







# Global Organic Market Access

# **ORGANIC EQUIVALENCE TOOLS**

International Requirements for Organic Certification Bodies (IROCB)

and

Guide for Assessing Equivalence of Organic Standards and Technical Regulations (EquiTool)

Version 2







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### Version 2

Developed by the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) and The Global Organic Market Access (GOMA) Project

#### An Initiative of the

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

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#### **PREFACE**

The Global Organic Market Access (GOMA) project continued a partnership of FAO, IFOAM and UNCTAD, which began in 2002 when the three organizations convened the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF). The objective of this partnership has been to facilitate trade in organic products in the context of the proliferation of organic standards and technical regulations worldwide. The ITF recognized harmonization and equivalence of organic regulatory systems as key means to increase access to organic markets and facilitate international organic trade. To foster equivalence among organic regulatory systems, the ITF developed two practical Tools for supporting equivalence assessments. The *International Requirements for Organic Certification Bodies (IROCB)* aims to support equivalence assessment of organic certification systems, and the *Guide for Assessing Equivalence of Organic Standards and Technical Regulations (EquiTool)* aims to support equivalence assessment of the requirements for organic production and processing.

The ITF Tools were first published at the end of the ITF in 2008. Since then, the GOMA project has been disseminating them, educating potential users, and providing technical support for their implementation. In response to feedback received in the course of these activities, the GOMA project implemented several revisions in the Tools, published as Version 2. Version 2 of IROCB adds a requirement for the legal and financial stability of certification bodies and clarifies the obligation of certification bodies to specify documentation required of operators. Version 2 of EquiTool includes a new instrument, Common Objectives and Requirements of Organic Standards (COROS), to assess equivalence of standards within the framework of common objectives for organic production and processing. Additional detail about each Tool is given in its preface and introduction.

The GOMA website, www.goma-organic.org, features information about obtaining copies and electronic versions of the Tools, including spreadsheet versions for practical use.

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# International Requirements for Organic Certification Bodies

(IROCB)

Version 2

#### An Initiative of the

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

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#### **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.

This document was developed, with financial support from donors, in an extensive consultative process with stakeholders in the private and government sectors worldwide. IROCB can also be used directly for accreditation of organic certification bodies.

IROCB is a 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. A spreadsheet version of IROCB is also available to facilitate comparative assessment of other certification requirements to the IROCB.

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.

FAO, IFOAM and UNCTAD continue to support IROCB through a follow-up project, Global Organic Market Access (GOMA). Version 2, which is published under the auspices of the GOMA Project, adds a requirement regarding the legal and financial stability of certification bodies and clarifies the obligation of certification bodies to specify documentation required of operators. Further information on IROCB, including the spreadsheet version and contact information, is available on the GOMA website, www.goma-organic.org.

#### **ABBREVIATIONS**

GOMA: Global Organic Market Access

ITF: International Task Force on Harmonization and Equivalence in Organic Agriculture

IROCB: International Requirements for Organic Certification Bodies

IAC: IFOAM Accreditation Criteria

ISO: International Organization for Standardization

IAF: International Accreditation Forum

IEC: International Electrotechnical Commission

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#### 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. IROCB aims 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 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.

#### 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.

<sup>1</sup> Version 2005, published by the International Federation of Organic Agriculture Movements (IFOAM).

<sup>2</sup> 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.

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 AND FINANCIAL STABILITY

The structure and resources 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;
- c. Identify the management (body, group or person) that has overall responsibility for the functioning of the certification body, including its finances, and;
- d. Have the financial stability necessary for the effective operation of a certification system, including provisions to manage liability risks where relevant.

#### 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

- 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;
- 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, analyze 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;
- 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 docu-

ments) 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 periodically<sup>3</sup> 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. 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;

<sup>3</sup> It is industry practice to conduct performance reviews of personnel responsible for evaluation, inspection and certification on an annual basis.

- 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 and to ensure continuous traceability from receipt of inputs or products to release of products. This shall include specification of the time period for documents to be maintained.

#### 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:

- 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.

- 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<sup>4</sup>.
- b. 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 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

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

- 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	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	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.
	decisions include e.g.  • refusal to accept an application,		
	<ul> <li>refusal to proceed with an inspection/audit,</li> </ul>		
	• corrective action requests,		
	<ul> <li>changes in certification scope,</li> </ul>		
	<ul> <li>decisions to deny, sus- pend or withdraw certifi- cation, and</li> </ul>		
	any other action that impedes the attainment of certification		

Certification	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.	IAC	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.)
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 procedures and management for carrying out certification of conformity.	IAC	
Complaint	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	
Conformity	Fulfillment of a requirement.	ISO 9000:2000	

Conformity assessment	Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled	ISO	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: Thisindicates 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 case conformity assessment is performed by a body that is independent of both supplier and customer organizations.  See definition of certification
Corrective action	Action to eliminate the cause of a potential nonconformity or other undesirable situation.	ISO 9000:2000	
Evaluation	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	
Exception	Permission granted to an operator by a certification body to be excluded from the need to comply with requirements of the standards.	IAC	

Group Certification	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.	According to IAF Guidance on the application of ISO/IEC Guide 62:1962 Annex 3 Multi-side Certification	
Inspection	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 judgment accompanied as appropriate by measurements, testing or gauging.
(Internal) Quality management system:	Management system to direct and control an organization with regard to quality.	ISO 9000:2000	Management system is a system to establish policy and objectives, as well as measures to achieve those objectives.
Non-conformity	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.)	IAC (modified)	ISO 9000:2000:  Nonconformity: non-fulfillment of a requirement
Operator	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.

Requirement	Need or expectation that is stated, generally implied or obligatory.	ISO 9000:2000	
	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.		
Standards	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.	ITF Glossary (World Trade Organization/ Technical Barriers to Trade)	Note: The recognized body can be any constituency.

# Guide for Assessing Equivalence of Organic Standards and Technical Regulations

EquiTool

Version 2

#### An Initiative of the

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

Version 1, 2008

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#### **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.

Regional differences in standards and technical regulations for organic production and processing are often justifiable and even desirable due to diverse geography agronomic conditions, culture and stage of development for organic agriculture throughout the world. But on the other hand, variations in standards cause 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.

To promote equivalence as a solution to this problem, the ITF developed a guidance document, "Guide for Assessing Equivalence of Organic Standards and Technical Regulations" (EquiTool). This guideline aims to facilitate and harmonize assessments of equivalence of organic production and processing standards and technical regulations. The scope of this guideline is limited to the equivalence assessment process. It does not include guidance for preparing and maintaining an equivalence agreement. Such agreements often cover both equivalence of conformity assessment and standards and technical regulations for organic production and processing. Equivalence may also be established in practice without the framework of a formal equivalence agreement.

Version 2 of EquiTool includes a revised Annex Two, which is entitled "Common Objectives and Requirements of Organic Standards" (COROS). COROS is a practical instrument for assessing equivalence of organic standards by basing the assessment on common objectives. A spread-sheet version of COROS, which facilitates assessments of organic standards to the COROS objectives and requirements, is available in electronic format.

EquiTool is a 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 guidelines as they see fit for non-commercial publication as a separate document. Reference to the EquiTool is expected for such use.

This document was developed in a consultative process with stakeholders in the private and government sectors worldwide. Financial support for the development of EquiTool came from the Swedish International Development Cooperation Agency (Sida), Norwegian Agency for Development Cooperation (Norad) and the Government of Switzerland.

FAO, IFOAM and UNCTAD continue to support EquiTool through a follow-up project, Global Organic Market Access (GOMA). Version 2 is published under the auspices of the GOMA Project.

