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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

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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 labelling**[1] 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) - *in compliance with Article 5(2)(b),(e), (f) of Regulation No 882/2004*	
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) - *in compliance with Article 5(3) of Regulation No 882/2004*	

[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: • 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 interpretation[2], 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 MS[3].

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**.

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[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 features[4].

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 exempted[5].

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-backed 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 activities[6].

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.

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[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

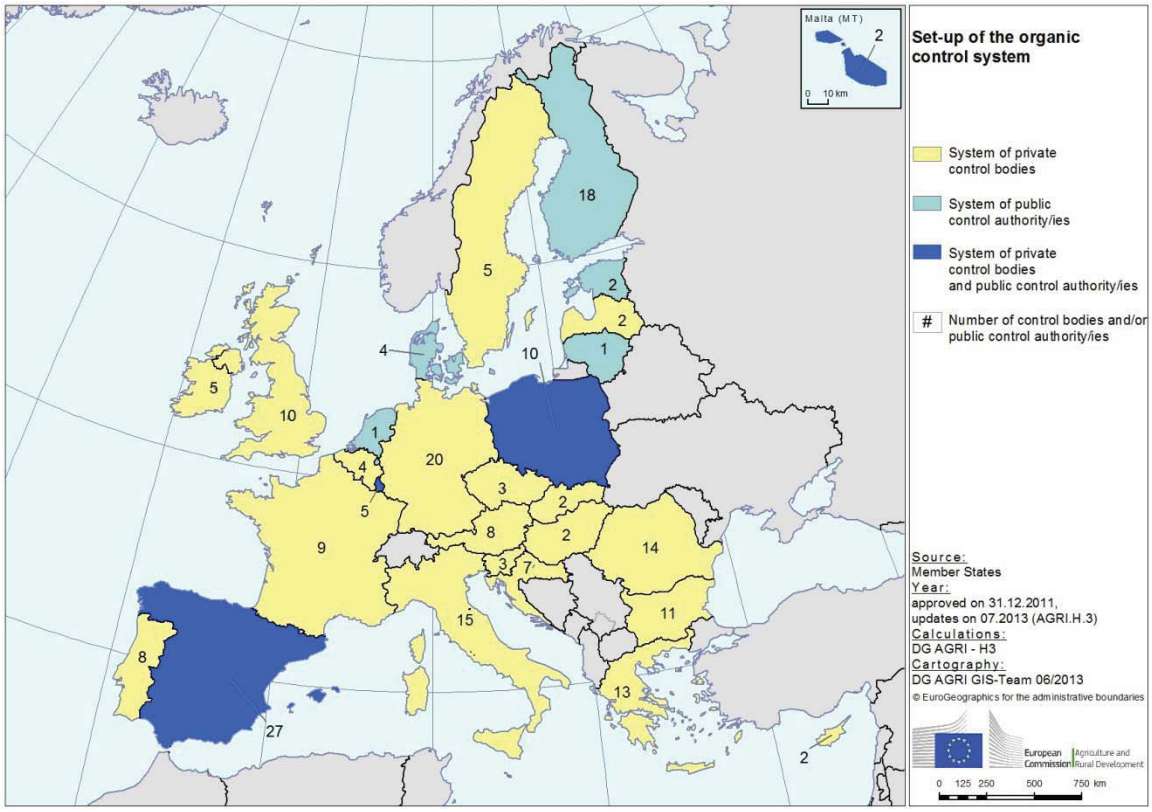
A. Delegate its control tasks to one or more **private Control Bodies** that it shall approve and supervise, or

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:

