

INTERNATIONAL TASK FORCE
ON HARMONIZATION AND EQUIVALENCE IN ORGANIC AGRICULTURE (ITF)



UNCTAD
UNITED NATIONS
CONFERENCE ON
TRADE AND
DEVELOPMENT



INTERNATIONAL FEDERATION OF
ORGANIC AGRICULTURE MOVEMENTS



FOOD AND AGRICULTURE
ORGANISATION
OF THE UNITED NATIONS

ITF Secretariat: Tel: +49 228 926 50 10, Fax: +49 228 926 50 99, E-mail: d.bowen@ifoaam.org, m.fecht@ifoaam.org

Discussion Paper
International Task Force on Harmonization and Equivalence
in Organic Agriculture

**CURRENT MECHANISMS THAT ENABLE
INTERNATIONAL TRADE IN ORGANIC PRODUCTS**

Prepared by:

Diane Bowen

International Federation of Organic Agriculture Movements (IFOAM)

March 2004

Contents

Executive Summary	1
Introduction	2
<i>An overview of the current mechanisms for enabling international trade, and includes definitions of related terms</i>	
Definitions	2
Overview of government and private sector schemes	3
Private Sector Provisions:	
The IFOAM Organic Guarantee System	4
<i>Description of harmonization and transparency mechanisms within the international private organic guarantee system. Analysis of the current state of harmonization and transparency achieved through this scheme.</i>	
IFOAM's System for Approval of Other Standards	4
IFOAM Accreditation & the Multi-lateral Agreements	5
National Government Regulatory Provisions:	
Bilateral Agreements and Approval Schemes	7
<i>Government mechanisms for enabling trade, including compliance and equivalence. Analysis of the current state of harmonization and transparency achieved through these provisions and agreements. Emphasis is on the major importing countries.</i>	
Overview	7
EU	7
Mechanisms for Imports	7
Implementation	8
Transparency	8
MAFF Japan	10
Mechanisms for Imports	10
Extent of Implementation	11
Transparency	11
USDA NOP	11
Mechanisms for Imports	11
Extent of Implementation	11
Transparency	12
IV. Inter-Governmental Bodies	13
<i>Description of the impact of international standards setting processes on harmonization and transparency. Analysis of the current influence of Codex Alimentarius on harmonization and transparency in the organic sector.</i>	
CODEX Alimentarius	13
Production, Processing, Labeling and Marketing of Organically Produced Foods	13

International Task Force on Harmonization and Equivalence in Organic Agriculture

Certification and Inspection	14
ISO Guidelines	16
ISO Guide 65	16
V. Limitation of the Current Systems	16
<i>Presentation of some key factors that limit equivalence and mutual recognition of organic standards and conformance assessment systems.</i>	
VI Conclusions	17

Executive Summary

This paper focuses on how some of the government organic regulations and the two international systems (IFOAM and Codex Alimentarius), provide mechanisms to enable the international flow of trade in organic products – a process that in the context of these papers, is referred to as “convergence”.

Mechanisms to accommodate international trade exist in the organic regulations of the three major importing countries and in the IFOAM Organic Guarantee System. Some of these mechanisms are based on determination of compliance, and others are based on determination of equivalence. This paper describes these mechanisms and the extent to which they are currently implemented. Also addressed is the current impact of Codex Alimentarius and ISO Guidelines on harmonization and transparency. The paper concludes with an analysis of some of the limitations of the current systems to bring about convergence. These are the following:

- In general, government systems are not based on an internationally recognized standard.
- There are no precedents for international multilateral equivalence and mutual recognition in government systems, and few precedents for bilateral equivalence.
- Government systems require bilateral equivalency.
- Existing and pending government determinations of equivalence are not transparent.
- The private international system has a mechanism for multilateral equivalency, but is not integrated with the government regulatory systems.
- The private international system does not entirely reconcile equivalency.

Introduction

The three major organic importing government authorities (EU, Japan, US) have compliance, mutual recognition and equivalence-based mechanisms for enabling their systems to accommodate the flow of trade in organic products. Transparency of these processes is an important factor in achieving credible and stable mechanisms. This paper examines the current mechanisms for enabling trade, the extent to which they have been implemented, and assesses their transparency. It is useful to begin with some definitions along with some examples of their application in the context of organic regulation and trade.

