU to ensure himself of the unavailability of the ingredients concerned in the organic form.

Farmers willing to convert to organic farming have to undergo a conversion period, during which they have to fully apply the rules of organic farming but they cannot sell their products as organic.

Parallel conventional production on organic farms is prohibited according to the first paragraph of Article 11 of Regulation 834/2007. However, the following paragraph introduces the possibility to run a holding with organic and conventional production, under specific conditions: the holding has to be split into clearly separated units and different animal species or different plant varieties have to be involved.

The use of **genetically modified organisms** (GMOs) and of ionising radiation is prohibited in organic farming.

The perception of the public is that organic production rules should be strengthened (see Annex 2).

1.4. Current situation regarding GMOS

Council Regulation (EC) No 834/2007 prohibits

- the use of genetically modified organisms or GMOs,
- products produced from GMOs and
- products produced by GMOs⁴².

One exception only is made for veterinary medicinal products (vaccines and others).

As organic systems are not isolated from the general production chain, low and accidental presence of GM crops in non-GM farming systems such as organic farming cannot be completely excluded. Council Regulation (EC) No 834/2007 clarifies that the general rules on adventitious and technically unavoidable presence of authorised GMOs apply i.e. that the horizontal rules of Regulation (EC) No 1829/2003⁴³ on GM Food and Feed apply equally to products used in organic farming. That Regulation provides that food and feed containing, consisting of or produced from a GMO must be labelled. Exceptionally, a product is exempted

⁴² Products produced "by GMOs" are mentioned in Council Regulation (EC) No 834/2007, but they are not defined in Regulation (EC) No 1829/2003 on genetically modified food and feed. Therefore only products produced "from GMOs" are considered in the analysis.

⁴³ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed – UE OJ L 268, 18.10.2003, p. 1.

from this labelling requirement where it consists of, contains, or is produced from GMOs in a proportion not higher than 0,9%, and provided that this presence is adventitious and unavoidable.

Council Regulation (EC) No 834/2007 also introduces specific provisions in Article 9 (3) on the responsibility of the organic operator for avoiding the presence of GMOs in organic products. The leading principles are to have the lowest possible adventitious presence of GMOs in organic products, as set out in recital 10, and at the same time to avoid undue constraints and additional burden on organic operators.

In order to ensure that no GMOs or products produced from GMOs are used as inputs for production processes, the Regulation stipulates in its article 9 (2) that operators can rely on the labels accompanying products or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC⁴⁴, Regulation (EC) No 1829/2003 or Regulation (EC) No 1830/2003⁴⁵ unless they have obtained information indicating that the labelling of the product in question is not in conformity with those Regulations for instance when the labelling threshold of 0,9% of adventitious presence of GMOs is exceeded.

Products produced from GMOs which are not food or feed are not covered by the GMO legislation and therefore no labelling and traceability obligations are imposed on them. Council Regulation (EC) No 834/2007 provides in its article 9 (3) that the organic operator has to request in such cases a confirmation or vendor declaration to be signed by the supplier of the products. In this document, the vendor must declare that his product has not been produced from GMOs. The vendor declaration represents a commitment of the supplier with legal value.

Council Regulation (EC) No 834/2007 provides within the exceptional production rules the possibility for the Commission to foresee exceptions to the prohibition of using products produced from GMOs when it would be necessary to use food and feed additives and other substances that would not be available on the market other than produced from GMOs. The Commission has not granted such exceptions so far.

1.4.1. Coexistence

The Commission's report to the Council and the European Parliament of 2009 on the coexistence of genetically modified crops with conventional and organic farming⁴⁶ concluded that GM crops have not caused any demonstrable damage to existing non-GM farming. On 13 July 2010 the Commission issued a Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops⁴⁷, which recognises that the potential loss of income for producers of particular agricultural products such as organic products may occur as a result of the presence of GMO traces at levels even lower than the GM labelling threshold set out in EU legislation at 0.9 %.

⁴⁴ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – UE OJ L 106, 17.4.2001, p. 1.

⁴⁵ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC – UE OJ L 268, 18.10.2003, p. 24.

⁴⁶ COM (2009) 153 final of 2.4.2009 Report from the Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming
http://ec.europa.eu/agriculture/gmo/coexistence/index_en.htm

⁴⁷ Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200 of 22 July 2010

Moreover, the Recommendation acknowledges the specific implications for producers of particular products such as organic farmers, impacting also the final consumer, since such production is often more costly, as it requires stricter segregation efforts to avoid GMO presence to guarantee the associated price premium.

In this same context, the Commission has submitted a Regulation proposal to the European Parliament and to the Council which, once adopted, would allow MS to restrict or prohibit cultivation of GMOs on their territory on grounds other than those based on a scientific assessment of health and environmental risks.

1.4.2. Facts, figures and recommendations resulting from the autumn 2012 hearings

- 180 mio ha of GMOs cultivated worldwide, mainly for feed purposes. They represent a 70 Bio\$ market in the US. There are 118 single GMOs authorised worldwide. In the EU, there is a “0” tolerance for non-approved varieties but for feed (not for food) there is a 0,1% tolerance when there are adequate detection methods.
- In the 96 EU laboratories that analyse presence or not of GMOs, the research is conducted in relation to the application of EU legislation. Laboratory analyses complement paperwork. A recommendation was made to the Commission to consult with laboratories when legislating.
- Totally GM free products represent a challenge. A study has been conducted by an external consultant on behalf of the Commission to examine in detail the issue of GM free labelling taking into account the existing schemes and labelling systems, consumers' expectations, feasibility, in order to have the necessary background to launch a reflexion on the possible need for EU harmonisation of GM free labelling. It is possible to ensure imports of GM free supply of soya in the EU, for feed uses.
- Co-existence has a high cost.
- The lower the threshold, the larger the sample to be analysed, the higher the cost of testing. To test for 0,1% you need to test a sample of at least 3000 particles of a product. The cost of testing a sample varies between 300 and 500€. If the sample tests positive, then there needs to be a quantification per ingredient. If the sample tests positive for an unauthorised GMO, the cost of the analysis can run to 10.000€.
- Operators have complained that the "polluter/payer" principle is not being applied for accidental presence of GMOs.
- A balance has to be found between cost and risk.
- Attention must be paid to labelling in order not to confuse the consumer.

1.4.3. Results of the public consultation

- 77,47% of respondents buy organic products because they want GM free products
- 89,5% of respondents consider that GMOs are incompatible with the concept of organic farming
- 51,14% are aware of the 0,9% labelling threshold for adventitious and technically unavoidable presence, and 47,45% are not.
- 68,25% think that organic products should be subject to the same labelling rules as conventional products.

- 56% declared that they are prepared to pay a higher price for a lower labelling threshold and 31,55% are not.

1.4.4. GMO Identified issues relate to:

- Adventitious presence of EU-authorized GMOs in organic products and labelling threshold

Council Regulation (EC) No 834/2007 forbids the use of GMOs, but the labelling rules set in the EU Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed apply. In the absence of specific rules, the horizontal rules of the EU Regulation on Genetically Modified Food and Feed thus apply equally to products used in organic farming. That Regulation lays down a general labelling threshold of 0.9% for the adventitious or technically unavoidable presence of authorised GMOs or products from authorised GMOs. Feed and in particular soya has been singled out as a product category likely to contain adventitious and unavoidable presence of EU-authorized GMOs below 0,9%. As regards organic products grown in an environment where GMOs are cultivated, the Organic Regulation does not determine the responsibility for the costs of analysis and of a possible declassification of the product due to EU-authorized GMO presence in harvest above the 0,9% labelling threshold, as this is an exclusive competence of the MS. The Commission Recommendation on guidelines for the development of national co-existence measures⁴⁸ to avoid the unintended presence of GMOs in conventional and organic crops, recognises that the potential loss of income for producers of particular agricultural products such as organic products may occur as a result of the presence of GMO traces at levels even lower than the 0,9% GM labelling threshold. Moreover, the Recommendation acknowledges that the admixture of GMOs has specific implications for producers of particular products such as organic farmers, impacting also the final consumer, since such production is often more costly, as it requires stricter segregation efforts to avoid GMO presence to guarantee the associated price premium.

- Availability of certain products

Some substances such as vitamins, enzymes and amino-acids are regularly reported as available only produced by GMOs and cannot be used in organic production.

1.4.5. Analysis of options

The introduction of a lower GMO labelling threshold for organic food products was considered and extensively discussed.

The information collected during the hearings and in meetings with stakeholders shows that the cost for all operators of such an option would be significant and disproportionate in relation to the dimension of most EU organic operators. From the results of the hearings it can be concluded that the lower the threshold, the larger the sample to be analysed, the higher the cost.

⁴⁸ Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200 of 22 July 2010

Following the discussions in the Council⁴⁹ (May 2013) and the broad consultation with the sector⁵⁰ and with stakeholders, the Commission has concluded that the status quo in relation to the EU approach and legal provisions on GMOs for labelling of organic products are adequate. It was highlighted that current provisions provide a reasonable balance between benefits and costs. In particular, a specific lower tolerance threshold does not appear realistic in view of the practicalities, burden and costs of analysis.

⁴⁹ See a detailed analysis in Annex 6 on production rules.

⁵⁰ In particular during discussions at the AGOF meeting of December 2012.

2. POSSIBLE EXCEPTIONAL RULES UNDER ART 22 OF REGULATION 834/2007

Article 22 of Regulation 834/2007 provides for conditions for possible exceptional production rules. These exceptions shall be kept to a minimum and, where appropriate, limited in time. They are usually granted by MS competent authorities, but some of them can be delegated to the CBs.

2.1. Overview

Exceptional rules intend to provide flexibility, enabling adaptation of the production rules to specific climatic, geographical and structural constraints or stages of development (Article 22 of Regulation (EC) 834/2007 and Chapter 6 of Regulation (EC) 889/2008). Many exceptions are related to the principle according to which the use of external inputs should be restricted to inputs from organic production (Article 4(b) of Regulation (EC) 834/2007). Exceptions can be granted where they are necessary to ensure access to inputs which are not available in organic form on the market (Article 22). Granting exceptions is thus necessary where no alternatives exist; but can also lead to distortion, because non-organic inputs are often cheaper than the organic alternatives.

Exceptions can be granted by the competent authority of the MS if inputs are not available in organic form on the market (or during catastrophic circumstances where temporary measures are necessary to protect organic production).

The possible exceptions according to Article 22 are the following:

- Up to 40% of non-organic female mammals on a holding for the renewal of a herd or flock,
- Management of animals (dehorning, etc),
- Retroactive recognition of a conversion period,
- Tethering of animals in small holdings,
- Parallel production of plant varieties that cannot be easily differentiated,
- Parallel organic and non-organic livestock of the same species for agricultural research or formal education,
- Parallel organic and non-organic bee-keeping units on the same holding,
- Bringing non-organically reared poultry into an organic poultry production unit when a flock is constituted for the first time,
- Use of non-organic beeswax,
- Use of seed or vegetative propagating material not obtained by the organic production method,
- Indoors final fattening phase of adult bovines for meat production (1/5 of their life),
- Use of non-organic feedings stuffs, renewal or reconstitution of a herd or flock, etc due to catastrophic circumstances.

The following possible exemptions are now being phased out:

- Use of non-organic protein feed of plant and animal origin for livestock. Where farmers are unable to obtain protein feed exclusively from organic production, the use of a limited proportion of nonorganic protein feed is allowed for porcine and poultry species. The maximum percentage of non-organic protein feed authorised per period of 12 months for those species shall be 5 % for calendar years 2012, 2013 and 2014.
- Bringing non-organically reared pullets for egg production of not more than 18 weeks into an organic livestock unit when organically reared pullets are not available (31 December 2014).
- Using natural eggshell colouring agents for traditional boiled Easter eggs (31 December 2013).
- The possible addition of non-organic yeast extracts has to be examined by the end of 2013.

In addition, some exceptions are based on other Articles of Regulation 834/2007, notably on Article 40 (transitional measures).

The three main⁵¹ exceptional measures providing temporary authorisation to use non-organic inputs (young poultry, feed and seeds) and the transitional rules for animal housing have been subject to a specific analysis in the framework of the external evaluation. In order to assess the justification for non-organic input use, the following aspects were considered: (a) current availability of organic farm inputs, (b) reasons for undersupply, (c) actions taken (or need to be taken) to develop an appropriate supply, (d) evolution of the supply in the past years, (e) implications of the exceptional rule, considering likely impact on developing supplies, and where appropriate on achieving the objectives of organic farming and on consumer confidence. Where quantitative evidence was available it is presented in the following, along with the analysis of provisions, experts' points of view and literature.

2.2. Exceptional rules for using non-organic young poultry

2.2.1. Legal provisions

Article 42 of Commission Regulation (EC) No 889/2008, based on Article 22 of Council Regulation (EC) No 834/2007, provides that (1) non-organic young poultry up to 3 days old can be introduced when constituting or reconstituting a flock (without specified time limited) and (2) until 31 December 2014 (initially 31 December 2011), non-organic⁵² reared pullets for egg production of not more than 18 weeks may be brought into an organic livestock unit, when *organically reared pullets are not available in sufficient numbers*. There are currently no EU rules for the production of organic chicks or for the rearing of organic pullets.

⁵¹ Based on stakeholders interviews

⁵² Among producers these pullets are often referred to as part-organic, because the articles states that the organic feeding and disease prevention rules must be complied with by the pullet rearing enterprise.

2.2.2. Issues

Current availability of organic pullets: Out of the 13 countries considered by the evaluation, exceptions provided by Article 42 apply in all MS under various conditions, except for Denmark, which has set up national rules for the production of organic young poultry. In Denmark farmers must get supplied with organic young poultry for laying hens as well as broiler production. The supply in young organic poultry is thus adequate in Denmark. Also in Germany the use of non-organic poultry is forbidden, but producers can use non-organic eggs for hatching without derogations. Some regions like North Rhine-Westphalia are starting to set up stricter regulations; for example that from 1st March 2013 mixed flocks (organic and non-organic chicks) have to be built, and unavailability-declarations have to be issued by suppliers. In many other MS, the production of broilers or laying hens relies on the use of non-organic chicks, fed with organic food since the age of one day. Experts from Austria, Denmark, France and the Netherlands reported that there was no need for exceptional rules for young poultry, while experts from the Czech Republic, Estonia, Italy, Poland and Slovenia stressed that there is no or only a limited supply of organic young poultry in their countries.

Causes of the undersupply of organic young poultry: The lack of EU production rules regulating young organic poultry production constrains the development of the sector, as MS are reluctant to develop production rules at national level to avoid potential disadvantages for their producers. This is referred to in Recital (3) of Commission Regulation (EC) 505/2012 of 14 June 2012, *“the development of harmonised organic production rules for young poultry at Union level is complex, the viewpoints on technical requirements vary widely between the parties concerned.”* As a result, Recital 3 states that *“in order to allow more time to develop detailed rules for the production of organic pullets, the exceptional rule for using non-organic pullets should be prolonged.”*

Actions to develop the supply of organic chicks and pullets have been taken in Denmark. The Ministerial Order N° 1112 of 21 November 2008 of production and marketing of organic pullets sets provisions related to marketing conditions, feeding, welfare demands (physical production demands), prohibitions of trimming of beaks and the use of allopathic veterinary medicinal products and treatments. **According to Danish operators and experts interviewed, the provision of using organic pullets led to the development of an appropriate production of organic pullets.** In France and the United Kingdom producers tend to support the introduction of EU production rules for rearing organic pullets, but wish to maintain exceptions on using non-organic chicks for the time being. In France, producers appreciate the great diversity of breeding species that the exceptional rule allows them. Operators interviewed by the contractor have also highlighted that introducing organic chicks from organic breeding stocks will (a) raise the price of organic pullets (see further below) and (b) bring strong technical and sanitary constraints in breeding stock management, particularly because of the mandatory open-air access areas.⁵³

Implications of the exceptional rule for using non-organic pullets: The existence of these exceptional rules, (one of them with no end date, the other extended recently), has an adverse effect on the development of the organic supply. In case study countries, authorities and/or operators agreed that a 100 % organic supply would be possible if there were no market

⁵³ This point would not affect northern countries that require access to open-air areas only if weather conditions permit.

perturbation like the possibility provided by the exceptional rule. To postpone the ending date hampers the development of supplies and is not fair for sectors that have started to adapt to the end of the exception. In Denmark, the use of conventional young poultry has been prohibited for many years which fostered the development of a market for young organic poultry. Differences in supply, whether it is from (non-)organic chicks or part-organic pullets, leads to significant differences in costs.

In the United Kingdom, experts estimate full organic rearing of pullets to be approximately 40 % more expensive than part-organic pullets and in France the price of organic chicks is estimated to be twice as high as of conventional day-olds.⁵⁴

2.3. Exceptional rules for using non-organic feed

2.3.1. Legal provisions

For the feeding of pigs and poultry, Article 43 of Commission Regulation (EC) No 889/2008 based on Article 22(2, b) of Council Regulation (EC) No 834/2007 authorises the use of a maximum percentage of non-organic high protein feed when organic quality high protein feed is not available.⁵⁵ Initially, the exception was in force between 2009 and 2010. In 2012, the 5 % rate was extended until the end of 2014.

2.3.2. Issues

Current availability of organic high protein feed: Typical high protein content feed for monogastrics is usually soy products, corn gluten or potato protein, because it contains specific amino acids such as lysine and methionine. **It is not possible to estimate the availability of organically sourced protein feed in the EU, since official data on feedstuff demand and availability do not exist.** The ICOPP⁵⁶ project (Improved contribution of local feed to support 100 % organic feed supply to pigs and poultry) will assess available feed resources and the current demand in selected MS. A survey on feed resources is now in progress in 12 countries, making use of national information to provide best estimates. A report is due at the end of the project in October 2014.⁵⁷

Interviewed experts declared that these types of protein crops are not available in sufficient quantities from organic sources at EU level, and that **the majority of pig and poultry farmers rely on the exceptions of the 5 % non-organic high protein feed rule.** Insufficient supply of organic feed was specifically mentioned by experts from Austria, Czech Republic, Germany,

⁵⁴ Example of costs of production difference in United Kingdom (exchange rate EUR/GPB = 1.19):

- Costs of organic chicks for broilers: £0.70/per bird (0.83 €) whereas non-organic chicks likely at £0.40/per bird (0.47 €)
- Fully organic reared pullets for layers (using non-organic chicks): £6.00 to 6.95/ per bird (7.12 to 8.25€). Part reared (free range using only organic feed): £4.40 to £4.70 (5.22 to 5.58 €).
- Rapport ITAVI (text A), 2010 compares the price of conventional chicks of slow growing strains of 29.61€ for 100 heads to the price of organic chicks of intermediary growing strains of 65€ for 100 head).

⁵⁵ This rule does not apply to herbivores.

⁵⁶ The project is coordinated by the International Centre for Research in Organic Foods Systems (ICROFS) and funded under the CORE Organic II - FP7 ERA-Net project).

⁵⁷ The report will present estimates of organic stock numbers of all animals (including herbivores) and of organic production of concentrated feedstuffs including protein, broken down by crop/type in 12 countries as well as balancing calculations and tentative conclusions.

Denmark, Estonia, France⁵⁸ and Slovenia. They are concerned about the threat represented by imports of organic feedstuff from third countries (mostly China and India); with little guarantee on control and large carbon footprints. Recent cases of melamine contamination in organic soy imported from China and fake organic soy traded from Italy have had an impact on the demand for locally produced protein feedstuffs, which the market is unable to meet.

Causes of the systematic use of the 5 % of non-organic protein exceptional rule: Interviewed experts stated that a 100 % organic diet could hardly meet animal requirements (mostly with high performance breeds), and supplementation with non-organic high protein feed (as well as amino acids) is a necessity to reach a balanced supply of methionine and lysine for the high performance standards. Natural amino-acids are provided by corn gluten or potato protein incorporated in the 5 % of non-organic authorised ingredients, and by increasing the share of soy in feed. The obligation of 100 % organic feed would force farmers to find new sources of natural amino-acids, since corn gluten or potato protein are not available organically.⁵⁹ A number of potential high protein feed sources (rapeseed, peas & beans but also micro-algae) could be developed as alternatives, but some require further research. As part of the EU funded EEC (organic) 2092/91 Revision Project, Sundrum et al. (2005) carried out a meta-analysis of the available literature to evaluate whether restrictions in protein supply can be compensated for by other measures that are more in line with organic objectives and principles. The report concluded that due to the restricted availability of feedstuffs with a high content of limiting amino acids, growth rates and protein accretion of organic pigs and poultry are clearly lower in organic compared to conventional production. However, it claimed that there is sound scientific proof that both poultry and pigs can compensate to a high degree for imbalanced feed rations without the onset of specific health and welfare problems, with the exception of the animal's first weeks of life. Strains with a high genetic yield capacity seem to be more sensitive to suboptimal feed rations than slow growing strains or robust breeds. There also are numerous studies that describe the undesirable side effects of breeding for high protein accretion, especially in poultry production, making the lower intensity of feeding potentially an asset of organic production and suggesting that organic production of pigs and poultry needs to be protected from unwanted intensification through feed ingredients (Sundrum et al., 2005). The ICOPP project is expected to contribute to new approaches of ration formulation.

Implications of the exceptional rule for using non-organic high protein feed: In the current situation, the financial implications of the phasing-out of this exceptional rule would represent an increase of the total feed budget⁶⁰ to reach the required level of 100 % organic feed, because of the increase in price between non-organic and organic protein feed.⁶¹ Another impact would come from the change of the feeding content. Since some high value protein feedstuffs (e.g. potatoes protein, maize gluten, soy meal) used to balance rations are not (or not fully) available from organic sources, farmers will increase the overall protein content when increasing the share of organic raw materials to achieve a diet that provides adequate amounts of the limiting amino acids. This could result in a decrease in yield and, as a consequence, an increase in price. Consumers perceive organic husbandry as a production method based on natural/healthy feed (e.g. Zanoli et. al 2004). They are not aware of the details of production rules and expect

⁵⁸ For example in France, according to expert estimates, the need for organic soy for animal feed is around 55 000 tons, and national production is 5 000 tons, which means that 90 % of organic soy for feed is imported (mainly from third countries).

⁵⁹ EGTOP (2011), Final report on feed, 3rd plenary meeting on 29 and 30 June 2011

⁶⁰ According to United Kingdom expert interviewed, to move from 95 % to 100 % will cost producer + £15/t in increased feed cost and +3p/doz in production cost.

⁶¹ This assumption doesn't take into account potential adjustments such as adaptation of breeds

livestock used for organic meat to have been fed 100 % organic feed and their preference goes to local feed sources. **The organic principles for farming oblige farmers to practice land-related livestock production** and the feeding rule also express a preference for feed from the farm or region.

2.3.3. Results of the public consultation

As an immediate and transitional measure, the use of synthetic amino acids for organic monogastric feed production is discussed in some MS (for example Germany). The argument is made that in this case animal needs and species-specific feeding should have higher priority than the principles to use 100 % organic inputs. However, some representatives of the organic farming movement e.g. in Germany, strongly dismissed this suggestion as not being in line with organic principles and stated that instead the search for alternative solutions needs to be intensified. **Only 1% of the respondents to the public consultation would agree with such a measure.**

The majority of the respondents (66%) 29575) stated that the effective solution for reduction of insufficiency in terms of organic protein-rich feed in Europe was to introduce in the EU legislation initiatives to boost European production of organic protein crops. Following, as many as 27336 (61%) questioned citizens found that in order to address this issue a specific organic protein-crop production strategy should be developed. In turn, only 11% (4947) claimed that the organic sector should be allowed to continue to rely on imports if needed. Promising alternatives are already developed: methods to produce methionine via enzymatic fermentation based on organic raw materials, or the use of insect larvae or algae as a protein source for feed (method in development). These new techniques are considered by interviewed experts as very promising, but not entirely ready for a broad practical use yet.

2.4. The use of seed or vegetative propagating material not obtained by the organic production method

2.4.1. Legal provisions

The general rule imposes the use of organic seeds: "for the production of products other than seed and vegetative propagating material only organically produced seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons." (Article 12 1) i).

Exceptions are possible according to Article 22 b) where it is necessary to ensure access to seed and vegetative propagating material (seeds) where they are not available on the market in organic form. According to Article 45 of Commission Regulation (EC) No 889/2008, MS can authorise the use of seed from a production unit in conversion to organic farming or the use of non-organic seed if not available from organic production. Non-organic seed may be used provided they are not treated with plant protection products not allowed in organic farming.

MS may delegate the responsibility for granting the authorisation referred to in paragraph 1) b) to another public administration or to the control bodies in charge of the controls of the organic production on its territory.

Species for which it is established that organically produced seeds are **available in sufficient quantities** and for a significant number of varieties in all parts of the EU are set out in Annex X to Regulation 889/2008 and their use in the non-organic form may not be authorised. **This list has always been empty.**

According to Article 48 of Regulation 889/2008, each MS shall ensure that a **computerised database** is established for the listing of the varieties for which seeds obtained by the organic production method are available on its territory. Varieties for which seeds produced by the organic production method are available shall be registered in the database at the request of the supplier. Conditions for registration include the demonstration that the seeds to be placed on the market comply with the general requirements for organic production. Any variety which has not been registered in the database shall be considered as unavailable. However, there is no legal obligation for suppliers to notify their organic seed to the database.

The system of national seed databases is intended to encourage the use of the available organic seed supply nationally by making it easier to find information about availability. The management of the exceptional rule system is done at MS level based on three categories: (1) where organic seed availability for species/varieties is sufficient, exceptions are no longer granted; (2) species or varieties with partial availability of organic seed, so exceptions apply and (3) species or varieties where there is no organic seed available, so a general authorisation to use non-organic material is given (see Table 1).

Table 1: Management of the non-organic seed exceptional rule in 2011 in some EU MS

	Category 1 Out of derogation	Category 2 Number of species and varieties concerned by derogation	Category 3 General authorization to use non organic material
AT	None	55 sp. 522 var.	13 sp.
BG	None	56 sp. 152 var.	None
DE	None	124 sp. 173 var.	180 sp.
DK		546 sp. 99 var.	~ 170 sp.
EE	None	17 sp. 84 var. (incl. 28 tomato var.)	All species not available in the database
ES	None	70 sp.	yes ^c
FR	YES (~13 sp.) ^a	3 000 var., belonging to 149 sp. are registered in the data base Alert screen: var. that will soon be included in cat 1 ^b	8 sp. and 7 var. of vegetables 15 sp. and 3 var. of field crop
NL	YES (>70 sp.)	159 sp. >1064 var.	Arable: 8 sp. Vegetable: 9 sp. Covered: 5 sp.
PL	None	201 sp. 1 629 var. As long as organic seed material is available, no derogation is granted	None
SI	None	Ca. 99 sp. Ca. 346 var. Var. database prepared by the Ministry	None
UK	None	Ca. 598 sp. Ca. 4 000 var.	None

var. = varieties, sp. = species

^a Exceptional cases of derogation for these species have been granted (for ex. 49 concerning maize in 2011).

^b In 2010: carotte nantaise, chicorée frisée, oignon jaune hybride, triticale.

^c The national report does not mention category 3 as such but states that, in Spain there is no offer of organic seed for many species, including : maiz, chickpeas, lentils, bitter vetch, canola, garlic, asparagus

Source: Own data from on case studies and annual national reports

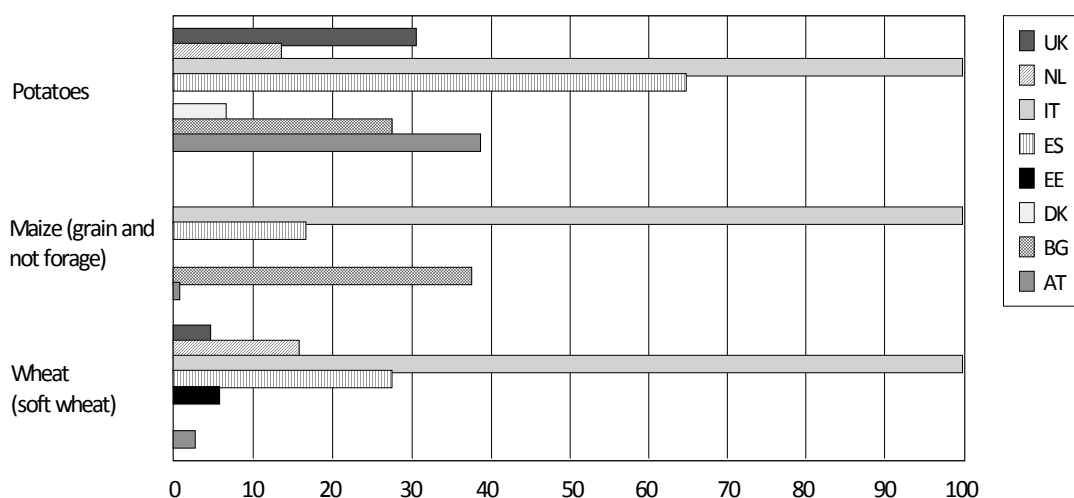
Bodies designated to grant authorizations to use non-organic seeds shall report to the MS competent authorities.

MS competent authorities shall send **an annual summary report** to the Commission and to the other MS.

2.4.2. Issues

Current availability of organic seeds and propagation material: The organic seed market is growing, but levels of supply vary between MS and crops. In Austria, Germany, Denmark and France the organic seed supply is reaching satisfactory levels overall, according to interviews with authorities and professionals (see Figure 2), exceptions for seeds were reported to be necessary in Bulgaria (although farmers usually use their own seeds), the Czech Republic, Spain, Italy, Poland and the United Kingdom. The sectors that mostly rely on exception requests are fruit and vegetable producers, as they use a wide range of species and varieties. To assess the degree of use of the exceptional rule system, the share of the organic area grown with conventional non-treated seeds (exceptional seeds) has been compared with total organic area, for three different crops in 8 MS. The data are presented as an index, the highest proportion for each crop being given an index of 100.

Figure 2: Share of area grown with exceptional rule non-organic seeds of total organic area, 2011 (ha)



Note: The index is calculated from the quantitative data registered in the statutory annual report of 2011 for each member state (Art. 54 of Reg. 889/2008). The amount of non-treated conventional seeds granted through derogations were converted in areas, using the following seeding rate - soft wheat (kg/ha): 175; grain maize (kg/ha): 30; potatoes (kg/ha): 2000. (This does not cover all the non-organic seeds use, because some non-treated seed can be used without requiring derogation when there is permanent derogation: In Denmark, general derogations are granted on soft wheat and grain maize species, whereas in Estonia, general derogations are granted on soft wheat and potatoes varieties). Then the corresponding area were divided by the total organic area, and indexed so that the max rate was equalled to 100. In United Kingdom, data concerning maize are not available but organic maize cultivation is very limited.

Source: Data from the consultant

Among the countries observed, supply of organic varieties of wheat, maize and potatoes seems to be limited in Italy (the highest rate of use of non-organic seeds). This might also be the case in Denmark and Estonia, where the use of species or varieties classified in category 3 with general exception (see definition of categories below) means there is no record-keeping of non-organic

seeds used. This may lead, in turn, to farmers favouring cheaper non-organic seeds, even when adequate organic supply is available for specific varieties. However, very high levels of organic supply for soft wheat have been achieved in Austria and the United Kingdom. For maize, the share of organic areas cultivated from organic seed is close to 100 % in the Netherlands, Austria and Spain. Organic supply for seed potatoes is adequate in Austria, Bulgaria, Denmark, the Netherlands and the United Kingdom (index below 30%).⁶²

Of the 12 countries studied⁶³, only France and the Netherlands developed a list of species for which organic seed supply is sufficient in quantity and diversity (Category 1).⁶⁴ The majority of countries operate a regime where exceptions have to be justified for each species on a case by case basis. Requested exceptions vary significantly and can reach up to 4 000 varieties of around 600 species (United Kingdom). The third category, a list of species and varieties under permanent exception, is active in six MS.

Causes for undersupply: The reasons for the low level of organic seed use are twofold, technical and economic.

- According to ITAB (French Organic Farming Technical Institute) quoted by the consultant, obtaining organic seeds from conventional breeding techniques is not straightforward, since very few producers are compliant with organic principles. Research studies have been launched by multi-actor partnerships like ITAB and ECO-PB (European Consortium for Organic Plant Breeding), to further develop organic seed supply and quality, and are addressed in some research projects (e.g. SOLIBAM).⁶⁵
- From a financial perspective, organic seeds are more expensive than non-treated conventional ones, which is an adverse incentive at individual and collective level to use or develop organic seed production. Odefey et al (2011) compared the production costs of some organic enterprises with conventional in five countries. Based on FADN data, they showed that seeds represent an important share of production costs in organic crop production (from 21 % in Sweden to 35 % in France for wheat; from 18 % in Germany to 25 % in Sweden for potatoes). Indeed, the average costs for organic seeds are higher than for conventional seeds (two to four times higher in Sweden and Germany for wheat; two to five times higher in Sweden and Austria for potatoes). As a result, the potential to use non-treated conventional seeds under the exceptional rule leads to financial advantages.

⁶² Stakeholders in the United Kingdom mentioned that supply of organic seed potatoes has fallen dramatically in the last two years, because one major supplier withdrew from the organic market.

⁶³ Data from Czech Republic could not be analysed.

⁶⁴ No conventional seeds can be used by the operators for these crops, except for exceptional cases under appropriate justifications (e.g. specific use, e.g. pop-corn).

⁶⁵ Strategies for Organic and Low-input Integrated Breeding and Management, financed by the European Commission under the 7th Framework programme- <http://www.solibam.eu/>

Implications of the exceptional rules for using non-organic seeds: The organic seed supply was first limited by the size of the sector, which did not provide a large enough market. The sector has grown but the seed price difference is significant and the diversity of supply might not be sufficient to meet the need of the sector. Now, providing access to the conventional seed market through this exceptional rule plays against the development of the organic seed sector.

Generally, exceptions have increased over the past years. The overview (see Table 3) shows that there is only a limited number of cases where the quantity of exceptional seeds has decreased with regard to the respective organic area: for potatoes in Italy, for wheat and spelt in Denmark and for carrots in Italy and the Netherlands (of the thirteen MS considered, complete data was only available for Denmark, Spain, Italy, the Netherlands, Poland and the United Kingdom).⁶⁶ The diversity of the varieties managed through the databases has increased in most cases. This data and the previous information on the use of the seed management database, shows generally **an extensive and increasing use of the exceptional rule system at EU level**. Accordingly, Annex X of the EC Regulation has remained empty, showing the limited progress made towards supply of organic seeds and propagating material at EU level.

The mandatory use of organic seeds will reduce the risk of contamination with pesticides and GMOs from using conventional seeds and propagation material. However, organic principles also require the use of locally adapted varieties, of which seeds are less likely to be available in organic quality. For this the reason, some stakeholders see the use of non-organic seeds as a necessity for the sector to develop, even though it impedes or slows down the development of organic seed production.

⁶⁶ Decreased in greater proportion than the area or increased in smaller proportion.

Table 3: Analysis of the evolution of the exceptions granted (volume and diversity) compared to the development of organic areas between 2007 and 2011 (Rate 2011 over 2007)⁶⁷

		Den- mark	Spain	Italy	Nether- lands	Poland	UK
Potatoes	Organic area	38%	n. a.	-8%	9%	56%	-30%
	Seeds under exception (quantity)	1523%	118%	-95%	217%	284%	-29%
	Diversity (Number of varieties effected by the exceptions)	88%	26%	33%	132%	85%	13%
Wheat & Spelt	Organic area	52%	n. a.	-13%	-26%	n. a.	-11%
	Seeds under exception (quantity)	-79%	733%	14%	-75%	834%	120%
	Diversity (Number of varieties effected by the exceptions)	-71%	6%	-9%	100%	8%	-5%
Carrots	Organic area	41%	n. a.	-25%	50%	n. a.	n. a.
	Seeds under exception (quantity)	113%	174%	-95%	44%	21%	-92%
	Diversity (Number of varieties effected by the exception)	-13%	0%	n. a.	23%	100%	-2%

2007 data is the average 2006-2007, and the 2011 data is the average of 2010 and 2011 (except for DK where only the 2006 data were available).

Calculation is based on Eurostat data for organic areas and national seeds reports. When registered in seed units, the derogations were changed into kg using the following coefficient: potatoes (0.05); wheat and spelt (0.000045) and carrot (0.0000012). Then, the rate of change was calculated : $[(\text{average of 2011 and 2010}) - (\text{average of 2006-07})] / (\text{average of 2006-07})$.

Source: calculation of the consultant based on national reports and Eurostat.

2.5. Issues with the exceptional rules allowing the use of non-organic inputs

The possibilities of use of non-organic inputs when they are not available in their organic form have been introduced with precautions in the EU legislation.

In particular, **transparency about the availability of the inputs in their organic form** has been sought. For instance, the availability of organic seeds should be known thanks to national seeds databases. In other respects, MS are required to notify their authorizations of use of non-organic ingredients in organic processed products via the "organic farming information system" (OFIS), a Commission software.

This transparency has entailed high administrative burden on national administrations (see assessment of administrative burden in Annex 17). The procedures in place often involve individual applications and decisions, which become numerous and difficult to manage for MS competent authorities. The seed database has been identified as particularly burdensome.

The transparency policy has not helped limiting the use of exceptions. To the contrary, the external evaluation shows that **exceptions are more and more used**. Inputs producers are not encouraged to develop inputs in their organic form, since the possibility of derogation is known and used.

⁶⁷ Sufficient data allowing the analysis of both (a) exceptions granted and (b) organic areas for the selected species (potatoes, wheat and spelt, carrots) were available only in 5 countries. One of the limiting criteria was the different units used to specify the volume of exceptions, which prevented a clear view of the total amount granted.

2.6. Transitional measures concerning animal housing

2.6.1. *Legal provisions*

Transitional measures were designed to allow progressive adaptation to the EU production rules, by allowing flexibility regarding animal housing conditions (stocking density, Article 95(2) of Commission Regulation No 889/2008), and cattle tethering in buildings existing before August 2000 (Article 9(1)). These measures were intended to end on 31 December 2010, but they were extended until the 31 December 2013.⁶⁸

Both measures have been extended in a significant number of MS: the transitional measure concerning tethering of animals still applies in ten of the thirteen studied countries (Austria, Bulgaria, Czech Republic, Germany, Denmark, Estonia, France, Netherlands, Poland and Slovenia); and the measure regarding stocking density in nine of the 13 studied MS (as above but not in Slovenia). In countries which have extended these measures operators had a 13-year transition period from 2000 to 2013. Both rules are justified by the cost of adapting animal housing to organic welfare standards introduced in 2007 in Council Regulation (EC) 834/2007. To support the transition, specific aid is offered under rural development programmes, which enables farmers to invest in new buildings corresponding to the new requirements. However, this aid is offered/implemented with specific provisions for organic farming only in very few countries (e.g. Austria, parts of Germany).⁶⁹

Both transitional rules are exceptions to the animal welfare standards as stated in the principles of organic production (species specific behavioural needs and meeting consumers demand).

2.6.2. *View of stakeholders*

Stakeholders interviewed by the consultant argued that transitional measures concerning animal housing were adequate and justified to stop farmers quitting organic farming and to help to maintain supply on the market. However, when asked whether the transitional rules should continue or stop after 2013, views differed. On one hand, some stakeholders in Germany, Estonia, Italy and Netherlands considered that tethering is not in line with the organic principles and that the sector has had sufficient time to adapt and reorganise. On the other hand, some interviewees suggested that tethering of cattle, when done in conditions that respect animal welfare (regular exercise provided, access to outdoor pasture, spacious stables with sufficient bedding, etc.), could be allowed permanently (Czech Republic, Poland, Netherlands).

⁶⁸ There also is a permanent exceptional rule related to structural constraints, the tethering exemption for small holders in Article 39 of Regulation (EC) 889/2008.

⁶⁹ See information about Measure 121: Modernisation of agricultural holdings in Sanders et al. (2011).

3. CONCLUSIONS

3.1. Scope

Harmonised and clear rules at EU level are essential to guarantee a level playing field for all EU organic operators. This is needed to ensure a smooth and well functioning EU market and to avoid unfair competition and fraud.

The three options that have been examined for the impact assessment, address the scope issue in the same way and include a clarification of the scope of the legislation by listing precisely the products covered, which can be labelled as "organic". The result will be to improve transparency and legal certainty for all operators of the sector and for consumers also. It will also contribute to reducing the administrative burden resulting from the frequent questions on scope that are put to the Commission and to the national administrations. Improved clarity and transparency will have a positive effect on consumers' and producers' confidence in the EU organic system.

The findings of the Commission's report, of the hearings and of the consultations did not show or justify the need for the inclusion of additional products or sectors of activity. In particular, as regards mass catering which hardly has any cross-border dimension, there is no evidence, at this stage, of an EU added value that would result from its inclusion in the scope of the European organic rules or from the elaboration of EU guidelines. Therefore the extension of the scope of EU organic legislation to mass catering was discarded.

The same conclusion was drawn for textiles and cosmetics. The introduction of EU production rules for textiles and cosmetics was considered but discarded because the need for EU action was not demonstrated.

To further encourage the consumption of organic products, the Commission intends to include in the Action Plan a general recommendation to prioritize the use of organic products in public procurement schemes.

3.2. GMOs

It results from the fact finding exercise and consultations carried out during the impact assessment that the GMO question is complex and cannot be addressed only from an organic agriculture point of view but must be considered for all agricultural crops. The issue is relevant to ensure GMO free organic (protein) feed.

The results of the public consultation have shown that consumers of organic products want GMO free products and the organic sector is committed to meet this expectation.

However, the sector is concerned about the consequences of the introduction of a lower labelling threshold notably for reasons of practicality, burden and costs. Lowering the labelling threshold or introducing a specific threshold for organic products would involve significant costs for operators which they do not consider worthwhile. Laboratories have also warned that this would

involve heavy analysis costs. Furthermore, there is no specific request from MS to change the current rules (see 2013 Council conclusions⁷⁰).

An on-going exercise conducted by the Commission is examining the appropriateness and workability of introducing or allowing "GM-free" labelling and what this would encompass.

