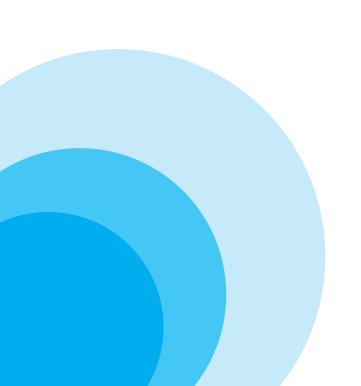






International Requirements for Organic Certification Bodies

(IROCB)









International Requirements for Organic Certification Bodies

(IROCB)

An initiative of the

United Nations Conference on Trade and Development (UNCTAD), Geneva Food and Agriculture Organization of the United Nations (FAO), Rome International Federation of Organic Agriculture Movements (IFOAM), Bonn

PREFACE

The International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) was convened from 2003 to 2008 by the Food and Agriculture Organization of the United Nations (FAO), the International Federation of Organic Agriculture Movements (IFOAM) and the United Nations Conference on Trade and Development (UNCTAD). It served 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 was to facilitate trade in 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. Not only do organic production standards vary, but requirements for organic certification bodies to conduct third party conformity assessment also vary. This causes difficulties for governments and certification bodies to recognize and accept organic products certified in other systems or programs, and therefore also for organic producers to get certified organic products accepted in different markets. The ITF developed a normative document, "International Requirements for Organic Certification Bodies" (IROCB) as a tool to enable governments and organic certification and accreditation bodies to recognize certification bodies outside of their own system, and thus facilitate the acceptance of organic products certified by these bodies.

Because IROCB is a norm, it may also be used directly for accreditation of organic certification bodies. This document was developed in an extensive consultative process with stakeholders in the private and government sectors worldwide.

IROCB is a non-proprietary public document that can be adopted by governments and private sector organizations at their convenience, without need to request permission for use. Governments and private stakeholders may use all or portions of these requirements as they see fit for non-commercial publication as a separate document.

Financial support for the development of IROCB came from the Swedish International Development Cooperation Agency (Sida), Norwegian Agency for Development Cooperation (Norad) and the Government of Switzerland.

Further information on IROCB, including contact information, is available on the ITF website, www.itf-organic.org.

The ITF Steering Committee

Nadia El-Hage Scialabba, FAO Selma Doyran, Joint FAO/WHO Standards Program Antonio Compagnoni, IFOAM Gunnar Rundgren, IFOAM Ulrich Hoffmann, UNCTAD Sophia Twarog, UNCTAD

ABBREVIATIONS

UNCTAD: United Nations Conference on Trade and Development

IFOAM: International Federation of Organic Agriculture Movements

FAO: Food and Agriculture Organization of the United Nations

ITF: International Task Force

IROCB: International Requirements for Organic Certification Bodies

IAC: IFOAM Accreditation Criteria for Bodies Certifying Organic Production and Processing

ISO: International Organization for Standardization

IEC: International Electrotechnical Commission

CAB: Conformity Assessment Body

CONTENTS

Prefacev						
At	brev	iationsv	ii			
1.		oduction				
		Foreword				
	1.2.	Scope				
		1.2.1 Evaluation methods				
		1.2.2. Chain of custody	2			
2	Con	eral requirements	2			
4.		Responsibility				
	2.1.	2.1.1. Legal structure				
		2.1.2. Certification agreement				
		2.1.3. Responsibility for certification decisions				
		2.1.4. Acceptance of prior certification				
	2.2	Personnel				
	۷.۷.	2.2.1. General				
		2.2.2. Qualification criteria and documentation				
		2.2.3. Capacity building				
		2.2.4. Assignment of personnel				
		2.2.5. Assignment of committees				
		2.2.6. Subcontracting (outsourcing)				
	23	Impartiality and objectivity				
	2.3.	2.3.1. Organizational structure and stakeholder involvement				
		2.3.2. Management of impartiality				
		2.3.3. Division of functions				
		2.3.4. Accessibility				
	24	Access to Information.				
	۷.٦.	2.4.1. Publicly accessible information				
		2.4.2. Confidentiality				
		2.4.3. Reference to certification and use of certification logo (mark)				
	2.5	Quality Management System (QMS)				
	2.5.	2.5.1. General				
		2.5.2. Management system manual				
		2.5.3. Control of documents				
		2.5.4. Records system.				
		2.5.5. Internal Audit and management review				
		2.5.6. Appeals and complaints				
			\sim			