Definitions

Convergence: Any process of trade coordination in a generic way that fosters the flow of products

Compliance: This paper uses the term “compliance” to indicate adherence to the specific provisions of a standard, technical regulation, or requirement for conformance assessment. Entities that are directly regulated by a government authority or private program are required to be in compliance with all the provisions of a governing document. Compliance is at the root of a given system of technical regulation, regardless of layers of equivalence that might be built above it to harmonize differences among systems. However, compliance can also apply between nations and systems. If a government regulatory program has a mechanism to assess the compliance of foreign entities, *inter alia* certification bodies, producers, traders with its regulation - this can facilitate trade. An example of such a compliance-based approach is the USDA’s direct accreditation of foreign certification bodies to the requirements of the US National Organic Program (NOP). While these certification bodies may be subject to the organic regulations of their home country, they may also design their certification program to comply with the US organic regulations. So therefore a provision based on compliance can also be regarded as a way to converge.

Equivalence: Equivalence is a mechanism to recognize and accept another system by acknowledging that variations between the systems uphold the respective systems’ objectives.¹ With respect to conformity assessment, ISO defines equivalence as the sufficiency of different conformity assessment results to provide the same level of assurance.² Equivalence can be structured bilaterally or multilaterally, and is forged through determinations of equivalency of standards and technical regulations. Although achieving an equivalence determination is a complex process, equivalence mechanisms can operate far more efficiently than compliance mechanisms with respect to

¹ WTO Agreement on Technical Barriers to Trade, article 2.7

² ISO/IEC CD2 17000

international trade. Currently there are no mutual recognition agreements for equivalence of organic regulations in the government sector, although some unilateral equivalence determination have been forged, including a few that recognize the organic regulations of developing countries as equivalent. In the private sector, the IFOAM Organic Guarantee System provides a platform for multi-lateral mutual recognition among participating certification bodies. The extent to which this equivalence operates is addressed later in this paper.

Mutual Recognition: A tool in which only the conformity assessment bodies are deemed to be equally capable and does not include any convergence of the standards against which products are judged.

Transparency: Transparency means access to information on the mechanisms for implementation of standards, regulations and agreements as well as for the individual processes and decisions undertaken within these frameworks. Equivalence is internationally feasible only with transparency. This premise is acknowledged and supported by the WTO Agreement on Technical Barriers to Trade.³ The TBT Agreement in the Uruguay Round established a requirement for governments to notify other governments when establishing any technical regulations that depart from “relevant international standards” and also when forging equivalence agreements with other governments. Because transparency is so critical to the success of harmonization efforts, this paper addresses elements of transparency as applied to the specific cases of the major importing countries and the private IFOAM Organic Guarantee System.

Overview of the Private and Government Systems

The IFOAM Organic Guarantee System establishes baseline compliance requirements for standards and conformance assessment upon which equivalence among certification bodies may be further established. Transparency of these mechanisms and their implementation is necessary to ensure that the systems are not discriminatory, therefore constituting barriers to trade.

Government Technical Rules/Regulations: All three of the organic technical regulations of the major importing countries plus IFOAM’s Basic Standards differ from one another in some key respects. Neither the US National Organic Standard nor the EU Regulation 2092/91 were formally modeled on an existing international standard. Therefore they are widely considered to have their own national basis and standing, which is not within an international context. In this respect, they may not conform to the WTO TBT Agreement, which states that technical regulations should follow relevant international standards. However, the criteria or definition of a “relevant standard” is not given. IFOAM Basic Standards (IBS) have existed in the private sector for more than 20 years, but their longevity does not necessarily qualify them as “relevant standards” under WTO. History of the IBS development until recently shows few ties with government or international standardizing structures. Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods are an initiative of governments with private sector participation, but their development and approval came after the

³ WTO Agreement on Technical Barriers to Trade, article 2

initiation of the US and EU organic regulations and did not influence them to any significant extent. And although Codex Alimentarius was a reference point for the development of the JAS Standard, elements of Japan's organic regulation differ in significant ways from other national and international standards; for example, its requirements for "grading" of organic products throughout the production and distribution chain.

Conformance Assessment: A number of key government conformance assessment requirements are based in some way on ISO Guidelines. IFOAM's conformance assessment requirements for certification bodies, the Accreditation Criteria, are also based on ISO Guidelines. However, the degree to which these systems are based on ISO is significantly different.

Private Sector Provisions for Trade: The IFOAM Organic Guarantee System

Harmonizing Standards: IFOAM's System for Approval of Other Standards

The IFOAM Organic Guarantee System includes a provision to harmonize various other standards with the IFOAM Basic Standards (IBS) while recognizing that it is a delicate balance to combine a need for regional variations with the international harmonization that is needed for trade, fair competition and consumer trust in organic product claims. IFOAM acknowledges that there may be conditions where climate and geography, technical problems, or factors such as economics, regulations, and/or culture require variation to the IBS requirements. IFOAM also considers the IBS as "standards for standards" and expects that regional standards used for certification may well be more detailed than the IBS. Variations in other standards may be acceptable as long as they are consistent with the general aims of the Standards and Accreditation Criteria. IFOAM has instituted a formal procedure for approving other standards as meeting its international norm, the IBS.⁴ The foundation of the procedure is a set of Criteria for Variations. These criteria describe how and under what conditions, variations to the IBS may or may not be approved by IFOAM. The criteria require that need and necessity for the variation is established, and that alternative methods of production and processing systems are compliant with the Principal Aims of the IBS and do not contradict other general principles in relevant sections of the IBS. Also, variations must represent distinguishable improvement over conventional production and processing systems, and they cannot result in substantially distorted trade. Approved standards will be recognized in the IFOAM Accreditation Program as long as the regional standard corresponds to the region in which a certification body is certifying. The practical result of this approval system is that multiple regional standards can be judged equivalent within the private system.

