

Implementing rules on Import

Summary

1. Comment on AGRI F5 – Working document -16.11.2007

- IFOAM acknowledges the efforts made by the EU Commission to elaborate the first elements for the implementing rules for import (Draft of 16.11.2007).
- The assessment reports of IOAS should be accepted as sufficient according to the articles of the implementing rules.
- The certification bodies should be requested to notify the standards applied including a comparison with the EU Regulation. For IFOAM the principle of equivalence is very important.
- Accreditation bodies and other supervising bodies should harmonize their approach toward the assessment of certification bodies active in third countries. Furthermore the full application of the standards (EU Regulation or equivalent standards) must be ensured and supervised by the supervisory bodies.
- Rules for electronic certification covering the certificate referred to in Article 33(1) point (d) should be described in Art. 12.

2. Guidelines should be elaborated for the following three areas

- Acceptance of accreditation and supervisory bodies
- Harmonization of accreditation approach
- Assessment of compliance and equivalency, taking into account the International requirements for Organic certification bodies (IROCB) and the Tool for Equivalence of Organic Standards and Technical Regulations (EquiTool) as discussed in the International Task Force on Harmonization and Equivalence in organic agriculture, where both the EU as well as IFOAM are involved.

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3. Sufficient personnel and financial capacities should be provided by the EU Commission for the implementation of Council Regulation (EC) No. 834/2007

1. Comment on AGRI F5 – Working document -16.11.2007, DRAFT COMMISSION REGULATION

IFOAM acknowledges the efforts made by the EU Commission to elaborate the first elements for the implementing rules for import (Draft of 16.11.2007). There are many good elements contained in this proposal.

However IFOAM thinks that still a number of improvements should be made to make these rules more consistent and workable.

IFOAM, together with the FAO and UNCTAD, is steering the **International Task Force** on Harmonization and Equivalence in organic agriculture, in which the European Commission is also involved. Its achievements should be taken into consideration when designing implementing rules for imports. Core of Harmonization is a equitable approach for all involved.

Another body with long experience in organic accreditation and oversight is the **IOAS (International Organic Accreditation Service)**, which was created by IFOAM. The IOAS is fully qualified and with vast experience in the assessment of certification bodies operating in and outside of Europe on the basis of EU Regulation 2092/91. IOAS is ready to provide the assessment reports as outlined in Art. 32 (2) and Art. 33 (3). The assessment reports of IOAS should be accepted as sufficient according to the articles of the implementing rules.

For IFOAM it is important that the implementing rules for imports of organic products from third countries ensure equitable, reliable and effective control measures applied to operators in third countries. This must be ensured by certification bodies (CB) with headquarters in the EU as well as by CBs with their main offices in countries outside of the EU.

IFOAM identified two main problem areas:

1. The draft Commission regulation on imports does not require EU-based control bodies acting in third countries to provide detailed proof of how they are applying the EU Regulation (or the equivalent standards) and thus achieve full compliance (or equivalence) to the EU Regulation on Organic Agriculture.
2. The draft regulation specifies neither the procedure for approval of EU-based CB acting in third countries nor the implementation of an effective supervision system.

Therefore IFOAM EU Group proposes:

- The certification bodies should be requested to notify the standards applied including a detailed comparison with the EU Regulation to ensure an equal level playing field for operators within and outside of the EU. For IFOAM the principle of equivalence is very important.
- It is understood that the approval and supervision process by the EU shall be based on the results of the evaluations of certification bodies acting in third countries by accreditation bodies and/or other supervisory bodies. Accreditation bodies and other

supervising bodies should harmonize their approach toward the assessment of certification bodies active in third countries. Furthermore the full application of the standards (EU Regulation or equivalent standards) must be ensured and supervised by the supervisory bodies. Such assessment has to be part of the assessment report.

- The approval and supervision of certification bodies and authorities should not only be based on the review of documents, but focus on practical assessments of the operations of certification bodies active in third countries.

IFOAM proposes that in the Article 7.1.b the text is changed. In most cases it is impossible to provide "types and estimates of the quantities of agricultural products and foodstuffs intended for export" for all the activities of a CB in a third country. If the CB provides an estimate of the current situation it can be completely changing after a couple of weeks already. A CB does not know which projects/operators will apply to be certified by the CB. Instead it is proposed to require a detailed description of the implementation of Regulation (EC) No. 834/2007 in third countries.