Further information on EquiTool, including the COROS spreadsheet and contact information, is available on the GOMA website, www.goma--organic.org.

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#### **INTRODUCTION**

#### THE CONCEPT OF EQUIVALENCE

Organic agriculture is a systems based approach that accounts for specific local agro-ecological conditions. Organic norms are generally set with respect to local, national or regional environment including the state of sector development and market conditions.

The acceptance that different standards or technical regulations on organic agriculture fulfill common objectives, otherwise known as equivalence, is a pathway to reduce rising trade barriers caused by the emergence of many organic standards and technical regulations worldwide. The concept of equivalence is common in international trade policy where several models of application exist. Application of the equivalence concept in organic agriculture provides opportunity to improve trade in organic products and spread the benefits of organic agriculture globally.

The use of common procedures and assessment tools by governments and private sector parties to establish and recognize equivalent standards will enhance access to markets for all legitimate parties operating in countries with as well as without regulations of organic production, processing and labelling.

The procedure and tools outlined in this document and corresponding annexes, is a proposed guide for determining equivalence between standards for organic production and processing. It is developed in line with the WTO TBT and Codex Alimentarius frameworks for equivalence (see annex 5) as well as in consideration of experience in equivalence assessment in the organic sector worldwide, in particular by the International Federation of Organic Agriculture Movements (IFOAM). It is applicable for government to government as well as private sector equivalence determinations, both multilateral and unilateral.

It is recognized that equivalence can be established in other ways than through the use of this guide, for example through regional or bilateral trade agreements (using procedures established for their negotiation) or through unilateral determination by one party without participation of other parties.

#### USE OR REFERENCE TO INTERNATIONAL STANDARDS

It is recommended to have an international standard serve as the reference for determination of equivalence.

There are currently two international reference standards for organic agriculture, CAC/GL 32, Guidelines for the Production, Processing Labeling and Marketing of Organically Produced Food and the IFOAM Basic Standards.

#### **DETERMINATION OF EQUIVALENCE BASED ON COMMON OBJECTIVES**

Both WTO and Codex mention that determination of equivalence should be based on objectives. But many regulations and standards – organic or otherwise – have not stated specific objectives for the range of requirements set. However, implied objectives of organic standards and even "common" objectives can be deciphered from such standards or regulations. Annex 2, COROS, is an instrument for assessing equivalence of standards according to whether they fulfill common international objectives. Comparing standards to the objectives and related requirements in COROS is an alternative to directly comparing standards in order to assess equivalence.

#### **CLEAR PROCESS INCLUDING CRITERIA FOR DIFFERENCES AND VERIFICATION**

Key elements of an equivalence determination process include provision of relevant texts, comprehensive comparisons, criteria and process for considering differences in measures/requirements.

This document includes criteria to evaluate variations in specific requirements in organic standards or regulations. These can be individual requirements or sets of related requirements.

Finally, it offers provisions for exclusion where problematic requirements may be excluded from the scope of equivalency, to isolate or mitigate their effect.

#### PROVISION FOR EXCLUSIONS

Full equivalence may not always be achievable. When consensus on certain elements proves elusive and is blocking progress, a possibility to specify exclusions should be allowed. For example, inputs for organic agriculture accepted in one regulation may not wholly be accepted in another. Such inputs may be treated as exclusions while establishing equivalence<sup>1</sup>. It is also possible that parties may later review the merits of such provisions and may amend or revise such provisions.

#### PROVISION FOR TRANSPARENCY

Trust building in the market place is essential for market acceptance of an equivalence agreement. Transparency is a key component for trust and should be maintained throughout the equivalence assessment process.

# GUIDE FOR EQUIVALENCE OF ORGANIC STANDARDS AND TECHNICAL REGULATIONS

#### 1. SCOPE AND USE

This guide provides common procedures and assessment tools to establish and recognize equivalence among standards for organic production, processing and labelling.

This guide can be used for government-to-government or private sector purposes. It is designed for use in bilateral or multilateral negotiations and can be adapted to be employed in a unilateral equivalence assessment of one standard to another.

This guide is also a resource for further development of regulations and procedures to foster equivalence.

#### 2. DEFINITIONS

Terms	Definitions
Base standard	The standard or regulation that constitutes the basis of the equivalence assessment

<sup>1</sup> The exclusion of a certain input, category or technology from equivalence doesn't necessarily mean that the affected products can't be traded. They might be granted market access in other ways, e.g. by complementary labelling.

	·
Base standard party	The principal party representing the standard or technical regulation that constitutes the basis of the equivalence assessment.
Evaluated standard	The standard or regulation for which a determination of equivalence with the base standard is sought
Evaluated standard party	The party representing the standard or technical regulation for which a determination of equivalence with the base standard is sought.
Principal parties	The parties seeking an equivalence agreement with each other
Standards	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 labelling requirements as they apply to a product, process or production method.
Technical Regulation	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 labelling requirements as they apply to a product, process or production method.
Conformity Assessment	Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled
Harmonization	The process by which standards, technical regulations and conformity assessment on the same subject approved by different bodies establishes inter-changeability of products and processes. The process aims at the establishment of identical standards, technical regulations and conformity assessment requirements.
Equivalence	The acceptance that different standards or technical regulations on the same subject fulfill common objectives
Recognition	Arrangement (either unilateral, bilateral, or multilateral) for the use or acceptance of results of conformity assessments.

### 3. ELEMENTS OF EQUIVALENCE ASSESSMENT

#### 3.1 CHOICE OF BASE STANDARD

Principal parties involved should identify the choice of a base standard, where equivalence of other standards/regulations to the base standard forms the basis of the equivalence assessment.

The following scenarios may be considered in choosing a base standard.

#### a. Multilateral equivalence assessment scenario

Choice of base standard may be an international standard or one of the many participating standards/regulations. Equivalence assessment is done for each of participating standards

against the base standard. Equivalence to selected base standard constitutes equivalence to all other participating standards/regulations.

#### b. Bilateral equivalence assessment scenario

Choice of base standard may be an international standard, or one of the two participating standards/regulations. In case of the latter, equivalence assessment will be conducted twice with one of the applicable standards against the other in turn.

#### c. Unilateral equivalence agreement scenario

Choice of base standard may be an international standard (preferable), or the standard/regulation against which equivalence is sought.

#### 3.2 ROLE AND APPOINTMENT OF EXPERT ASSESSMENT PANEL

An impartial assessment of equivalence increases the credibility of the process and acceptance of results by principal parties and other sector stakeholders. Besides appointment of their respective negotiating representatives, principal parties should consider a joint appointment of an independent expert assessment panel to offer expert opinion to support their respective decision on equivalence.

The members of such a panel should be agreed upon by the principal parties.

If principal parties prefer not to appoint an independent expert assessment panel, the panel can be composed of representatives of the principal parties to the equivalence negotiation.

#### 3.3 IDENTIFICATION OF REFERENCE OBJECTIVES

Clarification and agreement on a common set of specific reference objectives should be established before proceeding with the assessment of specific requirements. Objectives of the base standard, including specific objectives for different aspects of organic production and processing covered, should be specified at the onset of the process by the base standard party and agreed to by the evaluated standard party.

Where specific objectives are elaborated in the base standard, they should take preference as reference objectives. Where no specific objectives are elaborated in the base standard or if they are unclear, the principal parties should come to agreement on a common set of specific reference objectives. If an expert panel is appointed, it should facilitate clarification and agreement between the principal parties.

This guide is developed for determining if requirements in one set of standards/regulations meet the objectives of organic production and processing in another set of standards/regulations. Some organic standards and regulations include or are accompanied by stated objectives for having the standard/regulation in the first place (for example, to protect consumers), which are often called regulatory objectives. Before commencing with the equivalence assessment, principal parties should decide whether objectives relevant to the assessment also include regulatory objectives.