After having issued the first Best Practice Document for coexistence of genetically modified crops with conventional and organic farming on "maize crop production", the European Coexistence Bureau is now working on honey and co-existence. MS remain in charge of devising co-existence rules on their territory.

The conclusion is not to change the current rules and to leave the competences inside the Commission as they are, including as regards the European Coexistence Bureau.

Therefore the options that are being considered do not contain any proposal to amend the current approach or the EU legislation in force.

3.3. Exceptional rules

Exceptional rules have been identified as a key-issue, which is addressed in three different ways in the three policy options:

- Option 1: status quo
- Option 2: integration of exceptions as permanent rules in the EU legislation on organic production,
- Option 3: removal of exceptions to the rules.

Impacts:

Options 1 and 2 would have negative consequences on the long-term because exceptional rules contradict organic principles and consumers' expectations. Their existence can adversely impact on the organic sector, notably by harming the development of the organic market and preventing the development of organic inputs.

In addition, option 1 is associated with heavy and increasing administrative costs (see Annex 17).

Option 3 could have short-term adverse but limited economic impacts on the production sector, notably organic chicks, seeds and propagating material. Precise data on the number of producers concerned is not available. The external evaluation shows that exceptions are more and more used. The sector had already time to adapt and at one point a decision to stop the exceptions is needed, otherwise the exceptions become the rule. Appropriate transitional measures should be decided. Exceptions in the case of catastrophic circumstances should in any case remain possible.

Several research projects financed by the Commission have been designed to find solutions to the issues of insufficient availability of some inputs in their organic form. Their results are

⁷⁰ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/agricult/137076.pdf

expected in 2013 and 2014. It should help the transition towards the end of exceptions planned end 2014 (allowing the use of 5% non-organic feed and of non-organic pullets).

In the longer term, the sector will benefit from stricter rules which will maintain consumer confidence in organic products, allowing further developments of the market. In addition, the sector of "organic inputs" (organic seeds, organic pullets and cheeks) will be boosted.

ANNEX 7: AUTHORISATION OF SUBSTANCES AND TECHNIQUES IN ORGANIC FARMING

1. CURRENT SITUATION AND LEGAL FRAMEWORK

Organic farming relies on objectives and principles, as well as practices designed to minimise the impact on the environment. The substances and products used as inputs should follow as much as possible these principles.

Organic farming rules include:

- Restrictions on chemical synthetic pesticide and synthetic fertiliser use, livestock antibiotics, food additives and processing aids.
- Prohibition of the use of genetically modified organisms.

The legal base for the general principles is title II of Council Regulation (EC) No 834/2007⁷¹ "objectives and principles of Organic farming".

Title III "production rules" provides the specific requirements for each of the different productions from general farm production with rules for plants, seaweed, livestock and aquaculture to the production of processed feed and food, including yeast.

The Commission is in charge of the authorisation of substances and products in accordance with Article 16 of Regulation (EC) No 834/2007. Restricted lists of products and substances that may be used in organic farming are established for the following purposes:

- plant protection products;
- fertilisers and soil conditioners;
- non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition;
- feed additives and processing aids;
- products for cleaning and disinfection of ponds, cages, buildings and installations for animal production;
- products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.

Products and substances contained in the closed lists may only be used if the corresponding use is authorised in the MS concerned in accordance with the relevant EU provisions and/or national provisions.

⁷¹ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189 , 20/07/2007, p. 1.)

Beside these general and specific rules, Commission Regulation (EC) No 889/2008⁷² implements and develops more detailed rules, through positive lists (Annexes I to XIII) covering substances and products such as:

- Fertilisers, soil conditioners and nutrients in Annex I,
- Pesticides and plant protection products in Annex II,
- Minimum surface areas in Annex III,
- Maximum number of animal in Annex IV,
- Feed materials in Annex V,
- Feed additives in Annex VI,
- Products for cleaning and disinfection in Annex VII,
- Certain products such as food additives, carriers, processing aids in Annex VIII,
- Products for use in the wine sector in Annex VIII a,
- Products not produced organically but needed for the food organic industry in Annex IX,
- Aquaculture in Annex XIIIa.

Although Articles 15 to 21 of Council Regulation (EC) No 834/2007 explain in detail the criteria for the authorisation of substances and the rules of production, still in many cases, it is difficult for the Commission to judge if certain substances and/or techniques requested by MS to be included in the annexes, fall under these objectives, principles and criteria. Therefore, the Commission consults experts with technical and scientific knowledge in order to get advice on whether to update the legislation (usually Commission Regulation (EC) No 889/2008) and whether to include new substances or practices.

In the past this technical advice was provided by ad-hoc expert groups working on a temporary basis. In order to streamline this work, the 2004 European Action Plan on organic food and farming proposed the setting up of a group of experts for technical advice in the field of organic production (Action No 11).

Commission Decision 2009/427/EC,⁷³ establishing the expert group for technical advice on organic production (EGTOP) was the first step towards the implementation of Action No 11. Further steps included (i) the publication of a call for applications with a view to select the relevant experts, followed by (ii) the appointment of the experts and the setting up of the pool list

⁷² Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, OJ L 250, 18.9.2008, p. 1–84

⁷³ COMMISSION DECISION of 3 June 2009 establishing the expert group for technical advice on organic production (2009/427/EC) L139/29

by Commission Decision 2010/C 262/03⁷⁴, and (iii) the publication on Internet of the rules of procedure⁷⁵ for the group.

The expert group has ensured access to highly qualified technical expertise and has provided recommendations to the Commission on different fields such as plant protection products, feed, additives, food processing aids or greenhouse production.

The experts work under the principles of "Independence, Excellency and Transparency"; therefore, members of the group make an annual declaration of their commitment to act in the public interest and a declaration of interests indicating either the absence or existence of any interest which might be considered prejudicial to their independence.

However, as the sector is so specialised, the number of experts is limited.

2. THE PROCESS OF EVALUATION OF SUBSTANCES AND TECHNIQUES

In order to request to include or withdraw a substance or a product from the lists in the Annexes to Commission Regulation (EC) No 889/2008, or to amend specifications of use, MS have to send a technical dossier to the Commission and to the other MS, on the basis of Article 16 (3, b) for farm production and Article 21 (2) for processed food.

On the basis of the dossier, the Commission drafts a **mandate** on which EGTOP is requested to give its advice in a given period of time.

The mandate is presented first to the SCOF (Standing Committee on Organic farming) and then to the plenary EGTOP group. The plenary group can consider and decide on the selection of member experts that may participate in a subgroup that will be created for evaluating that specific mandate. The experts from that subgroup are chosen from the pool of experts. The subgroup experts are temporary members, who have the mission to draft a report with some recommendations about the specific subject. Once it has been finalised, the report is adopted by the EGTOP plenary group.

Once the recommendations are adopted by EGTOP plenary group, under consensus decisions, the report is published together with the minutes of the meeting and the names of the experts who have participated in the subgroup.

So far EGTOP has met six times in plenary sessions (twice a year) and four times at subgroup level, on specific topic/s (e.g. fertilisers, plant protection products, etc.). The outcomes of those meetings are 6 final reports on: Feed, Fertilisers and soil conditioners, Plant protection products, Food (I), Poultry and greenhouse production. Two mandates are on-going in 2013, Food (II) and Aquaculture.

Once the reports are published, the Commission takes decisions on the basis of the EGTOP recommendations and possibly proposes to the SCOF the appropriate amendments of Commission Regulation (EC) No 889/2008.

⁷⁴ COMMISSION DECISION of 28 September 2010 appointing the members of the group for technical advice on organic production and drawing up the pool list

⁷⁵ http://ec.europa.eu/agriculture/organic/files/eu-policy/expert-recommendations/expert_group/rules_of_procedure_20-21_June.pdf

3. ISSUES

More and more requests are received by the Commission, because the organic sector is growing and there is a need for technical advice on developing sectors such as greenhouses, pullets, processed food, etc.

The process by which EGTOP can provide technical recommendations to the Commission is complex, technical and time-consuming, for which a high degree of specialisation is required. The rules of procedure of EGTOP are intended to prevent any conflict of interest but a complete independence of the experts cannot always be ensured.

EGTOP experts work on a voluntary basis and perceive only the travel costs and per diem.

In November 2011 the Budget Authority voted at the initiative of the Parliament EUR 2 million in reserve on committees. The reserve was lifted only when the Commission committed to revise the rules on experts group⁷⁶⁷⁷. MEPs considered that smallholder farmers are underrepresented in DG Agri expert and advisory groups.

4. CONCLUSIONS AND OPTIONS

Two possibilities have then been envisaged during the impact assessment:

Examination by an expert group organised by the Commission, under options 1 (improved status quo) and 3 (principle-driven). The horizontal Commission Decision No 2004/391/CE⁷⁸ of 23 April 2004 provides the possibility of designating such expert groups. Although that Decision will be revised in the near future, it relies on a longstanding procedure, well established and simpler than the EGTOP procedure. The technical requests would be examined by experts proposed by the stakeholders organisations already represented in the AGOF, who would transmit their conclusions to the Commission.

Impacts:

In one hand, it will solve one of the issues highlighted in the reserve from the European Parliament as smallholder farmers will be represented and in the other hand, the procedure of examination of the requests would be quicker and innovative techniques and practices could be incorporated more easily in the production rules. It would be to the benefit of organic producers' competitiveness.

The Commission could ensure a balanced representativeness of experts working on the technical assessment of requests.

⁷⁶ <http://register.consilium.europa.eu/pdf/en/11/st17/st17470-ad05.en11.pdf>

⁷⁷ In particular, the Commission committed to modify the rules on expert groups as to adopt common selection criteria through out all DGs, that guarantee balance among different categories of stakeholders and absence of Conflict of Interests for experts. It was agreed to establish an obligatory open selection process with a public call and a published mandate of each expert group which goes beyond a simple representation of Member states authorities.

⁷⁸ Commission Decision No 391/2004 of 23 April 2004 on the advisory groups dealing with matters covered by the common agricultural policy UE OJ L 120, 24.4.2004, p. 50.

Authorisation of substances and practices for organic farming under the responsibility of the sector under option 2.

The requests would be transmitted for examination to representative stakeholders, who would transmit their conclusions to the Commission.

Impacts:

It can be difficult in practice to determine the representative stakeholders. There is a risk of watering down of the standard, which could undermine consumer confidence. Finally this option raises the issues of transparency.

ANNEX 8: LOGO AND LABELLING

1. GENERAL RULES ON LABELLING OF ORGANIC PRODUCTS

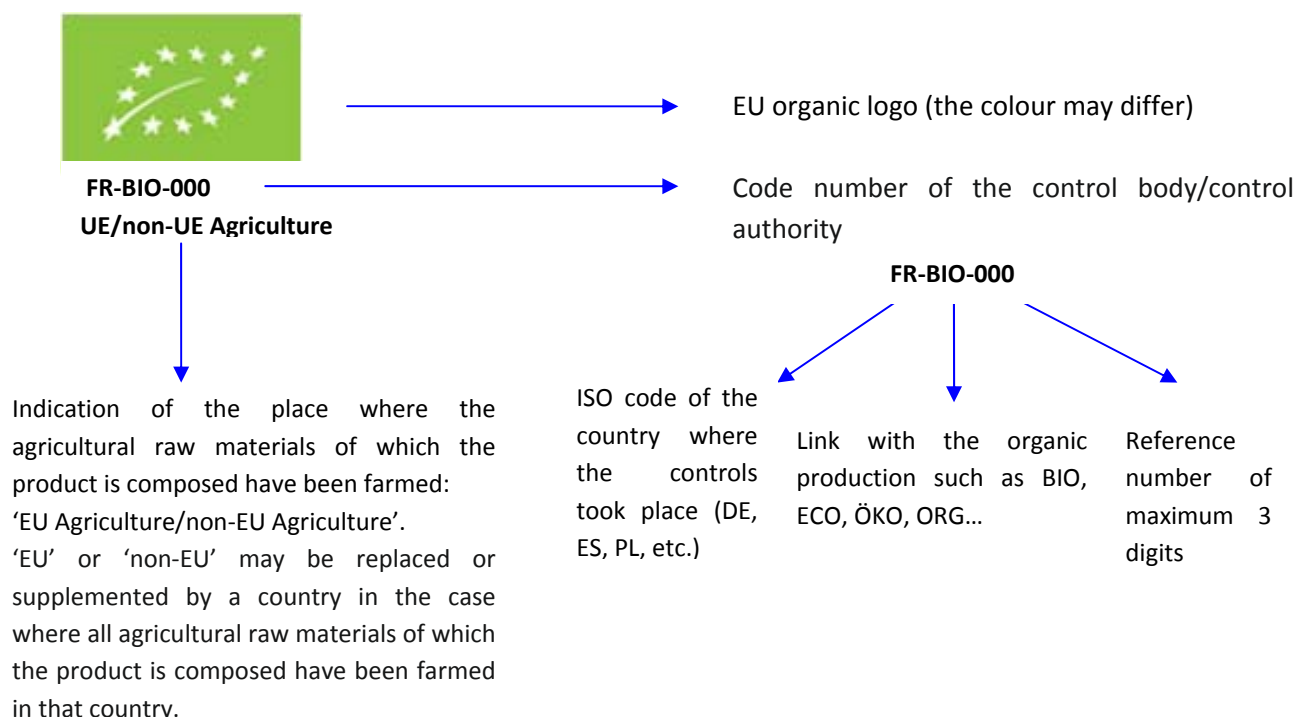
General rules on labelling of organic products are defined in detail in Title IV of Council Regulation (EC) No 834/2007. These rules are specified and defined (notably as regards the model of the EU organic logo) in detail in Title III of Commission Regulation (EC) No 899/2008.

Article 23 of Council Regulation (EC) No 834/2007 provides for the **protection of the terms** referring to the organic production method. These terms are listed in the Annex to this Regulation in all EU languages. The use of these terms and their derivatives and diminutives such as "bio" and "eco" for purposes of labelling and advertising is restricted to agricultural products produced according to the provisions of this regulation throughout the EU and in any language of the EU.

The **labelling rules and the use of the EU organic logo** are laid down in Articles 24 and 25.

Article 24 defines the **compulsory indications** where terms referring to the organic production method are used: code number of the control authority/body who carried out the most recent production or preparation operation, EU logo and an indication of the place of origin.

The following model shows the logo and the compulsory indications as printed on the product:



Rules on the use of the **organic production logo** are laid down in Article 25. The use of the EU logo is not exclusive, national and private logos are allowed. The use of the logo is optional for products imported from third countries.

The use of this logo and the compulsory indications are obligatory for the labelling of processed pre-packaged food since 1 July 2010⁷⁹:

**New labelling
rules apply
1 July 2010**

Transition period:
*Products labelled before
1/7/2010 to be sold until
stocks exhausted*

1 July 2012



The EU organic logo may be displayed on non-pre-packaged or imported food products on a voluntary basis. When used on a product, the EU organic logo indicates that this product is in full conformity with the rules laid down in the EU Regulations. For processed products it means that at least 95% of the agricultural ingredients are organic.

The EU organic logo is registered since 2010 as a trade mark⁸⁰ in the EU and has international registrations⁸¹ in key third countries such as Switzerland, the United States, Japan and Norway.

⁷⁹ Even if the EU organic logo was compulsory from 1 July 2010 on, the gradual placing of the new logo on the market lasted until 2012. This transitional period was designed to help operators adapt to the new regulation and to avoid waste of existing packaging.

Packaging material compliant to the organic legislation as in force before the introduction of the new logo could be used, and possibly renewed, until 1 July 2012, with or without the old organic logo. Products produced, packaged and labelled before 1 July 2010 could continue to be placed on the market and sold until stocks are exhausted.

⁸⁰ The logo was filled as an individual and collective trademark in the Office for Harmonization in the Internal Market (Trade Marks and Designs) – OHIM. It is registered and protected as an individual trademark since 2010 and as a collective trademark since 2012.

⁸¹ The international registrations followed the EU legal protection and were completed in 2010-2012 period (with the exception of China). Internationally the logo is registered as a collective trademark.

2. AWARENESS OF THE EU LOGO, CONFUSION ASSOCIATED WITH MULTIPLE LOGOS

According to a Eurobarometer survey conducted in July 2012, the EU organic logo had already gained **24%⁸² of the citizens' awareness**. Taking into account 2 years of transitional period (to facilitate operators adapting to the new rules) and lack of costly campaigns, this result can be considered as successful. The logo was selected through a competition among students and finally chosen by European citizens through an Internet vote, which gave it already some recognition. In comparison the logo identifying Protected Designations of Origin (PDO) and Protected Geographical Indication (PGI) is recognised by 14% of the population.

Overall knowledge of the EU organic logo varies widely between MS (from 13% to 39%) depending on how developed the organic sector is and whether there was a strong national logo before.

The vast majority of respondents to the public consultation (35357, or 79% of the total), declared that they recognize the European organic logo. Only 20% of the questioned publics were not familiar with the European organic logo. This result confirms that the respondents to the public consultation were mostly familiar with the organic sector, but cannot be interpreted as a level of awareness among the general EU population.

The national and European logos were equally known by the respondents to the public consultation. National logos (66%; 29605) and the European logo (66%; 29416) are the most common and trusted indications of distinguishing organic among conventional products.

The EU organic logo has a long term potential: once understood, it can be easily recognised by European consumers in all MS without a need for translation every time it crosses an EU language border.

In addition, there are many private logos relating not only to private organic standards but also to other schemes, which add to the confusion⁸³.

⁸² Eurobarometer report n° 389 (What Europeans think of food security, food quality and the relation between agriculture & the countryside - July 2012)

⁸³ SODEXO, COPA-COGECA, Carrefour, ECF-European Coffee Federation, Vossen&Co (organic essential oils) Autumn hearings





Proliferation of quality (including organic) labels:







Fewer labels would likely diminish confusion amongst consumers, especially if consumers can reliably begin to attach credible association with one well known and well understood label:



Examples of organic logos:

Name	Region	Label
Europe		
EU Organic farming	EU	 FR-BIO-000 EU/Non EU agriculture
Austria Bio garantie	Austria	
AB – agriculture biologique	France	
Bio-siegel	Germany	

Name	Region	Label
Biogarantie	Belgium	
EKO	Netherlands	
Soil Association	UK	
Organic farmers and growers	UK	
North America		
USDA National Organic Program (NOP)	USA	
Canada Organic	Canada	

Other		
Australian certified organic	Australia	
NASAA certified organic	Australia	
JAS	Japan	
Bio-Gro	New Zealand	

3. INDICATION OF THE PLACE OF FARMING: COMPLEX BUT IMPORTANT FOR CONSUMERS

Whenever the EU organic logo is used on a product, it always has to be accompanied by the code number of the control body and the place where the agricultural raw materials of which the product is composed have been farmed.

The geographical origin of food is considered very important by the majority of European consumers. The introduction of the obligatory indication of the place of farming on the packaging of organic products, besides the organic logo in Regulation 834/2007 was an improvement in this respect.

However, stakeholders have reported that the rules for the indication of the place of origin are complex and that they could be simplified.

4. THE ISSUE OF DOUBLE LABELLING OF COUNTRY OF ORIGIN

The horizontal legislation provides with several cases where the indication of the country of origin of primary ingredients is required, notably Regulation (EU) No 1169/2011⁸⁴ on food information to consumers (not yet implemented). In these cases, it has been suggested that the legislation on organic farming should not impose the same indication twice. Currently the indication of country of origin is obligatory for beef and beef products in the EU. Mandatory origin provisions have been developed on the basis of vertical approaches for instance for honey, fruit and vegetables, fish, beef and beef products and olive oil. There is also a possibility to extend mandatory origin labelling for other food products. In particular, on the basis of Article 26(8) of Regulation (EU) No 1169/2011 the Commission shall

⁸⁴ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 – OJ L 304, 22.11.2011, p. 18.

adopt by 13 December 2013 an implementing act concerning the mandatory indication of the country of origin or place of provenance for meat of swine, sheep and goat, and poultry. The aim is to simplify the labeling of county of origin and avoid double labeling of products falling under the provisions of Regulation (EU) No 1169/2011.

5. COMPLEXITY OF THE LABELLING OF ORGANIC PROCESSED PRODUCTS

According to the legislation on organic production, the country of origin can only be indicated on the packaging of processed products if all agricultural raw materials of which this product is composed are farmed in this country. The threshold for ingredients allowed from other origin is only 2 % by weight. This has as consequence that in the case of organic processed products including ingredients from various origins, the indication "EU agriculture", "non EU agriculture" or even "EU/non EU agriculture" has to be used. The sector has requested this 2% limit to be expanded to 5%, in order to be consistent with the possibility for processed food to be sold as organic provided they include at least 95% by weight of organic ingredients of agricultural origin.

Inexact obligatory labelling on organic aquaculture products

The legislation on organic production imposes to use the indication "EU agriculture", "non EU agriculture" or "EU/non EU agriculture", instead of "EU Aquaculture" / "non-EU Aquaculture" / "EU/non EU Aquaculture".

6. POLICY OPTIONS

Labelling issues are addressed by measures proposed proposed in the improved status quo option, and are therefore extended to all options. They are supported by stakeholders and MS.

The following improvements are proposed:

- Measures to avoid double labelling of the origin
- Simplification of the labelling of organic processed products (see above).
- Introduction of the possibility to use the indication "EU Aquaculture" / "non-EU Aquaculture" or "EU/non EU Aquaculture" instead of "EU agriculture", "non EU agriculture" or "EU/non EU agriculture" on the labelling of organic aquaculture products,

Impacts: the proposed measures intend to simplify the labelling requirements, thus improving the competitiveness of operators. It will also bring clarification to consumers, in particular in the case of aquaculture products.



Brussels, 24.3.2014
SWD(2014) 65 final

PART 3/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on organic production and labelling of organic products, amending Regulation (EU)
No XXX/XXX of the European Parliament and of the Council [Official controls
Regulation] and repealing Council Regulation (EC) No 834/2007**

{COM(2014) 180 final}
{SWD(2014) 66 final}

ANNEXES 9 to 17

TABLE OF CONTENTS

ANNEX 9: CONTROL SYSTEM	4
1. LINK WITH CONTROLS ON FOOD AND FEED	4
1.1. The legal framework	4
1.2. Identified problems	5
1.3. Review of official food and feed controls	6
2. COVERAGE	7
2.1. Activities and operators	7
2.2. Identified problems	7
2.3. Opinion by MS and Stakeholders	8
2.4. Conclusion	9
3. SET-UP OF THE CONTROL SYSTEM	9
3.1. Private control bodies, public control authorities or mixed system	9
3.2. Identified problems	10
3.3. Conclusion	11
4. SUPERVISION AND CONTROL CHAIN	11
4.1. Roles and responsibilities	11
4.2. Identified problems	15
4.2.1. Supervision by the Commission	15
4.2.2. Supervision by MS Competent Authorities	16
4.2.3. Accreditation	16
4.3. Opinion by MS and stakeholders	17
4.4. Conclusion	17
5. CONTROL FREQUENCY	18
5.1. Minimum control frequency and risk based approach	18
5.2. Identified problems	19
5.3. Position by Stakeholders	20
5.4. Conclusion	21
6. PAPER-BASED CERTIFICATION	21
6.1. Documentary evidence	21
6.2. Certificate of inspection	23
6.3. Conclusion	24
7. IRREGULARITIES, INFRINGEMENTS AND SANCTIONS	24
7.1. State of play	24
7.2. Identified problems	25
7.3. Position by stakeholders	26

7.4.	Evaluation and studies.....	26
7.5.	Conclusion.....	27
8.	FRAUD CASES REPORTED IN THE MEDIA	27
	ANNEX 10: COSTS OF CONTROLS IN THE EU ORGANIC PRODUCTION SCHEME.....	29
1.	INTRODUCTION.....	29
2.	OVERVIEW OF THE MAIN TYPES OF CONTROL RELATED COSTS IN THE ORGANIC CHAIN	29
2.1.	Control system set-up.....	29
2.2.	Public support of certification costs	30
3.	CONCRETE EXAMPLES OF CONTROL RELATED COSTS IN SOME MS.....	31
3.1.	Inspection fees paid by operators to control bodies and to control authorities	31
3.2.	Cost of approval and supervision of control bodies borne by the national authorities	33
3.3.	Cost of accreditation.....	34
3.4.	Aggregated control data	34
4.	CONCLUSIONS.....	35
	ANNEX 11: PRESENCE OF NON-AUTHORISED SUBSTANCE RESIDUES IN ORGANIC PRODUCTS.....	36
1.	OVERVIEW EU LEGISLATIVE FRAMEWORK	36
2.	IDENTIFIED ISSUES	37
2.1.	Situation in the EU	38
2.2.	Situation concerning imported products	40
2.3.	Conclusion.....	41
3.	CONSUMERS' EXPECTATIONS.....	42
4.	CONCLUSIONS.....	42
4.1.	Investigation requirement.....	42
4.2.	A critical level for the commercialisation of organic products.....	42
4.3.	Product oriented approach.....	43
	ANNEX 12: THE EU TRADE REGIME FOR ORGANIC PRODUCTS.....	48
1.	IMPORT REGIME	48
2.	EQUIVALENCE.....	50
2.1.	Equivalence assessment and recognition	50
2.1.1.	Third Countries recognised for the purpose of equivalence	50
2.1.2.	CBs recognised for the purpose of equivalence	52
2.1.3.	Issues with the equivalence regime	52
2.1.4.	Compliance.....	53
3.	SUPERVISION.....	57

4.	POSSIBLE IMPACTS OF A MOVE TO COMPLIANCE ON DEVELOPING COUNTRIES	58
4.1.	Analysis of the standard	58
4.2.	Analysis of the trade flows.....	63
5.	EXPORTS	66
6.	CONCLUSIONS.....	66
	ANNEX 13: ENVIRONMENTAL IMPACTS OF ORGANIC FARMING.....	68
1.	IMPACTS OF ORGANIC FARMING ON THE ENVIRONMENT.....	68
1.1.	Biodiversity	70
1.2.	Energy	70
1.3.	Greenhouse gas emissions (GHG)	70
1.4.	Air quality and water management	71
1.5.	Soil	72
1.6.	Land use	72
2.	ENVIRONMENTAL PERFORMANCE.....	73
2.1.	Ecolabel for food and drink products.....	73
2.1.	EMS.....	74
	ANNEX 14: ANIMAL WELFARE.....	83
1.	INTRODUCTION.....	83
2.	LEGAL BACKGROUND	83
3.	CURRENT LEGISLATION ON ORGANIC FARMING AND ANIMAL WELFARE.....	84
4.	RESULTS OF THE CONSULTATIONS WITH CONSUMERS AND STAKEHOLDERS	86
5.	IMPROVEMENTS IN ANIMAL WELFARE STANDARDS OF ORGANIC FARMING REQUESTED BY ANIMAL WELFARE ORGANISATIONS	87
6.	OPTIONS AND THEIR IMPACTS	88
7.	CONCLUSION	88
	ANNEX 15: SMALL FARMS AND ENTERPRISES: SIMPLIFICATION; GROUP CERTIFICATION.....	89
8.	INTRODUCTION.....	89
9.	DATA ON SMALL AGRICULTURAL HOLDINGS IN THE EU	89
9.1.	Difficulties for small agricultural holdings to join the organic sector	90
9.1.1.	Current situation.....	90
9.1.2.	Issues	91
10.	SIMPLIFICATION.....	91
11.	GROUP CERTIFICATION, CURRENTLY IMPLEMENTED IN THIRD COUNTRIES	92

11.1. Definition	92
11.2. Experiences and evaluation	96
11.3. Opinion by stakeholders	98
12. CONCLUSIONS	100
ANNEX 16: ASSESSMENT OF ADMINISTRATIVE COSTS	102
1. INTRODUCTION.....	102
2. WORK DONE AND RESULTS OBTAINED	102
2.1. Mapping of information obligations	102
2.2. Qualitative assessment	103
3. CONCLUSIONS	104
ANNEX 17: REFERENCE DOCUMENTS	131

ANNEX 9: CONTROL SYSTEM

1. LINK WITH CONTROLS ON FOOD AND FEED

1.1. The legal framework

Council Regulation (EC) No 834/2007 on organic production and labelling¹ requires MS to set up and manage a control system to ensure that organic products are produced in compliance with its rules.

It places the organic control system under the general umbrella of the **official controls on food and feed (OFFC)** laid down in **Regulation No 882/2004** that applies to all food, organic or not, produced or imported in the EU in order to guarantee food safety, fair practices and the protection of consumers' interests.

To cater for the specific needs of organic production, it sets out additional control requirements and/or derogations as appropriate to the food and feed official control rules.

Commission Regulation No 889/2008 provides the detailed control implementing rules.

The following table gives an overview of the organic control provisions:

Table 1: Control provisions

	Regulation No 834/2007	Regulation No 889/2008
Set-up of the control system	Article 27(1) and (2)	Title IV: minimum control requirements
Nature and frequency of controls	Article 27(3)	Title IV: Articles 65 and 90 Title V: Article 95(2)
Possibility to confer control competences to control authorities	Article 27(4)(a)	
Possibility to delegate control tasks to (private) control bodies	Article 27(4)(b) Article 27(5) Article 27(5)(b),(d),(e) - <i>in compliance with Article 5(2)(b),(e), (f) of Regulation No 882/2004</i>	
Criteria to approve control bodies	Article 27(6)	
No possibility to delegate supervision and granting of exceptions	Article 27(7)	
Audits of control bodies	Article 27(8) - <i>in compliance with Article 5(3) of Regulation No 882/2004</i>	

¹ OJ L 189 of 20.7.2007, p. 1.

	Regulation No 834/2007	Regulation No 889/2008
Additional criteria for supervision of control bodies	Article 27(9)	
Control bodies: code number, access to facilities, report on control activities	Article 27(10) to (14)	
Specific control requirements for: <ul style="list-style-type: none"> • plants & plants products • livestock & livestock products • preparation of products • imports • contracting to third parties • units preparing feed 		Title IV

1.2. Identified problems

The interaction of different acts makes the legal framework quite complex and entails a number of **gaps, overlaps, grey areas and inconsistencies**.

Some official controls provisions are repeated or mirrored in the organic legislation while others - for instance, controls at market or retail level - are not.

The definitions are not always the same in the regulations on official controls and on organic: for instance, control authority(ies) are only referred to in the legislation on organic production.

This has led to several requests for interpretation², uncertainties and/or different approaches by MS in implementation of the rules, including **non-effective implementation**.

The audits carried out by the Food and Veterinary Office of the European Commission (FVO) in 2012 and 2013 to verify the proper functioning of the organic control system showed **weaknesses in market controls** in the audited MS³.

Other than on market controls, several issues have been brought up as regards the interaction with the official food and feed regulation: **unannounced control visits, risk-based approach and sampling** as well as **sanctions** – on which please see sections 5 and 7 of this annex.

Secondly, the architecture of the official food and feed controls relies on a system of **several competent authorities**.

Here again, the audits carried out by the FVO show that the **coordination** between these authorities is **not always effective or efficient**.

² DG AGRI prepared in 2011 a Working document on official controls in the organic sector (http://ec.europa.eu/agriculture/organic/files/eu-policy/data-statistics/control_guidelines_version_08072011_en.pdf) to explain a number of aspects of the control system set by EU organic legislation and by EU horizontal legislation on food and feed controls. It also produced two interpretative notes on specific control aspects for the organic sector: RIPAC Notes No 2 and 3/2012.

³ See under section 4 for an overview of the findings of the audits carried out by the FVO.

1.3. Review of official food and feed controls

In **May 2013**, the Commission adopted a **proposal** (COM(2013)265 final) to review Regulation No 882/2004 on official food and feed controls.

The proposal aims at tackling the gaps, overlaps and inconsistencies due to the presence of control requirements in different pieces of legislation.

- It explicitly refers to organic as part of the scope of official controls, thereby removing previous uncertainties on market and border controls that have to be carried out in the organic sector.
- It mentions the control authorities and control bodies in the organic sector, hence clarifying their specific situation (eg. possibility to delegate application of measures in case of non-compliance), and provides for derogations to address the identified inconsistencies and, more in general, the organic sector specific features⁴.

The main principles and rules for the official controls are kept in the basic act (EP/Council regulation), while delegated acts will supplement them on specific and/or additional aspects so as to cater for the needs of the various sectors.

The Commission is therefore empowered to adopt a delegated act concerning controls on organic production under the future OFFC Regulation.

This act would lay out, as it is currently the case in Council Regulation (EC) No 834/2007, specific or additional measures such as on control responsibilities and tasks, minimum control frequency (=annual inspection requirement set out in Council regulation No 834/2007), measures for non-compliance, specific reporting obligations and allow for derogations as appropriate.

The integration of specific rules on official controls in the organic sector under the reviewed OFFC would only apply once the basic act and delegated acts are adopted. At this stage, it is estimated that the reform will enter into force in 2016.

The Commission proposal is taken into account in the impact assessment as part of the **baseline scenario**.

⁴ The proposal extends mandatory fees to most official controls: however, the official controls performed for the verification of compliance with the rules governing the organic production and labelling of organic products are exempted from mandatory official control fees.

2. COVERAGE

2.1. Activities and operators

The EU organic control system covers the activities performed by operators at all stages of the production, preparation and distribution chain: from farm to fork.

Any operator who produces, prepares, stores, imports or places on the market organic products shall notify his activity to the MS competent authority and shall submit his undertaking to the control system (article 28(1) of Regulation No 834/2007).

MS may exempt retailers (operators who sell products directly to the final consumer or user) from adherence to the control system if they:

- do not produce or prepare organic products;
- do not store organic products, other than in connection with the point of sale,
- do not import organic products,
- have not contracted to a third party the activities of production, preparation including labelling, storage or import of organic products.

Subcontracted activities are also subject to the organic control system. In particular:

- The main operator (= the one who contracts out some activities to a third party) shall notify the subcontracted activities to the MS competent authority.
- The subcontracted activities shall be part of the description of activities of the main operator; the subcontractor shall provide his written agreement that his holding will be subject to the control system (Article 86 of Regulation (EC) No 889/2008).
- Finally, the main operator and his subcontractor shall provide a declaration, if they are checked by different control bodies, that the two control bodies can exchange information (Article 92(1) of Regulation (EC) No 889/2008).

2.2. Identified problems

- The wording of Article 28(1) of Regulation (EC) No 834/2007 is not very clear as to whether exporters are covered by the control system. This uncertainty can concern third countries importing organic products from the EU.
- Retailers may be treated differently across the EU: some may be covered by the control system and some may not, depending on MS choices.

A documentary analysis carried out as part of the external evaluation on 13 case study countries shows that the exemption is applied in all of them (in detail: Austria, Bulgaria, the Czech Republic, Denmark, Estonia, France, Germany, the Netherlands and Poland - preliminary findings, September 2013).

In addition, the wording of Article 28(2) of Regulation (EC) No 834/2007 is somehow cumbersome on the conditions to be fulfilled for granting the exemption to retailers. This can lead to different interpretations across MS, as it is shown by the preliminary findings of the external evaluation.

Several requests for clarifications have been addressed to the Commission, in respect of which concrete activities fall into the category of preparation, of what can be considered a storage in direct connection with the point of sale, of which operators can be exempted⁵.

Can MS exempt from the control system operators who prepare organic products, if they do the preparation activity at the point of sale and do not pre-package the products (e.g. bakers or butchers)? In other words: do the words “other than in connection with the point of sale” in this article only refer to “store” or to they also refer to “produce” and “prepare”?

Should the process of baking off pre-baked be considered as an act of preparation?

Can operators who bake-off pre-baked bread and who sell this bread to the final consumer/user be exempted from the control system?

What is the status of Internet commercial platforms for sale of organic products?

Overall, the exemption to retailers makes management, as well as supervision and control, more difficult.

- Finally, MS have some difficulties to understand and apply the rules concerning controls of subcontractors and subcontracted activities⁶.

2.3. Opinion by MS and Stakeholders

Recent discussions with MS in the framework of the Standing Committee on Organic Farming (SCOF) – established to ensure close cooperation with the authorities responsible for the organic sector and guarantee uniform application of EU organic legislation - showed that some MS may be against the possibility to include retailers in the control system.

As for stakeholders, Eurocommerce considers that including retailers in the specific organic control system will increase the costs for retailers and the costs of organic products without adding any value for consumers. While not providing figures for the operators concerned, it mentions that in practically all MS all "regular" retailers are selling organic products and in several MS retailers have also developed their own brand organic products.

Bio-Austria, in the free contribution submitted to the Commission as part of the stakeholders' consultation – also indicated that including retailers in the control system would not improve the quality of controls and would reduce the number of retailers offering organic, ultimately weakening the market.

IFOAM considers that pre-packed products do not need more controls at the retail level.

⁵ The Commission services produced an interpretative note (RIPAC): Note No 2012/3, Exemption from control, Council Regulation No 834/2007, article 28(2).

⁶ Interpretative note (RIPAC note) No 2012-02, May 2012.

2.4. Conclusion

With a view to addressing the identified problems, the following actions are proposed:

- **Clarification** of the provisions on **exporters** and **subcontractors**, under the **improved status quo (1) policy option** – as for all other measures under this option, it is also included in the market-driven (2) and the principle-driven (3) policy option.
- **Removal** of the **possibility for MS to exempt retailers** from the control system, as a sub-option under the **improved status quo (1) policy option**.

Retailers are in direct contact with the consumers and play a key role for consumers' confidence in organic products. They carry out several activities that require due verification as part of the MS measures to ensure correct use of labelling.

The impact of this action on operators is difficult to assess because the number of the retailers concerned, in the MS that apply such exemption, is not known. Figures, or estimations, were requested but could not be obtained.

However, retailers are subject to general control requirements under the food law: the specific control requirements as organic operators – for which the control frequency may be adapted - are not expected to generate a significant additional burden.

3. SET-UP OF THE CONTROL SYSTEM

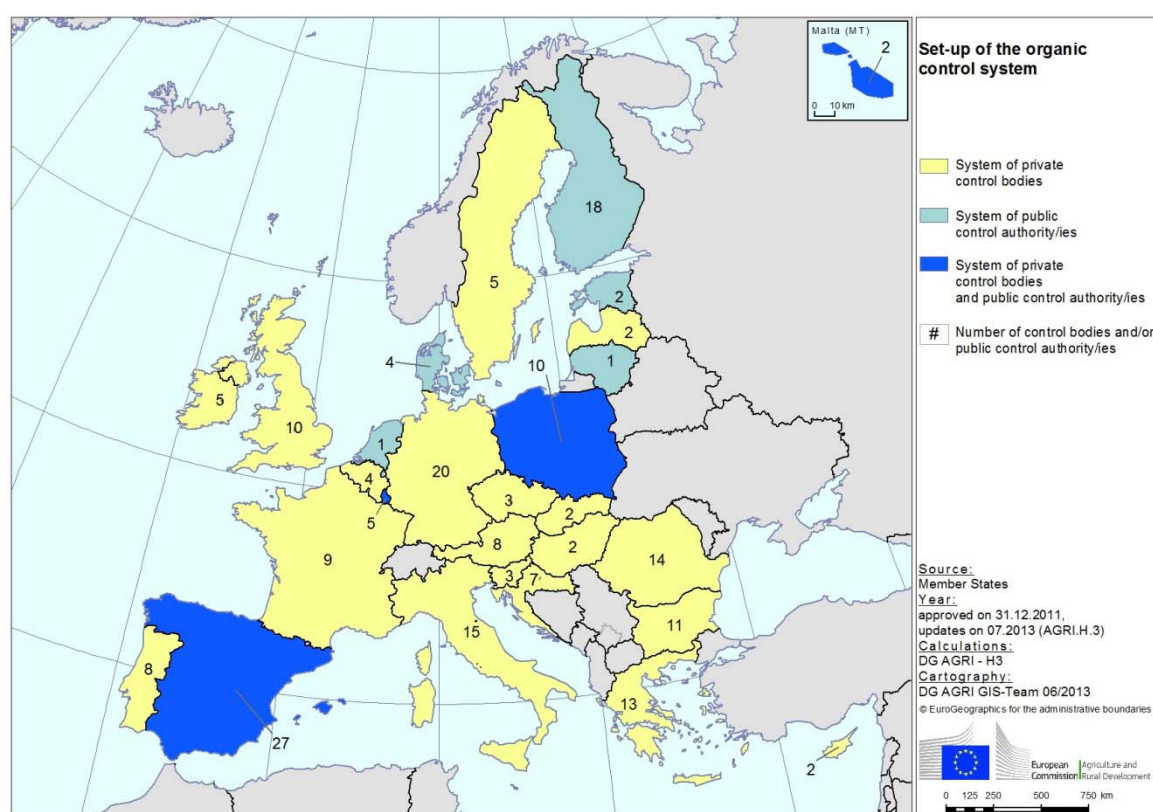
3.1. Private control bodies, public control authorities or mixed system

Each MS shall designate one or more authority(ies) responsible for controls in organic. This **Competent Authority** may

- A. Delegate its control tasks to one or more **private Control Bodies** that it shall approve and supervise, or
- B. Confer its control responsibility to one or more **Control Authority(ies)**.
- C. A **mixed system**, with private control bodies and public control authority(ies) is also possible.

The picture below shows the **set-up of the control system** in the **EU 28**:

Chart with the set-up of the organic control system in the EU 28



The control system with **private control bodies** is applied in the wide majority or **19 MS**. In total, **143** control bodies operate in these countries.

In **5 MS** (DK, EE, FI, LT, NL), the control system is based on **public** control authorities.

Finally, a **mixed** system is in place in **4 MS** (ES, LU, MT and PL).

3.2. Identified problems

- In MS with a system of **private control bodies**, each operator is free to choose any of the control bodies that have been approved by the competent authority(ies) to operate in the MS territory.

The high competition among control bodies can entail **loosening control requirements**: operator may choose or change control body with a view of having lower requirements, sanctions etc. ("control body shopping").

- The control bodies charge operators with a **fee** for their control and certification services. In general, fees are not regulated and vary across and within MS; information on the amount of fees charged to operators and on the methodology for applying them is not publicly made available by control bodies.

The stakeholders' consultation showed that for **small farms** the control and certification costs – together with the record keeping obligations – are considered amongst the major barriers to entry into the organic system. Annex 10, with the cost of controls in the EU organic production scheme, provides details.