3.	Pro	cess requirements to conduct organic certification	9
		Application procedures	
		3.1.1. Information for operators	9
		3.1.2. Application form and operator obligations	9
	3.2.	Evaluation	9
		3.2.1. Scope	9
		3.2.2. Review of application and preparation of inspection	9
		3.2.3. Inspection protocol	10
		3.2.4. Particular requirements to address high risk situations	10
		3.2.5. Requirements for group certification systems	11
		3.2.6. Reporting	11
	3.3.	Decision on certification	11
		3.3.1. Division of functions	11
		3.3.2. Decision basis	11
		3.3.3. Documentation	11
		3.3.4. Dealing with non-conformities	12
		3.3.5. Exceptions on certification requirements	12
		3.3.6. Issuing of certification documents	12
	3.4.	Extension and renewal of certification	12
		3.4.1. Re-evaluation	12
		3.4.2. Inspection frequency	12
		3.4.3. Notification of changes made by the operator	13
		3.4.4. Changes in the certification requirements	13
		-	
Aı	nex	1 Definitions	14

1. Introduction

1.1. **Foreword**

This document sets out international requirements for organic certification bodies (IROCB). These requirements are intended to represent a consensus on good practices in organic conformity assessment among private and public institutions. They aim to provide a baseline for assessing the equivalence of services performed by various certification bodies outside a specific organic system. The IROCB would thus serve as a tool for enabling recognition of those certification bodies' services in international trade by other certification bodies and systems, so that governments or accreditation/approval bodies could approve each other's requirements as equivalent in order to allow products certified to enter the system.

Application of these requirements is intended to ensure that certification bodies provide 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.

IROCB is based upon the requirements in ISO/IEC Guide 65: 1996 (E) "General requirements for bodies operating product certification systems." However, given that organic certification has certain features that differ from certification of products and services covered by ISO/IEC Guide 65, IROCB also takes into account the IFOAM Accreditation Criteria for Bodies Certifying Organic Production and Processing (IAC)¹ and includes sector-specific requirements². It also includes reformulated and amended ISO paragraphs and additional requirements to cover issues confronting a certification body when undertaking organic certification.

In general, existing regulations must be applied and laws respected. Moreover, it must be noted that a certification body's authority often is restricted under regulatory systems compared to the requirements outlined in ISO/IEC Guide 65 and IAC. Certification bodies are mandated to perform functions on behalf of authorities, which reserve the right to take final decisions or exercise control (e.g. complaints resolutions, withdrawal of certification, ownership of logo). The document does not cover organic production standards. It is recommended that equivalence of organic production standards be judged according to internationally recognized standards or guidelines such as IFOAM Basic Standards and the Codex Guidelines CAC/GL 32: Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.

For the purpose of this document the definitions presented in annex 1 apply.

Version 2005, published by the International Federation of Organic Agriculture Movements (IFOAM). Additional or divergent requirements to ISO/IEC Guide 65 can also be found in organic regulatory systems such as the National Organic Program (United States of America), and the EU regulation EEC 834/2007 and its implementing rules.

1.2. Scope

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

1.2.1. Evaluation methods

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

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

1.2.2. Chain of custody

The certification body shall assure that any product used by an operator in a product subject to its certification is duly certified (see section 2.1.4 regarding the acceptance of prior certification).*

* Explanatory note: for example, when a certified operation purchases raw material certified by another program for being processed in multi-ingredient product for which the respective operator seeks certification.

