IOAS Inc.

Operating Manual-EU

Information and requirements specific to

Assessment and Surveillance under equivalence to Regulation (EC) 834/2007

Valid from: Oct 1, 2018

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Assessment and Surveillance of equivalence to Regulation (EC) 834/2007

1. Introduction

This operating manual contains specific information and requirements of the European Recognition Scheme implemented by IOAS on behalf of the scheme owner, the Organic Unit of the Directorate General for Agriculture of the European Commission (COM). It should always be read in conjunction with IOAS General Operating Manual which contains a full description of IOAS and its overall approach to its work conducting accreditation and surveillance of certification bodies (hereinafter called control bodies in the terminology of the European Commission) working in the field of organic and sustainable agriculture and related fields which is performed in line with ISO/IEC 17011.

It is IOAS' approach to harmonise the assessment process for the increasing range of schemes offered, so as to reduce the burden of accreditation to all certification bodies. We are also continually working to gain recognition or equivalence of our work with scheme owners and government authorities such that we can offer 'one assessment, many accreditations'.

2. Scheme owner

2.1 The Organic Unit of the Directorate General for Agriculture (DG AGRI) of the European Commission (COM) coordinates the 'scheme' which is described in Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 and various implementing rules as foreseen by Art. 38. Various Commission guidelines also apply.

2.2 The COM is supported by a regulatory committee (Regulatory Committee on Organic Production or RCOP) of organic production as referred to in Art. 37 of Regulation EC 834/2007. This committee consists of representatives from each of the EU Member States competent authorities.

2.3 Regulation No 834/2007 lays down rules for the approval of control bodies (certification bodies) within Member States which requires accreditation to ISO/IEC 17065 and compliance with the production standards and control measures set out in the regulation and its various supporting regulations.

2.4 Article 33 of this regulation and specifically implementing Regulation (EC) No 1235/2008 set out arrangements for imports of organic products which establish various mechanisms for recognition of equivalence of export country systems and of individual control bodies. Regulation No 1235/2008 requires that any organic product entering the EU must originate from a country system that has been deemed equivalent by the COM or be certified by an individual control body that has subjected itself to equivalence assessment and been approved by the COM. It is the latter that is the subject of this operating manual and in which IOAS has a role.

3. IOAS EU Recognition Scheme

3.1 IOAS service of assessment and on-going surveillance to control bodies is open to control bodies anywhere in the world (including control bodies based in the EU with activity in third countries).

3.2 The initial decision on equivalence of a control body is made by the COM based upon an application made by a control body which includes an assessment of equivalence of both the production standard used by the control body and its control procedures against Regulation No 834/2007 and the various relevant implementing rules. Continuing recognition by the COM requires annual reports from the control body to the COM which include updated information from independent surveillance. Control body recognition of equivalence by the COM is made known by publication of amendments to Regulation No 1235/2008 which lists in its Annex IV all recognised control bodies and their scope of activity.

3.3 According to the COM Guidelines the assessment and surveillance of equivalence can be provided by:

- competent authorities (either of the third country, or of a Member State)
- a national accreditation body with competence in organic agriculture
- an international supervisory or accreditation body that is specialised in organic agriculture

IOAS is the latter.

3.4 IOAS EU Recognition Scheme is provided to control bodies alongside other assessment and accreditation services and the procedures are harmonised to enable simultaneous implementation, thereby reducing cost and time demands.

3.5 In addition to accreditation against ISO/IEC 17065, recognition by the COM requires assessment of equivalent production standards and control measures so the control body must apply to IOAS under two schemes - ISO/IEC 17065 and European Recognition Scheme. IOAS provides this service as a formal accreditation against ISO/IEC 17065, issuing a certificate of accreditation which states that the control body has been found to be compliant with ISO/IEC 17065 with respect to the reference standard used by the control body for their EU equivalent programme. The

decision on ISO/IEC 17065 accreditation lies with IOAS but that decision does not confer recognition of equivalence which relies upon the control body submitting a complete and satisfactory application to the COM.

3.6 IOAS does not take responsibility for the result of the decision by the COM.

3.7 The reference standard used in the third country cannot be Regulation (EC) No 834/2007 and its implementing rules themselves as these contain requirements that can only be satisfied within EU Member States. Therefore control bodies need to implement a production standard of their own or a common standard designed for the purpose[1] for certification of their operators applying for EU equivalent programme. IOAS will review the chosen standard for equivalence against the requirements of Regulation (EC) 834/2007 and implementing rules as part of the assessment process.