#### 3.4 Specification of the scope and legal context of the standard

The scope of the equivalence assessment should be established by the principal parties at the onset of the process. The scope should include geographical area of application, and the range of products and processes covered.

Other legal texts relevant to the implementation of the base and evaluated standards should be disclosed by the respective principal parties e.g. applicable phytosanitary requirements that are not described in the standards and their relationship to the application of the base and evaluated standards.

#### 3.5 METHODOLOGY OF ASSESSMENT

The equivalence assessment of the expert panel should form the basis for decision by the principal parties for the purpose of concluding an equivalence determination.

The expert panel may request clarification and interpretation of specific requirements from one or more of the principal parties as necessary for its assessment.

The expert panel should consider inviting public comment on their assessment.

Assessment by the expert panel should be made by consensus, or if consensus can't be reached by noting the different opinions.

#### 3.6 EQUIVALENCE ASSESSMENT BASED ON SET CRITERIA

Whether or not the evaluated standard meets the agreed reference objectives is the primary focus of the equivalence assessment. The process and basis for equivalence should include consideration of the following:

a. Equivalence or compliance to an international standard as basis of equivalence to the base standard, i.e.

Accept equivalence or compliance of the evaluated standard to one or both of the international standards, i.e. Codex Alimentarius or IFOAM, as basis for equivalence to the base standard as a whole.

#### b. Equivalence of individual and/or sets of related requirements

If the above is considered insufficient, principal parties involved can resort to assessing equivalence of requirements within the relevant standards. These can be individual requirements or sets of related requirements.

A comparison of specified requirements will be necessary. If agreed by the principal parties, the comparison may be based on concise and/or paraphrased versions of the relevant standards/regulations and related legal texts, not the actual full texts. Consolidated/paraphrased versions that emphasize outcomes rather than prescriptive details of the standards/regulations can greatly facilitate the assessment process.

Where the evaluated standard requirements differ, they should be accepted as equivalent based on a similar level of fulfilment of the relevant objectives of the base standard.

Where an individual requirement in the evaluated standard is assessed as not equivalent or where there is no requirement in an evaluated standard corresponding to one in the base standard (omission), equivalence may be determined on the basis that a set of related requirements in the evaluated standard (including related legal texts) fulfil the relevant objectives of the base standard, e.g. for soil fertility management.

#### c. Criteria for variations of requirements

Equivalence assessment of requirements (either individual requirements of sets thereof)

should include acceptance of variations in requirements of the evaluated standard based on the following criteria:

- Legitimate reasons including conditions such as climate, geography, technical problems as well as economic, regulatory or cultural factors that rationalize the difference as an equivalent variation from the base standard.
- Evidence that the evaluated standard reflects the consensus of the organic sector on the issue, where it is applicable.
- Variant standards maintain practices that distinguish organic from non-organic practices.

See Criteria for variations [Annex 3] for further elaboration.

#### 3.7 ACCEPTANCE OF EXPERT PANEL ASSESSMENT AND RESOLUTION OF OUTSTANDING ISSUES

The expert panel assessment provides the basis for decision by the principal parties. Principal parties should accept the equivalence assessment of the expert panel and focus on resolving outstanding issues to conclude their equivalence agreement.

Outstanding issues may be resolved through the following means:

a. Revision of specific requirement(s) and/or addition of other provisions by the evaluated standard party(ies) to address outstanding issue(s).

Proposals of revision or additional provisions may be accepted by base standard party without involving additional assessment by the expert panel.

b. A waiver or amendment of requirement(s) related to outstanding issue(s) by the base standard party.

On the appeal of the evaluated standard party(ies), the base standard party may waive or amend specific requirement(s) related to outstanding issue(s) in consideration of conditions where the evaluated standard applies.

#### c. Exclusion or reduction of scope

Where resolution and agreement on full equivalence is not possible the option of specifying exclusions such as exclusion of certain requirements or production inputs or product categories from the equivalence agreement or reducing the scope (such as limiting the equivalence to only crop production) should be considered.

#### 3.8 TRANSPARENCY

Principal parties should ensure that the process for determining equivalence is as transparent as possible, while reflecting legitimate constraints of diplomacy and commercial confidentiality where appropriate. Public notification of key events, including at least a description of the process in the beginning and the rationale of the outcome of the final agreement at the end, should be made public. Public notifications should be issued in at least all the official language(s) of the principal parties, and it is recommended to include other languages (such as English) that would enhance transparency for non-principal parties.

Where possible, opportunity for stakeholder input in the equivalence assessment should be facilitated.

Government principal parties may need to issue notifications of resolution prior to final agree-

ment in line with WTO TBT requirements (see bibliography).

#### 4. PROCEDURES FOR EQUIVALENCE ASSESSMENT

#### 4.1 INITIATION

The initiation phase includes the following steps to be taken by the principal parties:

- a. Make known to each other their interest in seeking equivalence determination.
- b. Specify and agree on whether a multilateral, bilateral or unilateral equivalence determination is desired.
- c. Specify and agree on the use of this guide and/or other protocol(s) as means of reaching equivalence determination.
- d. Specify whether additional consideration besides meeting objectives of organic production and processing standards is necessary for an equivalence determination.
- e. Review this guide and agree to amendments or alternative procedure and tools, including
  - choice of base standard (section 3.1)
  - applicable scope of equivalence assessment (section 3.4)
  - basis for equivalence including criteria for variation (section 3.6 & Annex 3)
  - specific amendments to procedure and guides (section 4) or alternatives
  - projected dates of commencement and completion
  - how cost of process will be covered
  - responsible representative(s) of each party
- f. Specify and agree on the degree of transparency including which steps and information in the equivalence assessment will be made public and which will not.
- g. Appoint an expert assessment panel (section 3.4). The panel could be composed of independent experts or representatives of the principal parties.

#### 4.2 CLARIFICATION OF OBJECTIVES

On concluding the above principal parties, with or without the support of an expert panel, should proceed to

- a. Specify objectives of the base standard (see 3.3), including specific objectives for the different aspects of organic production and processing covered in the standard. Decide whether or not to include any regulatory objectives.
- b. Disclose all related legal texts and documents (see 3.4)
- c. Clarify and agree on a common set of specific reference objectives before proceeding with the assessment of specific requirements.

#### 4.3 COMPARISON AND EQUIVALENCE ASSESSMENT OF REQUIREMENTS

Equivalence assessment between individual and/or sets of requirements should be conducted on an agreed basis for equivalence and criteria for variations.

After establishing a common set of specific reference objectives, principal parties should either prepare or delegate to the expert panel to prepare a comprehensive standards comparison (including related legal texts) which identifies requirements of the evaluated standard that are different, omitted or additional to the requirements of the base standard. Note: See Annex 4 for a template for preparing a comparison.

The expert panel should then:

- a. Assess the equivalence of the evaluated standard with the base standard (see 3.6),
- b. Issue a preliminary equivalence recommendation.
- c. Invite comments, including supplemental information, from the evaluated standard party(ies) and the base standard party.

Note: Consideration should be given at this point to make the preliminary assessment available for public comment

- d. Revise the equivalence assessment and equivalence recommendation as appropriate relative to the comments received.
- e. Submit revised assessment and recommendation to the principal parties.

A submission from a principal party should be copied to all other principal parties.