3.3. Conclusion

With a view to addressing the identified problems, the following actions have been taken (taken into account in the impact assessment as part of the **baseline scenario**).

- **Commission Regulation (EU) No 392/2013** to amend the implementing rules on the control system was adopted in April 2013. The new provisions, applicable as from 1 January 2014, enhance supervision on Control Bodies.
- A **new cycle of audits by the Commission** to assess the proper functioning of the organic control system both in MS and in Third Countries and recognised Control Bodies for imports into the EU resumed in 2012 and are now part of the annual work programme of the Food and Veterinary Office in DG SANCO.

and the following action is proposed to be taken:

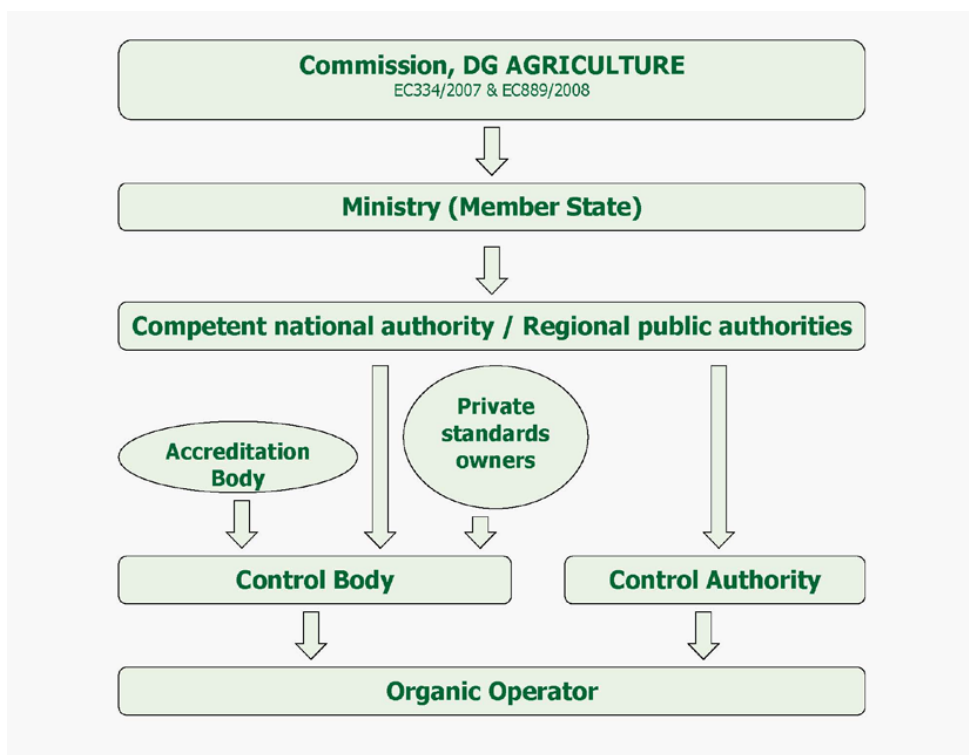
- **Group certification**, as a sub-option under the **principle-driven (3) policy option** to address the problems that small farmers face in entering the system. Please see further details in Annex 16, Small farms and enterprises: simplification, group certification.

4. SUPERVISION AND CONTROL CHAIN

4.1. Roles and responsibilities

The chart below shows the authorities and bodies in the supervision and control chain

Chart: the organic supervision and control chain (Source: Zorn et al, Economic Concepts of Organic Certification, 2009)



In detail, their roles and responsibilities are as follows:

European Commission

- **Supervision on MS** to ensure that they fulfil their responsibilities, through:
 - the assessment of **information** on the functioning of the control system. MS provide specific notifications on irregularities and their follow up as well as regular reporting on their supervision and control activities under the Multiannual National Control Plans as required by the general provisions in the food and feed official controls;
 - **system audits**. The **Food and Veterinary Office (FVO)** in DG SANCO, in close cooperation with DG AGRI, carries out audits on the control systems set up for the organic production and labelling of organic products. In terms of scope, these audits assess the performance of the Competent Authorities as well as the organisation of the controls carried out by Control Bodies, including import controls, controls of operators producing, preparing and distributing organic products, controls of the labelling and marketing of organic products, and verification procedures and audits⁷.

DG AGRI carries out audits on the implementation of **Rural Development Programmes** that in most cases include amongst agri-environmental measures support to the conversion to, or maintenance of, organic farming. These audits verify the implementation of the measure supporting organic farming from the point of view of any risk for the Fund. In particular, they assess the system for the cross notification of findings detected respectively by the control bodies (during their inspection and certification of organic operators) and by the Paying Agency for rural development (during its on-the-spot checks).

- Supervision of the **Third Countries** and of the **Control Bodies/Control Authorities recognised as equivalent**, through the assessment of information on notified irregularities and their follow-up as well as through the assessment of annual reports and through on-the-spot examinations and audits by the FVO⁸.

MS

- Set-up the organic control system, in compliance with the official controls in food and feed, and ensure its proper functioning
- Ensure that any operator who complies with the organic rules and who pays a reasonable fee is entitled to be covered by the control system
- Notify irregularities and infringements to the organic provisions to other MS and to the Commission⁹
- Investigate irregularities and infringements to the organic provisions that are notified by other MS and inform them of the results of action taken

⁷ The FVO carried out, between January 2012 and July 2013, audits to six MS (Portugal, Poland, Italy, Romania, United Kingdom and Germany).

⁸ The FVO carried out, between January 2012 and July 2013, audits to three TCs (India, Tunisia and Israel). Please see annex 12, The EU trade regime for organic products, for more details on the Commission's supervision.

⁹ Please see section 7 of this annex for further details.

- Take measures and put in place procedures for the exchange of information amongst control bodies, and with the paying agency for rural development in case of irregularities by operators who benefit from rural development support (notably for the conversion to or maintenance of organic farming as part of agri-environmental measures¹⁰)
- Publish an updated list of organic operators
- Report to the Commission on supervisory and control activities on organic, as part of the multiannual national control plans and annual reports under the official food and feed controls legislation

Competent authority in MS

- Approve, suspend and withdraw approval of control bodies
- Define a catalogue of measures in case of infringements and irregularities

Accreditation Body

- Accreditation and surveillance of Control Bodies.

Accreditation is a third party attestation related to a conformity assessment body (in this context a control body performing certification in the organic sector) conveying formal demonstration of its competence to carry out specific conformity assessment tasks. Accreditation is performed by an authoritative body – whose authority is generally derived from government.

Regulation No 834/2007 introduced the mandatory requirement of accreditation for control bodies, by setting out that they shall be accredited to the most recent version of standard EN 45011 or ISO Guide (article 27.5.c)¹¹.

¹⁰ For a comprehensive review of support to organic farming under the CAP, Study Report: Use and efficiency of public support measures addressing organic farming, 2011, http://ec.europa.eu/agriculture/external-studies/2012/organic-farming-support/full_text_en.pdf

¹¹ The standard specifies the conditions that control bodies have to fulfil, in respect of their organisation and functioning, to be able to operate the (organic) certification system. It is superseded by international standard EN ISO/IEC 17065:2012. The date of cessation of presumption of conformity is set on 15 September 2015, in the Commission communication in the framework of the implementation of Regulation (EC) No 765/2008, Decision No 768/2008/EC and Regulation (EC) No 1221/2009 of the European Parliament and the Council, published in the Official Journal C 258 of 7.9.2013.

Subsequent legislative developments entailed additional requirements:

- Regulation No **765/2008** on **accreditation and market surveillance**¹², applicable as from 1 January 2010, provides for the first time a comprehensive and harmonized framework for accreditation. Accreditation may only be granted by a (single) national accreditation body, which shall be member of the European Cooperation for Accreditation (EA) and shall have successfully undergone peer evaluation.
- The EA, in cooperation with DG AGRI, recently developed **guidelines** for the **accreditation of organic production certification** with a view to addressing the specific features and needs of the sector¹³.

Control body

Vis-à-vis the competent authority(is)	Vis-à-vis other control bodies	Vis-à-vis operators
<ul style="list-style-type: none"> • Reporting obligations: list of operators + summary report of control activities 		<ul style="list-style-type: none"> • Carry out an annual physical inspection of each operator + additional risk-based visits
<ul style="list-style-type: none"> • Information if operator changes control body or withdraws from the control system • Immediately exchange information in case of irregularities/infringements • Exchange relevant information on control results 	<ul style="list-style-type: none"> • Hand over control file if operator changes control body • Immediately exchange information in case of irregularities/infringements • Exchange relevant information on control results 	<ul style="list-style-type: none"> • Verify the operator's declaration and documentary accounts • Take and analyse samples • Draw up a control report • Provide documentary evidence (certificate) to each compliant operators • Prohibit operator from marketing organic products, if case of irregularities or infringements

¹² Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 – OJ L 218 of 13.8.2008, p. 30. For the purpose of this Regulation, accreditation shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity. Please see further information on accreditation in the Europa website: http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/accreditation/index_en.htm

¹³ EA Policy for the Accreditation of Organic Production Certification (Ref: EA-3/12 M: 2013), <http://www.european-accreditation.org/publication/ea-3-12-m>

4.2. Identified problems

4.2.1. Supervision by the Commission

- The ECA recently audited the effectiveness of the organic production control system, focusing on how the various actors involved had carried out their responsibilities.

In its special report No 9/2012, published on 26 June 2012¹⁴, the Court concluded that **MS' reporting to the Commission** was very limited, often incomplete and subject to major delays.

At the time of the audit, organic production issues were not included in the annual **audit** work programme by the FVO, which considered food safety as the main risk factor. A recommendation was therefore made to remedy the identified weaknesses.

- A second identified problem for the Commission's supervision of MS is that, apart from the infringement procedure, there are currently **no specific EU enforcement measures** in the organic sector in case MS do not comply with their responsibilities.

Community enforcement measures set out under the food and feed controls apply in case of evidence of a serious failure in a MS' control system which may constitute a possible and widespread risk for human health, animal health or animal welfare. They are not relevant for organic as such.

NB. this problem does not refer to the possible misuse of EU funds, in case the irregularities concern beneficiaries of support under the CAP that are dealt with through conformity clearance procedures.

- As concerns the **import regime**, the control system does not provide the same level of supervision with regard to CBs recognised by the Commission for the purpose of equivalence as for CBs in the EU which are supervised by MS Competent Authorities.

Please see annex No 12, The EU trade regime for organic products, for further details on the identified issues and on the proposed actions to address them.

¹⁴ European Court of Auditors Special Report No 9/2012: Audit of the control system governing the production, processing, distribution and imports of organic products (26 June 2012), www.eca.europa.eu

4.2.2. *Supervision by MS Competent Authorities*

- ECA's audit identified several **shortcomings** in supervision of control bodies by the MS competent authorities: in three of the six audited MS with a system of private control bodies, the Court concluded that the procedures for approving, withdrawing or supervising control bodies were not sufficiently detailed.

These findings were confirmed by the audits carried out in 2012 and 2013 by the FVO and by DG AGRI, which identified shortcomings in several MS.

- Another aspect that weakens competent authorities' supervision of control bodies is the fact that most MS do not have a **graduated system of sanctions** towards non-compliant control bodies. The only measure clearly set out by the organic control legislation is the withdrawal of control bodies' approval. It is not effective as most of the times it would be disproportionate for the findings of the audit on control bodies and hence very rarely used in practice.

4.2.3. *Accreditation*

- By their very nature, the surveillance activities carried out on control bodies by the national accreditation body **overlap**, to a certain extent, with the supervisory activities carried out by the competent authorities. This entails a duplication of activities and increases the cost of the control system.
- There are **no specific rules** in the organic legal framework as regards the cooperation and the exchange of information between MS competent authorities and accreditation bodies. As a consequence, the situation largely varies across MS.
- The requirements on accreditation are **not the same** for control bodies **in the EU and in Third Countries**.

Accreditation bodies based in Third Countries that are not members of the European cooperation for Accreditation (EA) and are not signatories to the Multilateral Recognition Agreement (MLA) under the auspices of the International Accreditation Forum at international level may not adhere to the same level of surveillance on control bodies applicable in the EU.

This may lead to an uneven playing field amongst control bodies, and ultimately amongst operators, in the EU and in Third Countries.

4.3. Opinion by MS and stakeholders

During the hearing held by the Commission services on 25 and 26 October 2012 to discuss supervision and control issues, the following remarks were made:

- FiBL (Research Institute for Organic Agriculture, Austria): supervision should enhance risk orientation; importance of qualifications of accreditation bodies; supervise the effectiveness of control bodies
- DakKS (National Accreditation Body, Germany): the surveillance approach needs to be risk-oriented (focus on non-compliant control bodies); surveillance by different institutions should be well coordinated
- IFOAM (International Federation of Organic Agriculture Movement): accreditation – need to improve standards; clear requirements of experience of accreditation bodies
- Certisys (Belgian control body): request for regulated tariffication system for controls (fees to control bodies)
- Copa-Cogeca: Commission to strengthen supervision of MS through more frequent audits; MS to strengthen supervision of control bodies – need for harmonized approach to supervision of control bodies in the EU

A representative from the European cooperation for Accreditation (EA) made a presentation to the ISSG group in its meeting of 30 May 2013, describing all the various formal and practical steps of accreditation.

4.4. Conclusion

With a view to addressing the identified problems, the following actions have been taken (taken into account in the impact assessment as part of the **baseline scenario**).

- **Commission Regulation (EU) No 392/2013** was adopted in April 2013 to amend the implementing rules on the control system for organic production. The new provisions, applicable as from 1 January 2014, enhance MS supervision and control activities.
- **Commission audits** resumed in 2012 and are now regularly carried out to assess the proper functioning of the organic control system. The audit reports identify shortcomings, on which recommendations for remedial action are made to the Competent Authorities, and describe good control practices¹⁵.

¹⁵ All MSs and TCs visited by the FVO between January 2012 and July 2013 had control systems for organic production in place, with Control Bodies (CBs) entrusted with inspection and certification tasks. In general, staff of the Competent Authorities and CBs were competent and had the powers to fulfil their tasks. The shortcomings found refer to weaknesses in market controls and in the import control system for organic products, as well as a lack of appropriate supervision of CBs. The audits also show significant differences between CBs regarding the quality and intensity of inspections at operators - mitigated in some countries by harmonised provisions on sanctions, risk assessments of operators, off-farm verification programmes and sampling. Furthermore, a wide range of shortcomings related to derogations, exemptions and management of animals were found, and not all inspections observed by the audit teams were effective. The audits also revealed problems regarding a clear separation of accreditation and supervision tasks, which in some cases led to duplications and incomplete checks. The FVO presented the audit findings in the meeting of the Standing Committee on Organic Farming (SCOF) of 26 September 2013.

and the following actions are proposed to be taken:

- **Clarification** of the general rules for the **accreditation** of Control Bodies, both in the EU and in Third Countries, in respect of the standard against which they should be accredited and of the conditions to be fulfilled by the accreditation bodies, under the **improved status quo (1) policy option**. This will enhance legal certainty for the organic sector and ensure a level playing-field for control bodies, and ultimately operators, in the EU and in Third Countries.
- Introduction of a system of **electronic certification**, integrated in a EU-web database, under the **improved status quo (1) policy option**.

This will contribute to the competitiveness of organic operators, to simplification, and through the improvement of transparency and traceability, to the enhancement of the supervision and control chain.

5. CONTROL FREQUENCY

5.1. Minimum control frequency and risk based approach

As a general rule, all operators shall be subject to verification of compliance **at least once per year** (article 27 of Regulation No 834/2007). The implementing rules regulation qualifies this annual verification of compliance as a **physical inspection** (article 65 of Regulation No 889/2008).

Exception: can be inspected less frequently than once per year:

- wholesalers who deal only with pre-packaged products
and
- retailers who do not produce or prepare organic products, do not store organic products other than in connection with the point of sale, do not import organic products and have not contracted to a third party the activities of production, preparation including labelling, storage or import of organic products

Regulation (EC) No 834/2007, while maintaining in any event the obligation of an annual verification of compliance for all operators, introduces a **risk-based approach** to controls. Namely, it sets out that the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements.

Commission Regulation (EC) No 889/2008 details the implementing rules as follows:

- in addition to the annual inspections, the control body or control authority shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules.

Three risk factors shall be taken into account for the risk evaluation:

- (1) the results of previous controls,
- (2) the quantity of products concerned and
- (3) the risk of exchange of products.

DG AGRI gave practical guidance for control bodies and control authorities as to how the risk based approach to control should be applied in chapter 8 of its Working document on official controls in the organic sector, 2011¹⁶.

- New provisions will apply as from 1 January 2014 for the risk assessment and the related organization of the control visits:
 - the risk analysis shall provide the basis for the intensity (=number) of the unannounced or announced control visits
 - random visits in addition to the annual inspection shall be carried out on at least **10%** of operators in accordance with the risk category
 - at least **10%** of the total annual inspections and additional random visits shall be unannounced

Example: a control body with 100 operators shall carry out at least 100 annual physical inspections and 10 additional random, risk-based, visits = 110 in total. At least 10% of them=11 inspection and control visits shall be unannounced.

5.2. Identified problems

- **Wholesalers and retailers** might be treated differently in different MS as regards to the control frequency. In addition, it is not clear who – the MS competent authority or the control body - should determine the control frequency for these operators.
- The **risk based approach**, applying to the organic sector as from 1 January 2009, is still relatively new.

ECA's recent audit on organic production detected **shortcomings** related to risk assessment in 7 out of the 12 selected control bodies.

- Some MS and stakeholders consider that the **mandatory physical inspection of all operators prevents the full implementation of the risk-based approach**.

Operators with a consistently clean record cannot be inspected with less frequency. This **does not represent an efficient use of resources**, which should rather focus on riskier operators. So far, the major fraud cases in the organic sector (Gatto con gli stivali, Italy, 2011) did not affect the yearly inspected producers but traders selling conventional products as organic with import certificates: control visits to address effectively such cases are more difficult and time-consuming.

¹⁶ http://ec.europa.eu/agriculture/organic/files/eu-policy/data-statistics/control_guidelines_version_08072011_en.pdf.

- The current control rules that require annual inspection of **all** operators (articles 27(3) and 28 of Regulation No 834/2007) **do not allow group certification**¹⁷ that is accepted for small producers in Third Countries as a measure of equivalent control effectiveness in case of imports.

5.3. Position by Stakeholders

The Inter-Service Steering Group (ISSG) set up as part of the process for the Impact Assessment of the review of the organic farming regulation organised a **hearing** on 25/26 October 2012 to discuss supervision and control issues¹⁸.

Main remarks/suggestions on the *risk-based approach*:

- FiBL (Research Institute for Organic Agriculture): Focus should be put on 10 % of operators with risk of irregularities; the burden for compliant operators should be reduced by removing the obligation for a mandatory annual inspection; flexible risk assessment
- DakKS (National Accreditation Body for Germany): intensification of risk-oriented controls, in particular in third countries
- Finnish Food Safety Authority (Evira): lowered inspection frequency should be an option for the future; additional inspections should focus on higher risk operators
- Ecocert Group (Control Body): need for guideline for risk based inspections
- IFOAM (International Federation of Organic Agriculture Movement): clear guidance on how risk-based inspections should work is needed for consistency across EU and outside. The contribution that IFOAM subsequently developed - June 2013 - states that the focus on the risk-based approach should not undermine the audit approach (announced inspection) of each operator; moreover, parameters for risk classification as well as possible risk-orientated control measures need to be pre-defined at EU level.
- Certisys (Belgian control body): annual inspection needed for wholesalers; no parallel selling & communication rules for retailers; notification in case of subcontractors is not clear.

The **stakeholders' consultation** showed the following results on the *minimum control frequency*: while only 49,7% of stakeholders participating to the consultation actually know that organic operators are inspected at least once per year, the majority of respondents (57%) are for maintaining the annual inspection¹⁹.

The free contributions submitted to the consultation show that the European Poultry Association, the Soil Association, Bio-Austria, the FNSEA, Synalaf are in favour of the annual inspection.

¹⁷ Under the group certification scheme, group members operate under contractual or binding membership requirements that specify their commitment to comply with the organic production rules and allow inspection. Please see further details in annex 16, Small farms and enterprises: simplification, group certification.

¹⁸ A technical meeting with experts took place on 26 June 2013 to examine the issues identified for small farms, including in respect of the control system (e.g. cost of certification, group certification as applied in Third countries, reflections on possible simplified requirements for small farms).

¹⁹ Full report posted in the Europa organic farming page: http://ec.europa.eu/agriculture/organic/files/eu-policy/of_public_consultation_final_report_en.pdf

Only 35% of respondents to the public consultation would support a reduced control frequency for operators with a proven clean record (in addition to FiBL and IFOAM, this was also the position by the Norwegian Food Safety Authority).

As for *group certification*, 70% of respondents to the public consultation would support it, with variations across stakeholders' categories (from 55% for farmers up to 80% for public authorities in Third Countries).

In detail, Slow Food, the Soil Association, the Women of Europe for a Common Future are in favour. Bio-Austria and Copa-Cogeca are against. IFOAM EU is positive towards group certification, under conditions still to be developed.

5.4. Conclusion

With a view to addressing the identified problem, the following action has been taken:

- **Commission Regulation (EU) No 392/2013** was adopted in April 2013 to amend the implementing rules on the control system. The new provisions, applicable as from 1 January 2014, further enhance the risk-based approach. This action is taken into account in the impact assessment as part of the **baseline scenario**.

and the following action is proposed to be taken:

- Reinforce the risk-based approach **under the policy-driven option (3)** by **adapting the control frequency** through the removal of the obligation of a mandatory annual physical inspection for all operators independently from their risk profile.

This action is expected to lead to a fairer balance of the control pressure on operators by reducing the burden on those with a proven track record of compliance with the rules.

It is also expected to help achieve better control effectiveness, by targeting MS resources towards higher risk situations and operators, and control efficiency.

6. PAPER-BASED CERTIFICATION

There are two different types of certificates provided by Regulation (EC) No 834/2007: the **documentary evidence** attesting that an operator has placed his undertaking under the organic control system (Article 29) and the **certificate of inspection** that accompanies a given lot of imported organic products and certifies that the product has been produced according to equivalent production rules and subject to equivalent control measures (Article 33).

6.1. Documentary evidence

More than 225 000 organic producers²⁰ submitted their operation to the organic control system, in accordance with Article 28 of Regulation (EC) No 834/2007, and were registered in the EU-27 in 2011.

²⁰ Farmers which produce, produce and process or produce and import organic products.

Documentary evidence is issued by the control authority or control body after a satisfactory annual inspection of the operator under its control and is generally valid for a year until the next annual inspection.

Operators throughout the organic production chain have to verify that the operators from whom they purchase organic products are subject to the control system and have valid documentary evidence. Equally, they must provide documentary evidence attesting their status as organic operators at the request of other operators, control authorities or control bodies.

Documentary evidence is drawn up on the basis of a model in EU legislation (annex XII to Regulation No 889/2008) that is not mandatory in its layout and text.

Identified problems

- **Different models** of documentary evidence **exist across and within MS**, depending on specific conditions and needs, which make the control of documents and products by both control bodies and competent authorities more difficult. A questionnaire prepared to gather structured information on the existing situation showed that only in 12 MS a harmonised model for documentary evidence (= a compulsory model detailing the content, wording and layout of information) exist at MS level²¹.
- Paper-based documentary evidence is vulnerable to **forgery, fraudulent issuance or continued use** during the stated period of validity despite withdrawal or suspension of the operator.
- Documentary evidence does not enable a **real-time verification** that the amount of products originating from the operator is within the estimated production quantities or exceeds these.
- **Consumers cannot easily access traceability information.** Consumers buying organic products are paying a premium price based on their trust in the integrity of the system, symbolised by the organic logo. The responses to the public consultation show that they place very high value in traceability of organic production and information about the organic operator. They are not offered a user-friendly means of verifying who carried out the last substantial production process.

Operators in third countries not recognised as equivalent must subject their operations to a control body or control authority accredited for EU-equivalent organic production certification. Equivalent production rules and control measures must include an annual inspection and issuance of documentary evidence to the operator. Consequently, **the above listed problems equally apply to documentary evidence issued to such third country operators.** Whilst recognised CBs and CAs must maintain an up-to-date list of certified operators on their website, they have no obligation to publish the equivalent documentary evidence, which presents an added risk.

²¹ Information as of September 2013: a compulsory model for the content, wording and layout of information exists at MS level in CR, CZ, DK, EE, EL, FI, DE, IT, LT, NL, PL, SK. In the other 16 MS the model varies.

6.2. Certificate of inspection

A certificate of inspection is a document issued by the control authority or control body of the exporter in accordance with Article 13 of Regulation (EC) No 1235/2008 to certify the organic status of the product for import into the EU. The certificate is only valid for the lot of organic products identified on the certificate.

The **original paper-based** certificate of inspection must be presented for endorsement at import into the EU.

The certificate of inspection is the **only document indicating the organic nature of the imported products** as the customs import declaration does not allow the identification of organic products. The presence of a certificate of inspection can be indicated on the customs import declaration, but this is optional and handled differently by MS. Unless national customs require the identification of the certificate of inspection on the customs import declaration, there **is no link between the certificate and the customs import declarations**.

The certificate of inspection, which must be based on a mandatory model (Annex V of Regulation (EC) No 1235/2008), is **not linked to the documentary evidence** issued to the operators in the third countries. To be considered equivalent, control measures must enable the traceability of processed products' ingredients and control bodies and control authorities must be able to provide the documentary evidence therefore.

Recognised control bodies and control authorities can only issue certificates for products exported from third countries and belonging to product categories for which they are recognised.

Identified problems

- **Cumbersome** administration of the original certificate of inspection (delays /not presented at import). Operators complain about the administrative burden of presenting an original paper-based certificate of inspection at every import and about the delays in forwarding the originals that pose problems for the clearance of perishable imported organic goods.
- Paper-based certificate of inspection is **vulnerable to forgery and fraudulent issuance**. Fraudulent issuance implies a certificate being issued for a scope, geographical or product category, for which the third country or the CB/CA is not recognised or whose recognition has been reduced. Equally, fraudulent issuance can concern a processed product for which the CB/CA has not verified that the ingredients were purchased from operators under the control of a recognised CB/CA, from an EU country or from a recognised third country.
- **Traceability** of organic chain behind imported organic products is **difficult**. Equivalent control systems should ensure traceability throughout the organic production chain. Where this is based on obtaining copies of equivalent documentary evidence, the above-described problems apply in equal measure to recognised Third countries, recognised Control Bodies or Control Authorities. Recognised CBs and CAs have to publish a web-based, up-to-date list of certified operators. Whilst this facilitates the verification of the status of an operator, it does not necessarily facilitate traceability of organic products covered by a certificate of inspection.
- Under the import regime with recognised Control Bodies **MS no longer have a verification role** before the certificate of inspection is issued as it was the case for import

authorisations. However, MS continue to endorse the certificate of inspection upon entry into the EU.

6.3. Conclusion

With a view to addressing the identified problems, a system of **electronic certification** integrated in a EU web-database is proposed to be introduced, under the **improved status quo (1) policy option**.

7. IRREGULARITIES, INFRINGEMENTS AND SANCTIONS

7.1. State of play

Regulation No 882/2004 on food and feed official controls to verify compliance with the rules aiming, in particular, at guaranteeing fair practices and protecting consumer interests, including labelling (article 1), includes the following **enforcement measures**:

- When the **competent authority** identifies **non-compliance**, it shall **take action** to ensure that the operator remedies the situation (article 54), with a wide choice of measures that it deems appropriate. NB: The competent authority cannot delegate action to be taken in case on non-compliance (article 5.1).
- **MS** shall lay down the **rules on sanctions** applicable to the infringements of feed and food law and take all necessary measures to ensure they are implemented. Sanctions shall be effective, proportionate and dissuasive; the provisions on infringements shall be **notified to the Commission** (article 55).

According to **Regulation No 834/2007** on organic production and labelling

- when an **irregularity** is found, the control authority or control body shall ensure that the reference to organic production is removed from the entire lot affected, and where **severe infringements** or **with a prolonged effect** are found the operator shall be prohibited from marketing organic product for a period to be agreed (article 30).
- Information on **infringements and irregularities** shall be **immediately communicated** between Control Bodies, Control Authorities, MS and where appropriate the Commission (article 30).
- The **competent authority** has the following responsibilities:
 - when approving a control body, take into account the measures that it intends to apply in case of detection of irregularities and/or infringements (article 27.5);
 - as part of its supervision of control bodies, take cognisance of the irregularities and infringements found and corrective measures applied (article 29).

Regulation No 889/2008 requires the control body or control authority to take action in substantiated suspicion that an operator intends to place on the market a non-compliant product. It has recently been amended to require **Competent Authorities** to adopt and communicate to control bodies a **catalogue** at least listing infringements and irregularities that affect the organic status of the products and corresponding **measures** to be applied (new article 92d). This provision will apply **as from 1.1.2014**.

In case **organic operators benefit from financial support under the CAP**, MS shall adopt all legislative, regulatory and administrative provisions and take any other measures necessary to ensure the effective protection of the EU financial interests, according to **Council Regulation (EC) No 1290/2005** on the financing of the CAP²². In particular, they shall prevent and pursue irregularities and recover lost sums.

They shall communicate to the Commission irregularities and suspected fraud cases in the organic sector that have or would have consequences for the EU budget through the **OLAF's Irregularities Management System (IMS)**.

7.2. Identified problems

- The **legal provisions are not clear and/or not entirely consistent**.

The terms in the **food and feed** official controls and the **organic regulation** differ: the former refers to "non-compliance" and "sanctions", while the latter mentions "irregularities", "infringements" and corresponding "measures". The two acts are not entirely consistent: the food and feed official control regulation prevents the competent authorities from delegating to control bodies the measures to be taken in case of non-compliance, which creates a problem for control bodies in the organic sector.

The organic farming regulations include the terms "irregularity", "severe infringement" and "infringement with a prolonged effect" without providing a definition.

When organic operators benefit from financial support under the CAP, the EU provisions on the protection of the EC financial interests - both in the general and sectoral legislation – apply which include specific definitions for irregularities and fraud²³.

Irregularities and fraud, when referred to in the organic sector, include therefore both the unlawful use of the organic labelling provisions, through the marketing of conventional products or products not complying with the organic rules, and the potential misuse of EU funds – in the latter case, with additional responsibilities for sound financial management by MS and the intervention by OLAF.

- The **absence of specific tolerance levels** and/or the **lack of a harmonised approach** is dealt with in Annex 11.
- The ECA concluded in its special report 9/2012 that in several MS the competent authorities have **not defined detailed categories of non-compliance and corresponding sanctions**. Namely, this was the case for 3 out of the 6 audited MS (Germany, France and the UK).

²² Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy, OJ L 209, 11/08/2005, p. 1.

²³ Irregularity shall mean an infringement of a provision of Community law resulting from an act or omission by an economic operator which has or would have the effect of prejudging the general budget of the Community or budget managed by them, either by reducing or losing revenue accruing from own resources collected directly on behalf of the Community or by an unjustified item of expenditure (Regulation No 2988/959, article 1.2).

Fraud, in respect of expenditure, is defined by the Convention on the protection of the Communities' financial interests as any intentional act or omission relating to the use of presentation of false, incorrect or incomplete statements or document which has as its effect the misappropriation or wrongful detention of funds from the general budget of the EU or budget managed by or on behalf of the EU; non-disclosure of information.

- As a consequence, each CB defines the non-compliance and applies sanctions in a different way, with considerable differences in control results. This situation leads to **operators being sanctioned differently**, across MS and even within the same MS, for the same case of non-compliance.
- On-the-spot audits carried out by the FVO in 2012 confirmed weaknesses in some **MS' follow up to cases of non-compliance**. They did not always ensure that irregularities were followed-up and sanctions were imposed in a systematic and timely manner.

7.3. Position by stakeholders

The stakeholders' hearing held on 25 and 26 October 2012 in the context of the Impact Assessment process for the review of the EU political and legal framework for organic production showed the following remarks and suggestions.

- BMWFJ (Federal Ministry of Economy, Family and Youth, Austria): there should be one single sanction catalogue for the EU, one single sanction catalogue for equivalent CBs
- Copa-Cogeca (Committee of Professional Agricultural Organisations-General Committee for Agricultural Cooperation): need to clarify infringement and irregularity and corresponding sanctions and to promote good practice. Statistics for each MS/CB should be published annually by the Commission.
- DakS (National Accreditation Body for Germany): suggestion to set up a clearing facility for complaint cases.
- Ecocert group (Control Body): need to define irregularities and infringements; EU catalogue of sanctions; EU practical guidelines with stakeholders' participation
- EOCC (European Organic Certifiers Council): define irregularity/infringement; set out a basic EU sanction policy
- FiBL (Research Institute of Organic Agriculture): envisage an international complaint procedure at EU level, a rapid alert system and a whistleblower system.
- IFOAM: guidance on sanctions, with procedures and measures relevant to all operators in case they fail to meet the requirements of good organic quality management.

7.4. Evaluation and studies

Amongst the wide array of studies carried out within the CERTCOST project, one consisted in the **statistical analysis of German supervision and control data**: all CBs' activities for a two-year period, 2006-2008 were reviewed. The number of irregularities and infringements detected and the sanctions imposed showed significant statistical differences with regard to sanction behaviour.

This underpins the first recommendation included in the report "Improving the organic certification system – How to increase the effectiveness and efficiency of organic certification". It is recommended to harmonise supervision of the certification system, namely to **clearly define at EU level different types of non-compliance and sanctions to allow an easy understanding by all stakeholders** – to be developed in a participatory process; to harmonise the use of terms and

definitions as well as data collection specifications, and to produce and publish annually a supervision report at EU level.

7.5. Conclusion

With a view to addressing the identified issues, the following action has been taken (taken into account in the impact assessment as part of the **baseline scenario**):


- **Commission Regulation (EU) No 392/2013** was adopted in April 2013 to amend the implementing rules on the control system for organic production. The new provisions, applicable as from 1 January 2014, require the Competent authorities to adopt and communicate to the Control bodies a catalogue of infringements and irregularities affecting the organic status of the products and corresponding measures to be applied to the operators concerned.
- The Commission proposal (COM(2013)265 final) to review Regulation No 882/2004 on **official food and feed controls** includes new provisions that aim at a more effective enforcement. In particular, MS will be required to ensure that the financial penalties applicable to intentional infringements at least offset the economic advantage sought by the perpetrator of the violation.

and the following action is proposed to be taken:

- **define irregularities and infringements** and require MS to set measures that ensure the **liability of all operators** in the control chain, under the **policy-driven option (3)**.

8. FRAUD CASES REPORTED IN THE MEDIA

A non-exhaustive selection of articles, translated and available on-line by PressEurop, is shown below²⁴

	<p><i>Politika</i>, 8.8.2011, Warsaw, Circulation: 200,050²⁵ The article refers to particularly attractive conditions for subsidy-hunters in Poland in the case of organic walnuts, amongst other things due to alleged lax controls by the control bodies.</p>
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²⁴ Translation online at Press-europe: <http://www.presseurop.eu/en/category/section/economy/agriculture>

²⁵ <http://www.polityka.pl/rynek/1518054.1.jak-polacy-doja-unie-na-eko-zywnosci.read>



Die Welt, 25 February 2013²⁶ - City: Berlin, Circulation: 263 000

The article reports the investigation launched in 2011 and revealed by the weekly Der Spiegel.



Die Tageszeitung, 21 May 2013, City: Berlin, Circulation: 57,000²⁷

The article covers the Green War operation. Fraud in the organic farming sector is described as thriving international industry, made up of a complex network of companies bearing all the marks of traditional organised crime. The president of Federbio, the umbrella organisation for organic producers, processors and distributors in Italy, is quoted: "They have been able to carry on because supervisors have failed time and time again to do their jobs".

²⁷ <http://www.taz.de/Italien-und-Lebensmittelbetrueger/!116553/>

ANNEX 10: COSTS OF CONTROLS IN THE EU ORGANIC PRODUCTION SCHEME

1. INTRODUCTION

This annex aims at providing:

- an overview of the main types of costs resulting from the EU organic control and certification system, and
- some concrete examples as to the actual level of costs borne by different actors along the chain.

It is based on information from the CERTCOST - Economic Analysis of Certification Systems in Organic Food and Farming – project²⁸.

2. OVERVIEW OF THE MAIN TYPES OF CONTROL RELATED COSTS IN THE ORGANIC CHAIN

The most evident cost of the organic production control system is the cost for obtaining a documentary evidence (=certificate) that the operator's production meets the requirements set by the EU organic regulation. Certification costs are considered to be a major factor for operators to decide about participating in a particular quality scheme, including organic.

The distribution of the costs of controls between different actors of the chain varies among MS. It largely depends on the choice of the control system set-up made by the MS and on the choice of the public measures to support operators' certification costs that are implemented by the MS.

2.1. Control system set-up

Each MS has the possibility to:

- delegate control and certification of operators to one or more private control bodies which it has to first approve²⁹ and then supervise³⁰ (this is known as "system A" and is currently used by 18 MS), or
- confer the control and certification of operators to one of more public control authorities (this is known as "system B" and is currently used by 5 MS, or
- set-up a mixture of both (system of control bodies and control authorities) known as "system C", currently used by 4 MS.

²⁸ It is a research project under the EU 7th Framework Programme, run by a consortium of 11 institutions (universities, research centres and two private control bodies working in the organic sector) from 11 countries, from 2008 to 2011. The full set of reports is available under www.certcost.org. The most relevant information regarding the cost of controls is to be found in report D21.b (Report on total costs of three organic certification systems in six European countries with particular focus on organic supply chain) http://www.certcost.org/Lib/CERTCOST/Deliverable/D21_B.pdf.

²⁹ Approval of control bodies is to be understood as (one-off) verification carried out by the competent authority to ascertain that the control body to which tasks will be delegated fulfils all conditions and requirements set by Council Regulation (EC) No 834/2007.

³⁰ Supervision of control bodies is to be understood as the (continued) verification carried out by the competent authority to ascertain that the control body performs the delegated tasks in a satisfactory manner.

Currently, there are approximately 150 private control bodies and 40 public control authorities operating in the EU.

The different implications on the distribution of control costs between the different actors in "system A" and "system B" are shown in Table 1 below.

Table 1: Overview of main types of control related costs incurred by different actors along the chain

Actor	System of private control bodies (=System A)	System of public control authorities (=System B)
Competent authority (= MS)	Costs related to approval and supervision of control bodies	No costs of approval and supervision but direct control cost of control authorities
Control body (private entity)	Costs of accreditation to EN 45011 Costs of control and certification of operators (in terms of resources needed) NOTE: The costs incurred by control bodies are fully compensated by the fees charged to the operators	N/A
Control authority (public entity)	N/A	Costs of control and certification of operators, in terms of resources needed NOTE: These cost are (partly) compensated by fees charged to operators
Operators (farmers, processors, traders, etc.)	Fees paid to control body for control and certification (=inspection fees)	Fees paid to control authority for control and certification (=inspection fees) or no fees (controls and certification free of charge – e.g. Denmark)

2.2. Public support of certification costs

MS have the possibility to implement support schemes, which may compensate the organic farmers for their control costs.

The current rural development programmes give the possibility, under Axis 1, to use measure 132: "Participation of farmers in food quality schemes"³¹. Several MS or regions use this measure to cover part of the control and certification costs incurred by farmers (Austria, Belgium, Cyprus, Estonia, Germany, Greece, Malta, the Netherlands, Poland, Portugal, Slovenia, most regions of Italy and Spain and parts of the UK). However, not all farmers that apply can be supported as resources are limited.

Certification costs of organic processors or other organic operators are not supported in any of the EU countries except Denmark. In Denmark, the control of organic farmers, processors and other organic operators is provided by the public control authorities free of charge.

³¹ See Annex 3, Main instruments of the Common Agricultural Policy supporting the organic farming policy, for more details.

It is to be added that organic farmers can be also subsidized under other measures in Axis 1, 2 and 3 of the rural development programmes. Out of these, agri-environmental payments under measure 214 are the most important. With the exception of the Netherlands and France³², all MS have implemented specific area payments for organic farming under the measure 214. However, those payments are not meant to cover directly the certification costs but rather overall organic management.³³

3. CONCRETE EXAMPLES OF CONTROL RELATED COSTS IN SOME MS

3.1. Inspection fees paid by operators to control bodies and to control authorities

In general, inspection fees mainly depend on type of operator (e.g. higher fees for processors than for farmers), complexity of operations (e.g. higher fees for operators with parallel production), and size of operations.

Inspection fees also largely vary both across MS and, within MS, across control bodies.

According to the CERTCOST project, the inspection fee is the most relevant monetary expenditure for organic operators with respect to the certification costs. The level of the inspection fee has been estimated on average as 900 – 1000 €per farm, which corresponds to a share of up to 0.4 % of the raw income³⁴ of a farm and up to 1 % of the organic turnover of processors.

For the CERTCOST study countries³⁵, the median of the inspection fee amounts to 500 €per farm, (ranging from 318 €in the Czech Republic to 647 €in the UK). For processors, the median varies considerably from 477 €per processor in the Czech Republic up to 1.400 €per processor in the UK.

To illustrate the variety of fees across the EU, tables 2 and 3 provide information on fees charged by selected control bodies/control authorities in different MS.

³² France has implemented conversion and maintenance payments for organic farming under the 1st pillar of the CAP on the basis of Article 68 of Regulation No 73/2009.

³³ A detailed mapping of the public support measures which are currently in place in the EU MS can be found in a study report "Use and efficiency of public support measures addressing organic farming – Institute of Farm economics - Thünen Institute – financed by the European Commission, November 2011. The main results are presented in Annex 2 to this report.

³⁴ Raw income is calculated as revenues minus variable and fixed costs however without the imputed labour costs of the farm family.

