

**INTERNATIONAL ORGANIC
ACCREDITATION SERVICE Inc.**

OPERATING MANUAL
for
**European Recognition
Programme**

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Preface

This Operating Manual is provided to give an overview of the IOAS and the service it offers to certification bodies active in organic agriculture and food production in any part of the world with regard to assessment and surveillance under the European Council Regulation (EC) 834/2007.

The manual is divided into four parts:

Section A is an introduction to the IOAS, and the background to Regulation (EC) 834/2007.

Section B covers the scope, structure, and some fundamental policies of the IOAS European Recognition Programme (ERP)

Section C explains the application, evaluation, and accreditation procedures.

Section D provides information on the rights and responsibilities of certification bodies, and the IOAS in relation to this programme.

The manual should be regarded as a guide to the operation of the IOAS ERP. It is provided to all applicants and is available to other interested parties. It is not the official policy manual of the IOAS. Full policies are contained in the IOAS Quality Manual. Individual policies referenced here are available from IOAS offices.

The IOAS Quality Manual describes the measures in place to guarantee a high quality of work and continuous improvement in its implementation of the ERP. As part of its efforts to continuously improve its performance the IOAS periodically amends its policies and procedures. Resulting differences between the descriptions of policies contained in this manual and the actual policy may occur. In such event the official policy document of the IOAS takes precedence over the description provided herein.

Ken Commins
Executive Director
Jamestown, ND
USA

December, 2010

Definitions

The following definitions apply within the context of this manual:

Accreditation: Third party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks.

Annual Report: A report submitted by the control body to the European Commission Organic Unit each year before March 31st. Its contents are described in section 6 of the Guidelines for imports of organic products (2008)

Annual Update Report: A report submitted annually to the IOAS by control bodies as part of the Annual Surveillance procedure.

Annual Surveillance: Procedure involving submission of an annual update report and on-site visits to a specified schedule, whereby the IOAS monitor ongoing compliance of control bodies.

Appeal: Request by a control body for reconsideration of any adverse decision made by the IOAS

Applicant Body: A control body that has applied to the IOAS under the European Equivalence Programme and has yet to be confirmed as recognised by the European Commission Organic Unit.

Assessment Body: as designated by the European Commission in their 'Guidelines on import of organic products' (2008) the body that can write the assessment report on control bodies is referred to as an assessment body and may be any one of three types of organisations as follows: 1. competent authorities (either of the third country concerned, or of a Member State); 2. a national accreditation body with competence in organic agriculture; 3. an international supervisory or accreditation body that is specialised in organic agriculture.

Assessment report: the report referred to in Art. 33(3) prepared by the assessment body which forms the major part of the application by the control body for recognition by the European Commission Organic Unit. The required contents of the assessment report are described in the Guidelines for imports of organic products (2008).

Category of Certification: A field of certification activity such as crop production, animal feed, or aquaculture.

Certification: The procedure by which a third party gives written assurance that a clearly identified process is methodically assessed such that adequate confidence is provided that specified products conform to specified requirements.

Control body: The body that conducts certification according to, or equivalent to, (EC) 834/2007.

Certification Programme: System operated by a control body with its own rules and procedures and management for carrying out certification of conformity.

Complaint: An objection to the policies, procedures or performance of the IOAS. A complaint may also be an objection to the performance or activities of an control body lodged with the IOAS by a third party.

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Deficiency: A failing on the part of the control body to comply with reference standards and criteria but of a lesser grade than a non-conformity. Generally, this will mean that while the procedure or policy is in place, the details of the criteria or standards have not been fulfilled.

Evaluation: The systematic process of examining the extent to which the performance of a control body fulfills specific requirements.

Evaluation Report: The written findings of the evaluator, following the evaluation visit.

Evaluation Visit: The visit to the premises of the control body and subcontracted parties and to the premises of the operators certified under the relevant certification programme as part of the evaluation.

Evaluator: Person appointed by the IOAS to carry out the evaluation visit.

Inspection: Visit on site to verify that the performance of an operation is in accordance with the production or processing standards.

Inspector: Person appointed by a control body or by an inspection body to undertake the inspection of an operator.

Interested parties: Parties with a direct or indirect interest in the assessment programme.

Internal Review: An assessment of the objectives and performance of a body that is undertaken by the body itself.

