



Food and Agriculture
Organization of the
United Nations



International Federation
of Organic Agriculture
Movements



United Nations Conference
on Trade and Development

INTERNATIONAL TASK FORCE ON HARMONIZATION AND EQUIVALENCE IN ORGANIC AGRICULTURE

Common Objectives of Organic Standards Systems

September 2006

Draft

Prepared by Jane Earley, LLC
1101 King Street, Suite 444
Alexandria, Virginia 22314
U.S.A

Secretariat:
Diane Bowen Secretary
d.bowen@ifoam.org
phone +1 414 352 5789
fax +1 253 669 7921

Matthias Fecht Coordinator
m.fecht@ifoam.org
phone +49 228 926 5018
fax +49 228 926 5099

Table of Contents

Introduction	3
Glossary.....	6
Common Organic Objectives	7
Recommendations	20
Details, Details	21
Venues.....	22

Introduction

A report prepared by this author for the Task Force on Organic Standards Harmonization in October of 2005¹ focused on common objectives in organic programs, and divided those objectives into several categories:

- guiding principles, or the formally articulated reasons for creating the program, most often expressed in lofty language relating to social or environmental goals.
- programmatic objectives, which establish the context within which more specific guidance is given to producers and information transmitted to consumers, and
- objectives of the programs aimed at the two important audiences for organic certification systems, producers and consumers, which include objectives relating to environment and production and those relating to value chain, consumption and trade.

For the purposes of this report, the basic objectives can be combined into one category, expressed as “common organic objectives.” For the most part, these will include the guiding principles, values and programmatic objectives as they are expressed through, and underline, the more detailed program guidance.

This report is intended to follow on the previous one, essentially summarizing and comparing organic objectives, proposing a set of common organic objectives and exploring how they might be more formally identified. The report, while drawing on the former one, also references more current versions of some of the documents in which organic objectives are articulated. The specific standards documents referenced for this report are described below. Others to which the author has referred or used as the basis for observations, are contained in the bibliography.

In addition to new standards documents that have emerged since the last report, other changes have occurred in the regulatory environment since the date of the last report. The US government has added a proposed regulation on equivalency to the USNOP. The Codex Alimentarius Committee on Food Import and Export Inspection and Certification systems has issued a document for discussion described as a Proposed Draft Appendix to the Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems,” and other discussions have taken place in relevant international fora that could affect the outcome of the effort to harmonize organic standards.

The texts considered for this exercise include the following, but the standards of the latter two organizations are referenced only where substantially different from other organizations.

EU - Council regulation (EC) no. 2092/91 attempts to set forth a framework for organic production across the 25 EU Member States, in effect harmonizing organic production and certification systems within the EC. This requires that each Member State establish a competent authority to implement the regulation. It does not eliminate the many national organic production and certification systems that preceded it. The regulation is available as

¹ Earley, Jane, (2005) “*Objectives of Organic Standards Programs: Exploring Approaches to Common Regulatory Objectives*,” for the International Task Force on Harmonisation and Equivalence in Organic Agriculture

Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 22.7.1991, p. 1). However, this regulation, while in force, is dated in many respects, and new efforts that have been made to revise it have produced a draft for consideration by the Council of the European Union (Inter-institutional file: 2005/0278 (CNS), Brussels, 28 June 2006, 10782/06). This paper uses the draft for the purposes of comparison rather than the original regulation.

JAS – The Japanese Organic Standards program was initiated by administrative regulation of the Ministry of Agriculture, Forestry and Fisheries in 2000. It is implemented under a law enacted in 1950 and ordinances promulgated in 1951 governing labeling and standardization of agricultural products. It is available from the website at <http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html>. It has granted equivalency to the US NOP. Changes to the regulation were notified to the WTO in 2005. A 2005 Notification (Notification No. 1608 of the Ministry of Agriculture, Forestry and fisheries of October 27, 2005) defines criteria of production methods for organic livestock products.

US – The US NOP, or National Organic Program, was implemented by a “final rule” in 2003 pursuant to legislation enacted by the US Congress in 1990. The many years between the original date of enactment and the final rule allowed significant stakeholder input and debate on the final rule, which is available at <http://www.ams.usda.gov/nop/NOP/standards.html>. The original 1990 legislation is available at <http://www.ams.usda.gov/nop/archive/OFPA.html>. Several countries have applied for equivalency determinations but none has yet been granted.

OFDC – The Organic Food Development Center of China is part of its State Environmental Protection Administration. Established in 1994, it has implemented the largest organic certification program in China. Its standards, based on the IFOAM Norms, are available at http://www.ofdc.org.cn/index_en.htm. This has since been superseded by publication of an official “National Standard of the People’s Republic of China.” This has been used as the basis for this paper. This is described as GB/T 19630.1 – 19630.4-2005

IFOAM – The International Federation of Organic Agriculture Movements is the oldest – and arguably the only – private sector global standards and verification program for organic foods. Initiated in 1972, well before most governments recognized the need for an organic certification program, it set the standard for organic standards in many countries. Its system is now the basis for harmonization of many divergent standards systems worldwide. The IFOAM norms are available and can be downloaded from the IFOAM website at <http://shop.ifoam.org/bookstore>. For the purposes of this paper, the author has been allowed access to a comparison of the IFOAM norms to the IBS. This is a document that is not yet publicly available.

Codex Alimentarius Commission – The Codex Alimentarius Commission is an international standards-setting body for food and food products jointly run by the UN Food and Agriculture Organization and the World Health Organization. As such, it is recognized as a standardizing body by the World Trade Organization’s Agreement on the Application of Sanitary and Phytosanitary Measures. WTO Member governments are required by the Agreement to base their standards on international standards, including those of the Codex Alimentarius (the body of standards). Its Organic Food Standards are available at http://www.codexalimentarius.net/web/index_en.jsp.

Soil Association – The Soil Association is arguably one of the world’s first environmental non-governmental organizations, and was one of the first national bodies to generate organic standards, as it was founded in 1946 by “a group of farmers, scientists and nutritionists who observed a direct connection between farming practice and plant, animal, human and environmental health.” Its standards are available at <http://www.soilassociation.org/web/sacert/sacertweb.nsf/B4/index.html>.

