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

**EXISTING AND POTENTIAL MODELS AND MECHANISMS  
FOR HARMONIZATION, EQUIVALENCY  
AND MUTUAL RECOGNITION**

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## **Executive Summary**

This paper is one of a series of background papers commissioned by the International Taskforce on Harmonisation and Equivalence in Organic Agriculture established by FAO, IFOAM and UNCTAD in 2003. Its purpose is to review the mechanisms used in other industries to facilitate free but regulated trade and to highlight those that may show promise for use in the organic agriculture sector.

The objective sought is the integrity of organic products with free and equal access to markets by all producers that comply with agreed requirements and with appropriate regulation.

Regulatory systems generally comprise a rule or standard and an agreed mechanism for ensuring conformity with the standard. Both components must be addressed in working towards the above objective.

Harmonisation, equivalence and mutual recognition are tools used by many sectors to facilitate free but regulated trade. Many modifications of these tools are used and rarely in isolation.

Existing models from other sectors are analysed which involve:

- Harmonisation of standards;
- Equivalency in conformity assessment;
- Mutual recognition of conformity assessment; and
- Mixed models that combine two or more convergence tools.

Key factors relating to organic agriculture including the dynamics of private-public actors, continuous development of standards and the importance of the co-ordination process are highlighted and the different ways in which convergence can proceed are summarised.

The initial lessons learnt from such an analysis include that:

- There are benefits from the involvement and collaboration of both the private and public sector.
- Trust building activities are required to provide confidence from all parties, government to government as well as government to industry.
- Equivalence of standards will certainly be a required tool, preferably built upon harmonisation towards an international standard detailing core values.
- Continuous development of organic standards present a challenge.
- Movement toward harmonisation of conformity assessment procedures is necessary.
- Monitoring of conformity assessment may be achieved through an international or national model.
- A neutral international forum for bringing together the various parties and overseeing all elements as exemplified by the ISTA model may be required.

Taking these models and requirements of the organic industry together, potential solutions are discussed in relation to convergence and rationalisation of conformity assessment systems and standards.

In conclusion a four-step approach is presented.

## **Introduction**

On 15 September 1904, delegates to the International Electrical Congress, being held in St. Louis, USA, adopted a report that included the following words:

"...steps should be taken to secure the co-operation of the technical societies of the world, by the appointment of a representative Commission to consider the question of the standardization of the nomenclature and ratings of electrical apparatus and machinery." (IEC website)

The problem of harmonisation and facilitating 'free but regulated' trade is neither new nor confined to trade in products of organic agriculture.

The increasing global market for many products and the decrease in tariff barriers to trade has increased the focus of private industry and governments in general, on the barriers to trade created by domestic regulations. The 1994 WTO agreement on Technical Barriers to Trade (TBT) drew wide attention to this issue and set down guidelines for members on reducing such barriers. Achieving the balance between protecting the consumer, whether in terms of safety of marine equipment or an organic label claim, and offering that same consumer free choice at competitive prices is a common challenge and one that involves many stakeholders, both public and private. From the point of view of the producer or manufacturer, free access to markets with minimal, and certainly no disadvantageous, regulation is of primary concern.

The other papers in this series have explained the history and operation of the current mechanisms that regulate trade in organic products and have demonstrated some of the inefficiencies and inadequacies that exist at a practical level. The International Task Force on Harmonisation and Equivalence in Organic Agriculture (ITFH) wishes to stimulate discussion and develop proposals that reduce the regulatory burden on the industry whilst maintaining the integrity of organic products.

To assist in this process, this paper attempts to bring together examples and models from other industries which are similarly engaged in seeking a balance of 'free but regulated trade', to learn from their experience and if possible, identify some models and/or components (structures, mechanisms) that may be applied to the organic trade.

This paper seeks to:

- Clarify the objective being sought
- Establish a common understanding of key terms.
- Describe existing models for equivalency and mutual recognition in other industries
- Review how such existing models or their components may contribute to regulated, free trade in organic products

### *The objective of free but regulated trade*

The basic objectives sought here are:

- Integrity of organic products as judged by ‘international’ consensus
- Free and equal access to markets by all producers in all nations
- Appropriate regulation

### *Definitions*

Regulatory systems are generally made up of two parts; a ‘**rule**’ of some kind which can be a technical regulation, private standard or guideline against which a product or process is judged and a ‘**conformity assessment system**’ which is a method and mechanism of assessing operators against the standard. All three organic regulations in the EU, USA and Japan define both technical rules and the methods by which compliance with those rules shall be assessed.

The classical model of standards and conformity assessment establishes a framework for trade that is based on the principles of (1) **harmonisation** and **equivalency** of standards and regulations and (2) **mutual recognition** of conformity assessment systems. These terms are used widely and in different ways.

#### **Harmonisation**

Generally used, harmonisation implies systems, activities or rules in agreement, working together and certainly not impeding.

The ISO Guide 2 (ISO/IEC, 1996) defines harmonisation of standards as ‘standards on the same subject approved by different standardizing bodies, that establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards’. It goes on to say that ‘the term ‘equivalent’ standards is sometimes used to cover the same concept as harmonised standards’.

The EU Commission suggest the term implies commonality or sameness and consider that ‘harmonisation may be regarded as the drawing up of common or identical rules by a group of authorities, with the intention that the mandatory rules governing a product or service shall be the same among them (EU Commission, 2001). The authors differentiate this from ‘international standardisation’, which has as its aim ‘the elaboration of a common set of requirements at international level, with the involvement of those who have a legitimate interest in them: governments, economic entities such as industry, and users, without the intention that mandatory rules and technical practice should always be the same.

This principle that harmonisation is based on the notion that national standards and regulations should adopt, reference, or be based on relevant international standards is accepted by ISO, the WTO/TBT, and by OECD, the EU, and the US (Vaupel, 2001:21). However harmonisation is frequently used to describe any process of convergence at less than international level and as implied by ISO Guide 2 can encompass ‘equivalence’.

**For the purpose of these papers, we therefore propose to use the term ‘harmonisation’ as the drawing up of common or identical rules, or the referencing of international standards. To describe any process of trade coordination in a generic way we propose to use the term ‘convergence’.**

A process of harmonisation may aim to agree upon similar rules; this is not only difficult to achieve but may not be the most desirable outcome (EU Commission, 2001) The EU ‘New Approach’ was born partly out of the frustration with previous attempts at total harmonisation

within Europe, stemming from the landmark Cassis de Dijon case in 1979 in which the European Court of Justice determined that a member state could no longer prevent the marketing within their borders of any product lawfully manufactured and marketed in another member state (Majone, 1999). This resulted in a change of approach, which outlined that the principle of total harmonisation was to be restricted to essential health and safety requirements. This principle has also been taken up within the Codex system. Such approaches permit and protect national or regional diversity in the detail but convergence and assurance of the important principles.

Harmonisation or convergence in standards in itself, does not imply mutual recognition (see below) of certificates (EU Commission, 2001) Even when the rules of two parties are the same, the acceptance of certificates of conformity by one party is based upon that party's trust in the conformity assessment procedures of the other. For regulated, free trade to occur, a degree of harmonisation (or equivalence) needs to be combined with a level of mutual trust in the conformity assessment system of the parties.

Harmonisation implies convergence; however convergence may be one-sided, meaning that between two or more parties, one party makes changes to come into line with the other. This has occurred in some of the examples considered below where other parties have modelled their regulatory systems based on those of the European Commission, given the importance of its internal market; this has also been seen in the organic market where, because of Europe's strength as an import market, third country national regulations have been written to fulfil the demands of EU Regulation 2092/91.

Harmonisation of conformity assessment procedures may be less difficult and less sensitive to achieve than technical standards and some common understanding of procedures certainly facilitates mutual recognition. For example, the multilateral agreement between the International Accreditation Forum (IAF) members is founded on the basis that its members are committed to developing conformity assessment procedures in line with ISO/CASCO guides and standards and adopted in accordance with ISO rules (IAF web site).

### **Equivalence**

**Equivalence is a mechanism to recognize and accept another system by acknowledging that variations between the systems uphold the respective systems' objectives (WTO, 1994). With respect to conformity assessment, ISO defines equivalence as the sufficiency of different conformity assessment results to provide the same level of assurance. (ISO/IEC).**

Equivalence therefore refers to achieving the same end even though either standard and/or the conformity assessment mechanism is/are not the same. Within Europe, this was another outcome from the Cassis de Dijon case in which the court reasoned that the basic aims of national regulations such as protection of human health are generally the same everywhere and even though the specific methods to achieve the aims may be different, since they all try to achieve the same objective, they should normally be accepted as equivalent.

The TBT sets out an obligation for members to "give positive consideration to accepting as equivalent technical regulations of other members, even if those regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations." (WTO/TBT Article 2 2.7)

The issue of equivalence arises in international trade when an importing country requires imported goods to meet its national regulatory requirements. If there is no equivalency agreement, the goods must meet the regulations of the exporting country and also those of the importing country. If there is an equivalency agreement between the countries the regulations of

the exporting country are deemed equivalent to the requirements of the importing country and the goods need to meet only one set of requirements: the exporting country's.

Where a regulation in one territory has the same regulatory objective as that in the other, and the two sets of regulations both actually fulfill this objective, the authorities can agree to regard them as equivalent. Agreement can then be reached that products conforming to the exporting territory's requirements (including conformity assessment measures where necessary) can be placed on the market in the territory of either party as though it conformed to the rules in force in that jurisdiction. The end point is the same, but the cost and problem of converging standards is not necessary. The strength of 'equivalence' as a tool of convergence is that it permits regulatory autonomy of the parties and allows for flexibility through some differences in national rules.

The disadvantage of equivalency is that the assessment to determine equivalence may be technically complex and when requirements are revised, a new determination is likely to be needed (EU Commission, 2001). This has particular relevance to the organic industry where standards are evolving and will continue to do so through a process of continual improvement, parallel to further development of the sector.

Recognition of equivalence, like harmonisation, does not itself imply recognition of conformity assessment unless specifically included (EU Commission, 2001). Together with recognition of conformity assessment, recognition of equivalence of technical regulations ensures that a product needs to comply with only one set of technical requirements and is tested and assessed only once, by the public or private conformity assessment bodies that are most familiar with the requirements against which the product is being assessed.

Such reduction of duplication is most easily achieved when the technical regulations are very similar in their objective and the requirements of each regulation can be seen to satisfy the objectives of the other. This is most likely when both are based on a common international standard i.e. there is some degree of harmonisation at least of core values (EU Commission, 2001)

### **Mutual recognition**

**Used in isolation, mutual recognition is a tool in which only the conformity assessment bodies are deemed to be equally capable and there is no attempt to converge the standards against which products are judged.** Such a mechanism reduces regulatory burdens by avoiding duplication of testing but demands no regulatory changes by the parties involved. For a product to be sold on both the home and export markets, two conformity assessments would be required. With an added equivalence agreement, one test would suffice for both markets.

Mutual recognition agreements (MRAs) therefore do not require or assume harmonisation or recognition of equivalence of the technical requirements though some mutually acceptable basis for the conformity assessment procedures must be in place (EU Commission, 2001).

