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INTERNATIONAL TASK FORCE ON HARMONIZATION AND EQUIVALENCE IN ORGANIC AGRICULTURE

## International Requirements for Organic Certification Bodies (IROCB)

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# 1. Introduction

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## 1.1. Foreword

The International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF), convened by FAO, IFOAM, UNCTAD, serves as an open-ended platform for dialogue between private and public institutions involved in trade and regulatory activities in the organic agriculture sector

The overall objective of the ITF is to facilitate trade of organic products as a response to difficulties faced by organic producers and exporters due to the hundreds of different organic regulations, standards and labels worldwide. Similar to varying standards, requirements for organic certification bodies to conduct third party conformity assessment also vary. This causes difficulties for certification bodies to recognize and accept organic products certified by another system/program and finally for organic producers to get organic certified products accepted in different markets.

The ITF in this document specifies international requirements for organic certification bodies (IROCB) to facilitate the recognition of certification bodies' services in the course of international trade. IROCB is intended to represent an international consensus on good practice in organic conformity assessment between private and public institutions and hereby facilitates the mutual recognition of conformity assessment results in the organic sector.

The requirements are considered as a baseline to assess the equivalence of service performed by another certification body outside a certain organic system. It is understood as a tool for governments or accreditation/approval bodies to approve each other's requirements as equivalent to allow products certified to enter the system. It could also serve as a tool for certification bodies to recognize service provided by another certification body and finally it could serve as basis for developing requirements for accreditation.

Application of these requirements is intended to ensure that certification bodies operate third party certification of organic operators in a consistent and reliable manner. If an evaluation reveals that a certification body is performing organic certification in line with these requirements it should be considered competent to conduct organic certification, and its service should be considered as equivalent to services provided under any other organic system.

IROCB is based upon the requirements in ISO/IEC Guide 65: 1996 (E) "General requirements for bodies operating product certification systems". However organic certification has certain features different from certification of products and services covered by ISO/IEC Guide 65. IROCB includes sector specific requirements; it includes reformulated and amended ISO paragraphs and additional requirements to cover issues confronted by a certification body conducting organic certification. Additional or divergent requirements to ISO/IEC Guide 65 can also be found in regulatory systems such as NOP, USDA, EU regulation and the IFOAM accreditation system.

In general existing regulations must be applied and laws respected. It also must be noted that certification body's authority often is restricted under regulatory systems compared to the requirements outlined in ISO/IEC Guide 65. Certification bodies are mandated to perform functions on behalf of authorities who reserve the right to take final decisions or control (e.g. complaints resolutions, withdrawal of certification, ownership of logo).

The document does not cover organic production standards. Differences in organic standards shall be observed and taken into account by other measures.

## **1.2. Definitions**

For the purpose of this document the definitions given in annex 1 (A1) apply.

## **1.3. Scope**

IROCB specify baseline requirements a certification body conducting organic certification shall meet if it is to be recognized as competent.

### **1.3.1. Evaluation methods**

Evaluation methods shall consist of document review, appraisal of quality management systems and on-site inspection visits. Sample analyses, testing should serve as supporting tools to verify information.

Evaluation methods shall be applied systematically according to defined certification procedures. Procedures shall address initial and ongoing evaluation in order to assess whether a production process **continues** to meet the applicable organic standard.

### **1.3.2. Chain of custody**

The Certification body shall assure that any product used in the course of its own certification is duly certified (section 2.1.4 applies to address the acceptance of prior certification)\*.

*\* Explanatory note: e.g. products, raw material used by certified operators that are certified by another certification body.*

## **2. General requirements**

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### **2.1. Responsibility**

#### **2.1.1. Legal structure**

The structure of the certification body shall foster confidence in its certifications. In particular, the certification body shall

2.1.1.1. have documents which demonstrate its a legal entity;

2.1.1.2. have documented the rights and responsibilities and duties relevant to its certification activities;

2.1.1.3. identify the management (body, group or person) having the overall responsibility of the functioning of the certification body, including finances.