OTA – The Organic Trade Association, based in the United States, administers the American Organic Standards. These standards predate the NOP and in their newest iteration attempt to provide a baseline for North American organic standards and serve as a basis for harmonization. The 2003 version is available at <http://www.ota.com/pics/documents/AOS032003.pdf>. This discussion is based on proposed 2005 revisions.

Glossary

All terms in this paper are meant to be consistent with this Glossary, which has been created by the International Task Force on Harmonization and Equivalence in Organic Agriculture

Term	Definition	Reference	Comment
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 labeling requirements as they apply to a product, process or production method.	WTO/TBT	<u>Note:</u> The recognized body can be any constituency.
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.	WTO/TBT	<u>Note:</u> technical regulations can refer to, or be based on, standards.
Conformity Assessment	Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.	ISO	
Requirements for Conformity Assessment	Any procedure or criteria used directly or indirectly to determine that the relevant technical regulations or standards are fulfilled.	ISO modified	This could include requirements on the body itself.
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.	WTO modified (WTO defines “harmonized standards”)	
Equivalence	The acceptance that different standards or technical regulations on the same subject fulfil common objectives.	ITF	
Recognition	Arrangement (either unilateral, bilateral, or multilateral) for the use or acceptance of results of conformity assessments.	ISO Modified	

Common Organic Objectives

There is no formal text laying out the common organic objectives, but from a reading of the current standards and their rationales they could be boiled down to a fairly basic set of production-related factors. These include:

- Protecting and enhancing soil quality
- Minimizing or avoiding use of synthetic chemical fertilizers, pesticides and fungicides
- Protecting and enhancing biodiversity
- Avoiding pollution
- Responsible use of other resources (e.g., soil water and air)
- Responsible treatment of farm animals
- Prohibiting use of other technologies (biotechnology and irradiation),
- Planning for (management plan) organic production,
- Verifying (certifying to) all of the above (this includes use of organic seeds, auditing, traceability of products and labeling for the market), and
- Maintaining the organic integrity of the processing systems used for organically produced products

This is, of course, a very simplistic list and it could be supplemented by many additional “objectives.” For instance, respect for natural systems, ecological balance and other kinds of philosophical and visionary objectives are an integral part of organic objectives. But tying them to specific principles and criteria is difficult, and they are also well-represented in the more specific directives under which organic production takes place. Likewise, there are in many systems provisions calling for respect for farm workers and attention to social conditions. While these are very important to the functioning of organic systems, they are also taken up by other systems and so are not unique to them. For this reason, they have not been highlighted as “organic” objectives.

The following discussion explores how each of the above objectives is expressed in the most important national systems and IFOAM, both in text and in matrix form, and concludes with a recommendation on how each might be more formally identified; in essence, prospects for progressing multilateral agreement on the objective in an appropriate venue.

1. Protecting and enhancing soil quality

Of all of the common organic objectives, this is perhaps the most important from an historical point of view, since it was the advent of synthetic fertilizers that drew early proponents of organic systems to maximize soil quality considerations. This has been expanded by many systems to include ecosystem conservation and broader environmental goals, but the basic objective and the one most frequently articulated is the one that pertains to soil.

IFOAM	2.2	..”The objective [are] to conserve and improve the living soil. Standards must require the return to the soil of residual nutrients, organic material and other natural by-products of the operation, prevention of land degradation including as applicable, erosion, salinization, grazing management and land preparation techniques
	4.3	Soil and soil management is the foundation of organic production, Organic growing systems are soil-based, care for the soil and surrounding ecosystems and provide

		support for a diversity of species, while encouraging nutrient cycling and mitigating soil and nutrient losses.
EU	Article 3	to establish a sustainable management system for agriculture that: (i) respects nature’s systems and cycles and sustains and enhances the health of soil, water, plants and animals... (iii) makes responsible use of the natural resources, such as water, soil, organic matter and air
US	205.203	“The producer must manage soil fertility to maintain or improve the physical, chemical and biological condition of soil and minimize soil erosion...” (see guidelines for implementing these objectives at http://www.attra.org/attra-pub/summaries/organic_soil.html)
JAS	Article 2	“sustain and enhance the natural recycling in agriculture, the productivity of the farmland derived from the soil properties shall be generated...and the organic agricultural products shall be produced in fields adopting such cultivation management method as reducing the load derived from the agricultural production on the environment as much as possible..”
CODEX	FWD 7(a) Annex 1	“An organic production system is designed to .(b) increase soil biological activity; (c) maintain long-term soil fertility. “ “The fertility and biological activity of the soil should be maintained or increased, where appropriate, by...”
China	4.2.3	“Practices of recycle, regeneration and supplementing of soil organic matters and nutrients shall be adopted to compensate soil organic matters and nutrients that have been taken away by harvesting”

Generally, the soil quality objective, while articulated differently in each text, is also integrated in different ways among the programs. For instance, the new EU text first mentions it in the context of establishing a sustainable management system for agriculture (Article 3), then as a principle applicable to farming (Article 5, sub(a)), and then more extensively in a number of “Plant production rules” in Article 8 which require, among other practices, “cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity and prevent soil compaction and soil erosion,” and use of approved soil conditioners (sub. c). The latter requires use of a list of approved substances.

In contrast, the CAC Guidelines establish soil considerations as a fundamental aspect of organic production systems (Forward, sub 7), and then proceed to require specific criteria for listing of approved soil conditioners (Section 4).

A more specific approach is taken by China’s Guidelines, which list as “Normative References” an “Environmental quality standard for soils,” (Part 1, section 2), and effectively require organic soil quality to meet Grade II Standards (GB 15618-1995). The OFDC text deals with “soil and fertilizers management” in Section 4.2.3, requiring recycling, other practices to maintain and improve soil fertility, defining organic fertilizers and prohibiting use of certain substances.