In the private sector, mutual recognition is generally understood as the process by which conformity assessment bodies develop confidence that the reports or certificates of another body have the same value. To achieve mutual recognition, confidence must be established in the technical competence of each body. (Vaupel, 2001: 23)

Mutual recognition between accreditation bodies usually means that they recognize the technical equivalence of the accreditation system operated by the other body, but it does not mean that they grant their own accreditation to bodies accredited under the other system. MRA's are generally managed so that lists of approved certification bodies, and the standards against which they must certify, are clear (Vaupel, 2001: 23)

In practice, harmonisation, equivalence and mutual recognition may be utilised one in support of the other and in some of the examples detailed below; all three may be employed in some way. For example, mutual recognition does not rely on harmonisation or equivalence of standards but does rely on at least recognition of equivalence of the conformity assessment system. Similarly, an equivalence judgement is made easier if there has been at least some harmonisation of core values and objectives.

Figure 1 is a diagrammatic summary of the relationship between these tools in the context of overall convergence.

## Existing models for harmonisation, equivalency and mutual recognition in other sectors

With the goal of increased coordination to facilitate “free but regulated trade”, regulatory trade regimes use harmonisation, equivalence and mutual recognition as tools of coordination in different ways, sometimes in combination with each other. Adding another layer of complexity, in some of the models presented the focus is on standards, while in other models, the focus is on conformity assessment. In others still, the regulatory framework addresses both. This following section has tried to categorise the tools used to provided clarity but even where models are presented as examples of mutual recognition or harmonisation, it should be noted that these examples have arisen out of a historical process that may have included previous harmonisation or other coordination activities, which led to the development of the particular model outlined here.

### *Models involving harmonisation of standards*

Within the global pharmaceutical sector, a major harmonizing effort is through the **International Conference on Harmonisation (ICH)** (see Figure 2). The objective of the ICH is “the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, efficiency and regulatory obligations to protect public health (OECD 1999: Para 128 in Vaupel 2001). The main actors in the ICH are the EC, the Japanese Ministry of Health and Welfare, the US FDA and their corresponding pharmaceutical industries, the European Federation of Pharmaceutical Industry Associations, the Japanese Pharmaceutical Manufacturers Association and the US Pharmaceutical Manufacturers Association. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) was asked to provide the secretariat for the ICH. The ICH functions through three primary groups (safety, quality and efficacy) with a number of expert groups (EWGs) established under each area to work on specific topics proposed by the ICH steering committee. The steering committee is made up of two senior officials from each of the six principals while the expert groups are comprised of scientists, clinicians and/or regulators from the six parties. Furthermore, ICH has held major conferences periodically since 1991. Through these processes, the ICH develops trilateral guidelines. The three regulatory bodies have agreed that once an ICH document is official, it will be “regarded as the prevailing guideline on the subject” and if necessary, “national regulation or legislation will be created or modified...” (Lubiniecki, 1997: 351). By 2000, 45 guidance documents had been generated (Murano 2000: 303).

The EC, through the European Agency for the Evaluation of Medicinal Products (EMA) played a leadership role in the development of the ICH, contacting the other players in the mid-1980s.<sup>1</sup>

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<sup>1</sup> The EMA was established by the Commission resulting from Council Regulation (EEC) No 2309/93 of July 1993 and is managed by a Board consisting of two representatives per Member State, two representatives of the Commission and two representatives appointed by the European Parliament.

While the US was initially reluctant to participate, given EC dominance in the industry and Japanese agreement to cooperate, the US was compelled to join the negotiations by 1991 (Braithwaite and Drahos 2000: 372, 381). This power dynamic has had certain impacts on the negotiations. There have been cases where US FDA agreed to an ICH consensus and then had to back away from that consensus when faced with a backlash from the US pharmacological research community. At the same time there have been a number of important accomplishments through the ICH process. Through these negotiations, the US FDA moved to approve drugs on the basis of foreign data for the first time, a significant breakthrough in saving costs through duplicative testing (Braithwaite and Drahos 2000: 372). The harmonisation process through the ICH also seems to have made an impact on making products available to consumers faster (Vogel 1998 in Braithwaite and Drahos: 2000; 394). The harmonisation in pharmaceutical regulations between the EC, Japan and the USA leaves little room for third countries to do anything other than follow suit.

### *Useful lessons from the International Conference on Harmonisation model*

- The market dynamics described above highlight similarities with the organic industry where we can also see the regulatory impacts of the EU being one of the largest organic markets resulting in third countries following EU regulatory leadership in order to gain access to its market.
- A further point to note from this model is the strong role played by the private sector in the ICH represented in all major research and decision-making forums. Industry views of the process are generally positive as participation of industry has allowed the ICH guidance documents to be created with access to industrial data, allowing for more consistent and science-based regulatory outcomes (Lubiniecki 1997: 355).

A second example of harmonisation of standards is seen in the **US-EC Understanding on the Principles for Data Privacy Protection, otherwise known as the “Safe Harbour Principles”** (see Figure 3). This is a unique de facto model of one-way standards (and to some extent, conformity assessment) harmonisation that targets firm behaviour directly, rather than through convergence of government regulations. Under this agreement, firms based in the USA can self-certify that they meet the Safe Harbour Principles, allowing them to receive data from Europe without threat of legal challenge from European member states. As these principles go beyond US regulatory requirements, they constitute a ‘regulatory floor’ only affecting specific firms involved in specific activities (Shaffer 2002: 39).

This agreement was reached as a solution to the very different regulatory regimes for data privacy protection of the US and the EC. Under the new EC Privacy Directive’s criteria, there was concern that the US would not provide for ‘adequate’ data privacy protection (Shaffer 2002: 44). US and EC officials began negotiations with the aim of avoiding a ban on data flows to the USA. The Safe Harbour Principles were developed to be in line with the EC’s internal requirements. These principles are Notice (to individuals about the purposes and uses for data collected), Choice (to opt out of the provision of personal information), Onward Transfer (in the case of disclosure of information to third parties), Security (to protect the data), Data Integrity (to ensure integrity of processing), Access (to ensure individuals may access personal information held about them), and Enforcement (requiring mechanisms for enforcement and sanctions for non-compliance).

Companies join the program by self-certifying compliance to the ‘Principles’. The US Department of Commerce then places the company’s name on its website. This self-certification is backed by a meta-regulatory pyramid to ensure compliance. The first level is the company

declaration followed by audits from private certification organizations such as BBB Online or TRUSTe and finally backed by the US government.<sup>2</sup>

While technically allowing both the EC and the US to maintain sovereignty over their data protection regulatory regimes, the programme has encouraged the ratcheting up of private industry standards whereby the EC's more demanding requirements become a baseline standard given the high costs of working with two different sets of rules for European and US databases. Similarly private certification bodies in the US (such as BBB Online) have strengthened their own standards to comply with the Safe Harbour Principles (Shaffer 2002: 50).

### *Useful lessons from the Safe Harbour Principles model*

- This model is interesting for organic regulators in a number of ways. The use of private-public networks is due at least in part to the recognition that government officials in both the US and EC do not have the resources to enforce the Safe Harbour Principles (and the EC directive) on their own (Shaffer 2002: 53).
- This example also illustrates a new approach to reduce the impacts of regulation of one jurisdiction on another although the result is a type of one-way (not mutual) recognition of US certification bodies to verify an EC level standard but with impact on the US implementation by firms directly.
- The effects of the 'dominance'<sup>3</sup> of one party over another is also demonstrated here

### *Models involving equivalency in conformity assessment*

One example that focuses primarily on the convergence tool of equivalency in conformity assessment is the **Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems** (see Figure 4).

The Codex Alimentarius Commission was created in 1961 as a joint establishment of the FAO and the WHO. With 165 countries as current members, Codex is the most important international organisation in the globalisation of food standards, a sector with a long history of regulation. While it is generally categorized within the classical model of standardization as it is an international body comprised of national government representatives (See Vaupel 2001: 5, 14), Codex seeks substantial participation of NGOs that receive observer status. The make up of delegations is the responsibility of member countries. The Codex Rules of Procedure outline the role of observers including international government organizations and international NGOs, allowing for their participation except in final decision-making (Vaupel 2001: 15-16).

In terms of the legal status of Codex standards, in order for a Codex Standard to be effective in a given national context, it must be incorporated into legislation or accepted in some other way by the nation state. Among international bodies, Codex standards for food safety have generally been recognised with support for the referencing or adoption of standards into national law (Vaupel 2001: 16). Under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), Codex standards, guides and recommendations are explicitly referenced (Vaupel 2001: 15-16). In the WTO Appellate Body decision in *EC-Sardines* dispute, the panel determined

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<sup>2</sup> Another way for US firms to secure unchallenged access to EC data is to sign ad hoc agreements with member state data privacy authorities.

<sup>3</sup> Dominance in the sense of one party having something the other party wants, in this case EC data.

that Codex Stan 94 was a “relevant international standard” within the meaning of Article 2.4 of the TBT Agreement. Contrary to the arguments of the European Communities, it was also confirmed that the “relevant international standard” does not have to have been arrived at by consensus. Accordingly, the TBT agreement also covers documents that are not explicitly based on consensus (Mosoti 2003).

The objective of Codex is the establishment of international standards that will facilitate harmonisation. In this context Codex has looked increasingly to other principles of coordination, such as equivalence. The Codex Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Certification Systems (CAC/GL 34) provide a structure and outline a process to follow between countries acting bilaterally or multilaterally, to develop equivalence agreements concerning food import and export inspection and certification systems. These may cover trade in one or multiple directions between trading partners. The model is intended to provide a framework for the facilitation of the international trade of food products while at the same time, ensuring their safety and integrity. While it is focused primarily on equivalence of conformity assessment, the guidelines state that this process will be “...facilitated by the use of Codex standards, recommendations and guidelines by both parties” (Codex 1999: S7 5.27). Again, harmonisation will facilitate equivalence.

The process outlined in the guidelines includes considerations before entering into discussions and an initial discussion stage that would articulate the scope of the proposed agreement. This is followed by a consultative process whereby the importing country makes available the texts of its relevant control measures and the exporting country provides information that demonstrates that “its own safety control system achieves the importing country’s objectives and/or level of protection, as appropriate” (p. 4 – S7, 3.36). As this is necessarily an information intensive exercise, information should be exchanged on aspects such as legislative frameworks, control programs and operations, decision criteria and action, facilities, equipment, transportation and communications as well as water quality, laboratories (and information about accreditation) and “details of the exporting country’s systems for assuring competent and qualified inspection through appropriate training, certification, and authorization of inspection personal...” (S.7 28).

In order to ensure that the exporting country’s control systems operate as outlined, procedures for periodic audits and the correction of any problems identified should be established where the importing country determines that “the exporting country’s control measures, even if different than those of the importing country, meet the importing country’s objectives.” (S.7 26). The guidelines also provide for an opportunity for public comment on the draft agreement and for the possibility of a trial or pilot study before entering into the agreement. Both these measures are designed to enhance public and partner confidence in the equivalency of the control systems.

#### *Useful lessons from the Codex Guidelines for the Development of Equivalence Agreements*

- Given that Codex is the main intergovernmental international standards body on food issues and thus has organic agriculture within its scope, and as one of its parent organisations, the FAO, is actively engaged in facilitating international coordination of organic regulatory regimes, Codex is a likely catalyst for any future process of convergence.
- Advantages of the process described in the Guidelines compared with current bilateral arrangements are the neutral space provided by Codex, clear and transparent procedures and the possibility of multi-party discussions leading to multilateral equivalency agreements. A process to facilitate equivalency agreements for organic conformity assessment systems is certainly an important component in the organic regulation coordination toolbox.