IFOAM's policy for harmonizing standards was completed in 2002. In 2003, IFOAM is currently processing its first application for approval of another standard and so for the first time, it is evaluating another standard against the Criteria for Variations.

⁴ IFOAM Policy 25, Policy on Variations in Standards and IFOAM Policy 42, IFOAM Approval of Other Standards.

Equivalence and Mutual Recognition in Certification: The Multilateral Agreement⁵

IFOAM Accreditation provides a common platform upon which IFOAM Accredited Certification Bodies (ACBs) can streamline their operations and support the flow of international trade in organic products. Indeed, the ACBs have built a multi-lateral mutual recognition agreement (MLA) in which most of them are currently participating.

History of the MLA

The ACBs began to work on crafting the MLA in 1997, using as resources several existing bilateral agreements, an ISO 9000 report on mutual recognition agreements, and model MLAs in other ISO settings. In 1999, nine ACBs were initial signatories to the MLA.

Scope of the MLA

The following points define the scope of the MLA:

- It is owned and controlled by the ACBs themselves, not by IFOAM.
- The MLA is open to ACBs only.
- It provides recognition of functional equivalence among certification bodies. Functional recognition is established for the system of conformance assessment (certification) at the level of the IFOAM Accreditation Criteria, and for equivalence of organic standards at the level of the IFOAM Basic Standards.
- Its tangible result is a process for one ACB to accept products certified by another ACB. This process is known as “certificate acceptance,” and stands in contrast to the process of conducting full certification document reviews and re-certifying a product. This is useful when a party certified by one ACB wishes to purchase a product certified by another ACB for use as an ingredient in a multi-ingredient product, or for re-sale. However, it does not automatically transfer the logo of a second ACB to the supplier of the ingredient or product for re-sale.

Two Levels Are Involved in Implementing the MLA, as follows:

- Level One = Multi-lateral recognition
 - Certification Systems are mutually recognized since they all meet the IFOAM Accreditation Criteria.
 - Organic Standards are equivalent at the level of the IFOAM Basic Standards. However, certification bodies may declare to the ACB group that they will require compliance to additional standards requirements when deciding case-by-case certificate acceptance.
- Level Two = Bilateral acceptance
 - At this level, the process for accepting certificates is established between two ACBs, who will need to consider each other’s additional requirements, if any, and work out a system to verify that these additional requirements were met in the production of the product.

⁵ The section is reproduced (with revisions) from the following publication: Bowen, Diane and Annie Kirschenmann, “The Multi-lateral Agreement amongst IFOAM Accredited Certification Bodies,” In IFOAM, FAO, UNCTAD, 2003. The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence (ISBN 3-934-055-23-0)

International Task Force on Harmonization and Equivalence in Organic Agriculture

- At this level, ACBs are accepting products purchased by their certified operators.

Status of Implementation

In order for the MLA to function at the practical level, ACBs must complete bilateral arrangements with one another. In cases where there are frequent transactions from one certification system into another, ACBs have usually worked out bilateral arrangements. Where there are rare or no transactions of product from one certification system to another, the bilateral arrangements have not been made.

Challenges to full implementation

Communication: The worldwide distribution of ACBs can make follow-up on the mechanisms of bilateral certificate acceptance difficult.

Additional Requirements: The provision within the MLA for certification bodies to require that accepted products meet additional standards requirements beyond the IBS have constrained the functional implementation of equivalence among ACBs. At least eight ACBs have declared additional requirements. The number of additional requirements set by certification bodies varies from just one or two to more than twenty. Having many additional requirements eliminates motivation and justification for bilateral certificate acceptance because compliance with each of these additional requirements must be checked and verified on a case-by-case basis between the two certification bodies.

ACBs have offered the following justifications for setting additional requirements:

- There may be legal constraints on the ACB in the form of government regulations that require full standards compliance.
- Consumer expectations about a particular certification seal or in a particular country/region may require compliance with certain additional standards.
- Clients of the ACB have expectations of fairness and parity in requirements.