#### 4.4 RESOLUTION OF OUTSTANDING ISSUES

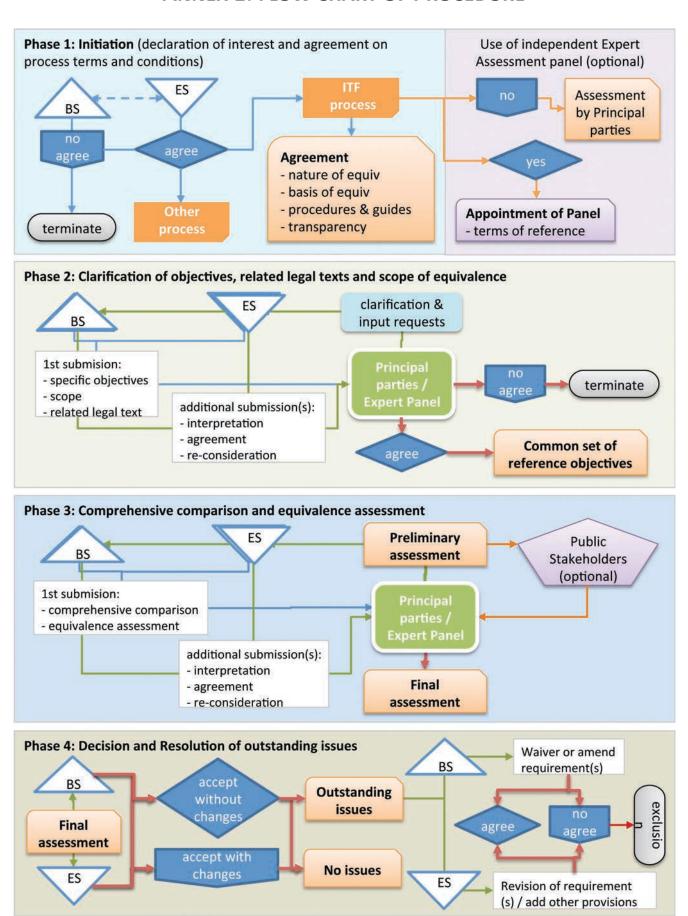
Based on the expert panel's final assessment, the evaluated standard party(ies) may choose to resolve outstanding issues, if any, by one or more ways below (see 3.7):

- a. Revision of specific requirement(s) and/or addition of other provisions by the evaluated standard party(ies) to address outstanding issue(s).
- b. A waiver or amendment of requirement(s) related to outstanding issue(s) by the base standard party.
- c. Exclusion or reduction of scope

Resolution discussion, including face-to-face meeting between parties, may continue for as long as necessary until agreement or decision to terminate process is reached.

The final decision on equivalence or decision to terminate process should be notified to the public, including a summary of the process and rationale for the final outcome of the process.

#### **ANNEX 1: FLOW CHART OF PROCEDURE**



# ANNEX 2: COMMON OBJECTIVES AND REQUIREMENTS FOR ORGANIC STANDARDS (COROS)

#### **INTRODUCTION**

Organic agriculture is a production system that sustains the health of soils, ecosystems and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects. Organic agriculture combines tradition, innovation and science to benefit the shared environment and promote fair relationships and a good quality of life for all involved. The system is often further described by standards, which govern labeling and claims for organic products. A large number of standards have proliferated all over the world as a result of private and public initiatives to provide labeling and consumer assurance in both private and government contexts. There is now a need to support trade of organic products by finding ways and means of assessing the equivalence of organic standards.

#### **DEVELOPMENT**

The Common Objectives and Requirements of Organic Standards (COROS) was developed as a joint venture of the IFOAM Organic Guarantee System (OGS) and the GOMA (Global Organic Market Access) project undertaken by FAO, IFOAM and UNCTAD. The concept of COROS was first developed by the International Task Force on Harmonization and Equivalence (ITF) through the Annex of the Guide for assessing Equivalence of Organic Standards and Technical regulations (EquiTool) in 2008 (www.goma-organic.org). The document was compiled on the basis of the IFOAM Basic Standards and Codex Alimentarius as the two pre-existing international reference organic standards, and through the review of a significant number of existing standards and regulations across the world.

#### **SCOPE AND CONTENTS**

COROS articulates the broad objectives that the production rules in organic standards and regulations commonly seek to achieve, and presents common detailed requirements that relate to these various objectives. COROS contains only requirements that were commonly found in organic standards and regulations globally. It includes production requirements related to general organic management, crop and animal production, beekeeping, processing and social justice. Organic aquaculture, textile processing and cosmetics are not included in the scope of the COROS, primarily due to the fact that these are emerging scopes that are not yet covered by the majority of organic standards and regulations.

#### **PURPOSE**

COROS is intended for use in international equivalence assessments of organic standards and technical regulations. In the context of the GOMA project, it is proposed as a template to guide governments and other stakeholders in conducting objectives-based equivalence assessments of two or more organic standards for production and processing. EquiTool encourages equivalence assessments to be based on reference objectives, an approach that is consistent with WTO guidance for judging equivalence. By basing equivalence discussions and assessments on objectives, parties may avoid tedious line-by-line assessments of one detailed standard against another. Instead parties can assess whether the details of one standard, although they

may vary from those of another standard, meet common objectives. To download EquiTool or read more about it, visit the GOMA website, www.goma-organic.org.

In the context of the IFOAM Organic Guarantee System, COROS serves as an international reference against which organic standards and technical regulations can be assessed for the purpose of inclusion in IFOAM's Family of Standards. Governments could also consider using the Family of Standards as a basis for authorizing imports of organic products. Governments may also use the equivalence assessments done by IFOAM against the COROS as a resource to facilitate their own unilateral or bilateral assessments on equivalence.

#### STRUCTURE AND FUNCTIONING OF THE COROS

A high degree of functionality of COROS is provided in the form of an electronic spreadsheet containing three worksheets:

- The first sheet is a data entry sheet: requirements in the COROS are laid out following the most classical structure of organic standards. For each requirement, the person or group performing the assessment can enter the corresponding requirement(s) in the assessed standard, and a judgment on whether the requirement(s) is/are equivalent, additional (positive variation) or absent/incomplete (negative variation). The evaluation matrix also contains space for the owner of the assessed standard to provide justification for the observed variations to the COROS if appropriate, and for the assessors to place comments and to agree (or not) with the justification provided.
- The second sheet is a template for objectives-based assessment: all this data is automatically fed into the second sheet that reorganizes this analysis according to the broader objectives that the requirements help to achieve. Hence the second sheet enables the assessor to look at the equivalence assessment results from an objective-based angle and to judge how well the assessed standard is addressing the various Common Objectives of Organic Standards and Regulations.
- <u>The third sheet facilitates summary</u>: this sheet is provided to help assessors summarize the results of the equivalence assessment for the purpose of making the final decision and communicating with other parties or the public. The summary should provide a quick view of the strength and weaknesses of the assessed standard as compared to the COROS.

COROS is also provided in the form of a standard document, which is featured in printed versions of EquiTool and facilitates easy reading and comprehension of the objectives and requirements related to them. The spreadsheet and standard document should be considered flexible templates. Parties who are assessing equivalence of standards may use either of them in the following ways:

- Common understanding: it serves as general background information to gain common understanding of typical objectives for organic standards in order to assist them to identify the objectives inherent in their owns standards (many standards do not spell these out explicitly). Such a common understanding is a useful platform for starting equivalence discussions.
- Method for assessment: the template can be used for comparing the stated objectives (if any) and requirements of evaluated standards to COROS, or to a "customized" version that is agreed by the parties to the equivalence discussion. Sets of standards that sufficiently address the objectives as measured by comparing relevant requirements, could be considered to achieve the same main objectives.