- The role of private sector actors in such a process is less clear. Consistent with the classical model, the guidelines recognize non-governmental actors only as players in inspection and certification through a process by which they have been “formally approved or recognised by a government agency having jurisdiction” (S2 9). Given this, the IOAS, a major private actor at the level of accreditation in international organic regulation, would currently fall outside the scope of the guidelines.

### ***Models involving mutual recognition of conformity assessment***

While the previous model illustrated how equivalency agreements for conformity assessment systems could be developed, the next example focuses on the more limited coordination principle of mutual recognition. Following on from the so-called New Transatlantic Agenda, the **US-EC Mutual Recognition Agreement** was signed in 1997 in order to reduce duplicative regulatory compliance costs and address concerns about access to the EU single market by US firms (see Figure 5). The framework agreement was negotiated by the Office of US Trade Representative and the European Commission’s Trade DG while each of the six sectoral annexes negotiated by the appropriate regulatory agencies responsible for the sector. The six sectoral annexes cover telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices and pharmaceutical good manufacturing practices (Shaffer 2002). While the agreement was negotiated between government officials, the Transatlantic Business Dialogue (TABD – see below), representing large business interests in the USA and the EC promoted the concept of mutual recognition agreements and pressured officials to move forward with the MRA process.

With the exception of the pharmaceutical annex, the scope of the agreement is the mutual recognition of test results by “conformity assessment bodies” in the exporting country, in accordance with the required standards and procedures of the importing country. These bodies are evaluated for compliance with relevant international standards set forth in ISO/IEC Guides. Within the sectors covered under the agreement, the relevant international standard-setting bodies are ISO, the IEC (International Electrotechnical Commission), Codex, the ICH, the Global Harmonisation Task Force (for medical device standards) and the International Maritime Organisation. While the EC-US agreement is focused on mutual recognition, this coordination of conformity assessment is based on harmonisation through international standards and conformity assessment guidelines (Shaffer 2002: 9).

Within negotiations for the sectoral annexes for telecommunications and electromagnetic compatibility, the parties have agreed to recognize test reports and conformity assessment certificates issued by Conformity Assessment Bodies (CABs) located in each exporting jurisdiction and designated by the responsible authority. The recreational craft annex was relatively simple to negotiate given that the US Coast Guard had previously allowed self-certification of products by firms; while this is not the case with the EC, the simple regulatory regime in one country allowed for straightforward negotiations of MR, given that each importing country still requires compliance to its own standards. Negotiations for the other sectoral annexes have proven more difficult. The electrical safety annex has not been fully implemented given disputes with OSHA (a division of the US Department of Labour) over European designation of CABs, the very objective of the MRA. The medical devices annex is even more limited than the others as instead of CABs selected by each responsible authority, the FDA insisted that the process be conducted by “joint assessment”. In the final annex on pharmaceuticals, the intent was to permit regulatory authorities in the importing country to rely on their corresponding regulatory authorities in the exporting country to conduct on-site visits of facilities along with an inspection

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report regarding compliance with good manufacturing practices. This then relies on the determination of equivalence of the regulatory systems; the FDA has recognized equivalence of only two member state systems. It should be noted that the FDA has a more onerous task than its EC counterparts given the number of regulatory authorities in Europe for which equivalence assessment is required.

### *Useful lessons from the US-EC mutual recognition agreement*

- Prior to the MRA, a common practice was for an importing country CAB or ‘notified body’ to sub-contract the services of a domestic testing body in the exporting country. Given this, it has been noted that the impacts of the MRAs are relatively limited given that this is a slight extension of the already existing practice (Shaffer 2002: 14).
- A major problem in the negotiation of the MRA was that given that the sectoral annexes were negotiated by government agencies representing a particular sector, the EC agencies involved had a dual mission of ensuring free trade within the internal market and ensuring public safety, while the facilitation of trade was not covered in the mission of US Agencies such as the FDA and OSHA (though trade facilitation was added to the FDA’s mission in 1998 by Congress). Such structural differences between negotiating parties are critical to keep in mind in any process toward organic regulatory coordination.
- Mutual recognition in this case has posed significant challenges for regulatory cooperation as regulators are unfamiliar and uneasy with different foreign standards (Shaffer 2002: 5). This example may have direct lessons to be learned for any future convergence of organic regulation along these lines. For example, it should be noted that market forces can also constrain implementation of such agreements. Manufacturers have not reacted as favourably to the EC-US MRA as had been earlier expected. Manufacturers typically develop long-term relationships with certifying laboratories. Given the investment of time and knowledge in that relationship, the cost of changing laboratories could be significant. In addition, a laboratory’s mark in some markets may be important. Given these issues, many companies have preferred to use their same laboratories and work through sub-contracting arrangements. The parallels with organic certification bodies and their markets are strong. Similarly, the cost of gaining the status of an approved Conformity Assessment Body may be significant, including the attendance of seminars, training programs, audits and joint inspections that may be required (Shaffer 2002: 36-37).
- However, the bilateral MRA model may hold other benefits. Such a bilateral MRA can be seen as a stepping-stone to reaching similar agreements with third countries. The WTO TBT and GATS “explicitly encourage and lend legal support to the expansion of transatlantic MRAs (Nicolaidis: 1996 in Shaffer 2002: 29). Nicolaidis notes that a “contagion effect” could influence third countries to enter into negotiations out of fear of missing out on opportunities for their own firms (Nicolaidis 2001 in Shaffer 2002: 29). For example, in addition to the US-EC agreement, the EC has signed MRAs with a number of countries including Canada, Australia, Israel, Japan and New Zealand (Shaffer 2002: 29-30).

### *Mixed Models*

#### **Harmonisation of standards and equivalency in conformity assessment**

Linked to the US-EC MRA framework above but broader in scope is the **US-EC Mutual Recognition Agreement on Marine Equipment** (see Figure 6). The text was agreed in June 2003 but the agreement has yet to be signed (Lantz 2003). With the objective of allowing marine equipment approved by the US Coast Guard to be used on ships registered in the EC and vice versa, this agreement is interesting in the fact that it is based on the coordination principle of equivalency, both in terms of standards and in conformity assessment. Unlike in the last example, coordination to the extent of equivalency was made possible through pre-existing harmonisation of standards through the International Maritime Organization (IMO) (Shaffer 2002: 26).

Using the US-EC framework agreement as a starting point, the parties commissioned Bureau Veritas to do a comparative study of the US and EC equipment standards in this area with the idea being that where the standards were similar or the same, equivalency of the standards could be determined while where there were differences, harmonisation efforts would take place (US Coast Guard website 11/27/01). The study was presented at a workshop where the goal, scope and process for the development of the agreement were outlined. A staged approach was agreed where the first round of items to be included would be those where there was significant agreement on standards with other items added over time (website). Under this agreement, “each parties’ standards and procedures” are recognized “as ‘equivalent’ for the purposes of certifications issued by conformity assessment bodies located in either parties’ territory” (articles 3 and 4 in Shaffer 2002: 25). This was further facilitated by up-front approval of the certification bodies designated by both parties.

### *Useful lessons from the US-EC Mutual Recognition Agreement on Marine Equipment*

- In this example, significant prior harmonisation of standards through an international forum paved the way for an agreement based on equivalency. The linkage between harmonisation of standards and equivalency of conformity assessment procedures is a strong one.
- The staged approach is also important to consider, allowing relatively rapid regulatory coordination and trade facilitation gains in the first instance with further progress over time as confidence builds and more difficult issues are addressed.
- While the model is important to consider, it is important to note that in this particular example, there were only two parties to this agreement and both were governments.

### **Harmonisation of standards and conformity assessment**

The models presented in this section are based primarily on the principle of harmonisation, applied both to the standards and to conformity assessment procedures. These include a UNECE model for technical harmonisation, the Technical Barriers to Trade Agreement of the World Trade Organisation (WTO), an international standards and international accreditation model of the International Seed Testing Association and the private regulatory regime of the World Association of Nuclear Operators (WANO).

In its Recommendation “L”, the United Nations Economic Commission for Europe (UNECE) proposed “**an International Model for Technical Harmonisation Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards**” (see Figure 7). This model, proposed by the UNECE ad hoc team of specialists on Standardization and Regulatory Techniques (START), sets out a platform and a process for the creation of sector-based harmonisation of technical regulations, based on UNECE experience in the harmonisation of national technical regulations such as in the area of

motor vehicles. Within this model, the nature of the harmonisation task is limited to the “Common Regulatory Objectives” (CROs). The scope of the CROs will include both specifications applicable to products and the relevant conformity assessment procedures, though a distinction should be made between the two. According to the model, “Countries that have agreed on a CRO would assure that products, which comply with the CRO, could be placed on their market for free circulation without being subject to any additional product or conformity assessment requirements (e.g. testing or certification)” (UNECE Secretariat: S10). Interestingly, if a country imposes additional requirements despite having agreed on a CRO, it must inform the other parties. In this case, the other countries would be free to take appropriate measures including restricting the circulation of products from that country.

The UNECE Model is primarily based on two basic principles: 1) to persuade regulators to base their technical regulations on (preferably) international standards, or in their absence, on applicable regional/national standards, with the goal of creating a level playing field for companies and 2) that the “Common regulatory objectives” which form the basis of technical regulations should be based on mutually agreed safety and other legitimate requirements (i.e. environmental). This means that regulators should not harmonise existing regulations but try to agree on what safety levels (etc) they would like to achieve and what standards could be used for this purpose (Kouzmine 2003).

The process for establishing a CRO is the following:

A UN member country can ask the UNECE to launch a call for participation by other member countries in order to explore the interest in creating a CRO. The next step is that interested countries cooperate to develop a draft. The model allows for other UN member countries to join the group as observers. International standards should be referenced in the CRO; where these do not exist, a parallel standards development process could be undertaken through international standardizing bodies. The participating countries then announce their intent to implement the CRO in national technical regulations with other member countries invited to do the same. In terms of implementation, this may take the form of a Supplier’s Declaration of Conformity or third party assessment through recognized Conformity Assessment Bodies. The procedures for designating such bodies (specifically the technical competence requirements) will be set out in the CRO. A list of CABs should be made publicly available. Participating countries are responsible for market surveillance in their own jurisdiction and have the right to withdraw products where they are not in compliance with the CRO (UNECE secretariat: S12-21).

### *Useful lessons from the UNECE International Model for Technical Harmonisation*

- This example provides another possible platform and process for the convergence of organic regulations. With the use of international standards and the development of harmonized technical regulations addressing product and conformity assessment requirements, “regulated but free” trade is facilitated. The objectives of the model are certainly in line with organic regulatory convergence requirements.
- The deterrence approach for countries with additional requirements is interesting but may not work on countries with large internal markets and significant imports.
- Furthermore, like Codex, this is also based on the classical model of participation by member states.

A second example is the **Technical Barriers to Trade Agreement (TBT) of the World Trade Organisation** (see Figure 8). As part of the Uruguay Round documents signed at the Marrakesh

Ministerial in April 1994, the Agreement establishing the WTO contained two specific categories of rules on standards: the Agreement on the Application of Sanitary and Phyto-Sanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). The TBT Agreement was developed with the objective of facilitating the conduct of international trade and improving efficiency of production through encouraging international standards and conformity assessment systems while at the same time ensuring that such systems do not create unnecessary obstacles to international trade (TBT, preamble, p. 117; Sajejev 2001).

