

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



UNCTAD
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CONFERENCE ON
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FOOD AND AGRICULTURE
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Discussion Paper

**STRATEGY ON SOLUTIONS FOR HARMONIZING
INTERNATIONAL REGULATION OF
ORGANIC AGRICULTURE**

DRAFT 2

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Abbreviations and definitions

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| Accreditation | Procedure by which an authoritative body gives a formal recognition that a body or person is competent to carry out specific tasks. |
| CAB | Conformity Assessment Body. In the organic regulatory environment more normally called Certification or Inspection Body |
| Certification | Procedure by which a third party gives written assurance that a clearly identified process has been methodically assessed, such that adequate confidence is provided that specified products conform to specific requirements. |
| Codex | Codex Alimentarius Commission of FAO and WHO |
| Codex Guidelines | Codex Guidelines for the production, processing, labelling and marketing of organically produced foods. GL32-1999, Rev.1-2001 |
| Conformity assessment | Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled |
| Equivalence | The acceptance of different standards or technical regulations on the same subject that fulfill common objectives |
| EU Approach | EU model, known as the “New Approach” for harmonization of standards and the “Global Approach” for conformity assessment |
| EU Regulation | Council Regulation 2092/91 (and its amendments) on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. |
| FAO | Food and Agriculture Organisation of the United Nations |
| Guide ISO61 | ISO/IEC Guide 61: 1996 ‘General requirements for assessment and accreditation of certification/registration bodies’ |
| Guide ISO65 | ISO/IEC Guide 65: 1996 ‘General requirements for bodies operating product certification systems’ |
| Guide 17011 | ISO/IEC Guide 17011: 2004 ‘ |
| Harmonization | The process by which standards on the same subject approved by different bodies establish inter-changeability of products, processes and services, or mutual understanding of test results or information provided according to these standards. The process may include the application of identical standards or technical regulations, mutual recognition or determining equivalence (Ref. WTO modified) |
| IAF | International Accreditation Forum |
| ICH | International Conference on Harmonization – Pharmaceutical Industry regulatory mechanism |
| IFOAM | International Federation of Organic Agriculture Movements |
| IFOAM Norms | IFOAM Norms for organic production and processing comprising IFOAM Basic Standards and IFOAM Accreditation Requirements - 2002 |
| IOAS | International Organic Accreditation Service |

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| ISTA | International Seed Testing Association |
| ITF | FAO/IFOAM/UNCTAD International Task Force on Harmonization and Equivalence in Organic Agriculture |
| JAS | Japan Agricultural Standard |
| MLA | Multi lateral Agreement |
| NOP | US National Organic Programme |
| Safe Harbour | US-EC Understanding on the Principles for Data Privacy Protection, otherwise known as the “Safe Harbour Principles” |
| Recognition | Arrangement (either unilateral, bilateral, or multilateral) for the use of results of conformity assessments. (Ref: ISO modified) |
| Requirements for conformity assessment | Any procedure or criteria used directly or indirectly to determine that the relevant technical regulations or standards are fulfilled (Ref: WTO modified) |
| Standard | Document approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method (Ref : WTO/TBT) <u>Note:</u> the recognized body can be any relevant constituency |
| Technical regulation | Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method. (Ref: WTO/TBT) <u>Note:</u> technical regulations can refer to, or be based on, standards. |
| UNCTAD | United Nations Conference on Trade and Development |
| UNECE | United Nations Economic Commission for Europe |
| US-EC MRAs | US-EC Mutual Recognition Agreements |
| WANO | World Association of Nuclear Operators |

Executive summary

This paper proposes a long-term strategic goal for the practical implementation of a harmonized system for regulating the production and international trade of organic products and defines an initial 3-year work plan towards that end. The paper is the result of a process that was initiated in December 2002 by the initiation of the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) established by the Food and Agriculture Organisation, the International Federation of Organic Agriculture Movements and the United Nations Conference on Trade and Development.

The paper summarises the current regulatory environment for organic production and trade, reviews some of the major problems and establishes three main target areas for attention: the rationalisation of organic standards, the rationalisation of conformity assessment requirements and the rationalisation of the approval system for conformity assessment bodies.

Further, using the ideas raised in October 2003, which were again further discussed in a November 2004 meeting of the International Taskforce on Harmonization, the paper defines ten criteria for the assessment of any proposed solutions or model for harmonized regulation. Various models from other sectors previously investigated by the International Taskforce on Harmonization were evaluated against these criteria and several models (Codex Equivalence, UNECE, ISTA and IFOAM) appear to be worthy of further investigation, although aspects of others should not be discarded at this stage.

Based on this review, a long-term strategic goal was defined made up of the following components:

- the use and adaptation of existing structures and mechanisms of regulation, both private and public sector (the idea of establishing a new international entity was rejected at this time);
- production standards equivalent to a single international standard;
- one international requirement for conformity assessment ;
- common international procedures for approval or accreditation of conformity assessment bodies which reduce duplication of work and enhance access to markets including by countries in which regulatory infrastructure is absent or less well developed.

An initial work plan is presented, the results of which should be reviewed and redirected towards the end of 2007.

Introduction

This paper represents a further step in the development of proposals on harmonization of the regulation of production and trade in products from organic agriculture. The process was initiated by the establishment of the International Task Force on Harmonization and Equivalence in Organic Agriculture in December 2002. Annex 1 provides further detail of the overall objectives of the task force. At a first meeting of the task force in February 2003, an initial work plan was established which resulted in the preparation of five baseline papers:

- Commins (2003) reviewed the current status of existing international standards, regulations and private organic standards and both the current regulatory and private conformity assessment systems. It therefore provides an objective starting point for our discussion.
- Bowen (2003) described the current mechanisms, both public and private that enable international trade in organic products highlighting the differences between the various systems.
- Wynen (2004) provided an initial analysis of the potential impact of increased harmonization of regulation on the trade in organic product. Looked at it in another way, it discusses the cost of the lack of harmonization.
- Courville & Crucefix (2003) investigated and described potential models for regulation of other industries and reviewed and raised issues over their appropriateness for the organic sector.
- Arvius - Swedish Board of Trade (2003) presented a review of the obstacles to organic trade with special reference to the European Union and made recommendations for amendments to EU Regulation 2092/91

The first four papers were published in a compiled volume along with the reports of the first two ITF meetings (Michaud, Wynen & Bowen, 2004). All the above papers were reviewed by a follow-up meeting of the ITF in Geneva in October 2003.

This document attempts to build on these papers and the discussion on them at the Geneva 2003 meeting and to chart a course towards finding solutions to what is perceived as a lack of harmonization in regulating the organic sector. It aims to:

Summarise:

- the current situation
- the problems experienced, and
- the harmonization tools available

and then

- Establish criteria for assessing potential harmonizing models,
- Perform an initial analysis of likely models
- Recommend best options where possible
- Develop an initial work programme to lead towards a final workable harmonized model

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This paper was first amended following a comment round in early 2004 and then further discussed at a meeting of the ITF in Rome in November 2004. The document has been further updated to account for the comments and proposals agreed at that meeting. A separate report of that meeting has been prepared (ITF, 2004) and may be referred to for background on the discussion and finalising of priorities and direction.

1 Starting point

1.1 Current situation

Although growing and manufacturing of ‘organic’ products takes place without formal certification, the globalisation of the organic market has led to the situation that an organic product cannot be sold in major markets unless it is certified. Likewise there exists models of organic regulation that are variously called ‘peer’ or ‘participatory’ which do not involve third party inspection, but these are not the norm¹. There is then general agreement that an organic regulatory system is made up of four parts:

- Producers or operators – who actually produce the organic products
- Inspection bodies or conformity assessment bodies – who verify that the producers follow the rules
- An approval and supervision system, usually either a government department or a private/governmental accreditation body or a combination of these – which accredits or verifies that the conformity assessment bodies are competent and work consistently.
- A labelling system which is the practical result of all the above, which indicates to the buyer that a product has been produced and approved in compliance with the above mechanisms.

The various participants are guided by various sets of rules as follows:

- A production standard with which the farmer or producer must comply;
- A guideline or requirement for certification with which the third party inspection body must comply
- A guideline or requirement for approval/accreditation with which the approval or accreditation body must comply
- A labelling requirement

Despite this common overall structure, a number of models have evolved.

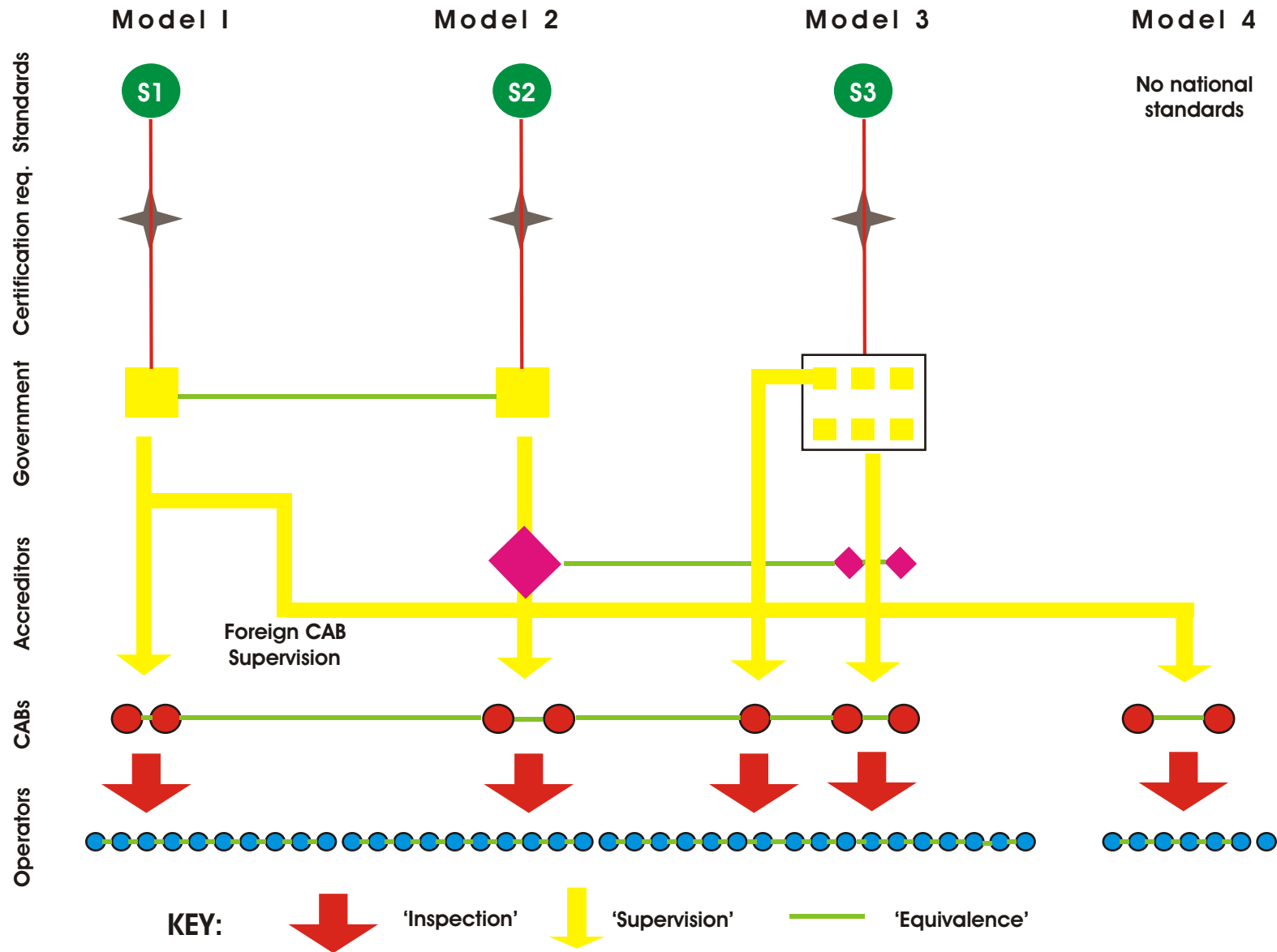
To help visualise the various models more clearly and establish our starting point, Figure 1 and Figure 2 summarise the current public sector and private sector organic guarantee systems as described in Commins (2003) and Bowen, (2003). For background, these are briefly described below.