#### APPROVAL AND MAINTENANCE OF THE COROS

The draft COROS underwent one round of public consultation in the fall of 2010, and another early in 2011. All comments were reviewed and taken into account prior to approval by the GOMA Steering Committee on one hand and by the IFOAM General Assembly on the other.

The first edition of the COROS is published by IFOAM, FAO and UNCTAD in Version 2of the Equitool and it is also available in electronic format on the GOMA website (www.goma-organic.org). It is also published by IFOAM under the 2011 edition of the IFOAM Norms (www.ifoam.org/ogs). The document is available for public use, free of charge. Although IFOAM will use the tool in the version in which it has been approved, governments and other stakeholders may use and adapt the tool to their own needs.

The COROS reflects the status of organic standards and regulations at the time it was developed (2010-2011). Organic standards and regulations are however not static, and issues that were not commonly included in standards in 2010-11 might become common requirements after a few years. The COROS will therefore be maintained and updated as necessary by IFOAM within frame of its Organic Guarantee System. Revision of the COROS will be done following the IFOAM Policies and Procedures related to the revision of the IFOAM Norms (see www. ifoam.org/ogs).

#### MAIN OBJECTIVES AND DETAILED REQUIREMENTS OF THE COROS:

#### 1. Organic Managemet is long-term, ecological and systems-based.

#### 1.1 All Farming Management Systems:

Organic management does not rely upon switching back and forth between organic and conventional management.

#### 1.2 Crop Production Management Systems:

Organic crop production systems conserve or improve the soil's structure, organic matter, fertility and biodiversity.

Organic crop production management includes a diverse planting scheme as an integral part of the system of the holding. For perennial crops, this includes plant-based ground cover. For annual crops, this includes diverse crop rotation practices, cover crops (green manures), intercropping or other diverse plant production with comparable achievements.

Organic crop production management employs interrelated positive processes and mechanisms for the management of pests, diseases, and weeds. These include but are not limited to site and crop adapted fertility management and soil cultivation, choice of appropriate varieties, enhancement of functional biodiversity, and in case additional measures are required, restricted use of crop protectants and growth regulators.

Organic crop production systems produce terrestrial crops in soil-based systems.

#### 1.3 Livestock systems

Organic operations producing livestock integrate crop and animal production at the farm or regional scale.

#### 1.4 Wild Collection Management Systems:

Organic collection management ensures that collection does not exceed sustainable yield of the collected species or otherwise threaten the local ecosystem.

Organic operators collect products only from within the boundaries of the clearly defined wild collection area.

#### 1.5 Transition/Conversion Requirements for Systems of Organic Production:

Organic guarantee systems clearly identify when organic practices begin and how long they are applied before the operation and products can be considered organic. This may include specific conditions for simultaneous transition/conversion of land and animals.

Organic guarantee systems require a period of time that is suitable for allowing the establishment of healthy soils and sustainable ecosystems before deeming a crop organic.

- Common minimum time periods:
- d. organic management for least 12 months for annuals and 18 months for perennials.
- e. the absence of any inputs that do not accord with organic principles and applicable standards for at least 36 months.

Organic guarantee systems require that animal production systems raise animals organically from birth or hatching, or when this is not possible from early ages subject to a minimum transition/conversion requirement.

Common minimum transition/conversion requirements: dairy – 90 days; eggs and poultry meat – 42 days; other meat – 12 months; bee colonies – time needed for wax replacement with minimum twelve months.

Organic beekeeping introduces bees coming from organic production units when available.

#### 2. Soil fertility is long-term and biologically-based.

#### 2.1 Soil Fertility Management:

Organic crop production systems enhance soil primarily by incorporating manures and other biodegradable inputs, and/ or by nitrogen fixation from plants.

Organic soil fertility management uses only naturally occurring mineral fertilizers and only as a supplement to biologically-based fertility methods.

Organic crop production does not use sodium (chilean) nitrate.

Organic guarantee systems restrict land preparation by burning vegetation.

3. Synthetic inputs at all stages of the organic product chain and exposure of people and the environment to persistent, potentially harmful chemicals are avoided/minimized.

#### 3.1 Crop Production:

Organic soil fertility management uses only crop fertility substances that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards.

Organic soil fertility management does not use synthetic fertilizers or fertilizers made soluble by chemical methods, e.g. superphosphates.

Organic crop production uses only active substances for pest/disease/growth management that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards.

Organic crop production ensures that co-formulants (e.g. inerts and synergists) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins.

Organic soil fertility management does not use human excrement on crops for human consumption without measures to protect humans from pathogens.

#### 3.2 Animal Production:

Organic animal management does not use any of the following synthetic feed rations: amino acids (including isolates), nitrogen compounds (e.g. urea), growth promoters, stimulants, appetizers, preservatives, coloring agents, or any solvent-extracted substance.

Organic animal management provides animals with vitamins, trace elements and supplements only from natural sources unless they are not available in sufficient quantity and/or quality.

Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs.

Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods.

• Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer.

When veterinary medical products are administerd to bees, conversion requirements apply.

Organic beekeeping disinfects hive and honeycomb only through methods and substances that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards.

Organic beekeeping does not use synthetic chemical bee repellents.

Organic beekeeping minimizes use of smoke and uses only natural smoking materials.

#### 3.3 Processing:

For food and feed production, organic processing uses only processing methods that are biological and physical in nature.

Organic processing uses only additives, processing aids, other substances that modify organic products and solvents used for extraction if they that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards.

#### 3.4. Contamination: all systems:

Organic management takes precautionary measures to avoid contamination (commonly this includes barriers/buffers in production, cleaning of farm equipment, separation and cleaning in processing).

Organic processing management identifies and minimizes risks of product contamination.

Organic collection management ensures that wild collection areas are not compromised by improper treatment or environmental pollution.

Organic beekeeping management places hives on organically managed fields or wild/natural areas with sufficient separation from conventional fields and other pollution sources, and in a way that minimizes the risk of contamination.

# 4. Pollution and degradation of the production/processing unit and surrounding environment from production/processing activities are minimized.

#### 4.1 Farm Production and Beekeeping:

Organic management maintains or enhances biodiversity in crop and non-crop habitats on the farm holding.

Organic crop production systems employ measures to prevent land degradation, such as erosion and salinization.

Organic soil fertility management prevents pollution of the environment, including land and water, by inputs and practices.

Organic management ensures that water resources are used sustainably.

Organic management does not undertake any actions that negatively impact high conservation value areas.

Organic guarantee systems restrict use of synthetic coverings and mulches in organic production systems.

Organic animal management systems manage stocking density to ensure sustainable land and water use.

#### 5. Certain unproven, unnatural and harmful technologies are excluded from the system.

#### 5.1 Genetically Modified Organisms

Organic management systems do not use genetically modified organisms (GMO) or their derivatives, except vaccines, in all stages of organic production and processing.

#### 5.2 Irradiation

Organic processing does not use irradiation (ionizing radiation) technologies.

#### 5.3 Breeding Techniques:

Organic animal management uses only breeding techniques consistent with organic production methods. This includes artificial insemination but excludes embryo transfer techniques and cloning.

Organic animal management does not use hormones to induce ovulation or birth, unless for medical reasons.

5.4 Nanotechnology (this aspect is increasingly being covered by organic standards but is still new and mostly non covered by regulations)

Organic production and processing systems do not intentionally manufacture or use nanomaterials. (see note worksheet 2 line 76)

#### 6. Animals are treated responsibly.

#### 6.1 Living conditions

Organic animal management systems ensure that living conditions (including housing) provided to animals:

- afford them comfort and safety
- allow them to exhibit natural behavior
- give them freedom of movement
- allow access, whenever weather allows, to pasture, open air and/or exercise areas, including shade.