IFOAM would further like to strengthen the importance of establishing rules for electronic certification covering the certificate referred to in Article 33(1) point (d). Such rules should be described in Title V "Certificate of Inspection for Import" (Article 12). This is to ensure equal administrative procedures for imports under the "equivalence" as according to the "compliance" procedures.

More detailed proposals are detailed below.

<i>Article</i>	<i>Draft 16.11.07</i>	<i>New proposal</i>
<i>Article 7</i>	<p style="text-align: center;">Inclusion of control bodies and control authorities in the list for the purpose of compliance</p> <p>1. The Commission shall consider whether to include a control body or control authority in the list in Annex II upon receipt of a request for inclusion from the representative of the control body or control authority concerned. Only complete requests that have been received within 6 months after the entering into force of this regulation shall be considered for the drawing up of the first list. For the following calendar years, only requests that have been received between 1 September and 31 October of each year shall be considered.</p> <p>2. The request shall exist of a technical dossier, established in one of the official Community languages and comprising all the information needed for the Commission to ensure that the conditions set out in Article 32 (1) and (2) of Regulation (EC) No 834/2007 are met for organic products intended for export to the Community. In particular, it shall comprise the following detailed information:</p> <p>(a) the types and an estimate of the quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in the said Article 32 (1) and (2);</p> <p>(b) a copy of the assessment report as set out in the 4th subparagraph of the said Article 32 (2) proving that the control body or authority has</p>	<p>1. The Commission shall consider whether to include a control body or control authority in the list in Annex II upon receipt of a request for inclusion from the representative of the control body or control authority concerned. Only complete requests that have been received within 6 months after the entering into force of this regulation shall be considered for the drawing up of the first list. For the following calendar years, only requests that have been received between 1 September and 31 October of each year shall be considered.</p> <p>2. The request shall exist of a technical dossier, established in one of the official Community languages and comprising all the information needed for the Commission to ensure that the conditions set out in Article 32 (1) and (2) of Regulation (EC) No 834/2007 are met for organic products intended for export to the Community. In particular, it shall comprise the following detailed information:</p> <p>(a) the types and an estimate of the quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in the said Article 32 (1) and (2); <u>a detailed description of the implementation of Regulation (EC) No. 834/2007 in the third countries;</u></p> <p>(b) a copy of the assessment report as set out in the 4th subparagraph of the said</p>

	<p>been satisfactorily assessed on its ability to meet the conditions set out in Article 32 (1) and (2), to give guarantees on the elements referred to in article 27, paragraphs 5 and 6 of Regulation (EC) No 834/2007 and to meet the control requirements and precautionary measures set out in [Annex XX of Commission Regulation (EC) No XXXX/2007, implementing rules on controls];</p> <p>(c) proof that the control body or authority has notified its activities to the authorities of the third country concerned and that it respects the legal requirements imposed on it by the authorities of the third country concerned.</p> <p>3. When examining a request for inclusion, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent experts. Furthermore, the Commission may organize an on-the-spot examination by experts it designates.</p>	<p>Article 32 (2) proving that the control body or authority has been satisfactorily assessed on its ability to meet the conditions set out in Article 32 (1) and (2), to give guarantees on the elements referred to in article 27, paragraphs 5 and 6 of Regulation (EC) No 834/2007 and to meet the control requirements and precautionary measures set out in [Annex XX of Commission Regulation (EC) No XXXX/2007, implementing rules on controls];</p> <p>(c) <u>proof that the control body or authority has effectively implemented its activities as set out in the 4th subparagraph of the said Article 32 (1)</u></p> <p>(d) proof that the control body or authority has notified its activities to the authorities of the third country concerned and that it respects the legal requirements imposed on it by the authorities of the third country concerned.</p> <p><u>3. When examining a request for inclusion, and also any time in risk-based intervals after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by dependent experts. shall request on-the-spot examination reports established by independent experts and any other information deemed necessary.</u> Furthermore, the Commission may shall organize an on-the-spot examinations by experts it designates <u>with the assistance of the member states</u> and independent experts.</p>
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<p><i>Article 8</i></p>	<p>Management and review of the list of control bodies and control authorities for the purpose of compliance</p> <p>1. If, after a control body or control authority has been included in the list, any changes are made to the measures applied by the control body or control authority, that control body or control authority shall notify the Commission thereof.</p> <p>2. By 31 March every year, the control body or control authority shall send a concise report to the Commission regarding the control activities carried out during the previous year.</p> <p>3. In the light of the information received, the Commission may at any time amend the specifications relating to the control body or control authority and may suspend or withdraw the entry of that body or authority in the list referred to in Annex II; a similar decision may also be made where a control body or authority has not supplied information required or where it has not agreed to an on-the-spot examination.</p> <p>4. The control body or control authority shall make available to the interested parties a continuously updated list of operators and products certified as organic.</p>	<p>Management and review of the list of control bodies and control authorities for the purpose of compliance</p> <p>1. If, after a control body or control authority has been included in the list, any changes are made to the measures applied by the control body or control authority, that control body or control authority shall notify the Commission thereof.</p> <p>2. By 31 March every year, the control body or control authority shall send a concise report to the Commission regarding the control activities carried out during the previous year.</p> <p>3. In the light of the information received, the Commission may at any time amend the specifications relating to the control body or control authority and may suspend or withdraw the entry of that body or authority in the list referred to in Annex II; a similar decision may also be made where a control body or authority has not supplied information required or where it has not agreed to an on-the-spot examination.</p> <p>4. The control body or control authority shall make available to the interested parties, <u>preferably by electronic means</u>, a continuously updated list of operators and products certified as organic <u>as well as suspended and decertified operators and products</u>.</p>
<p>TITLE IV</p> <p><i>LIST OF CONTROL BODIES AND CONTROL AUTHORITIES FOR THE PURPOSE OF EQUIVALENCE</i></p>		
<p><i>Article 9</i></p>	<p>The list of control bodies referred to in the third paragraph of Article 33 of Regulation (EC) No 834/2007 is set out in Annex III to this Regulation.</p>	<p>The list of control bodies referred to in the third paragraph of Article 33 of Regulation (EC) No 834/2007 is set out in Annex III to this Regulation.</p>