³⁵ Czech Republic, Germany, Denmark, Italy, UK, Switzerland and Turkey

Table 2: Fees of selected control bodies (2009-2010 data extracted from the CERTCOST database)

Control body	Fee for farmers	Fee for processors
ABCERT, Germany	Control fees for farmers are based on the type of production and the area farmed. The minimum control fee (lump sum) for farmers is 195 € and the maximum is 440 € per year. If inspection time included in the lump sum is exceeded, further time is charged with 65 € per hour.	Control fees for processors are structured into a lump sum based on the type of production and the time spent for controlling. The minimum fee is 160 € and the maximum fee is 260 € per year. Time spent for inspection and certification is charged with 65 € per hour.
Bio-dynamic Agriculture Association (BDAA), UK	Fees are set in bands according to farm size, different rates for horticulture and top fruit. A 50ha mixed farm (cropping and livestock) would have paid about €720 in 2009	Fees are set in bands according to turnover, lower rates apply for on-farm processing
Biokont CZ, Czech Republic	Basic fee: 8.4 € + travel costs: 24.4 € excl VAT; variable fee according to the size of the holding: 1,2 €/ha + inspector's time, which is priced at 14.3 €/15 minutes. Holdings with parallel conventional production must pay extra 20%.	Basic fee: 8.4 € + travel costs: 24.4 € excl. VAT; Variable fee according to size of the annual organic turnover: Less than 200000 € 78.8 € 200000 - 800000 € 201.7 € > 800000 € 399.2 € plus inspector's time which is priced at 14.3 €/15 minutes. Processors with parallel conventional production must pay extra 20%.
HS certifiering, Sweden	Plant production: < 20 ha: €312, 20 - 50 ha: €399.75, 50 - 100 ha: €438.75, 100 - 200 ha: €477.75, 200 - 500 ha: €507, > 500 ha: €585. Animal production incl. plant production: < 20 ha: €390, 20 - 50 ha: €516.75, 50 - 100 ha: €575.25, 100 - 200 ha: €672.75, 200 - 500 ha: €731.25, > 500 ha: €828.75. Poultry production > 3000 animals: €575.25	Processing on the farm: €165.75, Processing, simple, only organic: €370.50, Processing, simple, not fully converted: €516.75, Processing, comprehensive, fully converted: €517.75, Processing, comprehensive, not fully converted: €711.75

Table 3: Fees of selected control authorities (2009-2010 data extracted from the CERTCOST database)

Control authority	Fee for farmers	Fee for processors
Comité de Agricultura Ecológica de la Comunidad de Madrid, Spain	Basic application fee: 170 €+ a variable fee according to Ha, type of crop and number and type of animals. Variable fee: Crops: from 6 €/ha to 55 €/ha, maximum variable fee: 2100 €for each crop. Animals: from 0.9/each to 1,75 €/each depending on type, maximum variable fee for each animal species: 1000 €	Basic fee: Mixed organic and conventional processors: 550 € 100 % organic processors: 350€ Variable fee depending on the number of labels - e.g. 21,5 €for 2000 labels.
Danish Plant Directorate, Denmark	Free of charge	N/A
Danish Veterinary and Food Administration, Denmark	N/A	Free of charge
National Supervisory Authority for Welfare and Health, Finland	N/A	1st time registration fee: 105 €1st time control : 72 €Basic control fee: 72 €Variable control fee: 95 €hour Approval of derogations: 95 €case

In order to calculate the total control and certification cost incurred by an operator, the operator's effort connected to documentation of practices relevant for organic standard, preparing for the control visit and the control visit itself must be added to the inspection fee paid by the operator. The CERTCOST project calls these additional costs "opportunity costs" and calculates that their level ranges from 133 €per year for a farmer in the Czech Republic to 590 €per year for a farmer in the UK (for processors the range is higher).

3.2. Cost of approval and supervision of control bodies borne by the national authorities

For CERTCOST study countries, the workload of competent authorities for supervising the private control bodies ranges from 33 € per operator in the Czech Republic to 79 € per operator in Germany (2008 data).

As part of the impact assessment, MS have been requested in 2013 to complete this information.

According to an estimate provided by the German administration, approximately 300 working hours are spent on an approval of one control body. This amount of working hours, using the hourly earning rate for Germany (category clerk) provided by the EU Standard Cost Model, translates to an amount of 8.340 €per approval of one control body.

Regarding supervision, the German administration estimates that approximately 120 working hours (= 3.336 €) is spent annually per supervision of one control body. Other national administrations provided similar estimates: 92 hours (= 2.318 €) for annual supervision of one control body in Sweden and 155 hours (= 558 €) in Romania.

According to an estimate by the French administration, two full time persons are assigned annually for the approval of the 9 control bodies and their supervision, for a total of approximately 2.800 working hours. Using the hourly earning rate for France (category clerk) provided by the EU Standard Cost Model, this translates to an estimated amount of EUR 6.688 for the approval and annual supervision of one control body.

3.3. Cost of accreditation

The cost of accreditation is paid by control bodies as compulsory accreditation to EN 45011 (ISO 65 Guide). The cost includes a fee paid for the 1st time accreditation and an annual fee for maintenance of accreditation.

Table 4: Cost for the CB of accreditation for selected MS (2009-2010 data extracted from the CERTCOST database)

Member State	Fee paid for the 1 st time accreditation	Annual fee for maintenance of accreditation
Czech Rep.	10722 €	2600 €
France	3135 €	Fixed annual fee of €2289; Variable fee: $0,225 * (\text{Fixed fee} * \text{N}^\circ \text{ of systems accredited}) + 0,039 * (\text{fixed fee} * \text{No of equivalences})$
Germany	Fees depend on the number of employees of the control body: at least 2540 Euro (for bodies with 1-2 employees) excluding travel costs	At least 605 Euro (for bodies with 1-2 employees)
Spain	6.903 €	4.125 €
Italy	1550 € accreditation fee + 860 €/day for inspector	From 0,15 to 2,5% of the organic turnover of the control body (minimum fee 2066 €)
Austria	Basic fee: 5595 € plus 36 € per scheme (organic, PDO/PGI, TSG)	2180 € per standard area, e.g. product certification

3.4. Aggregated control data

CERTCOST estimates that about 1500 staff full time years were spent by the competent authorities, accreditation bodies, control authorities and control bodies on organic control in the 27 EU countries in 2008.

With 1500 employees the annual cost of the workforce of the organic certification sector was estimated to about EUR 35-55 million.

4. CONCLUSIONS

It has been observed that:

- In the system of private control bodies (=system A), the costs of control and certification are borne by the operators. In addition, the MS competent authority bears the costs for approval and supervision of control bodies.

One can assume that the fees charged by private control bodies are set in such a way as to fully cover all costs incurred by the control body, including costs of accreditation.

- In the system of public control authorities (=system B), the costs of control and certification are borne by the operators (but seem to be generally lower than in system A) or by the administration (in case controls and certification of operators is provided free of charge).

It is not known whether the fees charged by the public competent authorities fully cover all costs incurred by the control authority.

- In some MS, the costs for control and certification paid by operators are (partly) compensated by support paid under the RD Programmes.

Given that the certification fee is a major cost item in the total cost of organic certification, it could be reduced by reducing the cost for the control visit and thus the corresponding control fee. This could be achieved by reducing the number of control visit per operator, e.g. by introducing a risk-based control system where low-risk operators are controlled less often than high-risk operators.

The conclusion from CERTCOST underpins the proposed **action to reinforce the risk-based approach under the policy driven option (3)**.

ANNEX 11: PRESENCE OF NON-AUTHORISED SUBSTANCE RESIDUES IN ORGANIC PRODUCTS

This Annex describes the issues related to the presence of non-authorised plant protection products residues. The issues identified are examined in relation to the situation in the EU and concerning imported organic products, as well as in relation to the perception and expectations of consumers.

1. OVERVIEW EU LEGISLATIVE FRAMEWORK

The EU organic production legislative framework defines in a detailed way the **substances and plant protection products that can be used** by producers (Annex II of R. 889/2008 established in accordance with the provisions in Art. 16 of R. 834/2007).

The EU organic production legislative framework **does not lay down rules on any tolerance levels for accidental** presence of any substance other than those explicitly authorised in Annex II of R. 889/2008.

The substances explicitly authorised under organic production rules have to comply with the horizontal EU legislation. In particular, plant protection products that are authorised for use in organic production follow the rules under relevant EU legislation concerning the placing of plant protection products on the market (Regulation No 1107/2009³⁶) and the maximum residue levels (MRL) (Regulation No 396/2005³⁷). As a result, the list of substances and plant protection products authorised in organic farming is very limited. By principle, the use of most of synthetic substances used as pesticides in conventional agriculture is not authorised in organic farming.

Organic production is established according to the **principles of precaution and prevention** (Art. 4 of R. 834/2007), developed in different parts of the relevant legislation such as:

- the maintenance of plant health by preventative measures (Art. 5(f) of R. 834/2007)
- disease prevention and veterinary treatment (Art. 14(1)(e) of R. 834/2007)

For the implementation of the organic production control system, **operators are required to take precautionary measures in order to reduce the risk of contamination by unauthorised products or substances** and the cleaning measures to be taken in storage places and throughout the operator's production chain (Art. 63(c) of R. 889/2008).

Article 30(1) of R. 834/2007 stipulates that "*Where an irregularity is found as regards compliance with the requirements... shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by*

³⁶ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC - OJ L 309, 24.11.2009, p. 1–50.

³⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC - Text with EEA relevance - OJ L 70, 16.3.2005, p. 1–16

this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities".

Article 91 (1) of R. 889/2008 requires operators, **in case of suspicion**, to only put organic products in the market after elimination of any doubt as to compliance with organic production rules. In case of **substantiated suspicion with regard to compliance with EU organic production rules**, Article 91(2) of that Regulation enables control bodies and control authorities to suspend/prohibit the marketing of the products as organic.

Article 8 of R. 882/2004 on Official Food and Feed Controls stipulates that MS Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, inter alia, the areas referred to in Annex II, Chapter II, which, under point 5 require: *"Sampling procedures, control methods and techniques, interpretation of results and consequent decisions"*.

2. IDENTIFIED ISSUES

On different occasions, **residues of plant protection products not authorised for use** under organic production rules **are found** in products labelled as organic. This is regularly reported, among others, by the European Food Safety Authority (EFSA) in its annual reports on pesticide residues in food

Such cases can be differentiated between:

- substances that are authorised under horizontal EU legislation (i.e. in conventional production) but not authorised under the specific EU organic production legislation and,
- substances that are not authorised under horizontal EU legislation. In the latter case, the products cannot be marketed, even as conventional.

Under the following paragraphs, the issues related to the **accidental presence of pesticide residues in organic products that are not authorised under the specific EU organic production rules** are examined³⁸. As "accidental"³⁹ is considered the presence of any substance for which it can be established that no use⁴⁰ by the operator of the substance in question was made and that all the measures necessary to avoid such contamination were taken. The origin of such accidental presence may be related to:

- spray drift on the organic plant products by plant protection products used in neighbouring farms or cross-contamination in storage facilities;
- environmental pollution in case substances persist in the soil or the water where organic production is established;

³⁸ Similar issues can arise with substances used for other purposes, for instance cleaning and disinfection of buildings and installations which are not authorised under the EU legislative framework on organic production but can however be detected in organic products.

³⁹ The term "technically unavoidable" or "inadvertent" are also used to describe such cases.

⁴⁰ It should be noted that the term "use" is not defined under the EU organic production legislation.

EFSA noted in its 2010 report⁴¹ that "3,571 samples of organic origin were taken in 2010 by a total of 28 countries, which corresponds to 4.9% of all surveillance samples taken overall in the reporting countries. For fruit and nuts, a lower rate of MRL exceedances (0.9%) was found in comparison to conventionally grown fruit and nuts (2.9%). For vegetables, the exceedance rates of the surveillance samples were 1.0% and 3.8% respectively for organic and conventionally grown products. Overall, the MRL exceedance rate for organic food was 0.8%. In total, 131 different pesticides were found in organic products in measurable concentrations; of those, 26 pesticides were found in at least five samples. **It is noted that 25 out of these 26 substances are not allowed in organic farming**".

It should be noted that the issue of accidental presence of pesticide residues in organic products is closely linked to the approach applied by the laboratories that perform the relevant analysis of samples. This relates in particular to:

- the **scope of analysis**, i.e. which and how many substances are/or have to be sought in the sample analysis performed by the laboratories;
- the **'limit of determination'** (LOD)⁴², i.e. the validated lowest residue concentration which can be quantified and reported by the laboratory, which may vary according to the substance, the nature of the product (i.e. processed/unprocessed) and/or equipment used for the analysis of the sample.

At present, **no specific harmonised guidelines exist at EU level concerning the approach to be used by official laboratories for samples of organic products and interpretation of the results**. Guidance is available for samples of conventional products⁴³.

2.1. Situation in the EU

In the absence of specific EU rules concerning the accidental presence of pesticide residues in organic products, different approaches are implemented in form of national legislation adopted in some MS or guidelines put forward by stakeholders.

In MS like **Italy**⁴⁴ or **Belgium**⁴⁵ specific provisions were adopted in form of legislation to deal with accidental or technically unavoidable presence of pesticide residues and/or interpretation of analysis results. Discussions are on-going in the Czech Republic⁴⁶ and in other MS concerning the approach to adopt.

⁴¹ <http://www.efsa.europa.eu/en/efsajournal/doc/3130.pdf> - See comparative tables at the end of this annex.

⁴² Definition from the REGULATION (EC) NO 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

⁴³ Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed. Document N° SANCO/12495/2011

⁴⁴ Ministerial Decree No 309 of 13 January 2011 on "accidental and technically unavoidable contamination of phytosanitary products in organic farming".

⁴⁵ Order of the Regional Government of Wallonia on organic production and labelling of organic products, 11th of February 2010, Annex I, Chapter 3 concerning planning, execution and interpretation of analysis mentions.

⁴⁶ Guideline for handling pesticide residues in Czech organic production – FiBL, 6 June 2013

IFOAM EU Group⁴⁷ has issued/updated in 2012 a set of guidelines on the matter prompting an **action level** (general value of 0.01 mg/kg). Residues found equal or above the action level in an organic product trigger an investigation with reference to Article 91(1) of R. 889/2008. Products are not automatically decertified and no such specific level has been set for such decertification. "By this approach strong detailed investigations are made of the most serious contaminants".

IFOAM EU Group stresses that "*organic agriculture is a method, which cannot be replaced by the absence or presence of residues under or above a certain level*". It underlines that "*organic legislation is structured as legislation for a process based agriculture and food processing system. In the discussion about the need for harmonisation in the residue topic, we might make the mistake of transforming a more or less privately developed action level into a strict decertification level in the EU legislation*". In its contribution of 14 May 2013, IFOAM EU Group claimed that "*it could be a mistake to transform a more or less privately developed action level into a strict decertification level*".

EOCC⁴⁸ issued in 2013 specific guidelines⁴⁹ concerning presence of pesticide residues in organic products that uses an **action level** (set at 0.02 mg/kg). Findings equal or above the action level require an investigation. Reference is made to Art. 91(2) of R. 889/2008. The decision to block or not the product can be taken by the control body of the operator. For findings below the action level, the control body requires the operator to investigate the case and eliminate the cause. Reference is made to the provisions of Art. 91(1) of R. 889/2008.

The approach promoted by **BNN**⁵⁰, the Organic Traders and Processors Association in Germany uses an orientation value (set at 0.010 mg/kg). BNN members use the orientation value as a "**critical level**", meaning in practice that products exceeding it are not commercialised as organic.

In its contribution of 7 July 2013, BNN stated the following: "*... Therefore, pesticide residues might be evidence of illegal use of substances not permitted in organic agriculture. But those residues might as well be tracked back to unavoidable or accidental contamination. A threshold would have to reliably differentiate between usage of pesticides and unavoidable or accidental contamination. Because of the multitude of pesticides, plants, combinations and application techniques, defining such a threshold might be difficult and would imply the risk of decertification of products although they had been produced and processed according to organic regulations. This as well would result in an amount of extra-costs not yet estimated*". BNN praised a "**Case-by-case evaluation and investigation of pesticide findings in organic products still seems the most appropriate answer, preventing extra-costs and cutback of cultivation areas.**"

⁴⁷ IFOAM EU Group "Guideline for Pesticide Residue Contamination for International Trade in Organic" (http://www.ifoam-eu.org/workareas/regulation/pdf/Guideline_IFOAMEU_pesticides_residues_contamination_03.12.pdf)

⁴⁸ European Organic Certifiers Council.

⁴⁹ Pesticide Residues Guideline: A guidance document for the certification decision making process Version: January 2013 (http://eocc.nu/home/pdf/guidelines/EOCC_task_force_residues.pdf)

⁵⁰ BNN Orientation Value for pesticides1 – A guideline to evaluate pesticide residues in organic products (http://www.n-bnn.de/html/img/pool/BNNOrientierungswert_EN_1208.pdf)

2.2. Situation concerning imported products

Organic products can be imported in the EU under 3 different regimes, namely import authorisations granted by MS (in phase-out), from Third Countries or from CBs (Control Bodies/Control Authorities) recognised under the equivalency regime.

At different occasions in the past, questions were raised by stakeholders and MS concerning imported organic products containing low levels of accidental presence of residues of pesticides and other substances in organic products. This was for example the case with imports of organic fruits from different Third Countries containing residues of DDAC⁵¹ in 2012 (quaternary ammonium compound) or endosulfan in soya beans in 2011.

A specific approach concerning the presence of pesticides in organic products was recently adopted by the US⁵². It consists in establishing a threshold such as a **critical level** (5% of the US tolerance level for conventional products⁵³) above which any product cannot be commercialised as organic. Products below this threshold can still be commercialised as organic provided no use of the substance was made by the producer and that an investigation was carried out to identify the causes of the contamination. In addition, products that contain lower or equal to 0.01 parts per million (equivalent of 0.01mg/kg) of pesticides can still be commercialised as organic. Investigations are also required in this case in order to identify the source of contamination.

In the margins of the meeting of the Enlarged AGOF⁵⁴ of April 2013, a representative of a Third country recognised by the EU under the equivalency regime, sent the following statement:

"... notes that zero tolerance for the low-level presence of residues not included in the approved list of substances in EC No. 889/2008 may unnecessarily restrict trade by not sufficiently taking into consideration growing conditions in Third Countries. This potentially constitutes a trade concern for many of the European Union's (EU) key organic trade partners. Despite the implementation of accepted isolation measures, farm size, geography and climate can in some cases lead to the unintended low-level presence of residues on organic commodities from plant protection products used in conventional production. ... is concerned that an approach that does not consider growing conditions in Third Countries could lead to trade disruptions due to the unintended and unavoidable low-level presence of residues of non-listed substances. This situation could constitute a serious and unnecessary trade irritant for key EU trading partners."

Bio Suisse,⁵⁵ the federation of Swiss organic farmers, developed a decision chart concerning presence of pesticide residues in organic products. It sets at 0.01 mg/kg the general level which triggers an investigation and suspends marketing of the products in question. For products with substances below 0.01 mg/kg marketing is possible but investigations are carried out to identify the source of contamination.

⁵¹ Didecyldimethylammonium chloride.

⁵² NOP 2613 of 4 March 2013 - (<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5102727>)

⁵³ US tolerance levels are in general much higher than EU MRL due to the different interpretation or treatment of the statistic data obtained by the pesticide residue trials.

⁵⁴ EU Advisory Group for Organic Farming.

⁵⁵ http://www.bio-suisse.ch/media/en/pdf2011/e_bio_suisse_decision_chart_pesticide_06122011.pdf

2.3. Conclusion

The different initiatives adopted so far with respect to the presence of pesticide residues in organic products do not necessarily convey towards the same approach. They **substantially differ on issues related to:**

- **Action level:** the level of pesticide residues that needs to be reached in order for any action to be considered.
- The actions that are taken, such as **investigations** with regard to presence of pesticide residues in organic products.
- **Critical level:** the level of pesticide residues that, when exceeded, prevents the products from being commercialised as organic.

In several of the different approaches examined, particularly in Europe, the **value of 0.01 mg/kg** is used for the interpretation of the results of samples taken on organic products – value generally known as the "**baby-food directive**" **limit**⁵⁶. However, this value is used differently as shown above.

Technical progress with laboratories allows currently the detection of substances in products at very low levels⁵⁷.

The absence of specific tolerance levels in the EU organic legislation and/or the lack of a harmonised approach concerning the presence of pesticide residues in organic products, together with the interpretation of the analysis results, may have the following **impacts:**

- uncertainty for producers and Control Bodies/Control Authorities;
- potential differences in treatment of producers according to the MS and to the CB involved;
- economic losses, in case products cannot be commercialised as organic.

Similar impacts can occur with respect to international trade of organic products. In addition, there are risks of delays in EU customs as products remain without clearance until the situation is clarified.

⁵⁶ Directive 2006/141/EC also encompasses the specific rules on the presence of pesticides residues in infant and follow-on formulae, previously set out in Commission Directive 1999/50/EC. It requires that baby food contains no detectable levels of pesticide residues, meaning not more than 0.01 milligrams of pesticide residues per kilogramme.

⁵⁷ Costs for sampling of organic products may vary from one laboratory to the other. In general, it is estimated that they can vary from EUR 75 for one simple analysis to EUR 150 or higher for multiple pesticides residues analysis.

3. CONSUMERS' EXPECTATIONS

The public consultation of January to April 2013 in the framework of the review of the EU policy on organic production comprised a series of closed questions on the issue of pesticides. The replies showed that:

- 80% of respondents buy organic products because they want to avoid food containing pesticide residues or residues of other synthetic substances;
- 61% of respondents agreed that testing all organic products for pesticide residues should be made compulsory, even if it would increase production costs and so make them dearer for consumers. However, a significant share was against (25%) or had no opinion (14%);
- 88% of respondents agreed that the level of pesticide residues for organic products be set at a lower level than for conventional products;
- The issue of presence of non-authorized substance residues is very sensitive for the public, as shown by the results of the public consultation:

In addition to the replies to the questionnaire, several free text contributions from respondents concluded along the same lines. Interesting reaction presented below from a group of respondents on the issue.

*"... If a food may be classified as organic or not (in case of pesticide content) has to be decided on a case by case basis by control authorities and control bodies. **These decisions require clear procedures and a clear legal framework that should be further developed.** ..."*

4. CONCLUSIONS

With a view to address the shortcomings that can occur as a result of the different approaches applying in the EU concerning the interpretation of the results on accidental presence of pesticide residues in organic products, different options can be envisaged. These options, combined with the establishment of a requirement for an investigation on the causes of the contamination (see below) aim to maintain a high level of consumer trust. They may however produce different results and impact differently on operators.

4.1. Investigation requirement

The precondition for the application of any of the options envisaged below is to clearly set a **requirement for an investigation concerning the causes for presence of pesticide residues in organic products**. Such investigations have always to take place in order to confirm that the presence of pesticides in the products is accidental or not, to guarantee the principles of organic farming and also to allow taking any appropriate measures to avoid accidental contamination of organic products in the future.

4.2. A critical level for the commercialisation of organic products

Option No 1 (improved status quo) and Option No 3 (principle driven) foresee the introduction of a **critical level for non-authorized substance residues**, beyond which products may not be commercialised as organic - regardless of whether the presence of such residues is proven to be

accidental or not. Such a level could, for instance, be based on the "**baby-food directive**" limit (see above).

These options offer operators with a clear legal framework concerning the commercialisation of their products in case of accidental presence of pesticide residues above a certain level. They acknowledge the possibility for accidental presence of pesticides / technically unavoidable in organic products resulting thus in less economic losses. Such options are considered compatible with the proposed risk based approach regarding controls and are not expected thus to create additional controls costs.

4.3. Product oriented approach

Option 2 (market-driven approach) suggests that organic production will shift from process to a product oriented approach. Such approach will imply intensification of samples on organic products. The method used for the analysis of the results of the samples taken could either consist on specific to the organic products threshold or using an approach based on the "baby-food" directive limit as described above. On the basis of the information gathered on the presence of pesticide residues in organic products, such approach may be considered disproportionate⁵⁸. In all cases, such approach would result in additional costs for the organic operators and finally higher prices for consumers.

⁵⁸ Other than EFSA (see above), see also "10 years of organic monitoring 2002-2011" Baden-Württemberg (http://www.mlr.baden-wuerttemberg.de/mlr/bro/10_Jahre_Oekomonitoring_engl.pdf).

Comparative tables – sampling results by production (TABLE I: EU+NCP – SURVEILLANCE SAMPLING: RESULTS BY PRODUCTION TYPE FOR ANIMAL PRODUCTS, BABY FOOD, CEREALS, FRUIT, VEGETABLES AND OTHER PLANT PRODUCTS IN EFSA 2010 REPORT)

Animal products

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Battery production	13	13	100	80.7	100	0	0	0	19.3	0	0	0	19.3
Domestic or cultivated	56	54	96.43	87.9	98.9	2	3.57	1.1	12.1	0	0	0	5.1
Free range production	69	68	98.55	92.3	99.7	1	1.45	0.3	7.7	0	0	0	4.2
Industrial production	214	194	90.65	86	93.9	20	9.35	6.1	14	0	0	0	1.4
Non-organic production	1287	1226	95.26	94	96.3	61	4.74	3.7	6	0	0	0	0.2
Organic production	229	180	78.6	72.8	83.4	48	21	16.2	26.7	1	0.44	0.1	2.4
Other organic method	1	1	100	22.4	100	0	0	0	77.6	0	0	0	77.6
Production method unknown	3335	2803	84.05	82.8	85.3	526	15.8	14.6	17	6	0.18	0.1	0.4
Traditional production	55	54	98.18	90.4	99.6	1	1.82	0.4	9.6	0	0	0	5.2
Wild or gathered	2	1	50	9.4	90.6	1	50	9.4	90.6	0	0	0	63.2
Total	5261	4594	87.3	86.4	88.2	660	12.5	11.7	13.5	7	0.1	0.1	0.3

(a): Lower confidence limit;

(b): Upper confidence limit

Baby food

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Industrial production	252	252	100	98.8	100	0	0	0	1.2	0	0	0	1.2
Non-organic production	365	327	89.59	86	92.3	36	9.86	7.2	13.4	2	0.55	0.2	2
Organic production	297	268	90.24	86.3	93.1	27	9.09	6.3	12.9	2	0.67	0.2	2.4
Other organic method	2	2	100	36.8	100	0	0	0	63.2	0	0	0	63.2
Production method unknown	878	791	90.09	87.9	91.9	55	6.26	4.8	8.1	32	3.64	2.6	5.1
Traditional production	34	34	100	91.8	100	0	0	0	8.2	0	0	0	8.2
Total	1828	1674	91.6	90.2	92.8	118	6.5	5.4	7.7	36	2.0	1.4	2.7

(a): Lower confidence limit;

(b): Upper confidence limit

Fruit, vegetables and other plant products

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Domestic or cultivated	3	3	100	47.3	100	0	0	0	52.7	0	0	0	52.7
Industrial production	80	75	93.8	86.2	97.2	4	5	2	12.2	1	1.3	0.3	6.7
Integrated Pest Management	377	176	46.7	41.7	51.7	193	51.2	46.2	56.2	8	2.1	1.1	4.1

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Non-organic production	24204	12723	52.6	51.9	53.2	10455	43.2	42.6	43.8	1026	4.2	4	4.5
Organic production	2482	2189	88.2	86.9	89.4	269	10.8	9.7	12.1	24	1	0.7	1.4
Other organic method	1	0	0	0	77.6	1	100	22.4	100	0	0	0	77.6
Outdoor / open-air growing condition	1613	825	51.2	48.7	53.6	732	45.4	43	47.8	56	3.5	2.7	4.5
Production method unknown	27922	12097	43.3	42.7	43.9	15068	54	53.4	54.5	757	2.7	2.5	2.9
Traditional production	1842	944	51.3	49	53.5	856	46.5	44.2	48.8	42	2.3	1.7	3.1
Under glass / protected growing condition	425	246	57.9	53.1	62.5	173	40.7	36.1	45.4	6	1.4	0.7	3
Wild or gathered	45	39	86.7	73.7	93.7	6	13.3	6.3	26.3	0	0	0	6.3
Total	58994	29317	49.7	49.3	50.1	27757	47.1	46.6	47.5	1920	3.3	3.1	3.4

(a): Lower confidence limit;

(b): Upper confidence limit

Cereals

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Industrial production	6	5	83.3	42.1	96.3	1	16.67	3.7	57.9	0	0	0	34.8
Integrated Pest Management	20	16	80	58.1	91.8	4	20	8.2	41.9	0	0	0	13.3

Production type	N° of samples	Samples with no measures residues				Samples with residues below or at the MRL				Samples with residues above the MRL			
		N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)	N°	%	LCL ^(a)	UCL ^(b)
Non-organic production	1654	1054	63.72	61.4	66	580	35.07	32.8	37.4	20	1.21	0.8	1.9
Organic production	554	509	91.88	89.3	93.9	43	7.76	5.8	10.3	2	0.36	0.1	1.3
Outdoor / open-air growing condition	88	64	72.73	62.6	80.9	23	26.14	18.1	36.2	1	1.14	0.3	6.1
Production method unknown	1501	935	62.29	59.8	64.7	535	35.64	33.3	38.1	31	2.07	1.5	2.9
Traditional production	367	273	74.39	69.7	78.6	87	23.71	19.6	28.3	7	1.91	0.9	3.9
Wild or gathered	10	7	70	39	89.1	3	30	10.9	61	0	0	0	23.8
Total	4200	2863	68.2	66.7	69.6	1276	30.4	29.0	31.8	61	1.5	1.1	1.9

(a): Lower confidence limit;

(b): Upper confidence limit

ANNEX 12: THE EU TRADE REGIME FOR ORGANIC PRODUCTS

The EU Trade regime is provided in Title VI of Council Regulation No 834/2007, which covers in fact import rules only.

1. IMPORT REGIME

Two basic import regimes are provided: imports of compliant products and imports of products providing equivalent guarantees. The 'equivalence regime' itself has been developed according to three different approaches. The different possible approaches to import organic products into the EU are summarised in the following table.

Table: The different approaches and options of the import regime

Approach	Option	Status
Equivalence with EU production rules and control system	Option 1: Import authorisations granted to importers by MS competent authorities, consignment by consignment.	Implementation started under Council Regulation (EEC) No 2092/91. Prolongation as transitional measures under Council Regulation No 834/2007. To be halted in July 2014.
	Option 2: Recognition of third countries having a national system complying with principles and production rules equivalent to EU rules and applying control measures with equivalent effectiveness to EU rules.	Implementation started under Council Regulation (EEC) No 2092/91, currently under Article 33 (2) of Regulation 834/2007.
	Option 3: Recognition of control bodies competent to carry out controls and issue certificates in third countries on products produced according to principles and production rules equivalent to EU rules and applying control measures with equivalent effectiveness to EU rules. In principle for imports from non-recognised countries.	Implementation under Article 33(3) of Regulation 834/2007.

Compliance with EU rules	Option 4: Recognition of control bodies competent to carry out controls on products produced according to the EU rules and principles, and to issue a documentary evidence. Accreditation according to EN 45011.	Implementation according to Article 32 of Regulation 834/2007, postponed until October 2014.
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Imported products may bear the EU organic logo.

2. EQUIVALENCE

Because the compliance regime is not yet applied, only organic products produced according to equivalent production rules and controlled according to equivalent control measures can currently be imported into the EU.

The term 'equivalent' is defined in Council Regulation 834/2007, "in describing different systems or measures, means that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity". A more general definition of equivalence is provided in Codex Alimentarius Guidelines⁵⁹.

2.1. Equivalence assessment and recognition

2.1.1. *Third Countries recognised for the purpose of equivalence*

The following box summarises **the process for recognition of a third country** as equivalent.

Summary of the EU process for recognition of a Third Country as equivalent

- The starting point is **an official request** from the Third Country.
- The Commission services check if the preconditions listed in the Commission regulation are met: "The request shall be completed by a **technical dossier**, which shall comprise all the information needed".
- Once the preconditions are met, the assessment of the request can start and two co-reporting MS are appointed to assist the Commission.
- A side-by-side comparison of production standards and control systems is built up; then the assessment of equivalency can start, which may lead to the identification of differences with EU rules, ranging from minor variances to significant differences.

⁵⁹ CAC/GL 20-1995

The assessment has to take into account the relevant *Codex Alimentarius* guidelines. **Additional information** is usually needed to clarify points where there are differences. This generates exchanges of mails/letters on technical questions. When the examination is complete, **a list of "critical differences"** can be built up.

- The Commission assisted by co-reporting MS decides on critical differences. In the case of a mutual recognition, a negotiation on acceptance of those differences usually takes place with the third country.
- Once the issues linked to critical differences are solved, the competent unit in DG AGRI may organise **a mission in** the Third Country for on-the-spot verification, the objective of which is to verify the effectiveness of the control system. The **mission report** has to be agreed by both sides.
- If it can be concluded that the Third Country's production standard is equivalent and that the control measures are of equivalent effectiveness to those in force in the EU, the Third Country is proposed for inclusion in the list annexed to the Commission Regulation. The entire internal Commission procedure is followed: inter-service consultation, vote in the relevant committee, where **a majority is necessary**, written procedure, translations and publication in the EU official journal.

The EU recognizes presently 11 countries as equivalent: Australia, New Zealand, Argentina, Costa Rica, India, Israel, Tunisia, Switzerland, United States, Canada and Japan. While in general these agreements are unilateral, in recent years the Commission has developed mutual equivalence arrangements with third countries, notably with the U.S., Canada, Switzerland and Japan.

Besides these countries, there are presently **16 applications from other countries:** China, Turkey, Serbia, Taiwan, Thailand, Peru, Chili, Bolivia, Colombia, Paraguay, Salvador, Honduras, Ecuador, Nicaragua, Mexico and the Dominican Republic. The assessment of equivalence with those countries is underway.

Some countries recognised as equivalent have applied to **extend the scope of their recognition**. For example, after the adoption of rules for the production of organic wine, Australia, New Zealand and Argentina have applied for the recognition of their own wine-making rules as equivalent to the EU ones. Japan, Canada and Israel have similar requests on processed products including imported ingredients. For each of these requests, the Commission has to follow the same process as for a third country recognition, which is technical, long and resource-consuming; delays generate **trade irritants with applicant countries**.

2.1.2. *CBs recognised for the purpose of equivalence*

The process to recognise CBs as equivalent is similar to the process to recognise a third country. However, a CB applying for equivalence recognition shall provide a technical dossier which includes **an assessment report demonstrating and confirming the equivalence of the production standards and control measures** applied by the CB to the EU production standard and control measures. The assessment report is defined in Regulation 1235/2008 as follows: "means the assessment report referred to in Articles 32(2) and 33(3) of regulation (EC) No 834/2007 drawn up by an **independent third party** fulfilling the requirements of ISO Standard 17011 or by a relevant competent authority, which includes information on document reviews, including the descriptions referred to in relevant Articles of Regulation 1235/2008, on office audits, including critical locations and on risk-oriented witness audits conducted in representative third countries." The EU recognition is granted to a CB for a 3-year period.

The Commission currently recognizes 60 CB's, operating in more than 130 countries. Imports from equivalent CB's are currently the main route for imports of organic products. There is anecdotic evidence of the decline of import authorisation by more than 90 % as the equivalence regime for CB's started to apply in 2012.

2.1.3. *Issues with the equivalence regime*

The recognition of third countries as providing equivalent guarantees offers the most stable and reliable approach to organic imports. It is applicable to countries with sufficient administrative capacities to manage a control system as efficient as the EU one. However, the initial assessment of equivalence is a complex process, which has in the past led to some delays in the treatment of applications by the Commission. In addition, the monitoring of equivalence (assessment of annual reports, follow up of irregularities, etc) is resource-consuming.

The decision on the acceptability of minor differences is the result of a global negotiation, which can in practice lead to **somewhat different rules applying** to producers in the EU and in a third country. In addition, equivalence needs to be re-assessed each time there is a substantial change in the EU legislation or in the third country standard.

The recognition of CBs as providing equivalent guarantees allows imports of organic products from non-recognised countries. The system has been implemented from July 2012 and has already shown some weaknesses:

- **burdensome equivalency assessment**, since each CB can be recognised according to its own standard, or other non-EU standard,
- **it has been reported that CBs compete on the possibility to decide on exceptional rules** (seeds, conversion period, non-organic ingredients), which creates **unfair competition** for EU producers for which exceptions shall be decided by MS competent authorities,

- it has been questioned whether **control measures implemented by CBs** to address the specific risks for organic integrity are appropriate and sufficient.

Regulation (EC) No 834/2007 makes no distinction between equivalent production standards and control measures applied by the competent administration of a third country or applied by a private CB seeking recognition. This ignores the fact that differences in the standard applied by control bodies can have an effect on the costs to operators under their control and consequently distort the competition among control bodies. Whilst MS and third countries have control systems in place that supervise the use of exceptions, the fact that recognised CB can themselves grant exceptions to the rules can lead to concede a commercial advantage to operators under their control.

The Commission is **required to assess all applications** received for recognition for the purpose of equivalence, whatever the economic interest for the EU and its operators. This is a major source of concern to the Commission services, in view of the technical complexity of some files, requiring significant internal resources.

Any import of organic product is subject to **submission of an original certificate of inspection**, issued either by a CB directly recognised by the Commission or under the supervision of a recognised Third country, for the release for free circulation into the EU. It can create delays because of the time needed for forwarding the original certificate, and is considered as an excessive administrative burden by the operators.

2.1.4. Compliance

Under the compliance regime, products imported from third countries have to comply with **the same production rules that are applicable in the EU**, i.e. with Regulation 834/2007 and its implementing legislation as well as with all other relevant EU legislation.

From the international angle, the two regimes – equivalence and compliance - appear as parallel mechanisms of ensuring respect for the WTO national treatment principle. The EU is the only major importer of organic products recognizing CB's for the purposes of equivalency. **All other large organic markets (US, Canada, Japan) require CB's to comply with the countries' production standard.**

Moving from a system of equivalence to a system of compliance for CB's would reduce discretion in deciding 'equivalence' with the EU standard, thus levelling the field between internal and external producers of organic products.

But for the implementation of compliance, a clear and stable organic standard is needed. In the EU, there are two decision taking levels: the Commission and MS, which makes difficult the direct application of the EU organic standard in third countries. The current legislation provides in particular with the possibility to grant exceptions to the organic rules in certain situations, notably according to Article 22 of Regulation 834/2007

(exceptional production rules). The exceptions are dealt with at MS level. **The removal of the MS decision level on production rules seems to be a pre-condition to the applicability of the compliance regime.**

In view of the practical difficulties, the application of the compliance regime has been postponed to October 2014, and it has been decided to apply the equivalence regime first.

The following table provides a comparison between the equivalence and the compliance regimes:

Pros and cons of equivalence and compliance for CBs under the current rules

Equivalence	Compliance
Production rules	
<p>Pros:</p> <ul style="list-style-type: none"> • Easier adaptation to local conditions. • Flexibility in definition of 'equivalence' <p>Cons:</p> <ul style="list-style-type: none"> • Conflicts of interest, since CBs can be inclined to adapt their production rules in order to keep their clients, • Production rules progressively watered down because of competition with other CBs. 	<p>Pros:</p> <ul style="list-style-type: none"> • Clear and transparent production rules, applicable to all 3rd countries • Increased consumer's confidence in imported organic products as they all will be produced in compliance with EU rules • Simplification <p>Cons:</p> <ul style="list-style-type: none"> • Need to provide rules for treatment of exceptions, which are granted by MS in the EU. • Group certification cannot be applied in third countries if not authorised in the EU.
Competition among producers	
<p>Cons:</p> <ul style="list-style-type: none"> • Non-equivalent production rules or control measures being applied, thus creating unfair competition between EU and 3rd countries producers. 	<p>Pros:</p> <ul style="list-style-type: none"> • Level playing field in the EU and outside.

Procedure for recognition	
<p>Cons:</p> <ul style="list-style-type: none"> • Costly and burdensome application which includes assessment that the standard owned by the CB is equivalent to the EU production rules and control system, provided by an assessment body. • Recognition is limited to certain third countries and for categories of products. CBs have to apply for a scope extension every time they start working on new categories of products or new countries. 	<p>Pros:</p> <ul style="list-style-type: none"> • Application focussing on accreditation and on CBs control and certification procedures, less costly and burdensome. • Recognition without geographical limits and for all products covered by the scope of the EU legislation.
Controls	
<p>Cons:</p> <ul style="list-style-type: none"> • Complex because any non-compliance has to be assessed against each own CB standard. 	<p>Pros:</p> <ul style="list-style-type: none"> • Simpler - possible to standardize treatment of non-compliances • Risk lowered

Annex 12

The workload associated with both regimes has also to be taken into account. It is illustrated by the following table:

Workload for the implementation of equivalence and compliance for CBs

Equivalence	Compliance
Application by CB	
<p>Technical dossier includes a report from the accreditation body that the CB meets the conditions to control products against its own standard and control system, as well as an assessment that the standard owned by the CB is equivalent to the EU production rules.</p>	<p>Technical dossier includes a report from the accreditation body that the CB meets the conditions to control products against the EU production rules and control system.</p>
Examination of applications by the Commission	
<p>Complex and burdensome procedure for the Commission to assess applications, notably to check the equivalence of the CB production rules and control system with the EU ones. The experience has shown that this procedure is potentially source of mistakes and subsequently to unfair competition</p>	<p>Less burdensome procedure</p>
Recognition	
<p>Publication of a complex list of CBs with categories of products for which the CB standard has been recognised as equivalent and countries where the standard is applied, potentially source of errors – proved by experience.</p>	<p>Recognition by publication of a list of CBs without product categories and countries where the standard is applied.</p>

Supervision	
Obligation for CB to notify any change to its production rules or control procedures. Annual report complex because the equivalence assessment has to be updated according to changes in the EU legislation or to the CB production rules and control system. Complex audits.	Obligation for CB to notify any change to its control procedures. Annual report and audits less complex.

3. SUPERVISION

The Commission assisted by co-reporting MS **supervises the recognised third countries and CBs**, based on:

- **annual reports**, including assessment reports resulting from the accreditation body's surveillance of the CB.
- **assessing notified irregularities** and on their follow-up by the third country or by CB. Most of the notified irregularities are notified by MS, which remain responsible for the control of imported products on the market; in most cases, it is about findings of non-allowed substance residues in organic products.
- **on-the-spot examinations** the Commission may undertake or ask experts to undertake.