2. General requirements

2.1. Responsibility

2.1.1. Legal structure

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

- a. Have documents attesting to its status as a legal entity;
- b. Have documented the rights and responsibilities relevant to its certification activities; and
- c. Identify the management (body, group or person) that has overall responsibility for the functioning of the certification body, including its finances.

2.1.2. Certification agreement

The certification body shall provide its certification service based on an agreement signed by the applicants and operators. In particular, the agreement shall

- a. Include a description of the rights and duties of the applicants and operators offering certified products, including a commitment to comply with the relevant provisions of the certification program;
- b. Specify requirements, restrictions or limitations on the use of the designated certification logo and on the ways of referring to the certification granted in order to prevent misleading use or claims;

- c. Contain provisions to allow the certification body to exchange information with other certification bodies and authorities (approval bodies or accreditation bodies) to verify information, especially the certification status of certified products, as part of its ongoing evaluation;
- d. Provide to both the certification body and the responsible authorities the right of access to all appropriate facilities, including to non-organic production in the unit or related units, and all relevant documentation and records, including financial records.

2.1.3. Responsibility for certification decisions

a. The certification body shall have final responsibility for granting, maintaining, extending, suspending and withdrawing certification.

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* may be granted when equivalent certification procedures have been applied.

- * Explanatory note: there could be varying acceptance situations to be covered by appropriate acceptance procedures. For example,
 - 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

2.2.1. General

- a. The certification body shall employ sufficient personnel competent to perform certification functions and operate its system.
- b. The certification body shall ensure that personnel have knowledge relevant to the scope of certification issued (farming operations, processing facilities, geographic areas, group certification).
- c. The certification body shall maintain up-to-date records on personnel.

2.2.2. Qualification criteria and documentation

- a. The certification body shall define minimum criteria for the competence of personnel. Criteria should specify minimum education, training, technical knowledge and work experience relevant to the scope of certification issued.
- b. The certification body shall maintain up-to-date documents describing the respective responsibilities of assigned personnel.

2.2.3. Capacity-building

The certification body shall ensure that personnel involved in certification (i.e. inspectors and other certification personnel, including members of technical committees) have and continue to have up-to-date technical knowledge in their respective fields of activity to enable them to conduct evaluation and certification effectively and uniformly.

In particular, the certification body shall

- a. Review the competence of its personnel in light of their performance in order to identify training needs; and
- b. Ensure that new personnel have sufficient competence.*
- * Explanatory note: for example, new personnel could be required to complete a training course in conducting organic inspection and evaluation and/or undergo a defined on-site apprenticeship period.

2.2.4. Assignment of personnel

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

- a. Commit themselves to observing the policies and procedures of the certification body;
- b. Declare any prior or present association on their own part, or on the part of their employer, with an operator seeking certification to which they are to be assigned to perform certification procedures.

2.2.5. Assignment of committees

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

2.2.6. Subcontracting (outsourcing)

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 a. Take responsibility for such subcontracted work.

- b. Keep final responsibility for the granting, maintaining, renewing, extending, suspending or withdrawing of certification. Delegation of certification decisions may only take place based on the requirements in accordance with the provisions of the ISO/IEC GUIDE 68:2002(E).
- c. Ensure that the subcontracted body or person is:
 - Competent to perform the subcontracted work,
 - Not involved, either directly or through the body/person's employer, with the operation, process or product that is subject to certification in any way that may compromise impartiality, and
 - Committed to the policies and procedures as defined by the certification body.
- d. Monitor the performance of the persons or bodies subcontracted for the 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 that are subject to its certification in any way that compromises its impartiality.

Specifically, the certification body shall have a documented structure which safeguards impartiality by:

- a. Including provisions to ensure the impartiality of the operations of the certification body; and
- b. Providing for the participation of all 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 those of clients, other industry representatives, representatives of government services, or representatives of non-governmental organizations, including consumer organizations could be established to consider whether the certification body management meets the structural requirements.