Non-compliance: A failing on the part of the control body to comply with reference to standards and criteria. A non-compliance may be either a non-conformity or a deficiency.

Non-conformity: The absence of, or the failure to implement and maintain, a required system element of the reference standards and criteria, or a situation which would raise significant doubt as to the credibility of the certification.

Observation: An aspect of the control body's structure, policies, procedures or operation that is noted as deficient in a way not prescribed by the accreditation standards and criteria.

Operator: An individual or business enterprise.

Programme Manager: The person appointed by the IOAS to administer the assessment programme.

Review Audit: A review operator inspection conducted by the IOAS evaluator during the evaluation visit in which the accuracy of a previously conducted inspection is assessed. (see also witness audit)

Review Evaluation: The process of re-evaluating an accredited control body to ascertain whether it continues to be in compliance with the accreditation programme's requirements.

Sanction: An action taken by the IOAS in response to a failure by the control body to meet the requirements of accreditation.

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Scope of assessment: Specific conformity assessment services for which assessment is sought or has been granted.

Screening: An initial process whereby the IOAS, as part of the evaluation, assesses the conformity of an applicant body based on its documentation.

Standards: The standards for agricultural production or processing used by a control body, to which certified operators must adhere

Surveillance: Set of activities, except reevaluation, to monitor the continued fulfilment by control bodies of the requirements of the European Recognition Programme. Surveillance involves annual reporting by the control body and on-site visits by the IOAS to both control body offices and their operators according to a standard timetable and sampling policy.

Surveillance Contract: A formal agreement between the IOAS and a control body which lays out the rights and responsibilities of both parties.

Witness Audit: An operator inspection performed under normal control body procedures in the presence of the IOAS evaluator.

Abbreviations

The following abbreviations occur in the text:

DG Agri:	Directorate General Agriculture of the European Commission
ERP:	European Recognition Programme
ED:	Executive Director, IOAS
EU:	European Union
PM:	Programme Manager, IOAS
AMC:	Accreditation Management Committee
IOAS:	International Organic Accreditation Service Inc.
IFOAM:	International Federation of Organic Agriculture Movements
ISO:	International Organisation for Standardisation

Section A: Introduction

A1 IOAS Accreditation Programme for European Recognition under (EC) 834/2007

A1.1 On January 1, 2009 the European Regulation (EC) 834/2007¹ on organic production and labelling of organic products came into force and repealed the earlier version of the regulation, (EEC) 2092/91. With this new regulation came a new regime for import controls for organic products into Member States of the EU.

A1.2 The detailed implementation rules on imports published as (EC) 1235/2008 and the 'Guidelines for imports of organic products' published in December 2008 made it clear that the IOAS, as an 'international accreditation body that is specialised in organic agriculture' could operate as an assessment body for the drawing up of assessment reports on compliance and equivalence of control bodies to the Regulation (EC) 834/2007.

A1.3 With this assessment report a control body operating outside of Europe may apply to the European Commission Organic Unit in DG Agri to be recognised as providing **compliant** (under Article 32) or **equivalent** (under Article 33 of (EC) 834/2007) controls thus providing access for their clients to the European organic market.

A1.4 The IOAS can provide assessments of both **compliance and equivalence**. However IOAS services can only apply to control body activity outside of the EU according to Regulation (EC) 765/2008. In addition the Commission have made it quite clear that control activity outside of the EU is unlikely ever to be considered **compliant** with (EC) 834/2007 given that the work is conducted under a different legislative environment. This IOAS programme therefore will normally be based on equivalence with regard to the rules set out in (EC) 834/2007 and related implementing rules. Both compliant and equivalent options will however apply to application of ISO Guide 65 to control bodies active outside of the EU.

A1.5 The IOAS also provides other assessment and accreditation services such as IFOAM accreditation, ISO Guide 65 accreditation, assessment for the Canadian Organic Regime amongst others. All accreditations and assessments stand alone but where required, a control body may apply for any or all simultaneously, benefiting significantly from savings on combining the evaluation and surveillance process.

A1.6 For background, the remainder of this section describes the origins of the IOAS and the European Regulation (EC) 834/2007.

A2 International Organic Accreditation Service Inc.