3.8 As the reference standard used in third countries cannot be Regulation No. 834/2007 certificates issued by the certification body (once recognised as equivalent) may not claim compliance with the Regulation. Suitable language would be 'the operator has been inspected and found to be compliant with standard XXX (the standard used by the CB) which has been deemed equivalent to (EC) 834/2007'

4. Requirements for accreditation

4.1 The requirements against which a control body is assessed are:

- ISO/IEC 17065 - full compliance is required.
- Production standard of the control body – equivalence is required.
- Control measures and labelling requirements as set out in Regulation No (EC) 834/2007 and its various implementing regulations - equivalence is required.

A complete and current list of these requirements can be obtained from IOAS at any time and should be consulted before the control body applies to IOAS.

4.2 Equivalence is assessed by IOAS based on five criteria which are as follows:

Agroecology = the requirement is not applicable/reasonable for the specific conditions of the control body being assessed either on grounds of climate or geography.
Alternative means = the control body does not perform this requirement exactly as stated but achieves the same aim by other means

[1]For example the IACB Equivalent European Union Organic Production and Processing Standard. Contact the ACB administrator at sacompson@gmail.com

Detail = the control body does not have this requirement in its system but it is considered a small detail with no effect on the integrity of organic products.
Legislative = the requirement is covered by some other binding law(s) of the country(ies) in which the control body operates and therefore doesn't need to be addressed in the control body's own requirements
Socioeconomic = the requirement is not applicable/reasonable for the specific conditions of the control body either on grounds of culture, social or economic conditions or stage of development of the organic sector.

4.3 The obligations of applicant control bodies and IOAS are set out in a surveillance contract which is signed following application. A copy of the surveillance contract can be viewed here.

5. Procedures for assessment and surveillance
5.1 The general application, assessment and surveillance procedures detailed in section 7 of the IOAS General Operating Manual apply.

5.2 Control bodies may apply to IOAS at any time.

5.3 The application to IOAS must indicate the production standard which is to be assessed as equivalent and the categories of production to be covered. The options are the following:

A: Unprocessed plant products

B: Live animals or unprocessed animal products

B: Live animals or unprocessed animal products (beekeeping only)

C: Unprocessed aquaculture products and seaweeds

D: Processed agricultural products for use as food (excluding wine)

D: Processed agricultural products for use as food (including wine)

E: Processed agricultural products for use as feed
F: Vegetative propagating material and seeds for cultivation

5.4 Control bodies must be able to arrange at least one witness audit in EACH category for which they are applying by the time of the on-site visit by IOAS and have issued at least one certificate in each category they are applying for before their application to the COM.

5.5 Document review by IOAS results in a line by line comparison of the control body's production standard and control measures, each requirement being determined as compliant, equivalent or non compliant.

5.6 An on-site visit to the control body office or offices by IOAS must be conducted and all non-compliances must be resolved before IOAS prepares the assessment report to be submitted to the COM.

5.7 Applications to the COM for recognition of equivalence may take place at any time. Guidance on the content of the application to be submitted is detailed on the COM web page which describes 'How to become a recognised control body' and provides various documents and links including an application form and a list of documents to be provided. The control body is advised to read this carefully to ensure they have complied with all requirements before submission.

5.8 It is the control body's responsibility to submit the application to the COM. All required documents must be submitted via the COM OFIS portal. To be able to use this portal the applicant-control body must contact the COM and obtain from it access for registering there beforehand. The portal is the ONLY method for submission of an application.

5.9 After review (which may take 12 months) the COM will normally respond to the control bodies with questions or more demands. The control body should liaise with IOAS for any information that might be in the remit of IOAS or require further action by IOAS. IOAS will do all it can to respond to these requests, but it is the responsibility of the control body however to ensure deadlines for submission are met, allowing sufficient time for additional review or on-site visits.

5.10 As indicated above, the ISO/IEC 17065 accreditation that goes hand in hand with the European Recognition Scheme is both integral but also a separate process. On ISO/IEC 17065 accreditation by IOAS for the scope relevant to the control body's EU equivalent programme, normal surveillance procedures will commence. The first annual report that the control body is required to submit to the COM will be due by the first February 28 at the latest following recognition by the COM of equivalence.