2.3.2. Management of impartiality

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

- a. Require personnel, committee and board members to declare existing or prior association with an operation subject to certification. Where such an association threatens impartiality, the certification body shall exclude the person concerned from work, discussion and decisions at all stages of the certification process related to the potential conflict of interest;
- b. Follow defined rules for appointing and operating committees involved in certification activities to ensure that decisions taken are not influenced by any commercial, financial and/or other interest.

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 in addition to certification, it shall apply additional measures to ensure that the confidentiality, objectivity and impartiality of its certifications are not affected by these other activities. In particular the certification body shall not

- a. Produce or supply products of the type it certifies;
- b. 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, for example, non-conformities identified in the course of the certification process.

**Explanatory note: explanations regarding the standard production standard are not considered to be 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, ensuring 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, for example, 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 to ensure confidence in the integrity and credibility of its certification.

The certification body shall make available (through publications, electronic media or other means) on request:

- a. The standard to be met by operators in order to obtain/maintain certification;
- b. Information about procedures applied for evaluating whether operators meet the applicable standard:
- c. Information about procedures applied to cases where certification is extended;
- d. Information about procedures and sanctions applied where non-conformities with standards are detected:
- e. The fee structure for its services;
- f. A description of the rights and duties of operators, including requirements, restrictions or limitations on the use of any certification logo and on ways of referring to the certification granted;
- g. Information about procedures for handling general complaints and appeals against its certification decisions; and
- h. 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 make adequate arrangements to safeguard the 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

- a. Protect proprietary information of a client against misuse and unauthorized disclosure; and
- b. Grant the certification body the right to exchange information with other certification bodies and/or authorities to verify the authenticity of the information.

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

The certification body shall

- a. Exercise control over ownership, use and display of licenses, certificates and logos that it can authorize certified operators to use.
- b. Be able to request an operator to discontinue use of certificates and logos that it authorizes certified operators to use.
- c. Apply suitable actions to deal with incorrect references to the certification system or misleading use of licenses, certificates or logos that it authorizes certified operators to use.

2.5. Quality management system

2.5.1. General

- a. The certification body shall define, document and implement a quality management system in accordance with the relevant elements of these requirements so as to impart 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.
- b. 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

- a. The certification body shall address and document all applicable procedures, either in a manual or in associated documents, in order to ensure uniform and consistent application.
- b. The manual and associated documents, as appropriate for the type, range and volume of work performed, and considering the number of personnel involved in the process, shall contain:
 - An organizational chart showing lines of authority, responsibilities and allocation of functions;
 - A description of procedures applied by the certification body in the course of performing certification, including granting, maintaining, renewing, extending, suspending and withdrawing of certification;
 - Procedures for the recruitment, selection, training and assignment of the certification body's personnel (as outlined under 2.2.);
 - Policy and procedures for appeal against certification decisions and other complaints; and
 - Policy and procedures for reviewing quality (e.g. internal audits, management review).
- c. The certification body shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

2.5.3. Document control

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

- a. Shall, through authorized and competent personnel, review and approve documents for adequacy prior to their original issue or any subsequent amendment;
- b. Maintain a list of all appropriate documents with the respective issue dates and duly identify their amendment status; and

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

2.5.4. Maintaining and managing records

- a. The certification body shall maintain a system of records (either electronic or paper documents) to demonstrate that the certification procedures have been effectively fulfilled, particularly with respect to application forms, evaluation or re-evaluation reports, and other documents relating to granting, maintaining, renewing, extending, suspending or withdrawing certification.
- b. 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.
- c. Operator records shall be up to date and contain all relevant information, including inspection reports and certification history.
- d. Records shall also be kept on exceptions granted, appeals and subsequent actions.
- e. Records shall be kept for at least five years, or as required by law, in order to be able to demonstrate how certification procedures have been applied.