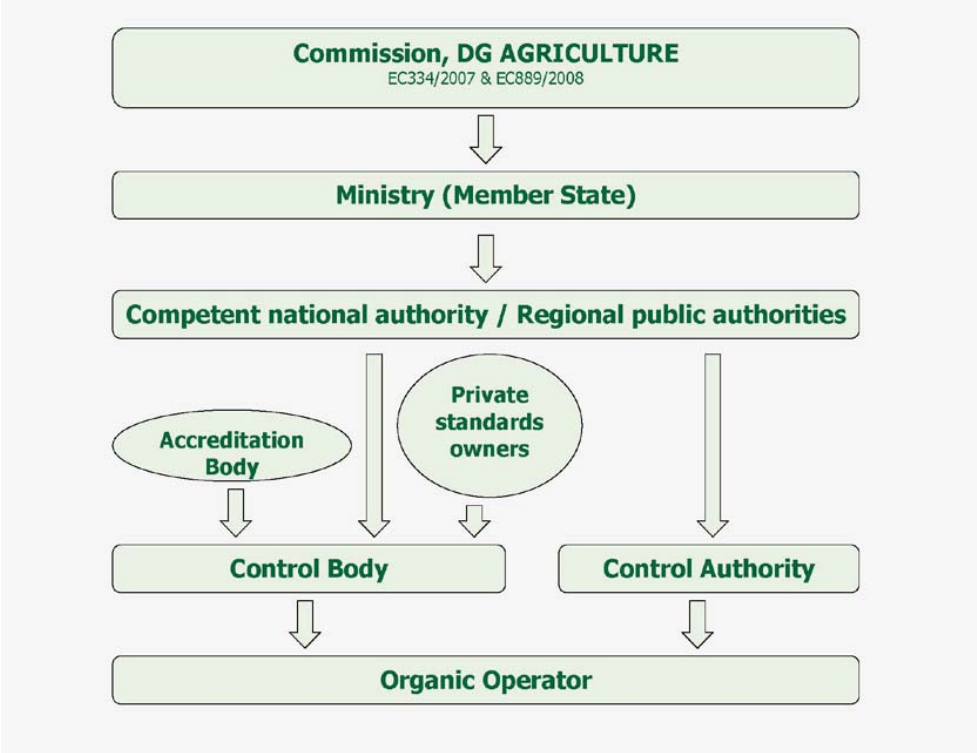
- **Group certification**, as a sub-option under the **principle-driven (3) policy option** to address the problems that small farmers face in entering the system. Please see further details in Annex 16, Small farms and enterprises: simplification, group certification.

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 audits[7].

    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 FVO[8].

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 Commission[9]
- Investigate irregularities and infringements to the organic provisions that are notified by other MS and inform them of the results of action taken

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[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 measures[10])
- 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 sector[13].

Control body

Vis-à-vis the **competent authority(is)**	Vis-à-vis **other control bodies**	Vis-à-vis **operators**
• Reporting obligations: list of operators + summary report of control activities		• Carry out an annual physical inspection of each operator + additional risk-based visits
• 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	• Hand over control file if operator changes control body • Immediately exchange information in case of irregularities/infringements • Exchange relevant information on control results	• 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 2012[14], 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 tarification 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 practices[15].

[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, 2011[16].

- 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 issues[18].

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 inspection[19].

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.

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[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 producers[20] 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 level[21].

- 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 CAP[22]. 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 fraud[23].

  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).

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[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.

- DakkS (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 below[24]

	*Politika, 8.8.2011, Warsaw, Circulation: 200,050*[25] 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.

[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 2013*[26] *- 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: 57,000*[27] 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 – project[28].

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 approve[29] and then supervise[30] (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.

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[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 France[32], 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 income[34] of a farm and up to 1 % of the organic turnover of processors.

For the CERTCOST study countries[35], 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.

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[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 1st time accreditation	Annual fee for maintenance of accreditation
Czech Rep.	10722 €	2600 €
France	3135 €	Fixed annual fee of € 2289; Variable fee: 0,225*(Fixed fee * N° of systems accredited)+ 0,039 *(fixed fee*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 1107/2009[36]) and the maximum residue levels (MRL) (Regulation No 396/2005[37]). 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***

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[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 examined[38]. As "accidental"[39] is considered the presence of any substance for which it can be established that no use[40] 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;

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[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 report[41] 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 products[43].

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 Republic[46] and in other MS concerning the approach to adopt.

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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 Group[47] 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*".

EOCC[48] issued in 2013 specific guidelines[49] 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 DDAC[51] 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 US[52]. It consists in establishing a threshold such as a **critical level** (5% of the US tolerance level for conventional products[53]) 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 AGOF[54] 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.

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[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 levels[57].

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.

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[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-authorised 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-authorised 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 loses. 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 disproportionate[58]. 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 developped 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.

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 Guidelines[59].

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	
Pros: • Easier adaptation to local conditions. • Flexibility in definition of 'equivalence' **Cons**: • 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.	**Pros:** • 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 **Cons**: • 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	
Cons: • Non-equivalent production rules or control measures being applied, thus creating unfair competition between EU and 3rd countries producers.	**Pros**: • Level playing field in the EU and outside.