5.11 The annual report is required to contain an update on the original technical dossier and assessment report so contains elements that are the responsibility of both IOAS and the control body. This annual report must report on implementation of any changes in European legislation that have come into effect in the previous year.

5.12 The COM requires annual on-site surveillance by IOAS of the control body. The COM requires IOAS to perform at least 1 witness audit for each category of activity (see 5.3) the control body has applied for to be done within one accreditation cycle, i.e over 5 years and again at each reassessment. For example, a control body working in categories A and D will need at least 2 witness audits at first assessment, at least 2 further witness audits over the 5- year cycle and again at least 2 witness audits in the

re-assessment year. Numbers may increase in-line with the guidelines mentioned below at 5.13.

5.13 Extension of activity by a control body to new categories of activity (eg. aquaculture, vegetative material and seeds, wine) requires document review and on-site visits by IOAS, and an application to the COM. These can take place at any time but are most cost effectively added at the time of your annual surveillance o re-assessment.

5.14 Guidelines for assessment and surveillance of EU-equivalence have been developed by the European Cooperation on Accreditation and are adhered to by IOAS. The Guidelines are available on the EA web site

5.15 IOAS will endeavour to inform control bodies of changes to the scheme requirements but in general communication is direct between the COM and the CB.

6. Reference to IOAS accreditation and the scheme owner

6.1 The accredited certification body may make reference to being accredited by IOAS in accordance with the requirements described and referred to in the IOAS General Operating Manual.

6.2 On being accredited, the certification body will receive a formal accreditation certificate which states that the organisation has been found to be 'ISO/IEC 17065 accredited' for the scope of' the chosen standard. No statement of equivalence to the relevant EU Regulations is made on the certificate. Accredited certification bodies will be added to the list of accredited certification bodies to ISO/IEC 17065 on the IOAS web site.

6.3 IOAS also makes public a list of control bodies that have entered the IOAS EU Recognition Scheme and are under surveillance. This list will indicate that the certification body is an applicant from the date of acceptance of the application by IOAS and the CB is 'recommended' once a positive report by IOAS is provided. However, only after the COM has published the name of the CB in Annex IV of (EC) 1235/2008 is the CB considered equivalent and products certified under that scheme may enter Europe.

6.4 The accredited certification body may make suitable claims on promotional material (brochures, web sites etc) that the specified scheme is under IOAS surveillance from the date of acceptance by IOAS of the application. However, the control body may not make any claim of being recognised as equivalent by the COM until their name has been published in Annex IV of Regulation (EC) 1235/2008.

6.5 Certificates of certification which correctly state compliance with a relevant production standard and where correct, refer to accreditation by IOAS in accordance with IOAS policy PL0515 may be issued by the control body at any time. However, no statement may be made of equivalence to Regulation EC (No) 834/2007, reference to recognition by the COM or use of the EU green flag logo until the control body's name has been published in Annex IV of Regulation 1235/2008.

7. Fees

The IOAS fee schedule is available at http://www.ioas.org/assessment/application/

For any specific questions on the European Recognition Scheme please contact your assigned Client Manager or Iris Rendon at rendon@ioas.org

8. Reference documents

COUNCIL REGULATION No (EC) 834/2007 of 28 June 2007 on organic production and labelling and repealing Regulation (EEC) 2092/91 (as amended).
COMMISSION REGULATION (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (as amended).
COMMISSION REGULATION (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (as amended)
The EU Organic Logo Graphic Guidelines.
Guidelines on imports of organic products into the European Union December 15, 2008.

IACBs Equivalent European Union Organic Production & Processing Standard for Third Countries.

Contact details
European Commission
Directorate General for Agriculture and Rural Development
H3 Organic Farming
Rue de la Loi
1049 Brussels
BELGIUM
E: agri-organic-imports@ec.europa.eu
W: http://ec.europa.eu/agriculture/organic/splash_en

IOAS Inc.
119 2nd Ave. West,

Dickinson, ND 58601, USA
T: +1 701 483 5504, F: +1 701 483 5508
E: info@ioas.org W: www.ioas.org