2.5.5. Internal audit and management 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.

- a. 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 periodically³ shall be part of the review
- b. 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 in place 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

- a. Take appropriate subsequent action to resolve complaints and appeals; and
- b. Document the action taken and its effect.

^{3.} It is industry practice to conduct performance reviews of personnel responsible for evaluation, inspection and certification on an annual basis.

3. Process requirements for conducting organic certification

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 for conducting certification. The certification body shall inform operators about

- a. Contractual conditions, including fees and possible contractual penalties;
- b. The operator's rights and duties, including the appeals procedure;
- c. The applicable standards;
- d. Program changes, including regular updates of procedures and standards;
- e. The evaluation and inspection procedures applied by the certification body in the course of certification; and
- f. 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 the operator's obligations

The certification body shall require completion of an 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:

- a. 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; and
- b. Provide information as to whether another certification body has denied certification.

3.2. Evaluation

3.2.1. Scope

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

3.2.2. Review of application and preparation of inspection

- a. Prior to the inspection, the certification body shall review the application documents to ensure that certification can be carried out and that application of certification procedures is possible. In particular, the certification body shall review whether
 - Documents submitted by the operator are complete;
 - The operator appears to be able to comply with all certification requirements (applicable procedures and standards);
 - The scope of the certification sought is within the scope of the certification services provided. (New scope could also be a new geographical area where the certification body is not yet active.)

- b. The certification body shall assign qualified personnel to the evaluation in line with the requirements of 2.2 and 2.3 above, and provide them with appropriate work-related documents.
- c. The certification body shall inform inspectors about any non-conformities and the associated requests for corrective action issued previously, to enable the inspectors to verify whether the non-conformities have been resolved.

3.2.3. Inspection protocol

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 non-discriminatory and objective inspection.

The inspection protocol shall at the very minimum undertake the following:

- a. Assessment of the production or processing system by means of visits to facilities, fields and storage units (which may also include visits to non-organic areas if there is reason for doing so);
- b. Review of records and accounts in order to verify flow of goods (production/sales reconciliation on farms, input/output reconciliation and the tracing back of audits in processing and handling facilities);
- c. Identification of areas of risk to organic integrity;
- d. Verification that changes to the standards and to requirements of the certification body have been effectively implemented; and
- e. Verification that corrective actions have been taken.

3.2.4. Particular requirements to address high-risk situations

The certification body shall amend and adapt its certification procedures to address higher risks found in certain situations specific to organic certification.

Potential high-risk situations and related measures include:

- a. Partial conversion and parallel production. In order to prevent co-mingling or contamination of organic products with other products that do not meet the standards, the certification body should verify whether handling and documentation regarding production or processing, storage and sales is well managed and makes clear distinctions between certified and non-certified products. In cases where products are not visibly distinguishable, specified measures should be applied during harvest and post-harvest handling to reduce the risk.
- b. Intensive production and high dependence of external inputs, short production cycles.

 Depending on the risk identified, the certification body should decide whether it is appropriate to increase the frequency of inspections.
- c. Where an operator is certified also by other certification bodies within the same organic scope, the certification body should seek information exchange with the other certification bodies involved to prevent misuse of certificates.

3.2.5. Requirements for group certification systems

- a. If the certification body conducts group certification based on an internal quality management system, it should apply a specific group certification program.
- b. The group certification program should specify the scope for group certification and requirements applicable to the group, including those for an internal quality management system, to ensure conformity by all group members to the applicable standards. These should follow an agreed code of good practices.
- c. When assessing the effective application of the internal quality management system to address the particular situation of group certification, the certification body should apply adapted measures to the regular on-site inspection protocol according to an agreed code of good practices.