Like the UNECE model, the TBT is a classical model of international standardisation, with the only 'Members' or parties to the agreement being WTO member states. While the TBT recognises that other actors such as local governmental bodies and non-governmental bodies may undertake standard setting and conformity assessment activities, members have the responsibility to take "reasonable measures" to ensure compliance by these other bodies to the TBT provisions (TBT Articles 3, 7 and 8). In order to extend its reach to non-members, Annex 3 of the TBT, the Code of Good Practice for the Preparation, Adoption and Application of Standards, is open to acceptance by any standardizing body within the territory of a WTO member, including a central government body, local government body or NGO; it is also open to any regional governmental or NGO standardizing body that has at least one member in the WTO or is located within a WTO member (TBT Annex 3, Paragraph B). Many of the core TBT principles are included in the Code. However, it has been noted by UNICE that a weakness in the Code is that, unlike central government standardising bodies, many private bodies are not bound by the Code of Good Practice (UNICE 2003: 3).

The TBT Agreement creates a broad framework for harmonisation of standards and conformity assessment, within which equivalence and mutual recognition principles are also located. The core GATT (1947 Article 1, Article III) principles of Most Favoured Nation and National Treatment are integrated in the TBT, with respect to both standard setting and conformity assessment of imported products (TBT Article 2 2.1, Article 5 5.1.1). In terms of harmonisation of standard-setting, the TBT requires members to use international standards (where they exist), "or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographic factors or fundamental technological problems" (TBT Article 2 2.4). Such exceptions are potentially interesting for organic agriculture. In addition, members 'shall' play a full part in the preparation of relevant international standards by international standardizing bodies (Article 2 2.6). The principle of equivalence is supported in the TBT as members are required to give "positive consideration to accepting as equivalent technical regulations of other members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations" (Article 2 2.7).

With respect to conformity assessment, similar principles are set out. Conformity assessment procedures are not to be more strict than necessary to give sufficient confidence for the importing member that products conform to the applicable technical regulations or standards, based on risk assessment (Article 5 5.1.2). There are also requirements for timely completion of conformity assessment procedures and for the publication of anticipated processing times and equitable fees. As in the Articles on Standard-setting, the TBT requires that central government bodies use technical regulations of standards and relevant guides or recommendations used by international standardising bodies as a basis for their conformity assessment procedures (where they exist or their completion is imminent) except whether these are inappropriate for reasons such as the protection of human health of safety, animal or plant life or health, or the environment, fundamental climatic and other geographical factors, among others (Article 5 5.4). As in the standard setting articles, in facilitating harmonisation of conformity assessment procedures,

members are required to participate in the preparation of conformity assessment procedures by international standardizing bodies (Article 5 5.5). Where relevant guides or recommendations do not exist, there are also procedures set out for members to notify, justify, receive and take written comments into account on the development of conformity assessment procedures where they may have significant trade effects (Article 5 5.6) with specific procedure for emergency situations (Article 5 5.7). The TBT also supports the principles of equivalence and mutual recognition in conformity assessment. It is stated that Members shall, whenever possible, accept the results of conformity assessment procedures in other Members, even when those procedures differ from their own, provided “they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures” (Article 6 6.1). It is recognised that this will require information exchange and consultation with accreditation as one possible way of ensuring confidence in the continued reliability of conformity assessment. Mutual recognition agreements that would allow for the mutual recognition of results of each party’s conformity assessment procedures are encouraged through the TBT (Article 6.3). A final note of interest is the support within the TBT Agreement for international systems for conformity assessment that comply with Articles 5 and 6 (Article 9). This includes requiring members (wherever practicable) to adopt international systems for conformity assessment, become members or otherwise participate in such systems.

While business recognises that the TBT Agreement goes beyond the traditional GATT non discrimination principle and obliges the membership to ensure that technical regulations do not become unnecessary obstacles to trade, business groups such as UNICE (Union of Industrial and Employers Confederations of Europe) criticise it for leaving too wide a margin of discretion on the part of the members, with vague definitions (such as the definition of an international standard) and vague writing (i.e. members shall use international standards as a basis for technical regulations ‘wherever possible’) (UNICE 2003). Furthermore, from the perspective of developing countries, the technical cooperation outlined in the TBT (Articles 10,11, 12) is seen as inadequate and the implementation of the TBT may require developing countries to modify their technical regulations to conform to those of developed countries, regardless of the impact and actual need for them ( Sajejev 2001).

### *Useful lessons from the TBT model:*

- The exceptions for harmonisation of standard-setting and conformity assessment are interesting for organic agriculture in that there may be a need for different regulatory approaches based on climatic or geographic conditions.
- One of the weaknesses of the TBT is its vagueness in definitions and requirements for application by members. Any move towards organic regulatory harmonisation would need to be specific in any exceptions or flexibility allowed.
- The TBT lends support to the harmonisation of conformity assessment through the promotion of international conformity assessment systems. As the only international conformity assessment system in organic agriculture, the IOAS could be examined in this light. However, compliance of the IOAS to the relevant Articles of the TBT would have to be examined (Articles 5 and 6). This is difficult conceptually given the fact that the TBT is based on the classical model of central government membership and participation.

A third example explored here provides a model based on harmonized standards and harmonized conformity assessment through an international accreditation system is the **International Seed Testing Association (ISTA)** (see Figure 9). The ISTA has as its objectives, “to develop, adopt and publish standard procedures for sampling and testing of seeds, and to promote uniform application of these procedures for evaluation of seeds moving in international trade” as well as to promote research in this area (ISTA 2003: 2).

The ISTA is an interesting hybrid of private and governmental actors, with multiple but related activities ranging from standard-setting, training, assessment leading to accreditation and research promotion and dissemination through conferences and journal publications. Since 1931, it has published procedures and techniques used in seed testing known as ISTA Rules; this has allowed for internationally harmonized rules applied all over the world. The ISTA comprises 201 members representing 155 laboratories in 72 countries. Of these member laboratories, 86 are accredited. ISTA also works in close cooperation with a number of international organizations including regional seed associations, the EU, the FAO, the International Laboratory Accreditation Cooperation, ISO, WTO, World Bank and the OECD (Muschick 2003). This coordination aims to reduce duplication and facilitates a “uniform approach in the field of seed quality evaluation with regard to the international trade of seed lots” (ISTA 2003: 6).

Membership is by laboratory and by person, with specific fees for each. Within each laboratory membership, one personal member is included. Personal members do not have to be affiliated with a laboratory but they should support the aims of the ISTA. In terms of structure, the ISTA has an elected executive committee, a secretariat based in Switzerland, 17 technical committees and task forces that perform comparative studies, surveys and exchange of information. Every three years a two-week congress is held including technical committee meetings (that propose revisions to ISTA rules), a seed symposium and an Ordinary Meeting where the ISTA rules are discussed and revised and the executive committee is elected. Since 2002 ISTA holds Annual Ordinary Meetings where rules proposals and general items regarding the Association’s policy and strategy are discussed and decided (Muschick 2003). It should be noted that only “Designated Members” are allowed to vote at the Ordinary meeting. These are persons “designated by their respective Designated Authority...” (ISTA 2003: 3). A Designated Authority is one designated by a government to act on its behalf in designating Designated Members. So while Designated Members and Designated Authorities may not necessarily be representatives or agencies of government, the ultimate authority for determining who votes in the ISTA is held by governments.

The accreditation procedure can be explained in five steps. First a laboratory interested in becoming accredited becomes a member of the ISTA. Second, the laboratory successfully participates in the ISTA inter-laboratory Proficiency Test Programme. Third, the laboratory is required to set up a quality assurance program according to the ISTA Accreditation Standard, based on ISO/IEC Standard 17025 but amended to meet the needs to seed testing laboratories. Fourth, the laboratory must undergo an audit by two ISTA auditors (Muschick 2003). Accredited laboratories undergo audits every three years. Once accredited, “authorization to issue the ISTA Certificates is obtained through agreement of the Designated Authority” (ISTA 2003: 5).

The Certificates issued by accredited member laboratories, under the authorization of their respective governments, are colour coded. Orange International Seed Lot Certificates are issued when sampling and testing are carried out by the same laboratory. Green certificates are issued when these are carried out by different accredited laboratories and Blue International Seed Sample Certificates are issued when the issuing laboratory tests the sample as submitted. (ISTA 2003: 4).

### *Useful lessons from the ISTA model*

- The ISTA model is interesting for organic regulatory actors in many ways. ISTA is essentially a hybrid system as it is largely an epistemic community for seed testing overlapping with a self-regulatory structure for its accredited members, authorized indirectly (in terms of the designated voting structure and the issuance of certification)

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through national governments. The organic industry has an epistemic community structured through IFOAM membership that carries out similar functions to the ISTA in terms of continual development of standards, promotion and dissemination of research through publications and conferences, and accreditation (through the IOAS). However, the main difference is the lack of government integration, and therefore legal authority, into the IFOAM system.

- The colour coding of certificates is another interesting idea, allowing for coordinated work by different laboratories but also providing a simple and transparent communication tool.
- The accreditation is an international, sector specific model, which is fully supported by governments.
- Finally ISTA coordination with international organizations is critical in ensuring that it is truly facilitating a ‘uniform approach’.

The fourth example in the international harmonisation of standards and capacity building is the **World Association of Nuclear Operators (WANO)** (see Figure 10). While nuclear operators do not engage in international trade, there are some interesting aspects to this example for organic regulators. WANO’s mission is to maximize the safety and reliability of the operation of nuclear power plants by exchanging information and encouraging communication, comparison and emulation among its members (Braithwaite and Drahos 2000: 317). WANO members include every nuclear power plant operator in the world. This is significant in two ways. Insurance agencies would not cover nuclear agencies that were not members of INPO, the US national equivalent to WANO. There may have been fears that the same would happen at the international level which has ‘encouraged’ full membership. Secondly, 100% membership illustrates an understanding of the common fate of all nuclear operators (Rees 1994, Heimer 1985 (in B&D 2002: 302)). WANO was formed in 1980, after Chernobyl. Given its membership, there are world leaders in nuclear power plant management and “nuclear basket-cases” (Braithwaite and Drahos 2000: 302).

WANO’s focus is fostering a safety culture, supported by nuclear professionalism. Through identifying best practice among its members, it is committed to the continuous improvement of its standards. In order to ensure the capacity of all its members to implement the standards, it carries out significant training and assessment programs. These include WANO inspections where 15-20 engineers from plants all over the world are sent to inspect a given power plant. These are voluntary but most members participate as they focus on learning, improvements through exchange of experience, rather than sanctions. WANO operates in this way as it is felt critical that all nuclear power plant operators in the world remain members and have the opportunity to improve practices. WANO also facilitates user groups of plants of similar design and has a pairing program to match stronger and weaker members, encouraging information exchange and learning. As a self-regulatory body, WANO has no legal enforcement powers; however, state regulators have moved to shut down plants when its legitimacy was repeatedly challenged by WANO (Braithwaite and Drahos 2000: 301-320).

### *Useful lessons from the WANO model*

- Of note in this example is the strong capacity building role leading to a ratcheting up of international standards. The conformity assessment component in this case, also takes on a capacity building focus, leading to improved and harmonized approaches.