A2.1 The IOAS was established in 1997 by the International Federation of Organic Agriculture Movements to operate the IFOAM Accreditation System, a private organic guarantee which had been operating within IFOAM since 1992. International Organic Accreditation Service Inc. is registered as a non-profit company in the United States.

¹ Reference to (EC) 834/2007 in this document implies reference to all associated implementing rules and guidance documents.

A2.2 In 2003, the IOAS launched an accreditation programme against ISO/IEC Guide 65 and in 2009 was recognised by the Canadian authorities to operate as a Conformity Verification Body under the Organic Products Regulations, 2009.

A2.3 The IOAS is the legal entity responsible for all accreditations and operates quite separately from IFOAM.

A3 The European Regulation on Organic Production and Labelling

A3.1 The original European regulation on organic production and labelling, (EEC) 2092/91, was published in 1991 and came into force in 1993.

A3.2 In 2006 a process of major revision started to simplify and improve the rules based on fifteen years of experience and this process resulted in the publication in 2007 of Council Regulation (EC) 834/2007 which finally came into force on January 1, 2009. This regulation is supported by a number of implementing rules and guidance documents.

A3.3 Implementing rules described in regulation (EC) 1235/2008 describe the arrangements for the control of imports of organic products into the European Union and further details are described in the 'Guidelines on imports of organic products' published by the Commission in December 2008.

A3.4 Some arrangements that were present in the previous regulation are maintained (the country to country equivalence) whereas new arrangements are also brought in which enable individual control bodies operating anywhere in the world to apply to the European Commission to be recognised as compliant or equivalent to the rules as applied in Europe. It is this latter system as applied by the IOAS that is the subject of the programme described in this operating manual.

A3.5 The IOAS functions as one of the 'assessment bodies' mentioned in the 'Guidelines' published by the Commission and through the programme described here offers to control bodies operating outside of the European Union the service of assessment and the preparation of independent expert reports which form the basis for the Commission decision on whether to recognise the control body as equivalent. Such recognition means that the control body will be entered on a public list. In turn products certified by the control body within the scope of the assessment will have free access to the European organic market.

A3.6 The first date for submission of applications to the Commission is October 31, 2009 and there is an annual deadline of October 31 subsequently. Applications may however be submitted at any time.

A3.7 Although the decision to recognise a control body rests with the European Commission, this programme operates much like any accreditation programme that IOAS currently operates (eg. IFOAM, ISO Guide 65) - see following sections.

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A3.8 All relevant documents of the European Council and Commission are available directly from or via the IOAS web site at www.ioas.org

Section B: Scope and Structure of the European Recognition Programme

B1 Scope of Programme

B1.1 The IOAS European Recognition Programme (ERP) is open to any control body in the world. Control bodies based in Europe are obliged to seek formal accreditation from their national accreditation body (AB) for their activity inside their home country according to Regulation (EC) 765/2008. However control activity outside of Europe must also be under the supervision of an appropriate assessment body and the control body can choose any appropriate AB.

B1.2 The scope of control activity covered by the programme is as described and updated in Regulation (EC) 834/2007. As of December 2010 this includes:

- Plants and plant products (including wild harvest)
- Plants and plant products (excluding wild harvest)
- Livestock and livestock products (including beekeeping)
- Livestock and livestock products (excluding beekeeping)
- Beekeeping
- Preparation of products
- Animal feed preparation
- Production contracted to third parties
- Aquaculture
- Producer groups

B1.3 Recognition by the European Commission Organic Unit under the IOAS ERP requires that control bodies must be compliant or equivalent to ISO/IEC Guide 65 'General requirements for certification bodies operating product certification systems' 1996 as well as the rules set down in regulation (EC) 834/2007 and related implementing rules. All control bodies applying for the IOAS ERP must therefore also apply for the IOAS ISO Guide 65 programme and must indicate whether they wish to be assessed against ISO Guide 65 as **compliant or equivalent**. Those control bodies choosing the equivalence option will see greater flexibility applied but will not receive a certificate of accreditation for ISO Guide 65. Otherwise the process of assessment and surveillance and the cost is the same. The European Commission Organic Unit will not discriminate between control bodies choosing equivalence over compliance.