These examples illustrate how the subject is dealt with in different systems, but the differences in structure do not defeat the unity of purpose. Soil quality is essential to all of the organic production system standards, and it is to be maintained and improved by the use of organic material, recycling, and the use of approved materials. There are some differences of preference (sewage sludge, mineral fertilizers, etc.) and also some regional differences (e.g., Chilean nitrate) in whether particular materials are to be allowed but the objective is generally upheld throughout each system.

2. Minimizing or avoiding use of synthetic chemical fertilizers, pesticides and fungicides (inputs)

This objective is deeply embedded in every organic agriculture production program, not just as it relates to soil conservation and enrichment, but as it relates to water effluent, and concerns about the adverse environmental and health effects of chemical fertilizers, pesticides and fungicides. It derives historically from an aversion to the chemical nitrogen fertilizers developed post WWII which replaced more organic methods, but has grown to encompass scrutiny of and preference for a number of techniques and products whose use is considered to be consistent with organic production principles, with a corresponding list of substances that are prohibited. This objective also extends into the processing arena, where most systems specify in some detail which processing aids and other inputs are permitted.

It is also premised on the concept of ecosystem balance: with an organic approach to agricultural production, inputs from outside the system will naturally be minimized and the health of the system and its inhabitants enhanced.

Every system qualifies the ability of producers to use inputs somewhat differently. Most require producers to avoid the use of generally referenced chemical fertilizers, pesticides and fungicides, and to use instead ones that have been specifically approved, but every system also has exceptions and defines the list of approved substances somewhat differently. However, there is on balance more agreement than disagreement, which should facilitate general consensus on the use of inputs if exceptions are allowed for some specific substances.

IFOAM	IBS 4.3	“practice crop rotation and avoid the use of fertilizers and pesticides that may have adverse health effects”
EU	Art. 4	“(b) restricting the use of external inputs of any type. Where they are required they are limited to (i) inputs from other organic production systems: (ii) natural or naturally-derived substances; (iii) low solubility mineral fertilizers, (c) unless the use is justified for specific environmental reasons, strictly limiting the use of chemically synthesized inputs to the following exceptional cases...”
US	205.206	..the producer must use management practices to prevent crop pests, weeds and diseases including but not limited to ...pest problems may be controlled through mechanical or physical methods...
JAS	Article 4	allowed to use specified agricultural chemicals, and prohibited from using others; preference for mechanical means of control, planning to avoid emergence of noxious animals and plants
CODEX	2.1	Pest and disease management is attained by means of the encouragement of a balanced host/predator relationship, augmentation of beneficial insect populations, biological and cultural control and mechanical removal of pests and affected plant parts. Permitted substance list maintained.
China	4.2.4	Disease, pest and weed control shall be based on the basic principles of holistic approaches for crop-disease ecosystem where control measures are integrated and taken to create environmental conditions that are against the propagation of diseases and pests and growth of weeds, but favorable to the multiplication of natural enemies with the aim of maintaining the balance and biodiversity of agroecosystem, and mitigation of the losses from various disease, pest and weed strikes.... If materials used are not listed in Annex B, they shall be evaluated by certification body in accordance with the guidelines of Annex D.

3. Protecting and enhancing biodiversity

This objective is articulated as such in most of the recent standards documents, less so in the older texts. In some it is subsumed into a more general objective of sustainable production or environmental protection: in others, it is associated with particular requirements as well

as general ones (soil health, for instance). Regardless of its treatment, it is fundamental to organic production systems that they preserve biodiversity, since that factor alone is in many places what is thought to separate organic systems from industrial, conventional, monocropped agricultural production systems. This is not to say that organic production cannot also assume a scale that might belie its commitment to this objective. The objective itself is fundamental even if it is not in some places obviously articulated.

IFOAM	2.1 IBS	The objective is that ecosystem management maintains, improves and closes ecological cycles, it facilitates biodiversity and it protects and conserves landscape
	2.1 IFOAM	Operators should maintain a significant portion of their farms to facilitate biodiversity and nature conservation. A farm should place appropriate areas under its management in wildlife refuge habitat. These include: a. extensive grassland such as moorlands, reed land or dry land; b. in general all areas which are not under rotation and are not heavily manured: extensive pastures, meadows, extensive grassland, extensive orchards, hedges, hedgerows, edges between agriculture and forest land, groups of trees and/or bushes, and forest and woodland; c. ecologically rich fallow land or arable land; d. ecologically diversified (extensive) field margins; e. waterways, pools, springs, ditches, floodplains, wetlands, swamps and other water rich areas which are not used for intensive agriculture or aquaculture production; f. areas with ruderal flora; g. wildlife corridors that provide linkages and connectivity to native habitat
	2.1.1	Operators shall take measures to maintain and improve landscape and enhance biodiversity quality
EU	Art. 3 (a)(ii)	Organic production shall...establish a sustainable management system for agriculture that...contributes to a high level of biodiversity
US	Definitions	<u>Organic production.</u> A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity
JAS	Art. 2.2	Does not use the word but refers to “preserving the ecosystem” (of collection fields)
CODEX	Art. 7, Sec. B 2 (c)	Organic agriculture is a holistic production management system which promotes and enhances agroecosystem health, including biodiversity, biological cycles, and soil biological activity...(and re livestock production, the objective is enhancing biodiversity and facilitating complementary interactions on the farm)
China	4.2.6	Priority shall be given to protect ecological environment and biodiversity.

It is easy to see how the organic production method in general might be seen as protecting biodiversity, but difficult to point to any particular provision that specifically supports it. Certainly, not using chemical substances that might harm biodiversity is a priority, but effect on biodiversity as such does not appear to be a criterion for listing decision for substances whose use is controlled in organic production system standards. Indeed, it is hard to point to any particular set of requirements specifically aimed at protecting biodiversity, other than general inclusion of the word in relation to soil cultivation practices. IFOAM goes about as far as any standard here, requiring in the *aquatic* context that “Production should maintain the aquatic environment and surrounding aquatic and terrestrial ecosystem, by using a combination of production practices that...provides for biodiversity through polyculture and maintenance of riparian buffers with adequate plant cover.” (9.2, Aquatic Ecosystems).