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- The common fate notion is to some extent applicable within organic agriculture, as food safety or other scandals could dramatically undermine the trust that consumers have in organic products, regardless of where the incident takes place.
- This is not a formal conformity assessment system, the participating actors are not in competition and no trade takes place between them.

### Harmonisation of standards and mutual recognition in conformity assessment

One example that has significantly influenced approaches toward regulatory convergence across a range of sectors and institutions is the **EU model, known as the “New Approach” for harmonisation of standards and the “Global Approach” for conformity assessment** (see Figure 11). The New Approach was set out in response to market distorting and market segregating impacts of multiple national standards and difficulty in appropriately overcoming them at the EC level (Shaffer 2002). Under the New Approach, EC institutions legislate framework directives for technical standards covering “essential requirements” and then delegate the determination of more detailed technical standards to quasi-public European standards organizations operating under the umbrella of CEN (Comite European de Normalisation), CENELAC (Comite European de Normalisation Electrontechnique) and ETSI (European Telecommunications Standards Institute). As noted in Vaupel (2001: 18), the ‘essential requirements’ are “considered threshold levels of protecting health and safety, and environment.” CEN, CENELAC and ETSI are made up of national standards bodies comprising representatives from government, industry and other social groups. The private sector standards developed and adopted under EU directives are not internally binding on member states; however, compliance provides “a presumption of conformity with the essential requirements in Directives” (Vaupel 2001: 19) (Shaffer 2002: 7). These standards have become *de facto* harmonized requirements for selling products within the EC (Shaffer 2002: 6-7)(Vaupel 2001: 18-19).

Under the “Global Approach” to conformity assessment products may be evaluated and certified within any member state. Certification allows products to receive the “CE” (Communité European- or EC) marking. Mandatory mutual recognition of CE certification between member states allows for the free circulation of certified products through the EC market. Accreditation of certification bodies at the national level plays a key role in this model with the use of EN 45000 series to ensure consistency of approach across national accreditation systems. According to DGIII for industry, national accreditation bodies include private or semi-private organizations structured so that the state maintains certain influence, a public agency of a part of a ministry. This approach establishes single national accreditation bodies that oversee certification bodies (notified bodies) within their respective jurisdictions. These national accreditation bodies meet periodically through the European Co-operation for Accreditation (EA) to exchange information, build capacity, develop mutual recognition mechanisms and build and maintain trust (see Shaffer 2002: 7-8 and Vaupel 2001: 19-20 for more information).

#### *Useful lessons from the EU New Approach/Global Approach*

- Of interest to organic regulators is the integration between public and private actors at different stages in the regulatory process from the level of technical standard setting through to accreditation and certification.
- However, as in the US-EC MRA example, market forces also play a role in mitigating the effectiveness of efforts to facilitate trade of products through this approach. While the CE marking is the only legal requirement, within certain member states, trade names and

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trade marks of national certification bodies (notified bodies) are advantageous for marketing purposes. National distributors and suppliers may also prefer national body certification as well Shaffer 2002: 8). As has been mentioned already, the role of preferred certification marks is also an issue in organic regulatory regimes, so this is an important point to note when looking at future models of regulatory convergence.

- Equivalence of accreditors is facilitated through the use of common conformity assessment guidelines and an MLA between EA members.

A final example of regulatory convergence through a combination of harmonisation of standards and mutual recognition of conformity assessment is the **International Electrochemical Commission System for Conformity Testing and Certification of Electrical Equipment (IECEE)** (see Figure 12). The main objective of the IECEE is “to facilitate trade by promoting harmonisation of the national standards with international standards and cooperation among product certifiers worldwide in order to bring product manufacturers a step closer to the ideal concept of ‘one product, one test, one market, where applicable’” (IECEE nd: 1).

The IECEE is managed by the Certification Management Committee (CMC), that reports to the Conformity Assessment Board of the IEC. Given that the IEC is one of the classical international standardization bodies, countries that have membership in the IEC can join the programme with the possibility of participation by non-member countries as well. In each country there is a National Committee that is responsible for designating National Certification Bodies (NCBs). These NCBs are in turn responsible for issuing and recognizing CB Test Reports and Certificates. In order for the scheme to operate, national standards must be “reasonably harmonized with the corresponding IEC standard for which participation in the CB scheme is desired” (IECEE nd: 1). Participation in the IECEE scheme by NCBs is on a standard by-standard basis with NCBs needing to seek recognition for each standard that they intend to use within the scheme. The IECEE secretariat takes responsibility for providing relevant and up to date information to all participating actors in the system including standards accepted for use in the scheme, statistics on CB Test Certificates issued previously and information on participating NCBs.

A manufacturer interested in obtaining a CB Test Certificate for a given product may submit an application to any “Issuing and Recognizing” NCB accepted for the relevant IEC Standard. The NCB will undertake the assessment and, assuming compliance with the relevant standard, a CB Test Certificate will be issued. If the manufacturer then wants to obtain product certification for a different country, an application is made to an NCB in the target country (the recognizing NCB) including the CB Test Certificate and CB Test Report from the Issuing CB. A sample of the product may be requested to ensure that the product is the same as initially tested by the Issuing NCB. A Standardised report format is used for the CB Test Report to facilitate understanding and recognition between NCBs. Through mutual recognition between NCBs, a secondary certificate can be issued for the target country.

Mutual recognition only works as a principle for regulatory coordination where there is sufficient trust in the quality and consistency of all participating conformity assessment bodies. The application process to become a recognized NCB within the IECEE CB scheme is as follows:

Interested NCBs submit applications through their member bodies in IECEE. The secretary reviews applications and appoints assessment teams. On-site assessments are undertaken to verify compliance with the requirements of the system and to ensure that member NCBs have the necessary technical capability and experience. Assessment teams include experts from NCBs and CB Testing Laboratories with reports circulated to all CMC members. The CMC evaluation group

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makes recommendations on the application to the CMC. The application process to become a CB Testing Laboratory is similar with the additional step of endorsement of the responsible NCB prior to the submission of the application. There are currently 43 member countries in the IECEE with 56 participating NCBs and 147 CB Testing Laboratories (IECEE nd; de Ruvo 2003).

### *Useful lessons from the IECEE model*

- Of interest in this scheme is the approach to national differences in standards. The scheme allows for some variations in national standards compared with the international standards of the IEC. Any differences from the IEC standards are openly declared and made available to the IECEE secretariat that will disseminate the information.
- Manufacturers can request NCBs to test products to national differences of a target country. NCBs are able to do this if they have demonstrated that they have the necessary expertise and equipment and any additional tests for the national country differences are included as supplements to the CB Test Report.
- Despite the mutual recognition of NCBs in this model, the process still requires the forwarding of documents to the importing country NCB, rather like that which sometimes occurs in the organic certification industry under recertification. However, the IECEE Executive Secretary stated within the context of third party voluntary product certification, submitting an application set of documents that shows compliance with the initial testing is reasonable. As a matter of fact, the Recognising NCB, by issuing its certification mark, engages its responsibility by endorsing the CB Test Certificate and CB Test Report. Until the last decade, manufacturers were obliged to seek multiple certifications associated with multiple type testing to be entitled to market their products in the target countries (de Ruvo 2003).
- The use of common report formats is interesting.

### *Lessons learnt*

Figure 13 summarises diagrammatically the extent of harmonisation of rules and conformity assessment system for each model described.

A number of useful lessons can be teased out from these models:

- There are various ways in which the private sector can interact with governments to their mutual benefit (see Figure 14). Such interaction can be beneficial in reducing cost to government and making the resulting regulatory system appropriate for the private sector (see below).
- Construction or agreement on standards and conformity assessment takes time and requires trust and confidence building exercises between the parties.
- Equivalence is likely to be a required tool in convergence of organic standards even if some harmonisation is achieved.
- The continuous development of organic standards is an important facet that creates some problems that are not well addressed by many of the models investigated.
- Harmonisation of conformity assessment procedures is necessary for mutual recognition.

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- Models address consistency of conformity assessment through accreditation/approval by the importing country, mutual recognition of approval by the exporting country or in one case an international, sector specific model.
- The construction of some kind of international forum which engenders neutrality, participation and respect from all actors is frequently used to co-ordinate the truly international mechanisms.

The issues of public-private sector interaction, continuous development of the standards and the processes of co-ordination are further investigated below.

### Dynamics of private-public actors

Any future organic regulatory model of convergence will need to consider how best to address the existence of public and private regulatory actors. In seeking to identify examples that may provide useful insights for organic agriculture, a number of models were examined for the characteristics of the actors involved. These include examples in which convergence is driven by private actors, government-led systems and initiatives that illustrate possible public-private networks. Examples of international regulatory convergence led by private actors include the World Association of Nuclear Operators examined above, the Transatlantic Business Dialogue (TABD), the International Chamber of Commerce (ICC) and its International Court of Arbitration and the International Accounting Standards Committee (IASC). The national level equivalent and precursor to WANO, INPO, was developed, at least in part, “to accomplish what they [industry] believe the state cannot...to regulate the sector more effectively in areas where they felt the NRC’s [national US government regulator] had been, and would probably continue to be, ineffective” (Campbell 1988: 2 in Braithwaite and Drahos 2000: 302). As mentioned, INPO and WANO are self-regulatory systems with ‘conformity assessment’ conducted through peer-review mechanisms.

The **TABD** was originally established in 1995 as part of the New Transatlantic Agenda. One of four dialogues (consumer, environment, labour, and business), the TABD’s creation was led by the US Administration (led by the Commerce Department in cooperation with the State Department and USTR) and the European Commission to identify areas of consensus for EU and US business and tap industry’s expertise on how to best foster transatlantic trade and investment opportunity. While the TABD is convened by the governments, the process has always been industry driven and funded. It has been criticized for being an exclusive club of large corporations with participation criteria open to ensuring just this: the CEO is pro-liberalizations and trade, represents a transatlantic company and its deemed constructive to the policy process. Currently under reform and leadership transition, the TABD has a small secretariat in Washington and Brussels and works through five working group themes including Standards and Regulatory Policy (promoting a regulatory model based on ‘approved once, accepted everywhere’), business facilitation, global issues, SMEs and the new digital economy. Approximately twenty specialist-working groups, each with a joint EU/US company chair, operationalise the policy process while the CEOs meet once a year to make recommendations to the EU and US governments. While TABD has been successful in the areas of promotion of mutual recognition of conformity assessment and harmonisation of standards, taking a leadership role in e-commerce and standardization of ‘third-generation’ wireless telecommunication systems, and encouraging better understanding of different US and EU positions, it is essentially a well-placed lobby group of highly influential players rather than a private regulatory system of its own accord (Coen and Grant 2001; Braithwaite and Drahos 2000; Werner 2003).

