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Equivalence and Mutual Recognition in Trade Arrangements

**Relevance for the WTO and the Codex Alimentarius
Commission**

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Preface

This report deals with the question of how equivalence and mutual recognition can be applied as trade facilitating tools in international food trade. It is written by Frode Veggeland and Christel Elvestad under a project financed by the Norwegian Ministry of Fisheries and Coastal Affairs. Svein Ole Borgen has read earlier drafts of the report and provided useful comments. Siri Fauske has been responsible for the final layout of the report.

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Ivar Pettersen

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Executive Summary

The report “Equivalence and Mutual Recognition in Trade Arrangements – Relevance for the WTO and the Codex Alimentarius Commission” contains five chapters.

Chapter 1 discusses the concepts of equivalence, mutual recognition and harmonization and how these concepts can be applied to facilitate trade. The important premise for this discussion is the fact that national regulatory systems, including regulations, standards and procedures for ensuring compliance with regulations and standards (cf. conformity assessment procedures), may cause impediments to world trade. Harmonization is one way of facilitating trade. The goal of harmonization is uniformity of trade measures on an international basis. The concept of equivalence, on the other hand, is based on the fact that regulatory goals, e.g., in relation to health and food quality, in practice may be fulfilled by the use of *different* kinds of measures. Trade barriers can thus be removed and the products can be accepted on the basis that they fulfil the relevant regulatory objectives – even though regulatory differences persist. Mutual recognition can simply mean that two or more parties mutually accept each other’s rules or conformity assessment procedures, i.e., the process through which products are evaluated for compliance with the rules. Mutual Recognition Agreements (MRAs) primarily involve conformity assessment procedures. Under these agreements the parties *mutually accept each other’s conformity assessment procedures as equivalent* in order to ensure compliance with prevailing regulatory requirements. Normally, an MRA is a voluntary agreement between governmental conformity assessment bodies.

Chapter 2 presents and analyses the work on equivalence and mutual recognition in the TBT Committee of the WTO (dealing with technical regulations, standards and conformity assessment), the SPS Committee of the WTO (dealing with measures related to food safety and animal and plant health) and in the U.N. food standardization body Codex Alimentarius Commission. The concepts of equivalence and mutual recognition and the way they can apply under WTO rules, have been discussed for many years in both the TBT and SPS committees. However, the SPS Committee has advanced the furthest with regard to equivalence assessments. This has resulted in a Committee Decision on the implementation of Article 4 on *Equivalence* of the SPS Agreement. Furthermore, on the request of the SPS Committee, the Codex Alimentarius Commission has developed *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (adopted in 2003). These guidelines supplement the *Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems*, which were adopted in 1999. The work on guidance on the judgement of equivalence of technical measures has not progressed in the same way. The TBT Committee has not produced any decision on the subject and the Codex Alimentarius Commission furthermore decided in 2003 not to pursue this

work. However, in principle there is no reason why equivalence assessments should not be just as relevant and important for technical measures as for SPS measures. Furthermore, some countries actually perform such assessments even today.

Chapter 3 presents a number of trade arrangements involving mutual recognition and equivalence assessments. Two main points should be highlighted from this empirical investigation. Firstly, examples from in particular the organic food sector show that assessment of equivalence is highly relevant with regard to technical regulations and standards. Secondly, there are many examples of mutual recognition agreements involving assessments of the equivalence of different national conformity assessment procedures. However, before entering into such agreements there are a number of factors one should consider, e.g., the costs vs. the benefits, the ideal scope of the agreements, and the need to build capacity and trust in order to negotiate and maintain the agreements. Thus, the decision on whether equivalence assessments are feasible should be made on a case-to-case basis.

In chapter 4 we present some critical points with regard to the application of mutual recognition and equivalence of technical measures. First, our investigation shows that it is easier to establish equivalence on conformity assessment than for rules. However, these two issues are strongly interrelated and it would thus be interesting to explore further situations where, in particular, the establishment of equivalence on rules is both relevant and feasible. Second, although equivalence assessments in the TBT area are more complicated and less clear-cut than in the SPS area, we basically see no reasons why such assessments cannot play an important role. However, there are several factors that should be kept in mind, *inter alia*,

- the open-ended character of the TBT Agreement involving a large number of potential legitimate objectives,
- the problem of identifying legitimate objectives separate from the design of the technical measures themselves,
- the need to separate performance criteria from design and product characteristics,
- and the need to sort out the relevance and importance of both private and governmental initiatives in providing relevant standards and guidelines.

In chapter 5 we make some concluding remarks and address the implications of the factors mentioned above for further international guidance on equivalence assessments on technical measures. We argue that many of the basic principles and arguments that apply to the SPS area also apply to the TBT area. In both areas, factors such as cost-benefit considerations, confidence building, and information exchange, enter into the co-operative work as important conditions. Further, in both areas the difficult, but nevertheless feasible task is to specify two or more different measures and the regulatory objectives they are meant to fulfil, and on this basis evaluate the “likeness” of the measures.

One important threshold for achieving equivalence is defining the regulatory objectives and based on these, setting the level (e.g., minimum protection level) that measures must reach. We argue that this exercise might be considered to be more complicated for TBT measures than for SPS measures. However, the argument can

also be turned around. Because TBT measures are not necessarily linked to essential requirements such as health protection, it may actually be easier to negotiate equivalence in many situations. In chapter 5 we also point to three ways of pursuing the work on international guidance for the application of mutual recognition and equivalence assessments in the food sector. First, there is a need for co-ordinated efforts by relevant international organizations, both private and intergovernmental, such as the WTO, Codex Alimentarius, ISO (International Standardization Organization) and IFOAM (International Federation of Organic Agriculture Movements). One element of these co-ordinating initiatives would be to evaluate already existing relevant guidelines, such as the ISO guide for arrangements for the recognition and acceptance of conformity assessment results and the different Codex guidelines involving conformity assessment and equivalence. Second, there is a need for co-ordinated national initiatives. Experiences from the SPS area show that an important condition for being able to proceed with the work is that certain states take the lead and provide convincing information and arguments (if these exist) in co-operation with other willing states, on the potential need for developing international guidance.

Generally, there is a need for more information sharing and confidence- and capacity building at the international level in order for equivalence and mutual recognition to play an even more important role in food trade. Moreover, mutual recognition and equivalence are potentially important trade-facilitating tools, but they must nevertheless be studied and applied in combination with international harmonisation and standardization.

1 Equivalence and Mutual Recognition as Trade Facilitation Tools

1.1 Divergent regulatory systems and world trade

First, a crucial distinction between two parts of regulatory systems must be done. Regulatory systems generally consists of (Sykes 1995: 2–3):

- *Rules* of some kind which can be technical regulations, standards or guidelines against which a product or production process or method is judged
- *Conformity assessment*, which refers to the process through which products are evaluated for compliance with the rules.

The important premise for the discussion on equivalence and mutual recognition as trade-facilitating tools is the fact that national regulatory systems, including regulations, standards and procedures for ensuring compliance with regulations and standards (cf. conformity assessment procedures), may cause impediments to world trade.¹ Spencer Henson (2000) points to three ways in which different national regulatory systems can cause trade impediments:

- First of all they can lead to import restrictions or unreasonably high production costs for individual suppliers;
- Secondly, the requirements can have a discriminatory effect on various trade partners;

¹ See for instance: Vogel (1995), Nicolaodis (1997), Pollack and Shaffer (2001), Trebilcock (2002).

- Thirdly, the total scope of the trade can be reduced due to higher prices or more stringent trade barriers for all potential suppliers.

The design and operation of regulatory systems may thus cause unnecessarily high costs for traders and may reduce the volume of trade and thus function as serious trade barriers. In food trade, both food safety/health measures (e.g. maximum residue limits for pesticides and acceptable daily intake of food additives) and technical/quality measures (e.g. mandatory labelling and required trade descriptions) may create trade barriers. Differences between regulatory systems may exist as a result of variations in taste, technology, resources, income level, administrative culture, risk assessment, societal goals or even by chance (Sykes 1995, 1999; Egan 1998). Some of the regulatory differences are clearly legitimate. Moreover, certain variations of regulations do not cause negative trade effects. However, national differences driven by protectionist capture, by bureaucratic indifferences or by information failures resulting in greater costs on foreign firms are true trade barriers (Sykes 1999).

Trade problems caused by food regulations raise four important questions: First, what objectives are the (trade restrictive) regulatory measures designed to fulfil? Second, in what way can these objectives be said to be legitimate? Third, are the measures in place absolutely necessary in order to fulfil these objectives? Fourth, what tools can be used to facilitate trade and ensure fair practise in trade without compromising legitimate national regulatory objectives?

In this report we shall examine how the concepts of equivalence and mutual recognition in food trade arrangements can contribute to reducing or eliminating undesired trade impacts caused by differences in national regulatory systems. We place special emphasis on how these tools are used with regard to technical measures, since previously this has been less explored than equivalence and mutual recognition with regard to food safety/health related measures. Moreover, studies of world food trade have shown that there are more trade barriers originating from the former than the latter (Gezelius et al. 2002). The concepts of equivalence and mutual recognition have been perceived and applied in many different ways. Thus, we wish to contribute to the much-needed clarification of these concepts. Our ambition is to identify situations where equivalence and mutual recognition have been perceived and applied as relevant trade-facilitating tools. Further, we aim at suggesting some of the conditions under which the different tools are more or less relevant. Hopefully, the results of our efforts may contribute to the discussion on the use of equivalence and mutual recognition in relevant international fora such as the Codex Alimentarius Commission (CAC) and the World Trade Organization (WTO).