1.1.1 Public sector models

Figure 1 demonstrates four public sector models (though there are a number of further variations), which are evident today. Models FIII are set in a framework of government legislation providing a typical structure, which can be related to the general one above:

¹ The Rome ITF meeting in November 2004 agreed that such peer review systems should not be discarded and may have a role in the future with particular respect to lowering the cost of regulation. The same could be said also of mechanisms of Self Declaration of Conformity, which was also raised during that meeting. It was however accepted that third party inspection systems have become the norm in organic agriculture and this must at least remain the starting point.

Figure 1 Diagrammatic representation of current public sector models regulating the organic sector



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- national production standards and labelling requirements (the green circles – S1, S2 etc in Figure 1),
- requirements against which conformity assessment bodies operate and can be assessed (the stars in Figure 1) and
- a government approval system for the conformity assessment bodies or CABs (the yellow squares in Figure 1).

All models have developed somewhat separately. In model IV, no such legislation exists and to date there may be no government interest in regulating the sector (and therefore it is not strictly a public sector model but is included here for completeness). Model III is a group of states governed by common legislation and we have in mind here the European Union in which harmonization is encouraged by the single market but implementation is performed at the Member State level.

In all four models, organic producers are inspected by conformity assessment bodies (CABs). These may be private sector organisations (USA, Japan and most Member States of the EU), part of, or related to government (Denmark, Czech Republic, Estonia) or a mixture (Spain). These CABs may either act solely as inspection bodies (not setting standards themselves) utilising the national or regional standard or may set private standards themselves. The conformity assessment bodies are normally approved by government (eg. Model I – however where the government is itself the CAB, there is generally no approval or oversight process) but written into the legislation may be the need for accreditation, (in the European Regulation, to Guide ISO65, a generic (ie not specific to organic certification) guide of the International Organisation for Standardisation) which is performed by the national accreditor – Model II. Where formal accreditation is active, equivalence of the work of the accreditors is governed by multi-lateral recognition agreements (MLAs) between accreditation bodies involving peer review visits. This latter peer review system functions under the auspices of the International Accreditation Forum or related regional entities such as European Accreditation.

In most countries, accreditation (rather than government approval) is optional and in fact a CAB may voluntarily undergo a private accreditor audit in addition to an audit by a government office. In still others a regional government structure may also impose its own requirements. In Italy for example, CABs are supervised by regional government offices, the Ministry of Agriculture and in addition many CABs have opted to undergo voluntarily, accreditation against Guide ISO65. Government approval systems generally range from a document audit only to full annual physical audits as would be done by accreditors. In model IV where there is no national approval system, one might find CABs approved by a foreign government or accredited by a foreign accreditor (and/or by the private system described below). CABs operating in such circumstances must obtain as many individual approvals as is necessary to satisfy their client's (the organic producers) need to access export markets.

Once individual government mechanisms are established, equivalence with other government systems may be sought or export countries may apply for approval. Through equivalence agreements or attaining approved status, CABs, and in turn their certified producers, may recognise product as equivalent and products may be traded. The green lines in Figure 1 represent recognition of equivalence. Such overarching recognition may not be available for all required trade routes, as is the case for the European Union where the majority of products still enter under Article 11(6) as described in Arvius – Swedish Board of Trade (2003). For fear of complicating the scheme in Figure 1, this mechanism has been omitted and is merely indicated as a gap in equivalence between CABs and by implication between operators.

Proponents of such government mechanisms argue that governments are obliged to protect their producers and consumers and only through government regulation can this be achieved. Private systems might be viewed by some as self-interested and lacking in rigour and the full force of the law.

1.1.2 Private sector model

The private sector mechanism (see Figure 2) was established by the International Federation of Organic Agriculture Movements, an international membership organisation of producers, traders, non-government organisations, researchers, conformity assessment bodies and consultants. The mechanism is made up of the same basic components as the public sector systems:

- international basic reference standard including labelling requirements (IFOAM Norms)
- international certification requirements against which a CAB is assessed (IFOAM Norms) and
- evaluation of CABs is performed by one organisation (International Organic Accreditation Service),

Proponents of the IFOAM Organic Guarantee system suggest that the international nature of the model and the reference to single guidance documents at each level avoids the need for equivalence negotiations or peer review between national accreditors. CABs recognise the equivalence of other accredited CABs on the basis of their accreditation, which permits organic producers supervised by the various CABs to trade freely.

1.2 The problems

The public and private sector systems work alongside each other and to some extent duplicate each other, as there is a lack of formal recognition (in both directions) between the two systems.

The five papers prepared for the Geneva 2003 ITF meeting indicate some of the problems with the current way in which the trade in organic products is regulated. Figure 3 attempts to summarise the problems identified in the papers and in the record of further discussion in Geneva 2003 and links them in a problem tree.

It can be argued that both public and private sector systems leave room for improvement in the way in which they serve the sector.

The public sector systems impose different requirements at both organic producer level and at the level of the CABs resulting at worst in multiple inspections and evaluations, and at best in reassessment of reports by different authorities. Claims of inconsistency in the way in which production systems and products are approved by different authorities are, whether true or not, likely to continue whilst different rules and procedures apply on the one hand, and whilst even unified rules may be interpreted differently by different authorities.

The private system is 'weakened' in some instances by the additional standards requirements imposed by some 'importing' CABs which leads to extra verification checks being required (represented as a break in the green equivalence links between one CAB and its operators

Figure 2 Diagrammatic representation of the private sector model (IFOAM Accreditation) regulating the organic sector

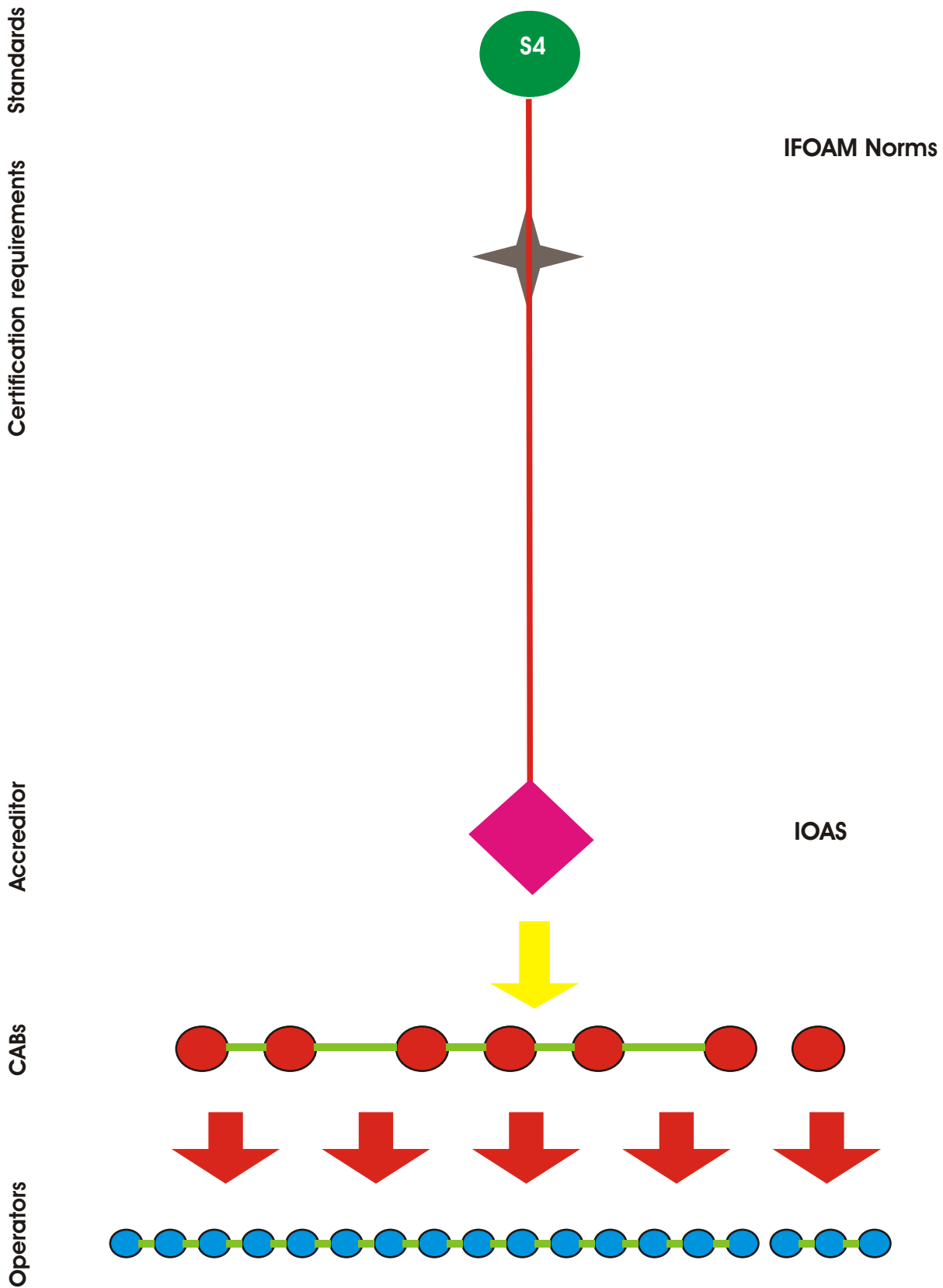
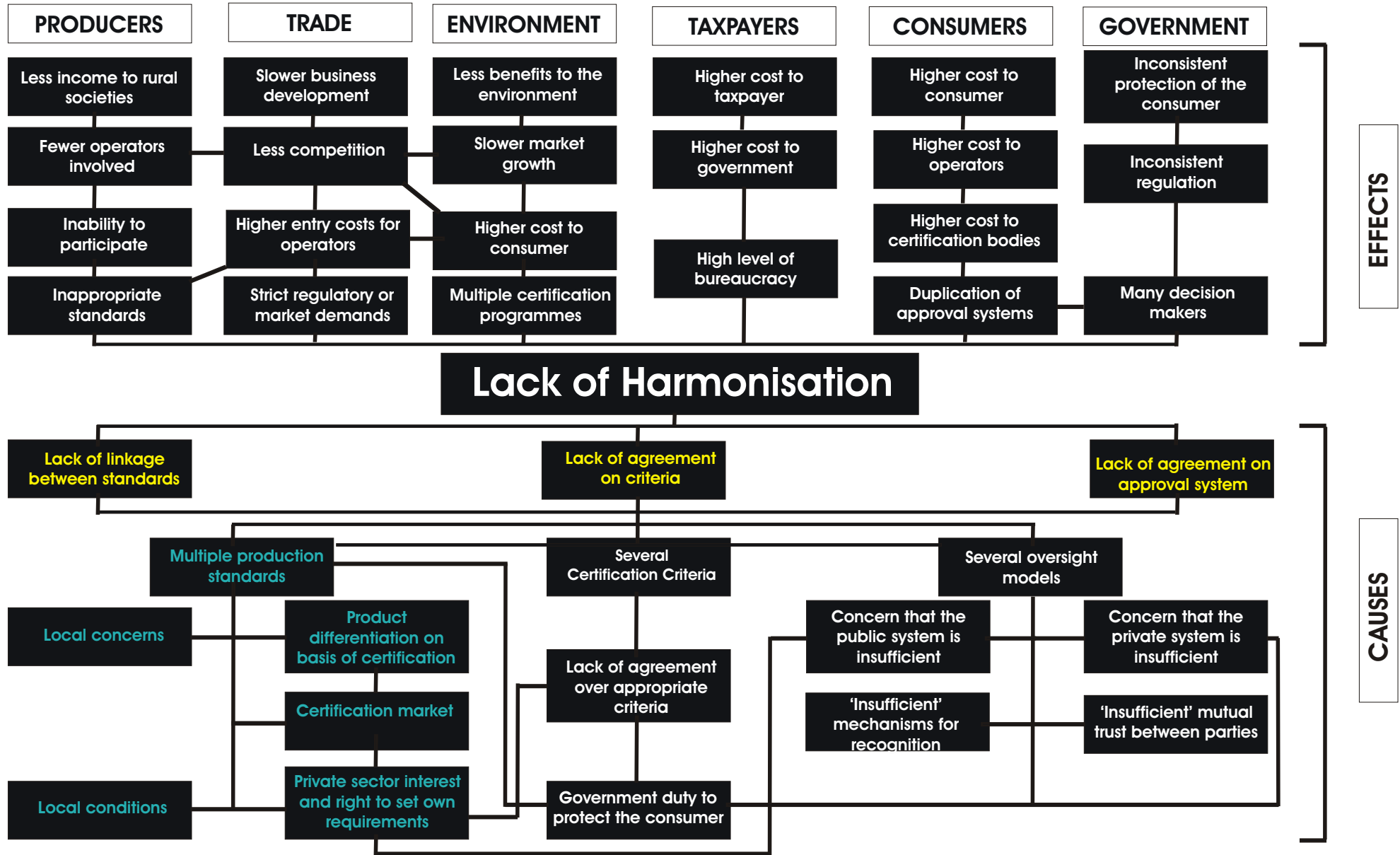


Figure 3 Summary of problems relating to trade in organic products represented as a problem tree



with the others in Figure 2). The IFOAM Accredited certifier group is reported to be working to eradicate such extra requirements, some of which are said to be required to comply with legislation. In addition, in some markets, the power of the private labels is such that even though legal access is possible without entering via the local private label, the latter remains the preferred option from a market acceptance viewpoint (see further discussion of private labels below).