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The **ICC** was founded in 1919 and exerts its global influence through a network of national committees and working parties. These national organizations, representing business in most developed and developing countries, nominate experts from their member companies to participate in the different ICC commissions and task forces on all major issues of trade and investment policy as well as on vital technical and sectoral subjects – financial services, telecommunications, information technologies, marketing ethics, the environment, transportation, etc (Bauer 2003). On the basis of actual business practice of merchants, the ICC formulates standard codes for the regulation of financial instruments from this ‘database of custom’. For example, the “Uniform Customs and Practice for Documentary Credits” were first adopted in 1933 and by 1966, it had been applied in 173 countries. Another universally used set of terms are the Incoterms (International Commercial Terms) issued for the first time in 1936. These have been revised several times to follow up with changes in trade practices. Among the most current terms used in international contracts are standard clauses such as FOB (free on board) or CIF (cost, insurance and freight) (Bauer 2003). Its power comes from its membership and the realization by international business of the need for harmonized standards. Of interest is its International Court of Arbitration established in 1923 that has administered over 12000 cases involving parties and arbitrators from over 170 countries and territories. It claims that it is able to do what national courts cannot given the unique nature of disputes between actors from different countries, allowing for less costly and time consuming processes compared with court litigation. Its authority comes from the 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards, signed by over 130 countries. The ICC and its Court of Arbitration do constitute a private regulatory system for its members. They provide global regulatory services to business actors that are not provided by state bodies. Given the powerful business network that the ICC comprises, it has been effective across a range of issues, from working to prevent financial fraud and piracy to addressing double-taxation and the harmonisation of international commercial law. The ICC has been effective in developing private regulatory systems where needed (where states have not been active), in working with governments to improve and harmonise regulatory systems and, at times, taking a leading role in enforcing government regulation. (ICC 2001a; ICC 2001b; Braithwaite and Drahos 2000).

The final example of a private regulatory system is the International Accounting Standards Committee (**IASC**). The IASC developed out of the 10<sup>th</sup> International Congress of Accountants in 1972 and is committed “to a process of continuous improvement in the development of international accounting standards for financial reporting by business” (Braithwaite and Drahos 2000: 121). It represents 100 professional accounting bodies in 50 countries. The accounting standards that the IASC develops are not norms of law but norms of good practice. The Committee then works to persuade various actors to use and support its standards. It has been effective in this endeavour with the 7<sup>th</sup> EC Directive on Consolidated Accounts being influenced by IASC standards and with the World Bank requiring its borrowers to comply with its rules. Through an agreement reached in 1995 with the International Organization of Securities Commissions (IOSCO) since 1999, companies that meet IASC standards can list on any capital market stock exchange. Furthermore, securities regulators in countries such as Italy, Japan and the USA, have insisted that domestic companies and foreign insurers comply with IASC standards. This is an effective example of private international standard-setting with harmonisation occurring through the implementation of these standards across a range of public and private forums. Given the current participation of government regulators in organic agriculture, it is clear that the future of organic regulation does not lie solely in the hands of the private sector and that some form of coordination or integration is needed.

Many of the examples outlined in this paper are government-led. These include the EC New and Global Approach, the US-EC MRA with its six sectoral annexes, the US-EC MRA on Marine Equipment, the US-EC Understanding on Principles for Data Privacy Protection, the IECCE CB

scheme and the Codex Guidelines for the Development of Equivalence Agreements. While most of these examples include private bodies in some capacity within their structures, perhaps as representatives on a standard-setting committee or as a certification body or laboratory, the actual decisions on the structures of convergence, using harmonisation, equivalency and mutual recognition tools in different ways, are made solely by governments. While important insights into convergence between organic regulatory bodies can be gleaned from these models and the spaces for convergence provided by them, this is a potential obstacle for meaningful participation by the organic industry and its own standard-setting and accreditation systems. Other examples such as the International Conference on Harmonisation and the International Seed Testing Association provide ideas on how public and private interests can be integrated, building on the strengths of the different actors involved. However, apart from the ICH to some degree, no model surveyed for the development of this paper, provides a clear example of how coordination between private and public regulatory bodies could be structured.

### **Continual development of standards**

It is inherent in the nature of organic standards that they will continue to develop, both with overall development of the sector and as research brings new technologies and management systems to light. For IFOAM, the continual development of its Basic Standards is a main function of the Federation. This process of standards development and revision provides a cultural core of its activities, providing a platform for IFOAM members to come together, to debate and to decide on changes that will shape the future of organic agriculture. Being able to participate in defining the meaning of organic agriculture ensures a strong sense of ownership among its members. The process of continual improvement of standards is a critical one in any dynamic regulatory system, ensuring that the standards reflect best practice and support innovation. Convergence examples featuring continual improvement of the standard-setting process include the IASC, WANO and ISTA. The IASC is committed to continuous improvement of its standards so that accounting standards around the world are harmonized to progressively higher standards, creating a regulatory ratcheting up effect (Braithwaite and Drahos 2000: 121). In a technology driven sector, WANO's standards are continuously improved to ensure the best possible regulatory environment to ensure nuclear safety. The ISTA has a well-structured system whereby outcomes of technical committee discussions are fed into ISTA rules decisions taken at Ordinary meetings. Its objective of promoting research in the area supports the primary standards-setting function of the association. Given the importance of dynamic standard-setting to organic agriculture, any future model of harmonisation or equivalency needs to take into account the need for continual improvement of standards in a timely manner.

### **Coordination is a process of information exchange and trust building**

A critical lesson to be learned from the examples of harmonisation, equivalency and mutual recognition, is that regulatory convergence between parties is a process over time that requires information exchange, mutual learning, training and trust building. For example, in order to overcome its mistrust of European Conformity Assessment Bodies, in the process of establishing the US-EC MRA sectoral annex on medical devices, the US FDA organized a 'joint confidence building program' including seminars, workshops, joint training exercises and observed inspections (Shaffer 2002: 22). In the WANO example, movement toward harmonisation is achieved through capacity building activities that bring nuclear safety standards up, from peer assessments, mentoring programs between strong and weaker members and user group exchanges, among others. Within the Codex Guidelines, it is recognized that "information exchange, joint training, technical cooperation and the development of infrastructure and food control systems can serve as building blocks toward the later development of agreements" (CAC/GL 34 s5 20). It is also stated that importing developed countries should consider

providing technical assistance to importing developing countries. A further example is the ISTA structure with its standard-setting role complemented by its research and information dissemination functions actualised through seed symposia, the publication of a scientific journal, the development of a wide range of technical handbooks and the organizing of ISTA proficiency test programme. The TBT Agreement of the WTO has specific articles devoted to information and assistance in the implementation of the Agreement (Article 10) and to the provision of technical assistance and special consideration for developing countries (Articles 11 and 12). Through these diverse examples, a common thread is information exchange and training leading to better understanding of partner competencies and trust building, necessary prerequisites to any effective regulatory convergence.

### ***Different ways in which convergence can proceed***

As has been seen in the examples outlined above, regulatory convergence at the international level takes place in a number of different ways (see Figure 15). Conceptually, these approaches can be categorised according to the specific structures and drivers of convergence. In some examples, leadership by one powerful actor has been critical in driving regulatory convergence. This is seen in the International Conference on Harmonisation (ICH) case study with European leadership driving the process. Industry associations also played a strong leadership role in moving the ICH process forward. This is also seen in the accounting sector with the IASC, taking on a leadership role in the international harmonisation of accounting standards and in the work of the ICC. A second typology is the bilateral (or tri-lateral) negotiation of convergence that leads to a ratcheting up of global regulatory convergence. In this case, a convergence mechanism established at the bilateral level becomes a model for third countries to follow, leading to a globalised process whereby the convergence bar is raised over time, affecting more jurisdictions than originally intended. This is seen in the case of the US-EC Mutual Recognition Agreement of 1997. A third approach is the treaty or protocol model whereby all parties agree on the convergence model and ‘signatories’ work to implement the model over time. This approach is seen in the IECEE CB scheme and the UNECE Model for Technical Harmonisation. The Codex Guidelines for the Development of Equivalence Agreements appear to be a hybrid between the bilateral ratcheting up approach and the treaty approach. A further approach is a communication strategy approach whereby a process is set up between the affected parties to talk to each other and share experiences. With every meeting or interaction, the strategy is to move step by step toward regulatory convergence. This is seen in the WANO model. This approach often co-exists with other approaches as has been seen in the US-EC MRA sectoral annex on medical devices. The approaches described here are not exhaustive but serve to illustrate that there are a range of different possibilities of processes that can lead to convergence. By better understanding how other regulatory convergence examples have developed, we can examine what approaches might be most usefully applied within the context of the organic sector.

## **Potential solutions to equivalence and mutual recognition in organic agriculture**

The previous sections have illustrated some of the successes and difficulties in facilitating regulated, free trade in different sectors. There may be no one model that can be applied to cater for the characteristics of the organic industry but there may well be some ideas and mechanisms that may be incorporated into a solution.

### ***Models in relation to specific aspects of organic agriculture***

The existing mechanisms for regulation in the organic sector have been described in the other papers in this series but it is useful to clarify the special characteristics of the trade in organic

products; who is involved and what mechanisms already exist to regulate the sector. These should be borne in mind when assessing the usefulness of other models in the next section.

Organic product trade and regulation is characterised by:

- Movement of mostly food items, often perishable, bought directly by consumers as opposed to a medical device that is purchased by a business or health organisation.
- Organic label currently secures a price advantage, so mislabelling and fraud is a danger.
- Many small producers
- Third party certification (as opposed to self declaration)
- Process not product certification i.e. an organic product cannot yet be tested in the marketplace to determine its organic integrity. Only a paper trail can establish this
- Two 'international' standards (Codex and IFOAM)
- Standards in continuous development
- National and supra-national legislation - in many countries but not all and not necessarily based on the international standards.
- Certification bodies may be public or private sector and private certification standards and certification 'brands' in some countries.
- Several dominant markets - EU, US and Japan
- Overall market value relatively insignificant compared to the food industry as a whole or the market for pharmaceuticals or motor vehicles
- Several conformity assessment guidelines available - ISO65, IFOAM Norms
- Approval of certification bodies performed by government, national accreditors (government or quasi-government) and international private accreditor (IOAS).
- Market surveillance - in some countries only e.g. EU Member States.
- Cross cuts government sector interests - agriculture, food, environment, trade, consumer affairs.

### ***The starting point***

Some of the current mechanisms utilized for facilitation of trade in organic products are listed here and are categorized to some extent to help in relating the situation with the organic industry to the models described above:

#### **Harmonisation**

Both IFOAM and Codex Alimentarius have published international standards for organic agriculture.

The IFOAM Basic Standards have been a considerable force for harmonisation as they were the first international standards published and to a degree, most subsequent standards have been influenced by them. The IFOAM Criteria for certification bodies were a later development and have had less harmonizing effect. The ISO65 guideline could be said to have had a bigger harmonizing effect as both the EU and US regulations refer to it and it is the basis for the IFOAM Criteria.

Within the European Community organic products can move freely due to the single regulation providing for one inspection, one mark (the EU Organic Farming mark). In theory this is sufficient to allow free movement and sales in all Member States without further conformity assessment procedures. In practice however, recertification often takes place in the import market because consumers prefer to see the local certification mark. This is as true of the national AB logo of France as it is of some private certification labels in for example Sweden and the United Kingdom.

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### Equivalence

The big three organic regulations (containing technical rules and conformity assessment guidelines) in the EU, Japan and the USA have developed without much reference to each other or international standards and have since sought equivalence. Smaller exporting countries interested in sending product to these markets have either had to seek approval of equivalence or individual conformity assessment bodies have sought separate approval.

Negotiations on equivalence have occurred between the European Commission and MAFF in Japan such that MAFF have unilaterally accepted the EU Regulation as equivalent. Japan has not however recognised the European control bodies as competent without an individual evaluation from MAFF. The EU has not reciprocated the recognition at any level.