1.2 Trade facilitation tools – the different concepts

1.2.1 Harmonization

Harmonization is probably the most well known trade-facilitating tool. The goal of harmonization is uniformity of trade measures on an international basis. However, full harmonization may not be achievable in practice or even not desirable for legitimate reasons like for instance differences such as perceived acceptable protection levels etc. Still, having the same product standard or regulation and the same conformity assessment procedures on a world – wide basis can seem very intriguing. In theory it would remove the costs of adapting to multiple regulations and the trading conditions would be the same for all firms regardless of nationality.

The WTO is placing great emphasis on the role of harmonization through the use of standards. Even though compliance with international standards is voluntary, standards may in practice be ascribed a certain semi-binding authority through the WTO². This is due to the fact that WTO members, on the basis of the SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures) and the TBT Agreement³ (Agreement on Technical Barriers to Trade), are committed to participate in establishing new international standards and to base their national regulations on relevant international standards when such exists. In the lack of international standards, it is necessary to identify and compare variations between the national regulations, standards or procedures and to remove these differences on a bi- or multilateral basis. To harmonize national measures will then imply transforming two or more rules into one, the result being that two or more countries recognize, establish and apply the same regulatory measures.

Further, governments are more frequently making references to standards in regulations instead of including detailed specifications and requirements of goods in legal texts. “The New Approach to Product Regulation” of the European Union has established the principle that community directives are limited to determine the *essential requirements* that products must meet to be placed on the market. Technical specifications of products, meeting these essential requirements, are laid down in standards established by (inter-) governmental or private standardization bodies. Following a standard automatically gives a presumption of conformity with the corresponding essential requirements (European Communities 2000). In the food sector, international harmonization can, e.g., be achieved through the elaboration of new standards through the food standardization body Codex Alimentarius Commission and by ensuring that the member states change their rules accordingly. As states adapt their regulatory systems to international standardized solutions, there will be reduced variation as to how food is produced, manufactured and controlled. Harmonization thus leads to a situation where states implement the same measures based on the same regulatory objectives.

² See for example the WTO rulings in the dispute between the EU and Peru concerning trade description of sardines (WTO 2002i). The EU lost the case because it had not based its regulation on the relevant Codex standard.

³ See e.g. Article 2.4 and 2.6 of the TBT-agreement and Article 3 of the SPS-agreement.

Against this background, the work of international standardization bodies have become of greater importance. The process of harmonization may, however, be quite time consuming, and full harmonization can thus be difficult to accomplish. In fact, some claim that harmonization is a rigid tool that does not respond well to changes. Hence, harmonization is not always necessary or the appropriate tool to use in many situations (Sykes 1999). Below, we shall elaborate on how equivalence and mutual recognition can be used as alternative trade facilitating techniques allowing for regulatory differences under certain conditions. Harmonization, equivalence and mutual recognition are not mutually exclusive, but complementary means of reducing trade barriers while at the same time achieving regulatory objectives, such as consumer protection.

1.2.2 Equivalence

Equivalence assessment and acceptance is an alternative way of facilitating trade. In fact, the equivalence concept is based on the fact that regulatory goals, e.g., in relation to health and food quality, in practice may be fulfilled by the use of different kinds of measures. For instance, Australia uses heat treatment of milk for the production of hard cheese to ensure food safety. Switzerland uses raw milk, however still attaining at least the same level of pathogen destruction as pasteurisation through a special manufacturing process (WTO 2001a). New Zealand for instance accepts a "no risk"– period of import of cucurbits from Australia during the winter as an alternative health-measure instead of requiring the use of chemicals as a treatment to avoid the spread of fruit flies (WTO 2001b). This implies that Australia has demonstrated that the method they apply for fulfilling the objectives for sanitary/phytosanitary measures are just as effective as the methods required by New Zealand. Then, New Zealand can accept the use of the alternative measure without undermining the objectives of the national regulation. An example in relation to technical measures is Japan's acceptance of the U.S. standard for organic agricultural products as equivalent to the relevant Japanese standard, allowing products labelled in accordance with the U.S. standard on the Japanese market (WTO 2002, see also case description in chapter 3 of this report). In other words, Japan considers the U.S. standard and labelling practices to be ensuring the interest of the consumers in a way just as effective as its own standard and practices. These examples illustrate that equivalence recognition can lead to the same results as harmonization; trade barriers are removed and the products can be accepted on the basis that they fulfil the relevant regulatory objectives – even though regulatory differences persist. Agreements involving equivalence assessments make it possible to *maintain distinct national regulatory measures while at the same time removing the measures' trade restrictive effects.*

1.2.3 Mutual recognition

A third way of facilitating trade is to accept regulatory differences by way of mutual recognition, which is a tool that can be conceived and applied in different ways.

Mutual recognition can simply mean that two or more parties mutually accept each other's rules. Such acceptance is used in situations where differences in

national regulatory measures and objectives are considered to be of no such nature as to allow for trade restrictions. A classic example of this conception of mutual recognition is the so-called “Cassis de Dijon doctrine” (see Box 1) of the European Union, which implies that a product lawfully produced in one member state must be accepted into another member state. According to this doctrine national food legislation cannot be invoked to prevent trade unless necessary for reasons of public health, fiscal supervision or consumer protection. *Mutual recognition in this sense means that producers that comply with the regulatory requirements of an exporting country, automatically should be allowed into an importing country.*

BOX 1: Mutual recognition in the EU: The “Cassis de Dijon” case

In the “Cassis de Dijon” case, the European Court of Justice struck down a German import prohibition, which banned the import, sale and/or marketing of liqueurs that didn't meet minimum German alcohol standards. The case involved a French liqueur (“Cassis de Dijon”) manufactured from black currants. Cassis contains 15%–20% alcohol and the German standards prescribed 25%. The European Court of Justice ruled that because Cassis met French standards, it could not be kept out of the German market. The European Court rejected the German health argument as unconvincing and dismissed its consumer protection justification. The “Cassis de Dijon doctrine” was further confirmed by the European Union’s ‘new approach’ to standardization, adopted in 1985 (see European Commission 2000 and BOX 2 in this report).

A second conception of mutual recognition is linked to so-called *Mutual Recognition Agreements (MRAs)* on conformity assessment procedures. The mutual recognition aspect means that the involved *parties mutually accept each other's conformity assessment procedures as equivalent* in order to ensure compliance with prevailing regulatory requirements. Normally, an MRA is a voluntary agreement between governmental conformity assessment bodies. Certification bodies in two countries may, *inter alia*, accept each others certification as equivalent. Agreements between non-governmental agencies are usually called Mutual Recognition Arrangements. MRAs could for instance enable a supplier to submit a test report from the accepted laboratory in its home country to obtain certification in another country without a repetition of costly testing. Different accreditation bodies may also accept each others systems, competence and results as equivalent and establish agreements on mutual recognition. Then, a certification body could for instance use its assessment report supplied by the accreditation body in the home country for attaining accreditation in another country without repetition of a full on-site assessment (ISO Bulletin, October 2002)⁴.

⁴ The International Accreditation Forum (IAF) is the world association on conformity assessment accreditation bodies in the fields of products, services, management services, personnel and other programmes of conformity assessment. One of the main goals of IAF is to develop a single worldwide program for conformity assessment assuring that accreditation

MRAs do not presuppose harmonization or recognition of equivalence of regulations or standards (Nicolaodis 1997). Hence, the exporting country checks conformity according to the rules or standards of the *importing country*. Products can then be approved before export in the country of production reducing or eliminating the need to check conformity with the rules of the importing country again at arrival. In such cases, companies must still bear the costs of producing their goods in accordance with both the product requirements of their national market and other sets of requirements for exports. However, they have the benefits of a “one stop” control removing duplicated inspections and fees and reducing the time for the product to reach the market.

It is important to be aware that, in practice, MRAs can involve a mix of several elements. MRAs can include, e.g., equivalence judgement and acceptance in relation to conformity assessment procedures, the acceptance of certain differences in both procedures and objectives of national regulatory systems without any equivalence assessment involved (mutual recognition in the “Cassis de Dijon” version of the concept), as well as elements of compliance, for instance procedures to ensure compliance with the other states’ rules.

MRAs on conformity assessment also provides for a more efficient system with better division of labour between countries and between public and private control bodies helping to spread the cost of assuring compliance (Merill 1998). However, the most favourable solution would be to produce the goods in accordance with only one set of product requirements (regulations and standards are either harmonized or recognized as equivalent) as well as getting the products tested and declared just once (agreements on mutual recognition of conformity assessment). Thus, harmonization, equivalence and mutual recognition of conformity assessment are often interlinked in trade facilitating agreements.