Buffer zones are also generally required to separate land farmed organically from land farmed conventionally in most systems, but this is at least as much related to the verification objective as it is to protection of biodiversity. And it could be argued that the prohibition of GMO materials and techniques actually serves to reduce biodiversity, since it would add

new genes to the environment (of course, the effect of these genes on biodiversity is a debate topic that has not been resolved to the satisfaction of anyone in the field).

Indeed, even when biodiversity is lumped into environmental, or ecosystem protection, there are few actual practices that are advocated for that purpose alone in organic production system requirements. Happily, this is an area where work is being done to make environmental system requirements more clearly articulated and specific to organic production processes. But for now, while biodiversity protection is a general shared goal of most of the organic production systems covered here, it is not specifically endowed with actual standards.

4. Avoiding pollution or damage to the environment (and human health?)

As the converse of protecting or enhancing the natural environment, avoiding pollution is also a theme, or objective, that is very evident in organic standards systems, sometimes in general terms and often with respect to a specific concern.

IFOAM	2.2 2.4.3	<p>Organic processors and handlers should install systems that permit the responsible use and recycling of water without pollution or contamination either by chemicals, or by animal or human pathogens</p> <p>The collection or harvest area shall be at an appropriate distance from conventional farming, pollution and contamination.</p> <p>Avoiding contamination: All relevant measures are taken to ensure that organic soil and food is protected from contamination....Operators should take reasonable measures to identify and avoid potential contamination.</p> <p>In case of risk, or reasonable suspicion of risk that contamination may occur, the standard-setting organization should set limits for the maximum application levels of heavy metals and other pollutants.</p> <p>The standards should place emphasis on detection of contamination sources, improvement of the production system taking into account the procedures developed for HACCP, and the assessment of background contamination levels.</p> <p>Accumulation of heavy metals and other pollutants should be limited and the appropriate remedial measures implemented where possible.</p> <p>The standards should establish parameters for the acceptance/rejection of organic products based on analysis.</p> <p>The standards should establish a procedure on how to evaluate organic products in case of reasonable suspicion of pollution based on due expert consideration and the precautionary principle.</p> <p>Contamination that results from circumstances beyond the control of the operation does not necessarily alter the organic status of the operation.</p>
	IBS	<p>Standards will ensure that operators take measures to prevent pollution, and otherwise preserve water quality.</p> <p>Organic agriculture should be managed in a precautionary and responsible manner. The objective is to ensure that organic production is conducted in a manner that seeks to maintain the integrity of the product by avoiding contamination through precautionary practice. This objective does not imply that organic producers are responsible in anyway for drift from external practices outside of the control of the operator....</p>
EU	Art. 3© Art. 4 Art. 5 Art. 8 Art. 11.2, .4	<p>...aim at producing a wide variety of foods...that responds to consumers' demand for goods produced by use of processes and substances that do not harm the environment, plant health or animal health and welfare.</p> <p>..methods based on risk assessment, precautionary and preventive measures..</p> <p>..taking account of the local or regional ecological balance when taking production decisions</p> <p>all plant production techniques used shall prevent or minimize any contribution to contamination of the environment</p> <p>their use (of substances) does not result in unacceptable effects on the environment or contribute to the contamination thereof and; their use has the lowest negative impact on</p>

		human, animal or plant health.
US	205.2 205.207 205.600	<u>Nontoxic</u> . Not known to cause any adverse physiological effects in animals, plants, humans, or the environment. A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment ..The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
JAS		no mention of either pollution or environment
CODEX	Art. 6, Art. 7	Organic agriculture is based on minimizing the use of external inputs, avoiding the use of synthetic fertilizers and pesticides. Organic agriculture practices cannot ensure that products are completely free of residues, due to general environmental pollution. However, methods are used to minimize pollution of air, soil and water....promote the healthy use of soil, water and air as well as minimize all forms of pollution thereto that may result from agricultural practices;
China	4.1.3 D.1.2.3	Organic production shall be carried out under appropriate environment conditions. Organic production bases shall be located far away from urban centers, industrial and mining areas, main and auxiliary transportation lines, industrial pollution source, as well as living waste sites, etc If organic production area is possibly affected by the pollution from neighboring conventional production areas, buffer zones or physical barriers shall be established between organic and conventional production areas so as to prevent the prohibited materials drifting from conventional production areas and ensure organic production areas free from pollution If any suspicion of fertilizer pollution exists, tests shall be conducted to analyze heavy metals or other pollutants before its application Reliable experimental data may prove that the use of the materials shall not lead to or cause unacceptable influences or pollution on the environment.

The wide divergence in treatment of this objective is perhaps a result of the rapid growth of consumer health and safety concerns in the food sector generally, not just as they may pertain to organic foods. It is clear the older systems do not recognize the need to avoid pollution in the context of organic food systems even though they might endeavor to enhance environmental protection, while the newer ones both recognize the intensity of pollution in the producing environment and seek to isolate organic systems from it, and also seek to ensure that organic products meet recognized health and safety, as well as environmental, standards. IFOAM is the clear leader in articulating the need for health and safety systems, but perhaps this is because national regulatory systems have other legislation or regulation on the books to deal with human health concerns. China is the clear leader in attempting to ensure that organic production systems are not built on top of existing polluting disasters.

There are two issues here: whether organic standards systems ought to address either, or both environmental and human health and safety concerns, and whether and to what extent they can live with existing environmental and agrochemical pollution. Clearly, both issues are evident to consumers – yet they are not explicitly dealt with by most systems. The growth of assurance systems focused on health-related concerns – such as Eurepgap and IQS – may at some point cause the public to focus on the relative lack of symmetry in organic systems.

This may be a good time to focus on how organic systems explicitly contribute to meeting health and safety concerns in terms of a common objective. Articulating what they do as an objective, rather than leaving implicit the fact that lower pesticide levels, for instance, contribute to consumer health, might serve the organic movement well. On the other hand, integrating specific health-related objectives into organic standards might be a daunting task

that even proponents might wish to leave to regulatory authorities and to other programs. Few organic standards programs presently articulate specific health-related objectives, either in an environmental or human health context, although they commonly require sanitary practices, particularly in processing.