#### **2.1.2. Certification agreement**

The certification body shall have an agreement for the provision of certification activities to its operator in line with these requirements. In particular the agreement shall

2.1.2.1. include a description of the rights and duties of applicants and operators offering certified products, including a commitment to comply with the relevant provisions of the certification program;

2.1.2.2. specify requirements, restrictions or limitations on the use of the designated certification logo and on the ways of referring to the certification granted to prevent misleading use or claims;

2.1.2.3. have provisions to allow the certification body to exchange information with other certification bodies and authorities (approval bodies, accreditation bodies) to verify information especially the certification status of certified products as part of its ongoing evaluation.

#### **2.1.3. Responsibility for certification decisions**

The certification body shall keep final responsibility for granting, maintaining, extending, suspending and withdrawing of certification and shall not delegate such decisions.

#### **2.1.4. Acceptance of prior certification**

Where products in the production chain have been certified by other certification bodies the certification body may accept prior certification according to defined procedures.

\*. Acceptance maybe granted when equivalent certification procedures have been applied.

*\*Explanatory note: There could be varying acceptance situations to be covered by appropriate acceptance procedures e.g.:*

- acceptance of certificates issued by another certification body under the same certification program and authority;
- acceptance of certificates issued by another certification body working under a different certification program and authority;
- certification bodies collaborating based on a defined agreement .

## **2.2. Personnel resources**

The certification body shall employ sufficient personnel competent for performing certification functions and operating its system. In particular it shall

- have processes to ensure that personnel have knowledge relevant to the scope of certification issued (farming operations, processing facilities, geographic areas, group certification);
- employ a sufficient number of personnel relating to the type, range and volume of work performed including consideration of geographic areas in which it operates.

The certification body shall maintain up to date records on personnel resources.

### **2.2.1. Qualification criteria and documentation**

2.2.1.1. The certification body shall define minimum criteria for the competence of personnel to ensure that evaluation and certification is carried out effectively and uniformly. Criteria should include minimum education, training, technical knowledge and work experience relevant to the scope of certification issued.

2.2.1.2. The certification body shall maintain up to date documents describing duties and responsibilities of assigned personnel.

### **2.2.2. Continuous training**

The certification body shall train personnel involved in certification (inspectors and other certification personnel including members of technical committees) to ensure that personnel have and continue to have technical knowledge and experience for performing functions in organic certification.

In particular the certification body shall

2.2.2.1. provide training targeted to the specific function personnel is performing (e.g. inspection: farm inspection, inspection of processing facilities; review of application; evaluation etc.).

2.2.2.2. review the competence of its personnel in light of their performance in order to identify training needs.

2.2.2.3. ensure that new personnel have sufficient competence\*.

*\*Explanatory note: e.g. new personnel to complete a training course in conducting organic inspection and evaluation and/or undergo a defined on-site apprenticeship period.*

### **2.2.3. Assignment of personnel**

The certification body shall require personnel including committee members involved in the certification process

2.2.3.1. to commit themselves to policies and procedures of the certification body.

2.2.3.2. to declare any prior or present association on their own or on the part of their employer, with an operator subject to the certification of which they are to be assigned to perform certification procedures.

### **2.2.4. Assignment of committees**

The certification body shall have formal rules and structures for the appointment and operation of any committees which are involved in the certification process reflecting requirements of 2.2.1 and 2.2.2.

### **2.2.5. [Subcontracting (outsourcing)]**

*[Request to discuss whether subcontracting of inspection duties should be allowed]*

When a certification body decides to subcontract work (outsourcing) related to certification (e.g. inspection) to an external body or person, an agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The certification body shall

2.2.5.1. take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, renewing, extending, suspending or withdrawing certification

2.2.5.2. ensure that the subcontracted body or person:

- is competent to perform the subcontracted work;
- is not involved either directly or through the person's employer with the operation, process or product subject to certification in such a way that impartiality would be compromised;
- is committed to the policies and procedures as defined by the certification body;

2.2.5.3. monitor the performance of persons or bodies providing subcontracted work.