B1.4 Control bodies applying to the IOAS which already have ISO Guide 65 accreditation with another entity will not be excluded from the requirement to apply for IOAS ISO Guide 65 accreditation unless a cooperation can be established between the IOAS and the other supervising entity to ensure the control body is fully assessed and continuously supervised for all requirements.

B1.5 Control bodies operating outside of the European Union (including EU-based control bodies) cannot apply the various regulations directly as this is only possible in the legislative framework of the EU. Therefore a control body applying for equivalence assessment under this programme must nominate an organic standard of their own or of another organisation to be assessed for equivalence against the organic standard components of the regulations. This standard must be issued to the operators.

B2 Structure of the IOAS

(PL0101, PL0104, PL0204, PL0902²)

B2.1 The management and operation of the IOAS European Recognition Programme is the responsibility of the IOAS. The IOAS and its Board of Directors operate independently from any other organisation.

B2.2 The Board of Directors of the IOAS is constituted with a balance of interests taking into account geographical and gender spread. Normal length of tenure is three years. A current list of Board Members is available on the IOAS website (www.ioas.org/who.htm)

B2.3 The International Organic Accreditation Service Inc. is a non-profit corporation registered in the United States. The aims of the IOAS include the following;

- To provide a means whereby certification bodies involved in the certification of organic agriculture and the products thereof can submit themselves for evaluation against internationally agreed criteria, thereby enabling them to gain accreditation status;
- To improve the certification of organic products, thereby facilitating international trade in organic products on an equitable basis;
- To make its services available to outside interested parties, thereby facilitating international trade in organic products on an equitable basis.

B2.4 The structure of the IOAS and procedures for accreditation under the ERP are laid down in the IOAS Quality Manual. Individual policies may be obtained from the IOAS head office.

B2.5 IOAS Staff Members

In December 2010, there are currently six full-time professional staff members responsible for the day to day management of the accreditation programme; Executive Director (ED), Assistant Executive Director and Programme Manager (PM) and four Client Managers with offices in the USA, UK, Spain, Bulgaria Brazil. The ED is responsible for the overall operation of the IOAS and the PM is responsible for the administration of the accreditation process. An Office Manager supports the team of professional staff. A current staff list can be found at www.ioas.org/who.htm

B2.6 Accreditation Management Committee (PL0304)

A staff Accreditation Management Committee is appointed to make procedural decisions concerning the review of a control body file at certain stages of evaluation.

B2.7 Evaluators (PL0402)

² References to IOAS policy and procedure documents

Evaluation visits are undertaken by evaluators who have reached a required degree of professional competence. This includes a formal degree in agricultural science or equivalent education plus knowledge of, and experience in, organic inspection and certification. Evaluators serve an apprenticeship period before conducting evaluations. Most evaluation visits are performed by in-house professional staff. Any allocated evaluators should not have been employed by a control body in a position or within a period of time that might affect their impartiality. The criteria relative to an evaluator's expertise includes, among others:

- Knowledge and understanding of the ERP (certification criteria and procedures);
- Knowledge of the organic standard components of (EC) 834/2007 and related regulations and generally accepted experience (practical experience in production, processing, inspection or certification management) relative to conformity assessments;
- Knowledge of evaluation methods including, among others, interviewing techniques and an ability to draft reports;

B3 IOAS Policy

B3.1 The IOAS has a comprehensive quality manual in which all its policies are laid down. The following policies are of particular importance.

B3.2 Confidentiality(PL0203)

Members of the IOAS board, the staff, evaluators and other relevant personnel are required to sign a confidentiality agreement that is based on a comprehensive Confidentiality Policy. Full confidentiality is maintained regarding evaluation reports, application forms and any information which is regarded as commercially sensitive. Except for confidentiality restrictions, the IOAS principle is one of transparency, and the names of all evaluators are published (www.ioas.org/who.htm) A list of control bodies and their status under the IOAS EEP is published and continuously updated on the IOAS web site.

B3.3 Conflicts of Interest (PL0202, PL0305, PL0401)

The IOAS is committed to a policy of neutrality in carrying out the ERP. Among other measures, the following procedures and policies are adhered to.