Standards relating to existing pollution may be easier to deal with because assumptions of environmental and human health attributes of organic food production may be more important to sustain in an increasingly polluted growing environment. This is implicitly acknowledged in the “subtext” of the USNOP, and increasingly a subject of concern in areas where biotech crops or government-led spraying or propagation programs, are common. This may be an area in which it would be good to have explicit agreement on the common objective of avoiding existing pollution, as well as an opportunity to explore the extent to which organic production methods need to adapt to new requirements and expectations.

It may also be an opportunity to address as a common objective avoiding pollution and other environmentally damaging practices (conversion of native prairie, for example) on an ecosystem basis rather than at the level of a particular farm. While this is not an objective expressly articulated very often, it probably deserves more attention.

5. Responsible use of other resources (e.g., soil, water, air)

Every system has some provision for responsible use of resources, some focusing on renewables and some on more specific practices with respect to fertilizer and water use, etc. While some systems articulate this in general terms, others, such as China’s are very specific. With the exception of China’s requirements, which are aimed at ensuring that organic production must meet current standards, none specify actual metrically-measurable standards for dealing with other resources that are unique to organic systems.

Granted, the national systems do not have to replicate already existing legislation covering agricultural operations in general. But it is worth noting that these systems, by failing to specify higher standards for organic production, allow organic production to replicate many of the kinds of agricultural operations that have attracted adverse attention because of their poor environmental practices, such as feedlots that contribute huge nutrient loads to rivers and streams. It is also worth noting here that many organic systems fail to include the basic “conformity with local law provisions” of other standards and certification systems. This is perhaps because other laws are considered less relevant to organic operations, and perhaps because organic production is for the most part assumed to exceed base requirements of local laws governing water and air pollution. However, it would not hurt organic systems to achieve explicit agreement both on the objective of responsible use of natural resources and some explicit measures for accomplishing it, even if this simply reiterates the obligation to comply with governing legal provisions.

IFOAM	IBS	<ul style="list-style-type: none"> • the return to the soil of residual nutrients, organic material and other natural by-products of the operation prevention of land degradation including as applicable, erosion, salinization, grazing management, and land preparation techniques. • that water use does not excessively exploit and deplete water resources, • measures to prevent pollution, and otherwise preserve water quality.
	2.1	Organic farming methods conserve and grow soil, maintain water quality and use water efficiently and responsibly
EU	3	makes responsible use of the natural resources, such as water, soil, organic matter and air

US	Def. 205.200	<u>Natural resources of the operation.</u> The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife. Production practices...must maintain or improve the natural resources of the operation, including soil and water quality
JAS		no specific language
CODEX	Fwd 7	...An organic agricultural system is designed to :.. d) recycle wastes of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources, e) rely on renewable resources in locally organized agricultural systems; f) promote the healthy use of soil, water and air as well as minimize all forms of pollution..
China	4.1.2	Environmental Requirements for the Production Base. Environmental quality of the organic production base shall meet the following requirements:..(b) Irrigation water quality shall meet the requirements of GB 5084. (c) Ambient air quality shall meet Grade II standard of GB 3095-1996 and the requirements of GB 9137.

6. Responsible treatment of farm animals

Principles for organic livestock could be among the most controversial of any of the organic objectives because there is significant and well-known divergence and detail in many of the areas in which these standards are implemented. With the advent of technologically sophisticated breeding and feeding operations, and with the spread of veterinary techniques supportive of global livestock trade, this area has mushroomed in importance in the last decade, as have public concerns about the health and safety consequences of many of these techniques. Efforts to address this diversity and complexity have led to a number of divergent approaches, particularly where organic systems have effectively met the challenge of countering industrial livestock production.

There is general agreement on the basic tenets of organic animal husbandry. These include, at their most general level,

- Selection of breeds to be used
- Use of organically-bred stock
- Use of defined organic feed and other inputs, including in processing
- Disallowance of defined non-organic breeding methods and specific pest and disease treatments
- Identity preservation of organically produced animals through their life cycles and processing (including conversion, traceability, etc.)
- Living conditions that conform to organic principles (free-range, tethering)
- Humane husbandry, transport and slaughter

But there are many, many other objectives that could be listed, since regulations affecting livestock seem to proceed immediately to a level of detail not articulated in other areas. These include stocking densities, prohibition of GMO's in animal feed, colostrum and milk for young mammals, air quality and ventilation system design, etc.

A recent paper by Lockeretz and Merrigan² tracks this detail in a comparative study of most of the systems included here and also includes some non-organic standards. This paper will not replicate their findings. However, for the purposes of adding to their comparison, the matrix below illustrates where the new EU text, the Chinese program and the Japanese standards stand on the areas listed above.

² need approval to cite?