#### 6.2 Physical alterations:

Organic animal management does not generally perform physical alterations on animals.

Standards may allow specific exemptions when good management practices are insufficient to
ensure the health and welfare of the animal and/ or operator or when it is specifically required
for meat quality. Physical alternations performed under exceptions employ measures to minimize suffering.

Organic beekeeping does not clip the wings of queen bees.

#### 6.3 Breeding:

Organic animal management uses breeds that reproduce successfully under natural conditions and without routine human involvement.

#### 6.4 Transport and Slaughter:

Organic animal management avoids animal stress and suffering during the movement, handling and slaughter of animals.

• Does not use any injurious devices such as electric prods, and tranquilizers and stimulants.

Organic beekeeping does not deliberately kill bees during honey harvesting.

#### 7. The natural health of animals is promoted and maintained.

#### 7.1 Nutrition

#### **Livestock production:**

Organic animal management systems provide a weaning period for young mammals, which is based on the natural behavior of the species.

Organic animal management includes feed rations that meet the nutritional and dietary requirements of the species, for example access to roughage for ruminants.

Organic animal management does not feed animals slaughter products of the same species or any type of excrements, and does not feed slaughter waste to ruminants.

#### Beekeeping:

Organic beekeeping management ensures that harvesting methods provide sufficient food reserves left behind for the survival of the colony during the dormancy period.

In cases of temporary feed shortages, organic beekeeping provides supplementary feed that is organic.

#### 7.2 Health Care

#### *Livestock production:*

Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs.

Organic animal management never withholds medical treatment considered necessary for the welfare of an animal in order to maintain the organic status of the animal.

#### Beekeeping:

Organic beekeeping management achieves health and welfare of bee colonies primarily through good management and hygienic practices, followed if necessary by phytotherapeutic and/or homeopathic treatments, and then by substances that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards.

#### 8. Organic integrity is maintained throughout the supply chain.

#### 8.1 Crop Production

#### Seeds and Planting Material

Organic crop production uses organic seed and planting materials unless such seed and materials are unavailable.

Organic crop production systems non-chemically treated seeds and planting materials whenever available.

#### Parallel and Split Production

Organic management completely and clearly separates the non-organic and organic parts and products of holdings with split or parallel production, e.g. physical barriers, management practices, storage of inputs and products.

#### 8.2 Animal Production:

Organic animal management takes measures to ensure the organic integrity of animals during movement, handling and slaughter.

Organic animal management limits the use of non-organic feed to non-accessibility of organic feed and organic guarantee systems apply time limits or review periods to its use.

#### 8.3 Processing and Handling

Organic processing management takes measures to prevent co-mingling of organic products with non-organic products in processing, packaging, storage and transport.

Organic processing uses only organic ingredients except for when they are not available.

Organic processing never uses the same ingredient in both organic and non-organic form in a single product.

Organic processing only uses minerals (including trace elements), vitamins, essential fatty, amino acids, and other isolated nutrients when their use is legally required or strongly recommended in the food products in which they are incorporated.

Organic management employs only those systems for cleaning and disinfecting surfaces, machinery and processing facilities that prevent contamination of organic product.

Organic processing management systems control pests according to a hierarchy of practices starting with prevention, and then physical, mechanical, biological methods and substances that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards. Where these practices are not effective, and other substances are used, they do not come into contact with the organic product.

Organic processing restricts disinfecting and sanitizing substances that may come in contact with organic products to water and substances that are on (a) list(s) referenced by the standard. Such lists are based on lists and/or criteria in international organic standards. In cases where these substances are ineffective and others must be used, organic processing ensures that these other substances do not come into contact with any organic products.

Organic processing ensures that packaging and storage/transportation containers do not contaminate the organic product they contain.

#### 9. Organic identity is provided in the supply chain.

Labeling fully discloses ingredients, including whether or not they are organic.

Labeling identifies the person or company legally responsible for the product and the body that assures conformity to the applicable organic standard.

Claims that processed products are "organic" are made only if the product contains at least 95% organic ingredients (by weight excluding water and salt).

Claims that processed products are "made with organic ingredients" or similar terms are made only if the product contains at least 70% organic ingredients (by weight excluding water and salt).

Labeling does not make "organic" or "made-with organic ingredients" or similar terms, or make any organic certification claims on products with less than 70% organic ingredients (by weight excluding water and salt), although "organic" may be used to characterize ingredients on the list of ingredients.

Labeling clearly distinguishes in-conversion products or similar terms from organic products.

## 10. Fairness, respect and justice, equal opportunities and non-discrimination is afforded to employees and workers

\*\*\* this objective is commonly addressed in private standards although not usually in the scope of government organic standards.

Organic operations in countries where social legislation is not in place or not enforced have social policies in place. Such policies should be in accordance with the International Labor Organization's Declaration on Fundamental Principles and Rights at Work.

Organic operations ensure that employees and contracted workers have the freedom to associate, the right to organize and the right to bargain collectively.

Organic operations provide all employees and contractors with equal opportunities and do not subject them to discrimination.

Organic operations do not violate human rights and they provide fair working conditions for employees and contracted workers.

Organic operations do not use any type of forced or involuntary labor.

Organic operations guarantee the integral well-being of any children who work in the operation.

#### Additional assessment (related to Objective 3 mainly):

#### **Lists of substances:**

Compare list of approved substances in the standard with lists in a reference international standard. Is it overall equivalent? (Also look for allowed/prohibited substances in the body of the standards)

#### **Criteria for lists of substances:**

Compare criteria for the inclusion of substances used by the standard setter with criteria in the COROS (these may be criteria of the standard setter or international criteria). Is it equivalent?

#### **COROS DEFINITIONS:**

**Additive**: A substance that is added to a processed product for a technological purpose and becomes a component of the final product and/or affects its characteristics.

**Biodiversity**: The variety of life forms and ecosystem types on Earth. Includes genetic diversity (i.e. diversity within species), species diversity (i.e. the number and variety of species) and ecosystem diversity (total number of ecosystem types).

**Breeding**: Selection of plants or animals to reproduce and / or to further develop desired characteristics in succeeding generations.

**Certification**: The procedure by which an operator or a group of operators received written and reliably endorsed assurance that a clearly identified process has been methodically applied in order to assess that the operator is producing specified products according to specific requirements or standards.

**Contamination**: Contact of organic crops, animals, land or products with any substance that would compromise the organic integrity.

**Conventional**: Any production or processing practice or system that does not conform to organic production practices and standards.

**Conversion**: The time of transition from non-organic to organic farming.

**Crop Rotation**: The practice of alternating the species or families of annual and/or biennial crops grown on a specific field in a planned pattern or sequence so as to break weed, pest and disease cycles and to maintain or improve soil fertility and organic matter content.

**GMO Derivative**: A substance that is produced by or from a GMO. This is traced one step back from the substance to its source. 'Produced from GMO' means that it consists in whole or in part of a GMO. 'Produced by GMO' means that it is a GMO metabolite.

**Disinfect**: To reduce, by physical or chemical means, the number of potentially harmful microorganisms in the environment to a level that does not compromise food safety or suitability.

**Holding**: The total area of land under control of one farmer or collective of farmers, and including all the farming activities or enterprises. The farm holding may consist of one or more farm units.

**Genetic Engineering**: Genetic engineering is a set of techniques from molecular biology (such as recombinant DNA) by which the genetic material of plants, animals, microorganisms, cells and other biological units are altered in ways or with results that could not be obtained by methods of natural mating and reproduction or natural recombination. Techniques of genetic engineering include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation. Genetically engineered organisms do not include organisms resulting from techniques such as conjugation, transduction and natural hybridization.