The **supervision of both recognised countries and CBs does not provide proportionate sanctions**. The EU can only decide to withdraw a CB or a country from the list. The implications and risks of such process were not fully envisaged when adopting Regulation (EC) No 834/2007.

In addition, surveillance of recognised CBs is carried out by accreditation bodies. CB's operating within the EU shall be accredited. Therefore, they are subject to the provisions of Council Regulation No 765/2008⁶⁰. It is considered that the accreditation of CBs operating in third countries by an accreditation body signatory of an agreement implemented by the International Accreditation Forum (IAF) is equivalent. Accreditation body

⁶⁰ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance) - OJ L 218, 13.8.2008, p. 30.

members must declare their common intention to join the IAF Multilateral Recognition Agreement (MLA) recognising the equivalence of other members' accreditations to their own.

However, in the context of the application of equivalence to CB's operating in 3rd countries, **the EU accepted accreditation could be made by an international supervisory or accreditation body that is specialised in organic agriculture**. This allowed IOAS (International Organic Accreditation Service, created by IFOAM and not a member of IAF) to be able to accredit control bodies for equivalence. Actually, 28 CB's (almost half of the total recognized CB's) are accredited by this organisation. Besides the issue of principle that it raises (e.g. accepting recognition of private companies' standards as equivalent to the EU's organic farming regulations), such delegation of powers is particularly challenging, as it charges private companies operating in the global market to manage the equivalency.

The Commission needs to ensure equal treatment between organic producers in the EU and in third countries. The accreditation of CB's recognised for the purpose of equivalence in third countries based on the EU framework for accreditation would create a level playing field in the organic trade.

4. POSSIBLE IMPACTS OF A MOVE TO COMPLIANCE ON DEVELOPING COUNTRIES

In this part the possible impacts of the implementation of the compliant regime, in particular for developing countries, are analysed.

4.1. Analysis of the standard

A sample of CBs already recognised as equivalent by the EU for their activities in third countries has been chosen in order to assess the possible impact of a move from equivalence to compliance.

The system on recognised control bodies permits imports from 113 developing countries, including 37 least developed countries (LCDs).

The sample was selected with a view to cover different situations in terms of CBs' size or location of the headquarter and on the basis of significant differences noted in the inventories of differences established by the accreditation or assessment bodies when assessing the equivalence of the organic production rules and control measures. It cannot therefore be considered as exhaustive but focuses on relevant cases. The sample includes:

- One CB headquartered in the EU;
- One CB headquartered in the US;
- One CB headquartered in Latin America;
- One CB headquartered in India;
- One CB headquartered in Africa.

The analysis of the differences shows that:

- Most provisions included in standards applied by CBs are identical to EU provisions.
- Cases where the provisions are different are mostly related to provisions of the EU Regulation on which MS have to decide.

The following table displays examples of provisions considered as equivalent to those of the EU Regulation:

Table 1: "equivalent" provisions applied by CBs in third countries where the EU Regulations provide for MS decision

Reference in the EU legislation	Description of provision applied by CBs and comparison with EU	Location of the CBs concerned
R889, Art 36	Derogations granted by CBs in order to shorten the conversion period , on the basis of documentary evidence. In the EU, only MS competent authorities can decide on retroactive recognition of the conversion period, in strictly limited cases (application of agri-environmental measures on the basis of an EU scheme).	EU, Latin America, Africa
R834, Art 19.2.c	Derogation granted by CB for the use of non-organic agricultural ingredients in organic processed products. In the EU, a list has been adopted at EU level (annex IX to Regulation 889/2008). In addition, MS can allow the use of other non-organic agricultural ingredients on a temporary basis.	Africa
R889, Art 47	Derogation granted by CB in case of catastrophic circumstances (force majeure) . In the EU, only MS can decide.	Africa
R889, Art 39	Derogation granted by CB for the tethering of animals in small holdings . In the EU, only MS can decide.	Africa
R889, Art 45	Derogation to use non-organic seeds granted by CB. , Because of the absence of seeds database, the decision is usually taken on the basis of declarations of three local seeds suppliers showing that no organic seeds are available. In the EU, there is an obligation for MS to manage a computerized database to show the availability of organic seeds.	EU, Latin America, Africa India
R834, Art 28.1.a	No notification of activity to the competent authority but to the CB. In the EU: notification to MS competent authority.	Africa
R834, Art 14.1.b.iii or R889, Art 14.7	Reference is made to national legislation instead of EU legislation	Africa

CBs in third countries take the opportunity of the equivalence regime to decide on many aspects that are dealt with by MS competent authorities in the EU. It is particularly noticeable for the Africa based CB.

In other words, although in the EU the decision to grant derogations is made by public authorities, under the equivalence regime it is often the CB – a private company – that takes this decision. Yet, in some instances the derogation granted can have a decisive economic impact for the operator concerned, who is the customer of the private CB. This situation can lead CBs to compete on the possibility to decide on exceptional rules and derogations.

The following table shows that in similar cases, **some CBs apply strict provisions with no flexibility** instead of taking the role of an EU MS:

Table 2: Stricter "equivalent" provisions applied by CBs in third countries where the EU Regulations provide for MS decision

Ref.	Description	Location of the CBs concerned
R834, Art 19.2.c	The use of non-organic agricultural ingredients in organic processed products is strictly limited to the list of annex IX to Regulation 889/2008 (the one adopted at EU level). In the EU, MS can allow the use of other non-organic agricultural ingredients on a temporary basis.	EU, US
R889, Art 39	Tethering of animals in small holdings is not allowed. In the EU, MS can grant derogations.	US, Latin America
R889, Art 27.4	There is no possible exception to use non-allowed substances for the traditional decorative coloring of boiled eggs, like there is in the EU.	US
R889, Art 40	No parallel conventional production allowed on organic holdings. In the EU, there are some possibilities according to Article 11 and to Article 22 of Council Regulation 834/2007.	Latin America

These examples show that on certain issues compliance with more stringent EU rules is possible.

The following table displays other examples of "equivalent" provisions applied by CBs in third countries which would not be possible with the current provisions of EU regulation under a compliance regime:

Table 3: Other "equivalent" provisions currently applied by CBs in third countries which would not be possible under a compliance regime

Ref.	Description	Location of the CBs concerned
R834, Art 27-28	Group certification	Africa, Latin America, India, EU
R889, Annex II.6	Calcium carbide is allowed for flower induction of pineapple (ethylene is allowed by Annex II)	India

R834, Art 12.1.d	CBs may authorize the use of products for purposes different than those mentioned in the annexes	Africa
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Group certification is currently not allowed in the EU. Group certification is by contrast developed in India, in African countries and in Latin America. The move to a compliance regime without introduction of group certification in the EU standard would have a significant impact. According to AGRO-ECO Louis Bolk Institute (AGOF meeting, 11 April 2013), **the majority of products imported from developing countries, all categories, are produced under the group certification scheme.** The analysis of trade flows of a short list of developing countries from Latin America, Asia and Africa (see below) shows indeed that group certification is used by a slight majority of the control bodies assessed. If compliance should be applied under the current European legislation, the organic products concerned would therefore need to apply individual control rules to be accepted in the EU. Nevertheless, the implementation of an individual certification could entail disproportionate administrative burden and cost for organic producers in some of those developing countries.

The two other provisions mentioned are about the authorization of substances in organic farming. Calcium carbide is not allowed in the EU, but it is accepted in the Indian CB's standard, with the argument that it is cheaper than substances accepted in the EU, and despite the risks associated with its use. The Africa based CB's standard allows the CB to authorize the use of the substances authorized by the EU organic standard, such as plant protection products, but for different purposes, although they have not been evaluated for these different uses.

These elements indicate that under the currently applied equivalence regime, some provisions of the EU standard are somehow abused; the CBs concerned can take advantage of the flexibility associated with the recognition for the purpose of equivalence, which can potentially lead to unfair competition.

4.2. Analysis of the trade flows

With a view to assess any possible impact on the trade flows imported into the EU from developing third countries, we have collected data from the annual reports received by 31 March 2013 from the control bodies recognized for the purpose of equivalence by the EU.

The ACP country coverage for this analysis includes:

Botswana	Fiji	Madagascar	Senegal
Burundi	Ghana	Mauritius	South Africa
Cameroon	Guyana	Mozambique	Swaziland

Côte d'Ivoire	Jamaica	Nigeria	Tanzania
Dominican Republic	Kenya	Papua New Guinea	Uganda
Ethiopia	Lesotho	Rwanda	Zimbabwe

The list is composed based on the quantities imported from the selected ACP countries and on the activity of CBs in the region.

These 24 countries are covered by the equivalent CBs system: 21 CBs are active in these countries, with 3 of them being active in 10 countries or more.

The data gathered from the CBs' annual reports (annual report were available for 17 CBs; 4 CBs were recognised as equivalent in 2013) shows that a total of 234.224 tons of organic products were imported into the EU from the 24 third countries concerned, during the period ranging from 1 July to 31 December 2012 (the equivalent CBs system was applied as from 1 July 2012). The following table identifies the products corresponding to the highest quantities imported.

Table 4: Main organic products imported from a limited list of developing countries into the EU from 1 July to 31 December 2012

Products (or group of products)	Quantity (tons)
Bananas	145865
Coffee	38352
Citrus fruit	21619
Cocoa	15869
Grapes	2414
Dates, figs, pineapples, avocados, guavas, mangoes...	2128
Fruit juices	1716
Fruit and nuts	714
Tea	657
Vanilla	623
Plants used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes	618
Other fruit, fresh	516
Coconuts, Brazil nuts and cashew nuts	511
Ginger, saffron, curcuma, thyme, curry and other spices	368
Natural honey	167

The imported products are mostly plant products. The only animal product imported in substantial quantities is honey (167 tons). Livestock products as such hardly appear in the list.

Group certification was investigated too. Data shows that out of the 17 equivalent control bodies concerned, 10 of them apply group certification for a total of 129 producers groups. This data shows the significance of the practice of group certification in developing countries.

It was also noted that 2 exceptions allowed by the current EU production rules are commonly applied by the equivalent control bodies: the retroactive recognition of the conversion period and the use of non-organic seeds. The move to compliance, if accompanied by a suppression of these

exceptions, would result in more stringent rules for organic producers in developing countries, as they would be for EU organic producers. More stringent organic rules would entail costs, but also maintain EU consumers' confidence in organic products, which will be to the benefit of both EU and developing countries' producers.

5. EXPORTS

Export of organic products is not addressed in Council Regulation (EC) No 834/2007. The provisions for the recognition of third countries are unilateral. In recent cases, the Commission has been following a reciprocal approach. In most cases such mutual recognition has been achieved through parallel administrative arrangements and only in the case of Switzerland through a bilateral agreement. In 2012, the Commission signed a mutual equivalence arrangement with the US.

The possibility offered to recognise third countries for the purpose of equivalence provides an alternative to bilateral agreements. Negotiations can be entered into when the technical dossier is considered satisfactory and at short notice as they do not require a mandate. They are conducted only on organics and thus avoid being slowed down by blockages on other trade issues. Importantly however, there is no assurance to obtain a quid pro quo in parallel administrative arrangements unlike negotiations for a bilateral agreement.

Issues on exports

The absence of a **specific export policy** for organic products hampers the future potential growth of the EU market. An export policy would be important to allow EU organic producers to benefit from fast growth of the World market for organic products. **Developing mutual recognition agreements is necessary** to focus discussion on equivalence with 3rd countries in the areas of key economic and political interest to the EU, allowing better value for the sector in full respect of the EU international obligations.

The development of a specific export policy is in line with the support from citizens and stakeholders to request more market access for EU organic products from third countries.

6. CONCLUSIONS

The shortcomings of the trade regime for organic products are addressed differently under the 3 policy options.

Option 1 includes the following improvements:

- implementation of electronic certification
- harmonisation of accreditation rules for control bodies active in third countries with the rules for control bodies operating in the internal market.

Option 2 proposes the re-introduction of import authorisations.

Under option 3 the following actions are developed:

- Specific export policy, with a general mandate from the Council in order to negotiate organic equivalency agreements with third countries and the development of specific provisions on export in the basic Regulation on organic farming, in particular the introduction of an export certificate for the certification of organic products intended for export.
- Balanced approach towards equivalence with third countries – Equivalence with third countries negotiated on the basis of mutual and reciprocal agreements. Multilateral agreements for countries having very similar systems to the ones existing in the EU will be possible.
- Imports from non-recognised third countries based on control bodies applying a regime of compliance.

There are concerns that the compliance regime, with more stringent production rules, would become an obstacle for organic producers in developing countries willing to export to the EU. But this analysis shows that compliance with more stringent EU production rules is possible. However, the issue of group certification which is widely applied in developing countries is raised. The application of option 3 without its sub-option on group certification would request the growers to be individually certified and in some developing countries it would entail disproportionate burden and costs.

Option 3 would be beneficial, because:

- It would remove any possibility for CBs to compete on the granting of exceptions to the rules, with the associated risk of dilution of organic production rules;
- It would prevent abuses leading to unfair competition for EU and third country producers.

ANNEX 13: ENVIRONMENTAL IMPACTS OF ORGANIC FARMING

This Annex summarises current data and research results on the environmental impacts of organic farming. It also takes into account preliminary results of the external evaluation on the EU organic farming policy available in September 2013.

Firstly the possible direct and indirect impacts of the provisions of the EU organic standard on environment have been analysed. They are summarised in a table in paragraph 2.6.4 of the report and are described here with more details. Secondly a literature review has been conducted. It has to be noted that in some areas, notably on the impacts on greenhouse gas emissions, water and energy savings, data is partial and it is difficult to draw conclusions.

This Annex also includes a presentation of the issue of environmental performance management when producing organic agricultural products.

1. IMPACTS OF ORGANIC FARMING ON THE ENVIRONMENT

The environmental impact of organic farming has not been extensively studied hitherto. Existing scientific studies are somewhat divided on the impacts related to greenhouse gas emissions, land use and energy use. More research is needed in this field. Nevertheless, as shown hereafter, there is clear evidence that organic farming, when compared to conventional agriculture, has positive effects on biodiversity, soil and water.

The EU rules on organic farming and their possible (direct and indirect) positive impact areas are summarised in the following table:

Rules (EU Organic Regulations Article numbers refer to Council Regulation (EC) 834/2007 [A] and Commission Regulation (EC) 889/2008 [B]	Respect natures systems/ cycles	Contribute to bio- diversity	Make responsible use of natural resources			
			Energy	Water	Soil	Air & climate
Prohibitions [A: 4 (a) iii and (c)]						
No mineral nitrogen fertilisers [A: 12.1 (e)]	√	√	√	√	√	√
No herbicides, only authorised products can be used [A: 12 (h), B: Annex II]	√	√	√	√	√	√
No landless livestock production [B: 16]	√		√			√
No hydroponic production [B: 4]	√			√	√	
No use of GMOs [A: 9]	√					
Strict control of external inputs [A: 4 (b)], minimisation of the use of non-renewable resources [A: 5 (b)] and recycling of wastes and by-products [A: 5 (c)]						
Only permitted fertilisers : low-soluble mineral fertiliser [A: 4 (b) iii] and soil conditioners when need proven [B: 3, Annex I]	√	√			√	
Only authorised plant protection products when established threat [A: 12.1 (h), B: Annex II]	√	√			√	√
Feed primarily from holding or same region (with exceptions) [A: 14.1 (d)]	√		√			
Stocking density and use of livestock manure restricted to maximum of 170 kg N/ha and year [B: 3 & 15.1]	√	√	√	√	√	√
Obligations to use good husbandry practises and prevention [A: 4 (a) iv and 5]						
Multiannual crop rotation including legumes and other green manures [A: 12.1 (b)]	√	√	√	√	√	
Tillage and cultivation practices that maintains organic matter, and protects soil [A: 12.1 (a)]	√	√	√	√	√	
Maintain crop health through prevention (natural enemies, the choice of species and varieties, crop rotation) cultivation techniques and thermal processes [A: 12.1 (g)]	√	√	√		√	
Number of livestock limited to minimise overgrazing, poaching, soil erosion or pollution [A: 14.1 (b) iv]	√	√		√	√	√
Preference for inputs from organic origin (Art 4b with exceptions (Art 4d))						
Manage entire holding organically (with exceptions) [A: 11]	√	√	√	√	√	√
Only organic seed (with exceptions) [A: 12.1]	√					
Only organic feed (with 5 % exceptional rule for monogastrics) [A: 14 (d) ii]	√					

1.1. Biodiversity

According to the preliminary results of the evaluation of EU legislation on organic farming, some practices favourable to biodiversity are directly prescribed by the EU regulation (e.g. ban of synthetic mineral fertilisers, use of organic fertilisation, multiannual crop rotations including the use of legumes and cover crops, lower stocking rates, no use of herbicides and chemical pesticides). Others are indirect results of the above prescriptions (such as more likely use of spring sown crops because the ban on herbicides may lead to a higher prevalence of weeds) or reflect common practices of organic farmers, such as higher presence of landscape features like hedges, trees or grass strip corridors, shallow tillage, or use of local/endangered breeds and varieties. The scientific literature underlines positive impacts derived from general organic production practices in increasing significantly abundance of plants, birds and predatory insects, particularly in simple landscapes, such as regions with a high prevalence of arable production. The studies do not necessarily make a clear distinction between direct and indirect impacts.

1.2. Energy

The strict limitation of the use of chemically synthesised inputs or the incentive to use forage rather than concentrated feed for livestock have an indirect impact on the sustainable use of energy. Scientific literature found, for most organic crops, the energy use to be lower, both per unit area and per unit yield, than in conventional production (with some exceptions like potatoes or tomatoes, where disease pressure in organic farming is high and organic yields relatively low).

1.3. Greenhouse gas emissions (GHG)

Greenhouse gas emissions are generally lower per hectare in organic than conventional farming⁶¹. In particular, organic farms avoid the N₂O emissions associated with the manufacture and use of mineral nitrogen fertiliser, since the main sources of nitrogen are biological nitrogen fixation and organic nitrogen, more slowly released. The incorporation of fertility building grass-clover leys and the use of livestock manures within diverse crop rotations also contribute to enhanced carbon sequestration. However, related to the quantities produced, GHG emissions remain equivalent or, sometimes higher for organic production.

⁶¹ “Les enjeux de la production d’agriculture biologique en France”

<http://www.agreste.agriculture.gouv.fr/IMG/pdf/analyse501207.pdf>, Biblio AB_enviro_RMT_DevAB

1.4. Air quality and water management

Regarding air and water protection, positive impacts arise from the prohibition of most synthetic pesticides and fertilisers as well as from limits on stocking rates and organic fertilisers use. Scientific literature demonstrates that organic farming contributes to preventing nitrogen leaching and eutrophication. Regarding water use, the organic farming Regulation does not provide any direct requirements, but organic production uses potentially less water because of individual choices and cultivation practices⁶².

Quantitative and qualitative management of water is little addressed in the organic production rules, except for plant production rules which contain a reference to the Nitrates Directive and for aquaculture rules.

⁶² Stanhill (1990) and Lotter (2003) found that organic crops show higher ability to cope with drought than conventional ones, mainly due to better soil properties. More recently, a French study comparing 151 organic holdings to 281 conventional ones (Caplat, 2006) revealed that only 8 % of the organic areas were irrigated, whereas it reached 33% in conventional holdings.

1.5. Soil

The organic legislation contributes directly to soil health and quality through the obligations to use organic fertilisers and manure and to practise a crop rotation, even if the diversity of the rotation is not further specified. Individual management decisions at farm level influence the impact of the rotation and of the use of machines (e.g. cultivation for weed control) on soil structure. The positive impact of organic farming on soil is significant and abundantly documented in scientific literature⁶³.

However, the fact that organic farming relies on the use of copper fungicides as one of the main phytosanitary treatments is potentially negative for the environment, because copper can accumulate in soils. This issue is particularly relevant for certain crops (grapevine, apple, potato) where multiple applications of copper fungicides is common. To address this concern, the organic farming legislation has limited the amount of copper that can be applied as fungicide to 8 kg/ha/year in 2002 and reduced it further to 6 kg/ha/year from 2006 onwards⁶⁴. There have also been EU research projects⁶⁵ that have looked for possible solutions to replace copper fungicides (e.g. REPCO, Blight-MOP). A solution can be found in the combination of resistant varieties, preventive management methods and alternative treatments. However, the fact that the issue remains a concern for civil society was underlined during an ISSG meeting. Further improvements and solutions should continue to be looked for.

1.6. Land use

There is an ongoing debate on whether extensive production systems are better for the environment than intensive production systems. Because intensive production systems use less land to produce the same amount of agricultural products, they would allow to preserve natural areas intended to protect nature and biodiversity and would therefore be more environmentally friendly⁶⁶. To be able to conclude on which system is better for the environment, a scientific study taking into account all the impacts of both systems would be needed, but it is not possible to conclude with the current scientific knowledge.

⁶³ Interim report (May 2013) for Evaluation of the EU legislation on organic farming.

⁶⁴ Commission Regulation (EC) No 473/2002. OJ L 75, 16.3.2002, p. 21

⁶⁵ European Commission, Directorate-General for Research and Innovation - A decade of EU-funded, low-input and organic agriculture research (2000-2011).

⁶⁶ Mondelaers, K; et al, 2009, A meta-analysis of the differences in environmental impacts between organic and conventional farming, *British Food Journal* 111 (10): 1098-1119.

It is important to note that EU organic agriculture is more extensive than conventional agriculture, but it is still far more intensive than many conventional agricultural systems in the world. It is because agriculture is in general very intensive in the EU. In most regions of the world, organic production performs equally or even better than conventional agriculture in terms of yields, thanks to practices like crop rotation or intercropping.

In any case, the potential for converting to organic farming in the most intensive growing areas of the EU is not seen as very significant. However, a study from the JRC⁶⁷ (Joint Research Centre) highlighted that the production of organic products, as well as other quality labelled products, may be a key element to prevent land abandonment and to maintain traditional landscapes.

Food security, which remains a key objective of the CAP, is regularly raised as an argument against the development of organic farming. In fact, lower yields are observed on organic crops such as cereals or oilseeds compared with conventional agriculture in Europe. However, there is potential to increase yields in organic farming systems⁶⁸, while high yields in conventional systems in the EU rely on mineral nitrogen, phosphates and potassium fertiliser inputs.

2. ENVIRONMENTAL PERFORMANCE

2.1. Ecolabel for food and drink products

Some years ago, it was envisaged that the concerns regarding the need to consider the whole lifecycle of food and feed products could be addressed by applying the EU Ecolabel to food and feed products, including organic ones. In this respect, the recently revised Ecolabel Regulation (66/2010)⁶⁹ required the Commission to carry out a study on the feasibility of developing Ecolabel criteria for food and feed products, with a special attention to organic products. This study⁷⁰, completed in October 2011, underlined in particular the confusion that could result for the consumer about the meaning of the Ecolabel and the organic logo. As an alternative to placing the Ecolabel on organic products, it was suggested "to amend the Organic certification [...] to cover the full life cycle of food products, including the processing and packaging and [it was called] on the European Commission to give due consideration to this option, to improve the performance of the existing Organic Regulation."

Along this line, a request has been formulated by IFOAM EU to have operators downstream of primary production, i.e processors and traders, manage their environmental performance via an EMS (e.g. ISO 14001 or EMAS). Citizens expressed a similar opinion during the on-line public

⁶⁷ Assessing the risk of farm abandonment in the EU - European Commission, JRC Scientific and Policy Reports – 2013.

⁶⁸ Nafferton Ecological Farming Group (NEFG) (Newcastle University) September hearing

⁶⁹ Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27 of 30.1.2010, p.1

⁷⁰ http://ec.europa.eu/environment/ecolabel/documents/Ecolabel_for_food_final_report.pdf

consultation on the review of the EU policy on organic agriculture⁷¹. Indeed, a large number of respondents, namely 24458 (61%), requested that producers and traders should be required to implement an EMS to improve their environmental performance in addition to other European requirements. Such a move would respond to the above-mentioned recommendation from the EUEB that the organic farming legislation should cover a wider part of the life cycle of food products. This would in turn reduce the need to establish an Ecolabel for food and drink products.

These expectations have been looked into (see section 2.1 below) and taken up as a sub-option in the present impact analysis.

2.1. EMS

An EMS is a tool that provides organisations with a method to systematically manage and improve the environmental aspects of their production processes. It helps organisations to achieve their environmental obligations and performance goals. In addition to EMAS and EN ISO 14001, non-formal EMS exist in the EU. Many of them have been adopted by both private and public organisations. These EMS are mostly designed to cover organisations with a specific size (e.g. SMEs) and organisations coming from specific areas or specific sectors of activities.

With regard to the extent of the use of EMS, some data could be found only for EMAS via the EMAS helpdesk⁷². This data indicates that EMAS is not much used in the food processing and trade sectors, and that EMAS registration in these sectors is most popular in Germany, followed by Italy and Spain. In the other MS the number of registrations is low (see following two tables).

Table 1: Number of EMAS registered companies per relevant sector and category

	Food processing	Wholesale agri-business	Retail agri-business	Total
Micro enterprises	17	1	1	818
Small enterprises	39	5	1	1181
Medium enterprises	37	3	1	1044
Large enterprises	47	2	0	703

⁷¹ http://ec.europa.eu/agriculture/organic/files/eu-policy/of_public_consultation_final_report_en.pdf (page 70)

⁷² Data requested in July and September 2013.

Total	140	11	3	3746
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Table 2: Number of EMAS registered companies per relevant sector and Member State

	Food processing	Wholesale agri-business	Retail agri-business	Total
DE	77	8	2	771
IT	23	1		1081
ES	16	1		1126
AT	3	1		257
DK	1			59
BE	1			48
CY	8		1	51
GR	1			41
CZ	5			26
SE	3			22
HU	1			23
PL	1			41
PT				59
UK				52

Given the low numbers of registered companies in the agri-food processing and trade sectors and the fact that the EMAS scheme has been in place for nearly 20 years, it does not seem that these sectors choose to improve their environmental performance on a voluntary basis via EMAS. Such sectors may prefer other EMS (ISO 14001 or simplified EMS). However, no data was found to confirm or refute whether such a choice was made.

Should an additional requirement for applying an environmental management scheme be imposed on organic processors and traders, this is likely to involve for those operators additional administrative burden and costs. It is difficult to assess whether this would, in turn, have an impact on

consumers' behaviour. Nevertheless the online public consultation has shown that the respondents are prepared to pay more for organic products. 16,06% of respondents are prepared to pay up to 10% more, 39,71% between 10 and 25% more and 10,65% between 25 and 50% more. Also 79,21% of respondents buy organic products because they are concerned about the environment.

A study was carried out in 2009 to analyse the costs and benefits to organisations of EMAS registration as well as the incentives and barriers for potential new registrants⁷³.

The results indicate that for all sizes of organisation the **costs** in the first year are between 1.5 and 2 times higher than annual costs over subsequent years (see table 3 below). The costs faced by organisations increase relative to the size of the organisation, but micro and small organisations faced higher fixed and external costs than medium and large organisations. This suggests that, the costs faced by micro and small organisations in the first year act as a significant barrier to registration.

In contrast, medium and large organisations seem to benefit from economies of scale, with a higher proportion of costs borne internally by environmental departments and lower external costs associated with the use of consultants.

In order to address this issue, EMAS in its latest revision offers derogations for small organisations (Article 7 of Regulation (EC) No 1221/2009⁷⁴), i.e. verification of full EMS and audit program validated in a four-yearly frequency (instead of a three-yearly frequency); validated updated environmental statement every two years (instead of every year).

In addition, in order to facilitate the process towards EMAS-registration and maintenance of EMAS registration for small and medium sized organisations (SMEs), EMAS Easy, a lean and standardized methodology has been developed with small and micro businesses in mind⁷⁵. Implementing EMAS via the EMAS Easy methodology is one way for SMEs to reduce their first year and annual implementation costs. Data originating from the study on the Costs and Benefits of EMAS to Registered Organisations were combined with recent estimates based on data provided by SMEs during evaluations performed at EMAS capacity building seminars for SMEs, and during various EMAS Easy coaching in different MS. This resulted in the indicative numbers on cost reductions that are included in Table 4 below.

⁷³ Study on the costs and benefits of EMAS to registered organisations (2009). Milieu Ltd and Risk and Policy Analysis Ltd for DG Environment of the European Commission.

http://ec.europa.eu/environment/emas/pdf/news/costs_and_benefits_of_emas.pdf

⁷⁴ Regulation (EC) n° 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC, O.J. L 342, 22.12.2009, p.1

⁷⁵ http://ec.europa.eu/environment/emas/tools/emaseasy_en.htm

On top of the figures on potential annual efficiency savings, the EMAS 'Toolkit for small organisations' provides many other examples of benefits/costs savings.

The data in the 2009 study on the costs and benefits of EMAS further indicate that the costs of registration are highest in Northern Europe and lowest in the new MS; but this largely reflects general cost differences between the countries. Ongoing annual costs are again highest in Northern Europe and lowest in Southern Europe, due to the lower average cost of internal staff.

Increased efficiency and energy savings were identified as main **benefits** for registered organisations (see tables 5 and 6 below for indicators). In terms of quantified benefits, the results show clear evidence of substantial financial savings following EMAS adoption from increased energy and resource efficiency. However, this comes with the caveat that additional efficiency improvements are unlikely to be achievable year on year, meaning that the cost saving may tail over the long term once all possible measures have been implemented.

The second most widely acknowledged benefit of EMAS was a reduction in negative incidents. Regarding market access, it appears that EMAS registration may be more important for retaining existing customers than for winning new business. Survey respondents also indicated that EMAS has improved relationships with regulators more than with any other stakeholder group. Finally, while many organisations also had expectations of regulatory relief from EMAS registration, the evidence of organisations actually benefiting from regulatory relief was limited.

In addition, the results of this study indicate that financial support provides the greatest stimulus for organisations to register, much more than guidance documents and technical support, helpful as they may be.

For SMEs in the supply chain, EMAS registration of client companies can have a direct impact. A growing number of small companies will need to demonstrate (or have already demonstrated) a recognized track record of systematic environmental management. In fact, often supplier companies are required to have EMAS registration in order to gain market access. For instance, in industry sectors close to the customer, suppliers note that their customers request EMAS registration⁷⁶. The public consultation has shown that this is important for the citizens and consumers in the EU.

With the introduction of the requirement for certain organic operators to set up an EMS, the most impacted MS will be the ones with the highest production of organic processed products: Germany, France and Italy. It will entail increased efficiency and energy savings, which are likely to more than compensate the additional costs, as shown by the results of the above mentioned 2009 study on the costs and benefits of EMAS. As shown in the following tables, potential annual efficiency savings for small enterprises amount to 20.000 to 40.000 Euro, with the annual cost to run the system at 22.000 Euro. For medium enterprises, the savings exceed 100.000 Euro, while the annual cost is 17.000 Euro. However, the

⁷⁶ http://ec.europa.eu/environment/emas/tools/faq_en.htm#Section4Question0 (question 3)

implementation cost the first year is higher than the savings. For micro-enterprises, the savings do not compensate for the additional costs. Therefore, the obligation to run an EMS would have an economic impact on micro-enterprises.

Table 3: EMAS Estimated Actual Costs by Organisation Characteristics

Organisation Characteristic		First Year Costs				Annual Costs			
Size	Region/Sector/Ownership	External Costs	Internal Costs	Fixed Costs	Total Costs	External Costs	Internal Costs	Fixed Costs	Total Costs
SME	Southern Europe	€ 3,507	€ 11,483	€ 19,439	€ 34,428	€ 1,857	€ 8,110	€ 8,110	€ 17,676
	Northern Europe	€ 10,409	€ 19,866	€ 9,592	€ 39,867	€ 2,317	€ 9,570	€ 9,570	€ 16,907
	New Member States	€ 5,502	€ 20,725	€ 2,475	€ 28,702	€ 1,575	€ 23,950	€ 23,950	€ 26,825
Large	Southern Europe	€ 6,297	€ 23,673	€ 27,879	€ 57,849	€ 3,272	€ 16,442	€ 16,442	€ 34,283
	Northern Europe	€ 8,819	€ 48,625	€ 17,637	€ 75,081	€ 3,630	€ 28,023	€ 28,023	€ 42,602
	New Member States	€ 9,375	€ 18,125	€ 7,950	€ 35,450	€ 1,500	€ 14,000	€ 14,000	€ 22,000
SME	Public	€ 9,132	€ 15,328	€ 18,103	€ 42,563	€ 2,785	€ 11,833	€ 11,833	€ 20,657
	Private	€ 5,023	€ 13,141	€ 16,045	€ 34,209	€ 1,735	€ 8,295	€ 8,295	€ 17,076
Large	Public	€ 8,804	€ 28,267	€ 16,490	€ 53,560	€ 2,045	€ 17,451	€ 17,451	€ 25,930
	Private	€ 6,931	€ 37,498	€ 24,347	€ 68,775	€ 3,813	€ 23,706	€ 23,706	€ 42,067
SME	Manufacturing	€ 4,879	€ 11,211	€ 19,687	€ 35,776	€ 1,364	€ 7,252	€ 7,252	€ 16,856
	Services	€ 5,860	€ 15,972	€ 13,769	€ 35,601	€ 1,865	€ 10,297	€ 10,297	€ 17,601
Large	Manufacturing	€ 6,942	€ 35,484	€ 24,335	€ 66,762	€ 3,571	€ 22,113	€ 22,113	€ 34,177

Services € 8,563 € 29,289 € 18,398 € 56,250 € 4,025 € 16,656 € 16,656 € 26,464

Source: Study on the costs and benefits of EMAS to registered organisations (2009)

Table 4: Costs and potential annual efficiency savings in EMAS

Organisation size	Potential annual efficiency savings (€)	First year implementation costs of EMAS (€)	EMAS Annual costs (€)	EMAS Easy First year implementation costs (€)	EMAS Easy Annual costs (€)
Micro	3,000 – 10,000	22,500	10,000	11,000	2,200
Small	20,000 – 40,000	38,000	22,000	17,000	3,300
Medium	Up to 100,000	40,000	17,000		
Large	Up to 400,000	67,000	39,000		

Source: http://ec.europa.eu/environment/emas/tools/emaseasy_en.htm

Table 5: Benefit likelihood indicators by organization size

Organisation size	Energy and resource saving	Financial saving	Improved stakeholder relationships	Improved staff recruitment/retention	Increased market opportunities	Productivity improvement	Reduction in negative incidents
Micro	+++	0	+++	+	+	0	++
Small	+++	0	++	0	+	+	++
Medium	+++	0	++	0	+	+	+++
Large	+++	0	+++	0	+	+	+++

Source: Study on the costs and benefits of EMAS to registered organisations (2009)




Table 6: Benefit likelihood indicators by relevant industry sectors

Sector	Energy and resource saving	Financial saving	Improved stakeholder relationships	Improved staff recruitment/retention	Increased market opportunities	Productivity improvement	Reduction in negative incidents
Agriculture, forestry and fishing	+	0	+	+	0	0	+++
Food, drink and tobacco	++	0	+	0	0	+	++

Textiles, leather, footwear and clothing	++	0	++	+	0	0	+++
Retail trade and repair	-	-	-	-	-	-	-
Hotels and catering	++	+	+	+	+	+	+

Source: Study on the costs and benefits of EMAS to registered organisations (2009)

Another recent study presented in an information letter of the German state of Saxony⁷⁷ established a comparison between various systems of environmental management, i.e. EMAS, ISO 14001 and two simplified systems applied in Saxony. The results of this comparison are presented in the table below.

	Environmental management systems (EMS)		Environmental management approaches (EMA)	
	 EMAS	DIN EN ISO 14001	 ÖKOPROFIT®	 Qualitätsverbund umweltbewusster Betriebe (QuB) (Quality association of environmentally conscious firms)
Basis	European Regulation which includes the requirements of the standard ISO 14001	Private-sector standard, not legally binding	Licence agreement with the cities of Graz and Munich, municipal project sponsors required	Participation criteria
Scope	Up to now EU-wide, from 2010 worldwide	Worldwide	Worldwide, most widespread in Austria and Germany	Germany-wide
Target group	Organisations of all kinds with their locations	Organisations of all kinds	Small and medium-sized enterprises (SMEs) in all sectors, also suitable for municipal firms and agricultural holdings	Small and medium-sized enterprises (SMEs) in all sectors
Project aim	Continual improvement of environmental performance, compliance with the environmental rules, environmental declaration for the public, image gain through European award	Continual improvement of the environmental management system, image gain through internationally valid certificate	Reduced operating costs through environmental relief, legal certainty, networking in the region, image gain through regional award, establishment of responsibilities	Image gain through award of the QuB seal, legal certainty, Reduced operating costs through environmental relief, establishment of responsibilities, networking in the region
Requirements	Very high	High	Medium	Medium
Focal points as regards content	Environmental management system, environmental statement, involvement of employees, compliance with the legal provisions, continual improvement of environmental performance	Environmental management system	Subject areas: organisation and communication, data and monitoring, energy, emissions, waste, water, hazardous substances, law, purchasing, health and safety at work, welfare; flexible setting of subject focal points possible	Subject areas: legal inventory, location, resource consumption (input/ output balance), emissions, waste, hazardous substances, energy, environmentally relevant installations, staff training courses, product information, customer satisfaction, safety at work
Initial introductory work for the participant	12 to 18 months	12 to 18 months	About 12 months, 10 half-day workshops, four half-day on-the-spot discussions, mandatory worksheets (Excel)	About. 6 months Four half-day workshops, about two on-the-spot discussion days, documentation (QuB files)
Initial examination	Validation of the environmental declaration by state-approved and monitored environmental experts, entry in the EMAS register with participation of the environmental authorities	Certification by accredited certification associations	90-minute commission examination by environmental experts from the business chambers and the municipal project sponsor	Half-day entrance examination by environmental auditors from LGA Intercert

⁷⁷ <https://publikationen.sachsen.de/bdb/artikel/11704>

responsible

Proof	Validated environmental declaration, EMAS register entry and registration certificate, use of the EMAS logo	Certificate, monitoring sign	Certificate of the municipal sponsors use of the ÖKOPROFIT® logo	Certificate of LGA-Intercert GmbH, use of the QuB seal
Period of validity and continuation	3 years; annual validation of the updated environmental statement (relief for SMEs)	3 years; annual monitoring audits	2 years; continuation possible in the ÖKOPROFIT® club and/or in the course 'From ÖKOPROFIT® to Öko Audit'	2 years; in the meantime possible to take part in a working group; Guide on action to further development towards EMAS available
Costs of introduction	Depend on firm size and environmental relevance	Depend on firm size and environmental relevance	Own share €1 500 to €2 000 for SMEs, no additional examination costs	Own share €500 to €1 000 € for SMEs, certification costs €290 (up to 10 staff) up to €1 030 (> 100 staff)
Support	Support for SMEs in accordance with Saxony's guidelines on medium-sized enterprises Advice: €240 per day's work, maximum 30% of costs, maximum 20 days' work in three years Validation: 50% of costs, maximum €5 000	Support for SMEs in accordance with Saxony's guidelines on medium-sized enterprises Advice: €240 per day's work, maximum 30% of costs, maximum 20 days' work in three years Certification: 50% of costs, maximum €5 000	Regional licence financed by Saxony; support for SMEs in accordance with Saxony's guidelines on medium-sized enterprises Project support for group projects up to 50% of expenditure, maximum €20 000, in the case of participation by more than 10 SMEs maximum €26 000	Support for SMEs in accordance with Saxony's guidelines on medium-sized enterprises Project support for group projects up to 50% of expenditure, maximum €20 000, in the case of participation by more than 10 SMEs maximum €26 000 Individual projects: Advice: €240 per day's work, maximum 30% of costs, maximum 20 days' work in three years
Added value	Membership of the Saxony environmental alliance possible, independently of that list of administrative-law facilities, 30% fee reduction	Membership of the Saxony environmental alliance possible, then the list of administrative-law facilities applies	Basis for UMS, Membership of the Saxony environmental alliance possible	Basis for UMS, Membership of the Saxony environmental alliance possible
Further information	www.emas.de www.emas-register.de	www.djn.de	www.umweltallianz.sachsen.de/oekoprofit www.argum.de/datenbank	www.qub-info.de www.umweltallianz.sachsen.de

Source: English translation of "Umweltallianz Sachsen - Infobrief Sonderausgabe. Der stufenweise Einstieg ins Umweltmanagement. August 2010".

Simplified environmental management approaches, such as those described in the above table, though seemingly less burdensome, would however not necessarily be available to all operators in the EU and outside. Nevertheless, they could constitute a first step towards the implementation of a more complete EMS. Both Ökoprofit and QuB are part of the 20 non-formal EMS that are considered compatible with EMAS⁷⁸.

⁷⁸ http://ec.europa.eu/environment/emas/tools/faq_en.htm (see question 4)

ANNEX 14: ANIMAL WELFARE

1. INTRODUCTION

The citizens of the European Union have become more and more concerned about the ethical treatment of animals in the last years. The European organic farming standard provides high level animal welfare standards. Further attention is being paid to this issue in the context of the review.

2. LEGAL BACKGROUND

The Lisbon Treaty 2009 recognizes animals as sentient beings and requires that the Union and the MS shall pay full regard to the welfare requirements of animals in formulating and implementing the Union's policies on agriculture, fisheries, transport and research. 3 horizontal legal documents are relevant in animal welfare:

- (1) Council Directive 98/58/EC⁷⁹ concerning the protection of animals kept for farming purposes and European Convention for the Protection of Animals kept for Farming Purposes (to protect farm animals against any unnecessary suffering or injury caused by their housing),
- (2) Council Regulation (EC) No 1/2005⁸⁰ on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 and
- (3) Council Regulation (EC) No 1099/2009⁸¹ on the protection of animals at the time of killing.

Horizontal legislation on animal welfare is currently being reviewed according to the Commission Staff Working paper of 19.1.2012⁸². In 2012, the European Union Strategy for the Protection and Welfare of Animals 2012-2015⁸³ was adopted, which contained important indications to consider for farm animals in organic farming. The Strategy has foreseen in its general objectives a level of protection of animal welfare, which is in line with citizens' concerns. The level playing field on animal welfare is also important at international level to ensure global competitiveness of EU operators.