Objective	EU	China	Japan
Selection of breeds	Appropriate breeds shall be chosen – choice shall also “contribute to the prevention of any suffering and to avoiding need for mutilation..”	Breeds selected for “high adaptability and strong disease resistance considering local conditions”	Disease should be prevented “through appropriate husbandry practices.”
Use of organically-bred stock	Organic livestock shall be born and raised on organic holdings	Organically reared livestock and poultry shall be introduced (defined conversion periods)	Domestic animals shall be bred from mothers raised organically
Defined organic feed and other inputs	Livestock shall be fed with organic feed that meets the animal’s nutritional requirements at the various stages of its development. Non-organic feed materials..certain products used in animal nutrition and processing aids shall be used only if they have been approved..growth promoters and synthetic amino acids shall not be used	Livestock and poultry shall be fed on organically produced feedstuffs (some convention feed also allowed under defined conditions). Ruminants shall be guaranteed with roughage to satisfy their daily nutritional demand. Feed additives allowed if listed, specific products prohibited.	Feeds other than 1) Organic feeds and feeds produced in house for organic livestock..2) natural substances or the substances derived from natural substances..., and 3) silkworm pupae, if less than 5% in dry weight) shall not be provided
Disallowance of defined non-organic breeding methods and specific pest and disease treatments	Reproduction shall be by natural methods..not induced by hormone treatment..cloning and embryo transfer shall not be used. Chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary (limited use defined)	Reproduction based on natural methods (no hormone treatment), plus other methods (artificial insemination) if they do not affect genetic diversity (cloning, embryo transfer). Allowed substances for disease treatment are listed, use of antibiotics and chemically synthesized medicines for preventive treatment prohibited.	Breeding methods disallowed. Veterinary drugs prohibited, with exceptions except where required by law or where no alternative exists. Prescribed drugs and antibiotics not allowed except when no alternative. Likewise, no growth stimulants allowed.
Identity preservation of organically produced animals through their life cycles and processing (including conversion, traceability, etc..)	Animals on the holding may be deemed organic after a specific period..organic livestock shall be kept separate from other livestock.. production of processed organic food and feed shall be kept separate in time or space from production of non-organic processed feed..	Parallel production allowed but livestock must be kept separated. Conversion measures specified. The main feed ingredients from agricultural origin in compound feeds shall be organically certified. Livestock ..clearly marked so as to be identified at all stages of loading, transportation...	Organic livestock products should be managed so as not to be mixed with livestock products which are not produced in compliance with the criteria of (the regulation..).
Living conditions that conform to organic principles (free-range, tethering)	Appropriate stocking densities required, livestock shall have permanent access to outdoors.. tethering prohibited	Stocking densities required to avoid adverse environmental impacts, and conditions shall meet the livestock’s biological and ethological needs, provide for adequate movement in space and time, good ventilation, sunshine, drinking water meeting specifications, access to outdoors	Housing conditions specifically prescribed, including size of area, sanitary equipment, appropriate temperature, ventilation and bright sunlight, access to feed and fresh water, ...
Humane	Duration of transport	Feeding by force is prohibited,	no electric stimulation

husbandry, transport and slaughter	minimized, suffering kept to a minimum	conditions for humane transport and slaughter specified in some detail	and tranquilizers, slaughter to minimize stress and suffering
------------------------------------	--	--	---

7. Prohibiting use of other technologies (biotechnology and irradiation),

No matrix is needed for this requirement because it universally applied. The EU chooses to “exclude the use of ionising radiation for treatment of organic products or their ingredients..and exclude the use of GMOs,” and also to exclude “rearing artificially induced polyploid animals.” Further, “reproduction shall not be induced by hormone treatment, unless in order to treat reproduction disorders; (iii) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used. This is fairly standard language in most of the texts, except that it appears in different parts of the standard. The intent is clear. However, the objective as articulated is not, since each time a new technology appears it must be added to the list. It might be more effectively, and permanently, articulated as a requirement for “natural” breeding methods (scientifically defined) rather than as a prohibition on other kinds.

8. Planning for (management plan) for organic production

Management is as integral to organic systems as it is to ISO’s Environmental Management standards family, if not more so. Management drives the organic production system, because without careful seed and crop selection, crop rotation and use of organic techniques and inputs, the system cannot produce benefits. A lot of study has gone into organic management systems and almost every system explicitly requires organic operators to have a management plan. This also extends to processing and handling. Whether the plan must be formally submitted for approval, and what it must contain, are requirements that vary from system to system. In terms of process, this should be an objective that every organic system can agree.

IFOAM	3.1	Conversion Requirements. “there should be a clear plan to proceed with the conversion.. The plan should be updated as necessary and cover all aspects relevant to these standards.”
EU	Art. 3	(a) to establish a sustainable management system for agriculture
US	205.201	The producer..must develop an organic production or handling system plan...
JAS	Ch. titles	General management. Management concerning transportation , selection, processing, cleaning, storage, packaging, and other processes
CODEX	Fwd, 7 9	Organic agriculture is a holistic production management system... It emphasizes use of management practices in preference to the use of off-farm inputs. An integral component of certification is the inspection of the organic management system. Procedures for operator certification are based primarily on a yearly description of the agricultural enterprise as prepared by the operator in cooperation with the inspection body. Likewise, at the processing level...
China	4.1.2	Organic producers, processors and handlers shall develop and maintain management system for organic production, processing and handling activities according to the requirements set forth in GB/T 19630.1 ~ GB/T 19630.3. The management system shall develop documents required in 4.2 of this part and shall be implemented and maintained.

9. Verifying all of the above (This includes use of organic seeds, auditing, traceability of products and labelling for the market.)

Although some may prefer to separate these areas into different objectives, they are all joined in one unifying principle: organic plants and animals must be identifiable as such.

Unlike other products in trade that may be identified by appearance or content or by marks applied at some stage of processing to delineate sometimes subtle physical differences in weight or appearance, organic plants and animals are identified by origin alone. Origin is not visible either to the consumer or to the customs inspector. Therefore, credible and sometimes elaborate systems of segregation must be created and enforced. This extends from sources of organic crops and animals (seeds, breeding stock) to their ultimate destination (labeling at consumer level) and points in between (conversion from conventional to organic, and auditing and verification systems that check or confirm adherence to organic production practices). Moreover, this is generally not just a common objective but a common regulatory objective in which the organic production industry is united with government or other regulatory authorities to enforce a common set of standards for their mutual benefit.

The matrix below does not attempt to do a side-by-side comparison of all of the rules and regulations in this area. This has been done by others, and reference material is readily available on comparative rules affecting production and use of organic seed and breeding stock, conversion periods and labelling requirements. Rather it illustrates how rules in each of these different sectors underscore the common objective: verification of organic identity.