1.2.4 Work on equivalence and mutual recognition in international organizations

The WTO agreements on sanitary and phytosanitary measures (SPS Agreement) and technical barriers to trade (TBT Agreement) both explicitly address the problem of trade restricting regulatory measures (regulations, standards and conformity assessment procedures, see definitions below). Further, both agreements encourage international harmonization of food standards and the use of equivalence to facilitate trade. In addition, provisions of the TBT Agreement include the use of mutual recognition of conformity assessment procedures (cf. Article 6).

The SPS Agreement covers regulatory measures designed to protect human, animal or plant life or health from risks arising from the entry, establishment or spread of pests, and diseases. The term conformity assessment is not used in the agreement, but SPS measures include control, inspection and approval procedures and thus also cover conformity assessment procedures (Annex A (1) and Annex C

can be relied upon across borders. Within Europe, the parallel body to IAF is The European Cooperation for Accreditation - EEA.

of the SPS Agreement). The SPS Agreement sets out different criteria for the use of *health/sanitary protective regulations* (e.g., requirements regarding scientific evidence, risk assessments, appropriate level of protection) to ensure that the *least trade restrictive measures* are applied. The TBT Agreement covers technical regulations, standards and conformity assessment procedures. *Technical regulations* means mandatory requirements, other than regulations defined as sanitary measures, in relation to product characteristics, processes and methods (Annex I of the TBT agreement)⁵. A main purpose of the TBT Agreement is to ensure that technical regulations do not create unnecessary trade barriers.

Technical regulations include requirements regarding quality, marking or labelling, trade descriptions, packaging, terminology etc. In contrast to regulations, *technical standards* are non-mandatory rules, guidelines or characteristics for products or related processes and production methods that provides for common and repeated use. Standards are producing uniformity by establishing general product or product related requirements. Annex 3 of The TBT Agreement is a code of good practice for the preparation, adoption and application of standards open to acceptance by any standardization organization. *Conformity assessment procedures* are any procedure aimed to determine that relevant requirements in technical regulations or standards are fulfilled⁶. Some examples are inspections, testing and sampling, certification, management system assessment and registration, process evaluation, and accreditation of the competence of those activities and recognition of an accreditation program's capability. Food control and inspection is thus one way of performing conformity assessment.

Certification and accreditation are activities closely related to conformity assessment. Certification involves providing consumers assurance that, e.g., a company produces its products *in accordance with the requirements of specific standards or regulations*. Certification is thus a formal acceptance of this company's ability to ensure conformity. The certification process often includes comprehensive and repeated evaluations of documentation combined with on-site audits. Certified companies may be granted the right to use specific labels on their products to communicate to the consumer that their products conform to the relevant standard or rule. The bodies performing certification must be accredited, meaning that the *body is recognized as competent* to perform tasks related to conformity assessment, e.g., testing, calibration or certification.

Both the SPS Committee and the TBT Committee have addressed how the concepts of equivalence and mutual recognition can be applied to facilitate trade in relation to regulations, standards and conformity assessment procedures. However, these concepts also play a key role in conjunction with Codex Alimentarius norms, in assisting the most efficient and effective application of both sanitary and technical food standards (Gascoine 1999). Codex Alimentarius Commission (CAC) was created in 1963 by FAO and WHO, to develop food standards, guidelines and

⁵ See point 2.4 for a discussion on SPS vs. TBT- measures.

⁶ See e.g. descriptions of the concept of conformity assessment on the websites of the International Organization for Standardization (ISO): <http://www.iso.ch> and the American National Standards Institute (ANSI): <http://www.ansi.org>

related texts. Today CAC, with over 170 members, has become the seminal global reference point for consumers, food producers and processors, national food control agencies and international food trade. The main purposes of CAC are protecting consumer health and ensuring fair practices in food trade and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.⁷

CAC is responsible for developing standards, recommendations, guidelines, etc. These are relevant for both sanitary measures (SPS) and technical measures (TBT) and thus important in facilitating food trade. CAC is also important for developing guidance for conformity assessment through its work on food import and export inspection and certification systems. However, with regard to conformity assessment, the standards and manuals elaborated by other organizations, e.g. the International Organization for Standardization (ISO), the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF) are also important. ISO is a non-governmental body having a complementary role to Codex and other governmental standardizations bodies. The ISO standards do not prescribe actual product requirements like Codex standards do. ISO standards describes how to implement and comply with product requirements for instance in terms of methods for testing and analysing, resulting in harmonization of conformity assessment procedures.

Over the past years, CAC has increasingly focused its work on sanitary measures, i.e. food safety and hazard related standards. However, work on technical standards, including quality requirements and elements of conformity assessment systems, is still part of the mandate (cf. ensuring fair practise in trade). Moreover, technical standards still play an import role in both national food regulations and as impediments to world trade. CAC elaborates standards related to technical regulations under both horizontal committees (e.g., Codex Committee on Food Labelling) and vertical/commodity committees (e.g., Codex Committee on Fish and Fishery Products). The work in Codex Committee on Food Import and Export Inspection and Certification Systems is of special relevance for conformity assessment with regard to food standards.

1.3 Methods and available empirical data

In the preparations for the report we conducted interviews with persons that have been involved in the work on equivalence and mutual recognition in addition to performing a comprehensive document and literature review. We also made extensive searches for information on the Internet. Still, the report suffers from a lack of comprehensive documentation regarding the presented examples of the use of mutual recognition and equivalence. We utilized the limited available empirical data as much as we could. In an “ideal world” much more documentation would have been provided. Thus, the report does not contain an in-depth analysis of the included cases, but merely descriptive presentations. However, we think that the report

⁷ Cf. Article 1 of the Statutes of CAC: <http://www.codexalimentarius.net/>

provides an overview of the field and that it may be a useful input for further discussions and investigations.

1.4 The structure of the report⁸

The report is structured as follows: In chapter 2 we present the work on mutual recognition and equivalence in the WTO and the CAC. We furthermore also touch upon other international organizations' work on these issues in. In chapter 3 we present actual examples of the use of equivalence and mutual recognition as trade-facilitating tools with regard to technical measures and conformity assessment procedures. First, we present examples from the food sector. Then, we present examples from other sectors that may be interesting and relevant for the food sector. In chapter 4, we pinpoint some critical issues and pose some central questions with regard to the process of reaching agreement on equivalence and mutual recognition. In chapter 5, we ask how relevant equivalence and mutual recognition are as trade-facilitating tools in a TBT context. Finally, we present some considerations and recommendations in relation to pursuing the work on international guidance on these issues.

⁸ This report is a continuation of the work that was initiated and presented in NILF Working Paper 2002-36: "Equivalence and Mutual Recognition Agreements in Relation to Technical Measures".

2 Equivalence and Mutual Recognition in the WTO and the CAC

2.1 Introduction

In this chapter we investigate how the concepts of equivalence and mutual recognition are perceived and applied in the WTO, the CAC and other international organizations handling food-related issues. The purpose is to analyse the role of these trade-facilitating tools in world trade today. Moreover, we consider the potential for developing further international guidance, e.g. in a TBT and Codex context, on how these tools can be applied in practise in co-operative arrangements between national regulatory systems.

2.2 The work on mutual recognition and equivalence in the WTO

2.2.1 The SPS and TBT Agreements under the WTO

The SPS and TBT Agreements of the WTO are the most relevant agreements with regard to the use of equivalence and mutual recognition in facilitating food trade. The SPS Agreement covers sanitary measures and associated food control and inspection systems; the TBT Agreement covers technical measures, standards and conformity assessment.

Specifications for the use of equivalence are laid down in Article 4 of The SPS Agreement:

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Measures aimed to protect health must be scientifically justified based on a risk assessment defining a corresponding "Appropriate Level of Protection – ALOP". The main provision on equivalence in the SPS Agreement, Article 4.1, opens for accepting different ways of achieving a defined protection level – ALOP. Paragraph 2 of the article also encourages members to enter into equivalence agreements. Mutual recognition or MRAs are not mentioned in the SPS Agreement.

The TBT Agreement includes both the concept of equivalence and mutual recognition. The main provisions on equivalence in the TBT Agreement are Article 2.7 on technical regulations and Article 6.1 on conformity assessment procedures:

2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

6.1 Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:

Article 2.7 of the TBT Agreement is less specific than Article 4 of the SPS Agreement as to the legitimate objectives technical regulations can fulfil, reflecting the more "open-ended" character of the TBT Agreement. While SPS measures are adopted for health protection objectives only, TBT measures may fulfil a wide range of legitimate objectives, e.g., national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or environmental protection (Article 2.2 of the TBT Agreement). Thus, the goal of the technical regulation must be (made) explicit before assessing whether the different means used to achieve this specific goal can be accepted as equivalent.

Article 6.1 is quite specific as to the application of equivalence in relation to conformity assessment. Moreover, the agreement goes more into detail on the relevance of equivalence for conformity assessment procedures than for technical regulations. Establishing equivalence of conformity assessment procedures simply means accepting that different procedures can be used for compliance checks achieving the same level of conformity assurance. Article 6.3 encourages the

members to enter into agreements on mutual recognition of conformity assessment procedures (MRAs):

6.3 Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures. Members may require that such agreements fulfil the criteria of paragraph 1 and give mutual satisfaction regarding their potential for facilitating trade in the products concerned.