- Members of the IOAS Board are drawn from all sectors with an interest in organic accreditation but with no single interest predominant.
- The interests of all IOAS Board members are on file, are updated regularly, and are formally reviewed once a year. Failure to declare an interest is sufficient cause for dismissal.
- All Board members are obliged to declare any perceived conflict of interest and to absent themselves from the meeting before deliberations commence regarding an applicant or accredited body.
- The interests of all evaluators are on file in the IOAS office and are consulted in the assignment of evaluators. Failure to declare an interest is sufficient cause for removal of the evaluator from the approved evaluator list.
- Applicant bodies have the opportunity to object to the assignment of an evaluator.

B4 Review of the IOAS

(PL0106)

B4.1 The IOAS ERP is subject to periodic internal review in line with its Internal Review Policy. It entails an assessment of its structure, criteria, and procedures and results in a revision of those areas where a need for improvement is noted.

B4.2 In August 2004, the IOAS was first recognised by the National Institute of Standards and Technology (a technical institute which forms part of the United States Department of Commerce) as compliant with ISO17011. The IOAS is subject to continuous ongoing surveillance and reassessment by NIST.

Section C: The Assessment Process

The procedures for assessment and ongoing surveillance under the ERP involves six phases;

- Application and screening of documentation with time for corrective actions
- Assessment of control body performance with time for corrective actions
- Preparation of the report on equivalence
- Control body submission to the Commission and decision
- Surveillance
- Re-assessment

In general the procedures follow the standard IOAS accreditation/assessment procedures which enables all IOAS programmes to run concurrently should the control body be applying for more than one.

C1 Application and Screening Procedures

(PR0501, PR0502)

C1.1 Following inquiry the IOAS forwards to the control body an application pack which contains full details of the procedures of application. Potential applicants must assure they have consulted the documents referred to under A3 above.

C1.2 The applicant returns the completed application form and the required documentation together with the application and assessment fee. The applicant must provide its Quality Management System Manual, and any additional documents deemed essential to the assessment to the IOAS as well as the organic standard against which operators are being assessed for the control body European programme.

C1.3 Given that the European Commission have established an annual deadline of October 31st for applications for recognition, the IOAS are unable to provide guarantees of completing the assessment process in time for that annual date unless the control body application is submitted to the IOAS before January 1 of the same year. Although the IOAS will do its utmost to meet any desired deadline, given the joint responsibility of meeting the assessment schedule and the unknown status of the control body applying, the IOAS cannot be held responsible for not meeting an application deadline.

C1.4 The IOAS sends acknowledgement of receipt within five working days after reception of the application and proceeds with the assessment.

C1.5 The documentation is reviewed for completeness. Where documentation is manifestly incomplete the IOAS informs the applicant of the necessary additional documentation before further processing the application.

C1.6 The control body is sent a surveillance contract and arbitration contract to sign and return to the IOAS. This contract makes clear rights and obligations on both sides. These contracts are open-ended.

C1.7 The IOAS screens the documentation against the requirements of ISO/IEC Guide 65 and the relevant parts of regulation (EC) 834/2007 and implementing rules.

C1.8 For all norm requirements, the IOAS considers the compliance/equivalence of the control body measures and applicable organic standards. For judgement of equivalence, the IOAS take into account both the Codex Alimentarius Guidelines CAC /GL 32 and the International requirements for organic certification bodies published by the International Task force on Harmonisation & Equivalence. Both documents are available via the IOAS web site. In addition the IOAS has developed its own system for categorising equivalence as follows:

1. Agroecology = the requirement is not applicable/reasonable for the specific conditions of the CB being assessed either on grounds of climate or geography.

2. Alternative means = the CB does not perform this requirement exactly as stated but achieves the same aim by another means

3. Detail = the CB does not perform this requirement but it is considered a small detail with no effect on the integrity of organic products.

4. Legislative = the requirement is covered by some other binding law of the country and therefore doesn't need to be addressed in the CB's own requirements

5. Socioeconomic = the requirement is not applicable/reasonable for the specific conditions of the CB either on grounds of culture, social, economic or stage of development of the organic sector.

C1.9 Where the IOAS considers a control body measure or standard to be equivalent to the European requirements, an explanation in the line by line analysis is provided.

C1.10 A compliance report is prepared by the IOAS, which indicates any non-conformities which cannot be considered compliant or equivalent with the standards and criteria and requests for further information where necessary. This is sent to the applicant control body requiring it, within a set time limit, to take the necessary actions to come into conformity or equivalence with the requirements.