MAFF, Japan has recognised that the USDA's national organic standards for the production, handling and processing of plant-based organic agricultural products meet the requirements of the Japanese Agricultural Standards.<sup>4</sup> Again Japan has not however recognised the US control bodies without an individual evaluation from MAFF.

One-way equivalence with a unilateral recognition of the conformity assessment mechanisms is seen in the acceptance by the European Commission of Third Countries. The applicant country is required to demonstrate equivalence of production rules and system of inspection and approval is dependent upon physical visits.

Under both the Japan Agricultural Standard (JAS) and USDA regulations, all registered conformity assessment bodies are required by law to accept as equivalent all other registered conformity assessment bodies. This is not the case under the EU Regulation but free movement is required.

The active multilateral agreement between IFOAM Accredited certification bodies is based on accreditation by IOAS to common baseline standards and conformity assessment guidelines. This is an equivalence agreement based on a strong harmonisation component in which each CAB can accept other certificates as equivalent.

### Mutual recognition

USDA has determined that several foreign government (Denmark, United Kingdom, New Zealand amongst others) conformity assessment programmes are sufficient to ensure conformity to the technical standards of USDA's National Organic Program (NOP), the so-called Option 2 of the NOP.

Within the EC, individual CABs mutually recognise each others competence based on approval or accreditation by their respective authorities. This is supported by the basis of a common Regulation containing standards and conformity assessment procedures.

Mutual recognition of a type occurs between CABs at certification level when CAB X sub-contracts an inspection by CAB Y to the standards of CAB X. CAB X recognizes the competence of CAB Y to perform the procedure. Often this recognition is based upon being an approved body under a national regulation but also occurs between IFOAM Accredited certifiers based on their common accreditation.

### Other tools

The USA and Japan perform direct approval ('accreditation') of individual foreign certification bodies, recognising them as competent to inspect to the NOP or JAS rules respectively to allow

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<sup>4</sup> The recognition agreement does include some limitations stipulating, however, that certain ingredients may not be used in raw or processed organic food exported to Japan.

exports to these countries. The foreign inspection bodies must bring themselves into line with the requirement of the importing country.

For more details see other papers of this series.

### ***Models and mechanisms for future investigation***

#### **Conformity Assessment**

##### *Mutual recognition agreements*

As has been seen above, moves to facilitate trade which involve the need for harmonisation of standards or conformity procedures can be problematic as they may require deep-seated changes in national legislation which may not be acceptable or even feasible given the legislative and institutional framework of certain participants. Mutual recognition agreements may be the simplest first step towards reducing over-regulation (although some examples had and still have their problems which may be related to the degree of previous harmonisation).

One possibility is the negotiation of mutual recognition - in a similar manner to the Agreement on Mutual Recognition between the EC and the USA; in this scenario, negotiations would largely be in the hands of the public sector, with the possibility of input from the private sector such as the role the TABD played in the US-EC example (see Figure 16). The end point would be at least that CABs in the exporting country would be recognised as competent to verify compliance of organic producers to the standards of the importing country. This recognition would not be based on approval or accreditation of the CAB from the importing country, as is now the case, but by the authorities in the exporting country. This could deliver some regulatory saving.

Both the EC and US regulations refer to the ISO65 Guideline as a basis for conformity assessment providing a good basis for understanding. The JAS law however, does not refer to ISO65 and its conformity assessment criteria have a quite different basis. Many other countries (or where regulations do not exist, individual CABs) however have been forced to use ISO65 (or become ISO65 accredited) as a result of the demands set down by the EU Regulation that CABs must 'satisfy the requirements of EN45011 (ISO65). Therefore, apart from Japan, there is a considerable common basis for conformity assessment upon which such mutual recognition could be agreed.

The positive aspects of this approach would be that it may be 'relatively easy' (politically) to secure given that national standards remain unaffected, governments can maintain jurisdiction and organic standards in one nation or region can retain their local character at least for the local market. On the import side, market access should be assured as the organic production has already been assessed to the required standards. Of course market access does not mean market acceptance and the issue of preferred certification brands at different levels may remain in some countries.

The negative side is that producers and CABs will have to deal with an increasing number of different standards as more and more national standards are drafted and those producers who are exporting will be obliged to comply with a standard set for another country. A trader exporting product to a number of markets would have to demonstrate through audit trail that all product were certified to each appropriate standard of the target market – a considerable administrative burden. At the level of approval or accreditation of CABs there is currently a mixture of private national accreditors, government authorities and the private IFOAM Accreditation involved in the process. Rationalisation or mutual recognition at this level would be required which would first require some agreement on the conformity assessment guidelines to be used.

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Such a process of negotiation could be encouraged by the private sector but it is likely that the organic private sector will remain with relatively little power compared to a group such as TABD and so the will to negotiate would rest in the hands of governments.

Issues for discussion and clarification:

- The retention of local standards and legislation without any equivalence is both a positive and negative. The negative aspect of dealing with many standards would need to be addressed.
- Given the current approval/accreditation of national CABs by both governments, national accreditors and an international accreditor, how would equivalence be assured between them?
- The participation of the private sector would ideally need to be addressed.

*Government model – through Codex*

The Codex Guidelines for the Development of Equivalence Agreements could offer a solution to the limited benefits of the above mutual recognition approach by adding in equivalence agreements on organic standards and by providing a neutral platform for the negotiation of such agreements (see Figure 17). The clear benefit would be the reduction in the number of standards that operators and CABs would have to deal with and one inspection to one standard in one country would suffice for the country of origin and any other country that had signed the Equivalence agreement.

The already existing Codex Standards for Organic Production would offer a good basis for developing such equivalence. The problem as has already been stated is that few national regulations to date have referenced the Codex Guidelines, so there is little common structure to commence the process (see other papers in this series). There would either have to be considerable government will to move standards towards the Codex Guideline or some complicated equivalence judgements would have to be made and continue to be made as standards evolved. However given that there is likely to be common regulatory objectives in many national regulations, equivalence agreements could be reached if all participants focused on essential elements in the spirit of the EU New Approach.

Although the Codex Guideline suggests that this process can occur on a multilateral basis, experience from the models from other sectors above suggest that such negotiation is difficult enough on a bilateral basis. However as has been pointed out above, if initial discussions took place between the EC, the US and/or Japan, other nations would be forced into the system. For many export oriented countries, the priority is gaining access to the EU, US or Japanese markets. This may raise the problem of inappropriate standards being developed for one region solely to comply with the demands of another.

The role of the private sector also remains uncertain in this model although there is no reason why negotiations on equivalence could not involve private sector participation on a country basis. Mechanisms for allowing meaningful participation of international private sector bodies would need to be investigated.

Issues for discussion and clarification:

- What willingness is there on the part of the main three regulatory blocks to move toward more harmonised standards such as the Codex Guideline or the IFOAM Norms?
- Based on the experience from other sectors, it is difficult to see how such a process could commence other than on a bilateral basis given the complicated nature of organic standards and the quite different regulatory environments. This would drag other nations to comply, which is not in keeping with the idea of appropriate regional standards.

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However, the hybrid approach of the Codex Guidelines for the Development of Equivalence Agreements may provide a mechanism by which bilateral or trilateral negotiations may take place within the context of wider transparency and participation by third countries.

- The role of the private sector would again need to be addressed.
- As for the mutual recognition model above, the nature of equivalence of accreditation would also need to be addressed.

### *IFOAM accreditation model*

IFOAM has continuously promoted the IFOAM Accreditation model as a way of facilitating regulated, free trade in organic products. The operation of the accreditation programme and aspects of harmonisation have been described in other papers of this series

The model is international in nature and is based on international technical standards and conformity assessment requirements (the IFOAM Norms) set by IFOAM, an ISO recognised international standards body. The accreditation programme has been operational since 1992. The scheme is currently voluntary, is not officially integrated into the government regulatory systems (although is referenced in some) and operates alongside it as a private guarantee system. Accreditation is performed currently by one international accreditor (IOAS), which is specific to the sector much like the ISTA model.

The advantages of the IFOAM model cited by its proponents are its international nature, its sector specific rules and conformity assessment criteria (an adaptation of ISO Guide 65, similar in approach to the ISTA accreditation standard, based on ISO Guide 25) and its implementation by one international body, the IOAS. This negates the need for mutual recognition at the accreditation level. It also has the ability to operate without the need for local national legislation thus allowing access to markets from exporting countries with less well-developed legislative and institutional infrastructures. Accredited CABs recognize each other as equivalent, permitting the acceptance of each other's certificates as their own. This does not prevent the existence of private certification labels (as discussed above) and in some cases their existence remains as a barrier to mutual acceptance.

The main disadvantage of the IFOAM model is its current lack of integration with the governmental regulatory authorities. The reasons for this lack of acceptance include the following:

- Governments do not recognize the legitimacy of a small sector-specific private organization such as IFOAM to either set standards or operate an accreditation programme within their jurisdictions.
- As a private membership organization where voting members must be significantly involved in organic activities, governments have no say in the setting of Norms or the operation of the accreditation programme.
- IOAS is not part of a peer review system, which provides for the basis of mutual recognition between national accreditors such as in the case of the International Accreditation Forum. Essentially, IOAS is not subject to oversight so there is no check on its operation to internationally accepted norms.
- For operators and CABs, alongside the already heavy and unavoidable burden of the regulations, IFOAM Accreditation is one further obstacle, remains voluntary (not required for government regulations) and is an 'extra' cost.
- International convergence models are based on coordination between national accreditors. IOAS, as an international accreditor is an anomaly. Given this, national accreditors view the IOAS position as monopolistic.

Given the distinct attraction of the ‘one certification, one accreditation’ approach that the IFOAM model proffers, there may well be reward in reworking the model to address some of these concerns.

Looking at the examples of models discussed above, the ISTA model has some parallels and further investigation may assist in addressing the concerns of legitimacy and lack of involvement by bringing government representatives into the IFOAM Accreditation system (see Figure 18). If IOAS were the right vehicle for this process then they would certainly be required to give up some of their independence and autonomy and cede more influence to government and international organisation membership such as is the case with ISTA where FAO, ISO, OECD have a role. Alternatively the role of sole international accreditor played by the IOAS, could be removed so that accreditation would be undertaken by any accreditor using the agreed Norms, although this would negate one of the advantages of the system mentioned above.

Following the ISTA model, governments could designate members (such as certification bodies) and the accreditation system could remain voluntary. Clear benefits could arise from being accredited, as the accreditation once awarded (as in the ISTA system), would essentially be an authorization ultimately from government through designated authorities; legal authorization through a private-public sector collaboration.

Given the strong influence of governments and international organisations in the ISTA system there appears to be no question of the integrity of the ISTA accreditation. National accreditation is generally favoured by the classical standardisation organizations; however, in the ISTA model, this requirement appears to have been dropped in favour of a clear, international, sector-specific accreditation.

Issues for discussion and clarification:

- What oversight, if any, is there over the ISTA accreditation system?
- How exactly does the designation of members, and therefore government participation, operate in the ISTA system?
- What role do the international organizations have in the ISTA?
- How could the current organic situation develop towards such a model?
- What is the willingness of governments to reference such a system in regulations and cede power to an international organization within which they had voting rights?
- What is the willingness of IFOAM to cede power to an international organisation where governments actively participated and where they are likely to yield majority power?