2.2.2 Sanitary and phytosanitary measures vs. technical food measures

The different nature of SPS and TBT measures may have implications for the application of equivalence and mutual recognition as trade-facilitating tools.

In the food sector, sanitary measures are linked to the goal of ensuring food safety and reducing food hazards and risks. The key question is whether the measures are safe or not in order to achieve a given level of health protection. As mentioned above, equivalence assessment is then aimed at determining whether two different SPS measures are both capable of achieving the same level of protection.

In contrast, TBT measures can be adopted for various reasons making it harder to find comparable rules. Technical measures can be based on everything from culture and religion (such as rules for halal meat and kosher food) to historic traditions and regional interests (such as different criteria for using the trade description "Sardine"). Further, descriptive characteristics of technical measures are often intertwined with the objective itself or the objectives are not specified. In addition, it seems to be difficult to find the criteria for comparing TBT measures with regard to equivalence. While SPS measures have to be scientifically justified and based on risk assessment, there are no such conditions for introducing TBT measures. Consequently, there is no parallel to the SPS criteria of appropriate level of protection (ALOP). Assessment of equivalence for technical measures thus involves potentially a more complicated process of identifying both legitimate objectives and parameters that can be used for comparison. Against this background, it may at first sight seem harder to grasp the potential for equivalence recognition in the TBT area than in the SPS area.

However, the concept of mutual recognition of equivalence of conformity assessment is clearly relevant for both sanitary/phytosanitary and technical measures. The key question for determining equivalency of conformity assessment systems is whether these systems have the capacity to ensure compliance with a given set of requirements.

Mutual recognition, in the meaning of automatic acceptance of a product produced under foreign rules to enter the market, would also be just as relevant for SPS measures as for TBT measures.

2.2.3 The SPS Committee's work on equivalence

Equivalence has been a subject of attention in the SPS Committee for several years. Naturally, the work of the SPS Committee has been focusing on the implementation of Article 4 – the equivalence provision of the SPS agreement. The experi-

ences of the member states with regard to equivalence recognition have been important for the discussions, including a special focus on the views of developing countries.

In July 2001, the General Council of the WTO requested the SPS Committee to prepare specific recommendations for the implementation of Article 4 of the SPS Agreement. A decision on this issue was adopted in October 2001 (WTO 2001a). In recent years, several revisions and additions have been made to this Decision (WTO 2002e, 2003l, 2004a, 2004b, 2004c). In this section, we will present the main elements of the SPS Committee's decisions on the implementation of Article 4. To illustrate, we will present some of the notifications made by member states on their experiences with equivalence recognition. Finally, the link between the SPS Committee and other international organizations will be addressed.

An important element in the SPS Committee's Decision on the implementation of Article 4, is the clarification on *the different roles of the importing vs. the exporting country* in relation to equivalence recognition. The Decision states that the importing country is responsible for explaining the objective and rationale of the sanitary or phytosanitary measure. Further, the importing country should identify the associated risk, provide for a copy of the risk assessment and indicate the appropriate level of protection that the measure is designed to achieve. In general, the importing country should provide the information necessary to aid the exporting country in demonstrating equivalence of their measures. The Decision also states that the importing country shall respond in a timely manner to any requests on equivalence recognition from exporting countries, normally within a six-month period. The exporting country has the burden of demonstrating that the measure satisfies the protection level of the importing country through scientific and technical documentation. However, the importing country should be given access to inspection or testing in relation to the equivalence assessment.

The SPS Committee adopted a specific working programme on further implementation of Article 4 on equivalence in March 2002 (WTO 2002d). This programme was completed in March 2004. Through this work, further clarification of the Decision on equivalence made in 2001 has been reached on several *issues also related to the equivalence assessment process*. Further clarifications have been made in relation to the aspects of “accelerated procedure” and “historic trade” (paragraph 5 of the Decision), “trade disruption” (paragraph 6) and “comparison of protection levels” (paragraph 7). The issues of accelerated procedure and historic trade concerns the possibilities for speeding up the equivalence assessment process based on familiarity and confidence between the parties due to trade relations prior to the equivalence assessment. Argentina, New Zealand and Australia were engaged in this debate with special submissions (WTO 2002e, 2002f, 2002g). The Committee states that available information and experience, if directly relevant to products or measures under consideration, should be taken into account in recognition of equivalence of measures proposed by the exporting country.

The Committee also specifies the relevant information and experience to be considered: historic knowledge of the competent authorities in the exporting country, available evaluation and recognition of product related systems of inspec-

tion and certification, available scientific information and relevant information concerning SPS measures of other products when useful. The importing country should also consider the risk of the product in order to accelerate the procedure in cases of low risk. Information already available should not be sought again. The Decision also underlines that for accelerated procedures, the importing country should draw up a schedule of the necessary steps and timeframes for the equivalence assessment process in order to provide predictability (WTO 2004b).

In relation to the issue of “disruption of trade”, the Decision of the Committee makes clear that requests for equivalence recognition shall not in itself be a reason to disrupt or suspend on-going imports from the requesting country. The SPS Committee actually underlines that such an act would be in apparent violation of the obligations under Article 2 of the SPS Agreement. However, recognition of equivalence does not impede on the right of an importing country to implement necessary SPS measures even if this should coincide with requests for equivalence recognition. To avoid any misinterpreted linkage of issues, the Committee recommends that the importing country should give an immediate and comprehensive explanation of the reason for its actions in restricting trade to the affected party.

The ability of SPS measures to fulfil the appropriate level of protection, ALOP, is an essential point of equivalence assessment that members seem to find difficult in practice. Australia and Argentina (WTO 2002g, 2002h) gave special submissions on this item. The main issues in the discussion were that it could be difficult for the exporting country to demonstrate that the alternative SPS measure satisfies the ALOP of the importing country. This would be the case when the importing countries have failed to define their ALOP precisely or the ALOP is not explicit at all. In these situations there is a need for an objective basis for comparison. The SPS Committee has developed special “Guidelines to Further the Practical Implementation of Article 5.5” of the SPS Agreement that may assist members in judging equivalence with regard to ALOP (WTO 2000b).

In October 2000, the General Council of the WTO requested the SPS Committee to examine the concerns of developing countries regarding equivalence of SPS measures and to come up with concrete options on how to deal with them. Some of the developing countries have faced difficulties when trying to get their alternative SPS measures accepted. Some developing countries furthermore seem to perceive the requirements of the developed countries more as demands for “sameness” of measures instead of acceptance of alternative measures. The Decision of the Committee on this issue recognizes the importance of transparency, exchange of information and confidence building to achieve agreement on equivalence. The Committee calls the attention to Article 9 of the SPS Agreement, which states that developing countries shall receive technical assistance to facilitate the implementation of Article 4 on equivalence. The Decision points out that such assistance may involve helping an exporting country to identify and implement measures which can be recognized as equivalent or to otherwise enhance market access opportunities.

Several member countries have reported on their practical experiences with equivalence to the SPS Committee, among them Australia, New Zealand, United

States, EU, Japan, Indonesia, Fiji, Thailand and Chile. However, some of the notifications give little information about both the alternative SPS measure in question and about experiences from the equivalence assessment process. Several of the notifications mention equivalence acceptance in relation to one specific product, e.g., acceptance of alternative health measures in the manufacturing process of cheese or different kinds of alternative treatment of fruit and vegetables to avoid spread of disease. The notifications of the United States and the EU stand out as two of the most comprehensive inputs to the SPS Committee. Below, we shall briefly present the main elements of these notifications.

The U.S. government informed the SPS Committee that it has established several sets of criteria for equivalence assessment of food regulatory systems of other countries. Special criteria for assessment of equivalence in relation to meat and poultry regulations are established. All countries wanting to export meat or poultry to the United States must first undergo an equivalence assessment. However, the situation for meat and poultry is special, since 85% of all food imports to the United States must not be subjected to any equivalence assessment. The assessment consists of a questionnaire, review of documents and an on-site audit of the inspection system of the exporting country. If equivalence is established, the country is placed on a list of approved exporters. Thus, this system does not include any formal agreements. In 2000, 36 countries had achieved equivalence recognition of their control and inspection systems for meat and poultry.

Criteria for equivalence assessment in relation to seafood and HACCP control systems (Hazard Analysis and Critical Control Point) are also in place. Among other elements, the United States reports that in their experience, equivalence determination requires a significant investment of technical and trade experts to address and resolve safety issues. Even in situations where ALOPs and governmental institutions may appear to be similar, determination of equivalence has taken several years to establish. The United States pinpoints various practical challenges that should be kept in mind when implementing the concept of equivalence, e.g., the need to consider whether the potential trade benefits can justify the administrative burden of making a determination of equivalence.

The EU also informs of several practical examples of implementations of the concept of equivalence, making their system of equivalence recognition in relation to seafood inspection and certification systems a case in point. Third-country regulations on fish and fish products must at least be equivalent to EU regulations. Equivalence in relation to health certificates is of special importance. In 2002, the seafood control and inspections systems of 62 countries had been recognized as equivalent. These countries are included in a list of approved fish exporters to the EU. An important advantage for the approved exporting countries is reduced number of inspections at the border. The EU reports that inspections have been reduced from 100% to 50% or 20% for certain products depending on the associated risk. Thus, the EU points out that equivalent levels of inspection and certification systems, e.g. for fishery products, lead to facilitation of trade.