Eliminating additional requirements altogether when there are differences in standards requires that ACBs determine “equivalence.” This is a complex process requiring the establishment of criteria, and may not be justifiable or otherwise feasible at the certification body level

Extent of Global Harmonization

Of the approximately 360 certification bodies worldwide⁶, 26 are IFOAM accredited and of these, 22 have signed the MLA. However, these tend to be large certification bodies that operate internationally, and which account for a high percentage of organic products traded internationally. On the other hand, the MLA applies only to the certification body’s “IFOAM Accredited programs”. A number of certification bodies run multiple organic certification programs for a variety of standards, and are IFOAM accredited for only one program. Therefore, the “IFOAM Accreditation” of a certification body may describe only a portion of its operation.

⁶ Estimated in The Organic Standard, Issue 28, August, 2003.

Transparency of the MLA

The signatories to the MLA are published on the website of the International Organic Accreditation Service (IOAS). Additional requirements of the individual ACBs are available upon request.

National Government Regulatory Provisions: Bilateral Agreements and Approval Schemes

The European Union: EEC 2092/91

Mechanisms for Imports⁷

Article 11 of Regulation 2092/91, as amended, specifies requirements for importing products from countries outside the EU. EU regulations apply to all processed and unprocessed food products from plants or animals to wild products. Currently there are three methods for meeting the requirements for importing organic foods into the EU.

1. *Approval of third countries (Article 11.1)*

Article 11 of Regulation (EEC) No 2092/91 establishes the basic system for approval of third countries for the purpose of importing organic products. More detailed rules for implementing the arrangements are laid down by the Commission Regulation (EEC) No 94/92 of 14 January 1992. It requires the EU authorities to evaluate and approve a third country's organic standards and to recognize its organic inspection system. In cases where inspections are carried out by private certification bodies, the EU will evaluate the exporting country's system for accrediting private certification bodies. The evaluation of the third country system includes physical visits by the Commission's own experts. Such evaluation visits may also occur at any time following approval of the third country. Approved countries appear on a list annexed to Commission Regulation (EEC) No 94.92. The list may specify approved regions, production units, or inspection bodies within the country. Through this method, inspection bodies are approved by the EU only for their work within the country on the Article 11 list, and not for certifications outside the country. To be added to the Article 11 list, a country representative must apply to the Commission and provide sufficient information to enable the Commission to ensure that the requirements are met for organic products intended for import into the EU. Formatted tables for enabling a comparison of third country standards against those of the EU are provided. The information must include the following: types of products intended for export, rules of production, rules on the inspection system and a description of how it is organized, and any available reports on the effectiveness of the implementation of production and inspection rules. [Commission Regulation (EEC) No 04/92 Article 2.(2)]

⁷ This section is reproduced (with revisions) from the following publication: IFOAM, FAO, UNCTAD, 2003. *The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence* (ISBN 3-934-055-23-0)

2. *Member state authorization of products: the importer derogation (Article 11.6)*
Council Regulation (EEC) No 2083/92 amended the Regulation to enable the government authority with jurisdiction over organic standards in individual EU Member States to authorize an importer to import products from a country not included in the Article 11 list. This provision is commonly referred to as the “importer derogation.” It is scheduled to expire on 31 December 2005. In order for imports to be approved under this method, the importer must furnish the Member State with sufficient evidence to show that:
 - The imported product was produced according to organic production rules equivalent to EU standards;
 - The imported product was subject to inspection measures equivalent to EU inspection requirements’
 - The inspection measures will be permanently and effectively applied [Council Regulation (EEC) No 2092/91, Article 11 par6, as amended], and
 - The certification body operates in compliance with ISO/IEC Guide 65/EN45011.

Each importer must obtain a separate authorization for each imported product. If an importer imports the same product from different countries or with certifications from different certification bodies in the same country, a separate authorization must be obtained for each. Member states are required to notify the Commission of each authorization, and other Member states are subsequently notified.

The process to license the importer to import a particular product from a particular country not on the Article 11 list is the responsibility of individual Member States, not the responsibility of the Commission. Member States and even regional authorities implement this provision differently with respect to the nature of the evidence that must be supplied and the length of validity of the product import authorization.

3. *Commission approval of inspection bodies in a third country (Article 11.7)*
An amendment to Council Regulation 2092/91 allows an EU Member State to assess a third country’s inspection body (certification body) and request the Commission to approve it. The Commission may approve the inspection body and add it to the Article 11 list [Council Regulation (EEC) No 2092/91, Art. 11 par.7 as amended by Commission Reg (EEC) No 1935.95, Art 1, par. 31]. The intent of this provision is to provide a mechanism under which certification organizations approved in EU countries could be approved for certifying imports from third countries into the EU.