⁷⁹ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, OJ L 221, 8.8.1998, p. 23–27

⁸⁰ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97, OJ L 3, 5.1.2005, p. 1–44

⁸¹ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance), OJ L 303, 18.11.2009, p. 1–30

⁸² Commission Staff Working Paper, Executive Summary of the Impact Assessment (19.1.2012)

⁸³ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the European Union Strategy for the Protection and Welfare of Animals 2012-2015 (15.2.2012)

3. CURRENT LEGISLATION ON ORGANIC FARMING AND ANIMAL WELFARE

There are no separate rules for animal welfare in the current Regulation (EC) No 834/2009, but there are several important references to the application of high animal welfare standards throughout the documents.

In Regulation (EC) No 834/2007 animal welfare is mentioned in:

- whereas (1)" ...The organic production method thus plays a dual societal role, where it on the one hand provides for a specific market responding to a consumer demand for organic products, and on the other hand delivers public goods contributing to the protection of the environment and animal welfare, as well as to rural development."
- whereas (17) "Organic stock farming should respect high animal welfare standards and meet animals' species-specific behavioural needs while animal-health management should be based on disease prevention. In this respect, particular attention should be paid to housing conditions, husbandry practices and stocking densities. Moreover, the choice of breeds should take account of their capacity to adapt to local conditions. The implementing rules for livestock production and aquaculture production should at least ensure compliance with the provisions of the European Convention for the Protection of Animals kept for Farming purposes and the subsequent recommendations by its standing committee (T-AP)."
- whereas (31) " In order to ensure that organic products are produced in accordance with the requirements laid down under the Community legal framework on organic production, activities performed by operators at all stages of production, preparation and distribution of organic products should be submitted to a control system set up and managed in conformity with the rules laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules."

In Regulation (EC) No 834/2007 it is mentioned in:

- Article 3 (a) (iv) that organic farming "respects high animal welfare standards and in particular meets animals' species-specific behavioural needs)". According to Article 3 (c) organic farming methods "aim at producing a wide variety of foods and other agricultural products that respond to consumers' demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare."
- Article 5 that "In addition to the overall principles set out in Article 4, organic farming shall be based on the following specific principles:

...

(h) the observance of a high level of animal welfare respecting species-specific need....."

- Article 14 laying down the livestock production rules that "1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to livestock production:

...

(b) "with regard to husbandry practices and housing conditions:

- (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;
- (ii) husbandry practices, including stocking densities, and housing conditions shall ensure that the (exemption for veterinary, welfare, safety reason for individual animals for a limited period of time) developmental, physiological and ethological needs of animals are met;
- (iii) the livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation;
- (iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;
- (v) organic livestock shall be kept separate from other livestock. However, grazing of common land by organic animals and of organic land by non-organic animals is permitted under certain restrictive conditions;
- (vi) tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for safety, welfare or veterinary reasons;
- (vii) duration of transport of livestock shall be minimised;
- (viii) any suffering, including mutilation, shall be kept to a minimum during the entire life of the animal, including at the time of slaughter;....."

In concrete terms, the organic animal welfare standards are higher than in conventional farming. They are guaranteed by bigger space and special areas available for the animals and maximum stocking densities. The stocking density in buildings shall provide for the comfort, the well-being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. Throughout the lifetime of the animals, their access to open-air areas (depending on climatic conditions) has to be ensured. Organic stock farming should respect the animals' species-specific behavioural needs (that may go beyond Community welfare standards). The transport of the animals shall ensure that the welfare of animals is kept at the highest possible level.

In the Organic farming legislation there are no references to the horizontal legislation of animal welfare, but general rules apply.

4. RESULTS OF THE CONSULTATIONS WITH CONSUMERS AND STAKEHOLDERS

- Results of public consultation have shown that 66% of the respondents would like to see higher animal welfare standards not only for organic farming, but for all types of farming methods (conventional).
- 55% of the respondents agreed that they choose organic because organic production respects animal welfare.
- One of the free contributions of the consultation referred to other guidelines: "the EU regulation should at least aspire to the guidelines/standards of farming associations:

prohibition of dehorning cows, castration; more space per animal (other organizations [eg. Neuland] have better housing conditions than EU organic provisions).

- In general, respondents would like to see stringent standards, for example: "Strengthen the animal welfare standards and ban the mass animal husbandry".
- Reference to other standards of organic farming: " Animal welfare rules should be strengthened - the only good rules are '...' - their harmonization is needed but to higher standards."
- There are two important organizations advocating animal welfare issues Eurogroup for Animals and Compassion in World Farming (CIWF). Consulted organisations suggest that allopathic tranquilisers, or electrical stimulations should not be permitted.

5. IMPROVEMENTS IN ANIMAL WELFARE STANDARDS OF ORGANIC FARMING REQUESTED BY ANIMAL WELFARE ORGANISATIONS

1. Origin of animals: in principle the animals need to have organic origin, but exemptions are permitted, therefore non-organic animals are allowed if there are not enough available animals of organic origin. The poultry reared on organic farms for example should come from slow-growing strains of organic origin or the rearing should avoid intensive methods in order to avoid suffering of the animals.
2. *Eurogroup for Animals suggests that exceptions or permission for derogations regarding tethering should be not accepted. Compassion in World Farming (CIWF) requests that close confinement or tethering should only be accepted for veterinary reason. Conditions for keeping the animals: tethering or isolation of livestock should be prohibited but tethering and isolation may be allowed only for the following exceptional reasons: veterinary, welfare, safety for individual animals for a limited period of time). The current rules provide that " tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for safety, welfare or veterinary reasons". Organic stock farming should respect high animal welfare standards and meet animals' species-specific behavioural needs while animal-health management should be based on disease prevention. CIWF requests that ducks for example should have access to water at any time. The idea is that all the needs of the animals, including nutritional and physiological, should be covered. To ensure this, there is pressure from the advocating organisations to allow the use of amino-acids and certain other substances which today are not allowed under the EU organic production rules. The current legislation provides that "husbandry practices, including stocking densities, and housing conditions shall ensure that the (exemption for veterinary, welfare, safety reason for individual animals for a limited period of time) developmental, physiological and ethological needs of animals are met."*
3. CIWF requests that castration or mutilation should not be allowed without a pain relief. Where cattles are required not to have horns, disbudding should be practiced. Eurogroup asks that no physical castration should be permitted. According to the current legislation suffering, including mutilation, shall be kept to a minimum level. The duration of transport should be optimised: minimisation or maximisation of the trip. Eurogroup suggests that the duration of the transport should not exceed 8 hours. Up to know the minimisation of travel is encouraged according to the legislation. Consulted organisations suggest that allopathic tranquilisers or electrical stimulations should not be permitted. *According to the legislation, the use of sedative substances for transport is already*

forbidden except under veterinary supervision and that duration of transport of livestock shall be minimised.

4. Pre-stunning is encouraged by the advocating organisations and it is indeed applied as one of the methods in organic farming. *Organic legislation provides that "any suffering, including mutilation, shall be kept to a minimum during the entire life of the animal, including at the time of slaughter".*

The large majority of the concerns of the animal welfare organisations are addressed under the existing EU legislation. In fact, the main problem is implementation of these rules and the possibility for exceptions. Better enforcement of animal welfare rules and removal of exceptions would improve the situation as regards animal welfare.

6. OPTIONS AND THEIR IMPACTS

Baseline scenario: The animal welfare standard is higher in organic farming than in conventional. It is notably characterised by mandatory access to open-air areas and by rules of maximum stocking density.

Improved status quo: no change

Market-driven option: Deterioration of animal welfare because exceptional production rules would be integrated, meaning that an authorisation from the MS competent authority would not be required any more (dehorning, tethering of animals in small holdings, indoors final fattening phase of adult bovines for meat production, allowing non-organic origin of animals for breeding purposes). The exceptions would allow the farmers/operators to be more flexible in making choices. It makes the processes to manage animals faster and cheaper. The non-organic originated breeds are more vastly available, therefore it is less costly.

Principle-driven option: The removal of exceptional rules leads to the improvement of animal welfare. It would make the already strict rules even more stringent. The removal of exceptions for mutilations, castration, isolation or permanent tethering involves changes in the organisation of holdings, which can entail significant economic impacts, in particular in case new buildings would be needed. However, option 3 includes the possibility for competent authorities to authorize the tethering of cattle in micro-enterprises under certain conditions.

7. CONCLUSION

Many of the requests of the animal welfare organisations are already covered by the current legislation but putting an end to certain exceptions (ex: isolation, mutilations) would be an improvement in relation to the implementation of today's rules. The removal of exceptions is included in the principle driven option which is the preferred option of animal welfare organisations.

ANNEX 15: SMALL FARMS AND ENTERPRISES: SIMPLIFICATION; GROUP CERTIFICATION

8. INTRODUCTION

In recent years small farms have received increased attention in the political debate.

Small farms play an important role in supporting rural employment and maintaining the social fabric of rural areas and thus contribute to the objective of balanced territorial development. In addition, structural diversity in the farming systems contributes to the attractiveness and identity of rural regions.

The brief published in July 2011 by DG AGRI⁸⁴ showed that at the time of the last comprehensive survey (2007) the economic dimension of 40% of the EU farms was below 1 European Size Unit (ESU). The ESU is the potential gross value added of the agricultural holding calculated as the sum of the standard gross margins (SGM). The value of one ESU was 1200 Euro at the time of the study. 56% of the EU farms had an economic dimension below 4 ESU.

This annex provides background information on small agricultural holdings in the EU; highlights the main problems they face in entering in the organic sector; outlines the possible simplification measures; and describes group certification, to underpin its proposed introduction in the EU as part of the sub-option under the principles-driven option.

9. DATA ON SMALL AGRICULTURAL HOLDINGS IN THE EU

69% of all agricultural holdings have less than 5 ha of utilized agricultural area (UAA). This corresponds to a total of more than 8.3 million holdings.

Table 1. Share of holdings in different size classes in the EU

	< 5 ha	5-9.9 ha	10-19.9 ha	20-29.9 ha	30-49.9 ha	50-99.9 ha	100 ha or over
EU-27	69,20	10,88	7,51	3,15	3,29	3,26	2,70

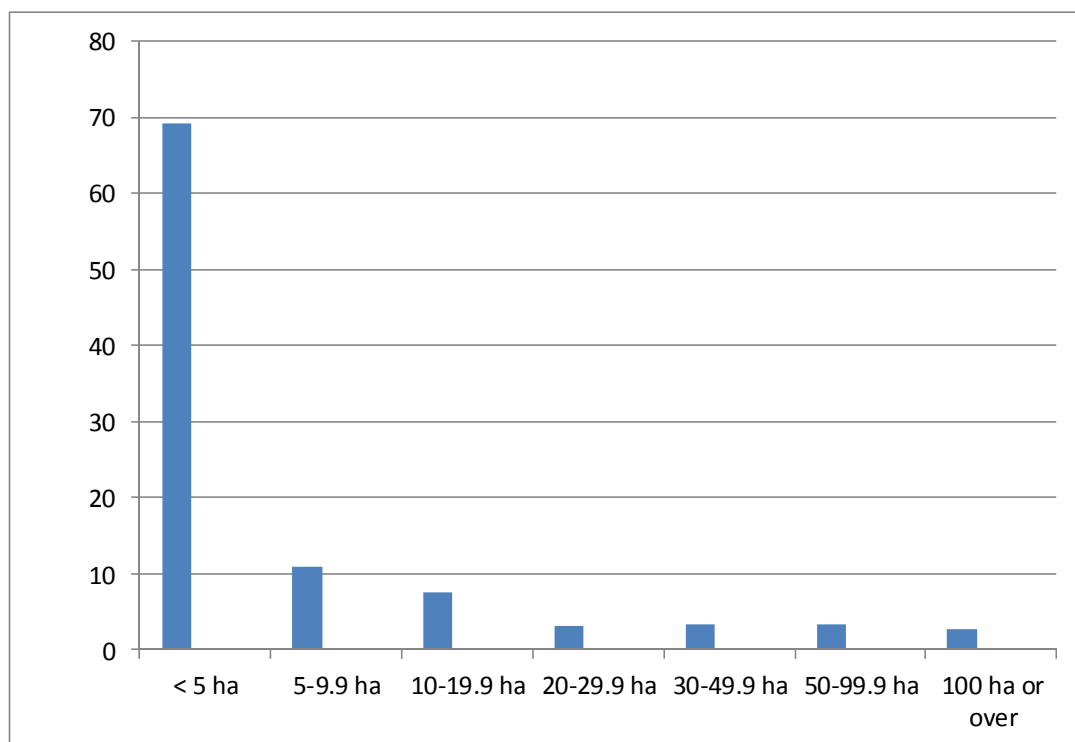
Source: European Commission – DG AGRI L2 Data Source: EUROSTAT (2010)

These small holdings:

- account for 7% of the total UAA in the EU,
- keep 18% of the total livestock,
- employ 44% of the agricultural labour force,
- generate 18% of the standard output in the EU.

⁸⁴ European Commission, Directorate General for Agriculture and Rural Development – EU Agriculture Economic Briefs: Brief No 2, What is a small farm?

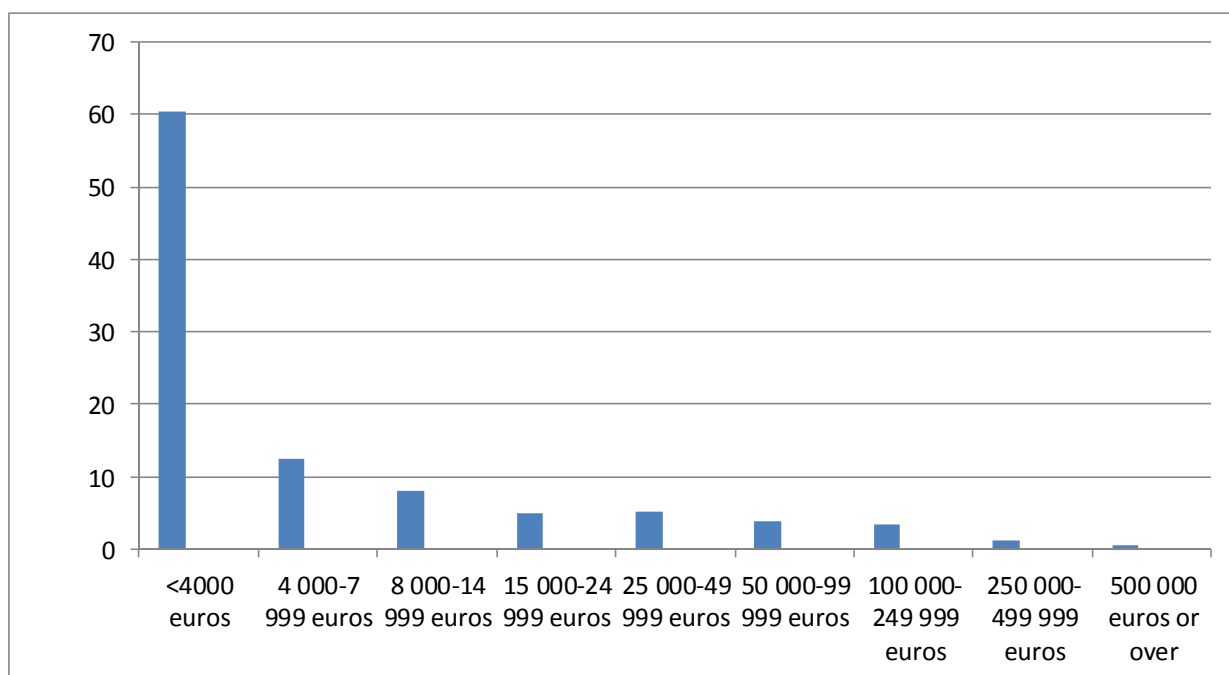
Graph 1. Share of agricultural holdings in different size classes in the EU



Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

Graph 2 shows that 73% of agricultural holdings have an output lower than 8 000 euros. This means that more than 73% of agricultural holdings are microenterprises (turnover below 10 000 euros).

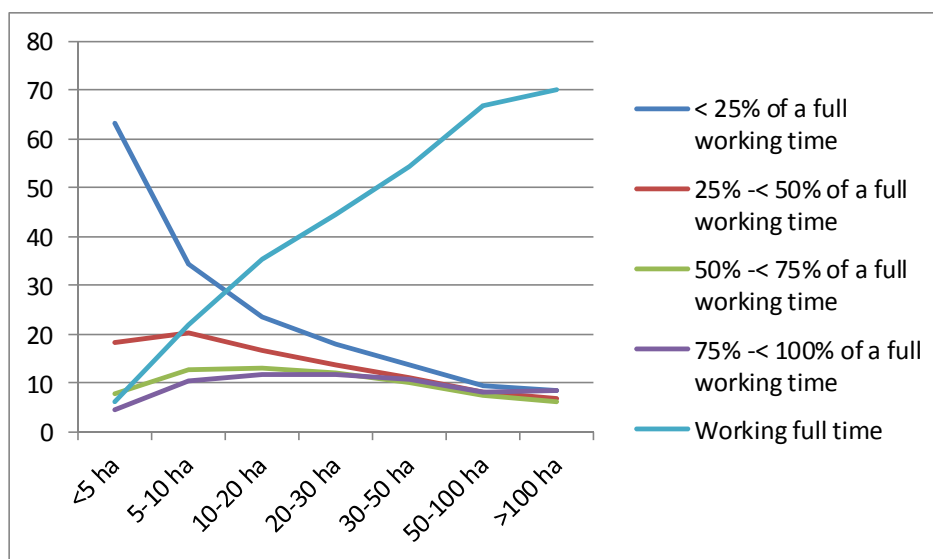
Graph 2. Share of agricultural holdings in different output classes in the EU



Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

Managers of small farms tend to have another source of income elsewhere.

Graph 3. Labour force categories: number of persons and farm work (AWU) in the holding by working time (% AWU) and agricultural size of farm (UAA)

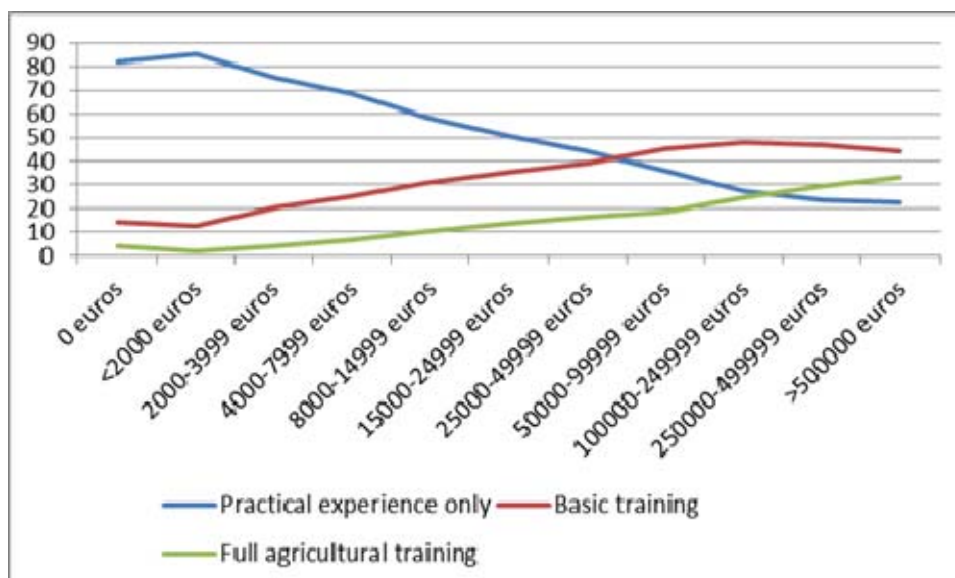


Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

Farms with small areas are specialized in general field cropping, mixed crop-livestock farming, olives, poultry, fruit (including citrus) and vineyards.

Managers of small farms are usually less well trained than those of bigger farms.

Graph 4. Agricultural training of farmers according to farm size



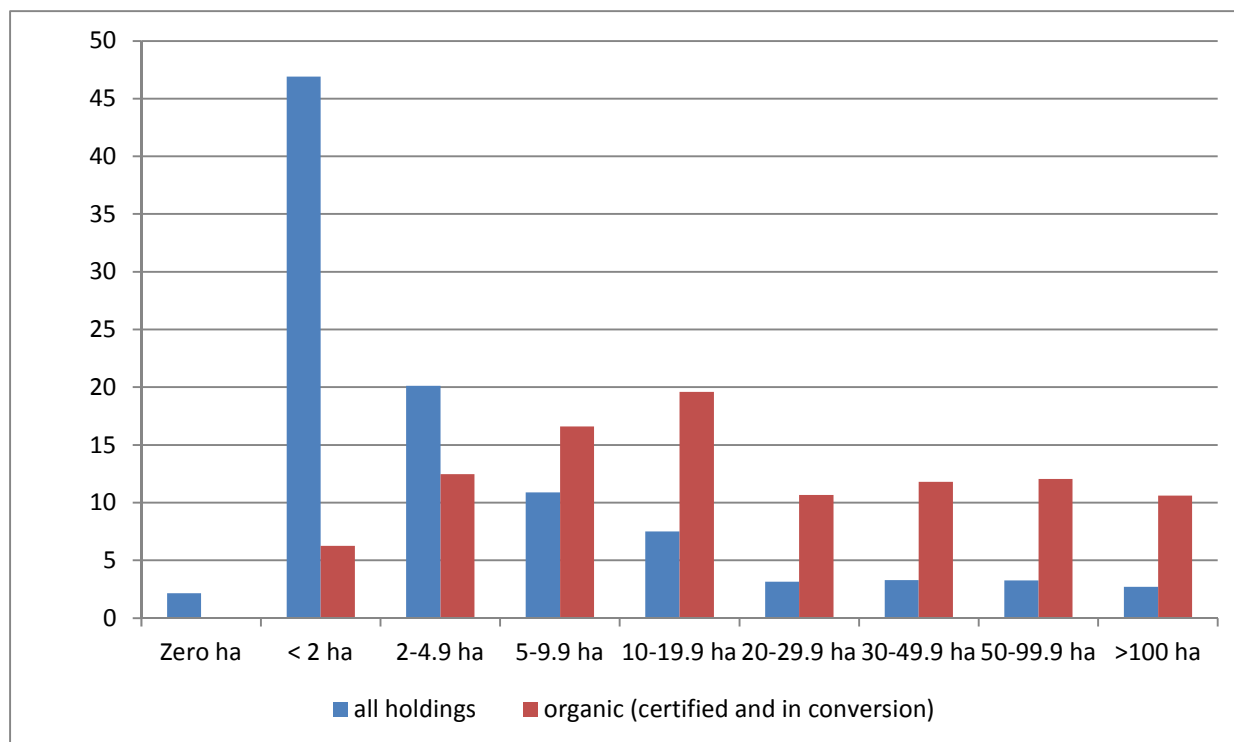
Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

9.1. Difficulties for small agricultural holdings to join the organic sector

9.1.1. Current situation

Small farms are under-represented in the organic sector. The share of small organic holdings is much lower than the share of small conventional holdings. While 69% of all agricultural holdings have less than 5 ha, only 18,7% of organic holdings have less than 5 ha. Average farm size in the EU is 14 ha. Average size of organic holdings is 33,6 ha.

Graph 5. Share of holdings in different size classes



Source: European Commission–DG AGRI L2. Data: EUROSTAT, Farm structure survey 2012

9.1.2. Issues

The main problems that small farms face to enter the organic sector can be summarized as follows:

- The **volume** produced is usually **insufficient** to get access to the main channels to market organic products: supermarkets, specialized shops in cities.
- Many small farms are located in **remote areas**, where there is little interest to sell organic products directly to consumers.
- **Inspection and certification costs**, together with the administrative burden linked to **record keeping**, are not always proportionate to the volume produced. They are considered to represent the main obstacles to enter the organic sector⁸⁵.

⁸⁵ Via Campesina on behalf of IFOAM EU at the hearing of 25 and 26 October 2012 on the EU organic production – controls and enforcement. On the cost of control, please see annex No 10 for further details.

- Farmers are often less **well trained** than those with bigger farms, and face difficulties in dealing with the requirements of organic certification.
- **Unequal treatment** in the EU and in third countries as group certification is not allowed in the EU while being accepted for organic producers in third countries as a measure of equivalent control effectiveness⁸⁶.

The high percentage of micro and small farms in the EU (see previous section) gives an indication of the importance of these issues.

10. SIMPLIFICATION

DG AGRI organised an **internal brainstorming** on simplification in the field of organic farming, in the context of the ongoing review of the organic policy and legal framework. The workshop, held on 19 March 2013, identified the following three areas where simplification would have an important impact and implementation is likely to succeed:

1. **EU organic production rules.** Clear and simple production rules, with no or less derogations that generate red tape, in particular when they have to be authorised by the public authorities upon individual requests of the operator, could mean significant reduction in the administrative burden for farmers and other operators, as well as cost savings for the national administrations.
2. **Controls:** a risk-based control – rather than controlling all operators once per year - would ensure better efficiency in a situation where several MS are confronted with budgetary efforts to cope with the economic and financial crisis. Electronic certification and, possibly, group certification also bring simplified individual administrative requirements for operators.
3. **Streamlined approach to trade,** as the current two-fold import system (compliance/equivalency) is very complex to manage and supervise.

As part of the stakeholders' consultation, a **technical meeting with experts** took place on 26 June 2013 to examine further the issues faced by small farms and operators. The meeting concentrated on gathering ideas for facilitating the conversion of small farms to the EU organic scheme, including through simplified requirements – which would also benefit larger farms and operators. A concrete suggestion was made to have a single administrative document giving a full description of the farm, to be updated once a year, which would represent a substantial simplification.

The proposals for simplification, as briefly outlined above, have been further explored in the impact assessment process as a cross-cutting theme for the review of the organic legal and political framework.

They have been taken into account under the proposals to address the identified issues that have been put forward under the various options. Further details are set out in annex 6 on the EU organic production rules, annex 8 on the logo and labelling, annex 9 on the control system and annex 12 on the EU trade regime for organic products.

⁸⁶ According to Agro Eco Louis Bolk Institute, the majority of organic products imported by the EU from developing countries, all categories, are now produced by producer groups (presentation to the AGOF meeting, 11 April 2013).

11. GROUP CERTIFICATION, CURRENTLY IMPLEMENTED IN THIRD COUNTRIES

In some third countries, **notably developing countries**, a system of group certification has developed to provide small farmers an opportunity to have access to the global organic market, in particular the EU market.

This is the case for the following countries, out of the 11 currently recognised for the purpose of equivalency: Canada, Costa Rica, and India. Several of the currently 60 recognised control bodies for the import of organic products under equivalency also apply group certification in a number of third countries – non exhaustive list: Ecuador, Mexico; Belize, Ghana, Madagascar, Senegal; Indonesia, Nepal.

11.1. Definition

The concept of group certification is defined or outlined in the following documents – nb non-exhaustive list:

- **IFOAM norms for organic production and processing**

The International Federation for Organic Farming (IFOAM) norms for organic production and processing – updated version dated 2012⁸⁷ - define group certification as "the certification of an organized group of small-scale producers with similar farming and production systems. The requirements for group certification apply only to such groups when the certification applies to the group as a whole and when special inspection arrangements have been applied".

The accreditation requirements for group certification are as follows:

- groups shall be constituted of operations with similar production systems.
- large farming units, processing units and traders shall not be included in the inspection arrangements for such groups.
- group members shall be in geographic proximity.
- a viable internal control system that assures compliance of individual members with production standards in an objective and transparent manner is required.
- the group shall have coordinated marketing.

- **national standards**

In the organic farming regulation for **Costa Rica**⁸⁸, a group is defined as the producers in a common geographic area with common crop(s), a central management responsible for compliance with the organic rules and an internal control system.

⁸⁷ http://www.ifoam.org/sites/default/files/page/files/ifoam_norms_version_august_2012_with_cover.pdf. The IFOAM Accreditation Criteria (IAC) were first approved by the General Assembly in 1992, and have been subsequently updated on various occasions.

⁸⁸ Executive decree No 29782/2001 (Reglamento de agricultura organica), chapter V.

The central management shall be in charge of the proper functioning of the internal control system, which shall ensure the annual inspection of each member of the group. The external inspection body (certifying agency) shall inspect annually at least 20 % of the members of each group.

In the **Indian** National Programme for Organic Production (NPOP), the guidelines for the certification of grower groups set up a size limit of 4 hectares for participating farms⁸⁹. Farms with land holding above 4 ha can also belong to a group but they have to be inspected annually by the external Inspection and Certification Agency (Control Body). The total area of such farms shall be less than 50% of the total area of the group. Processors and exporters can be a part of the same group but they have to be inspected annually by the Control Body.

The NPOP specifies how many farmers from a grower group have to be subject to external inspections annually. Depending on the total number of members of the group, this number varies between about 1% to 12%, for surveillance inspections.

Under the **Canada** Organic Regime (COR)⁹⁰, a grower group may be organised as a co-operative or as a structured group of producers affiliated to a processor.

All members of the group shall apply similar production systems and should be in geographical proximity. The practices of the grower group association shall be uniform and reflect a consistent process or methodology, using the same input and processes. Participation in the group shall be limited to those members who market their organic production only through the grower group, unless the member is individually certified.

The group shall have in place an effective and documented internal control system, including a mechanism to remove non-compliant group members from the list. The external Control Body shall suspend or cancel the certification granted to the grower group as a whole in cases where the grower group's internal control system fails to act on non-compliances.

- **the Commission's services guidelines on imports of organic products**

In 2008 the Commission services, in cooperation with the MS, updated guidelines - not intended to produce legally binding effects – on imports of organic products into the EU under equivalency⁹¹.

These guidelines include a specific section on the evaluation of the equivalence of organic producers group certification schemes applied in Third Countries. Namely, they clarify the scope (who can be considered as a group), the main features of the internal control system to be set up, and the role and responsibilities of the external control body, including in respect of the risk factors to take into account.

⁸⁹ http://www.apeda.gov.in/apedawebsite/organic/ORGANIC_CONTENTS/English_Organic_Sept05.pdf, section 5.

⁹⁰ The requirements for obtaining group certification of organic products under the Canada Organic Regime are set out in the Canada Organic Office Operating Manual (version 2012, part F).

⁹¹ Guidelines on imports of organic products into the European Union, 15.12.2008, http://ec.europa.eu/agriculture/organic/files/news/download-material/guidelines_for_imports_en.pdf. Guidelines on group certification were formerly published as Commission service guidance document on 6 November 2003.

- **the European cooperation for Accreditation's guidelines**

The European cooperation for Accreditation (EA) developed **guidelines** for the **certification** of the growing number of schemes entering the market through focus on the specific characteristics of the production process rather than of the products themselves. Such guidelines, applicable to its members – the (single) Accreditation Bodies in the EU that assess Control Bodies in Third Countries recognised and/or to be recognised as equivalent - as from 9 July 2013⁹², refer specifically to group certification.

Namely, group certification is defined as "a special case of certification where the scheme owners specify that less extensive sampling can be applied by certification bodies, through a focus on the management system of the umbrella organisation in combination with inspection of a sample of the sites. These schemes are often used to support small size producers that according to the scheme owner are at risk of being left out of the market unless these special conditions are applied. In the certification process the audit of the effectiveness of the supporting internal management/control system is essential."

The guidelines set out requirements for group certification. The following aspects are worthwhile mentioning:

- Group **members** are not identified in the certificate and are **not entitled to sell marked products** or make claims of being certified on their own.
- **Producers** shall be part of group certification only where the **cost of certification would exceed 2% of the individual producer's turnover**.

The specific **guidelines** for the **accreditation of organic production** certification, which will apply as from 1 January 2014⁹³, set out a number of risk criteria for the office and witness/review audits to be conducted by Accreditation Bodies for the initial accreditation and the re-accreditation of control bodies.

Group certification, for the control bodies in Third Countries, is considered an increase factor for the minimum on-site time to be devoted to the Accreditation Bodies' office assessments (+ one day).

11.2. Experiences and evaluation

- **IFOAM** has been working for several years on the concept of group certification, calling the stakeholders together to develop a consensus on the requirements for smallholder groups.

From 2001 to 2003, workshops were organised in the margins of the Biofach and a consensus was found on the issues of smallholder definition, group non-compliances and sanctions and the rate of re-inspection.

⁹² EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites, EA-6/04:2011, <http://www.european-accreditation.org/publication/ea-6-04-m>

⁹³ EA Policy for the accreditation of Organic Production Certification, Ref: EA-3/12 M: 2013, <http://www.european-accreditation.org/publication/ea-3-12-m>

A compilation of results, addressing group certification in the context of **developing countries**, was published.

IFOAM also initiated a **pilot project**⁹⁴ on Group Certification **in the EU**, which ran from August 2006 to March 2008. The project was coordinated by Agro Eco. It took place in Turkey, in France, in Italy and in Spain.

The pilot project objectives were to assess whether group certification in Europe is effective and efficient, compared to individual certification; whether it can be combined with other benefits, besides reducing costs; and whether it can accommodate the diversity of production and marketing channels.

Group certification was found effective in the pilot project with a centralised marketing channel and good product flow control (Turkey). In the other pilot projects, most of the internal control system documentation was complete, except for centralised documents of production and sales.

Farmers, sometimes combined with consumers, were successfully used as internal inspectors. However, the internal inspectors failed to detect some non-conformities, partly related to the maintenance of the ICS documentation and partly to the differences between the internal regulation and the EU regulation. The risk of non-conformities was considered low, either because of product flow control and general low use of inputs (pilot project in Turkey) or because of the social control within the group, the strict internal regulation, and the additional market surveillance (pilot projects in France, Italy and Spain).

The results showed that an internal control system does not only serve organic certification, but also has other benefits, such as farmer-to-farmer advice, quality improvement, joint marketing or promoting a specific agricultural region.

The overall costs of group certification in the first one or two years, when the ICS is set up, are higher than the costs of individual certification but in the subsequent years group certification is cheaper than individual certification.

The coordinator of the project recommended in particular to further discussing the objectives, target groups and criteria for farmers to be eligible for group certification. A follow up project was suggested but did not finally take place.

- The **CERTCOST** project, Economic Analysis of Certification Systems in Organic Food and Farming, included a report on the potential of alternative certification systems⁹⁵.

The report reviewed the certification schemes alternative to the EU organic system – US, Japan, group certification based on an internal control system, and participatory guarantee systems - as well as non-organic certification schemes with a view to identifying promising elements for the improvement of the EU system. It then provided an in-depth analysis of three promising elements: risk-based inspection, social network factors, and training and capacity building.

⁹⁴ Pilot Project Group certification in Europe, end report, Agro Eco, Ferko Bodnár, May 2008. The pilot project was funded through the "IFOAM-Growing Organic" programme and the "Fund for Sustainable Biodiversity Management" of the Dutch government.

⁹⁵ Deliverable No 21, 13.12.2011, H. Moschitz (editor).

Social networking and social control – which ultimately represents a compliance mechanism - are important elements in participatory guarantee systems and in group certification based on an internal control system.

Under a group certification, social control can be very high as the products are often collected and sold jointly as a single lot, so that any deviating farmer can jeopardise the certification of a large product lot.

11.3. Opinion by stakeholders

In the **hearing** organised on 25 and 26 October on control issues, IFOAM asked to alleviate the certification cost and paperwork burden for small-scale producers. In particular, IFOAM asked to:

- Recognize group certification for small-scale producer not only in developing countries (inside/outside EU).
- Strengthen the risk-based approach to control, by increasing control on high-risk operations and decreasing control (and cost) on low-risk ones.
- Consider Participatory Guarantee Systems and social control opportunities in EU COM revisions.

The **public consultation** on organic farming asked participants whether group certification, which is allowed for organic farmers in some non-EU countries, should be allowed in the EU. This was the case for **70% of respondents**, with some variations across the categories of stakeholders (from 55% for farmers up to 80% for public authorities in Third Countries)⁹⁶.

⁹⁶ Full report available in the Europa organic farming homepage http://ec.europa.eu/agriculture/organic/files/eu-policy/of_public_consultation_final_report_en.pdf

In detail, in the **free contributions** accompanying or complementing the replies to the online questionnaire, the following stakeholders expressed their favourable opinion on group certification in the EU: Slow Food, the Soil Association, the Women of Europe for a Common Future and IFOAM EU. Bio-Austria and Copa-Cogeca are against.

Many stakeholders specifically raised the problems linked to inspection and certification costs, as well as administrative burden:

"There should be help for small farms to be able to certify their farms as organic, as now very small farms cannot afford it⁹⁷." "There are too many small farms, which cannot afford the control costs⁹⁸." "There is a need to favour the creation of new farming systems in Europe, though the bureaucratic burden for small farmers is too high⁹⁹." "Costs of certification should be lowered to promote small organic farming concepts¹⁰⁰." "It should not be the case that the controls and requirements of organic production, result in excluding or less favouring small farmers¹⁰¹."

⁹⁷ Free contribution No DE 206 + 8.7

⁹⁸ Free contribution No DE 152 + 8.7

⁹⁹ Free contribution No FR 788

¹⁰⁰ Free contribution No EN 129

¹⁰¹ Free contribution No FR 373

"Primarily, the review should prioritise small-scale and local production as opposed to large-scale and intensive production. This includes minimising the burden on farmers in terms of paper-work. Grants offered should focus on small-scale, local and co-operative arrangements. Small-scale and local production should be further encouraged through provision of FREE training for those interested in benefiting their community with local organic produce. There should be incentives for switching to organic production focused on the education of the next generation of farmers in organic methods. This includes providing investment in training at school, college and life-long learning in how small-scale and local production is the only realistic long-term prospect for agriculture¹⁰²."

12. CONCLUSIONS

With a view to addressing the identified problems, it is proposed to **introduce group certification as a sub-option in the principle-driven (3) policy option**.

In particular, the proposal consists in removing the obstacles to group certification in the basic act - thereby amending the provisions in article 27.3 of Regulation (EC) No 834/2007 that foresees an annual inspection on each operator and article 28.1 that requires any operator to adhere to the control system – and introducing the possibility of group certification, according to criteria and conditions to be detailed in delegated and/or implementing acts.

Expected impacts:

- Group certification would reduce the certification costs that currently seem to represent a barrier to entry into the scheme for small farmers. The cost reduction would possibly not occur in the first year, in which the group certification is implemented, but from the subsequent years.
- New organic agricultural products would be brought on the EU market, providing additional supply of organic raw material for organic processors, retailers and traders.
- Group certification could also contribute to higher sales volumes, if joint marketing and promotion is used.
- The social effects of group certification are positive, as local networks are strengthened.
- Facilitate the introduction of compliance under the EU trade regime.
- Repatriation of responsibilities in case of non-compliances leading to a potential situation where a compliant farmer would lose its organic status, because the whole group is decertified, can be seen as a negative effect of group certification.
- The consequences for the receipt of support under the CAP have to be considered. The experience in third countries has shown that the decertification of a whole group is a measure decided only as the last resort. In case it happens, MS will have to get back the amounts granted to the group members.

N.B.: In addition, with a view to keep the administrative and cost burden for organic micro-enterprises as low as possible, option 3 also includes an exemption from the obligation to set up an EMS as well as the

¹⁰² Free contribution No EN 056

possibility for competent authorities to allow the tethering of cattle under certain conditions (see annexes 13 and 14).

ANNEX 16: ASSESSMENT OF ADMINISTRATIVE COSTS

1. INTRODUCTION

The current EU regulatory framework for the organic production imposes a number of information obligations that generate significant administrative costs for organic operators, private control bodies and public authorities.

In line with the Commission's general approach for reducing administrative burden imposed by the EU legislation, this annex aims at assessment of the administrative costs connected with the relevant options analysed under the present review.

The Commission's guidelines for the Impact assessment define administrative costs as the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be construed in a broad sense, i.e. including labelling, reporting, registration, monitoring and assessment needed to provide the information.

The administrative costs consist of two different components: the business-as-usual costs and administrative burdens. While the business-as-usual costs correspond to the costs resulting from collecting and processing information which would be done by the entity even in the absence of the legislation, the administrative burden stem from the part of the process which is done solely because of a legal obligation.

2. WORK DONE AND RESULTS OBTAINED

The Commission's methodology for the assessment of administrative burden contained in the Impact assessment guidelines was used as far as possible.

2.1. Mapping of information obligations

As a first step, a detailed mapping of the information obligations imposed on operators, control bodies and public authorities by the existing EU regulatory framework for the organic production has been carried out.

The mapping resulted in a list of 135 information obligations that are imposed by Council Regulation (EC) No 834/2007, and its implementing rules, Commission Regulations (EC) No 889/2008 and No 1235/2008. Only the information obligations remaining under the baseline scenario have been considered. A detailed description of all the information obligations is presented in table 1 (see Table 1). Out of these 135 obligations, 80 are imposed on operators (farmers, processors, importers of organic products and/or retailers), 11 on private control bodies and 41 on national administration in the MS and 3 on national administration in Third countries.

It is to be noted the obligation requiring MS to set-up a control system which is either run by public control authorities or by private control bodies, and in the latter case also the related approval and supervision of control bodies by MS, have not been considered as an information obligation imposing administrative burden. This is because the existence of a control system as such is inherent to the organic certification scheme and thus needs to be considered as a business-as-usual cost. Nevertheless, the quantitative data that have been provided by MS on the approval and supervision of control bodies are presented in Annex 10 dealing with cost of controls.

2.2. Qualitative assessment

Qualitative assessment of the information obligations imposed by the existing EU regulatory framework for organic production was carried out with the help of the MS and representatives of the organic sector.

MS and the members of AGOF were asked to identify five information obligations which impose the most significant administrative burden for them. Furthermore, they were asked to identify the actions/activities required to complete the information obligation and to quantify the burden where possible.

Replies from 17 MS and 3 organic farming umbrella organisations have been received.

Based on the replies received from the MS and from the members of the AGOF, and on the basis of the information available to the Commission, the significance of each information obligation has been rated as high, medium or low¹⁰³. Out of the total of 135 information obligations, 30 have been rated as high, 21 as medium and 84 as low.).