The SPS Committee has established co-operation with Codex Alimentarius Commission, OIE (The Office International des Epizooties) and the ICPM (The

Interim Commission on Phytosanitary Measures)⁹ with regard to equivalence issues. Member states are encouraged to participate in these standardization bodies and Codex, OIE and ICPM are invited to inform the SPS Committee about their activity on equivalence. The SPS Committee frequently refers to the ongoing work of these organizations or make reference to established standards and guidelines in relation to equivalence. In fact, the SPS Committee formally encouraged Codex to finalize their guidelines on the judgement of equivalence. The Committee also encourages OIE and ICPM to elaborate guidelines on equivalence recognition in relation to animal and plant health measures. In addition, the SPS Committee also requests these bodies to take into account the clarifications made by the Committee with regard to equivalence in their work.

To sum up, the impression is that the SPS Committee has carried out an extensive amount of work in relation to equivalence. Important clarifications have been made with regard to implementation of the equivalence provisions of the agreement. In addition, the opinions and experiences of the member states with regard to the practical use of equivalence have to a certain extent been mapped. A rather close contact has been established with the international standardization bodies Codex, OIE and ICPM. For instance, the SPS Committee has recognized the urgency for Codex to develop guidance on the judgement of equivalence.

The SPS Committee has no further working programme on equivalence, but it is decided that equivalence will be a standing agenda item for regular meetings in the SPS Committee.

2.2.4 The TBT Committee's work on mutual recognition and equivalence

The TBT Committee has repeatedly drawn attention towards the need to address the issues of equivalence, mutual recognition and MRAs under the TBT Agreement, including also the issue of mutual recognition of conformity assessment procedures (WTO 1997a, 2000a).

During the First Triennial Review of the TBT Agreement, the Members were invited to exchange views on how the concept of equivalence might apply in relation to voluntary standards and on their experience in the implementation of Article 2.7 relating to equivalence of technical regulations (WTO 1997a: 6). Further, the Committee recognized the emerging interest in concluding MRAs and the possible difficulties and problems associated with these, in particular for developing country Members (WTO 1997a: 10). The problems included those relating to cost, transparency, non-MFN nature,¹⁰ opportunity to enter into negotiations for the

9 OIE (or the World Organisation for Animal Health) is an intergovernmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries. In March 2004, the OIE totalled 167 Member Countries. The ICPM governs the implementation of the U.N. International Plant Protection Convention (IPPC), which is an international treaty relating to plant health, to which 127 governments (as of 26 February 2004) currently adhere. ICPM is presently composed of representatives from both contracting parties to the IPPC and FAO members. The commission meets annually and provides a forum for the discussion of international plant protection issues and sets the annual programme of work.

¹⁰ MFN: Most-Favoured Nation Principle.

conclusion of MRAs, the need to take into account the quality of the conformity assessment procedures rather than the origin of the product, and efficiency and effectiveness of MRAs to solve problems of multiple testing and conformity assessment procedures (ibid.). Hence, the member countries have been requested to notify MRAs. By early 2003, the Committee had received 44 such notifications.

Several of the Member's submissions made to the First Triennial Review discussed the issue of mutual recognition and – explicitly or implicitly – the concept of equivalence. New Zealand submitted a communication in 1997 titled “Requirements of the Agreement on Technical Barriers to Trade Concerning the Preparation, Adoption and Review of Technical Regulation” (WTO 1997c). In New Zealand's view, harmonization and recognition of equivalence are desirable where similar circumstances in each country make this a viable option. New Zealand thus sees equivalence and mutual recognition as potential viable options to pursue in order to reduce the problem of technical trade barriers but also recognizes the problems related to differences in national regulatory systems.

In 1997, Canada requested the First Triennial Review to “...consider mutual recognition of test results and conformity assessment procedures” and added that, “...this discussion should include mutual recognition issues with respect to both international and national technical regulations and standards” (WTO 1997b: 5). Canada also stressed the usefulness of having a discussion among the Members regarding “...their experience in negotiating MRAs with a view to develop draft guidelines for mutual recognition agreements” (ibid.).

In 1998, ISO submitted a Communication to the TBT Committee notifying that draft guidelines on MRAs were under development (WTO 1998a). This work was concluded in 2002, and in a submission to the TBT Committee in 2003, ISO announced the completion of ISO/IEC Guide 68:2002: “Arrangements for the recognition and acceptance of conformity assessment results” (WTO 2003e). The ISO Guidelines are meant to provide “...an introduction to the development, issuance and operation of arrangements for the recognition and acceptance of results produced by bodies undertaking similar conformity assessment and related activities” (WTO 2003e: 1).

In 1999, the WTO Secretariat prepared a stocktaking paper of the submissions by delegations on elements related to the Work Programme of the First Triennial Review, including the issues of equivalence and mutual recognition (WTO 1999). For example, Colombia had showed an interest to “...study and develop the areas of mutual recognition and equivalence with respect to eco-labelling” (WTO 1999: 3). In Columbia's opinion the application of the two concepts could solve some of the problems raised with regard to such schemes. Canada had provided several examples of technical regulations where it had referenced, or considered as equivalent, the technical regulations of other Members. The examples included consideration of data and testing methods as equivalent to Canadian data and testing methods, regulations which are considered obsolescent in relation to United States performance standards, and/or international standards and the use of technical regulations from other countries (WTO 1998c). Thailand had pointed out that the acceptance as equivalent of technical regulations of other members is provided in

the Industrial Product Standards Act of Thailand (WTO 1999: 5). However, because establishment of equivalence is proven difficult, Thailand prefers that equivalence would be best resolved with the adoption of international standards. If nothing else, the paper from the Secretariat showed the *relevance* of recognition of equivalence in a TBT context.

During the Second Triennial Review, the TBT Committee reiterated the importance of Members notifying MRAs (WTO 2000a: 8). Moreover, the Committee “reiterated the importance of giving positive consideration to accepting as equivalent technical regulations of other Members as provided for under Article 2.7” (WTO 2000a: 9). A reference was also made to equivalence assessments in arrangements involving accreditation bodies and their activities. However, the Committee stated that there already exist international standards and guides for such arrangements.

The TBT Committee further mentioned the possibility of unilaterally recognizing the results of foreign conformity assessment procedures and the relevance of Article 6.1 of the TBT Agreement in this respect (WTO 2000a: 27). In the absence of accreditation, the conformity assessment body may prove its competence by other means. One such mean is to unilaterally recognize as equivalent the competence of the conformity assessment body, foreign test reports and certificates. It is also worthwhile mentioning that the TBT Committee has emphasised that equivalence with regard to standards should only be applied when no international standard exists, and then only as an interim measure until suitable international standards are made available.

New Zealand has on several occasions stated that equivalence of standards has merit as a means of avoiding and further reducing unnecessary obstacles to trade and that arrangements for recognition of equivalence can provide a useful starting-point for agreement on content of future international standards (WTO 1998b, 2000c). New Zealand has also provided examples of how it has implemented its obligations under Article 2.7 of the TBT Agreement (WTO 1998c). One striking example is the Trans-Tasman Mutual Recognition Arrangement (TTMRA) where the key principle is that a good, which can be legally sold in one country, may be legally sold in the other, without having to meet further sales-related regulatory requirement. The agreement means that differing Australian requirements relating to sale are recognized as equivalent to meet New Zealand’s objectives and vice-versa. We will come back to this arrangement later in the report. New Zealand also mentions bilateral MRAs and referencing to other countries’ national standards in New Zealand’s regulations, as ways to facilitate trade under the TBT Agreement.

New Zealand has noted that even though Article 2.7 of the TBT Agreement addresses the issue of equivalence for technical regulations, no similar wording exists in the text referring to voluntary standards (i.e. Annex 3: Code of Good Practise). Consequently, in 1998 New Zealand proposed an inclusion in the Code of Good Practise of an additional paragraph that more or less would reflect the wording on equivalence in Article 2.7 (WTO 1998b). In the process leading up to the completion of the Second Triennial Review, New Zealand submitted a document containing a clarification of its position on recognition of equivalence (WTO

2000c). Here the proposal on changing the text of the TBT Agreement was withdrawn and replaced by a proposal on including a text on equivalence of standards in the TBT Committee report to the General Council of the WTO. Thus, in the Annual Report of the TBT Committee for 2000 the following text was included (WTO 2000d):

As an interim measure until suitable international standards were developed, the Committee noted that in some cases standardizing bodies or regulators in the territories of some Members had chosen to accept as equivalent standards originating from other Members, even though these standards differed from their own, on the basis that such standards fulfilled their objectives. The Committee considered that Members may find it useful to further explore equivalency of standards as an interim measure to facilitate trade in the absence of relevant international standards.

The TBT Committee further reiterated the importance of giving positive consideration to accepting as equivalent technical regulations of other Members as provided for under Article 2.7.

In 2001, Canada made a contribution to the TBT Committee concerning the application of mutual recognition (WTO 2001). In the document “A Policy Framework for Mutual Recognition Activity” Canada elaborated on its experience and policy framework related to mutual recognition activities in non-sanitary/phyto-sanitary product sectors.