Procedure for recognition	
Cons: • 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.	**Pros**: • 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	
Cons: • Complex because any non-compliance has to be assessed against each own CB standard.	**Pros**: • 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	
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.	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.
Examination of applications by the Commission	
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	Less burdensome procedure
Recognition	
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.	Recognition by publication of a list of CBs without product categories and countries where the standard is applied.

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 765/2008[60]. 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

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]	√					

Source: Interim report (September 2013) for Evaluation of the EU legislation on organic farming

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 farming[61]. In particular, organic farms avoid the N_2O 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.

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[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 practices[62].

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 literature[63].

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 particulary 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 onwards[64]. There have also been EU research projects[65] 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 friendly[66]. 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.

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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 JRC[67] (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 systems[68], 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 study[70], 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

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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 agriculture[71]. 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 helpdesk[72]. 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

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 registrants[73].

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 1221/2009[74]), 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 mind[75]. 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.

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[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 registration[76]. 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**
	Southern Europe	€ 3,507	€ 11,483	€ 19,439	€ 34,428	€ 1,857	€ 8,110	€ 8,110	€ 17,676
SME	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
	Southern Europe	€ 6,297	€ 23,673	€ 27,879	€ 57,849	€ 3,272	€ 16,442	€ 16,442	€ 34,283
Large	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 Saxony[77] 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.din.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 EMAS[78].

[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/EC[79] 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 1/2005[80] 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 1099/2009[81] 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 19.1.2012[82]. In 2012, the European Union Strategy for the Protection and Welfare of Animals 2012-2015[83] 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.

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[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 AGRI[84] 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

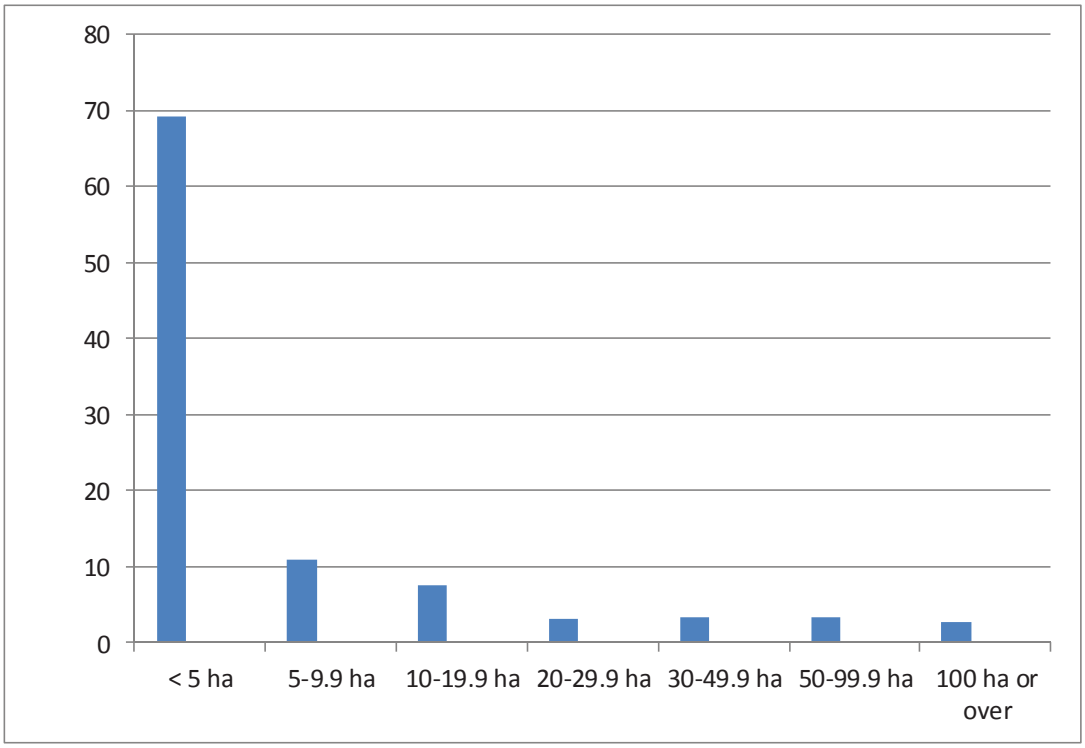
Source: European Commission – DG AGRI L2 Data Source: EUROSTAT (2010)

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?