It is to be noted that during the data gathering process several MS mentioned a high administrative burden linked to audits conducted by the Food veterinary Office and to the implementation of the organic farming scheme (as part of agri-environmental measures) co-financed under the Regulation (EC) No 1698/2008 on support from rural development by the EAFRD. A detailed study on the administrative burden reduction associated with the implementation of certain rural development measures¹⁰⁴, including the measure supporting organic farming, was conducted in 2011.

For each information obligation, it has been assessed whether the obligation is going to be maintained or removed under the three main policy options, i.e. "the improved status quo", "the market-driven option" and "the principle-driven option".

The assessment showed that 37 out of the total of 142 information obligations are going to be removed under the principle-driven policy option. In comparison, under the market-driven policy option and the improved status quo policy option, 34 and no obligations would be removed respectively.

The greatest administrative saving in the number of obligations achieved under the principle-driven policy option can be explained by the fact that all exceptional production rules and derogations, which are connected with a high number of information obligations, are proposed to be removed under this policy option.

The present Annex does not consider the economic impacts on the operators, such as possible higher production costs for the farmers who were benefiting from exceptional rules. This is analysed in the main report and in Annex 6.

¹⁰³ As a first step, the rating "high" was attributed in case the information obligation was identified by two or more actors as the most burdensome, the rating "medium" in case it was identified by one actor and the rating low for all the remaining obligations (not identified as burdensome by any of the actors). As a second step, the rating has been revised, in particular of the information obligations rated as medium, based on the information that is available to the Commission in the Organic Farming Information System (OFIS) and in other reports received from the MS, namely the "seed report".

¹⁰⁴ Study on administrative burden reduction associated with the implementation of certain rural development measures, 11 August 2011, available at: http://ec.europa.eu/agriculture/analysis/external/rd-simplification/index_en.htm

The positive impacts in saving administrative costs has to be balanced with the costs for national administrations and control bodies in adjusting the implementation, e.g. procedures, checklists, etc. that any change in the legislation entails.

The complete list with all information obligations resulted from the mapping, included their significance (high-medium-low) as rated by the MS and the sector and their evolution under the three main policy options (maintained-removed) is presented in table 1.

3. CONCLUSIONS

The assessment has revealed that the most advantageous option in terms of reduction of the number of information obligations is the principle driven option: under this option, 37 information obligations out of the total of 135 obligations contained in the present organic legislation would be removed. This is mainly due to the fact the principle driven option puts an end to numerous exceptions and derogations which are currently possible.

At the same time, the present impact analysis has looked into any new significant information obligation that would be introduced under the three main policy options. The results show that no new significant information obligations will be introduced except for the request to introduce an EMS (e.g. ISO 14001 or EMAS). This request takes part of a sub-option of the principle-driven option and concerns processors and traders of organic products. Some data on costs and benefits of EMAS are available in Annex 13. These costs would be borne by processors and traders, while there would be no significant administrative burden for national administration or control bodies coming from the introduction of ISO 14001 or EMAS requirement.

In order to keep the administrative burden and cost as low as possible for small farms and micro-enterprises, it is necessary to exempt them from certain requirements and to facilitate their access to and continued participation in the organic scheme. This is notably the case in the principle-driven option.

The Commission has already done a significant effort to facilitate implementation of the most burdensome information obligations to the national authorities and to the organic sector. In particular, the Commission has developed and put in place the Organic Farming Information System (OFIS) which greatly facilitates the obligation of information exchange on irregularities which is absolutely necessary for a proper functioning of the control system. The OFIS is continuously being developed, e.g. a new module for equivalent control bodies, allowing them submitting requests for recognition and subsequent annual reports, has been recently introduced in order to ease the burden linked to the recognition process. However, it is difficult to progress more without change in the legislative framework.

Table 1

The present table shows the detailed mapping of the information obligations (IOs) imposed on operators, control bodies and public authorities by the existing EU regulatory framework, i.e. the Council Regulation (EC) No 834/2007, and its implementing rules, Commission Regulations (EC) No 889/2008 and No 1235/2008.

The table contains information on the significance of each IO that has been classified as "high", "medium" or "low". Based on the replies received from MS, the members of AGOF and experts, the rating "high" was attributed in case the IO was identified by two or more actors as the most burdensome, the rating "medium" in case it was identified by one actor and the rating low for all the remaining obligations (not identified as burdensome by any of the actors).

It has been analysed if the IOs will be removed or maintained under each of the three policy options of the impact assessment. Number 1 stands for those IOs that will be maintained and number 0 has been attributed to the IOs to be removed under each policy option.

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
1	Operators	General production rules	"Operators using such non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs ."	Request vendor declaration on no presence of GMOs	RCE 834/2007 Article 9(3)	8	when the triggering event occurs	Low	1	1	1
2	Operators	General farm production rules: Simultaneous production	Simultaneous production "Where, in accordance with the second subparagraph, not all units of a holding are used for organic production, the operator shall keep the land, animals, and products used for, or produced by, the organic units separate from those used for, or produced by, the non-organic units and keep adequate records to show the separation."	Keep records to show separation in case of parallel production (farm level)	RCE 834/2007 Article 11	8	when the triggering event occurs	High	1	1	0
3	MS/CA	Autorisation of products and substances used in farming	Request for a new substance/technique "When a member state considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."	Request for modification of technical annexes of R 889/2008	RCE 834/2007 Article 16(3)(b) and Article 21 (2)	6	when the triggering event occurs	Low	1	0	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
4	MS/CA	Autorisation of products and substances used in farming	“Member States may regulate, within their territory, the use of products and substances in organic farming for purposes different than those mentioned in paragraph 1 provided their use is subject to objectives and principles laid down in Title II and the general and specific criteria set out in paragraph 2, and in so far as it respects Community law. The Member State concerned shall inform other Member States and the Commission of such national rules.”	Inform on introduction of national rules relating to the use of products and substances	RCE 834/2007 Article 16(4)	2	when the triggering event occurs	Low	1	0	0
5	Operators	Plant production: Use of fertilisers and soil conditioners	“Operators shall keep documentary evidence of the need to use the product (products referred to in Annex I to this Regulation).”	Keep documentary evidence of the need to use fertilisers and soil conditioners listed in Annex I	RCE 889/2008 Article 3(1)	8	when the triggering event occurs	Medium	1	0	1
6	Operators	Plant production: Use of products against pest, disease and weed management	“Operators shall keep documentary evidence of the need to use the product (products referred to in Annex II to this Regulation).”	Keep documentary evidence of the need to use plant protection products in Annex II	RCE 889/2008 Article 5 (1)	8	when the triggering event occurs	High	1	0	1
7	MS/CA	Seaweed production: simultaneous production	Parallel production. “Where minimum separation distances are set Member States shall provide this information to operators, other Member States and the Commission.” (minimum separation distances between organic and non-organic production units)	Inform on minimum separation distances for seaweed in case of parallel production	RCE 889/2008 Article 6b (2)	2	when the triggering event occurs	Low	1	1	0
8	Operators	Seaweed production	“An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year (...) The operator shall provide the environmental assessment to the control body or control authority.”	Prepare an environmental assessment (seaweed production of more than 20 tons per year)	RCE 889/2008 Article 6b (3)	8	Initial set up	Low	1	1	1
9	Operators	Seaweed production	“ Documentary accounts shall be maintained in the unit or premises” (to verify that the harvesters have supplied only wild seaweed produced) ; “documentary evidence shall be available that the total harvest complies with this Regulation” (when seaweed is harvest from a shared or common harvest area)	Keep records and evidence in case of sustainable harvesting of wild seaweed	RCE 889/2008 Article 6c (1) (3)	8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
10	Operators	Seaweed production	“Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.”	Record density in seaweed production	RCE 889/2008 Article 6d (3)	8	Regularly	Low	1	1	1
11	MS/CA	Animal production: poultry	Use of slow-growing poultry strains: “The competent authority shall define the criteria of slow-growing strains or draw up a list thereof and provide this information to operators, other Member States and the Commission.”	Define slow-growing poultry strains	RCE 889/2008 Article 12 (5)	1	Initial set up	Low	1	0	1
12	Operators	Animal production: simultaneous production of organic and non-organic livestock	“Operators shall keep documentary evidence of the use of provisions referred to in this Article.” (in case of simultaneous production of organic and non-organic livestock)	Keep records in case of simultaneous production of livestock	RCE 889/2008 Article 17 (5)	8	when the triggering event occurs	High	1	1	0
13	Operators	Animal production: poultry	“The operator shall keep documentary evidence of the application of this period cleaning premises (between batches of poultry).” Not applicable for free range poultry.	Keep documentary evidence of application of period of keeping empty runs for poultry	RCE 889/2008 Article 23 (5)	8	Regularly but not for free range	Medium	1	1	1
14	Operators	Animal production: use of allopathic medicines	Records of documented evidence of the occurrence of such circumstances shall be kept for the control body or control authority.	Keep records of treatment with chemically-synthesised allopathic veterinary medicinal products or antibiotics in animals	RCE 889/2008 Article 24 (4)	8	when the triggering event occurs	Low	1	1	1
15	Operators	Aquaculture	“Defensive and preventive measures taken against predators under Council Directive 92/43/EEC and national rules shall be recorded in the sustainable management plan.”	Record measures taken against predators (aquaculture)	RCE 889/2008 Article 25b	8	Regularly	Low	1	1	1
16	Operators	Aquaculture	“Operators shall keep documentary evidence of the use of provisions referred to in this Article.”	Keep records in case of simultaneous production of aquaculture animals	RCE 889/2008 Article 25c (3)	8	Regularly	Low	1	1	0
17	Operators	Aquaculture	“ Documentary evidence of their origin and treatment shall be provided for the control body or control authority.”	Keep documentary evidence on the origin of aquaculture animals	RCE 889/2008 Article 25d (1)	8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
18	Operators	Aquaculture	“ Documentary evidence shall be maintained.”	Keep documentary evidence in case of escape of aquaculture animals	RCE 889/2008 Article 25f (5)	8	Regularly	Low	1	1	1
19	Operators	Aquaculture	“ Documentary evidence shall be maintained.”	Keep documentary evidence on the use of oxygen in aquaculture	RCE 889/2008 Article 25h (4)	8	Regularly	Low	1	1	1
20	Operators	Aquaculture	“ Records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area.”	Keep records on the use of wild seed (aquaculture - production of bivalve shellfish)	RCE 889/2008 Article 25o (1)	8	Regularly	Low	1	1	1
21	Operators	Aquaculture	“The report shall be added as a separate chapter to the sustainable management plan.”	Prepare report on the bottom cultivation of molluscs (aquaculture)	RCE 889/2008 Article 25q (2)	2	Regularly	Low	1	1	1
22	Operators	Aquaculture	“Whenever veterinary medicinal products are used, such use is to be declared to the control body or the control authority before the animals are marketed as organic. Treated stock shall be clearly identifiable.”	Declare use of veterinary medicinal products in aquaculture	RCE 889/2008 Article 25t (5)	8	when the triggering event occurs	Medium	1	1	1
23	Operators	Processed feed and food	“When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;”	Inform CB and keep records in case of parallel processing	RCE 889/2008 Article 26 (5) (c)	8	when the triggering event occurs	High	1	1	1
24	Operators	Processed feed and food: authorisation of non-organic ingredients	Where an ingredient of agricultural origin is not included in Annex IX to this Regulation, that ingredient may only be used under the following conditions: “The operator has notified to the competent authority of the Member State all the requisite evidence showing that the ingredient concerned is not produced in sufficient quantity in the Community in accordance with the organic production rules or cannot be imported from third countries;”	Notify to the CA evidence in case of use of ingredients not included in Annex IX	RCE 889/2008 Article 29 (1) (a)	1	Exceptionally	High	1	1	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
25	MS/CA	Processed feed and food: authorisation of non-organic ingredients	“Where an ingredient of agricultural origin is not included in Annex IX to this Regulation, that ingredient may only be used under the following conditions(...) The competent authority of the Member State has provisionally authorised , the use for a maximum period of 12 months after having verified that the operator has undertaken the necessary contacts with suppliers in the Community to ensure himself of the unavailability of the ingredients concerned with the required quality requirements;”	Authorisation of non-organic ingredients	RCE 889/2008 Article 29 (1) (b)	6 9	Exceptionally	High	1	0	0
26	MS/CA	Processed feed and food: authorisation of non-organic ingredients	Where an authorisation as referred to in paragraph 1 has been granted, the Member State shall immediately notify to the other Member States and to the Commission, the following information: “(a) the date of the authorisation and in case of a prolonged authorisation, the date of the first authorisation; (b) the name, address, telephone, and where relevant, fax and e-mail of the holder of the authorisation; the name and address of the contact point of the authority which granted the authorisation; (c) the name and, where necessary, the precise description and quality requirements of the ingredient of agricultural origin concerned; (d) the type of products for the preparation of which the requested ingredient is necessary; (e) the quantities that are required and the justification for those quantities; (f) the reasons for, and expected period of, the shortage; (g) the date on which the Member State sends this notification to the other Member States and the Commission. The Commission and/or Member States may make this information available to the public .	Notification of non-organic ingredient authorisations granted and possibly their publication	RCE 889/2008 Article 29 (2)	1	Exceptionally	Low	1	0	0
27	MS/CA	Processed feed and food: authorisation of non-organic ingredients	“Where a Member State submits comments to the Commission and to the Member State which granted the authorisation, which show that supplies are available during the period of the shortage” “The Member State (...) shall inform the Commission and the other Member States of the measures it has taken or will take, within 15 working days from the date of receipt of the information.”	Reply to comments concerning a non-organic ingredient authorisation	RCE 889/2008 Article 29 (3)	2	Exceptionally	Low	1	0	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
28	MS/CA	Processed feed and food: authorisation of non-organic ingredients	"In case of an extension as referred to in the second subparagraph of paragraph 1, the procedures of paragraphs 2 and 3 shall apply"	Notification and reply to comments in case of an extension of notification of authorisation of a non-organic ingredient	RCE 889/2008 Article 29 (5)	1 2	Exceptionally	Low	1	0	0
29	Operators	Processed feed and food: simultaneous organic and non-organic collection	"The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control body or control authority."	Keep information relating to collection and transport of products in case of simultaneous collection of organic and non-organic products	RCE 889/2008 Article 30	8	Regularly	Medium	1	1	1
30	Operators	Processed feed and food: labelling/traceability when transport and packaging	"Operators shall ensure that organic products are transported to other units, including wholesalers and retailers, only in appropriate packaging .(...) The information referred to in points (a) to (d) of the first subparagraph may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier and/or the transporter."	Keep information relating to packaging and transport	RCE 889/2008 Article 31 (1)	4	Regularly	Low	1	1	1
31	Operators	Processed feed and food: transport and packaging	"Both the expediting and the receiving operators shall keep documentary records of such transport operations available for the control body or control authority of such transport operations."	Keep documentary records of transport operations	RCE 889/2008 Article 31 (2) (c)	8	Regularly	Low	1	1	1
32	Operators	Processed feed and food: transport of feed	"Operators shall record these operations,"	Record cleaning measures if vehicles also used for transport of non-organic products	RCE 889/2008 Article 32 (b) (i)	8	Regularly	Low	1	1	1
33	Operators	Processed feed and food: transport of feed	"The operator shall keep documentary records of such transport operations available for the control body or control authority;"	Record transport operation in case vehicles also used for transport of non-organic products	RCE 889/2008 Article 32 (b) (iii)	8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
34	Operators	Processed feed and food: transport of feed	“During transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded .”	Record quantity during transport	RCE 889/2008 Article 32 (d)	7	Regularly	Low	1	1	1
35	Operators	Aquaculture: transport of live fish	“ Documentary evidence shall be maintained for paragraphs 1 to 3.”	Keep documentary evidence on transport of live fish	RCE 889/2008 Article 32a (4)	8	Regularly	Medium	1	1	1
36	Operators	Transport	“The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in Article 66.”	Record result of verification upon reception of products	RCE 889/2008 Article 33	8	Regularly	Low	1	1	1
37	Operators	Trade from 3C	“The result of this verification shall be explicitly mentioned in the documentary accounts referred to in Article 66 of this Regulation.”	Record verification of imported consignments	RCE 889/2008 Article 34	8	Regularly	Low	1	1	1
38	Operators	Storage	“Operators shall record these operations.”	record cleaning measures of storage facilities is also used for storage of non-organic products	RCE 889/2008 Article 35 (4) (c)	8	Regularly	Medium	1	1	1
39	MS/CA	Conversion rules	No information obligation, but strong burden for MS. The competent authority may decide to recognise retroactively as being part of the conversion period any previous period in which: (a) the land parcels were subject of measures defined in a programme implemented pursuant to Regulations (EC) No 1257/99, (EC) No 1698/2005, or in another official programme, provided that the measures concerned ensure that products not authorised for organic production have not been used on those parcels, or (b) the parcels were natural or agricultural areas which were not treated with products not authorised for organic production. The period referred to in point (b) of the first subparagraph can be taken into consideration retroactively only where satisfactory proof has been furnished to the competent authority allowing it to satisfy itself that the conditions were met for a period of at least three years.	Retroactive recognition of conversion period	RCE 889/2008 Article 36 (2)		when the triggering event occurs	High	1	1	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
40	MS/CA	Conversion rules	No information obligation, but strong burden for MS. In the case of parcels which have already been converted to or were in the process of conversion to organic farming, and which are treated with a product not authorised for organic production, the Member State may shorten the conversion period referred to in paragraph 1 in the following two cases: (a) parcels treated with a product not authorised for organic production as part of a compulsory disease or pest control measure imposed by the competent authority of the Member State; (b) parcels treated with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.	Shortening of conversion period	RCE 889/2008 Article 36 (4)		If needed	Medium	1	1	1
41	MS/CA	Conversion rules	In the case of parcels which have already been converted to or were in the process of conversion to organic farming, and which are treated with a product not authorised for organic production, the Member State may shorten the conversion period referred to in paragraph 1 in the following two cases: (a) parcels treated with a product not authorised for organic production as part of a compulsory disease or pest control measure imposed by the competent authority of the Member State; (b) parcels treated with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State. In the cases provided for in points (a) and (b) of the first subparagraph, the length of the conversion period shall be fixed taking into account of the following factors: (a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant; (b) the harvest following the treatment may not be sold with reference to organic production methods. The Member State concerned shall inform the other Member States and the Commission of its decision to require compulsory measures.	Information on decision to require compulsory measures (disease or pest control measures)	RCE 889/2008 Article 36 (4)	2	when the triggering event occurs	Low	1	1	1
42	Operators	Labelling	“The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.”	Labelling (code number, logo, place of farming)	RCE 834/2007 Article 24(2)	3	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
43	CB/control authorities	Labelling	Where terms as referred to in Article 23(1) are used: the code number referred to in Article 27(10) of the control authority/body to which the operator who has carried out the most recent production or processing operation is subject, shall also appear in the labelling.	Labelling (code number of CB)	RCE 834/2007 Article 24(1)	3	Regularly	High	1	1	1
44	Operators	Control	“ Notify his activity to the competent authorities of the Member State where the activity is carried out;”	Notification of activity to the CA	RCE 834/2007 Article 28 (1)(a)	1	Initial set up	Medium	1	1	1
45	Operators	Control	“The operator shall verify the documentary evidence of his suppliers.”	Verification of documentary evidence of suppliers	RCE 834/2007 Article 29 (2)	8	Regularly	Medium	1	1	1
46	MS/CA	Control: Infringements	“Where an irregularity is found ... the control authority or control body shall ensure that no reference to organic production method is made ... Where a severe infringement or infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products ... for a period to be agreed with the competent authority of the Member State.”	Prohibition to label or refer to organic production and/or to market products	RCE 834/2007 Article 30 (1)	8	when the triggering event occurs	High	1	1	1
47	CB/control authorities	Control: Infringements	“Where an irregularity is found ... the control authority or control body shall ensure that no reference to organic production method is made ... Where a severe infringement or infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products ... for a period to be agreed with the competent authority of the Member State.”	Prohibition to label or refer to organic production and/or to market products	RCE 834/2007 Article 30 (1)	8	when the triggering event occurs	Medium	1	1	1
48	MS/CA	Control: Infringements	Where a Member State finds irregularities or infringements relating to the application of this Regulation in a product coming from another Member State and bearing indications as referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation, it shall inform the Member State which designated the control body or control authority and the Commission thereby.	Notification of irregularities between MS	RCE 834/2007 Article 30 (2) RCE 889/2008 Article 92 (2)	10	when the triggering event occurs	High	1	1	1
49	MS/CA	Control: Infringements	“The competent authorities, control authorities and the control bodies shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies.”	Exchange of information on results of controls	RCE 834/2007 Article 31	10	Regularly	High	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
50	CB/control authorities	Control: Infringements	“The competent authorities, control authorities and the control bodies shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies.”	Exchange of information on results of controls	RCE 834/2007 Article 31	10	Regularly	Medium	1	1	1
51	CB/Control authorities	Control	By 31 January each year at the latest the control authorities and control bodies shall transmit to the competent authorities a list of the operators which were subject to their controls on 31 December of the previous year.	List of operators	RCE 834/2007 Article 27(14)	10	Annually	Low	1	1	1
52	CB/Control authorities	Control	A summary report of the control activities carried out during the previous year shall be provided by 31 March each year.	Summary report on CB activities	RCE 834/2007 Article 27(14)	2	Annually	High	1	1	1
53	Operators	Control: Infringements	“In case of such doubt, the operator shall immediately inform the control body or authority.”	Inform the CB in case of doubt	RCE 889/2008 Article 91 (1)	2	when the triggering event occurs	Medium	1	1	1
54	MS/CA	Control	Member States shall designate an authority or approve a body for the reception of such notifications	Designate or approve a body	RCE 834/2007 Article 28 (3)		Once for all new operations	Low	1	1	1
55	CB/Control authorities	Control	The control authorities and control bodies shall keep an updated list containing the names and addresses of operators under their control. This list shall be made available to the interested parties.	Keep updated list of operators	RCE 834/2007 Article 28(5)	4	Regularly	Low	1	1	1
56	MS/CA	Control	“The Member States shall make available to the public , in an appropriate manner including publication on the Internet, the updated lists referred to in Article 28(5) of Regulation (EC) No 834/2007 containing updated documentary evidence related to each operator, as provided for in Article 29(1) of that Regulation and using the model set out in Annex XII to this Regulation. The Member States shall duly observe the requirements of the protection of personal data as laid down in Directive 95/46/EC of the European Parliament and of the Council”	Publish list of operators	RCE 889/2008 Article 92 (a)	4	Initial set up and regular update	High	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
57	Operators	Control: minimum requirements	“When the control arrangements are first implemented, the operator shall draw up and subsequently maintain : (a) a full description of the unit and/or premises and/or activity; (b) all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules; (c) the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain; (d) the specific characteristics of the production method used, where the operator intends to request documentary evidence in accordance with Article 68(2).”	Control arrangements and undertaking necessary to enter the scheme	RCE 889/2008 Article 63 (1)	10	Initial set up	High	1	1	1
58	Operators	Control: minimum requirements	“The description and the measures ... shall be contained in a declaration, signed by the responsible operator. ”	Sign declaration of control arrangements and undertaking	RCE 889/2008 Article 63 (2)	8	Initial set up	Low	1	1	1
59	Operators	Control: minimum requirements	“For the application of Article 28(1) of Regulation (EC) No 834/2007 the operator shall notify the following information to the competent authority:”	Notification of activity to the competent authority	RCE 889/2008 Article 63 (3)	1	Initial set up	Low	1	1	1
60	Operators	Control: minimum requirements	“The operator responsible shall notify any change in the description or of the measures referred to in Article 63 and in the initial control arrangements set out in Articles 70, 74, 80, 82, 86 and 88 to the control authority or control body in due time.”	Notification of any change in control measures	RCE 889/2008 Article 64	1	when the triggering event occurs	High	1	1	1
61	Operators	Control: minimum requirements	“A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.”	Sign the control report	RCE 889/2008 Article 65 (3)	8	At each control	Low	1	1	1
62	Operators	Control: minimum requirements	“Stock and financial records shall be kept in the unit or premises and shall enable the operator to identify and the control authority or control body to verify:”	Keep stock and financial records	RCE 889/2008 Article 66 (1) (2)	8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
63	Operators	Control: minimum requirements	“The operator shall: (a) give the control authority or control body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents ; (b) provide the control authority or control body with any information reasonably necessary for the purposes of the control; (c) submit, when requested by the control authority or control body, the results of its own quality assurance programmes. 2. In addition to the requirements set out in paragraph 1, importers and first consignees shall submit the information on imported consignments referred to in Article 84.”	Provide information and access to facilities to the CB	RCE 889/2008 Article 67 (1) (2)	8	Regularly	Medium	1	1	1
64	Operators	Control: plant production records	“Plant production records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. In addition to Article 71 such records shall provide at least the following information:”	Keep register of plant production records	RCE 889/2008 Article 72	2	Regularly	High	1	1	1
65	Operators	Control: seaweed	“Seaweed production records shall be compiled in the form of a register by the operator and kept available for the control authorities or control bodies at all times at the premises of the holding. It shall provide at least the following information:”	Keep register of seaweed production records	RCE 889/2008 Article 73b (1)	2	Regularly	Low	1	1	1
66	Operators	Control: animal production	“Livestock records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. Such records shall provide a full description of the herd or flock management system comprising at least the following information:”	Keep register of livestock records	RCE 889/2008 Article 76	2	Regularly	High	1	1	1
67	Operators	Control: animal production	“Whenever veterinary medicinal products are used the information according to Article 76(e) is to be declared to the control authority or body before the livestock or livestock products are marketed as organically produced.”	Declare use of veterinary medicinal products	RCE 889/2008 Article 77	1	when the triggering event occurs	High	1	1	1
68	Operators	Control: animal production	“Livestock treated shall be clearly identified , individually in the case of large animals; individually, or by batch, or by hive, in the case of poultry, small animals and bees.”	Identify livestock treated with veterinary medicinal products	RCE 889/2008 Article 77	3	when the triggering event occurs	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
69	Operators	Control: beekeeping	A map on an appropriate scale listing the location of hives shall be provided to the control authority or control body by the beekeeper. Where no areas are identified in accordance with Article 13(2), the beekeeper shall provide the control authority or control body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation.”	Provide a map listing location of hives	RCE 889/2008 Article 78 (1)	10	Regularly	Low	1	1	1
70	Operators	Control: beekeeping	The following information shall be entered in the register of the apiary with regard to the use of feeding: type of product, dates, quantities and hives where it is used.”	Keep register of the apiary	RCE 889/2008 Article 78 (2)	10	when the triggering event occurs	Medium	1	1	1
71	Operators	Control: beekeeping	” Whenever veterinary medicinal products are to be used, the type of product, including the indication of the active pharmacological substance, together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period shall be recorded clearly and declared to the control body or authority before the products are marketed as organically produced.	Record use of veterinary medicinal products in beekeeping	RCE 889/2008 Article 78 (3)	1	when the triggering event occurs	Medium	1	1	1
72	Operators	Control: beekeeping	The zone where the apiary is situated shall be registered together with the identification of the hives. The control body or authority shall be informed of the moving of apiaries by a deadline agreed on with the control authority or body.	Register zone of situation of apiary and inform the CB in case of move	RCE 889/2008 Article 78 (4)	10	Initial set up/when the triggering event occurs	Low	1	1	1
73	Operators	Control: beekeeping	Particular care shall be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measures to comply with this requirement shall be recorded.	Record measures on extraction, processing and storage of beekeeping products	RCE 889/2008 Article 78 (5)	10	Regularly	Low	1	1	1
74	Operators	Control: beekeeping	The removals of the supers and the honey extraction operations shall be entered in the register of the apiary.	Record removals of the supers and the honey extraction	RCE 889/2008 Article 78 (6)	10	Regularly	Low	1	1	1
75	Operators	Control: aquaculture	“The following information shall be provided by the operator in the form of a register which shall be kept up to date and made available for the control authorities or control bodies at all times at the premises of the holding”	Keep register of aquaculture production record	RCE 889/2008 Article 79b	2 8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
76	Operators	Control: Imported products	“On request of the control authority or control body, any details on the transport arrangements from the exporter in the third country to the first consignee and, from the first consignee's premises or storage facilities to the consignees within the Community shall be provided .”	Provide details on transport arrangements for imported products if requested by CB	RCE 889/2008 Article 83	2 8	Upon request	Low	1	1	1
77	Operators	Control: Imported products	“The importer shall, in due time, inform the control body or control authority of each consignment to be imported into the Community, providing:”	Inform of each consignment to be imported	RCE 889/2008 Article 84	2	Each time a consignment is imported	High	1	1	1
78	Operators	Control: Imported products	“Where the importer performs the import operations by different units or premises, he shall make available on request the reports referred to in the second subparagraph of Article 63(2) of this Regulation for each of these facilities.”	Provide declaration of control arrangements and undertaking for each unit run by the importer	RCE 889/2008 Article 85	2	Upon request	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
79	CB/Control authorities	Control: Imported products	The request for inclusion shall consist of a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(3) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:(a) an overview of the activities of the control body or control authority in the third country or third countries, including an estimate of the number of operators involved and the expected nature and quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;(b) a description of the production standards and control measures applied in the third countries, including an assessment of the equivalence of these standards and measures with Titles III, IV and V of Regulation (EC) No 834/2007 as well as with the associated implementing rules laid down in Regulation (EC) No 889/2008;(c) a copy of the assessment report as set out in the fourth subparagraph of Article 33(3) of Regulation (EC) No 834/2007;(i) proving that the control body or control authority has been satisfactorily assessed on its ability to meet the conditions set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;(ii) confirming that it has effectively implemented its activities according to those conditions; and(iii) demonstrating and confirming the equivalence of the production standards and control measures referred to in subparagraph (b) of this paragraph;(d) proof that the control body or control authority has notified its activities to the authorities of each of the third countries concerned and its undertaking to respect the legal requirements imposed on it by the authorities of each of the third countries concerned;(e) the Internet website where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;(f) an undertaking to comply with the provisions of Article 12;(g) any other information deemed relevant by the control body or control authority or by the Commission	Request for inclusion in the list of recognized control bodies and control authorities for the purpose of equivalency	RCE 1235/2007 Article 11 (3)	6	Initial set up and upon expiry of inclusion	High	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
80	CB/Control authorities	Control: Imported products	by 31 March every year, the control body or control authority shall send a concise annual report to the Commission. The annual report shall update the information of the technical dossier referred to in Article 11(3); it shall describe in particular the control activities carried out by the control body or control authority in the third countries in the previous year, the results obtained, the irregularities and infringements observed and the corrective measures taken; It shall furthermore contain the most recent assessment report or update of such report, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual reassessment as referred to in Article 33(3) of Regulation (EC) No 834/2007; the Commission may request any other information deemed necessary;	Annual report by recognized control bodies and control authorities	RCE 1235/2007 Article 12 (1) b	2	Annually	High	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
81	Third countries	Control: imported products	Equivalency Third country. The Commission shall only be required to consider a request for inclusion which meets the following preconditions. The request for inclusion shall be completed by a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(1) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely: (a) general information on the development of organic production in the third country, the products produced, the area in cultivation, the production regions, the number of producers, the food processing taking place; (b) an indication of the expected nature and quantities of organic agricultural products and foodstuffs intended for export to the Community; (c) the production standards applied in the third country as well as an assessment of their equivalence to the standards applied in the Community; (d) the control system applied in the third country, including the monitoring and supervisory activities carried out by the competent authorities in the third country, as well as an assessment of its equivalent effectiveness when compared to the control system applied in the Community; (e) the Internet or other address where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status and the product categories concerned; (f) the information the third country proposes to include in the list as referred to in Article 7; (g) an undertaking to comply with the provisions of Article 9; (h) any other information deemed relevant by the third country or by the Commission.	Request for inclusion in the list of recognized third countries for the purpose of equivalence	RCE 1235/2007 Article 8 (2) and Article 9 (1) a	10	Initial set up and update	Low	1	1	1
82	Third countries	Control:import ed products	Equivalency Third country. The Commission shall only be required to consider a request for inclusion when the third country undertakes to accept the following conditions: (...) (b) the annual report referred to in Article 33(2) of Regulation (EC) No 834/2007 shall update the information of the technical dossier referred to in Article 8(2) of this Regulation; it shall describe in particular the monitoring and supervisory activities carried out by the competent authority of the third country, the results obtained and the corrective measures taken	Annual report by recognized third countries	RCE 1235/2007 Article 9 (1) b	3	Annually	Low	1	1	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
83	MS/CA	Control:imported products	Equivalency Third country and control bodies. For each request received, and after appropriate consultation with Member States in accordance with the specific internal rules of procedure, the Commission shall nominate two Member States to act as co-reporters. The Commission shall divide the requests between the Member States proportionally with the number of votes of each Member State in the Committee on organic production. The co-reporting Member States shall examine the documentation and information as set out in Articles 4, 8 and 11 related to the request and shall draw up a report. For the management and review of the lists, they shall also examine the annual reports and any other information referred to in Articles 5, 9 and 12 related to the entries on the list	Co-reporting obligations of MS	RCE 1235/2007 Article 16 (2)	10	For each request received / continuous supervision	High	1	1	1
84	Operators	Control: Outsourcing of operations	“All the practical measures, including inter alia an appropriate system of documentary accounts , to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers.”	Keep documentary accounts to ensure traceability in case of sub-contracting	RCE 889/2008 Article 86 (c)	8	Regularly	Low	1	1	1
85	Operators	Control: feed preparation	“For the purposes of proper control of the operations, the documentary accounts referred to in Article 66 shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.”	Keep documentary accounts for units preparing feed	RCE 889/2008 Article 89	8	Regularly	Low	1	1	1
86	Operators	Control: Imported products	“The original of the certificate referred to in this paragraph shall accompany the goods to the premises of the first consignee; thereafter the importer must keep the certificate at the disposal of the control authority or the control body for not less than two years. ”	Import certificate must accompany the goods and be kept by the importer for at least 2 years	RCE 834/2007 Article 33 (1)	4	Regularly	Medium	1	1	1
87	Operators	Control: Imported products	Certificate of inspection 1. The release for free circulation in the Community of a consignment of products referred to in Article 1(2) of Regulation (EC) No 834/2007 and imported in accordance with Article 33 of that Regulation shall be conditional on: (a) the submission of an original certificate of inspection to the relevant Member State’s authority; and	Certificate of inspection (import certificate) must be submitted to the MS authority	RCE 1235/2008 Article 13 (1) (a)		Regularly	High	1	1	1
88	MS/CA	Control: Imported products	“(b) on the verification of the consignment by the relevant Member State’s authority and the endorsement of the certificate of inspection in accordance with paragraph 8 of this Article.”	Certificate of inspection must be endorsed by the MS authority before free circulation	RCE 1235/2008 Article 13 (1) (b) and 13 (8)	8	Regularly	High	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
89	Operators	Control: Imported products	“The first consignee or, where relevant, the importer may make a copy for the purpose of informing the control authorities and control bodies in accordance with Article 83 of Regulation (EC) No 889/2008. Any such copy shall carry the indication ‘COPY’ or ‘DUPLICATE’ printed or stamped thereon.”	Copy of certificate of inspection for control and notification purposes	RCE 1235/2008 Article 13 (6)	4	Regularly	Low	1	1	1
90	Operators	Control: Imported products	“The first consignee shall, at the reception of the consignment, complete box 18 of the original of the certificate of inspection, to certify that the reception of the consignment has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008.	Signature of the import certificate of the first consignee	RCE 1235/2008 Article 13 (9)	4	Regularly	Low	1	1	1
91	Operators	Control: Imported products	The first consignee shall then send the original of the certificate to the importer mentioned in box 11 of the certificate, for the purpose of the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007, unless the certificate has to further accompany the consignment referred to in paragraph 1 of this Article.”	Sending the import certificate by the first consignee to the importer	RCE 1235/2008 Article 13 (9)	4	Regularly	Low	1	1	1
92	CB/control authorities	Control: Imported products	3. To be accepted, the certificate of inspection must have been issued by the control authority or control body 4. The authority of body issuing the certificate of inspection shall	Issuing of the certificate of inspection and endorsement of box 15	RCE 1235/2008 Article 13 (3)(4)	4	Regularly	Medium	1	1	1
93	MS/CA	Control: Imported products	“After this preparation, the endorsed original of the certificate of inspection shall accompany the consignment, and shall be presented to the relevant Member State’s authority , which shall verify the consignment for the purpose of its release for free circulation.”	Procedure for warehousing or inward processing	RCE 1235/2008 Article 14 (1)	9	Regularly	Low	1	1	1
94	MS/CA	Control: Imported products	“After this procedure, the original of the certificate of inspection shall, where relevant, be returned to the importer of the consignment, referred to in box 11 of the certificate to fulfil the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007.”	Procedure for warehousing or inward processing	RCE 1235/2008 Article 14 (1)	4	Regularly	Low	1	1	1
95	Operators	Control: Imported products	“For each of the batches which results from the splitting, an extract of the certificate of inspection shall be submitted to the relevant Member State’s authority, in accordance with the model and the notes set out in Annex VI.	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	2	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
96	MS/CA	Control: Imported products	The extract from the certificate of inspection shall be endorsed by the relevant Member State's authorities in box 14."	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	2	Regularly	Low	1	1	1
97	Operators	Control: Imported products	"A copy of each endorsed extract from the certificate of inspection shall be kept together with the original certificate of inspection by the person identified as the original importer of the consignment and mentioned in box 11 of the certificate of inspection. This copy shall carry the indication 'COPY' or 'DUPLICATE' printed or stamped thereon."	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	4	Regularly	Low	1	1	1
98	Operators	Control: Imported products	"After the splitting, the endorsed original of each extract of the certificate of inspection shall accompany the batch concerned, and shall be presented to the relevant Member State's authority, which shall verify the batch concerned for the purpose of its release for free circulation."	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	8	Regularly	Low	1	1	1
99	MS/CA	Control: Imported products	which shall verify the batch concerned for the purpose of its release for free circulation."	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	8	Regularly	Low	1	1	1
100	Operators	Control: Imported products	"The consignee of a batch shall, at the reception thereof complete the original of the extract of the certificate of inspection in box 15, in order to certify that the reception of the batch has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008." "The consignee of a batch shall keep the extract of the certificate of inspection at the disposal of the control authorities and/or control bodies for not less than two years."	Procedure for splitting into different batches	RCE 1235/2008 Article 14 (2)	4	Regularly	Low	1	1	1
101	MS/CA	Control: Imported products	"Where a competent authority of a third country recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007 or a control authority or control body recognised in accordance with Article 33(3) of that Regulation is notified by the Commission after having received a communication from a Member State informing it of a substantiated suspicion of an infringement or irregularity as regards compliance of imported organic products with the requirements laid down in that Regulation or this Regulation, it shall investigate the origin of the suspected irregularity or infringement and..."	Notification of irregularities in imported products	RCE 1235/2008 Article 15 (4)	1	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
102	Third countries	Control: Imported products	“Where a competent authority of a third country recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007 or a control authority or control body recognised in accordance with Article 33(3) of that Regulation is notified by the Commission after having received a communication from a Member State informing it of a substantiated suspicion of an infringement or irregularity as regards compliance of imported organic products with the requirements laid down in that Regulation or this Regulation, it shall investigate the origin of the suspected irregularity or infringement and shall inform the Commission and the Member State which sent the initial communication of the result of the investigation and of the action taken. That information shall be sent within 30 calendar days ... ”	Reply to notification of irregularities in imported products	RCE 1235/2008 Article 15 (4)	2	Upon request	Low	1	1	1
103	CB/control authority	Control: Imported products	“Where a competent authority of a third country recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007 or a control authority or control body recognised in accordance with Article 33(3) of that Regulation is notified by the Commission after having received a communication from a Member State informing it of a substantiated suspicion of an infringement or irregularity as regards compliance of imported organic products with the requirements laid down in that Regulation or this Regulation, it shall investigate the origin of the suspected irregularity or infringement and shall inform the Commission and the Member State which sent the initial communication of the result of the investigation and of the action taken. That information shall be sent within 30 calendar days ... ”	Reply to notification of irregularities in imported products	RCE 1235/2008 Article 15 (4)	2	Upon request	Low	1	1	1
104	MS/CA	Control: Imported products	“The Member State which sent the initial communication may ask the Commission to request additional information , if needed, which shall be sent to the Commission and to the Member State concerned.”	Request for additional information in case of irregularities in imported products	RCE 1235/2008 Article 15 (4)	2	If needed	Low	1	1	1
105	MS/CA	Control: Imported products	“In any case, after receiving a reply or additional information, the Member State which sent the initial communication shall make the necessary entries and updates in the computer system referred to in Article 94(1) of Regulation (EC) No 889/2008”	Update of OFIS - module Irregularities imports	RCE 1235/2008 Article 15 (4)	2	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
106	MS/CA	Control	<u>Information on the competent authorities, control authorities and bodies</u> “Members States shall regularly transmit the following information to the Commission:(a) the names and addresses of the competent authorities and where appropriate their code numbers and their marks of conformity;	Information on designation of the competent authority	RCE 834/2007 Article 35 (a) RCE 889/2007 Article 94 (1) a	2	Initial set up and regular update	Low	1	1	1
107	MS/CA	Control	<u>Information on the competent authorities, control authorities and bodies</u> “Members States shall regularly transmit the following information to the Commission: (b) lists of control authorities and bodies and their code numbers and, where appropriate, their marks of conformity.”	List of control bodies and control authorities	RCE 834/2007 Article 35 (b) RCE 889/2008 Article 94 (9) b	2	Annually	Low	1	1	1
108	MS/CA	Statistical information	<u>Annual statistical information for the implementation and follow-up of the Regulation</u> “Member States shall transmit to the Commission the statistical information necessary for the implementation and follow-up of this Regulation” “Member States shall provide the Commission with the annual statistical information on organic production referred to in Article 36 of Regulation (EC) No 834/2007 by using the computer system enabling electronic exchanges of documents and information made available by the Commission (Eurostat) before 1 July each year.”	Statistics	RCE 834/2007 Article 36 RCE 889/2008 Article 93 (1)	2	Annually	High	1	1	1
109	MS/CA	Control: exceptions	Authorisations for tethered cattle		RCE 889/2008 Article 95 (1)	2	Exceptionally	Medium	1	0	0
110	Operators	Control: exceptions	Authorisation from MS housing conditions and stocking densities (till 31/12/2013). “The operators benefiting from this extension shall present a plan to the control authority or control body, containing the description of arrangements which are intended to ensure compliance with the provisions of the organic production rules by the end of the transitional period.”		RCE 889/2008 Article 95 (2)	2	Exceptionally	Low	1	0	0
111	Operators	Wine	“Operators using ‘Organic logo of the EU’ shall keep recorded evidence, for a period of at least five years after they placed on the market that wine obtained from organic grapes, including of the corresponding quantities of wine in litres, per wine category and per year;”		RCE 889/2008 Article 95 (10a) (b)	8	Regularly	Low	1	1	1