### **2.3. Impartiality and objectivity**

#### **2.3.1. Organizational structure and stakeholder involvement**

The certification body shall be impartial; it shall not be financially dependent on single operations subject to their certification such that impartiality is compromised. The certification body specifically shall have a documented structure

2.3.1.1. which safeguards impartiality including provisions to ensure the impartiality of the operations of the certification body;

2.3.1.2. providing for participation of parties concerned in a way that balances interests and prevents commercial or other interests from unduly influencing decisions\*.

*\*Explanatory note: a committee representing key interests such as clients, other industry representatives, representatives of governmental services, or representatives of non governmental organizations including consumer organizations advocating the certification body management is deemed to fulfill the structural requirements.*

#### **2.3.2. Management of impartiality**

The certification body shall identify, analyze and document the possibilities for conflict of interests arising from its provisions of certification including any conflicts arising from its relationships. Rules and procedures shall be established to prevent or minimize the threat. In particular the certification body shall

2.3.2.1. require personnel to declare existing or prior association with an operation subject to certification. Where an association threatens impartiality, the certification body shall exclude the person concerned from work, discussion and decisions in all stages of the certification process related to the potential conflict of interest.

2.3.2.2. follow defined rules for appointing and operating committees involved in certification activities. Rules shall ensure that committees are free from any commercial, financial and other interest that might influence decisions;

#### **2.3.3. Division of functions**

The certification body shall not provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions. In case the certification body also performs other activities than certification it shall apply additional measures to ensure that confidentiality, objectivity and impartiality of its certifications is not affected by these other activities. In particular the certification body shall not

2.3.3.1. produce or supply products of the type it certifies;

2.3.3.2. give advice or provide consultancy services to the applicant/operator as to methods of dealing with matters which are barriers\* to the certification requested\*\*

*\*Explanatory note: Barriers can be e.g. non-conformities identified in course of the certification process.*

*\*\*Explanatory note: Explanations regarding the production method standard are not considered as advice or consultancy. General information or training may be given as long as this service is offered to all applicants/operators in a non-discriminatory manner.*

#### **2.3.4. Accessibility**

The certification body shall make its services equally accessible to all applicants whose activities fall within its declared field of operation.

It shall work according to non-discriminatory policies and procedures safeguarding that no undue financial (e.g. with regard to the fee structure) or other conditions\* are applied.

*\*Explanatory note: Access shall not be conditional upon e.g. the size of the supplier or membership of any association or group, or number of certificates already issued.*

### **2.4. Access to Information**

#### **2.4.1. Publicly accessible information**

The certification body shall provide access to information in order to gain confidence in the integrity and credibility of certification.

The certification body shall provide (through publications, electronic media or other means), updates at regular intervals, and make available on request:

2.4.1.1. the standard to be met by operators in order to gain/maintain certification;

2.4.1.2. information about procedures applied in order to evaluate whether operators meet the standard applicable;

2.4.1.3. information about procedures to be applied in case certification is extended;

2.4.1.4. information about procedures and sanctions to be applied in case non-conformities with standards are detected;

2.4.1.5. the fee structure for its services;

2.4.1.6. a description of the rights and duties of operators, including requirements, restrictions or limitations on the use of the certification logo and on ways of referring to the certification granted;

2.4.1.7. information about procedures for handling general complaints, and appeals against its certification decisions.

2.4.1.8. a list of certified operations and the scope of their certification .

#### **2.4.2. Confidentiality**

In order to gain privileged access to information the certification body shall have adequate arrangements to safeguard confidentiality of the information obtained in the course of its certification activities at all levels of its organization, including

committees and external bodies or individuals acting on its behalf. Arrangements shall

2.4.2.1. protect proprietary information of a client against misuse and unauthorized disclosure;

2.4.2.2. grant the certification body the right to exchange information with other certification bodies and/or authorities to verify information.