**Genetically Modified Organism (GMO)**: A plant, animal, or microbe that is transformed by genetic engineering.

**Green Manure**: A crop that is grown and then incorporated into the soil for the purpose of soil improvement, prevention of erosion, prevention of nutrient loss, mobilization and accumulation of plant nutrients, and balancing soil organic matter. Green manure may include spontaneous crops, plants or weeds.

Habitat: The area over which a plant or animal species naturally exists. Also used to indicate

types of habitat, e.g. ocean, seashore, riverbank, woodland, grassland.

**High Conservation Value Areas**: Areas that have been recognized as having outstanding and critical importance due to their environmental, socioeconomic, biodiversity or landscape values.

**Homeopathic Treatment**: Treatment of disease based on administration of remedies prepared through successive dilutions of a substance that in higher concentration produces symptoms in healthy subjects similar to those of the disease itself.

**Ingredient**: Any substance, including an additive, used in the manufacture or preparation of a product and present in the final product although possibly in a modified form.

**Irradiation**: Technology using high-energy emissions from radio-nucleotides, capable of altering a product's molecular structure for the purpose of controlling microbial contaminants, pathogens, parasites and pests in products (generally food), preserving products or inhibiting physiological processes such as sprouting or ripening. (Also referred to as ionizing radiation although definitions of this term in technical and legal texts vary.) Irradiation does not include low-level radiation sources such as the use of X rays for foreign body detection.

**Nanomaterials**: substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional processing methods such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition.

**Operation**: For the purposes of this document an operation is an individual or business enterprise producing, processing or handling agricultural products.

**Organic Product**: A product that has been produced, processed, or handled in compliance with organic standards.

**Parallel Production**: A situation where the same operation is producing visually indistinguishable products in both an organic system and a non-organic system. A situation with "organic" and "in conversion" production of the same product may also be parallel production.

**Processing**: The handling, treatment, transformation or packaging of agricultural or wild collected products.

**Processing Aid**: Any substance used in the processing of a product to fulfill a technical purpose and which is not normally a constituent of the product. This includes filtration auxiliaries.

**Restrict**: Limit a practice, generally to conditions under which it may be used.

**Sanitizing**: Any treatment that is effective in destroying or substantially reducing the numbers of vegetative cells of microorganisms of public health concern, and other undesirable microorganisms.

**Split Production**: Conventional, in conversion and/or organic production, breeding, handling or processing in the same operation.

**Synthetic**: A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources. Substances created by naturally occurring biological processes are not considered synthetic.

Standards: Norms that specify how a product should be produced and processed. For the

purposes of this document standards are used to define organic production practices.

**Sustainable**: Use of a resource in such a way that the resource is not depleted or permanently damaged, hence is not used faster than it can be regenerated.

#### CRITERIA FOR SUBSTANCES USED IN ORGANIC PRODUCTION AND PROCESSING

These basic criteria will facilitate the equivalence assessment of lists of substances, which, although they may differ, should be able to be justified against set criteria. These criteria summarize criteria that are presented in two international standards, the IFOAM Standards and the Codex Alimentarius Organic Guidelines.

Substances used in organic production, processing and handling must be consistent with the principles and objectives of organic agriculture. Precaution and responsibility are the key concerns in management, development and technology choices in organic agriculture.

Standard setting bodies should at minimum use the following criteria when evaluating substances for inclusion in their standards.

#### **GENERAL CRITERIA**

All substances used in organic production and processing should meet the following criteria:

- i. use of the substance is consistent with the principles and objectives of organic agriculture
- ii. the substance is necessary/essential for its intended use.
- iii. approved alternatives are not available in sufficient quantity and/or quality
- iv. manufacture, use and disposal of the substance does not result in, or contribute to harmful effects on the environment
- v. The substance has the lowest negative impact on human or animal health or the environment when compared to alternative substances.
- vi. \* the consumer is not deceived concerning the nature and quality of the substance
- vii. \* consideration is given to social and economic impacts of sourcing and manufacturing the substance.

\*commonly and primarily used in the private sector for evaluating substances

In addition, the following criteria should be applied in the evaluation process:

- a. if the substance is used for fertilization and/or soil conditioning purposes:
  - it is essential for obtaining or maintaining the fertility of the soil or to fulfill specific nutritional requirements of crops, or specific soil-conditioning and rotation purposes which cannot be satisfied by other organic fertility practices.
  - the ingredients are of biological or mineral origin and may have undergone the following processes: physical (e.g., mechanical, thermal), enzymatic, microbial (e.g., composting, fermentation);
    - Synthetic nature identical products that are not available in sufficient quantity and quality in their natural form maybe allowed provided all other criteria are satisfied.
  - use does not have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality.

- use may be restricted to specific conditions, specific regions or specific commodities.
- b. if the substance is used for plant protection, growth regulation or weed control:
  - it must be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or other management practices consistent with this IBS are not effective.
  - it has the least harmful impact (compared to alternatives) on the environment, the ecological balance (in particular non-target organisms) and the health of consumers human, livestock, aquatic animals and bees.
  - substances must be of biological or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion);
    - Synthetic substances may be used by exception such as the use in traps or dispensers, or substances that do not come into direct contact with produce, or those for which no natural or nature identical alternative is available provided that all other criteria are met.
  - use may be restricted to specific target organisms, conditions, specific regions or specific commodities;
- c. if the substance is used as an additive and/or processing aid in the preparation or preservation of the product:
  - it must otherwise be impossible to produce or preserve the product
    - The substance is found in nature, and may have undergone mechanical/physical processes (e.g. extraction, precipitation), biological/enzymatic processes and microbial processes (e.g. fermentation).
    - Synthetic nature identical products that are not available in sufficient quantity and quality in their natural form maybe allowed provided all other criteria are satisfied.

#### **ANNEX 3: CRITERIA FOR VARIATIONS IN STANDARDS**

There may be conditions where climate, geographical, technical problems as well as economic, regulatory or cultural factors rationalize a variation from the base standard.

The need and necessity for a variation should be established on at least one of the following:

- a. Climatic, geographical and/or structural conditions, where the evaluated standard applies, prevent effective application of the base standard requirement;
- b. Compliant methods to the expectation of the base standard requirement are not achievable or feasible for operators where the evaluated standard applies;
- c. Application of the base standard requirement would prevent further development of organic agriculture where the evaluated standard applies;
- d. Application of the base standard requirement seriously contradicts generally accepted religious or cultural beliefs as opposed to the evaluated standard where applicable;
- e. Application of the base standard requirement would prohibit compliance with prevailing legal requirements or legitimate sector regulations where the evaluated standard applies;
- f. Application of the base standard requirement does not meet established consensus or 'state of the art' understanding of the organic sector due to a different historical development of organic practices where the evaluated standard applies

Further considerations for acceptance

The evaluated standard should be set through a documented standard setting process that includes open stakeholder consultation. Compliance to WTO TBT agreement or ISEAL<sup>2</sup> code for standard setting should be favorably considered.

The evaluated standard can demonstrate equivalence to international standards and/or acceptance by other private standard setters or government authorities.

The evaluated standard including variations maintain practices that clearly distinguish organic from non-organic production and processing practices.

The evaluated standard including variations does not contradict specified objectives of the Base standard.

Acceptance of variation does not unduly prejudice fair competition, consumer trust in organic and international harmonization necessary for international trade.

Adapted from IFOAM policy 42: "IFOAM Policy for Recognition of Certification Standards Based on the IFOAM Basic Standards"

<sup>2</sup> International Social and Environmental Labeling Alliance

# ANNEX 4: TEMPLATE FOR A COMPARISON, INCLUDING EQUIVALENCY ASSESSMENT AND CONCLUSION (REF. SECTION 3.6)

The template below is based on the matrix tool for IFOAM recognition of other standards. The actual template is an excel file. The objective is to provide an overview of how the evaluated standard compares to the Base standard.