The core problem in the centre of Figure 3 is designated 'Lack of Harmonization' with 'causes' below and 'effects' above. The 'affected sector' (producers, consumers etc) is indicated at the top of the diagram and it demonstrates the ultimate spread of the impact of the problems.

The diagram should be viewed primarily as an aid to visualising the problems and, broadly, their origins and effects but is unlikely to be complete. The evidence for stating a problem and its impact are currently based on common knowledge and experience rather than hard data. This lack of data on the impact of 'lack of harmonization' was also a problem in the preparation of the paper by Wynen (2004) and reference should be made to this paper for further detail. The collection of further data is likely to form part of the future work plan.

Nevertheless the message of this diagram is that there are three principal causes of problems shown in yellow text in the figure:

- lack of agreement, linkage or equivalence on standards;
- lack of agreement or equivalence on certification requirements;
- lack of agreement or equivalence on the CAB approval/accreditation mechanism.

The result suggested is that we have a higher cost and more burdensome regulatory system than is necessary achieving less than consistent results.

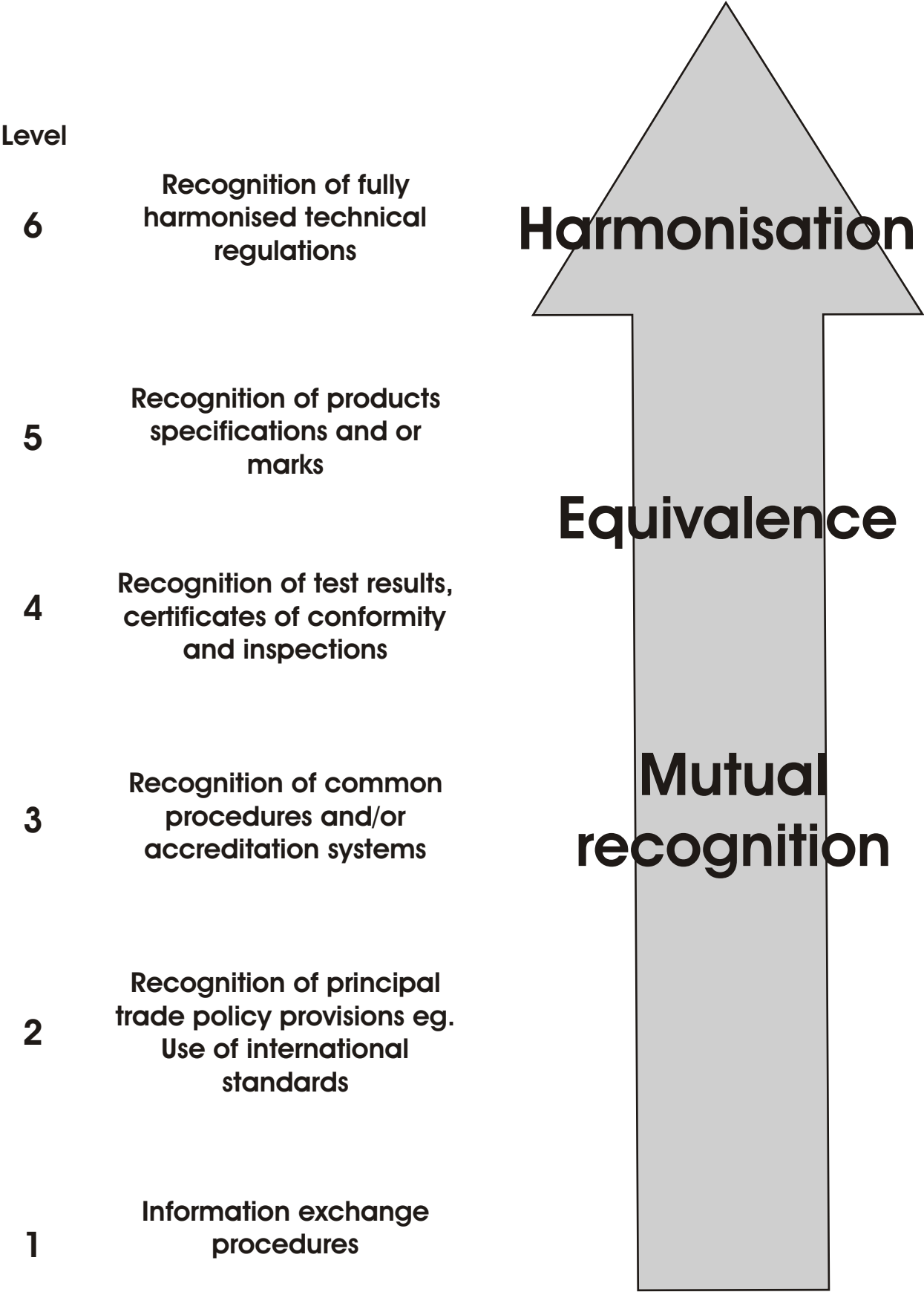
1.3 Harmonization tools

The box of tools available to us in harmonizing regulation of the organic sector was described separately in the papers by National Board of Trade (2003) and Courville & Crucefix (2003). Figure 4 adapts and combines this analysis.

Level 6 represents a high degree of harmonization, perhaps where all organic producers work to a single organic standard and where the CABs are approved by a single authority against the same certification requirements. Such a system exists under the National Organic Programme in the USA. The CABs operating in the USA (and overseas) act essentially as 'agents' of government operating a conformity assessment system, which must comply with NOP rules and in their turn, the organic producers must also comply with all details of the NOP production rules.

The US National Organic Programme also incorporates mutual recognition in that it 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.

Figure 4 Harmonisation tools
(adapted from National Board of Trade, 2003 and Courville & Crucefix 2003)



International Task Force on Harmonization and Equivalence in Organic Agriculture

Multi lateral agreements function between national accreditors under the auspices of the International Accreditation Forum, which provide for a mutual recognition of competence in performing the accreditation work. In turn this permits conformity assessment bodies and authorities to trust surveillance performed by signatories in other parts of the world. This may not lead to product equivalence given that standards assessment does not form a part of traditional accreditation evaluation.²

The active multilateral agreement between IFOAM Accredited certification bodies is based on accreditation by IOAS to common baseline standards and conformity assessment requirements. This is an equivalence agreement based on a strong harmonization component in which each CAB can accept other's certificates as equivalent. The fact that IFOAM Accreditation includes an assessment of organic standards as well as certification requirements provides an additional level of confidence in terms of product equivalence.

So it is clear that various harmonization tools are already being used in organic regulation and in any one system, a number of tools are being used. The higher up the arrow in Figure 4, the greater the convergence of procedures and standards and the greater potential simplicity of the system. It should however not be assumed that level 6 is necessarily the ultimate goal.

² Accreditation to Guide ISO65, for example, is an assessment of competence to perform certification to a reference standard identified by the client CAB. The evaluation assesses that the CAB has the capabilities to interpret and certify to that standard, but it does not assess the standard itself. In IFOAM Accreditation, an assessment of the chosen organic standard is performed against the IFOAM Basic Standard.

2 Considerations in finding long term solutions

2.1 Background

The meeting of Geneva 2003 included a brainstorming session to bring out potential solutions to the stated problems bearing in mind the tools available and focused on an overall model and the assumed components of such a model;

- governments/regulations,
- private standards,
- conformity assessment requirements,
- certification and
- accreditation.

The main points raised are summarised and structured as Figure 5.

The issues indicated are a mixture of **requirements** of the model (e.g. transparency), **recommendations** (e.g. that Codex Guidelines could be the reference international standard) and **question marks or alerts** (e.g. private labels). The diagram again helps us to visualise the potential components of a model that we will have to consider and their inter-relationships. The main points raised are summarised here but it must be realised that this does not necessarily imply agreement of the meeting on an issue or course of action.

Under **Regulations** the meeting raised the issues of requiring more flexibility and less detailed requirements and considered reference to Codex, IFOAM Norms and Guide ISO65 to be desirable.

When considering **Standards** the meeting recognised the existence of private labels and government sovereignty and raised again the issue of flexibility in relation to stage of development of organic agriculture in different parts of the world whilst maintaining fair competition.

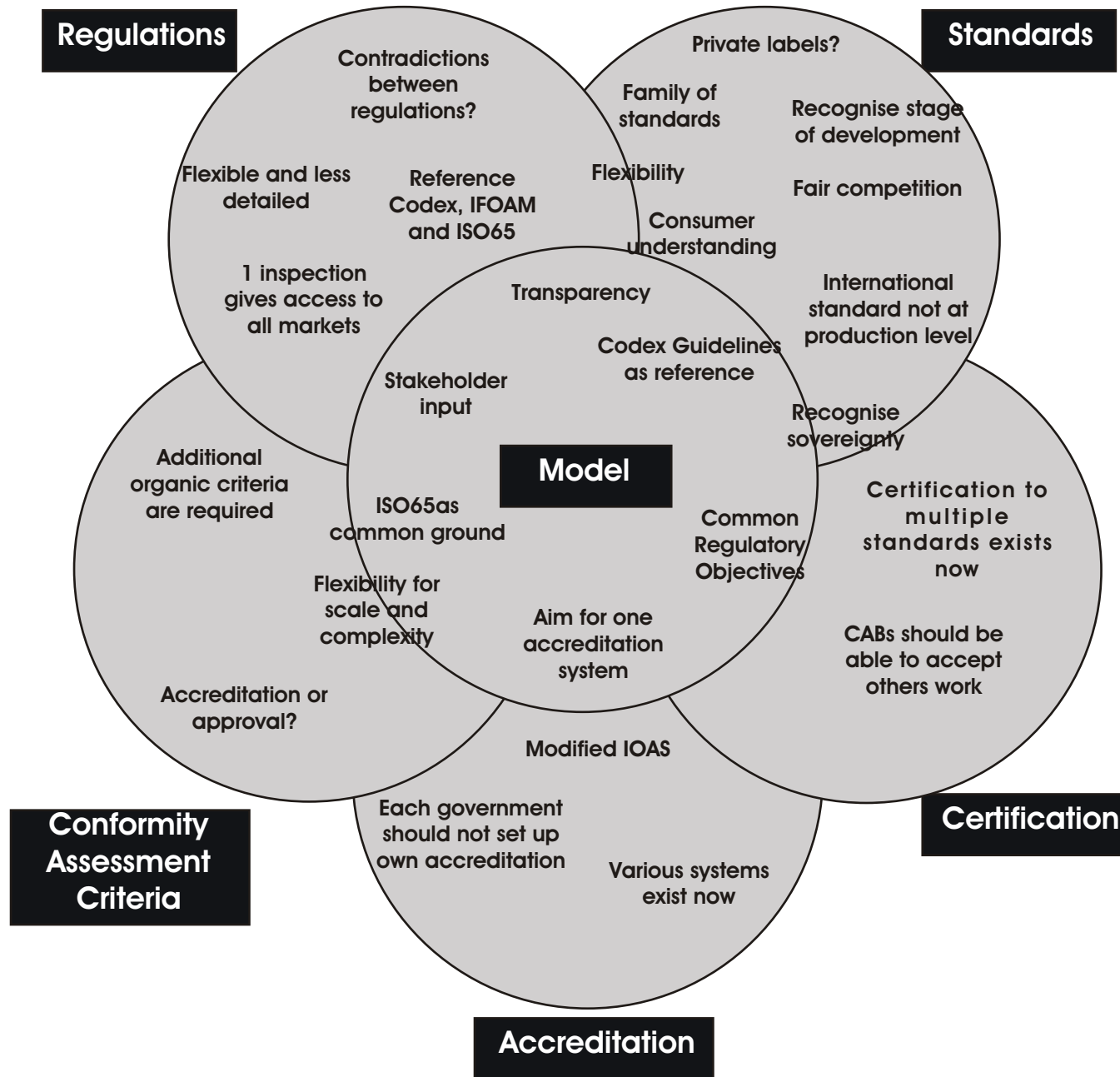
Multiple **Certification** was seen to already exist where CABs conduct one visit checking against a number of standards. The desire that CABs should be able to accept each other's work was also expressed; one inspection, all markets was a consistent desire expressed.