### **2.4.3. Reference to certification and use of certification logo (mark)**

2.4.3.1. The certification body shall exercise control over ownership, use and display of licences, certificates and logo it authorizes certified operators to use.

2.4.3.2. The certification body shall be able to request an operator to discontinue use of certificate and logo.

2.4.3.3. The certification body shall apply suitable actions to deal with incorrect references to the certification system or misleading use of licences, certificates or logo by operators and/or third parties..

## **2.5. Quality Management System (QMS)**

### **2.5.1. General**

2.5.1.1. The certification body shall define, document and implement a quality management system in accordance with the relevant elements of these requirements to give confidence in its ability to perform organic certification. The quality management system shall be effective and appropriate for the type, range and volume of work performed.

2.5.1.2. The management shall ensure that the quality management system is understood, implemented and maintained at all levels of the organization.

### **2.5.2. Management system manual**

2.5.2.1. The certification body shall address and document all applicable requirements either in a manual or in associated documents in order to ensure uniform and consistent application.

2.5.2.2. The certification body shall ensure that the manual and relevant associated documents are accessible to all relevant personnel

2.5.2.3. Depending on type, range and volume of work performed and considering number of personnel involved in the process the manual and associated documents shall refer to:

- an organizational chart showing line of authority, responsibility and allocation of function;
- a description of procedures applied by the certification body in course of performing certification (granting, maintaining, renewing, extending, suspending and withdrawing of certification);
- procedures for the recruitment selection, training and assignment of certification body personnel (as outlined under 2.2.);
- policy and procedures dealing with appeals against certification decisions and other complaints;

- policy and procedure addressing quality review (e.g. internal audits, management review)

### **2.5.3. Control of documents**

The certification body shall establish and maintain procedures to control its documents that relate to its certification functions. In particular the certification body

2.5.3.1. shall, through authorized and competent personnel, review and approve documents for adequacy prior to their original issue or any subsequent amendment;

2.5.3.2. maintain a list of all appropriate documents with the respective issue and/or amendment status identified;

2.5.3.3. control the distribution of all such documents to ensure that the appropriate documentation is provided to personnel of the certification body or suppliers when they are required to perform any function relating to the certification body's activities, and to prevent the unintended use of obsolete documents.

### **2.5.4. Records system**

2.5.4.1. The certification body shall maintain a system of records\* to demonstrate that the certification procedures have been effectively fulfilled, particularly with respect to application forms, evaluation reports, any re-evaluation activities and other documents relating to granting, maintaining, renewing, extending, suspending or withdrawing certification;

2.5.4.2. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information.

2.5.4.3. Operator records shall be up to date and contain all relevant information, including inspection reports and certification history.

2.5.4.4. Records shall be kept for [*exceptions granted*], appeals and subsequent actions;

2.5.4.5. Records shall be kept for a period of time so that continued confidence may be demonstrated for at least 5 years or as required by law.

*\*Explanatory note: Records may be either electronic or paper documents.*

### **2.5.5. Quality review**

The certification body shall demonstrate that it seeks and achieves continuous quality improvement. It shall perform management reviews and internal audits according to the type, range and volume of certification performed.

2.5.5.1. In particular it shall periodically review all procedures in a planned and systematic manner, to verify that the quality system and its procedures are implemented and effective. Performance reviews conducted periodically<sup>1</sup> shall be part of the review.

2.5.5.2. Review intervals shall be sufficiently short to ensure that the objective of quality improvement is fulfilled. Records of quality reviews shall be maintained.