### Standards

#### *Harmonisation to international standards*

The fact that international standards already exist for organic agriculture in the form of the Codex and IFOAM standards suggest that harmonisation based on such standards has some potential. A major problem is that neither of the big three regulated blocks has made much reference to such international standards (see other papers in this series). The other difficulty with organic standards is that regional variation based on agroecology, climate and stage of development will be required so one production standard for the entire world will not be desirable or acceptable. The international standard can only remain guidelines.

*Harmonisation by regional or national equivalence*

IFOAM, as a private membership organization, approaches this issue by designating its Basic Standards as a standard for standards, expecting individual standards to be further developed but nevertheless complying with the Basic Standard as a baseline. As detailed in other papers of this series, IFOAM has launched a mechanism to recognize approved regional standards and the first example was under consideration as of August 2003. Any CAB using such an approved regional variation would be deemed to be in compliance. This process requires an assessment of equivalence, which will of course require updating as both the Basic Standard and the regional variation are amended. The advantage foreseen, however, is that approved regional standards will replace the many private standards that already exist, perhaps resulting in a rationalisation to less than 10 organic production standards around the world all linked by a common international standard. Regional standards would, in a structured and formally approved way, permit variations related to agroecology or stage of development of organic agriculture, instead of the rather blunt instrument of a one-size-fits-all standard set by the biggest importing nation.

Arguments against such rationalisation include claims that innovation and development of standards will be slowed and the tendency will be towards the lowest common denominator. Some private standards setters see standards innovation as a core value and also as a way of differentiating themselves (true organic!) from other programmes.

So far the IFOAM regional variation process has taken place in isolation from the existing government regulations. Whether IFOAM on its own, as a small sector-specific private organization, can gain the legitimacy to liaise with the main regulatory blocks is in some doubt.

The Codex Commission (the other source of international organic standards), on the other hand may well have that legitimacy given that it is an international organization made up of national government representatives, with industry attending as delegation members. The problem here is that as noted above, for a Codex standard to be effective it must be incorporated into national legislation or accepted in some way by the nation states. No nation has embarked on this pathway despite the WTO, ISO, OECD and many nations committing themselves to adopt international standards.

The OECD concluded that ‘the importance of governments’ role in establishing mandatory regulations is greater where a significant public policy goal is concerned, such as health and safety, and protection against fraud’ (specific reference needed). Whether governments see the organic sector as particularly sensitive for any of these reasons is not clear but the potential for fraudulent labelling maybe the reason why governments feel obliged to develop their own rules and maintain sovereignty. If this is a factor then efforts to address this concern are required.

If adoption of Codex based standards by nations commenced, the end result would be similar to the IFOAM regional approach in that fewer standards around the world would exist, linked by a common international standard. This would allow for relatively easy judgments of equivalency. The main difference at present between the two is who is driving (or would drive) the process; private or public sector although the Codex approach also focuses on adoption of national standards based on the international guideline and IFOAM approach may be more focused on supra-national standards.

One way forward may be to combine the strengths of Codex and IFOAM in some forum that would result in one international standard instead of two (see Figure 19). With increased

legitimacy<sup>5</sup> on one side and flexibility on the other, the forum could work further either with the regional variation model or the adoption by nation states to provide a group of linked standards. Existing national or supra-national rules could possibly be adapted as the approved regional variation.

That private standard setters will continue to develop and issue their own standards must be expected. This however can be accommodated if the CABs with 'higher' standards accept products from the regional standard level as equivalent as judged on the basis of the international system so-established. This is likely to be easier politically for a CAB on the basis of an authorized variation of an international standard under the administration of a central international forum than the current situation of minimal coordination and some similarities between organic standards. The alternative would be a return to the current burden of recertification by document review.

Lastly in developing international standards or regional variations, consideration should be given to what is required to be set down in standards, taking a lead from the EU 'new approach'. Over-detailed standards at international or regional levels may impose inappropriate requirements on operators at local level.

In many of the other regulatory convergence models described in this paper, a number of activities such as international conferences, technical working groups, task forces, joint audits and benchmarking exercises are used to engender trust and understanding between the nations involved. Whatever international forum led such a process in the organic sector could appoint technical working groups to review the equivalence of developed standards. Working groups assessments followed by formal adoption by the international body would designate a standard as equivalent.

Issues for discussion or clarification:

- What forum could most appropriately gain the respect of both governments and private bodies, allowing for the development of such a mechanism? This links closely to the ideas expressed above relating to use of the ISTA model in which ISTA also sets the international standard.

Bi and tri-lateral 'harmonisation'

Under the current regulatory systems of the three main blocks, many CABs are currently approved and supervised by each of the three authorities for compliance and operate three separate programmes with modification of standards for each. Such a system is duplication to a high degree even though the objective of providing a rigorous consumer guarantee is an honourable one.

Given the dominance in the organic market of the EU, USA and Japan, bi- or tri-lateral negotiations to converge their various rules (including conformity assessment mechanisms) would make the process of equivalence of standards and perhaps mutual recognition of conformity assessment system much simpler and reduce the inevitable cost, which is ultimately paid for by the consumer and or tax payer.

The problem remains that the current policy of the three main blocks appears to be maintaining the status quo and seeking equivalence (see below). The alternative of harmonising standards

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<sup>5</sup> The legitimacy referred to here is with governments. In fact the IFOAM Norms and the associated accreditation system has its own legitimacy with the market and with CABs, otherwise it would have ceased to exist. So the legitimacy from both Codex and IFOAM can be combined in such a forum.

therefore appears to be too big a political step for those nations with existing regulations. However, as has been reported in other papers of this series, there are numerous nations involved in developing organic rules. Understandably, their priority is to ensure likely recognition by their main markets, so the inevitable tendency is for nations not to look to the Codex or IFOAM international standards (although India recently adopted a national standard based on the IFOAM Norms) but to focus on meeting the EU, US or Japan rules or all three if possible. This reinforces the trend away from international harmonisation on an equitable basis because the detailed nature of these standards may force inappropriate requirements upon an exporting country. Once established however, the inertia to reorient the standard to an international model is great.

Part of the problem rests in the fact that on all sides, the major parties have already established their rules with which they are presumably relatively happy. Everybody wants to harmonise, but everyone wants one-way harmonisation to their own standards.

Again the starting point may be to find a forum with a declared goal within which all (or at least initially some) parties are willing to participate (see Figure 20). The somewhat 'neutral' territory of the UNECE or Codex models do offer some scope, although governments would want to be assured that there would be give and take on all sides. As mentioned previously though, how the private sector enters into this scheme, if at all, is not addressed by either model. Both Codex and UNECE models require governments to initiate the process, which again brings back the question of whether there is interest by governments to reconsider this issue and whether they see protection of their consumers in the organic sphere as only their business or whether they are willing to share that burden with other governments and the private sector in some international forum.

Clearly the three main regulatory blocks have a great influence on the direction of the whole organic industry and any start towards harmonisation must commence with them.

Issues for discussion and clarification:

- Is there political will within the US, EC and Japan to harmonise towards an international standard or will their focus remain on maintaining their current regulations and negotiating equivalence?
- What forum, if any, could bring the US, EC and Japan to commit towards harmonisation?
- Even if some harmonisation took place, there would still be a need for equivalence judgements between nations.

### **Equivalency**

Complete harmonisation is not only hard but in the context of organic standards it is undesirable. This doesn't mean that any attempts to harmonise around an international standard should be abandoned because, as has been made clear in many examples, harmonisation of at least core values facilitates the process of judging equivalence. Equivalency will therefore certainly be part of the solution sought.

The equivalence sought between the three regulatory blocks mentioned have largely taken place without the involvement of the private sector; however if governments are to take the private sector seriously, then some integration or equivalency with the IFOAM system must also be explored. Existing equivalence negotiations have yielded some benefits such as the recognition by Japan of the EU Regulation 2092/91 as equivalent to the JAS law and the similar recognition of the NOP rule. However these equivalence judgements or negotiations are far from transparent and given the frequent changes in all organic regulations, it is not clear whether such judgements are to be updated with time. Also such judgements take considerable time. The NOP rule came into effect in October 2001 and despite considerable discussion between US and EC representatives,

no equivalence agreement is forthcoming two years later. Similarly the so-called Third Country list of the EU Regulation on which countries evaluated by the EC are added if deemed equivalent, was initially considered to be the main route for import. Twelve years after publication, eight countries are on the list but most product enters under the importer derogation referred to in other papers of this series, a process which relies on document review by Member State administrations; a considerable cost.

Issues for discussion and clarification:

- What role do governments see for the private sector in terms of standard setting and approval of CABs?
- Do governments consider that an international ‘clearing house’ forum could reduce some of the regulatory burden on the industry and reduce their own workload and expense on regulating the sector?

### ***Processes needed to build trust***

One of the key lessons learnt from the review of models from different sectors is that harmonisation, equivalence and mutual recognition efforts happen neither quickly nor easily and that trust and understanding must be built up to find solutions. Many activities at many levels and between different actors can contribute to this process and the ITFH is itself one of these activities. Others could include international conferences, one on one meetings, joint evaluations between CABs and between accreditors (including government approval mechanisms), sub-contracting of work (private-private and public-private). Some such events are happening already.

The WANO model may offer some ideas for CABs working in organic agriculture. Many CABs are already members of IFOAM but as a world wide group outside of the IFOAM Accredited CABs, they have no forum for interaction of their own. Within the EU, the EOCC is a lobby group on behalf of European CABs and within some countries (e.g. Italy) the CABs have formed groups to better represent themselves. The IFOAM Accredited CAB group has biannual meetings to discuss issues of mutual interest and to work on better ways to facilitate trade between their clients.

In line with WANO though, some of these activities could be taken a step further involving exchanges of personnel, sharing of databases, harmonisation of standard structures and as used by the IECEE model, common formats for inspection reports.

At the level of accreditation/approval of CABs, the IOAS has, for the last few years, been performing joint audits with national accreditors with a view to better understand each other’s working practices and ultimately to reduce work and cost burden on the CABs. Audits have been performed with observers from government authorities and negotiations with national approval schemes are also ongoing.

These activities need to be expanded and developed particularly between the private and public sectors.

## **Conclusions**

The purpose of this paper was to highlight the mechanisms used in other industries to facilitate regulated, free trade and to highlight those that may be used in the organic agriculture sector. It is too early to say which approaches are appropriate as there remains many issues for clarification,

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not only about some of the models but also about establishing shared objectives amongst the various participants. Agreement that there is a problem and that there may be a better way would be a first step.

It is likely that governments are unlikely to cede responsibility for protection of their citizens to a small, private sector organisation such as IFOAM or even to each other without considerable trust building activities and without the right forum for ensuring participation and impartiality. Finding or establishing such a forum and continuing and initiating new trust building activities may be a second step.

The potential solutions described above make clear that some degree of harmonisation of rules is desirable but that equivalency judgements will be needed to maintain the regional or even national appropriateness of organic standards. Placing those equivalence judgements into the hands of an independent, international organisation which operated transparently may be a third step. Harmonisation and equivalence of conformity assessment procedures should be included here.

Monitoring of the appropriate implementation of those conformity assessment procedures is a fourth challenge and the current options are based either around the national accreditation model with mutual recognition between accreditors based on peer review and/or the international model as demonstrated by ISTA in the seed testing sector and as already implemented in the organic sector as a private guarantee by the IOAS. The role of government approval systems would also have to be addressed. A combination of all three may be possible as long as common rules are utilised and there is some oversight mechanism in place. The solution to this would be a fourth step.

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