On considering **Conformity Assessment Requirements** the meeting again raised flexibility appropriate to scale and complexity, whilst recognising some common ground provided by Guide ISO65³ but also the need for additional 'organic' requirements such as are expressed in Annex III of the EU Regulation 2092/91 and as in the IFOAM certification requirements.

Under **Accreditation (or Approval)** the view was expressed that it does not make sense for each government to establish its own approval system, that various models exist now and that a 'modified' IOAS (an international accreditation model) could be a solution.

³ Although it is only the EU Regulation 2092/91 (Article 9.11) that directly requires that inspection bodies satisfy the requirements of EN45011 (ISO65), the US National Organic Programme requirements for CABs (expressed in subpart F) are based on ISO65 requirements.

Figure 5 Summary of issues and solutions raised during the brainstorming session of October 2003



Finally, in bringing these various deliberations towards an ultimate **Model**, the October 2003 meeting prioritised issues of working with a common international standard and common requirements for certification and developing one accreditation system, which could be established with stakeholder input and with transparency.

To take the problem analysis of Figure 3 further and compare issues with the discussion of Geneva 2003, some of the causes of the problems, like multiple standards, are perhaps a fact of life that we have to live with. This is highlighted (in red) in the lower left hand corner of Figure 3. The ITF discussion to date has already noted that ‘local production conditions’ (that is, the need for regional standards) are an accepted aspect of organic agriculture and something we have to work with, rather than eradicate or resolve. ‘Local consumer concerns’ are another issue though perhaps a little more complex.⁴

The issue of multiple standards and equivalence also relates to the level of detail in an international standard and there appears to be some broad agreement that any international standard must focus on core issues and avoid detail, the detail, if needed, being defined by regional or national standards; hence the ‘family’ of interrelated standards noted in Figure 5.

Another, ‘fact of life’ might be the right for private bodies to set their own standards and the right and duty of governments to impose legislation to protect consumers. Though they may give rise to problems (ie multiple unrelated standards), they need not be problematic in themselves and may be seen in a positive light (private standards are flexible and generally apply pressure upwards whereas legislation can provide a useful backdrop of enforcement). The problems they give rise to must be dealt with, but we cannot deny either governments or private bodies to act in this way.

Putting these issues to one side for now and focusing on the remaining issues, we can rationalise our problem tree into a more simplified version in line with the model discussion in Figure 5 and amend the problems to positive objectives and outcomes as shown in Figure 6.

The core problem has become our core objective of ‘Increasing Harmonization’ and this is made up of three main objectives:

- rationalising standards,
- rationalising certification requirements and
- rationalising CAB oversight models.⁵

The objectives remain purposefully wide ranging at this point in time, as it would seem wise not to narrow our options to exclude any possible solutions. Each one of these components can be dealt with using different harmonization tools and could be placed at different levels in

⁴ For example, citizens in one market may consider that organic milk must come from grazing cows. In another where this approach to land use is not customary, the market may not have such an expectation. The question is how one citizen’s expectation be rationalised with that of the other. If a respected international regulatory mechanism was able to state transparently that it was justified for producers in one country to keep ruminants without grazing access on the basis of sustainable land use, whilst in another that access must be provided, the question is, would the consumer be satisfied? Aspects of consumer acceptance are the subject of the planned work of the ITF and are raised in the work plan proposed later (Action C3).

⁵ We could add here a fourth objective, that of rationalising labelling and there may well be some interest in that. However, for now this is left to one side as it depends fully on the achievement of the previous objectives. It is however indicated in the final model in Figure 7.

Figure 6 Final simplified objective tree

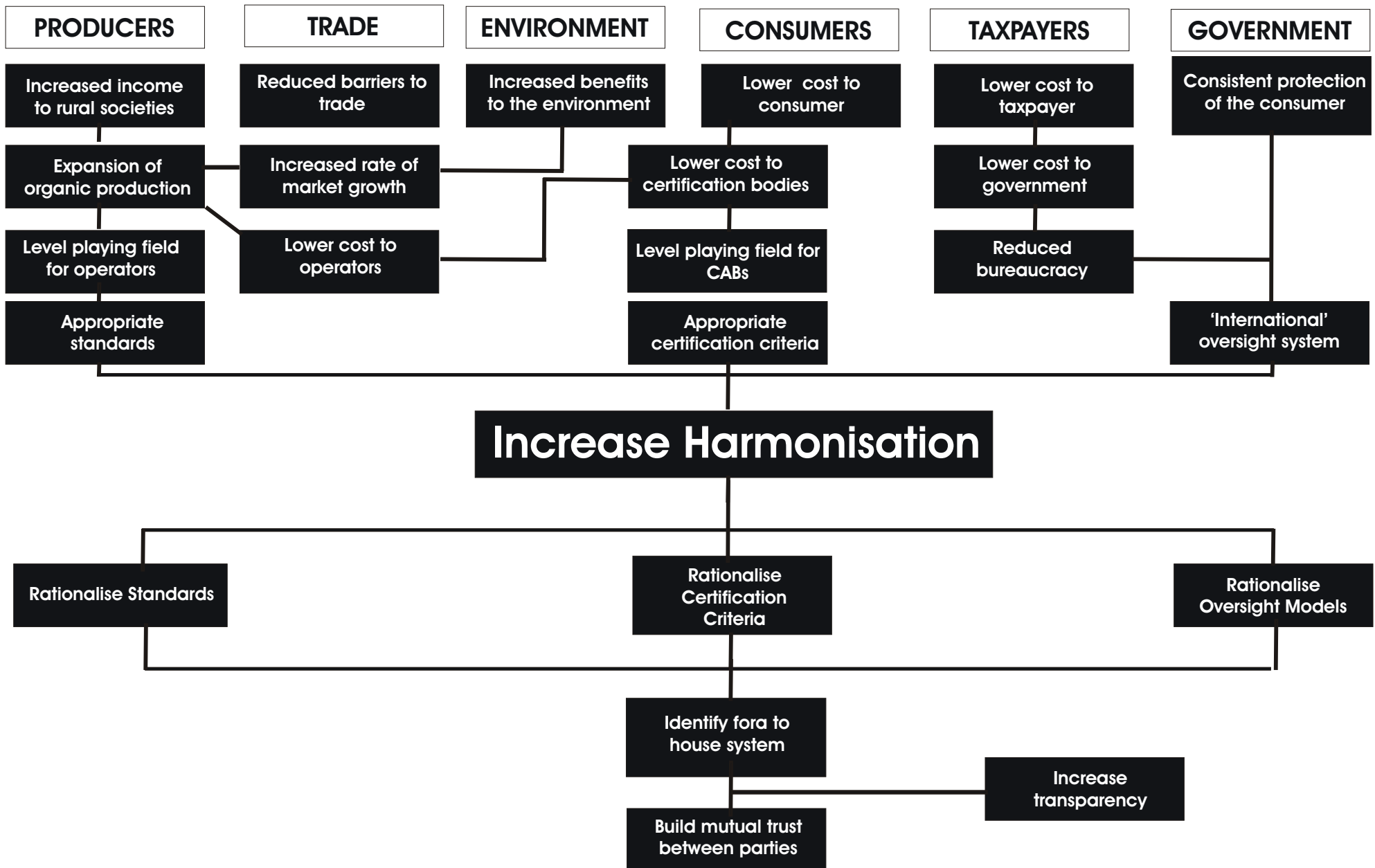


Figure 4.⁶ However a critical phase in initiating these first steps is likely to be building trust between participants and increasing transparency as indicated in the lower part of the figure.

2.2 Criteria for the assessment of solutions

With these broad goals identified we need to not only refine them but also consider what model or combination of models might achieve them. Reviewing the problems defined, the solutions raised in the discussion to date, the tools available and the characteristics of the organic trade described by Courville and Crucefix (2003) it is possible to propose the following broad requirements for the development and implementation of a harmonized regulatory system in the organic sector.

Overall the model should:

1 *Provide for continued growth of organic agriculture and maintenance of its principles.*

but more specifically be guided by:

2 *Access to markets with minimal bureaucracy*

The model should aim to provide access to all markets based on one inspection and as far as possible one certification decision. This is a common and expected aim of most harmonization efforts from which flows the need that the standards, inspection procedures and oversight can be seen to be the same or equivalent. By this means the model should remove unnecessary technical barriers to trade and in addition should in part reduce duplication of effort in rule setting and decision-making

3 *Fair competition between operators*

This is another essential and expected criterion that should guide the development of a harmonized model. Although this is a common aim, its achievement in bi- and tri-lateral agreements is limited only to the participating countries or bodies. If our aims are to provide for fair competition amongst operators across the world, then bi- or tri-lateral negotiated agreements would seem inadequate. On the other hand bi- or tri-lateral agreements may be seen as a practical way of proceeding in the absence of a broader agreement.⁷ The Rome ITF meeting emphasised that 'fair' should mean level playing field and not be allowed to lead to protectionist measures.

4 *Adequate and consistent consumer protection and trust*

This is a basic objective with the same limitations in relation to bi- and tri-lateral agreements.

⁶ Are we thinking of harmonization around one standard or considering equivalence for example?

⁷ There are a number of factors that affect competition that are outside the scope of this paper but which are nevertheless relevant to a discussion on fair competition. The initial and ongoing payments to EU farmers converting to organic farming can be argued to distort any idea of fairness. They may also distort what is reasonable and unreasonable to require in terms of organic production rules.

5 *Sensitivity to different biophysical, socio-economic environments*

This requirement addresses the need not only for sensitivity to different agricultural environments but also to stage of development of organic agriculture (which impacts on production standards), and to the institutional, legislative and economic situation of any country which in turn may impact on control systems and oversight. For example any model that required for its functioning, full legislation on organic agriculture and labelling in each territory would immediately exclude a good many participant countries. The third country recognition procedure of the EU Regulation is an example of this problem and the recently published EU Action Plan for Organic Food and Farming recognises this (European Commission, 2004).

6 *Stakeholder support and involvement.*

The issues of mutual trust and feelings of engagement are important here. Like it or not there are feelings of mistrust between private-private bodies, private-public and public-public bodies involved in the regulation of the organic sector. Additionally there exists the dominance of the import markets over the export suppliers. If a new regulatory model is to be truly respected by producers, private control bodies, governments and consumers, it must seek involvement from all such parties.

7 *Take account of national sovereignty and market choice*

Governments have a responsibility to serve and protect their constituency and this must be respected. Likewise there is a legitimate place for private companies to provide certification services, which may involve the setting of higher standards if there is a demand for such a service, or for buyers (whether at consumer level or trade level) to insist on higher standards to be met. At present this results in 'barriers' to trade. A new regulatory model must address this anomaly.

8 *Transparency of operation and decision-making*

Maximum transparency of operation and decision-making and provision of information is required to engender mutual trust and respect for any objective regulatory system.

9 *Led by principal trade policy provisions*

The WTO/TBT principles of reference to an international standard and recognition of equivalence where similar objectives are being met will be central to the establishment of a new regulatory system.

10 *Benefit to producers and consumers and the organic market as a whole.*

The regulatory systems' principal clients are the organic producers and consumers. All other participants may be important components, whether government or private sector control or accreditation bodies, but they are, in the end, just service providers.

2.3 Review of models against criteria

This section reviews the models described by Courville & Crucefix (2003), in the light of the above criteria, assigning a crude scoring system. The reader is referred to their paper for

background discussion of the models. The IFOAM Accreditation model is also reviewed as an existing international model in the organic sector.

We are seeking an international mechanism and not all the models are fully international in nature. Although the individual models may, as a result, be marked down in certain circumstances, this does not mean that components of such models may not be of interest. However this scoring process allows us to pinpoint an initial ‘best fit’ which may be the focus of initial investigation.

The overarching criterion (which was added at the Rome ITF meeting) of providing for continued growth of organic agriculture and maintaining its principles was not considered here given its specificity to the organic sector.