C1.11 Applicants may wish to seek review of specific conditions without officially appealing the overall decision. Such requests must include substantive reasons why the condition imposed is considered inappropriate or unjustified.

C1.12 Once the submitted information and standards or policy/procedure amendments have been accepted by the IOAS, to the effect that there are no outstanding non-conformities, an evaluation visit is arranged.

C2 Assessment of control body performance

(PR0503, PR0504)

C2.1 The evaluation visit is assigned to an approved evaluator. Evaluators must not have, or have had during the past five years, any interest in the organisation to be evaluated. A control body shall not be evaluated by the same person for more than two consecutive evaluations.

C2.2 The control body may challenge the appropriateness of an assigned evaluator.

C2.3 The evaluator is briefed and provided with the screening report and any necessary documentation.

C2.4 In circumstances where the control body has more than one office or sub-contracts inspection to a separate organisation, the IOAS will determine, based on activities of those offices, which offices and how many offices must be included in the on-site visit. Where relevant, this may include travel to more than one country.

C2.5 The IOAS sends to the control body the information, documentation and instructions for the visit including details of operators visits, as well as an estimate of expenses pertaining to this visit.

C2.6 The evaluation visit is made up of the following stages:

- Initial meeting with officers of the applicant body at the central office
- Interviews with managers and employees
- A detailed inspection of the control body office files in line with requirements of the European Union.
- Physical review audits of operators
- Post audit (review audit) operator inspections according to the requirements of the European Union
- At least one witness audit
- Exit interview held in the central office with opportunity for questions

C2.7 The evaluator requires access to all previous inspection documentation and may request an inspector or officer of the control body to accompany him/her on the review audits.

C2.8 The evaluator(s) will check, among other things, that:

- all documentation is complete and up to date and that there are no forms, inspection reports, or certification decisions missing;
- the inspection reports are comprehensive and enable sound certification decisions to be taken on the basis of the information provided;
- the certification decisions are consistent with the degree of compliance recorded in the inspection reports;
- where conditions or requirements for corrective action have been imposed on the operators by the control body, that their implementation has been adequately monitored and documented;
- the body is operating in a compliant or equivalent manner (whichever is appropriate) to that described in ISO/IEC Guide 65 and (EC) 834/2007;
- in the case of re-evaluations, previous conditions have been fulfilled;
- in the case of operator audits, that the practices of the operators conform to the standards of the control body and that the inspection files accurately record the production system.

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- Where control bodies operate in countries outside of their home territory, the evaluation will include office and/or operator visits in a sample of the countries concerned based on IOAS sampling policy PL0508.

C2.9 The evaluator will record the findings of the visit in the evaluation report. The evaluation report follows a set format and includes the findings of the office file checks and the operator visits.

C2.10 The IOAS submits a draft evaluation report to the applicant body. This assessment report shall contain comments on competence and conformity, and shall identify nonconformities, if any, to be resolved in order to conform with all of the requirements. The control body is thus invited to comment on the report's content and verify its accuracy. Comments and requests of modifications sent by the control body must be included in the report. If there are any divergences in opinion with the control body relative to comments and requests made, explanations shall be provided in the report.

C2.11 When the report is finalised, if no major problems are uncovered, the IOAS will send a final copy to the evaluated applicant body. The report may be referred to the Accreditation Management Committee for review.

C2.12 Following the visit, the IOAS identifies any additional non-conformities resulting from the visit. The applicant body is informed of these and is allowed a time period for taking the necessary corrective actions.

C2.13 Failure to meet the deadlines for the required corrective actions specified in C1.5 or in C2.12 may result in the IOAS proposing termination of the evaluation process.

C3 IOAS expert report on equivalence

(PR0506, PR0511)

C3.1 Once all noncompliances are resolved the IOAS prepares an assessment report for the control body in the format described in the Commission Guideline on imports of organic products.

C3.2 The report includes a narrative section which summarise the IOAS findings in relation to the control body quality system and its implementation and is supported by annexes containing the line-by-line review of equivalence of documentation.

C3.3 The assessment is reviewed by the control body and may be amended in light of any comments. Once complete, it is then the responsibility of the control body to submit their application to the European Commission in electronic form to the email address: agri-organic-imports@ec.europa.eu

C3.4 The Organic Unit of DG Agri of the European Commission is then responsible for reviewing the application and making a decision on whether to recognise the control body as

equivalent. The IOAS are not involved in the process, other than perhaps answering questions of clarification.