Extent of Implementation

As of August 2003, eight countries are listed on the third country list as follows: Argentina, Australia, Costa Rica, Czech Republic, Hungary, Israel, New Zealand, Switzerland. EU and US negotiators have taken steps toward a mutual agreement for equivalency, whose realization would mean the streamlining of a large volume of organic trade. A large majority of the organic products currently imported to the EU Member

States is authorized through the provision of Article 11.6. In 2000 and 2001 over 85 countries were able to export organic products to the EU under this provision.⁸ However, there are challenges for access to EU markets under this article. The particular, implications for developing countries, which are analyzed in another discussion paper in this series, “Background Paper Concerning the EU Regulation 2092/91 - implications for developing countries and relations to WTO rules.”

Transparency

Development of detailed procedures to implement EEC 2092/91, including mechanisms for approving organic product imports into the EU is delegated to a committee of member state representatives under Article 14 of the regulation. The “Article 14 Committee,” as it has come to be known, convenes regularly. However, records of their meetings and many procedural documents are not made publicly available. While the list of third countries approved under Article 11.1 is published, there has been lack of notification of these agreements with other countries under Article 10.7 of the WTO’s Technical Barriers to Trade (TBT) Agreement, which states that “Whenever a Member has reached an agreement with any other country or countries on issues related to technical regulations, standards or conformity assessment procedures which may have a significant effect on trade, at least one Member party to the agreement shall notify other Members . . . of the products to be covered by the agreement and include a brief description of the agreement.” At the October 2002 meeting of the TBT Committee, US representatives lodged a criticism in this matter.⁹ Neither the EU process for the determination of equivalence under Article 11.1 nor that of the individual member states under article 11.6 is available as a public record. The criteria and process under which the current EU/US equivalency negotiations are structured is not publicly known.

Japan: Japanese Agricultural Standards of Organic Agricultural Products and Organic Agricultural Product Processed Foods

Mechanisms for Imports¹⁰

The Japanese organic regulations (Notifications No. 59 and 60 of the Ministry of Agriculture, Forestry and Fisheries of January 20, 2000) provide three options for the trade of organic products into Japan. *Certification by a MAFF-registered certification organization (RCO) in Japan*

1. *An RCO in Japan certifies the production/processing in the exporting country.* The certified foreign operator can affix the Organic JAS label for export to Japan. The RCO may delegate inspections to a certification body in the exporting country through a “trust contract of providing inspection data,” provided that the certification body conforms to the following requirements: 1) is recognized and

⁸ Scharpe, Alberik, “The EU Regulation”. In IFOAM, FAO, UNCTAD, 2003. The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence (ISBN 3-934-055-23-0).

⁹ The Organic Standard, Issue 21, January 2003.

¹⁰ This section is reproduced (with revisions) from the following publication: Commins, Ken, and Ong Kung Wai, “Regulation of Imports into Major Markets.” In IFOAM, FAO, UNCTAD, 2003. The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence (ISBN 3-934-055-23-0)

International Task Force on Harmonization and Equivalence in Organic Agriculture

registered as a certification body by the government of the country, the local government, or an international organization with established reliability i.e. ISO, IOAS. 2) The organisation has considerable experience as a certification body for organic foods.

2. *Certification by a MAFF registered foreign certification organization (RFCO) in the exporting country*

For registration as a RFCO, a foreign organization must have its business establishment in a country that is deemed by MAFF to have a system equivalent to that of Japan. The RFCO certifies the production in the exporting country. The certified foreign operator may affix the Organic JAS label for export to Japan. RFCOs may also certify in countries other than the country of their business establishment (excluding Japan), provided that the foreign countries are included in “the area where the certification service is carried out” at the time of applying for registration. RFCOs may also delegate inspections (conclude a trust contract of providing inspection data) to Certification bodies in other countries (excluding Japan), provided that the certification body conforms to the same requirements as listed above. RFCOs intending to do so are requested to communicate in advance with Japan’s Standards and Labeling Division.

3. *Recertification*

In this procedure, an RCO in Japan uses data obtained in past on-site inspections to certify an importer of organic ingredients destined for use as ingredients in finished products marketed as organic in Japan. Production and processing of organic raw material is certified by a certification body in the exporting country. The RCO of the Japanese importer (processor) will assess conformity to the organic JAS for organic ingredients to be used for organic processed foods. The certified Japanese processor (importer) in Japan affixes the Organic JAS label. The RCO may use data obtained from previous inspections if the inspection was carried out by an organization that meets the criteria for certification bodies listed earlier, and if the RCO judges that the data is still “effective,” i.e. applicable. Data obtained more than one year ago is not thought to be effective. If such inspection data is inadequate for certification, the RCO must perform an on-site inspection. RCOs planning to utilize such data are required to communicate in advance with the Standards and Labeling Division.