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
112	Operators	Aquaculture and seaweed production	“Operators benefiting from this measure shall notify the facilities, fishponds, cages or seaweed lots which are concerned to the competent authority.”	Transitional measure for aquaculture and seaweeds units to operate under national rules	RCE 889/2008 Article 95 (11)	1	Exceptionally	Low	1	1	1
113	Operators	Exceptions	“The control authority or control body is notified of the harvest of each of the products concerned at least 48 hours in advance”	Inform CB prior to the harvest in case of parallel production	RCE 834/2007 Article 22(2) RCE 889/2008 Article 40(1) (a) iii	1	Each harvest	Medium	1	0	0
114	Operators	Exceptions	Parallel production “The producer informs the control authority or control body of the exact quantities harvested on the units concerned and of the measures applied to separate the products;”	Inform CB after the harvest in case of parallel production	RCE 889/2008 Article 40 (1) (a) (iv)	2	Each harvest	Low	1	0	0
115	MS/CA	Exceptions	"The conversion plan and the control measures referred to in Chapter 1 and 2 of Title IV have been approved by the competent authority ; this approval shall be confirmed each year after the start of the conversion plan"	Annual approval and confirmation of conversion plans by the MS	RCE 889/2008 Article 40(1) (a) (v)	8	Exceptionally	Low	1	0	0
116	Operators	Exceptions	“Appropriate measures, notified in advance to the control authority or control body, have been taken in order to guarantee the permanent separation between livestock, livestock products, manure and feedingstuffs of each of the units;”	Notify separation measures in case of parallel production of same animal species authorised for research or educational purposes	RCE 889/2008 Article 40 (2) (a)	1	Exceptionally	Low	1	0	0
117	Operators	Exceptions	“The producer informs the control authority or control body in advance of any delivery or selling of the livestock or livestock products;	Advance notification of selling or delivery in case of parallel production of same animal species authorised for research or educational purposes	RCE 889/2008 Article 40 (2) (b)	2	Exceptional, for research, educational purposes	Low	1	0	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
118	Operators	Exceptions	The operator informs the control authority or control body of the exact quantities produced in the units together with all characteristics permitting the identification of the products and confirms that the measures taken to separate the products have been applied.”	Information on quantities produced in case of parallel production of same animal species authorised for research or educational purposes	RCE 889/2008 Article 40 (2) (c)	2	Exceptional, for research, educational purposes	Low	1	0	0
119	Operators	Exceptions	“The operator shall keep documentary evidence of the use of this provision.”	Keep documentary evidence in case of exceptional authorisation to run organic and non-organic beekeeping units on the same holding	RCE 889/2008 Article 41	8	Regularly	Low	1	0	0
120	MS/CA	Exceptions	Prior authorisation of MS: Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply, and with prior authorisation of the competent authority, (a) when a flock is constituted for the first time, renewed or reconstituted and organically reared poultry are not available in sufficient numbers, non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old;	Authorisation of MS to bring non-organic reared poultry to the holding	RCE 889/2008 Article 42 (a)		When MS grants exceptions	Low	1	0	0
121	Operators	Exceptions	(herd, bees, feed, wine) “Upon approval by the competent authority, the individual operators shall keep documentary evidence of the use of the above exceptions.”	Keep documentary evidence on the use of exception granted by the MS in case of catastrophic circumstances	RCE 889/2008 Article 47	8	when the triggering event occurs	Low	1	0	0
122	MS/CA	Exceptions	“Member States shall inform each other and the Commission on the exceptions they have granted under points (c) and (e) of the first paragraph.”	Inform the MS and Commission of exceptions granted in case of catastrophic circumstances	RCE 889/2008 Article 47	2	when the triggering event occurs	Low	1	0	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
123	MS/CA	Exceptions	Member state may authorise use of non-organic seeds or vegetative material	Authorisation of non-organic seeds	RCE 889/2008 Article 45(1)(b)	6	when the triggering event occurs	High	1	0	0
124	CB/Control authorities	Exceptions	Member state may delegate the responsibility for granting the authorisation referred to paragraph 1(b) to another public administration under their supervision or to the control authorities or control bodies.	Authorisation of non-organic seeds	RCE 889/2008 Article 45(4)	6	when the triggering event occurs	High	1	0	0
125	Operators	Exceptions	"The authorisation shall be granted only to individual users for one season at a time and the authority or body responsible for the authorisation shall register the quantities of seed or seed potatoes authorised"	Authorisation of non-organic seeds	RCE 889/2008 Article 45(7))	2	Exceptionally	High	1	0	0
126	MS/CA	Seeds data base	"Each Member State shall ensure that a computerised database is established for the listing of the varieties for which seed or seed potatoes obtained by the organic production method are available on its territory."	Seed database set-up	RCE 889/2008 Article 48 (1) (2)	4	Initial set up and regular update	High	1	0	0
127	MS/CA	Seeds data base	"Each Member State shall inform the Commission and the other Member States of the authority or private body designated to manage the database."	Information on body designated to manage the seed database	RCE 889/2008 Article 48 (3)	2	Initial set up and regular update	Low	1	0	0
128	MS/CA	Seeds data base	"Varieties for which seed or seed potatoes produced by the organic production method are available shall be registered in the database referred to in Article 48 at the request of the supplier."	Registration of available seed in the seed database	RCE 889/2008 Article 49 (1)	7	Upon request of a supplier	Low	1	0	0
129	Operators (suppliers)	Seeds data base	For registration, the supplier shall: (a) demonstrate that he or the last operator, in cases where the supplier is only dealing with pre-packaged seed or seed potatoes, has been subject to the control system referred to in Article 27 of Regulation (EC)No 834/2007; (b) demonstrate that the seed or seed potatoes to be placed on the market comply with the general requirements applicable to seed and seed potatoes; (c) make available all the information required under Article 51 of this Regulation, and undertake to update this information at the request of the manager of the database or whenever such updating is necessary to ensure that the information remains reliable.	Information to be provided by supplier for registration to the seed database	RCE 889/2008 Article 50 (1)	2	Initial set up and regular update	Medium	1	0	0

N° crt	Target group	Type of rules	Description	Short description	Legal reference	Type IO	Frequency	Significance	Improved status quo	Market driven	Principle driven
130	Operators (suppliers)	Seeds data base	“The supplier shall immediately inform the manager of the database if any of the registered varieties are no longer available. The amendments shall be recorded in the database.”	Inform manager of the seed database if registered varieties are no longer available	RCE 889/2008 Article 51 (2)	2	When registered varieties are no longer available	Medium	1	0	0
131	MS/CA	Seeds data base	“The supplier shall immediately inform the manager of the database if any of the registered varieties are no longer available. The amendments shall be recorded in the database.”	Update of seed database	RCE 889/2008 Article 51 (2)	2	When registered varieties are no longer available	Low	1	0	0
132	MS/CA	Seeds data base	The information in the database referred to in Article 48 shall be available through the Internet , free of cost, to the users of seed or seed potatoes and to the public. Member States may decide that any user who has notified its activity in accordance with Article 28(1)(a) of Regulation (EC) No 834/2007 may obtain, on request, an extract of data concerning one or several groups of species from the database manager.	Publish the seed database on the Internet	RCE 889/2008 Article 52 (1)	2	Continuously	Low	1	0	0
133	MS/CA	Seeds data base	“The Member States shall ensure that all users referred to in paragraph 1 are informed , at least once a year, about the system and how to obtain the information in the database.”	Inform the users about the seed database	RCE 889/2008 Article 52 (2)	2	Annually	Low	1	0	0
134	MS/CA	Seeds data base	“The competent authority of the Member State shall, before 31 March each year, collect the reports and send a summary report covering all authorisations of the Member State from the previous calendar year to the Commission and to the other Member States.”	Seed report	RCE 889/2008 Article 55	2	Annually	High	1	0	0
135	MS/CA	Seeds data base	“The information shall be published in the database referred to in Article 48.”	Publish the seed report in the seed database	RCE 889/2008 Article 55	4	Annually	Low	1	0	0

ANNEX 17: REFERENCE DOCUMENTS

1. Economic data - organic farming sector

- **Facts and figures on organic agriculture in the European Union** – European Commission - DG Agriculture and Rural Development – October 2013
- Eurostat – Agriculture and Fisheries - Statistics in focus 10/2010
- **Eurobarometer report n° 389** (What Europeans think of food security, food quality and the relation between agriculture & the countryside - July 2012)
- **The world of organic agriculture statistics and emerging trends 2013** – FIBL and IFOAM
- **Analyse der Entwicklung des ausländischen Angebots bei Bioprodukten mit Relevanz für den deutschen Biomarkt** (analysis of imports of organic products with relevance for the German organic market) – BÖLN (Bundesprogramm Ökologischer Landbau and andere Formen nachhaltiger Landwirtschaft), Diana Schaak et al; 2011.
- **Organic Monitor: the Global Market for Organic Food and Drink: Business Opportunities and Future Outlook** (Third edition, 2010).
- **L'Agriculture biologique – ses acteurs, ses produits, ses territoires**, édition 2012. Agence Bio (France) + dossier de presse: le marché des produits bio, septembre 2013.
- **Gain Report Number: NL3003 Export opportunities for U.S. organics in the EU market** – 2/11/2013 The Hague
- **Organic versus conventional farming, which performs better financially?** An overview of organic field crop and milk production in selected Member States. Farm Economics Briefs, No 4, November 2013, European Commission, DG Agriculture and Rural Development.

2. Legal texts and related documents

Organic farming

- Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 22.7.1991, p. 1) and amendments
- Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91 and amendments
- **Report from the Commission to the European Parliament and the Council on the application of Council Regulation (EC) No 834/2007** on organic production and labelling of organic products Com 2012(212) final
- Commission Regulation (EC) No. 889/2008 of 5 September 2008 with detailed rules on production, labelling and control and amendments
- Commission Regulation (EC) No. 1235/2008 of 8 December 2008 with detailed rules concerning import of organic products from third countries and amendments

- Commission Decision 2009/427/EC of 3 June 2009 establishing the Expert Group for Technical Advice on Organic Production (EGTOP).
- Commission Decision 2010/C 262/03 of 28 September 2010 appointing the members of the group for technical advice on organic production and drawing up the pool list.
- Commission Decision No 391/2004 of 23 April 2004 on the advisory groups dealing with matters covered by the common agricultural policy UE OJ L 120, 24.4.2004, p. 50
- Codex Alimentarius Guidelines for the Production, Processing, Labelling and Marketing of Organically produced foods (GL 32-1999)
- Commission interpretative notes (RIPAC): Note No 2012/3, Exemption from control, Council Regulation No 834/2007, article 28(2) and No 2012-02, May 2012.

Controls and accreditation

- Regulation No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).
- Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation) - COM(2013) 265 final of 6.5.2013
- Working document of the Commission services on official controls in the organic sector (AGRI H3 – July 2011)
- Special Report No 9/2012 (discharge 2011) - 'Audit of the control system governing the production, processing, distribution and imports of organic products' from the European Court of Auditors', 25 June 2012
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 – OJ L 218, 13.8.2008, p. 30
- European co-operation for Accreditation (EA):
 - EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites (Ref: EA-6/04:2011)
 - EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members (Ref: EA-2/13 M:2012)
 - EA Policy for the Accreditation of Organic Production Certification (Ref: EA-3/12 M: 2013)
- Commission services' working document: Guidelines on imports of organic products into the European Union, 15.12.2008.

Other legal texts and related documents quoted in the report

- Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs - OJ L 343, 14.12.2012, p. 1.
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 – OJ L 304, 22.11.2011, p. 18.
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC - OJ L 309, 24.11.2009, p. 1–50
- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance - OJ L 70, 16.3.2005, p. 1–16
- Commission Directive of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC) - OJ L 175, 4.7.1991, p. 35–49
- Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, OJ L 221, 8.8.1998, p. 23–27
- Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97, OJ L 3, 5.1.2005, p. 1–44
- Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance), OJ L 303, 18.11.2009, p. 1–30
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed – UE OJ L 268, 18.10.2003, p. 1.
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – UE OJ L 106, 17.4.2001, p. 1.
- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC – UE OJ L 268, 18.10.2003, p. 24.
- Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999).
- Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200 of 22 July 2010

- Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy, OJ L 209, 11/08/2005, p. 1.
- Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), OJ L 342, 22.12.2009, p. 1
- Council Regulation (EC) No 814/2000 of 17 April 2000 on information measures relating to the common agricultural policy–OJ L 100, 20.04.2000, p. 7.

3. Policy

- Communication from the Commission to the Council and the European Parliament - **European Action Plan for Organic Food and Farming** - {SEC(2004)739}2004 and Commission staff working document - Annex to the Communication from the Commission {COM(2004)415 final}
- **The reform of the CAP towards 2020** - Consultation Document for Impact Assessment (DG AGRI)
- Commission staff working paper – Impact Assessment - Common Agricultural Policy towards 2020, accompanying proposals for Regulations of the European Parliament and of the Council (SEC(2011) 1153 final/2).
- Report from the Commission to the European Parliament and the Council on the application of Council Regulation (EC) No 3/2008 on information provision and promotion measures for agricultural products on the internal market and in third countries COM(2010) 692 final.
- Commission staff working document accompanying the Report from the Commission to the European Parliament and the Council on the application of Council Regulation (EC) No 3/2008 on information provision and promotion measures for agricultural products on the internal market and in third countries.

4. Studies – Research projects

- **External evaluation of the legislation on organic farming**, draft final report, September 2013. Coordination: Thünen Institute of Farm Economics Braunschweig/Germany.
- **A decade of EU-funded, low-input and organic agriculture research** (2000-2011) European Commission, Directorate-General for Research and Innovation
- **CERTCOST** (European research project on certification of organic food – 2008-2011): economic analysis of certification systems for organic food and farming. www.certcost.org
- **QualityLowInputFood** (integrated project funded by the European Commission – 2004-2009).
- **ICOPP** (Improved contribution of local feed to support 100 % organic feed supply to pigs and poultry) - project coordinated by the International Centre for Research in Organic Foods Systems (ICROFS) and funded under the CORE Organic II - FP7 ERA-Net project)

- **SOLIBAM** (Strategies for Organic and Low-input Integrated Breeding and Management), 7th Framework programme- <http://www.solibam.eu>
- Study report: **Use and efficiency of public support measures** addressing organic farming – Institute of Farm economics - Thünen Institute –financed by the European Commission, November 2011
- **Short Food Supply Chains and Local Food Systems in the EU**. A State of Play of their Socio-Economic Characteristics – European Commission, JRC Scientific and Policy Reports, May 2013
- **EU Ecolabel for food and feed products** – feasibility study (ENV.C.1/ETU/2010/0025) – Oakdene Hollins Research and Consulting
- **A meta-analysis of the differences in environmental impacts between organic and conventional farming**, Mondelaers, K; et al, 2009, British Food Journal 111 (10): 1098-1119.
- **Can Organic Farming Feed Us All?** Brian Halweil, World Watch Magazine, May/June 2006, Volume 19, No. 3.
- **Le Bio peut-il nourrir durablement la planète?** Marc Dufumier – Professeur d'agriculture comparée et développement agricole à AgroParisTech, Grand débat sur la Bio, journée débat organisée par la Chambre Régionale d'Agriculture des Pays de la Loire, France, le 19/11/2010.
- **Assessing the risk of farm abandonment in the EU** - European Commission, JRC Scientific and Policy Reports – 2013
- **The Reliability of Certification: Quality Labels as a Consumer Policy Tool** – Jahn et al. Journal of Consumer policy (2005) 28: 53-73.
- **The influence of subjective and objective knowledge on attitude, motivations and consumption of organic food**. Aertens et al. British Food Journal, Vol. 113 No 11, 2011 pp. 1353-1378.
- **Consumer knowledge, consumption, and willingness to pay for organic tomatoes**, Mesias et al. British Food Journal Vol. 114 No.3, 2012 pp. 318-334.
- **Consumer attitudes towards organic versus conventional food** with specific quality attributes – Stolz et al, NJAS – Wageningen Journal of Life Sciences 58(2011) 67- 72.
- Consumer perception of different organic certification schemes in five European countries - Janssen, M. and Hamm, U. (2011). Organic Agriculture 1(1):31-43.
- **Consumer market study on the functioning of voluntary food labelling scheme for consumers in the EU**. Draft final report by Ipsos and London Economics Consortium. September 2013
- **The state and consumer confidence in eco-labelling: organic labeling in Denmark, Sweden, The UK and the US** – Kim Mannemar Sønderskov - Carsten Daugbjerg. Department of Political Science, Aarhus University, Denmark. Agric Hum Values (2001) 28:507-517.
- **Les enjeux de la production d’agriculture biologique en France”**
<http://www.agreste.agriculture.gouv.fr/IMG/pdf/analyse501207.pdf>,
Biblio AB_enviro_RMT_DevAB

- **Pilot Project Group certification in Europe**, end report, Agro Eco, Ferko Bodnár, May 2008. The pilot project was funded through the "IFOAM-Growing Organic" programme and the "Fund for Sustainable Biodiversity Management" of the Dutch government
- **Study on administrative burden reduction associated with the implementation of certain rural development measures**, 11 August 2011, available at: http://ec.europa.eu/agriculture/analysis/external/rd-simplification/index_en.htm
- **Study on the costs and benefits to organisations of EMAS registration (2009)**- Study Contract No. 07.0307/2008/517800/ETU/G.2 – Milieu, environmental law and policy
- **What is a small farm?** European Commission, Directorate General for Agriculture and Rural Development – EU Agriculture Economic Briefs: Brief No 2
- **Informe Empleo verde en una economía sostenible (2012)**, Luis M. Jiménez Herrero (OSE) y Ana Leiva (FB).

5. Others

- Commission Communication — EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs. EU OJ 2010/C 341/04, 16.12.2010, p. 5.
- European Food Safety Authority – 2010 EU Report on Pesticide Residues in Food
- BNN (Bundesverband Naturkost Naturwaren): Orientation Value for pesticides - A guideline to evaluate pesticide residues in organic products (http://www.n-bnn.de/html/img/pool/BNNOrientierungswert_EN_1208.pdf)
- "10 years of organic monitoring 2002-2011" Baden-Württemberg (http://www.mlr.baden-wuerttemberg.de/mlr/bro/10_Jahre_Oekomonitoring_engl.pdf).
- USDA Organic – National Organic Programme: Instruction – Responding to Pesticide Residue Testing, NOP 2613 of 4 March 2013 (<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5102727>)
- Bio-Suisse – evaluation of pesticide residues in bud products:http://www.bio-suisse.ch/media/en/pdf2011/e_bio_suisse_decision_chart_pesticide_06122011.pdf
- Italian Ministerial Decree No 309 of 13 January 2011 on "accidental and technically unavoidable contamination of phytosanitary products in organic farming".
- Order of the Regional Government of Wallonia on organic production and labelling of organic products, 11th of February 2010, Annex I, Chapter 3 concerning planning, execution and interpretation of analysis mentions.
- IFOAM EU Group “Guideline for Pesticide Residue Contamination for International Trade in Organic”
- EOCC – Pesticide Residues Guideline: A guidance document for the certification decision making process Version: January 2013



Bruxelas, 24.3.2014
SWD(2014) 66 final

DOCUMENTO DE TRABALHO DOS SERVIÇOS DA COMISSÃO

SÍNTESE DA AVALIAÇÃO DE IMPACTO

que acompanha o documento

**Proposta de
REGULAMENTO DO PARLAMENTO EUROPEU E DO CONSELHO**

que diz respeito à produção biológica e à rotulagem dos produtos biológicos, que altera o Regulamento (UE) n.º XXX/XXX do Parlamento Europeu e do Conselho [Regulamento relativo aos controlos oficiais] e que revoga o Regulamento (CE) n.º 834/2007 do Conselho

{ COM(2014) 180 final }

{ SWD(2014) 65 final }

1. CONTEXTO

A presente avaliação de impacto centrou-se no seguinte:

- eficácia dos instrumentos legislativos, nomeadamente o **Regulamento (CE) n.º 834/2007 do Conselho¹ relativo à produção biológica e à rotulagem dos produtos biológicos** e os respetivos regulamentos de execução;
- importância de um **novo plano de ação** para a agricultura biológica na UE.

No Regulamento (CE) n.º 834/2007, o **Conselho destacou uma série de questões** sobre as quais a Comissão adotou um relatório² em maio de 2012. **O Conselho adotou conclusões³ sobre o relatório** em maio de 2013, instando ao desenvolvimento do setor da agricultura biológica a um nível ambicioso e à revisão do atual quadro jurídico.

Um relatório especial⁴ do **Tribunal de Contas Europeu** assinalou diversos pontos fracos no **sistema de controlo** da produção biológica e incluiu recomendações para os corrigir.

A revisão da legislação relativa à agricultura biológica é parte do **Programa para a adequação e a eficácia da regulamentação (REFIT) da Comissão⁵**.

A avaliação de impacto foi realizada com o apoio de um grupo diretor interserviços da Comissão. A análise baseia-se em audições de peritos e organizações, nos resultados de uma **vasta consulta pública** (quase 45 000 respostas) e de consultas específicas, nomeadamente aos Estados-Membros e ao Grupo Consultivo «Agricultura Biológica».

2. DEFINIÇÃO DO PROBLEMA

2.1. Problema geral e causas do problema

O objetivo geral do atual quadro político e legislativo da UE consiste em assegurar o desenvolvimento sustentável da produção biológica. Espera-se que a agricultura biológica se desenvolva em paralelo com o mercado biológico na UE. No entanto, o mercado biológico quadruplicou praticamente entre 1999 e 2011, mas a superfície dedicada à produção biológica na UE na década 2000-2010 apenas duplicou. A diferença entre a produção e a procura na UE é coberta por importações, o que tem como consequência:

- a perda de oportunidades para os produtores da UE,
- o risco de limitação da expansão do mercado biológico,
- o risco de limitação dos benefícios ambientais associados com a agricultura biológica.

¹ JO L 189 de 20.7.2007, p.1.

² COM(2012) 212 final.

³ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/agricult/137076.pdf

⁴ Relatório Especial n.º 9/2012 - 26 de junho de 2012.

⁵ COM(2012) 746 final.

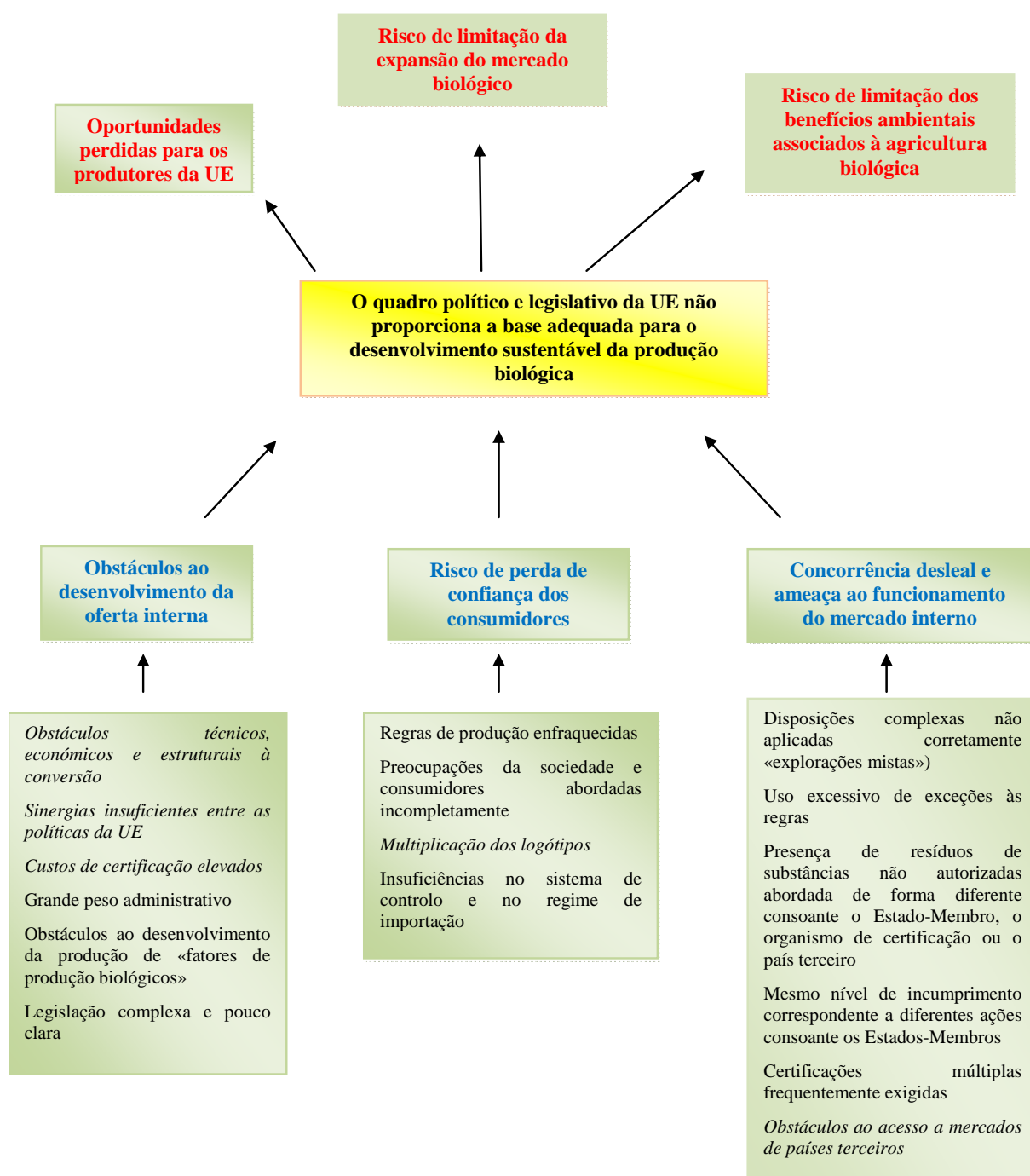
A insuficiente conversão para a agricultura biológica constitui o principal obstáculo ao desenvolvimento da produção biológica na UE. Quanto a outros aspetos, as variedades vegetais especificamente selecionadas na agricultura biológica e para a agricultura biológica seriam essenciais para aumentar a produção biológica, mas o atual quadro legislativo impede o desenvolvimento de fatores de produção, como as sementes, nas suas formas biológicas.

O desenvolvimento do mercado biológico baseou-se na confiança dos consumidores, mas está agora em risco. As regras de produção biológica são enfraquecidas por exceções e disposições pouco claras. A legislação não aborda o impacto ambiental ao longo de todo o ciclo da produção biológica. Algumas práticas permitidas pela legislação atual ignoram a exigência de um elevado nível de bem-estar dos animais na produção biológica. O desenvolvimento de regimes privados conduz à proliferação de logótipos que competem com o logótipo biológico da UE, o que se torna confuso para os consumidores. Têm-se constatado situações de fraude, possibilitadas por insuficiências do sistema de controlo e do regime de importação.

A concorrência leal entre os produtores não é garantida e o funcionamento do mercado único não é eficaz. Há disposições complexas, por exemplo respeitantes a explorações com uma produção convencional paralela, que não são devidamente aplicadas e controladas. Alguns Estados-Membros abusam do sistema de exceções às regras. O funcionamento do mercado único é perturbado pela multiplicidade de requisitos de certificação necessários para aceder a certos mercados e pelas diferentes abordagens adotadas pelos Estados-Membros quando são detetados nos produtos biológicos resíduos de substâncias não autorizadas. O mesmo nível de incumprimento pode dar origem a ações divergentes em diferentes Estados-Membros. O regime de reconhecimento dos organismos de controlo baseado na equivalência incentiva a competição entre esses organismos, o que provoca uma concorrência desleal entre os produtores da UE que, além disso, enfrentam obstáculos para aceder a mercados de países terceiros. Não foi possível estimar a gravidade da concorrência desleal.

A legislação é excessivamente complexa e implica uma sobrecarga administrativa excessiva. Muitas pequenas explorações estão excluídas do setor biológico, pois os custos da certificação são excessivamente elevados e os encargos administrativos excessivamente onerosos.

Esquematização do problema



As causas não regulamentares estão em itálico.

2.2. Cenário de referência

O desenvolvimento da oferta a nível nacional continuará a ser dificultado, embora alguns obstáculos económicos possam ser ultrapassados com novos instrumentos da PAC.

A confiança dos consumidores sofrerá provavelmente uma erosão, dado que as regras de produção biológica enfraquecem e as preocupações da sociedade não se refletem plenamente nessas regras. Esta situação estimulará a criação de novos regimes e de logótipos que entrarão em concorrência com o da UE. Será provável que ocorram fraudes. **O regime de importação tornar-se-á ainda mais complexo** com a aplicação de um regime de conformidade para os organismos de controlo a partir de 2014.

Os produtores biológicos confrontar-se-ão cada vez mais com uma concorrência desleal e o funcionamento do mercado único será posto em risco. Na UE, os Estados-Membros não disporão provavelmente dos recursos necessários para aplicar corretamente disposições e exceções complexas. Nos países terceiros, a concorrência entre os organismos de controlo levará a uma descida dos níveis exigidos.

2.3. Análise do princípio da subsidiariedade

O exercício atual consiste numa **atualização e um regime existente estabelecido no âmbito da PAC.**

A produção e o comércio de produtos agrícolas e géneros alimentícios no mercado interno e a garantia da integridade do mercado interno são competências da UE partilhadas com os Estados-Membros.

Um regime biológico a nível de toda a UE é mais eficiente que 28 regimes diferentes e facilitará o desenvolvimento harmonioso do mercado único e uma política de comércio externo coerente.

É necessária uma maior harmonização no respeitante às exceções às regras e aos casos de incumprimento que conduzem à retirada do estatuto biológico de um produto.

3. OBJETIVOS

3.1. Objetivos estratégicos específicos

- Remoção de obstáculos ao desenvolvimento da produção biológica na UE
- Melhoria da legislação a fim de garantir a concorrência leal e melhorar o funcionamento do mercado único
- Manutenção da confiança dos consumidores
- Simplificação

3.2. Objetivos operacionais

- Definição de regras de produção claras e não ambíguas
- Aplicação de um sistema de controlo baseado nos riscos

- Harmonização da abordagem em relação à presença de resíduos de substâncias não autorizadas nos produtos biológicos
- Simplificação dos requisitos administrativos, em especial para os pequenos produtores
- Aplicação de um sistema único e fiável de reconhecimento dos organismos de controlo nos países terceiros
- Criação de um regime comercial equilibrado
- Simplificação das regras de rotulagem
- Integração da evolução das preocupações da sociedade
- Aumento da transparência e da informação sobre o setor e o comércio biológico

4. OPÇÕES POLÍTICAS

As opções apresentadas, baseadas em diferentes visões a longo prazo para o setor biológico, foram estabelecidas em estreita cooperação com os interessados e têm em conta os resultados da consulta pública, revelando, em especial, que os cidadãos da UE preferem que as questões ambientais sejam mais plenamente tidas em conta, que haja uma maior harmonização e reforço das regras de produção e que seja posto fim às exceções.

4.1. Descrição das opções

- **Opção 1: *status quo* melhorado**

Esta opção inclui **medidas legislativas** com o objetivo de:

- clarificar o âmbito de aplicação e algumas regras de produção;
- simplificar ligeiramente as normas de rotulagem;
- reforçar o sistema de controlo (procedimentos harmonizados quando forem detetados nos produtos biológicos resíduos de substâncias não autorizadas; certificação eletrónica integrada numa base de dados Web da UE; clarificação sobre a acreditação dos organismos de controlo);
- supressão do regime de conformidade de importação.

Estas medidas, consideradas como uma resposta mínima aos problemas identificados, estão igualmente incluídas em todas as outras opções.

- **Opção 1.A: 1 + fim da possível isenção para os retalhistas**

- **Opção 2: opção impulsionada pelo mercado**

Esta opção pretende proporcionar as condições necessárias para responder dinamicamente à evolução do mercado graças a regras menos rigorosas. A opção inclui:

- **medidas legislativas** para integrar como disposições do regulamento da UE regras excecionais criadas pelos Estados-Membros e que vigoram desde há

muito, bem como a elaboração de regras de produção mais compreensíveis, integradas num documento único,

- **um plano de ação** que defina uma estratégia para a agricultura biológica a fim de permitir um rápido desenvolvimento do setor biológico.
- **Opção 2.A: 2 + análise sistemática de produtos biológicos para pesquisa da presença accidental de resíduos de substâncias não autorizadas**
- **Opção 3: opção impulsionada pelos princípios**

Esta opção tem por objetivo reorientar a agricultura biológica para os seus princípios. A opção inclui:

- **medidas legislativas** para reforçar as regras, nomeadamente através da supressão das exceções, reforço da abordagem baseada nos riscos do sistema de controlo através da supressão da inspeção anual obrigatória e substituição da equivalência pelo cumprimento no regime de importação do organismo de controlo;
- **um plano de ação** que defina uma estratégia para a agricultura biológica na UE, que inclua ações para superar problemas técnicos de produção, bem como uma política de exportação específica.
- **Opção 3.A: 3 + obrigação de medição do desempenho ambiental para as empresas envolvidas em atividades de transformação e comerciais**
- **Opção 3.B: 3 + certificação de grupo**

4.2. Questões relativamente às quais o Conselho solicitou à Comissão um relatório:

- A necessidade de regras harmonizadas a nível da UE para **os alimentos biológicos preparados por serviços de restauração** não foi demonstrada.
- As **disposições sobre OGM** devem manter-se inalteradas, dado que correspondem a um equilíbrio entre benefícios e custos.
- O **funcionamento do mercado único** foi abordado globalmente ao longo de toda a análise.

4.3. Posição das partes interessadas

Os principais interessados do setor biológico, IFOAM EU e COPA-COGECA, começaram por apoiar a opção 1, mas a sua posição deslocou-se para a opção 3. A opção 3 foi, em especial, apoiada por Via Campesina, Slow Food e organizações de proteção do bem-estar dos animais. A opção 2 foi apoiada sobretudo por Eurocommerce.

5. AVALIAÇÃO DO IMPACTO DAS OPÇÕES POLÍTICAS

Devido à falta de estatísticas fiáveis, a avaliação das opções é sobretudo qualitativa.

5.1. Opções 1 e 1.A

A maioria dos obstáculos ao desenvolvimento da produção biológica persiste, não se esperando impactos importantes a nível dos volumes de produtos biológicos no mercado. O funcionamento do mercado único melhora ligeiramente, mas não se alcançam condições de igualdade para os produtores, pois continuam a existir exceções e o regime de equivalência para o reconhecimento dos organismos de controlo continua a desencadear a concorrência entre esses organismos.

A confiança dos consumidores melhora apenas a curto prazo, pois as principais preocupações da sociedade e dos consumidores não são abordadas. O risco de fraude é reduzido graças à certificação eletrónica. Os regimes e logótipos privados continuam a multiplicar-se.

A opção 1A deverá reduzir ainda mais o risco de fraude.

5.2. Opções 2 e 2.A

São removidos poucos obstáculos ao desenvolvimento da produção biológica. A integração de exceções como regras permanentes na legislação conduz a regras mais flexíveis e a um aumento das conversões para a produção biológica no início do período. Os preços pagos aos produtores baixam, sobretudo devido à forte concorrência das importações. O setor torna-se progressivamente menos atraente. No mercado interno, a concorrência leal melhora com a integração das exceções como regras permanentes, igualmente acessíveis a todos os produtores. No entanto, a concorrência desleal com os produtos importados persiste.

A confiança dos consumidores sofrerá provavelmente uma erosão dado que as regras de produção são enfraquecidas e os novos regimes e logótipos proliferam, criando uma situação de confusão.

Dado que as regras de produção são menos rigorosas, os países terceiros mostram-se mais relutantes em reconhecer as regras da UE como equivalentes e alguns acordos/convénios estabelecidos com países terceiros podem ser postos em causa.

A opção 2.A aumenta a confiança dos consumidores mas implica custos importantes para os produtores.

5.3. Opção 3

São removidos muitos obstáculos ao desenvolvimento da produção biológica. Os agricultores biológicos que aplicam plenamente os princípios biológicos (sem recurso a derrogações) sentir-se-ão mais inclinados a permanecer no setor. A supressão das exceções reforça os fatores de produção biológicos, nomeadamente puros e sementes biológicos. A concorrência por parte dos produtos importados deverá diminuir. A concorrência leal melhora graças ao fim das exceções e à aplicação da conformidade pelos produtores de países terceiros no âmbito do regime dos organismos de controlo.

A confiança dos consumidores melhora graças a regras mais estritas. Haverá menos regimes e logótipos privados que poderão competir com o logótipo biológico da UE.

O aumento dos custos de produção poderá conduzir ao aumento dos preços dos produtos biológicos no consumidor, podendo tornar esses produtos menos acessíveis aos

consumidores com rendimentos mais baixos, causando uma contração do mercado, ainda que apenas a curto prazo.

Os acordos de equivalência em vigor com países reconhecidos têm de ser revistos, a fim de manter condições de igualdade para os produtores da UE.

A opção 3.A melhora a confiança dos consumidores, pois aborda preocupações de carácter ambiental. Esta opção tem impactos ambientais positivos mas implica encargos administrativos para os transformadores e comerciantes

A opção 3.B remove obstáculos adicionais ao desenvolvimento da produção biológica na UE.

5.4. Simplificação

É possível conseguir uma simplificação com todas as opções graças a disposições mais claras sobre o âmbito de aplicação, regras de produção, rotulagem e controlos. As disposições ineficazes seriam suprimidas sobretudo nas opções 3, 3.A e 3.B (fim das explorações mistas e reforço da abordagem baseada nos riscos para os controlos). As opções 2, 2.A, 3, 3.A e 3.B simplificariam a tomada de decisões sobre possíveis exceções. O regime de conformidade para os organismos de controlo seria mais fácil de gerir do que a equivalência (3, 3.A e 3.B). A simplificação para os pequenos produtores é alcançada por meio de exigências mais adequadas e específicas de manutenção de registos da produção biológica (todas as opções) e da certificação de grupo (3.B). A isenção dos controlos não seria compatível com as exigências de certificação dos produtos.

A legislação atual impõe 135 obrigações de informação que implicam custos administrativos, incluindo 80 aos operadores (consoante o tipo de operação), 41 às administrações nacionais e 11 aos organismos de controlo. Para os Estados-Membros, as obrigações mais pesadas são as seguintes: o fornecimento de dados estatísticos; o relatório sobre as autorizações de sementes não biológicas; a publicação de listas atualizadas dos operadores. Para os operadores, as obrigações mais pesadas são: a manutenção de provas documentais sobre a utilização de fertilizantes e produtos fitofarmacêuticos (autorizados) e sobre a (possível) coexistência das produções biológica e convencional; a manutenção de registos pecuários específicos; as disposições de controlo.

Nas opções 1 e 1.A, o nível dos custos administrativos manter-se-ia, sendo possível efetuar poupanças importantes com as opções 2, 2.A, 3, 3.A e 3.B, com o desaparecimento de, respetivamente, 34 e 37 obrigações de informação graças sobretudo à supressão das exceções e à redução dos registos a manter e relatórios a efetuar.

6. COMPARAÇÃO DAS OPÇÕES E CONCLUSÕES

6.1. Comparação dos impactos das opções

Opções		1	1.A	2	2.A	3	3.A	3.B
Impactos socioeconómicos	Evolução do mercado	+	++	++	+++	++	+++	++
	Superfície dedicada à produção biológica e número de explorações	+	+	++	++	++	++	+++
	Emprego nas explorações biológicas	+	+	++	++	++	++	+++
	Rendimento agrícola	0	0	-	+	+	+	+
	Integração das pequenas explorações	-	-	--	---	0	0	+++
	Desenvolvimento rural	+	+	+	+	++	++	+++
	Transformadores	+	+	++	++	++	++	++
	Importadores	+	+	+++	++	+	+	+
	Setor dos «fatores de produção biológicos»	0	0	---	---	+++	+++	+++
Ambiente	Biodiversidade, qualidade da água, qualidade do solo	+	+	+	++	++	++	+++
	Bem-estar dos animais	0	0	-	-	++	++	++

6.2. Comparação do potencial de cada uma das opções para satisfazer os objetivos específicos da reforma:

Opções	Remoção de obstáculos ao desenvolvimento da produção biológica na UE	Melhoria da legislação a fim de garantir a concorrência leal e melhorar o funcionamento do mercado interno	Preservar a confiança dos consumidores nos produtos biológicos
Opção 1	0	+	+
Opção 1.A	0	+	+
Opção 2	+	++	++
Opção 2.A	+	++	+++
Opção 3	++	+++	+++
Opção 3.A	++	+++	+++
Opção 3.B	+++	+++	++

À luz da avaliação, as opções que melhor asseguram os objetivos políticos específicos são as opções 3.B ou 3.A, seguidas das opções 3, 2.A e 2.

7. ACOMPANHAMENTO DA POLÍTICA

- Indicadores de resultados (PAC): proporção da superfície ocupada pela produção biológica em comparação com a superfície agrícola útil total; proporção do efetivo biológico no efetivo total.
- Indicadores de resultados (PAC): superfície ocupada pela produção biológica; número de produtores biológicos certificados.
- Indicadores adicionais sobre o efetivo pecuário, produção e transformação da produção vegetal, exceções, conhecimento do logótipo biológico da UE.