The general policy provisions as expounded by the WTO/TBT are included as a general guide to the process and the WTO ‘model’ is also therefore not reviewed in itself. Table 1 provides a summary of the review, which is described in more detail below.

1 Access to markets with minimal bureaucracy

The principle of access to markets with minimum regulatory burden is embodied in all the models except the WANO model in which this aim is not relevant. The bi- and tri- lateral models of the ICH, the US-EC Safe Harbour, the US-EC MRAs and the EU new approach are marked down to partial fulfilment on the basis that the access is limited to the parties involved and not to the rest of the world. The Codex, UNECE and ISTA models score well as, in theory, these models are open to all who participate. Additionally they are based on an international standard rather than rules negotiated between several parties as in the ICH and rules set by one party in the Safe Harbour and the US-EC MRAs. The IFOAM model is marked down on the basis that it does not in practice provide access to all markets although this has more to do with its lack of acceptance by authorities than any mechanistic problems.

2 Fair competition

Most models set out to achieve fair competition between producers although once more this is not really an objective of the WANO system. The international models are again given higher scores for the reason that less than all-inclusive models cannot achieve fair competition for those not involved.

3 Consumer protection

Similar scoring is achieved to fair competition for producers although the WANO model can also be included as this is surely the intention of this model.

4 All environments

This criterion receives the worst scores over all models principally because the bi- and tri- lateral models described require participants to provide similar institutional facilities. Such a requirement may for example require the existence of a manufacturers association or a government department responsible for trade and consumer protection. The lack of such institutions either excludes or makes negotiations difficult. The Codex and UNECE models however are also limited to working through governments and not all governments may currently view engaging in negotiations for equivalence for organic products as of sufficient

priority, leaving producers in those countries with access problems. Both ISTA and WANO receive positive scores here because of their relative independence from these ‘environmental’ factors.

5 *All stakeholders*

The pattern of scoring for involvement of all stakeholders is similar to that for environments above. It would be unfair to award low scores to those models other than ISTA and WANO as most models do attempt to address both public and private sector concerns. Bi- and tri-lateral agreements are marked down for lack of geographical coverage and Codex and UNECE are marked down because of the emphasis placed on governments.

6 *Take account of sovereignty and market choice*

National sovereignty is respected in all cases and this is interestingly achieved nevertheless in the models of WANO and ISTA, which emphasise more the private sector. This seems to be achieved through government involvement.

7 *Transparency*

This has been judged on the basis that transparency is provided where standards and procedures are published and publicly available which in most cases they are.

8 *Benefit to participants*

The scores here mirror those for fair competition and consumer protection as might be expected. Participants in this context refers to potential not actual, therefore regulatory mechanisms that have limited participation do not score as well as open participation models.

In summary, the Codex, UNECE, ISTA and IFOAM models score most promisingly. The various models exhibit some or all of the requirements emerging from our earlier analysis as follows:

- an international arbiter or oversight body
- stakeholder participation and transparency
- involvement of international organisations and governments
- one international rule set
- one international operating requirement set

Table 1 Evaluation of various models of harmonization against the proposed criteria⁸

| Criteria | ICH ⁹ | Safe Harbour ¹⁰ | Codex ¹¹ | US-EC MRAs ¹² | US-EC Marine ¹³ | UNECE ¹⁴ | ISTA ¹⁵ | WANO ¹⁶ | EU approach ¹⁷ | IFOAM Accreditation |
|-----------------------|------------------|----------------------------|---------------------|--------------------------|----------------------------|---------------------|--------------------|--------------------|---------------------------|---------------------|
| Access to all markets | --+ | --+ | + | --+ | --+ | + | + | NR | --+ | --+ |
| Fair competition | --+ | --+ | + | --+ | --+ | + | + | NR | --+ | + |
| Consumer protection | --+ | --+ | + | --+ | --+ | + | + | + | --+ | + |
| All environments | - | - | - | - | - | - | + | + | - | + |
| All stakeholders | --+ | --+ | --+ | --+ | --+ | --+ | + | + | --+ | + |
| Respect sovereignty | + | + | + | + | + | + | + | + | + | + |
| Transparency | + | + | + | + | + | + | + | - | + | + |
| Benefit participants | --+ | --+ | + | --+ | --+ | + | + | --+ | --+ | + |

⁸ Key: - Not provided for --+ Provided for in part + Provided for NR not relevant by or to the model reviewed

⁹ International Conference on Harmonization within the pharmaceutical sector with main actors being the US, EU and Japanese pharmaceutical sectors.

¹⁰ US-EC Understanding on the Principles for Data Privacy Protection

¹¹ Codex Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems

¹² US-EC Mutual Recognition Agreement covering six sectors: telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices and pharmaceutical good manufacturing practices.

¹³ US-EC Mutual Recognition Agreement on Marine Equipment

¹⁴ United Nations Economic Commission for Europe International Model for Technical Harmonization based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the use of International Standards.

¹⁵ International Seed Testing Association

¹⁶ World Association of Nuclear Operators

¹⁷ EU 'New Approach' for harmonization of standard and the 'Global Approach' for conformity assessment.

3 Long Term Goals and Strategies

It was originally proposed in this document that the long-term strategy for a new international regulatory mechanism for organic agriculture and trade adapts a model based on that of ISTA and/or IFOAM utilising the neutral territory offered by the Codex and UNECE models where possible. No doubt these models will still contribute certain aspects to a future harmonized system. However during the Rome ITF meeting, it was generally agreed that the solution must develop based on existing mechanisms within the organic sector, both public and private, rather than construct a new infrastructure and institutions.

The model should be designed to meet the criteria expressed in section 2.2 above through structures and mechanisms that provide for:

- production standards equivalent to one international reference standard;
- one international requirement for conformity assessment; and
- common or equivalent accreditation/approval mechanisms.

These have been seen as common characteristics in the models reviewed above that scored most highly against the established criteria. In more detail, the following characteristics of a harmonized system are proposed:

3.1 Production standards

3.1.1 An international set of basic standards agreed and maintained by an international forum with input from all stakeholders. This standard may be the existing Codex Guideline, the IFOAM Norm or possibly an amendment of the two.

3.1.2 This guideline standard should avoid too much detail and embody the ‘common regulatory objectives’ or the essence of ‘organic’ rather than the detail;

3.1.3 National governments could either reference the international standard in legislation or set their own national standard ideally following the format of the international standard. How this might be implemented needs some investigation.

3.1.4 Private standard setters within the jurisdiction of the legislation would be assessed to meet these standards but higher standards would be permitted.

3.1.5 To aid transparency, a common standards format might be agreed so that national and private standards can be seen to be equivalent.

3.1.6 Operators and CABs in countries where no legislation exists would not be disadvantaged because they could likewise establish their own private standard or in some way use the international standard as a baseline.

3.1.7 International trade, at least in terms of legal access to a market, would be on the basis of the international standard.

3.1.8 An approval mechanism to ensure that CABs were verifying production at an equivalent level of the international standard (or a higher national or private standard where appropriate) would be required.

3.2 Requirements for conformity assessment

It can be argued that there is greater scope and justification for harmonising conformity requirements at the level of certification than for production standards. They are less 'environmentally and institutionally' sensitive although care should be taken to ensure that the requirements provide for certification of integrity without favouring or penalising either large or small CABs or that procedures resulting from the norms are putting undue burdens on (disadvantaged) producers.

So the aims would be to:

3.2.1 Seek agreement on one harmonized set of conformity assessment requirements. Guide ISO65 and the adaptation of this document to organic inspection and certification, which form part of the IFOAM Norms should be the basis of this reference document but, as for the international production standard, in less detailed form.

3.2.2 Give consideration to ensuring the requirements are scale sensitive and provide some flexibility based on implementational context.

3.2.3 Seek an international forum for developing and maintaining such an agreement. In other words, what body will maintain and develop this document. It was recognised at the Rome ITF meeting that the Codex Guidelines do not include conformity assessment requirements.

Having said that there is a good basis for agreement of common international requirements for conformity assessment at the level of certification, there currently is some variation in the requirements in the three main regulations (US, EU and Japan) and that of IFOAM, not only in detail but also in the form in which they are described. For example, the EU Regulation 2092/91 references ISO65 in its entirety but in Annex III adds further requirements specific to the organic sector. Together these requirements come quite close to the requirements specified in the IFOAM Norms. The Japan Agricultural Standard specifies requirements on education of personnel in CABs but little detail on inspection and certification procedure. The conduct of inspection is largely influenced by the documentary requirements imposed on the operator, which in turn are influenced by the ISO9000 series on quality management. Such variation should be considered in trying to settle on a common conformity assessment requirement for certification.

3.3 Approval or Accreditation Model

The guideline for conformity assessment requirements at the level of accreditation is generally accepted as ISO61 and its recent replacement ISO17011. The IAF recently agreed that all members-accreditation bodies should be in compliance with the new guideline by January 2006. During 2004, the USDA approval system for CABs was assessed against ISO61. Also in 2004, the IOAS was evaluated and recognised as in compliance with ISO61 by the US Department of Commerce National Institute of Standards and Technology. Mechanisms of CAB approval and recognition in the EU Member States and Japan are less open to scrutiny.

What are less clear are the structures and mechanisms for implementation.

Although the international accreditation model illustrated in Figure 2 appears as the simplest and most transparent regulatory model, national models could also work if standards and

requirements are harmonized and should not be rejected at this stage. Both accreditation models already function in the organic sector and it was the general will of the Rome ITF meeting that any 'new solution' should grow out of current structures and mechanisms.

The international model is the model that eliminates the necessity for peer review between national accreditors. Oversight of the competence of the body implementing such a system may be required for credibility by some independent forum although this does not appear to be the case in the ISTA model. An international accreditation model may cut across certain governments' current policy that accreditation should be performed at national level by one body.

The national model is the traditional model and generally accepted by governments. One reported disadvantage experienced of the national model is the initial lack of expertise in the field of organic agriculture by some national authorities or accreditors. A further problem is that national accreditation bodies do not exist in many, especially less developed, countries. Advantages of the national model over the international model however, are the potential ability to do more frequent audits and spot checks, greater familiarity with local legislation and of working in the home language.

However, accreditation of CABs to ensure competence is only one route. None of the US, EU and Japan regulations require formal accreditation although certain EU Member States have required it in their own national legislation. In most circumstances government departments are charged with approval and oversight of CABs operating in their territory and in approval of foreign CABs verifying product destined for import into their country. The EU recently proposed to amend import approval by approving certain expert bodies (accreditation bodies) to conduct evaluation and oversight (EU Commission, 2004)

There would then appear to be several options:

3.3.1 Adopt the international accreditation model with its inherent single international norms.

3.3.2 Adopt a national accreditation model using harmonized conformity assessment requirements and standards.

3.3.3 Both national and international models continue in parallel but with an agreement on the single international standard and conformance assessment requirements.

3.3.4 A combination of the two models in an attempt to realise the advantages of both systems. Either an international model could use local personnel or a national model could use 'international organic' expertise.

3.3.5 Evaluation and surveillance by various expert entities, which provide reports to government authorities that in turn, make the final decision as to whether a CAB is approved.

Any one, or all, of these together could function as long as the elements in 3.1 and 3.2, that of an international reference standard and conformity assessment requirement, has been agreed and that approvals done by any one of the above mechanisms are deemed equivalent. In this way the 'one inspection - all markets' goal can be achieved.

Referring back to 3.1.8 above, consideration would also need to be given as to whether the assessment of compliance of standards is included in the accreditation/approval process, evaluated separately by another body remembering that the standard may either be embodied

in national legislation such as the NOP or a private standard developed by an NGO in a developing country.

A diagrammatic representation of the new model is presented as Figure 7.

3.4 Issues arising

A new solution would fulfil the criteria if:

- Inspection is performed of an operator against a standard clearly linked to and at the level of or above (ie equivalent to) the international standard;
- Inspection and certification is performed in line with the international requirements for conformity assessment at the certification level;
- The standards and certification are deemed to be in compliance by an international or national accreditation body or government office working to ISO17011;
- The body conducting the accreditation or approval is ‘recognised’; and,
- Trade takes place based on the level of the international standard.

The following issues would have to be considered in relation to each of the required criteria for assessment of solutions proposed earlier at 2.2:

3.4.1 Access to markets

In principle, the ‘one inspection - all markets’ goal can be achieved but there remain some uncertainties that must be addressed.