IFOAM	IBS 7	Organic agriculture is intended to produce high quality, organic products that contributes to preventive health care and well-being. Labelling provides transparency, trust and defines organic quality. The objective is to guarantee clear identification and proper labeling of what can be considered organic products Only products that have been subject to a recognized control scheme throughout the production and preparation process shall be labeled as such.
EU		Where, in accordance with the second subparagraph, not all units of a farm are used for organic production, the farmer shall keep the land, animals, and products used for, or produced by, the organic units separate from those used for, or produced by, the non-organic units and keep adequate records to show the separation. ...only organically produced seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons.
US		(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching;
JAS		Management in the transportation, selection, processing, cleaning, storage, packaging and other processes [should be] controlled in such a manner as not to be [ing] mixed with other agricultural products than the organic agricultural products
CODEX	Fwd 7	For livestock production, the competent authority should ensure, without prejudice to the other provisions in this Annex, that the inspections related to all stages of production and preparation up to the sale to the consumer ensure, as far as technically possible, the traceability of livestock and livestock products from the livestock production unit through processing and any other preparation until final packaging and/or labelling. ..handle agricultural products with emphasis on careful processing methods in order to maintain the organic integrity and vital qualities of the product at all stages..
China	7.1.1 7.1.2 7.1.3 7.1.4	Transportation vehicles used for both organic and conventional products shall be cleaned up before loading of organic products. Special marks or labels shall be made on transportation vehicles and containers to avoid mixture with conventional products. In the process of transportation and loading and unloading of products, clearly recognizable organic certification seal and statements concerned shall be stamped or affixed to packages. Transportation, loading and unloading of products shall be completely recorded and

As in other areas, there are many derogations from these rules and whole classes of organic production unaffected by them. Some systems extend to aquaculture while others do not. The US system's requirements for certification and submitting a system plan for approval apply only to operations whose gross agricultural income exceeds \$5,000 annually. This ultimately allows a certain degree of "leakage" in the system, and for some organic production to go unregulated while in especially "leaky" systems, some non-organic production may get into the mix. The regulatory overlay of national organic systems poses a particularly difficult problem for convergence in this area, since in many cases the rules in this area will be enforced by other authorities, and similarities to existing regulations in other sectors is preferable.

This is also an area in which trade rules play a role, and in which producers argue that some requirements needed to fulfil the objective of verification affect producers in different geographical areas differently. For instance, producers in tropical areas are said to be disadvantaged by extensive conversion requirements, because land used for new organic production has seldom been conventionally farmed. And lack of a supply of certified organic seeds has underscored the need for discretion to use conventional but non-treated seed where it is necessary.

However, perhaps because of the international trade significance of verification of product origin, international agreement on the rules pertaining to some elements of verification (labelling, for instance) is more easily obtainable. International labelling standards are to be used as the basis for national standards, as recent WTO litigation has underscored (Peru v. EU, on sardines), and there is a good argument for the primacy of Codex standards for this reason.

10. Processing systems should maintain product identity and be consistent with principles of organic production

In general, processing requirements for organic products follow the same basic template, with minor revisions in different systems. Basically, the intent is that the facility be environmentally friendly, segregate organic and non-organic product lines and inputs, refrain from using non-organic additives, prohibit use of synthetic additives or processing materials, use organic or environmentally friendly packaging material when available, and identify each product (and input, if necessary) appropriately. Some systems also cover transport. Like the matrix on verification, this one is illustrative rather than comparative. Differences are for the most part minor (although here, as on the production end, the devil is frequently in the details). Therefore, while some additives are permitted in some systems, they are banned in others.

While there is almost perfect consensus on maintaining product identity, there is less consensus on upholding principles of organic production at the processing end. There does not seem to be general consensus on such subjects because there is little consensus on what is "organic" at the processing level. Moving from the natural world to the factory introduces a number of considerations and conundrums. Local v. global production is one of them. Some organic proponents object to many processing aids as the product of big business

while others are prepared to accept that organic products can be produced at the scale of, and to the requirements of globalised agricultural production systems.

Perhaps more important is that the controversies rarely resolve the issue of what is truly “organic” about processing and what is not. The history of litigation of provisions of the US NOP indicate that some of these controversies are not likely to be resolved soon. If history is a guide, agreement on these issues, even at the level of a general objective, may not be easy.

Another issue is social justice. Social issues are difficult enough to tackle in an agricultural production system based on a family farm, or a small production unit. They are much less likely to be resolved at a factory level. Most organic production systems have not in fact extended social justice principles to processing, if they have articulated them at all. Perhaps the most easily achieved form of consensus on this issue is that it remain unaddressed by organic programs because it is addressed by other instruments (e.g., ILO conventions). Those could easily be referenced, rather than replicated.

IFOAM	6.3	Processing Methods. ..Processors should choose methods that limite the number and quantity of non-organic additives and processing aids. ...(6.3.1)..Any additives, processing aids, or other material that chemically react with or modify organic food shall be restricted and must appear in Appendix 4.
EU	Art. 6	producing organic food and feed from organic agricultural ingredients , except where an organic ingredient is not available on the market in organic form; (b) restricting the use of additives, other non organic ingredients with mainly technological and sensory functions as well as micronutrients and processing aids to a minimum extent and only in case of essential technological need or for nutritional purposes; Production of processed organic food shall be kept separate in time or space from production of processed non organic food.
US	205.270	Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.
JAS	Art. 2	To preserve the characteristics of the organic agricultural products..., which is the raw materials I the manufacturing the processing processes, the processing methods applying the physical and biological functions shall be used basically and the use of the food additives and drugs synthesized chemically shall be avoided...
CODEX	Art. 6 Fwd 7 Fwd 10	Organic food handlers, processors and retailers adhere to standards to maintain the integrity of organic agriculture products ..handle agricultural products with emphasis on careful processing methods in order to maintain the organic integrity and vital qualities of the product at all stages Therefore, the regulation of a process, rather than a final product, demands responsible action by all involved parties
China	4.4.2	Organic product processing shall not damage the main nutritional elements; such techniques as mechanical, refrigerating, heating, micro-waving and smoking may be used, as well as microorganism fermentation, extraction, concentration, sedimentation and filtration may also be used; and yet, the extraction solvents shall be limited to water, ethanol, animal and plant oil, vinegar, carbon dioxide, nitrogen or carboxylic acid that comply with national food hygiene standard, while other chemical reagents shall not be added in the process of extraction and concentration.

Recommendations

The history of the organic movement underscores the need for a holistic and global performance-oriented view of the organic production process, rather than the multiplicity of prescriptive standards that exist today and are further proliferating. From its origins in 1920's and 30's to its growth in the post-war era, and its widespread acceptance by consumers in the late twentieth century, the importance of organic products in the global marketplace has grown and multiplied exponentially. Enabling producers to meet this demand while upholding the high standards of the movement, and without forcing them to undertake the costs and burden of certification to multiple and sometimes mutually exclusive programs, is a challenge in a global economy. But the guiding principles, or “common objectives” of the organic movement perhaps should show the way.