	<p>This list gives all the information deemed necessary in respect of each control body or control authority to permit the identification of products covered by the rules and in particular:</p> <ul style="list-style-type: none"> – the name and address of the control body or authority, including e-mail and internet address – the third countries concerned in which the products have their origin, – the product categories concerned, – the production standards applied in the third country; – the duration of the inclusion in the list. 	<p>This list gives all the information deemed necessary in respect of each control body or control authority to permit the identification of products covered by the rules and in particular:</p> <ul style="list-style-type: none"> – the name and address of the control body or authority, including e-mail and internet address – the third countries concerned in which the products have their origin, – the product categories concerned, – the production standards applied in the third country; – the duration of the inclusion in the list.
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<p><i>Article 10</i></p>	<p style="text-align: center;">Inclusion of control bodies and control authorities in the list for the purpose of equivalence</p> <p>1. The Commission shall consider whether to include a control body or control authority in the list in Annex III upon receipt of a request for inclusion from the representative of the control body or control authority concerned. Only complete requests that have been received within 6 months after the entering into force of this regulation shall be considered for the drawing up of the first list. For the following calendar years, only requests that have been received between 1 September and 31 October of each year shall be considered.</p> <p>2. The request for inclusion shall exist of a technical dossier, established in one of the official Community languages and comprising 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. In particular, it shall comprise the following detailed information:</p> <p>(a) the types and, if possible, an estimate of the quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in the said Article 33 (1) and (3);</p> <p>(b) the production standards applied in the third country;</p> <p>(c) the control arrangements applied in the third country;</p> <p>(d) a copy of the assessment report as set out in the 4th subparagraph of Article 33 (3) on the ability of the control</p>	<p style="text-align: center;">Inclusion of control bodies and control authorities in the list for the purpose of equivalence</p> <p>1. The Commission shall consider whether to include a control body or control authority in the list in Annex III upon receipt of a request for inclusion from the representative of the control body or control authority concerned. Only complete requests that have been received within 6 months after the entering into force of this regulation shall be considered for the drawing up of the first list. For the following calendar years, only requests that have been received between 1 September and 31 October of each year shall be considered.</p> <p>2. The request for inclusion shall exist of a technical dossier, established in one of the official Community languages and comprising 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. In particular, it shall comprise the following detailed information:</p> <p>(a) the types and, if possible, an estimate of the quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in the said Article 33 (1) and (3);</p> <p>(b) the production standards applied in the third country;</p> <p>(c) the control arrangements applied in the third country;</p> <p>(a) <u>a description of the production standards and control measures applied in third countries including a detailed</u></p>
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	<p>body or control authority to meet the conditions set out in Article 33 (1) and (3) of Regulation (EC) No 834/2007;</p> <p>(e) proof that the control body or control authority has notified its activities to the authorities of the third country concerned and that it respects the legal requirements imposed on it by the authorities of the third country concerned.</p> <p>3. When examining a request for inclusion, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent expert. Furthermore, the Commission may organize an on-the-spot examination by experts it designates.</p>	<p><u>comparison with the requirements of Regulation (EC) No. 834/2007;</u></p> <p>(b) a copy of the assessment report as set out in the 4th subparagraph of the said Article 33 (3) on the ability of the control body or control authority to meet the conditions set out in Article 33 (1) and (3) of Regulation (EC) No 834/2007 <u>including a confirmation that the control body or authority has effectively implemented its activities as set out in the 4th subparagraph of the said Article 32 (1)</u></p> <p>(d) proof that the control body or authority has notified its activities to the authorities of the third country concerned and that it respects the legal requirements imposed on it by the authorities of the third country concerned.</p> <p>3. When examining a request for inclusion, and also any time after its inclusion, the Commission may shall request any further information, including the presentation of one or more on- <u>on a risk-based approach</u> on-the-spot examination reports established by independent experts <u>and any other information deemed necessary</u>. Furthermore, the Commission may shall organize an <u>random</u> on-the-spot examinations by experts it designates <u>on a risk based approach and in case of suspected irregularities</u>.</p>
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2. Guidelines should be elaborated for the following three areas