Issues

- a) Where national or private standards exist that are more stringent than the international standard, insistence that imports meet these requirements will create barriers to trade and weaken the ‘one inspection, all markets’ goal.
- b) This in turn raises the question as to the willingness of both government legislators and private sector standard setters to either reference, or use as a basis, an international standard given that at this point in time, a lot of time and money have been invested in setting up individual country and private standards? Legal access to the market may be more achievable. At least if this was achieved, then organic labels could be left to compete on a free market.

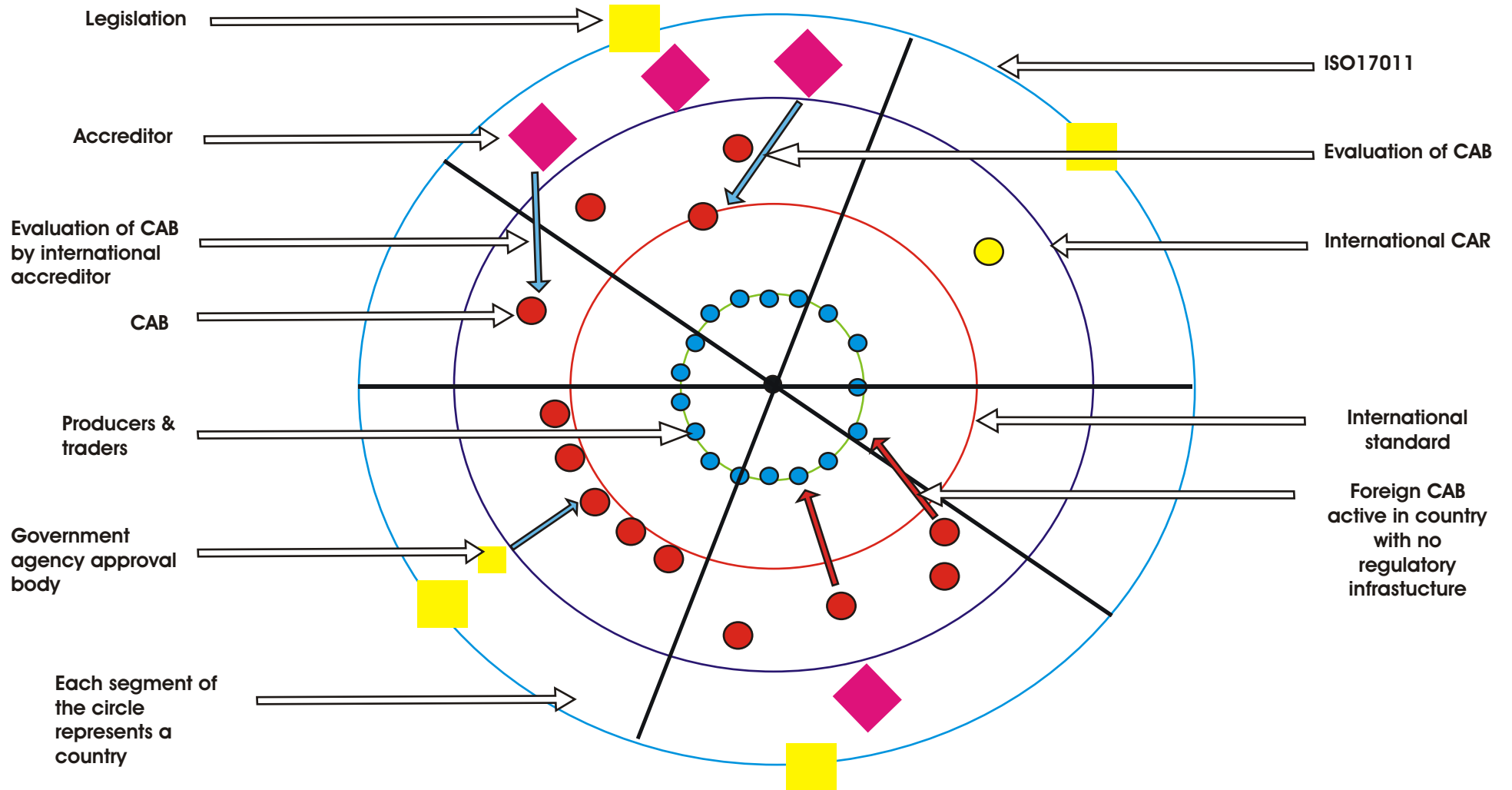
3.4.2 Fair competition

Again in principle, fair competition is assured by the reference to an international standard and requirements for certification but this is again threatened by the freedom to set higher standards.

Issues

- a) Producers in an export country with what are considered to be ‘lower’ standards compared to those of the importing country may be considered to have an advantage over the domestic producer. This could lead to downward pressure on standards or, at least, a settling of standards to a lowest common denominator permitted by the international baseline. Some

Figure 7 Diagrammatic representation of harmonized model for regulating the organic sector



would see this erosion as a threat to the existence of an organic identity. Others may see the ‘simplification’ or a reduction in stringency of organic standards as an acceptable price to pay for harmonization.

b) IFOAM has an ongoing effort to address equivalence and have developed Criteria for Regional Variations of the IFOAM Basic Standard. The American Organic Standard¹⁸ has been reviewed by this mechanism.

3.4.3 Consumer protection

The same issue arises. Consumers should be guaranteed organic integrity at the level of an international standard but again variation in standards whether between private bodies or between nations may be seen as confusing and undermining of the guarantee.

Issues

a) Is it acceptable for a product of ‘less stringent’ organic requirements to be sold as of the same organic integrity as a product of ‘more stringent’ requirements if there is sufficient transparency in the regulatory system. For example, if a private standard setter made quite clear in its standards that ingredients or products not certified by it were all at least at the level of a recognised international standard but could be below its own more stringent requirements.

3.4.4 All environments

The existence of international norms and an agreed system of approval that can operate nationally or internationally permits CABs, and therefore operators, in all countries to access the international market irrespective of whether adopted legislation is in place in their own country. Similarly no negotiation of equivalence is required between a powerful importer and a weak exporter

Issues

a) A related issue here is the important one of whether an international standard can be agreed given the wide variation in ‘environments’ in which it has to apply. Current international standards are criticised by some as being too weak and by others as being too stringent. The Rome ITF meeting generally agreed that international norms should focus more on principles but recognised, at the same time, that in such a system there may enter the element of interpretation, again leading back to a perceived inequality in standards from country to country and a return to the need to recheck compliance.

3.4.5 All stakeholders

The extent to which this is achieved would depend on the nature, structure and operating procedures of the fora, national and or international, that would oversee the maintenance of the international norms.

Issues

¹⁸ The American Organic Standard is a private sector standard developed through a consultation process in the USA led by the Organic Trade Association.

a) This then raises the question of which fora are envisaged to oversee the agreement and maintenance of the organic norms, both production standard and conformity assessment requirements. Given the Rome ITF meetings general conclusion that existing fora should be used rather than establish new ones, it may be that Codex Alimentarius should retain and strengthen its role as caretaker of the international organic standard. The proposed adaptation of Guide ISO65 though, raises the issue of who then will manage its maintenance and development. Accepting Guide ISO65 as it is has the advantage of not having to find a new home for it, but the disadvantage of continuing to work with an ill-adapted set of requirements. The same issue of stakeholder input and ownership is raised by the 'recognition' of bodies that may evaluate and approve CABs. The IAF currently offers a vehicle for peer approval for accreditors and use and adaptation of its 'services' would again avoid the need for inventing new structures. The Rome ITF meeting agreed to invite the IAF to contribute to these discussions.

3.4.6 Respect sovereignty and market choice

The model neither requires nations to enact legislation nor does it prevent them from doing so, nor indeed from setting higher standards.

Nor does the model prevent private standards setters from maintaining their own and stricter standards.

Issues

- a) As indicated above, to enable free trade, the model does require those who set higher standards to accept the international standard as the level for trade. This may be considered an incursion on sovereignty or undermining domestic producers.
- b) This then raises the question that, accepting that governments or the private sector may set higher standards, what is the willingness (and legality in terms of a label guarantee) of either to use the international standard as the basis for trade?

3.4.7 Transparency

The requirement to reference, link to, and structure standards and certification requirements in the same way as the international norms will assist transparency and simplify comparison and evaluation.

Issues

- a) Further effort will be required to achieve full transparency in terms of standard setting and approval of national norms.
- b) The CAB approval or accreditation system will also need to strive for maximum transparency without endangering confidentiality.
- c) In turn the system of recognition of bodies competent to evaluate CABs must also be transparent.
- d) Web based information may provide a useful tool for providing transparency.

3.4.8 Principal trade provisions

Reference to international norms is a clear requirement. Trade at the level of the international norm and acceptance of equivalence is also inherent in the model.

Issues

a) Questions relate to the willingness of nations and the private standard setters to reference an international standard in the spirit of harmonization and to accept as equivalent those standards and control systems that can be shown to 'meet the same regulatory objective'

3.4.9 Benefit to participants

Less duplication of effort and greater linkage and transparency in norm setting with an expected increased uniformity of application of standards and control should both reduce the cost of the guarantee system worldwide as well as improve its consistency and enhance confidence in organic integrity. All will benefit both producers and consumers and the organic trade as a whole.

Issues

a) Depending on how both governments and private organisations choose to engage and implement such a model, a decrease in the size of the organic regulatory sector could be expected which could lead to loss of jobs in some organizations. On the other hand, such a result would be construed as a benefit in other organizations where the human resource to administer the system is not available.

4 Work Plan

We have identified:

a) criteria for the assessment of solutions for harmonization of regulation of the organic sector. These have led us to develop initial objectives for a solution and should continue to guide us during the work programme established below.

b) three main areas for attention broadly called:

i) rationalization of standards

ii) rationalization of conformity assessment requirements at the certification level; and

iii) rationalization of the approval mechanism of CABs

c) a proposal based on one international standard, one international conformity assessment requirement and an array of possible mechanisms for recognition of CABs.

d) a number of considerations that require attention and investigation or information arising from other sources that should feed into the process as we move towards a harmonized system.

e) a number of alternative approaches to be investigated on the way.

What follows is a three-year work plan based on the original proposal in earlier versions of this document and the discussion held at the Rome ITF meeting in November 2004. It is comprised of six parts, the first three being focused on A) standards, B) conformity assessment requirements and C) the approval/accreditation mechanism as described above. In support of these main pillars of the work a further three parts will comprise D) identification of fora to house the development and maintenance of the work, E) collection of information to guide the development of the solution and F) administration and promotion of the work of the ITF and miscellaneous projects.

Given the many interested parties: governments, international institutions, NGOs, private business and producers and consumers throughout the world and the many initiatives happening, it has seemed wise to settle on an overall goal (even if all the details are not well defined) and develop a short-term work plan towards this end. In the second half of 2007, the ITF should reassess progress based on all the information gathered and the initiatives undertaken and should be in a better position, with a more informed stakeholder base, to define what might be a final work plan towards an active harmonised system.

Table 2 provides a summary of actions, outputs and approximate time frames until the end of 2007 and the details of each group of actions are described in the text below. Each action will now require the development of a more detailed concept note to guide their actual implementation. In some cases, no concrete actions are proposed at this time but external actions or considerations should feed into the work plan.

4.1 A - Rationalisation of organic standards

The rationale is the ultimate acceptance of **one international basic standard**, which can be accepted and used as a point of reference. Recognizing that we already have two such standards (Codex Guideline and IFOAM Norms) the focus of effort is to consider how we can bring one, both or an amendment thereof into a more prominent position as a regulatory tool. The preference at the November 2004 ITF meeting appeared to be to accept the Codex Guideline as the international standard. It is envisaged that the international standard could be referenced as is by national regulations and private standard setters, or be used as a baseline to which other requirements or detail are added to adapt the standard to local conditions. To a certain extent, this is already happening. What has not happened to date is that trade should be able to take place at the level of the international standard.

To assist in moving towards this goal the following short-term actions are proposed:

4.1.1 Database system for assessment of multiple Norms comparisons

Action 4.1.1 has the purpose of providing a tool to provide and manage up-to-date multiple analyses of the similarities and differences between the two international organic Norms and the three main regulations. The database design should anticipate that other Norms would be added later. A number of analyses have already been performed in recent years but quickly become out of date. In 2002/2003 a private Finnish company went some way to developing a database that could handle such comparisons with the aim of providing services to government authorities and organic processors but the project was shelved for commercial reasons. The EU addressed this issue in action 2 of its Action Plan on Organic Farming (EU, 2004). The EU database is under development and planned to be internet-based in order to be kept up to date by certification bodies themselves. Under FAO the FAOLEX database gives electronic access to organic agriculture regulations.