Although language differences exist in the manner in which the principle underlying organic agriculture are articulated and structured across different programs, and although they have changed over time and are represented differently in different contexts, they are remarkably similar in intent and effect. If over time the objectives were to be commonly articulated, and criteria and indicators expressed in terms of performance standards³, they would most likely in many cases be identical.

Common objectives are the necessary foundation of this process. Required by the Agreement on Technical Barriers to Trade as a basis for equivalence, and recognized by the few regulatory systems that have found a basis for equivalence, they have not yet been formally agreed by governing authorities in a way that might enhance the prospects for broader, or multilateral equivalence. The two primary issues that will be confronted in the process are the level of detail at which the objectives can or should be articulated and agreed, and what additional elements of substance or process will be unavoidable in the venues where this negotiation might take place.

Venue is important because multilateral, or even “hub and spoke” determinations of equivalence⁴ cannot take place outside a context in which governments are formally bound – within the frameworks required by their respective regulatory processes. Several venues exist that could be used for this process. Which ones might be most useful depends on which strategy is determined to most expeditiously facilitate equivalence on a multilateral level.

This strategy should be based on some of the observations arising from this paper, namely

- Some “common objectives” are more common than others
- Some are more fully articulated than others
- Some already have a home in a multilateral venue, while others are on their own in terms of where agreement to them might best be negotiated
- Some will lend themselves to agreement more easily than others because they are more easily translatable into performance standards, while others are not achievable without a certain amount of prescriptive language.

³ **performance standard:** A statement of general criteria that defines a desired result without specifying the techniques for achieving that result.

⁴ Ones in which a single system recognizes as equivalent two different systems, which can then proceed to recognize the equivalence of each other.

- The “devil” is in the details, so choosing an appropriate level of generality is important

Details, Details

This paper has opted to start with a high level of generality rather than a high level of detail, but it has been noted throughout that much additional detail exists within each of the ten general principles discussed here. Of the ten common objectives discussed above,

- Protecting and enhancing soil quality
- Minimizing or avoiding use of synthetic chemical fertilizers, pesticides and fungicides
- Protecting and enhancing biodiversity
- Avoiding pollution
- Responsible use of other resources (e.g., soil water and air)
- Responsible treatment of farm animals
- Prohibiting use of other technologies (biotechnology, irradiation, embryo transfer, etc),
- Planning for (management plan) organic production,
- Verifying (certifying to) all of the above (this includes use of organic seeds, conversion, auditing, traceability of products and labeling for the market), and
- Maintaining the organic integrity of the processing systems used for organically produced products

several stand out as ones that could pass muster in equivalence determinations with most of the national programs without a lot of additional work. These are; protecting and enhancing soil quality, responsibly using other resources, and planning for organic production. Not only are they at the heart of organic production method but they are relatively well-articulated, do not present huge problems of disparity of treatment within the systems compared here, and would find a receptive audience not only in the organic producing sector but in the consuming one.

Among the more technically articulated objectives, agreement to “minimizing or avoiding use of synthetic chemical fertilizers, pesticides and fungicides,” may have good prospects for agreement because lists have been agreed for the most part in the CAC, although national programs will always be free to maintain their own. Agreement to many of the objectives subsumed in this principle would also be possible, should the optimal level of detail be more specific than general. Likewise, “prohibiting use of other technologies” would be easy at this point to agree if a principle could be developed, rather than a list. Otherwise, in future it would perhaps need to be renegotiated, depending on what is developed and what is disallowed.

“Responsible treatment of farm animals,” and “verification”, could also be negotiated because there is agreement on most of the general objectives, if not the particular ways in which they might be implemented. Negotiating the minefield of organic animal husbandry, along with the other more technical objectives, may be a good opportunity for revisiting some of their more prescriptive provisions in light of whether they could be articulated in terms of performance standards. Adopting a performance-based interpretation of these objectives might facilitate agreement by officials in regulated systems who otherwise would have little flexibility.

This could be particularly important for those objectives that are not particularly well, or fully, articulated across all of the systems, or ones that are covered by legislation not tied to organic production systems in national systems. “Avoiding pollution,” and “protecting and enhancing biodiversity” are two such objectives. In the former lurks the big issue of whether organic standards should explicitly address health and safety concerns. Additionally, how to deal with existing pollution in organic systems is an issue on which there may be a huge gulf between countries, especially those whose agricultural environments are severely stressed. The latter objective is barely articulated in most standards, but clearly, if lumped together with environmental protection, one of the implicit objectives of organic systems. Performance standards here – articulated either in reference to other legislation or on their own – could greatly facilitate agreement.

Venues

As noted above, agreement on common objectives would ideally need to be formally endorsed, if not negotiated directly, by government officials who administer national organic programs and who are responsible for determinations of equivalence. Some venues exist that could lend credibility to this enterprise. The CAC, which has itself generated one of the standards (and along the lines of the IFOAM standards) and whose standards are to be the international standards on which national ones are based, is the obvious choice for most of the common objectives listed above.

Within the CAC either the Committee on Food Labeling or the Committee on Food Import and Export Inspection and Certification Systems are natural choices, the latter because it has recently issued specific guidelines on equivalency for SPS measures. Although it has consistently rejected work on equivalence of TBT measures, a case could be made for organic products rather than the full spectrum of TBT-related issues. Otherwise, The OIE might be a venue to negotiate agreement on objectives of organic animal husbandry. The IPPC might be useful for environmental (pollution and biodiversity) issues. The ISO is also potentially available for new work, although the US is not represented there in a governmental role.

Finally, the Task Force itself, perhaps in partnership with the UNECE, could host a process to generate agreement on common objectives of organic production. If it garners active participation by the organic standards programs discussed here it could generate a quasi-legal instrument at international level that could be used by national programs as a basis for equivalence determinations.