In a contribution to the Second Triennial Review, Canada elaborated on the application of MRAs to which Canada has become a Party involving conformity assessment (WTO 2000b). Canada has entered into these arrangements with the purpose of eliminating duplicative testing and certification requirements, and thus reducing the burden on industry and regulatory agencies, thereby facilitating trade. Canada’s MRAs cover specific sectors and include recognition of inspection results, test reports and/or conformity certificates issued by bodies located in the territory of the exporting party (or parties), but deemed capable of testing to the importing party’s regulatory requirements. An equivalence assessment of different conformity assessment procedures is thus included in MRAs. In Canada’s opinion, negotiation of MRAs can be a labour intensive exercise and there is therefore a need for clear criteria for undertaking MRA negotiations to ensure that these reflect economic and stakeholder interests. Canada further has an emerging preference for single sector MRAs over the multi-sector framework model because these are easier to negotiate and implement. In addition, they tend to avoid the heavy bureaucratic structure associated with multi-sector MRAs. Canada further stressed that MRAs may not be appropriate to every situation.

The work on the Second Triennial Review shows that the TBT Committee recognizes the importance of both MRAs and the recognition of equivalence for technical standards and regulations. Further, some countries, such as New Zealand, Canada and the EC, as will be further illustrated) have shown a particular interest in pursuing the work on mutual recognition and equivalence in the context of the TBT Committee.

In 2002, the European Commission issued a Communication to the TBT Committee titled “A Policy Framework for the Facilitation of Trade in the Fields of

Standardization and Conformity Assessment: A Toolbox of Instruments” (WTO 2002b). The document presented experiences of the European Commission in trade facilitation in the area of technical regulation, conformity assessment and certification. In addition, the document included an analysis of how to choose between different trade-facilitating tools, including mutual recognition and equivalence.

The European Commission stated that recognition of equivalence is a potentially powerful tool, but that the mechanism can be technically complex in practise, which could explain why it is rarely applied (WTO 2002b: 12). Further, because of the complexity involved the Commission does not believe that the principle of equivalency recognition can be considered of general applicability. The Commission nevertheless stated that where the principle can be applied, “...it is a valuable instrument of trade facilitation while fully respecting the regulatory autonomy of the parties” (WTO 2002b: 12).

Tabell 2.1 An indicative list of tools for addressing regulatory issues

No.	Issues	Some tools for addressing them
1.	Compatibility of approach	Regulatory co-operation
2.	Coherence of regulation	Harmonization of regulation International regulation Recognition of equivalence
3.	Coherence of standards	Harmonization of standards International standardization Recognition of equivalence
4.	Transparency and impartiality of regulations and standards	Harmonization International regulation and standardization Recognition of equivalence
5.	Appropriate level of regulation	Regulatory co-operation
6.	Transparency and impartiality in obtaining certification	Mutual recognition agreements Technical assistance
7.	Recognition of certificates	Mutual recognition agreements
8.	Compatibility of market surveillance	Regulatory co-operation Technical assistance
9.	Development of infrastructure	Technical assistance

The Commission further presented a “case study” containing instances of equivalence (see box 2) (WTO 2002b: 13).

BOX 2: Instances of equivalence reported in the EU

The EU's "New Approach" legislation does not set mandatory standards, but recognises them as a means towards achieving regulatory objectives. The standards give "presumption of conformity" with the (obligatory) requirements of the relevant Directive.

In an Agreement on Marine Equipment between the EU and the US, being negotiated in the context of the EU-US Transatlantic Economic Partnership (TEP), the potential recognition of equivalence of regulations would be based on the Conventions of the International Maritime Organization (IMO), which form the technical basis for the regulations both of the EU and the US in this sector.

The Commission also emphasised that MRAs could be important in facilitating trade, but not in all situations. The Commission's opinion was that MRAs are for use when "...the potential partners have paved the way by bringing their systems close enough to make MRAs workable, while either not addressing questions of harmonization, or accepting that harmonization is too remote an objective to be practicable within any reasonable time-frame" (WTO 200b: 15). The preparing of an MRA is thus conditioned on comparable levels of technical infrastructure between the parties. The costs and benefit of MRAs further have to be regarded in the light of political and commercial competition aspects.

The European Commission thus recognizes that equivalence and mutual recognition can play an important role as trade-facilitating tools, but nevertheless proposes a cautious approach in selecting the right instrument in concrete situations. According to the Commission the selection has to depend on "...the characteristics of the markets, the regulatory environment in the third country or region concerned, and the willingness on the part of industries, regulators and other parties to achieve the agreed objectives" (WTO 2002b: 22).

In March 2003, Japan submitted a paper to the TBT Committee titled "A Policy Framework for the Acceptance of Results of Conformity Assessment Procedures" (WTO 2003c). The paper included a discussion on the usefulness of MRAs and equivalence of conformity assessment procedures. The paper, which encouraged the acceptance of conformity assessment results conducted outside of the importing country, was presented in a Committee meeting in May 2003 (WTO 2003d). In this meeting, the Members recognized the usefulness of such exchanges of views and experiences and expressed the need for further discussions. In a subsequent submission, Japan further proposed to examine the use of appropriate accreditation schemes as a complement to or as a basis for MRAs (WTO 2003j). Japan also stressed the importance of strengthening the interrelation between mandatory regulations and voluntary conformity assessment systems in terms of reducing duplicative costs or in the light of the trend of de-regulation.

In 2003, several Member submissions were made to the Third Triennial Review. Under the heading “labelling”, the EC¹¹ stated in its submission the need “to examine the application of equivalence or mutual recognition where appropriate” (WTO 2003a: 3). The EC also mentioned equivalence and mutual recognition agreements as means to facilitate trade.

New Zealand stated in its submission, that it is a “...strong believer in the value of pursuing mutual recognition of conformity assessment procedures” (WTO 2003b: 1). The Trans-Tasman Mutual Recognition Arrangement was again presented as an example of how to better understand the circumstances in which an equivalence approach is likely to work.¹² New Zealand also presented several examples of standards equivalence from the non-food sector. However, it was also recognized that it is more difficult to operationalize equivalence in the TBT context than in the SPS context, and that transparency of equivalence agreements thus becomes even more important in the TBT context (WTO 2003b: 5). Still, New Zealand favours the application of the concept of equivalence under the TBT Agreement for both technical regulations and standards.

Egypt believes that equivalence should be considered in a pragmatic manner and that co-operation between regulatory authorities is an important way of enhancing equivalence (WTO 2003g). Brazil highlights the importance of developing mutually compatible and worldwide accepted conformity assessment programmes, e.g. through MRAs (WTO 2003h). The United States has recognized the relevance of mutual recognition, equivalence and MRAs for the TBT Committee, but in a submission to the Triennial Review, the U.S. government nevertheless stated that MRAs can be successful only in limited situations (WTO 2003i). The United States is more interested in focusing on the implementation of Article 6.4 of the TBT Agreement, which would enable suppliers to use qualified conformity assessment bodies of their choice to provide testing and certification to a given Member’s requirements. Thailand repeated its support of the view that equivalence is important in the TBT context and further suggested that the TBT Committee could consider compiling information on Members’ experiences in order to lay out actions to be taken to fulfil the obligations of Article 2.7 (WTO 2003k). Thailand also agreed with a proposal to invite ISO to share its action on a move to declare specific national, regional or international standards as equivalent rather than setting out one standard as the sole option ((WTO 2003k: 3).

The Third Triennial Review report was issued on 11 November 2003 (WTO 2003f).¹³ The report did not say much about the operation of equivalence and mutual recognition under the TBT Agreement and did little to enhance the work on these issues. This slow progress is probably due to both the limited number of submissions on these issues made by the member countries and to the lack of

¹¹ We use the term EC (European Community) instead of EU (European Union) because this is the name used in the EU’s dealings with the WTO.

¹² See also Chapter 6.12 of this report.

¹³ See Annex I in this report for the text on equivalency and mutual recognition in the Third Triennial Review of the Operation and Implementation of the Agreement of Technical Barriers to Trade.

initiatives with regard to taking the lead on these issues in the TBT Committee. In fact, such initiatives *were* taken in the SPS Committee concerning the issue of equivalence for sanitary measures.¹⁴

Nevertheless, the Third Triennial Review repeated the statement made at the Second Triennial Review on the importance of giving positive consideration to accepting as equivalent technical regulations of other Members as provided for under Article 2.7 (WTO 2003f: 3). Further, it was noted that equivalence can be an element of good regulatory practise and is relevant to conformity assessment as foreseen under Article 6.1 (*ibid.*). The TBT Committee stated that this should not detract the development of international standards. Concerning the issue of good regulatory practise, the Committee agreed to initiate a process of sharing experiences on equivalence, particularly with regard to how the concept is implemented in practise.

The Committee also referred to the Second Triennial Review, where an indicative list of different approaches to facilitate the acceptance of conformity assessment results was identified, namely:

- Mutual recognition agreements of conformity to specific regulations
- Co-operative arrangements between domestic and foreign conformity assessment bodies in the voluntary sector
- The use of accreditation to qualify conformity assessment bodies
- Government designation
- Unilateral recognition of results of foreign conformity assessment
- Manufacturer's/supplier's declarations.