C3.5 Following a positive decision by the European Commission the control body will appear on a public internet-based list which will denote that the control body has been formally recognised as implementing an equivalent system of control and standards to that described under (EC) 834/2007. The control body will be issued a number and the scope and countries of operation of the control body will be indicated.

C4 Surveillance

(PR0508)

C4.1 The IOAS is responsible for monitoring the compliance of listed control bodies on an ongoing basis. Control bodies are required to submit an annual update report and to undergo short surveillance visits to a specified schedule. After initial assessment the control body will normally receive surveillance visits in year 1 and year 3 of their first 4 year contract. In subsequent contract periods, the control body will normally receive one surveillance visit in year 2 of the contract period. This surveillance model depends on continued good performance of the control body, the details of which are available in IOAS document PR0508.

C4.2 By March 31 every year the control body must provide an annual update to the Organic Unit of DG Agri which must include an update on the technical dossier and the original assessment report. Using its surveillance conducted during the previous year the IOAS will provide to each listed control body under its surveillance, the necessary update information to be included in their report to the Commission.

C4.3 At any time, and upon its own initiative, the IOAS may carry out a supervision visit for any major non-conformance with the requirements of (EC) 834/2007. The IOAS may conduct unscheduled assessments as a result of valid complaints or changes that have affected corporate structure and directors, the administrative structure, etc.

C4.4 Detailed instructions for both the report and the visit during surveillance years are sent to listed control bodies in advance.

C4.5 The purpose of the update report is to enable the IOAS to monitor the general changes undergone by the control body over the previous year. Under the surveillance contract, substantial changes which may effect the status of the control body are required to be reported at the time they are being made.

C4.6 Surveillance visits are conducted (in relevant years) following review of the update report. At the surveillance visits the IOAS will:

- examine any additional material related to the update report;

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- review both general files and operator files. Particular attention will be paid to whether the control body has effectively implemented conditions that have previously been considered fulfilled;
 - the surveillance visit will include a witness audit of a scheduled inspection.
 - conduct an exit interview during which the evaluator will inform the control body of any findings;
 - complete a report of the visit and its conclusions and send a copy to the control body.

C4.7 In cases of significant noncompliance the report may be referred to the Accreditation Management Committee to review the results of the surveillance visit. The control body is informed of the outcome and of any additional conditions for continued equivalence.

C4.8 If the control body has failed to meet the deadlines for conditions or where the visit reveals that the control body has failed to effectively implement the corrective actions related to conditions that have previously been considered fulfilled, the IOAS may impose sanctions.

C4.9 Failure to meet any of the terms of the surveillance contract may result in the suspension or withdrawal of the contract or in the imposition of other sanctions in accordance with the IOAS policies and procedures. The action taken will be in accordance with the severity of the infringement. The Organic Unit of DG Agri will be informed.

C5 Re-Evaluations

(PR0510)

C5.1 As for all IOAS accreditations/assessments full reevaluation of control bodies will take place every 4 years. Procedures for the review evaluation are similar to those of the initial evaluation and include resubmission of all required documentation and a full evaluation visit.

C5.2 In cases where existing clients of the IOAS apply to enter the ERP, the surveillance and reevaluation schedule will be automatically synchronised with existing accreditations/assessments. Unless the assessment for this programme takes place at the same time as for other programmes the first assessment cycle for the ERP may as a result be shorter than 4 years.

C6 Timeframe for the accreditation process

C6.1 The time period from receipt of an application by the IOAS to the issue of the assessment report will vary depending on the initial level of non-compliance of the control body and the intensity of work done to rectify nonconformities. The time period can be expected to be 9 to 12 months.

C7 Fees

(LS0503, PL0312)

C7.1 The IOAS is a not for profit company and the ERP is run on a non profit basis. Charges are set to cover the operating and continued development costs of the programme. A current fee schedule is available from IOAS offices and www.ioas.org/fees.htm

C8 IOAS records

The IOAS maintains up to date the following information in relation to each control body under its ERP:

- Name and address of each control body;
- Scope of activity under this programme of each control body;
- Countries of activity under this programme of each control body;
- Information on noncompliances issued and their resolution;
- Internet address where the control body lists operators under this programme;
- All assessment and annual reports issued to the control body.