3.2.6. Reporting

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

- a. 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.
- b. The inspection report shall cover all relevant aspects of the standards, and adequately validate the information provided by the operator. It shall include
 - A statement of any observations relating to conformity with the certification requirements;
 - Date and duration of the inspection, persons interviewed, fields and facilities visited; and
 - Type of documents reviewed.
- c. The certification body shall promptly notify the operator of any non-conformity to be resolved in order to comply with applicable certification requirements.
- d. The certification body shall document and apply measures to verify effectiveness of corrective actions taken by operators to meet the requirements.

3.3. Decision on certification

3.3.1. Division of functions

The certification body shall ensure that each decision on certification is taken by a person(s) or committee different from the one(s) that carried out the inspection.

3.3.2. Basis for the decision

The decision shall be based solely on the conformity of the operation with the certification requirements specified, using information gathered during the evaluation process.

3.3.3. Documentation

Documentation of certification decisions shall include the basis for the decisions.

3.3.4. Dealing with non-conformities

- a. Certification decisions may include requests 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.
- b. Reasons for denial, withdrawal or suspension of certification shall be stated with clear reference to the applicable standard or certification requirement violated.

3.3.5. Exceptions to certification requirements

- a. The certification body shall have clear criteria and procedures for granting exceptions to requirements for certification.
- b. Exceptions shall be of limited duration, and not be granted permanently.
- c. The documentation of any exception shall include the basis on which the exception is granted.

3.3.6. Issuing of certification documents

The certification body shall issue official certification documents to each operator. Documents shall contain the following information:

- a. The name and address of the operator whose products are the subject of certification;
- b. Name and address of the certification body that issued the certification documents;
- c. The scope of the certification granted, including
 - The products certified, which may be identified by type or range of products,
 - The production standard that is the basis for the certification, and
 - The effective date and term of certification.

3.4. Extension and renewal of certification

3.4.1. Re-evaluation

- a. The certification body shall regularly re-evaluate operators in order to verify whether they continue to comply with the applicable standard. Mechanisms shall be in place to effectively monitor whether corrective actions have been implemented.
- b. The certification body shall report and document its re-evaluation activities, and shall keep operators informed about their certification status.
- c. Re-evaluation generally follows procedures outlined in 3.2. (i.e. Evaluation). However evaluation for the purpose of renewal may focus on certain measures related to risk, and might not repeat all procedures listed in 3.2.

3.4.2. Frequency of inspection

- a. The certification body shall decide on the frequency for regular inspections.⁴
- b. In addition to the regular inspection visit, the certification body shall conduct unannounced

⁴ Currently, it is common practice for operators to be inspected at least annually independent of any risk determination.

on-site inspections of certified operators, chosen randomly and/or chosen taking into account the risk or threat to the organic integrity of the production or products.

3.4.3. Notification of changes made by the operator

- a. The certification body shall require operators to inform the certification body about changes cited in 3.1.2.
- b. 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.
- c. In response to an application for amendment to the scope of a certificate already granted, the certification body shall decide what evaluation procedure, if any, is appropriate, in order to determine whether or not the amendment should be made, and shall act accordingly.

3.4.4. Changes in the certification requirements

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

Annex: Definitions

Term: Accreditation

Definition: 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.

Reference: IAC

Comment/applicable ISO definition: 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.

Term: Appeal

Definition: 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.
 - refusal to accept an application,
 - refusal to proceed with an inspection/audit,
 - corrective action requests,
 - changes in certification scope,
 - · decisions to deny, suspend or withdraw certification, and
 - any other action that impedes the attainment of certification

Reference: IAC

Comment/applicable ISO definition: 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.

Term: Certification

Definition: The procedure by which a third party (certification body) gives written assurance that a clearly identified process has been methodically assessed in a way that provides adequate confidence that specified products conform to specified standards.

Reference: IAC

Comment/applicable ISO definition: ISO/IEC 17000/2004

Third-party attestation related to products, processes, systems or persons.

(An attestation is the issue of a statement based on a decision following review that fulfillment of specified requirements has been demonstrated.)