The Committee agreed to further discuss these approaches with a view to analysing them in the light of Articles 5 and 6 of the TBT Agreement (WTO 2003f: 6).

Further on in the Third Triennial Review report the Committee explicitly mentions Article 6.3 of the TBT Agreement, which deals with MRAs. The Committee notes however, that “..appropriate confidence building measures, including accreditation, could facilitate the acceptance of conformity assessment results without entering into MRAs” (WTO 2003f: 7). Even though the Committee states that drawing up MRAs can be a useful approach to facilitate acceptance of conformity assessment results, it also recognizes the difficulties facing the negotiation and implementation of such agreements.

The Third Triennial Review report was adopted on the TBT Committee meeting on 7 November 2003. At this meeting a reference was made to the fact that the Codex Alimentarius Secretariat had made a request to the WTO Secretariat concerning the operation of equivalence and mutual recognition within the TBT Agreement. The WTO Secretariat also informed the Committee that a representative of the Secretariat would attend the meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems in Australia in December 2003 to explain the relevant provisions of the TBT Agreement on

¹⁴ Cf. personal communication with Australian delegate participating in SPS Committee meetings.

equivalence and mutual recognition and report on the work of the TBT Committee, especially the Third Triennial Review.

The Third Triennial Review report was placed on the agenda for the TBT Committee meeting on 23 March 2004. On this meeting the issues of MRAs, mutual recognition and equivalence were not afforded much attention. However, it was confirmed that a process of sharing experiences on equivalence would be initiated, particularly on how the concept was implemented with regard to good regulatory practise.

After the discussion on the Third Triennial Review was concluded, Columbia submitted a new communication on the issue of equivalence (WTO 2004). Here, Columbia stated that the TBT Committee should seek to design a procedure that facilitates equivalence of regulations between WTO member countries. Alternatively, the TBT Committee should try to develop a procedure that can shed light on the differences in regulatory processes and that makes it possible to working towards mutual adjustment (WTO 2004: 5).

To sum up, equivalence and mutual recognition have been recognized by the TBT Committee as important and relevant trade-facilitating tools with regard to mandatory technical regulations, voluntary standards, as well as conformity assessment procedures. Although discussing these issues for many years, the TBT Committee has not produced a document clarifying the operation of equivalence or mutual recognition within the TBT Agreement. Neither has the Committee given any guidance on the standing of food inspection and certification systems in relation to the application of these concepts. Further, the Committee has not yet requested Codex to the work on equivalence and/or mutual recognition. The Codex's position under the TBT Agreement is thus perceived to be less clear than its position under the SPS Agreement.

For many years, the Members have continued to exchange views and experiences regarding the application of the two concepts. Some members, such as New Zealand, Canada and the European Union, have actively expressed their will to discuss the issues of equivalence and mutual recognition in the TBT Committee and have also provided a number of contributions addressing these issues. Other members have been more passive in following up the work. Some of this passivity might be explained by the sheer complexity of the matter. However, it is also clear that there are different opinions among WTO Members on the question of how far this work should proceed within the framework of the WTO. The United States, for example, seems to be lukewarm to the attempts at pushing these issues high on the agenda. Thus, the work on equivalence in the TBT Committee seems to be a much slower process compared to the work on this issue in the SPS Committee. Moreover, so far not much information has been provided on the *practical* aspects of performing judgements of equivalence of technical regulations. Thus, there is still need for further information and experience sharing on these issues as well as stronger and more dedicated initiatives from key players.

2.3 The work on equivalence and mutual recognition in the Codex Alimentarius Commission

Equivalence and mutual recognition have been on the agenda of Codex Alimentarius for many years. As early as 1995, Codex adopted the document *"Principles for Food Import and Export Inspection and Certification"* including the principle of equivalence in relation to inspection and certification systems (CAC/GL 20-1995). In 1997 the new *"Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems"* included equivalence in two of its sections (CAC/GL 26-1997). However, in 1999 Codex adopted a special guide solely focusing on equivalence: *"Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems"* (CAC/GL 34-1999).

The SPS Agreement refers to Codex Alimentarius as the relevant international organization for the development of food standards, guidelines and recommendations. The emphasis on equivalence as a trade-facilitating tool in the SPS Agreement provides the necessary legitimacy for developing guidelines within the framework of Codex. The TBT Agreement also refers to the relevance of international standardizing bodies, but there is no explicit reference to Codex. However, the WTO dispute on trade descriptions for Sardines clearly illustrated that Codex also is an important reference point for the TBT Agreement (Hauser 2003). Consequently, it should also be legitimate to develop Codex guidelines on equivalence in relation to TBT measures. Codex also intends to further pursue work on these concepts in the years to come.

In the Strategic Framework for 2003-2007 the Codex members confirm under Objective 1 "Promoting Sound Regulatory Framework"¹⁵ that one of the priorities of Codex is to provide guidance for the practical application of the concepts of equivalence and mutual recognition for both sanitary and technical/quality measures. In the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), the issue of equivalence has been discussed since the Committee's fifth session in 1997. The Committee has noted that there is support for the development of guidelines that address the issue of equivalence judgements and priority has been given to the work on equivalence of sanitary measures. The work in CCFICS has so far resulted in the development of "Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems", which were adopted at the Codex Commission meeting in Rome 30 June - 7 July 2003. However, the work on guidelines for equivalence and mutual recognition in relation to TBT measures has not been that straightforward.

¹⁵ The whole text of this objective is included in Annex II of this report.

2.3.1 The CCFICS work on equivalence and mutual recognition guidelines for TBT measures

Harmonization is a key activity of Codex, but in many areas there are no international standards and different regulatory measures thus create uncertainty for consumers and trade problems. In such cases, one option is to enter into agreements involving judgement of equivalence.

For several years there has been a discussion in CCFICS on the need for developing the same type of guidelines for the judgement of equivalence for technical measures as for sanitary measures. In December 2000 at the 10th meeting of CCFICS, the *"Proposed Draft Guidelines for the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems"* were discussed. The proposed guidelines were set up much in the same way as the guidelines for sanitary measures. However, the Committee noted that there was a need for further clarification as to how equivalence should be handled with regard to technical measures. Thus, the work on these guidelines was deferred pending an elaboration of a discussion paper on this issue. The discussion paper was to include an examination of the need for the elaboration of guidelines on the judgement of equivalence of technical regulations to ensure conformity with essential quality requirements. Moreover, the paper should also include a presentation of pertinent examples for consideration and recommendations relating to the elements in the guideline.

The discussion paper was prepared by a drafting group led by Australia and was discussed at the 11th meeting of CCFICS 2–6 December 2002. The Committee had stated that there was still a lack of actual examples on the application of equivalence of technical regulations or conformity assessment procedures. Further, the Committee acknowledged that there was still a need for further clarification on how equivalence would be applied in relation to technical measures in contrast to SPS measures.

Thus, the Committee decided that a drafting group under the direction of Australia, with the assistance of Brazil, Canada, France, Norway, Switzerland and the United States, would revise the discussion paper for circulation, comments and further considerations at the next meeting. It was agreed that the paper would be revised on the basis of written comments submitted at the current meeting. The revision should also take into consideration comments to be submitted in response to a request for specific or potential examples of problems in trade that were or could be solved through the application of equivalence and mutual recognition agreements. Further, clarification would be sought from the WTO/TBT Committee, through the Codex Secretariat, on the operation of equivalence and mutual recognition within the framework of the TBT Agreement. It was noted that the discussion paper should be prepared to facilitate the Committee's discussions related to the potential of future guidelines.

Many countries signalled that they were negative to go further with the guidelines in their comments to the second draft. Canada felt that the necessary resources to develop such guidelines would greatly outweigh the benefits. Mexico

questioned the need for any guidelines at all. New Zealand did not support development of the guide at the time, and the United States could not see that any specific need for such work had been identified. The EU suggested in their response to the draft, that the CCFICS should confine its work to judgement of equivalence of conformity assessment since the terms of reference for the CCFICS is limited to inspection and certification systems. However, the EU did not reiterate the support for a guide on equivalence in relation to conformity assessment at the 12th meeting of the CCFICS.

In contrast to all these negative responses, several countries contributed with practical examples on equivalence in the preparations of the new draft. Australia gave examples of situations where food inspection and certification systems relating to technical regulations had created trade problems that could possibly be solved by the application of equivalence. Australia mentioned, e.g., that it could be of interest to accept different standards and certification for organic food and food labelling practices as equivalent in order to improve market access. Several countries stressed the problem of determining equivalence of many technical measures because of the difficulties of identifying objectives separate from the design and specifications. Uncertainties concerning the relationship between judgements of equivalence of technical measures vs. judgements of equivalence of conformity assessment procedures also seemed to be an element that needed further clarification. Another view was that challenges with regard to trade facilitation resided more with the legitimacy of a TBT measure than with the determination of its equivalence with another country's measure.