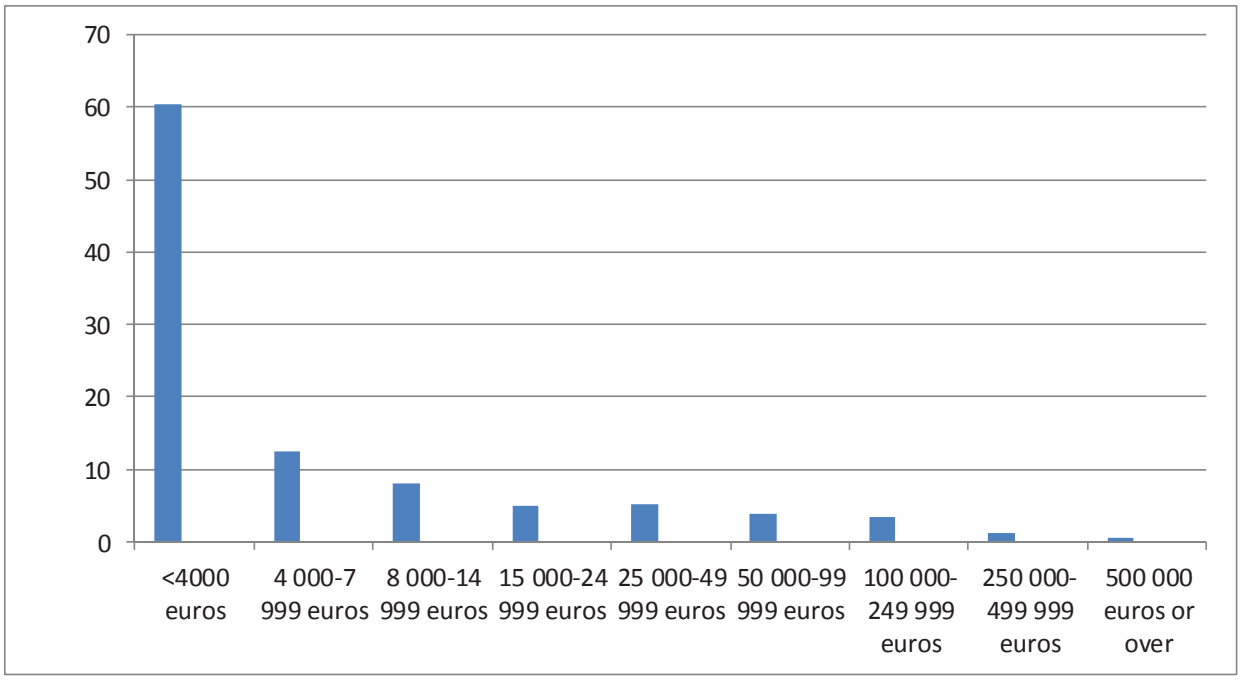
Graph 1. Share of agricultural holdings in different size classes in the EU



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).

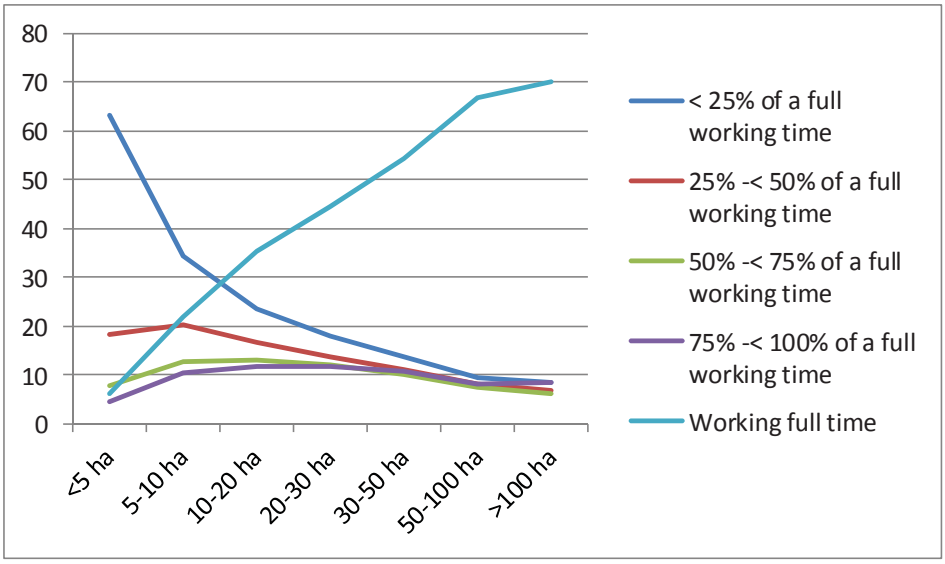
Graph 2. Share of agricultural holdings in different output classes in the EU