Although this example is for comparison of individual requirements, the template can be adapted for comparison of concise and/or paraphrased requirements. The example uses a section from the IFOAM Basic Standards in Column 2.

1	2	3	4	5			6		
BS ref.	Base Standard (BS) content according to published format or concise version in order of - section heading - specific objectives - sub-heading - requirements - additional legal text	Evaluated Standard (ES) or related legal text content, or paraphrased text.  In order of matching content to Base Standard	ES ref.	Assessment E: Equivalent N: Not Equivalent A: Additional O: Omission U: Undecided		Assessment party's comment			
	Objectives specified			E	N	A	0	U	
	Protecting and en- hancing biodiversity								
2.	Section heading: Organic Ecosystems	matching Evaluated Standard content							
2.1	Sub-heading  Ecosystem management (2)  figure in brackets indicates the number of requirements in the sub section	matching Evaluated Standard content							
2.1.1	Specific requirement Operators shall take measures to main- tain and improve landscape and en- hance biodiversity	matching Evaluated Standard content							Rationale for assessment of specific requirement
	Further explanation, interpretation or additional legal text  None	matching Evaluated Standard content							
2.1.2	Clearing of pri- mary ecosystem is prohibited	matching Evaluated Standard content							Rationale for specific assessment

	Further explanation, interpretation or legal text  None	Additional explanation, interpretation or legal text if any				
		Additional Evaluated Standard requirements if any				
Do the Evaluated standard requirements and related legal text in this section as a whole provide equivalent fulfilment of the applicable specified objectives of the Base standard?					Rationale for equivalence assessment of set of requirements	

### **COLUMNS**

	T						
1	Reference number of Base Standard content						
2	Base Standard content according to published format or concise version in hierarchical order of						
	<ul> <li>section heading</li> </ul>						
	<ul> <li>specific objectives</li> </ul>						
	- sub-heading						
	<ul><li>requirements</li><li>further explanation, interpretation or additional legal text (where applicable)</li></ul>						
3	Matching Evaluated Standard content according to published format or concise version to Base Standard for comparison						
4	Reference number of	Evaluated Standard content					
5	Status of equivalence assessment of Evaluated Standard against Base Standard. The different statuses are marked with different colors for easy identification.						
	E: Equivalent including equivalence based on criteria for variation						
	N: Not equivalent	requirements that are judged not to be equivalent, including if they are omitted in the evaluated standard.					
	A: Additional	for Evaluated Standard requirements that are not addressed in the Base Standard. The corresponding Base standard slot will be empty					
	O: Omission	for Base Standard requirements that are not addressed in the Evaluated Standard. The corresponding evaluated standard slot will be empty.					
	U: Undecided	indicating inability of the assessment party to decide equivalence at the time					
	The different statuses are split into separate columns for easier sorting and counting on numbers.						
6	Assessment party's co	omment related to assessment made					

The columns presented in the sample template represent the basic set. More columns can be added as need arises to track additional comments, proposed revisions of objectives and/or requirements as well as change in assessment or standards/regulations over time.

#### **Rows**

Each component of the Base Standard should occupy separate rows, i.e. separate rows for each heading, objective, sub-heading and requirement. Interpretations, explanations and legal text related to a particular requirement should occupy the row just below the requirement or the bottom rows within the related sub-heading if not related to any requirement.

At the bottom of each section or sub-section is the conclusion row where equivalence of the section or sub-section is noted.

Different row colors are used for headings, objectives, requirements and additional explanation and legal text for easy identification.

# ANNEX 5: FRAMEWORK REFERENCES FOR THE ITF EQUIVALENCE GUIDE

#### **WTO TBT AGREEMENT**

The Agreement on Technical Barriers to Trade states in Article 2.4 that "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

Where it is not appropriate for a country to adopt an international standard, or base their technical regulations on an international standard, Article 2.7 of the WTO-TBT agreement states that "Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations."

#### **CODEX ALIMENTARIUS**

Although the CAC/GL 34 Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems refers to conformity assessment and agreements between governments, many of its provisions offer applicable guidance for judging equivalence of standards and making agreements within the private sector as well.

The CAC/GL 34 Foreword mentions that 'Import requirements should be based in the principles of equivalence and transparency as set out in Principles for Food Import and Export Inspection and Certification.'

Sections of CAC/GL 34 include the following applicable provisions:

Section	Provision
5.7	The importing country considers and determines whether the country's measures meet the importing country's requirements. Any decision must, however, be made on the basis of objective criteria.
5.10	A country entering into discussion towards an equivalence agreement should be prepared to facilitate assessment and verification activity both before and after conclusion of the agreement.
7.16	As a first step in the consultative process, the importing country should make readily available the text of its relevant control measures and identify the objectives of these measures.
7.17	The exporting country should provide information that demonstrates that its own safety control system achieves the importing country's objectives and/or level of protection as appropriate.
18.	The development of equivalence agreements is facilitated by the use of Codex standards, recommendations and guidelines by both parties.

- 19. To facilitate the consultative process, information should be exchanged as appropriate, on (a) legislative framework, including the texts of all relevant legislation, which provides the legal basis for the uniform and consistent application of the food control system that is the subject of the agreement.
- 20. Countries may wish compare side-by-side tables to organize the above-mentioned information an identify differences in measures/requirements.
- 21. The importing and exporting countries should identify a process for jointly considering differences in measures/requirements.
- 22. Participants in the agreements should be able to a) satisfy themselves and verify that equivalence continues to exist after conclusion of an equivalence agreement, and b) resolve any problems identified during audit and verification.
- 28. Participants in the agreement should agree to procedures for terminating the agreement, in case either party is not satisfied that the terms of the agreement are being met.

## **BIBLIOGRAPHY**

Codex	CAC/GL 32: Guidelines for the Production, Processing, Labeling and Marketing of Organically produced foods.
	CAC/GL 34: Guidelines for the Development of Equivalence Agreements
	Regarding Food Import and Export Inspection and Certification Systems
IFOAM	IFOAM Basic Standards
	IFOAM policy 42: IFOAM Policy for Recognition of Certification Standards
	Based on the IFOAM Basic Standards
ITF	Experiences of Equivalence and Recognition Mechanisms in the Regulation of
	Organic Agriculture (5th ITF meeting)
	Common Objectives of Organic Standards Systems (6th meeting).
	This is an example derived from research, but not formally established through
	a stakeholder consultation process.
	International Requirements for Organic Certification Bodies
WTO	WTO TBT agreement
Others	Letter from Ministry of Agriculture, Forestry and Fisheries, Japan to the USDA,
	6 February 2001.









### **About GOMA**

Organic agriculture and trade afford the world a high level of agro-ecosystem services, and present social and economic opportunities for those in need of food security and ways out of poverty.

Among the foremost challenges for further development of organic agriculture is that trade pathways are blocked due to multiple organic standards and technical regulations. A product produced according to one set of organic standards and certification requirements may also need to comply with other organic standards and requirements in order to be traded. This constrains organic market development and denies market access to many, including hundreds-of-thousands of small producers in developing countries.

The Global Organic Market Access (GOMA) project is a partnership of the Food and Agriculture Organization of the United Nations (FAO), International Federation of Organic Agriculture Movements, (IFOAM) and the United Nations Conference on Trade and Development (UNCTAD). GOMA seeks to clear trade pathways for organic products through the mechanisms of harmonization and equivalence. For more information on the project, visit **www.goma-organic.org**.