Extent of Implementation

As of September 2003, MAFF-Japan had agreements to recognize the organic regulations and conformity assessment of the following countries: Australia, the EU, and US with the Japanese regulation. There are 16 RFCOs as of August 2003¹¹. Because several options exist to create avenues for import of organic products into Japan, there are opportunities for developing countries to access Japanese markets with their organic products. The initial difficulty for foreign operators and certification bodies (in developed and developing countries alike) to understand these options appears to have eased, and now MAFF has published an extensive question and

¹¹ The Organic Standard, Vol. 28, August, 2003

International Task Force on Harmonization and Equivalence in Organic Agriculture

answer section on its website, www.maff.go.jp, which provides some detailed guidelines for the options and how to deal with them. However, the cost and burden of market access is lower in the countries that Japan recognizes under equivalency, and this could confer some competitive advantage to these countries and their exporters and producers.

Transparency

Japan has notified other WTO members of its regulations and agreements according to the provisions of Article 10.7 of the TBT Agreement, and it has translated its law and guidance documents into English. As previously stated, there is an extensive English language Question and Answer section on the MAFF website, www.maff.go.jp, along with numerous other technical criteria and guidance documents. The MAFF procedure and criteria for the establishment of the equivalency agreements is not accessible, and there are some minor but non-transparent exceptions to the equivalence agreements with the EU and the US on substances for use in organic farming.

United States: The US National Organic Program (7 CFR Part 205)¹²

Mechanisms for Imports

Currently there are three official methods for meeting the requirement for importing organic products into the United States.

1. *Direct accreditation by USDA*

Section 205.500 of the Final Rule for the National Organic Program empowers the United States Department of Agriculture (USDA) to accredit “a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.” Accreditation by USDA covers the operations of the accredited certification body worldwide, regardless of where the certification body is located. Once accredited, all certification bodies are to be treated equally, regardless of whether they are based inside or outside the US, and regardless of whether they are government or private programs. Furthermore, all accredited certification bodies are required by the Rule to accept the decisions made by all other certification bodies that are accredited or accepted by the USDA. Under the direct accreditation option, certification bodies and the operations they certify must comply with the requirements of the Organic Foods Production Act of 1990 and with the Rule in order for the products they certify to be sold in the US. The Rule covers both the technical regulation and the performance of conformance assessment.

2. *Accreditation by a foreign government*

In lieu of direct accreditation by the USDA, the USDA will accept the accreditation of a certification body by a foreign government if the USDA determines upon the request of the foreign government to recognize that

¹² This section is reproduced (with revisions) from the following publication: IFOAM, FAO, UNCTAD, 2003. *The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence* (ISBN 3-934-055-23-0)

International Task Force on Harmonization and Equivalence in Organic Agriculture

government's conformance assessment, and also that the foreign government authority assures that the certification bodies can certify the production and/or processing to meet the requirements of the Organic Foods Production Act and the Final Rule. The foreign government would need to have a program to accredit a certification body to certify to the US standards, or optionally it would have to have national standards that are essentially the same as those of the US. The certification bodies operating under this option would be "approved" but not directly accredited by the USDA. In this scenario, USDA recognizes the equivalency of a foreign government's conformance assessment system for certification bodies, but the certification those bodies perform for products exported to the US must be for compliance with the US technical standard. The USDA has approved the following four foreign government entities and their accredited organic certification bodies: Denmark, New Zealand, United Kingdom, and the Province of Quebec, Canada.

3. *Equivalency*

The third option is equivalency. Under this option, a foreign government authority that accredits a foreign certification body must operate under an equivalency agreement that is negotiated between the US and the foreign government. Certification bodies that are accredited by governments that have negotiated equivalency agreements with the US would be "approved" but not directly accredited by the USDA.

Extent of Implementation

The USDA has not completed any equivalence agreements yet, although negotiations for such are underway with the European Union, and technical assessments of the two standards have been completed. However, the USDA has directly accredited 42 foreign certification bodies (out of a total of 106 USDA accredited certification bodies).¹³ The predominant means of access to US organic markets by foreign countries is through direct accreditation.

Transparency

The USDA publishes a comprehensive list of accredited certification bodies and applicants for accreditation on its National Organic Program website, www.ams.usda.gov/nop. A Question and Answer section is also posted on the site, as are the records of the National Organic Standards Board, which advises the USDA on the organic regulation. The website includes a list of countries which the USDA is evaluating for approval and those countries with which it is engaged in equivalency discussions.¹⁴

The criteria and process for determination of foreign country approval and equivalence are not publicly available. According to the USDA, the Terms of Reference for the equivalency negotiation between the US and EU are based on the general provisions of the TBT Agreement, but there is no precedent under the TBT for establishment of equivalency.¹⁵