Term: Certification Body

Definition: The body that conducts organic certification.

Reference: IAC

Comment/applicable ISO definition: ISO/IEC 17011:2004

Conformity assessment body (CAB): Body that performs conformity assessment services and that can be object of accreditation.

Term: Certification Program

Definition: System operated by a certification body with defined requirements procedures and

management for carrying out certification of conformity.

Reference: IAC

Comment/applicable ISO definition:

Term: Complaint

Definition: 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.

Reference: IAC

Comment/applicable ISO definition:

Term: Conformity

Definition: Fulfillment of a requirement.

Reference: ISO 9000:2000

Comment/applicable ISO definition:

Term: Conformity assessment

Definition: Any activity concerned with determining directly or indirectly that relevant re-

quirements are fulfilled

Reference: ISO

Comment/applicable ISO definition: According to ISO three types of conformity assessment are distinguished:

First-party assessment: This is the technical term used when conformity assessment to a standard, specification or regulation is carried out by the supplier organization itself. In other words, it is a self-assessment. This is known as a suppliers declaration of conformity.

Second-party assessment: This indicates that the conformity assessment is carried out by a customer of the supplier organization. For example, the supplier invites a potential customer to verify that the products it is offering conform to relevant product standards.

Third-party assessment: In this caseconformity assessment is performed by a body that is independent of both supplier and customer organizations.

See definition of certification.

Term: Corrective action

Definition: Action to eliminate the cause of a potential nonconformity or other undesirable

situation.

Reference: ISO 9000:2000

Comment/applicable ISO definition:

Term: Evaluation

Definition: 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.

Reference: IAC

Comment/applicable ISO definition:

Term: Exception

Definition: Permission granted to an operator by a certification body to be excluded from the

need to comply with requirements of the standards.

Reference: IAC

Comment/applicable ISO definition:

Term: Group Certification

Definition: 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 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.

Reference: According to IAF Guidance on the application of ISO/IEC Guide 62:1962 Annex 3 Multi-side Certification

Comment/applicable ISO definition:

Term: Inspection

Definition: Visit on site to verify that the performance of an operation is in accordance with the applicable certification requirements and standards.

Reference: IAC

Comment/applicable ISO definition: ISO/IEC Guide 2, ISO 9000:2000:

Conformity evaluation by observation and judgment accompanied as appropriate by measurements, testing or gauging.

Term: (Internal) Quality management system

Definition: Management system to direct and control an organization with regard to quality.

Reference: ISO 9000:2000

Comment/applicable ISO definition: Management system is a system to establish policy and objectives, as well as measures to achieve those objectives.

Term: Non-conformity

Definition: An instance where a particular standard or certification requirement is not being met.

• Major non-conformity: breach of applicable standard

• Minor non-conformity (violation): breach of certification requirements other than standard (organic integrity of the products remains unaffected.)

Reference: IAC (modified)

Comment/applicable ISO definition: ISO 9000:2000: Nonconformity: non-fulfillment of a requirement

Term: Operator

Definition: An individual or business enterprise, responsible for ensuring that production meets, and continues to meet, the organic standard on which certification is based.

Reference: IAC

Comment/applicable ISO definition: 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.

Term: Requirement

Definition: Need or expectation that is stated, generally implied or obligatory.

Note 1: Generally, implied means that it is custom or common practice that the need or expectation under consideration is implied for the organization, its customers and other interested parties.

Note 2: A qualifier can be used to denote a specific type of requirement (e.g. product requirement, quality management requirement or customer requirement).

Note 3: Requirements can be generated by different interested parties.

Reference: ISO 9000:2000

Comment/applicable ISO definition:

Term: Standards

Definition: 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, and packaging, marking or labeling requirements as they apply to a product, process or production method.

Reference: ITF Glossary (World Trade Organization/ Technical Barriers to Trade) Comment/applicable ISO definition: Note: The recognized body can be any constituency.