Section D: Rights and Responsibilities

The rights and duties of assessed bodies are documented in the Surveillance Contract for ERP, document number PL 0524, a sample of which is sent out as part of the application pack and is available from IOAS offices and from www.ioas.org/eucon.htm

D1 Surveillance Contract Period

(PL0518)

D1.1 The surveillance contract is open ended but the cycle of surveillance requires continued compliance/equivalence with the norms. This is verified through a full reevaluation every 4 years and annual surveillance based on reporting or an on-site visit in the interim.

D2 Use of Status of being in the IOAS EEP

(PL0503)

D2.1 Control bodies may refer verbally and in writing to their being under IOAS surveillance for the ERP from the date of IOAS signing the surveillance contract.

D2.2 References to being a participant in this programme may not however suggest any form of recognition or approval by the IOAS. Recognition under (EC) No.834/2007 may only be granted by the European Commission Organic Unit of DG Agri and is indicated by inclusion in the list referred to under Art 33(3) of that regulation. No claim of recognition by the European Commission may be made before being informed formally by the Commission and inclusion in that list.

D3 Notification of Changes and Extension of Certification Scope

(PR0512)

D3.1 Control bodies are required to inform the IOAS of any changes which may impact their status and of any changes which affect the scope of their activity

D3.2 Where the control body is introducing a category of certification not previously included in its assessment scope (see B1.2), a request for extension of scope must be filed with the IOAS. Appropriate standards of production and evidence of competence in this field must be submitted to IOAS for screening and evaluation. Any corrective actions must be taken before the commencement of the first certification decision.

D3.3 The control body must state the objectives and the reasons associated with the request for an extension of scope.

D3.4 When applying for an extension of its scope, the control body must also supply documents relative to the monitoring measures intended to be implemented as to support this extension.

D4 Appeals, Complaints and Sanctions

D4.1 Appeals

(PL0504)

The IOAS does not make an overall decision of recognition. This decision rests with the European Commission Organic Unit. Therefore the control body is unable to appeal an overall decision by the IOAS. However, individual compliance or equivalence decisions of the IOAS may be challenged by the CB. Such challenges must be directed to the IOAS and lodged within 30 days of notification of the disputed decision.

D4.2 Such challenges are considered by the Accreditation Management Committee. The decision of this Committee will be sent to the control body.

D4.3 As of December 2010 it is not yet clear whether the European Commission Organic Unit plans to establish an appeals process or mechanism for handling interpretations.

D4.4 Complaints

(PL0511)

The IOAS has formulated a detailed complaints policy which is available to interested parties on request and at www.ioas.org/complain.htm

D4.5 Complaints against IOAS

Complaints concerning the functioning of the IOAS ERP and its personnel should be addressed in writing to the IOAS office. Complainants will be informed of the decision.

D4.6 Complaints regarding control bodies under IOAS surveillance

Parties having complaints against control bodies should first address the issue to the control body in question as they are required to have complaints procedures in place and these are monitored by the IOAS as part of its surveillance procedure.

D4.7 Should the complainant not be satisfied with the control body response or the complainant considers it more appropriate, the complaint can be directed to the IOAS. The IOAS will investigate the complaint. Where the IOAS considers the complaint to be sufficiently substantiated and relevant to norms under supervision, it will inform the body concerned and invite a response. The matter will then be referred to the IOAS Board to formulate a complaint resolution. The complainant is informed of the complaint resolution. If the complaint is upheld, the IOAS may impose appropriate sanctions against the control body.

D4.8 Sanctions

(PL0505)

In the event of non-compliance with the surveillance contract, failure to fulfill conditions or gross breaches of the requirements of the ERP the IOAS may apply one or more of the following sanctions:

- issue a warning letter or letter of reprimand;
- impose additional conditions and insist on corrective action according to a timetable;
- require the control body to undergo a re-evaluation within a certain period;
- recommend to the European Commission Organic Unit suspension of recognition;
- recommend to the European Commission Organic Unit withdrawal of recognition.

D4.9 Only the European Commission Organic Unit can take the decision to suspend or withdraw recognition.

ANNEX 1: Addresses

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