¹³ The Organic Standard, Volume 28, August, 2003

¹⁴ www.ams.usda.gov/nop/NOP/TradeIssues

¹⁵ Personal communication with Keith Jones USDA NOP

Inter-governmental Bodies

Codex Alimentarius

The statutes of Codex Alimentarius refer to harmonizing objectives, including the following:

- Promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.
- Finalizing standards . . . and, after acceptance by government, publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other bodies . . . wherever this is practicable.¹⁶

This paper analyzes the degree to which the Codex Alimentarius has already influenced harmonization of organic standards and conformance assessment internationally, and in this regard it primarily addresses the work of the Codex Alimentarius Committee on Food Labeling. Another paper in this series, “Existing and Potential Models and Mechanisms for Equivalence and Mutual Recognition” analyses other Codex guidelines, for their potential utility in harmonization.

Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods

Organic guidelines were developed by the Codex Alimentarius Committee on Food Labeling. They are intended to facilitate the harmonization of requirements for organic products at the international level.¹⁷ The following table lists the current status of sections of these Guidelines.

Topic	Status	Year
General Guidelines	Final	1999
Livestock	Final	2001
Criteria for Substances	Final	2003
List of Permitted Substances (revision)	Step Five	2003

Initiated in 1993, the Guidelines are consistent although not identical with the IFOAM Basic Standards, which the Committee took into account (along with the EU Regulation 2092/91) during the development processes.¹⁸

¹⁶ Statutes of the Codex Alimentarius Commission

¹⁷ Doyran, Selma, “Codex guidelines on the Production, Processing, Labeling and Marketing of Organically Produced Foods.” In IFOAM, FAO, UNCTAD, 2003. *The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence* (ISBN 3-934-055-23-0).

¹⁸ Ibid.

Influence on Harmonization

Of the regulations of the three major importing countries - the EU, Japan, and the US - only Japan has acknowledged the use of Codex as a reference in formulating its national organic standard. The MAFF regulation was developed between 1999 and 2000, and could more logically reference the Codex standards. In contrast, the development processes of the EU Regulation 2092/91 and the USDA NOP were initiated in the early 1990s.

Codex Alimentarius Guidelines and IFOAM Basic Standards: Both Codex Guidelines and IFOAM Basic Standards serve as guidance documents for the development of national and private standards. For example, India based its technical organic regulation on the IFOAM Basic Standards and Japan referenced Codex in the establishment of its regulation.

The IFOAM Basic Standards serve an additional practical function in the realm of private sector enforcement. They are the technical document upon which Certification Bodies in the IFOAM Accreditation program must base their standards in order to gain accreditation. The accreditation process includes a detailed screening of the CB's standards in comparison to the IBS. Codex Guidelines have a less clear role in the enforcement realm, although they are available for reference in case of any trade dispute centered on organic standards. No such trade disputes have been filed with the WTO.

The IBS and Codex guidelines diverge in some places, as shown by comparison documents.¹⁹ An emerging difference is in the nature of the development of lists of permitted substances of the two international standards. The Codex Alimentarius Committee on Food Labeling presents its List as "indicative" of substances used in organic systems, but there is no process for technical screening of substances at the Codex level. Countries nominating substances for the Codex List are required to demonstrate that they have evaluated the substance against the Codex criteria, but Codex does not perform a technical review. IFOAM performs a technical review of substances proposed for addition to the IBS List of substances prior to taking a decision on them.

Transparency

The process to develop Codex Guidelines is designed for transparency. In the particular case of the organic guidelines, the establishment of a Working Group within the Committee for Food Labeling has enhanced transparency of the development of the documents. The Working Group is accessible by a wide group of stakeholders who are given ample opportunity for input at sessions during the annual Committee meetings and also access to drafting groups in between meetings.

Inspection and Certification

¹⁹ Schmid, Otto, "Comparison of EU Regulations 2092/91, Codex Alimentarius Guidelines for Organic Produced Food 1999/2001, and IFOAM Basic Standards 2000. In IFOAM, FAO, UNCTAD, 2003. The Organic Guarantee System: the Need and Strategy for Harmonization and Equivalence (ISBN 3-934-055-23-0)

The Draft Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Certification Systems (1999) provide a preliminary framework for the establishment of equivalence agreements on the certification system. Recently, the draft guidelines have been withdrawn, and a discussion paper regarding the scope of Codex Guidelines in this area has been circulated for comment. At issue is whether the Equivalence Guidelines from this branch of Codex should cover only conformance assessment, or if they should also include technical regulations. Another Codex document on equivalence is the recently adopted “Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems,” but these do not apply directly to organic certification. They address food safety (sanitary) measures but some of the principles are relevant to equivalence in general, especially the recommendations concerning transparency and the consideration by importing countries of the request of exporting developing countries for technical assistance. This is a recent text and it is too early to know how it will be used by member countries.