## **2.5.6. Appeals and complaints**

The certification body shall have policies and procedures for the resolution of complaints and appeals received from operators or other parties about the handling of certification or any other related matters. In particular the certification body shall

2.5.6.1. take appropriate subsequent action to resolve complaints and appeals;

2.5.6.2. keep a record of all appeals and complaints and remedial actions relative to certification;

2.5.6.3. document the action taken and its effect

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<sup>1</sup> It is industry practice to annually conduct performance reviews of personnel responsible for evaluation and inspection and certification.

### **3. Process requirements to conduct organic certification**

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#### **3.1. Application procedures**

##### **3.1.1. Information for operators**

The certification body shall provide to operators an up-to-date description of the procedures to be applied. The certification body shall inform operators about

3.1.1.1. contractual conditions including fees and possible contractual penalties;

3.1.1.2. operator's rights and duties including the appeals procedures;

3.1.1.3. the applicable standards;

3.1.1.4. the applicable evaluation and inspection procedures applied by the certification body in the course of certification.

3.1.1.5. documentation to be maintained by the operator to enable verification of compliance with applicable standards by the certification body.

##### **3.1.2. Application form and operator obligations**

The certification body shall require completion of an official application form, signed by a duly authorized representative of the operator. To enable evaluation and assignment of qualified personnel, the certification body shall require operators to:

3.1.2.1. agree to comply with the requirements for certification (certification requirements and procedures and standards applicable)

3.1.2.2. provide information about the scope of the desired certification including a description as specified by the certification body of the production, products and area to be certified;

3.1.2.3. provide to both the certification body and responsible authorities the right of access to all appropriate facilities including non-organic production in the unit or related units and all relevant documentation and records, including financial records,

3.1.2.4. provide information about denial of certification by another certification body

#### **3.2. Evaluation**

The certification body shall evaluate operators against all certification requirements specified. The evaluation consists of a review of documents and an on-site inspection visit.

When the scope of certification is for labeling of conversion to organic, verification of compliance with these requirements shall take place during the conversion period.

##### **3.2.1. Review of application and preparation of inspection**

3.2.1.1. Prior to the inspection, the certification body shall review the application documents to ensure that certification can be carried out and application of

certification procedures is possible. The certification body in particular shall review whether

- documents submitted by the operator are complete and significant
- the operator appears to be able to comply with all certification requirements (applicable procedures and standards)
- the scope of the certification sought is within scope of certification services provided\*.

*Explanatory note: new scope could also be a new geographical area the certification body is not yet active.*

3.2.1.2. The certification body shall assign qualified personnel to the evaluation in line with requirements of 2.2. and 2.3 of this document, and provide them with appropriate work documents.

3.2.1.3. The certification body shall inform inspectors about any non-conformity and corrective actions issued previously to enable the inspector to verify whether they have been implemented.

### **3.2.2. Inspection protocol**

The inspection is carried out in order to verify information and compliance with certification requirements applicable to the operator. It shall follow a set protocol to facilitate nondiscriminatory and objective inspection.

The inspection protocol shall at least address the following:

3.2.2.1. Assessment of production or processing system by means of visits to facilities, fields, and storage units (this may include visits to non-organic areas as well if there is reason for doing so);

3.2.2.2. Review of records and accounts in order to verify flow of goods (production/sales reconciliation on farms, input/ output reconciliation and trace back audits in processing and handling facilities)

3.2.2.3. Identification of areas of risks to organic integrity

3.2.2.4. Verification that changes to the standards and to requirements of the certification body have been effectively implemented.

3.2.2.5. Verification, that corrective actions have been fulfilled.

*[Commenter request: include more specific requirements regarding the inspection protocol such as length (not too long but sufficient time to carry out complete assessment; exit interview)]*

### **3.2.3. Particular requirements to address high risk situations**

The certification body shall apply additional measures to address higher risks\* found in certain situations specific to organic certification.

*Explanatory note: High risk situations and measures to deal with can be:*

3.2.3.1. Partial conversion and parallel production: in order to prevent commingling or contamination of organic products with other products not meeting the standards the certification body should verify whether documentation regarding production or processing, storage and sales is well managed and makes clear distinctions between certified and non-certified products. In case products are not visibly distinguishable measures during harvest and post harvest handling should be applied to reduce the risk.

