

IOAS Inc.



## **Operating Manual-EU**

**Information and requirements specific to  
Assessment and Surveillance according to  
Regulation (EU) 2018/848**



Valid from: March 14, 2022

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#### **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 (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007 and its various delegating and implementing acts as amended. Regulation (EU) 2018/848 is hereafter referred to in this document as the **Regulation**.

2.2 The Regulation establishes the date of **December 31, 2024**, by which control bodies operating in third countries recognised by the COM as equivalent under Regulation 834/2007 need to be recognised under the new Regulation.

2.3 The COM is supported by a regulatory committee (Organic Production Committee or OCP) as referred to in Art. 55 of the Regulation.

2.4 Regulation (EU) 2018/848 lays down rules for the approval of control bodies (certification bodies) which requires accreditation to ISO/IEC 17065 and compliance with the production standards and control measures set out in the regulation and its various delegated and implementing regulations.

2.5 Article 45 of Regulation (EU) 2018/848 defines requirements for imports of organic products into the EU from third countries. In summary:

- a) The product must be within the scope of the Regulation (Art. 2(1),
- b) Either of the following applies:
  - i. The product complies with Chapters II (Principles), III (Production Rules) and IV (Labelling) of the Regulation and all operators in the supply chain including exporters have been certified by CBs which are accredited and are recognised by the Commission under procedures of Art. 46, OR
  - ii. The product originates from a third country with which the EU has a Trade Agreement (Art. 47), OR

- iii. The product originates from a third country with which the COM has an equivalence agreement (Art. 48)

2.6 IOAS provides its assessment and surveillance service under Art. 46 *Recognition of control authorities and control bodies* based on IOAS being ‘an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.’ (Art. 46.3.b)

### **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). The service provided by IOAS requires accreditation to ISO/IEC 17065 with scope of control measures and production rules described in the Regulation. Once accredited, the CB can apply for recognition by the COM.

3.2 The initial decision on recognition of a control body is made by the COM based upon an application made by that control body which includes an assessment of the control body against the Regulation 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 compliance by the COM will be made known by publication of amendments to Regulation No 2021/2325 which lists all recognised control bodies and their scope of activity including approved products categories and countries of operation.

3.3 In addition to accreditation against ISO/IEC 17065, recognition by the COM requires assessment of compliance with 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 production rules and control measures prescribed in the Regulation. The decision on ISO/IEC 17065 accreditation lies with IOAS but that decision does not confer recognition which relies upon the control body submitting a complete and satisfactory application to the COM.

3.4 IOAS does not take responsibility for any adverse decision by the COM.

### **4. Requirements for accreditation**

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

- ISO/IEC 17065 - full compliance is required.
- Control measures and labelling requirements as set out in the Regulation and its various delegated and implementing regulations - compliance is required.

A complete and current list of these requirements can be referred to on various web sites and should be consulted before the control body applies to IOAS.

IFOAM Organics Europe: <https://www.organicseurope.bio/what-we-do/eu-organic-regulation/>

European Commission: [https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/legislation\\_en](https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/legislation_en)

4.2 The obligations of applicant control bodies and IOAS are set out in a contract which is signed as part of the IOAS application process. A sample copy of the contract is provided as part of the IOAS application process.

## 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 applicable production rules that the CB shall apply are defined in Chapter III of the Regulation and Annex II. The categories of production are the following:

- (a) unprocessed plants and plant products, including seeds and other plant reproductive material,
- (b) livestock and unprocessed livestock products,
- (c) algae and unprocessed aquaculture products,
- (d) processed agricultural products, including aquaculture products, for use as food,
- (e) feed,
- (f) wine,
- (g) other products listed in Annex I to Regulation EU 848/2018 or not covered by the previous categories.

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

5.5 Document review by IOAS assesses compliance of the CB against ISO/IEC 17065 and all relevant control measures prescribed in Regulation 2018/848 and relevant Delegating and Implementing Acts.

5.6 On-site visit to the main office and any offices of control body selected on the basis of EA-3/12 M: 2020 (see 5.14 here below) by IOAS must be conducted and all non-compliances identified during these visits must be resolved before IOAS prepares the assessment report to be submitted by the CB to the COM.

5.7 Applications to the COM for recognition of the CB may take place at any time. Details on the content of the application to be submitted is described in Delegated Regulation (EU) 2021/1698 . 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 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 as necessary.

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. Upon obtaining ISO/IEC 17065 accreditation by IOAS for the scope relevant to the control body's EU compliance programme, normal surveillance procedures will commence. .

5.11 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. 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.

5.13 Extension of activity by a control body to new categories of activity (e.g. aquaculture, wine, etc.) 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 or re-assessment.

5.14 A policy for assessment and surveillance of EU compliance has been developed by the European Cooperation on Accreditation and are compiled in EA-3/12 M: 2022 – Policy for the Accreditation of Organic Production Certification, relevant for operations in EU-member states as well as in third countries. This Policy is adhered to by IOAS in the planning and execution of the initial assessment and of the consequent surveillance of the EU programme of the certification bodies. The Policy is 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 Regulation (EU) 2018/848. 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 Implementing Regulation (EU) 2021/2325 is the CB considered recognised and products certified under that scheme may enter European Union.

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 by the COM until their name has been published in the relevant Annex of Commission Implementing Regulation (EU) 2021/2325.

6.5 Certificates which correctly state compliance with Regulation (EU) 2018/848 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 reference to recognition by the COM or use of the EU green flag logo may be made until the control body's name has been published in relevant Annex of Implementing Regulation (EU) 2021/2325.

## **7. Fees**

## IOAS Inc.

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 Service Manager or Iris Rendon at [rendon@ioas.org](mailto:rendon@ioas.org)

### **8. Reference documents**

Regulation (EU) 2018/848 of the European Parliament and of the Council

Secondary acts to Regulation (EU) 2018/848

EA - 3/12 M: 2022 – EA Policy for the Accreditation of Organic Production Certification

Official communications from the COM related to the implementation of Regulation (EU) 2018/848 and its secondary acts.

### **Contact details**

#### **European Commission**

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W: [http://ec.europa.eu/agriculture/organic/splash\\_en](http://ec.europa.eu/agriculture/organic/splash_en)

For any specific questions on IOAS accreditation and assessment services please contact your assigned Client Service Manager or Mafalda Carneiro on [carneiro@ioas.org](mailto:carneiro@ioas.org)

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