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)

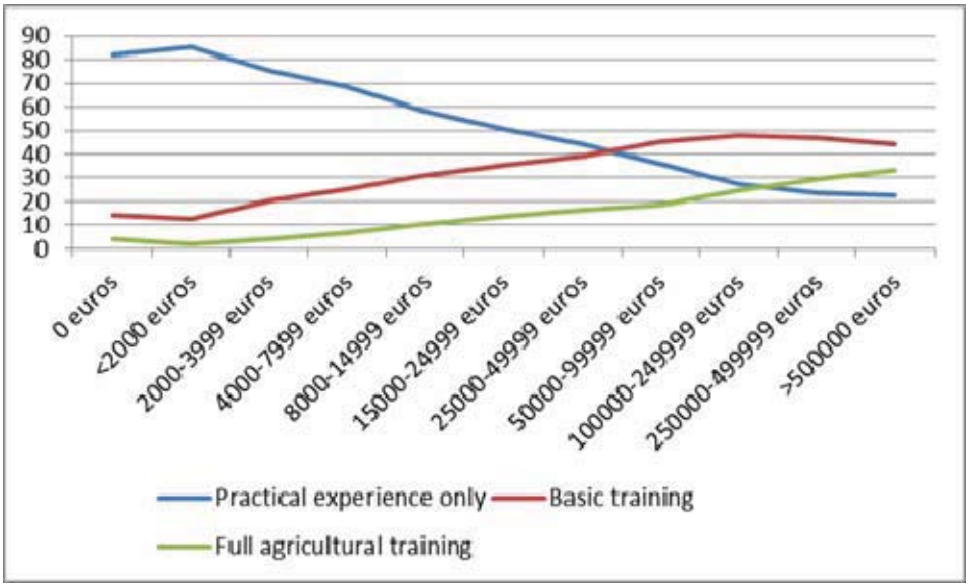


Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

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



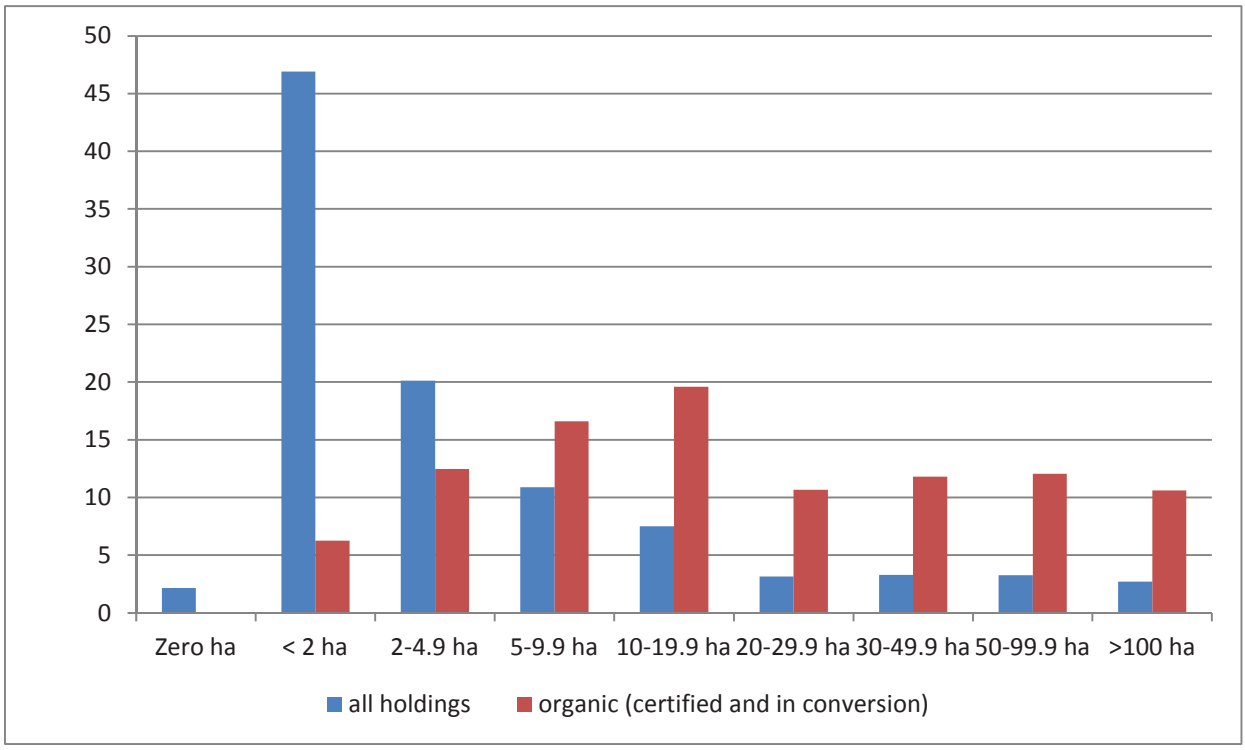
Source: European Commission – DG AGRI L2. Data Source: EUROSTAT