3.2.3.2. Intense production and high dependence of external inputs, short production cycles: depending on the risk identified the certification body may decide whether it is appropriate to increase the regular inspection frequency.

3.2.3.3. In case an operator is certified also by other certification bodies within the same organic scope, the certification body may seek information exchange with other certification bodies involved to prevent misuse of certificates.

*[ITF meeting to discuss whether high risk situations are covered adequately]*

#### **3.2.4. [Requirements for group certification systems]**

*[Requirements for group certification to be discussed at the ITF meeting: Please consider the revision of NOSB 2002 recommendation "Criteria for Certification of Grower Groups" currently under discussion. Changes proposed in the following paragraph address the most critical concern raised: "It is understood that an internal control system functions as a proxy for mandatory on-site inspection of each production unit and therefore is not permitted". For clarification language of this section has been amended to address the concern and to clarify the group certification concept, see also the definition reviewed in the definition section. The current discussion and the draft of the new guidance document issued recently shall be observed in order to make sure that the concept of group certification remains applicable.]*

3.2.4.1. If the certification body includes group certification based on an internal quality management system within its certification scope it shall apply a specific group certification program.

3.2.4.2. The group certification program shall specify the scope for group certification and requirements applicable to the group, including those for an internal quality management system to ensure the conformity of all group members to the applicable standards.

3.2.4.3. In order to address the particular situation of group certification the certification body shall apply additional measures to the regular on-site inspection protocol in order to assess the effective application of the internal quality management system:

- *On site inspection of a sample of group members to assess the effectiveness of the internal quality management system. Number of group members reviewed for standard conformity shall be determined according to defined procedures taking into account the risks identified and the number of group members.*
- *Witness of personnels' performance in conducting internal review of the management system applied by the group.*

- *Assessment of whether each group member is subject to internal review in line with requirements on inspection frequency.*
- *Assessment of whether non-conformities have been dealt with appropriately by the internal quality management system*
- *Assessment of whether inclusion of new group members follows documented procedures that have been approved by the certification body.*

### **3.2.5.**

### **3.2.6. Reporting**

The certification body shall report evaluation findings according to documented reporting procedures.

3.2.6.1. Inspection reports shall follow a format appropriate to the type of operation inspected and facilitate a non-discriminatory, objective and comprehensive analysis of the respective production system.

3.2.6.2. The inspection report shall cover all relevant aspects of the standards, adequately validate the information provided by the operator and shall include

- A statement of any observations relating to the conformity with the certification requirements
- date and duration of the inspection, persons interviewed, fields and facilities visited
- type of documents reviewed

3.2.6.3. The certification body shall promptly notify the operator of any non conformity to be resolved in order to comply with applicable certification requirements.

3.2.6.4. The certification body shall document and apply measures to verify effectiveness of remedial actions taken by operators to meet the requirements.

### **3.3. Decision on certification**

The certification body shall ensure that each decision on certification is taken by a person(s) or committee different from those who carried out the [*evaluation / inspection*].

*[According to the definitions provided, inspection is part of the evaluation. It should be discussed and clarified at the ITF meeting whether those who perform document review (as part of the evaluation e.g. before inspection is mandated) are eligible to take the certification decision or not, provided inspection is carried out by different personnel.]*

The decision shall be based solely on the conformity of the operation with the certification requirements specified, using information gathered during the evaluation process. Certification decisions shall be documented in a way that gives transparency to the basis for the decision.

### **3.3.1. Dealing with non-conformities**

3.3.1.1. Certification decisions may include requirements for the correction of minor non-conformities within a specified time period. In case of major non-conformities, a certificate shall be withheld or suspended until implementation of corrective actions can be demonstrated. In serious cases certification shall be denied or withdrawn.