Maintaining such a norms comparison database under the oversight of one organization is feasible. The first objective of a database would be to analyse the differences in regulations and the underlying political objectives with the ultimate goal to find ways to bridge the identified gaps. The ITF agreed in November 2004 that the database has to fulfil the following criteria:

- it is available publicly so that it can be used as a reference by countries/standard setters when developing their regulations;
- it is organized according to subject matter;
- it allows for multi standards comparison;
- it is multi-lingual;
- it is not meant to assess the quality of a standard.

Action 4.1.1: Development of a database system for preparation and maintenance of norms comparisons.

Time-frame: by June 2006

4.1.2 Comparison of Codex Guideline and IFOAM standards.

The Codex Guidelines and IFOAM Norms stand as the two international organic baseline standards and are already known to be quite similar in terms of production standards. The Codex Guideline however includes little that could be considered certification requirements, whereas the IFOAM Norms include requirements for conformity assessment (see action 4.2.1 below). A previous comparison of the standards was performed in 2002 comparing the EU Regulation 2092/91 with both Codex and IFOAM Norms (Schmid, 2002). A new comparison will update the analysis and will focus on the production standard, the purpose being their potential harmonisation as one international reference standard. It is noted that IFOAM standards are clearly written as 'standards for standards' whereas the Codex Guidelines are closer to a production standard and this should be taken into account when performing the comparison. Both however assume that more specific standards may be developed at the local level.

Action 4.1.2: Comparison of Codex Guideline and IFOAM standards with a view to their harmonisation and/or development of one single international standard.

Time-frame: by June 2006

4.1.3 Comparison between EU Regulation, USDA NOP and JAS requirements.

The three regulations in place in the main organic markets have influenced all others. All three include production standards and include or refer to separate certification requirements but are all structured quite differently and do not permit easy comparison. The European Action Plan for Organic Food and Farming (EU, 2004) notes that a comparison should be performed of the EU Regulation against the Codex guideline and the IFOAM norm. Liaison with this initiative is encouraged. It is also assumed that during the negotiations between the USA, Japan and Europe to determine equivalence, some analyses will have been performed. As before the main aim of these analyses is to provide a solid and objective basis for initiating moves to harmonise. The analysis should address both production standards and requirements for certification.

Action 4.1.3: Comparison of EU, USDA NOP and JAS regulations

Time-frame: by June 2006

4.1.4 National and private labels and trade at the level of an international standard

It can be anticipated that both national standard and private standard setters will wish to maintain control over the level of their standards adapting them to their own environment and stage of development. It was pointed out at the November 2004 ITF meeting that national and private standard setting is one of the few areas where farmers may still feel involved in the system and there was general agreement that any new regulatory solution should respect this need. The hope is that local standard setting may increasingly be done with reference to the international standard and perhaps in a standard format, so permitting easy comparison. The European Commission Action Plan also recognised private labels as an obstacle to trade.

In November 2004 the ITF considered that one way to address this problem is to accept the existence of differences in standards but to try overcoming the negative effects resulting from this situation. One example is the IFOAM System with its one international mark and its

mutual recognition agreement. The main action here is to investigate how national legislation and private standards could permit trade at the level 'equivalent' to the international standard, how such equivalence would be determined and under whose authority. Questions to be answered include what changes might be required in legislation and standards and what non-compliances might arise with relevant accreditation requirements?

A further issue to be considered is to what extent consumers understand the differences in organic standards that represent the foundation for the different marks and this will be taken up in the consumer survey proposed at 4.5.1.

Action 4.1.4: Investigation and documentation of current legislation and private standards and relevant accreditation requirements to determine how access could be permitted through equivalency to an international standard.

Time-frame: by end 2006

4.1.5 Considerations:

- a) In settling upon and/or amending an international organic standard consideration must be given to whether it serves the role as guiding principles or as a standard which can be taken off the shelf to use as a production standard.
- b) Should the international standard serve as a baseline below which no standard should go, thereby possibly being so low it has little meaning, or should the format of the standard allow for derogations under specified circumstances?

4.2 B - Rationalisation of conformity assessment requirements

4.2.1 Review of Guide ISO65 to adapt it to organic requirements

The IFOAM Certification Criteria published as part of the IFOAM Norms 2002 and the Guide ISO65 are the two formal reference documents currently used in the organic sector which describe the requirements for conformity assessment. The IFOAM requirements have been adapted from Guide ISO65 specifically for the organic industry. A comparison of the two documents has already recently been performed by the IOAS for IFOAM (Commins, 2003). At the November 2004 ITF meeting it was agreed that ISO65 is not adapted to the needs of organic conformity assessment being in some requirements too detailed and in others not detailed enough. The meeting agreed that a new look should be taken at Guide ISO65 to adapt it to organic needs taking into account that the IFOAM requirements were originally developed in exactly this way. The review should consider the recent changes to the IFOAM Norms which are removing some 'ISO65' elements that are considered unnecessary.

Action 4.2.1: Review Guide ISO65 with respect to the real needs of organic conformity assessment with a view to finalising one internationally accepted conformity assessment requirement.

Time-frame: by June 2006

4.3 C - Rationalisation of approval & accreditation model

Moving forward under the intention of having available a single international reference standard and conformity assessment requirement the issue of enforcement or verification then becomes the focus of attention. The November 2004 ITF meeting concluded that one international accreditation was probably not practical, despite its attractive simplicity but that the aim should be for one CAB evaluation which leads to multiple approvals by national or supra-national authorities. The aim should be that the CAB evaluation is conducted against the international norms, not any specific country norm, so one evaluation fits all. This again links back to the crucial acceptance that access to markets should be on the basis (equivalence to) of accepted international norms rather than full compliance with the domestic legislation and private standard.

No specific short-term actions by the ITF itself are proposed at this time other than the ITF to be informed on the following ongoing activities and considerations.

4.3.1 Considerations:

- a) ITF to be informed on the collaborations already ongoing between the IOAS and national accreditors in which joint CAB audits are being conducted and increasingly one audit is being performed which results in two accreditation decisions by the participating accreditors.
- b) ITF to be informed of the proposed collaborations between the IOAS and certain government authorities, which are also aimed to result in one evaluation and two decisions.
- c) ITF to be informed of the development of EU Commission proposal on import approvals which may identify expert bodies to conduct direct evaluation of CABs so allowing them access to an approved list for import.

4.4 D - Fora for maintenance and development of a harmonized model

It was a generally accepted conclusion of the November 2004 ITF meeting that a new regulatory model should avoid as far as possible the need to establish new institutions and therefore use existing structures, both national and international. Given the assumption, as has been argued by the ITF, that we need a new solution to regulating organic trade, then the emphasis becomes more on amending and adapting the systems and structures we have. Though other models that we have looked at may still provide us with ideas, we are focused more on utilising better what we already have.

Based on this premise, it is assumed that much decision-making is retained at the national level. Nevertheless, a new model may still require the involvement of international fora to house and maintain the international standards and conformity assessment requirements and to possibly to approve bodies competent to conduct accreditation and approval. Acceptance of the Codex Guideline as the international standard, Guide ISO65 as the international conformity assessment requirement and the IAF or national governments as the bodies able to designate approved accreditation bodies would bring us full circle to the position we are now in. However we have accepted that in its present form, this model is not working effectively.

No immediate actions are proposed here but the following should be considered as the actions progress.

4.4.1 Considerations

- a) By accepting the Codex Guideline, the Guide ISO65 or the IFOAM Norms as the international norms we have available a ready-made institution in which to house the Norms. The issue then becomes whether the various institutions can provide the necessary engagement and stakeholder input that our agreed criteria for assessing solutions requires. It is assumed that governments could more easily accept Codex and ISO than they could an NGO like IFOAM.
- b) Not every country has established a national accreditor and not every country has the legislation or the capacity for government departments to approve and oversee local CABs. The IOAS currently work internationally as do some IAF members. The IAF should be invited to contribute to the discussions of the IAF and to assist in developing a mechanism of approval of accreditation bodies that permits CAB approval worldwide.
- c) Given the current situation that government departments are providing approval to CABs rather than formal accreditation bodies, and that, at least domestically, governments are expected to want to continue with this system, how will equality of approval/accreditation be assured?

4.5 E - Evidence and information to support and guide the harmonized model

In support of the main actions described above the ITF has agreed the following activities to provide background information to the development of a new regulatory model.

4.5.1 Consumer survey

A consumer survey was first proposed as a necessary contribution to the work of the ITF in the initial work programme drafted in February 2003 and its brief will be further formalised through a detailed concept note.

Action 4.5.1: Consumer survey to investigate sensitivity to differences in standards and conformity assessment requirements.

Time frame: by June 2007

4.5.2 Equivalence judgement

It can be expected that judgement of equivalence between organic standards will continue to be a significant building block of an international system. IFOAM Policy 25 allows for approval of national or regional standards as an approved variation of the IFOAM basic standard. Policy 42 sets down criteria for assessing such variations. To the writer's knowledge, this is the only transparent attempt to conduct such an exercise and the experience gained from doing it will be invaluable in any future attempts at judging equivalence between organic standards. The American Organic Standard is already some way through this process and its finalisation should be encouraged. An Italian group of CABs have also submitted a unified organic standard to IFOAM to undergo the same process. The objective, in both cases,

from the proposers viewpoint is that once approved, the user would not need to submit them for assessment when applying for IFOAM Accreditation. The ITF's interest here is to learn from the experience and may wish to commission a report from IFOAM and the client on the difficulties experienced and proposed modifications. It is also likely that government personnel will have gained considerable insight into the judgement of equivalence in performing their regulation-to-regulation reviews and it would be beneficial to combine such knowledge into a guidance document specific to organic standards.

Action 4.5.2: Guidance document on judgement of equivalency of organic standards.

Time-frame: by end 2006

4.5.3 Considerations

a) The ITF should be kept informed of the current review during 2005 of the IFOAM Organic Guarantee System (comprising the IFOAM Norms and Accreditation Programme), which is subject to a comprehensive review. One of the main objectives of the review is to make the system more inclusive and more accessible. Various scenarios are being considered. The Accreditation Criteria could be made simpler and more "easy" to comply with, and similarly the development of the IFOAM Basic Standards as a real standard for standard can be taken much further and much of the detail could be taken out of the standard. The approval mechanism – currently the IFOAM Accreditation Programme - could also be simplified in a number of ways. There are also suggestions that the IFOAM Norms should be put in the public domain, which would allow other bodies to accredit to them. Such actions could lead to a more accessible programme, with lower costs and higher participation. The two major questions for such an approach are to what extent a more accessible system will be 'accepted' by major private sector certification bodies and to what extent the system will be seen as an interesting tool by the regulatory authorities in major importing countries. Essentially, can accessibility, which provides for harmonisation, still deliver integrity?

4.6 F - Administration and promotion etc

Further in support of the above actions, the following are proposed in particular to promote the work of the ITF, to make its efforts more widely known and to establish the ITF as a source of objective analyses that can assist the organic sector develop its regulatory system.

4.6.1 Development of Common Regulatory Objectives

It is widely recognised that the approach of defining common regulatory objectives (CRO) may serve as an important stepping-stone towards a harmonised system. As a result of the actions under 4.1 it should be possible to distil out such common regulatory objectives, which could form the basis for developing both individual and global regulatory systems in both public and private sector. The CRO should contain the essential elements in order to achieve the criteria proposed for the long-term strategy and may guide the rationalisation and perhaps address the suggestion from the ITF discussions of simplification of requirements (i.e. regulations, IFOAM Norms and ISO65 are all too complicated to form the basis of harmonisation). Such an agreed CRO would form the basis of the whole work programme in support of influencing existing and emerging regulations and private systems.

Action 4.6.1: Development of a Common Regulatory Objective

Time-frame: by end 2006

Promotion of ITF work to three main regulatory blocks

A number of developments are taking place amongst the three main import blocks: the European Union, USA and Japan. As was suggested at the ITF Geneva meeting in October 2003, the revision of the EU Regulation import rules during 2005 is an important event that the work programme should take into account. The European Action Plan on Organic Food and Farming published by the European Commission in June 2004 (European Commission, 2004) also contains some very encouraging comments concerning harmonisation, consideration of standards equivalence and the setting up of a specific accreditation system. Since publication of the US NOP in 2001, negotiations have taken place between US and EU authorities to agree equivalence. An agreement is still pending and can be expected to be currently under discussion. In Japan, new legislation on organic livestock is currently being drafted and amendments to import rules are being considered.