2.1 Acceptance of accreditation and supervisory bodies

- Guidelines are necessary to define the criteria for accreditation and other supervisory bodies whose assessment reports shall be accepted for the 4th subparagraph of Article 32 (2) respectively Article 33 (3). The accreditation or supervisory body accrediting the CB shall demonstrate its knowledge of and qualification and experience with EC Regulation 834/2007 and/or the current regulation and provide proof that it meets ISO 17011 by a peer review system.

2.2 Harmonization of accreditation approach

- Guidelines for accreditation bodies and other supervising bodies should be elaborated to harmonize the approach toward the assessment of certification bodies active in third countries including the assessment of the full application of the standards (EU Regulation or equivalent standards) and audits of the local offices as well as witness audits.

2.3 Assessment of compliancy and equivalency

- It is suggested to develop a tool to assess equivalency. The tool should include clear and transparent criteria for judging the equivalency of standards and conformity assessment systems taking into account the International Requirements for Organic Certification Bodies (IROCB) and the Tool for Equivalence of Organic Standards and Technical Regulations (EquiTool) as discussed in the International Task Force on Harmonization. Comparison tables should be a basis to monitor the implementation of the compliant as well as the equivalent judgements. Such comparison tables should be published to allow a transparent and harmonized interpretation of the EU requirements in Third Countries. IFOAM Accreditation is recognized when deciding which CBs can conduct equivalent certification for imports.
- The application of the compliance option should be limited to those cases where a system is fully compliant with the EU regulation. These guidelines should also cover a description on how equivalency may be achieved for critical issues, e.g.:
 - equivalent measures and criteria regarding the implementation of the seed requirements in Third Countries
 - Internal Control System, how can the existing EU Guiding Document be used to facilitate this system?
 - Which requirements not covered in the EU 824/2007 (since they are already covered in other EU legislation) should be covered by equivalent/compliant standards (e.g. burning of crops, water quality, animal welfare...)?

3. Other comments

- **Personnel capacities for implementation of Council Regulation (EC) No. 834/2007**

To insure an effective implementation of Council Regulation (EC) No. 834/2007 and the referring implementation rules it is of utmost importance that sufficient personnel and financial capacities are provided by the EU Commission. It is necessary to establish a unit with experts for coordination of the approval and supervision of control bodies. This unit should coordinate and supervise the Member States assistance for assessing requests of third countries and control bodies and authorities. The unit should further conduct respectively organize random on-the-spot examinations by experts it designates on a risk based approach and in case of suspected irregularities.

- **Complaints mechanism**

Complaints or suspicion of irregularities in the EU territory can be addressed to the competent authority of the EU Member State. There is no reference point to notify complaints or suspicion of irregularities about operations in third countries. The EU should establish a complaints procedure concerning imported products ensuring thorough investigation and follow-up in case of complaints respectively suspicion of irregularities.