3.3.1.2. Reasons for denial, withdrawal or suspension of certification shall be stated with clear reference to the applicable standard or certification requirement violated.

### **3.3.2. [Exceptions on certification requirements]**

*[For discussion: section should be deleted: IROCB provides the possibility to issue exceptions and provides a definition for exceptions. This would allow certification bodies to grant exceptions to existing regulatory standards?!. This provision may not be acceptable to many regulatory agencies.]*

3.3.2.1. The certification body shall have clear criteria and procedures for granting exceptions to requirements for certification.

3.3.2.2. Exceptions shall be limited in time and shall not be granted permanently.

3.3.2.3. The rationale for granting any exception shall be recorded in a way providing transparency of the basis of the decision.

### **3.3.3. Issuing of certification documents**

The certification body shall issue to each operator official certification documents. Documents shall permit identification of the following

3.3.3.1. the name and address of the operator whose products' are subject of certification;

3.3.3.2. Name and address of the certification body that issued the certification documents

3.3.3.3. the scope of the certification granted, including

- the products certified, which may be identified by type or range of products
- production standard on which certification is based upon
- the effective date and term of certification, if applicable.

### **3.4. Retention and renewal of certification**

The certification body shall re-evaluate operators in order to verify whether the operator continues to comply with the applicable standard. Mechanisms shall be in place for the effective monitoring of whether corrective actions are implemented. The certification body shall report and document its re-evaluation activities and shall keep operators informed about their certification status. Re-evaluation generally follows procedures outlined in 3.2. Evaluation. *[However evaluation for renewal*

*may concentrate on certain issues and might not repeat all procedures given in 3.2.]*\* In addition the certification shall take into account the following.

*\*[To be discussed at the ITF meeting: Basically amendment allows to apply different procedures for “initial evaluation” and “follow up evaluation”]*

### **3.4.1. Inspection frequency**

The certification body shall decide the frequency for regular inspections<sup>2</sup>  
In addition to the regular inspection visit the certification body shall conduct unannounced on-site inspections of certified operators, chosen randomly and/or chosen taking into account risk or threat to organic integrity of the production or products..

### **3.4.2. Notification of changes made by the operator**

3.4.2.1. The certification body shall require operators to inform the certification body about changes cited in 3.1.2, such as intended modification to the product, manufacturing process or, if relevant, its quality system, which affect the conformity of the product.

3.4.2.2. The certification body shall determine whether the announced changes require further investigations. If such is the case, the operator shall not be allowed to release certified products produced under the changed conditions until the certification body has notified the operator accordingly.

3.4.2.3. In response to an application for amendment to the scope of a certificate already granted, the certification body shall decide what, if any, evaluation procedure is appropriate in order to determine whether or not the amendment should be made and shall act accordingly.

### **3.4.3. Changes in the certification requirements**

The certification body shall ensure that each operator is notified of any changes in the certification requirements without unnecessary delay. It shall verify the operator's implementation of such change in a timely manner, considering the given implementation periods.

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<sup>2</sup> *Currently it is state of the art, that operators are inspected at least annually independent of any risk determination.*

## Annex 1 Definitions

Term	Definition	Reference	Comment/ applicable ISO definition
Accreditation:	Procedure by which an authoritative body or accreditor gives a formal recognition that a certification body is competent to carry out certification according to organic standards.	IAC	ISO/IEC 17011/2004 Third-party attestation related to conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
Appeal	Request by an operator for reconsideration of any adverse* decisions made by the certification body related to its desired certification status. *Explanatory note: Adverse decisions include e.g. <ul style="list-style-type: none"> <li>- refusal to accept an application,</li> <li>- refusal to proceed with an inspection/audit,</li> <li>- corrective action requests,</li> <li>- changes in certification scope,</li> <li>- decisions to deny, suspend or withdraw certification, and</li> <li>- any other action that impedes the attainment of certification</li> </ul>	IAC	ISO/IEC 17011/2004 Request by a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status
Certification	The procedure by which a <b>third party</b> (certification body) gives written assurance that a clearly identified process has been methodically assessed such that adequate confidence is provided that specified products conform to specified standards.	IAC	ISO/IEC 17000/2004 Third party attestation related to products, processes, systems or persons (Attestation: Issue of a statement based on a decision following review that fulfillment of specified requirements have been demonstrated)
Certification Body	The body that conducts organic certification	IAC	ISO/IEC 17011:2004 Conformity assessment body (CAB): Body that performs conformity assessment services and that can be object of accreditation
Certification Program	System operated by a certification body with defined requirements and procedures and management for carrying out certification of conformity	IAC	