The overall output of this group of actions is a greater awareness amongst the regulatory community of the benefits of harmonisation and some practical ideas and tools to assist in achieving it. A number of options are explored in the following actions, which will be used to feed into regulatory developments over the next few years:

4.6.2 Promote reference to agreed international standard and requirements

The acceptance of IFOAM and/or Guide ISO65 Accreditation by designated accreditors is being suggested in the EU Action Plan. A similar mechanism may also emerge in Japan. If such a mechanism is established, it is still likely that equivalence to the domestic regulation will be required rather than equivalence to any international standard requirements, which would be preferable in terms of harmonisation. This action would take the output of actions under 4 and make it available and promote it as the basis for international equivalence. This might be done through direct meetings with regulators or workshops with the wider organic sector at national level. Success even with this approach however will not solve the obstacle to access via smaller certification bodies from countries where equivalence has not been agreed or where accreditation is too costly.

Action 4.6.2: Promotion of reference to agreed international standard and conformity assessment requirements.

Time-frame: by end 2006

Two routes of collaboration between certification bodies themselves may assist this latter problem of access from emerging producer countries and where smaller CABs operate (even in the USA, the largest organic market in the world, many of the CABs are small companies which may not be able to afford formal accreditation) and are formulated as actions 4.6.4 and 4.6.5 below.

4.6.3 A blueprint for CAB-CAB approval

The current organic regulation in Japan permits a Japanese CAB to make trust agreements with foreign CABs to make it possible to accept their work as part of the certification process (Under the JAS, the foreign CAB must still be recognised within its own country or be accredited against ISO65 or IFOAM Norms). Similar practices occur within the environment

of the EU Regulation but they are not acknowledged in the legislation itself. The US NOP does not allow for such practices. Such a measure delegates authority to CABs to make the assessment of a foreign body as competent to perform the work. The IFOAM Norms include such measures either both on the level of overall acceptance of the foreign CAB or solely on the level of product. The action proposed here would raise discussion on these issues and develop an agreed blueprint for how CAB-CAB approval could operate and their possible incorporation into regulatory systems. An additional positive benefit of such collaboration is the increased contact between CABs with potential trust building and harmonising spin-offs.

Action 4.6.3: Development of a blueprint for CAB-CAB peer review

Time-frame: by end 2006

4.6.4 A blueprint for collaboration between CABs to facilitate imports

There is a number of emerging local certification bodies in developing countries. While the longer-term objective should be that they are accepted on their own account in import markets, there are also possibilities for them to act as “inspection agents” for other CABs. This serves as a good experience and introduction to the demanding international arena. It also serves as a business opportunity for CABs that have few other options for securing income, as local markets are often initially undeveloped. However, either the regulations themselves or their interpretations, or the demand from accreditors (national or international) may be placing such high demands on these arrangements that the local bodies need to be accredited in their own capacity to be able to be accepted by the foreign CABs. It may also sometimes be in the interest of a foreign CAB with an international scope to exaggerate these demands in order to motivate them using their own inspectors in such situations. However they may do so with reference to the demand from regulators or accreditors. This action would develop a blueprint for acceptable arrangements for inspection service, and encourage adoption within public and private sector approval requirements.

Action 4.6.4: Development of a blueprint for collaboration between CABs to facilitate imports

Time-frame: by end 2006

4.6.5 Advice and support to emerging regulations to encourage ‘trade-friendly’ and harmonising systems.

A number of governments are preparing or amending legislation on labelling of organic products. The Canadian government is currently considering proposals for a new mandatory system to regulate import and export of organic products. The Australian government is also in the process of revising its national standard. Both Chile and Peru are in the process of initial definition of regulations in the organic sector. There are many others. All these initiatives emphasise the need for encouraging engagement by governments in the ITF process but also require specific effort by the ITF to engage with key personnel in the organic regulatory sectors in these countries. Meetings with some key government figures have already taken place with IFOAM and IOAS personnel within 2003 and 2004. The main effort of this activity is to ensure that the “mistakes” in existing regulations are not just repeated by countries developing organic regulations. IFOAM, FAO and UNCTAD as well as a number of governmental or private development agencies are active in the support of government policy development for organic agriculture, including aspects of regulation. It is important

that this support is aimed at coaching countries towards a ‘trade friendly’ organic regulation. As a first step IFOAM, FAO and UNCTAD, based on the findings of the ITF, should develop a common policy brief as guidance, and as a second step ensure that it is brought to use by the various stakeholders. An extension of this option would be to develop and publish a guideline aimed at established and developing CABs on structure and function of CABs in the organic sector so as to move towards a more harmonised organic certification mechanism. The development of a designated ITF web site to provide a focus for the information should be considered.

Action 4.6.5: Advice and support to emerging regulations to encourage ‘trade-friendly’ and harmonising systems.

Time-frame: ongoing

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Table 2 Three-year work programme towards a harmonized system for regulating trade in organic products

| OBJECTIVE | ACTIVITY | OUTPUT | 2005 | | 2006 | | 2007 | |
|--|---|---|---------------|---|------|---|------|---------------|
| | | | 1 | 2 | 1 | 2 | 1 | 2 |
| Half year | | | | | | | | |
| A. Rationalisation of organic standards | | Single international organic reference standard | | | | | | |
| | 4.1.1 Database system for assessment of multiple Norms comparisons | System for handling and maintaining Norm comparisons | | | | | | ¹⁹ |
| | 4.1.2 Comparison of Codex guideline and IFOAM standards | Identified areas of convergence and divergence between Norms | | | | | | |
| | 4.1.3 Comparison of EU, NOP and JAS | Identified areas of convergence and divergence between key regulations. | | | | | | |
| | 4.1.4 Trade at level of international standard | Proposals on access to markets through equivalency | | | | | | |
| | <i>4.1.5a International standard as principles or production standard</i> | <i>Format of international standard defined</i> | ²⁰ | | | | | |
| | <i>4.1.5b International standard as baseline or with derogations</i> | <i>Format of international standard defined</i> | | | | | | |
| B. Rationalisation of CAR | | Single international conformity assessment requirement | | | | | | |
| | 4.2.1 Review of ISO65 to adapt to needs of organic | Single international CAR | | | | | | |
| C. Rationalisation of approval model | | Acceptance of approval model(s) | | | | | | |
| | <i>4.3.1a Progress of accreditor collaborations</i> | <i>Information to feed into the development of a rationalised approval CAB approval model</i> | | | | | | |
| | <i>4.3.1b IOAS-government collaborations</i> | | | | | | | |
| | <i>4.3.1c EU Commission amendments to import rules and its implementation</i> | | | | | | | |

¹⁹ At the end of 2007 an overall review of progress and a redefining of a new work plan is anticipated.

²⁰ These are not specifically actions by the ITF but either considerations or information resulting from actions being undertaken by other bodies.

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| OBJECTIVE | ACTIVITY | OUTPUT | 2005 | | 2006 | | 2007 | |
|--|---|---|-------------|--|-------------|--|-------------|--|
| D. Fora for maintenance & development of harmonized model | | Identification of fora for hosting international Norms and CAB approval model | | | | | | |
| | <i>4.4.1a Acceptability of existing institutions as caretakers of international norms</i> | <i>Ideas on fora in which to house the system</i> | | | | | | |
| | <i>4.4.1b Invite IAF to contribute to ITF</i> | <i>Ideas on fora for nomination of approval/accreditation bodies</i> | | | | | | |
| | <i>4.4.1c Government departments approval</i> | <i>Ideas on how government approval systems relate to accreditation systems</i> | | | | | | |
| E. Evidence to support and inform development of harmonized model | | Information in support of ITF work | | | | | | |
| | 4.5.1 Consumer survey | Understanding of sensitivity of consumers to differences in Norms | | | | | | |
| | 4.5.2 Equivalence judgement | Guidance document on judgment of equivalency of organic standards. | | | | | | |
| | <i>4.5.3a Information from IFOAM OGS review</i> | | | | | | | |
| F. Administration & promotion etc | | Work of ITF well known and understood in organic sector | | | | | | |
| | 4.6.1 Development of CRO | Simplified principles | | | | | | |
| | 4.6.2 Promote reference to international standards | Acceptance of principle of trade at level of international guidelines | | | | | | |
| | 4.6.3 Blue-print for CAB-CAB approval | Simplified import mechanism | | | | | | |
| | 4.6.4 Blue-print for CAB collaboration on inspection | Acceptance of guideline on sub-contracting inspection. Harmonisation of work practices. | | | | | | |
| | 4.6.5 Support to emerging regulations | Common policy brief leading to harmonisation of effort | | | | | | |

Conclusions

This document represents the agreement of the ITF on

- ten criteria for assessment of a ‘harmonized’ model for regulating the production and international trade in organic products;
- based on these criteria, a broad initial target for the structure and operation of the ‘harmonized’ model; and
- an initial work-plan towards the ‘harmonized’ model.

The target structure and operation of the model is based on current institutions and mechanisms that will respect national and private standard setting within the framework of an agreed and referenced international organic standard. Likewise one international conformity assessment requirement will be agreed. These two international documents will form the basis of evaluation and surveillance of the conformity assessment bodies, in whichever country(ies) they operate. Such a system should lead to the goal of one inspection providing access to all markets and contribute towards the continued growth of organic agriculture and maintenance of its principles.

Short-term actions by the ITF are proposed as follows:

Action 4.1.1: Development of a database system for preparation and maintenance of norms comparisons.

Action 4.1.2: Comparison of Codex Guideline and IFOAM standards with a view to their harmonisation and/or development of one single international standard.

Action 4.1.3: Comparison of EU, USDA NOP and JAS regulations

Action 4.1.4: Investigation and documentation of current legislation and private standards and relevant accreditation requirements to determine how access could be permitted through equivalency to an international standard.

Action 4.2.1: Review Guide ISO65 with respect to the real needs of organic conformity assessment with a view to finalising one internationally accepted conformity assessment requirement.

Action 4.5.1: Consumer survey to investigate sensitivity to differences in standards and conformity assessment requirements.

Action 4.5.2: Guidance document on judgement of equivalency of organic standards.

Action 4.6.1: Development of a Common Regulatory Objective

Action 4.6.2: Promotion of reference to agreed international standard and conformity assessment requirements.

Action 4.6.3: Development of a blueprint for CAB-CAB peer review

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Action 4.6.4: Development of a blueprint for collaboration between CABs to facilitate imports

Action 4.6.5: Advice and support to emerging regulations to encourage ‘trade-friendly’ and harmonising systems.

Other considerations and information from external sources are also noted.

As has been indicated in this document, for such a relatively small sector, the organic movement, trade and regulators have already put in place many of the components that are required for effective regulation and this is cause for considerable optimism. Although it is the incompatibilities and the differences between the various regulatory systems that are most frequently emphasised, we should also celebrate and build upon the relative degree of harmony that has already been achieved to date.

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Annex I

Terms of reference of the International Task Force on Harmonization and Equivalence in Organic Agriculture

As agreed in December 2002

The ITF

The UNCTAD/FAO/IFOAM Task Force on Harmonization and Equivalence in Organic Agriculture was established in December 2002 to serve as an open-ended platform for dialogue between public bodies and agencies and private sector institutions/companies involved in trade and regulatory activities in the organic agriculture sector, in order to facilitate international trade.

Aims of ITF

1 *Review the existing organic agriculture standards, regulations and conformity assessment systems including:*

- Their impact on international trade in organic agriculture products;
- Models and mechanisms of equivalency and mutual recognition;
- Extent of international harmonization

2 *To formulate proposals for the consideration of governments, Codex Alimentarius Commission, relevant bodies of FAO, UNCTAD and IFOAM and other appropriate organisations on:*

- Opportunities for harmonization of standards, regulations and conformity assessment systems;
- Mechanisms for the establishment of equivalence of standards, regulations and conformity assessment systems;
- Mechanisms for achieving mutual recognition among and between public and private systems;
- Measures to facilitate access to organic markets, in particular by developing countries and smallholders.

These proposals will take into account their impact on production systems, their relevance to consumers and the need for transparency.

3 *Advise stakeholders and provide information on developments following discussions of the above proposals.*