ISO Guidelines

ISO Guide 65

Among the Guidelines published by the International Organization for Standardization is the ISO/IEC GUIDE 65:1996(E) “General requirements for bodies operating product certification systems.” This guideline has had a significant impact on the international harmonization of conformance assessment at the level of certification. This influence began when the EU Regulation 2092/91 required that inspection bodies conform to the provisions of EN 45011, an EU regulation that is almost identical to ISO Guide 65. Subsequently, IFOAM Accreditation Criteria have substantially incorporated ISO 65. The USDA Accreditation Program also references ISO Guide 65. In contrast, MAFF-Japan does not reference ISO Guide 65 in the development of its Registration Program, and criteria to become MAFF Registered bear no resemblance to the ISO Guide 65 document. ISO Guide 65 is oriented toward product certification, and not process and production method (PPM) certification, which is conducted by organic certification bodies. This has created some gaps in the practical application of ISO 65 in the organic guarantee systems.

Limitations of the Current Systems to Bring About International Harmonization

While a host of propositions regarding limitations of the current situation could be put forward for further discussion by the ITF. This paper puts forward six as follows:

1. In General, Government Systems are Not Based on a Body of Internationally Recognized Standards.

National organic standards of two of the three major importing countries were not built on a foundation of relevant international standards and common principles. This makes it more difficult to design a harmonized approach to equivalence. Only the Japanese regulation was developed at a time when it was possible to reference a well developed Codex international guideline, but the Japanese regulations have added some significantly different provisions, most notably, the “grading” requirements.

2. There are No Precedents in Government Systems for Multilateral Equivalence and Few Precedents for Bilateral Equivalence.

Mutual equivalence agreements between governments are relatively rare, even for technical product specifications where they are presumably easier to achieve than for PPM requirements. In the case of product and production methods (PPM), which are reflected in organic standards, there is no precedent for forging mutual equivalence under a common international system. Individualized, and non-harmonized bilateral processes for equivalence lack transparency and consistency. Although Codex Alimentarius has been referenced in Guidelines for Equivalency of Sanitary and Phytosanitary measures, this does not tend to translate well for the judgment of equivalence on PPM standards.

3. Government Systems Require Bilateral Equivalency

There is currently no available mechanism for negotiating multilateral equivalency. Lacking a means for multi-lateral equivalency, the number of bi-lateral equivalency agreements required to achieve equitable global harmonization is very high. If there are 56 countries with regulations, this could mean over 3000 equivalency agreements. Codex Alimentarius organic guidelines (standards) are now established and both Codex Guidelines and IFOAM Basic Standards could serve as a harmonizing baseline for equivalency negotiations.

4. Existing and Pending Government Determinations of Equivalency are Not Transparent

Lack of transparency relative to the criteria and processes for establishing existing and pending equivalency agreements is a barrier to creating broader harmonization. Furthermore, non-transparent equivalency determinations may not withstand the scrutiny of trade rules.

5. The Private International System has a Mechanism for Multilateral Equivalency, but is not Integrated into the Government Regulatory System.

The IFOAM Organic Guarantee System is based on a visible international organic standard and an ISO-based conformance assessment system. However this private system is voluntary, and does not guarantee organic process and production methods to the level of any mandatory government regulation. This has limited the potential of the system to formally facilitate trade, although it has informally facilitated a lot of trade, particularly for third country imports into the EU under Article 11.6,

6. The Private International System Does Not Entirely Reconcile Equivalency.

The need and ability of certification bodies to maintain “additional requirements” within the Multilateral Agreement means that functional equivalency is not completely achieved in cases where additional requirements are specified. Also, the current system still requires bi-lateral arrangements between certification bodies that create inertia in the implementation of these systems of recognition.

Conclusions

International Trade of organic products in the context of multiple regulations is cobbled together and working on a basic level. Many exporters have a mechanism (given a particular export opportunity) to gain import authorizations in a destination country. All three of the major regulations provide at least three options for exporters to comply with import requirements for organic products. However, the current system is inefficient and some producers undoubtedly face insurmountable obstacles to some international markets because of the high cost of compliance with the organic regulations. The long term stability of the current systems is also questionable in the face of rapid growth of organic markets and opportunities worldwide. A few unilateral equivalency arrangements have been reached between governments, but generally these agreements lack transparency. Bilateral mechanisms are not an efficient means to achieve true international harmonization. A more efficient model of multilateral international equivalence is found in the private international Organic Guarantee System, but true equivalency through this system is not completely realized due to elements of system design such as allowing for additional standards requirements; and also this private system is not integrated in any formal way into the government regulatory systems. Clarification of the respective roles of the IFOAM Basic Standards and the Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods could be useful to future harmonization efforts in the area of technical standards.