<i>Complaint</i>	Expression of dissatisfaction, other than appeal, by any person or organization, to a certification body relating to activities of that certification body or of a certified operator, where a response is expected.	IAC	
<i>Conformity assessment</i>	Fulfillment of a requirement Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled	ISO 9000:2000 ISO	According to ISO three types of conformity assessment are distinguished: <b>First-party assessment:</b> This is the technical term used when conformity assessment to a standard, specification or regulation is carried out by the supplier organisation itself. In other words, it is a self-assessment. This is known as a supplier's declaration of conformity. <b>Second-party assessment.</b> This indicates that the conformity assessment is carried out by a customer of the supplier organisation. For example, the supplier invites a potential customer to verify that the products which it is offering conform to relevant product standards. <b>Third-party assessment.</b> In this case, the conformity assessment is performed by a body that is independent of both supplier and customer organisations. <b>See definition of certification</b>
<i>Corrective action</i>	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation	ISO 9000:2000	
<i>Evaluation</i>	Systematic assessment based on all relevant information obtained in order to make a certification decision. With reference to a certification decision this includes, but is not limited to, the inspection	IAC	
<i>Exception</i>	Permission granted to an operator by a certification body to be excluded from the need to comply with requirements of the standards	IAC	
<i>Group Certification</i>	Certification of an organized group of producers with a central office, similar farming and production system, working according to a common internal quality management system, which is laid down, established and subject to continued surveillance by the central office. Group certification applies to the group as a whole. Certificate is issued to the central office of the group and shall not be used by single group members.	According to IAF Guidance on the application of ISO/IEC Guide 62:1962 Annex 3 Multisite Certification	

<i>Inspection</i>	Visit on-site to verify that the performance of an operation is in accordance with the applicable certification requirements and standards	IAC	ISO/IEC Guide 2, ISO 9000:2000: Conformity Evaluation by observation and judgement accompanied as appropriate by measurements, testing or gauging
<i>(Internal) Quality Management System :</i>	Management system to direct and control an organization with regard to quality (Management system: system to establish policy and objectives and to achieve those objectives) an instance where a particular standard or certification requirement is not being met. - <i>Major non-conformity</i> : breach of applicable standard - <i>Minor non-conformity (violation)</i> : breach of certification requirements other than standard (organic integrity of the products remains unaffected.)	ISO 9000:2000	ISO 9000:2000: Nonconformity: non-fulfillment of a requirement
<i>Operator</i>	An individual or business enterprise, responsible for ensuring that production meets, and continues to meet, the organic standard on which certification is based	IAC	Note: ISO/IEC Guide Terminology: Supplier: The party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which certification is based
<i>Requirement</i>	Need or expectation that is stated, generally implied or obligatory Note 1: Generally implied means that it is custom or common practice for the organization, its customers and other interested parties, that the need or expectation under consideration is implied Note 2: A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement. Note 3: Requirements can be generated by different interested parties	ISO 9000:2000	
<i>Standards</i>	Document approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method	ITF Glossary (WTO/TBT)	Note: The recognized body can be any constituency

<i>Technical Regulation</i>	Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.	<i>ITF Glossary (WTO/TBT)</i>	<u>Note:</u> technical regulations can refer to, or be based on, standards
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