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 sector[85].

[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 effectiveness[86].

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.

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[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 2012[87] - 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.

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[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 agricoltura 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 farms[89]. 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% to12%, 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 equivalency[91].

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.

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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 2013[92], 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 2014[93], 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.

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[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 than 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 systems[95].

  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.

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[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 it[97]*." "There are too many small farms, which cannot afford the control costs*[98]*." "There is a need to favour the creation of new farming systems in Europe, though the bureaucratic burden for small farmers is too high*[99]*." "Costs of certification should be lowered to promote small organic farming concepts*[100]*." "It should not be the case that the controls and requirements of organic production, result in excluding or less favouring small farmers*[101]*."*

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 agriculture[102]."

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 low[103]. 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 measures[104], 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.

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[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	Signifi-cance	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: Simoultaneous production	***Simoultaneous 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	Signifi-cance	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	Mediu m	1	0	1
6	Operators	Plant production: Use of produtcs 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: simoultaneous 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)	Infrorm 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 assessement (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	Signifi-cance	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	Mediu m	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 allopatic 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	Signifi-cance	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	Signifi-cance	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	Signifi-cance	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: simoultaneous 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	Signifi-cance	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	Mediu m	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	Mediu m	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	Signifi-cance	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	Signifi-cance	Improved status quo	Market driven	Principle driven
43	CB/control authorities	Labelling	Where terms as refered 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	Mediu m	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	Mediu m	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	Mediu m	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	Signifi-cance	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	Signifi-cance	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, s**igned 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	Signifi-cance	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	Signifi-cance	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	Mediu m	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	Mediu m	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 trigerring 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	Signifi-cance	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	Signifi-cance	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	Signifi-cance	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	Signifi-cance	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:imported 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	Signifi-cance	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 lis	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 fo**r 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	Signifi-cance	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 cetificate of inspection must have been issued by the control authority or control body …. 4. The authority of body issuing the certificate of inspection shall ….	Issueing of the certificate of inspection and endorsment of box 15	RCE 1235/2008 Article 13 (3)(4)	4	Regularly	Mediu m	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	Signifi-cance	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	Signifi-cance	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	Signifi-cance	Improved status quo	Market driven	Principle driven
106	MS/CA	Control	Information on the competent authorities, control authorities and bodies "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	Information on the competent authorities, control authorities and bodies "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	Annual statistical information for the implementation and follow-up of the Regulation "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 cattel		RCE 889/2008 Article 95 (1)	2	Exceptionally	Mediu m	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	Signifi-cance	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	**Paralel 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	Signifi-cance	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 thecompetent authority,(a) when a flock is constituted for the first time, renewed or reconstituted and organically reared poultry are notavailable in sufficient numbers, non-organically reared poultry may be brought into an organic poultry productionunit, provided that the pullets for the production of eggs and poultry for meat production are less than three daysold;	Authrisation 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 othe 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	Signifi-cance	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 supervison 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	Signifi-cance	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	Mediu m	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	Continously	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

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