At the 12th Session, only Australia and Norway expressed their support to continue work on a guideline on equivalence for technical regulations in relation to inspection and certification systems. Norway stressed the need for further clarification of the links between technical regulations and conformity assessment procedures and the need to take into account the work of other international standardization organizations like ISO on these issues. Norway proposed that the Committee could continue to investigate further guidance on equivalence in parallel with the ongoing discussion in the WTO/TBT Committee. However, the CCFICS decided not to pursue work on the judgement of equivalence of technical regulations associated with food inspection and certification systems. The Committee nevertheless did leave open the possibility for coming back to the issue, since such work in fact was included in the Medium-Term Plan from 2003 to 2007.

2.3.2 Work on equivalence and mutual recognition in other international organizations

The fact that several other international organizations than Codex have established or are developing guidelines on equivalence and mutual recognition provides opportunities to exchange information and experience that all parties could benefit from.

In May 2003, the OIE – the international body for animal health (Office International des Epizooties) adopted “*The Terrestrial Animal Health Code*” including “*Guidelines for Reaching a Judgement of Equivalence of Sanitary Measures*” (Chapter 1.3.7).

This document treats e.g. the prerequisite considerations in a judgement of equivalence, principles for judgement of equivalence, and sequences of steps to be taken in judgement of equivalence. The Interim Commission on Phytosanitary Measures – ICPM is the body for implementation of the international plant health convention. The SPS Committee has requested the ICPM to develop guidelines on equivalence in relation to phytosanitary measures. In May 2004, the ICPM completed a quite comprehensive draft for consultation among the members: *“Guidelines on the Concept of Equivalence of Phytosanitary Measures and its Application in International trade”*.

The work of Codex, OIE and ICPM concerns intergovernmental standardization. In contrast, the work of ISO relates to non-governmental standardization. ISO has on several occasions reported to the TBT Committee on its work in relation to equivalence and mutual recognition. In its reports, ISO has for instance stated that “...the essence of the MRA is the recognition by each party of the equivalence of the activities of the other parties” (WTO 2003e: 7). However, ISO has also stated that the recognition of equivalence of applicable technical regulations or standards remains a difficult issue. The ISO/IEC *“Guide 68 on Mutual Recognition Arrangements”* was adopted in 2002. As accounted for in the presentation of the work of the TBT Committee, this guide provides an introduction to the development, issuance and operation of arrangements for the recognition and acceptance of results produced by bodies undertaking conformity assessment activities.¹⁶ The ISO guide is intended to apply to unregulated marketplace transaction extending across borders from one country to another.¹⁷

2.4 A short assessment of the international work

The use of equivalence and mutual recognition in facilitating trade is being discussed in intergovernmental, and private and semi-private international organizations. The WTO is the most influential intergovernmental organization with regard to regulating and governing global trade. The discussion on equivalence and mutual recognition in the SPS and TBT committees is therefore of utmost importance. The discussion on mutual recognition has been going on in the TBT Committee for many years. Equivalence is considered to be an important supplementary tool, together with standardization, under both the SPS and TBT agreements. Moreover, MRAs are relevant for regulations, standards and conformity assessment procedures under both agreements.

Until now, the SPS Committee’s work on equivalence has had more progress than the similar work on equivalence and mutual recognition in the TBT

¹⁶ The term Mutual Recognition Arrangement is normally used to indicate non-governmental co-operation, while the term Mutual Recognition Agreement indicates co-operation between government agencies.

¹⁷ In this connection it should be mentioned that the TBT Agreement also covers conformity assessment performed by non-governmental bodies, though in an indirect manner through Article 8.2: *“Members shall ensure that their central government bodies rely on conformity assessment procedures operated by non-governmental bodies...”*

Committee. Based on an initiative from the SPS Committee, the CAC actually developed and adopted a guideline on the judgement of equivalence associated with food inspection and certification systems. This illustrates that the WTO can (and maybe should?) play an important role in pursuing initiatives on developing models for the methods and mechanisms through which equivalence and mutual recognition can be applied on a bilateral and multilateral basis. Much of this work is presently going on at the national level and in international private or semi-private organizations such as ISO. This is also true for the application of equivalence and mutual recognition with regard to food trade. There is thus a need to co-ordinate the different activities related to these topics.

In the next chapter, we will present some examples of actual arrangements where equivalence and mutual recognition of technical measures and conformity assessment procedures have been involved. These examples illustrate both the relevance of the concepts for world trade as well as the potential for increasing our understanding of how the concepts can be operationalized and applied in concrete situations, by drawing on the experiences of states and international organizations.

3 Examples of Equivalence and Mutual Recognition in Food and Non-Food Trade Arrangements

3.1 Introduction

There are a number of trade arrangements that include mutual recognition and/or judgement of equivalence. However, many of the examples that can be found in the food sector primarily involve sanitary measures. We have not been able to find many examples of acceptance of equivalence in relation to technical measures. Still, quite a few mutual recognition agreements involve equivalence assessments of conformity assessment procedures. We will take a closer look at these examples and relate them to the previous discussion on equivalence and mutual recognition as trade-facilitating tools. We will also present examples from other sectors, insofar as these examples contain elements relevant for the food sector. Some of the examples were already presented in NILF Working Paper 2002-36.¹⁸ However, we have reanalysed them and placed them into the context of the present discussion.

¹⁸ See Elvestad (2002).

3.2 Mutual Recognition and Equivalence in the Organic Food Sector

3.2.1 International initiatives: IFOAM, Codex, UNCTAD and FAO

Organic agriculture is normally pursued with declared objectives of contributing to both food safety and quality. However, organic farming is first and foremost a mode of production that aims at utilising natural resources in a sustainable way. The term “organic” is a process claim, not a product claim. Products of organic agriculture are defined by the technology and inputs used, and not explicitly by the inherent properties of the product itself.¹⁹ The core question for determining what constitutes an organic product is not how safe it is, but how it was produced, e.g., in a sustainable and environmentally friendly way.

The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods define “organic” as a “labelling term that denotes products that have been produced in accordance with organic production standards and certified by a duly constituted certification body or authority”. The Codex standards that apply to the safety of organic products are the same as for conventional foods. Still, the Codex guidelines for organically produced food are important in ensuring a fair and transparent trading system for these products. The authenticity of the organic claim, including the labelling requirements, is particularly important. The Codex guidelines do in fact reflect the general approach of Codex to labelling (Doyran 2002).

Thus, a regulation or standard for organic farming will be more of a technical measure (such as labelling and production related requirements) than a sanitary measure (requirements related to the health hazards of the product itself).

So, what has this to do with equivalence and mutual recognition? The fact is that the organic market is growing rapidly and so does the “diversity” of both governmental and private sector organic standards, certification and accreditation. This has led to a non-transparent market place causing problems for producers and traders as well as consumers (Bowen 2002). Thus, an international effort has been initiated in order to address these problems through harmonization, equivalence and mutual recognition.²⁰

The Conference on International Harmonisation and Equivalence in Organic Agriculture was held in Nuremberg, Germany 18–19 February 2002. The Conference was organized by the International Federation of Organic Agriculture Movements (IFOAM) in co-operation with the Food and Agriculture Organization of the United Nations (FAO) and United Nations Conference of Trade and Environment (UNCTAD).

High on the agenda was the need to develop models and mechanisms for the use of harmonization and equivalence, as well as mutual recognition, as practical trade-facilitating tools. One of the models for the establishment of equivalence in organic

¹⁹ See Haen (1999).

²⁰ See in particular IFOAM (2002a, 2002b).

agriculture that was discussed, was the work on this issue in CAC. In particular, the Guidelines for Organic Foods, as well as the guidance documents on Food Import and Export Inspection and Certification Systems, including the proposed guidelines on the Judgement of Equivalence of Technical Regulations, were addressed. The Conference concluded that “the Codex Alimentarius model can facilitate negotiations around inter-governmentally agreed standards and mechanisms for harmonization and equivalence” (IFOAM 2002b).

The participants agreed on the need to develop an operating system that facilitates trade so that disputes involving organic standards can be prevented long before they reach WTO as (possibly) TBT related disputes. Thus, the Conference expressed the need to develop options for international equivalence, in addition to promoting bilateral recognition agreements.

Pascal Liu of FAO stated that the Conference had laid down the foundations for “..a collaborative process ultimately leading to some form of mutual recognition of organic agriculture standards and certification systems”, while the President of IFOAM, Gunnar Rundgren, concluded that the “...need to have a multilateral mechanism for establishing equivalence between different systems of regulation is apparent” (IFOAM 2002c).

An important result of the Conference was a joint initiative of IFOAM, FAO and UNCTAD to establish the International Task Force on Harmonisation and Equivalence in Organic Agriculture (ITF), which was launched on 18 February 2003 in Nuremberg, Germany (UNCTAD 2003). The Task Force was a practical response to the difficulties faced by organic producers and exporters due to the hundreds of different organic regulations, standards and labels worldwide, and a follow-up to the recommendations of the Conference.²¹

At its first meeting in February 2003 the Task Force stated that the work would commence with a review of the existing standards, regulations and conformity assessment systems. It will then move towards formulating concrete proposals on mechanisms for achieving harmonization and equivalence in the organic sector and means of facilitating access to organic markets, particularly by developing countries and smallholders. Moreover, the Task Force included in its work plan an initiative to develop discussion papers on WTO/TBT and organic trade facilitation, and on models and mechanisms for equivalence and mutual recognition (International Task Force on Harmonisation and Equivalence in Organic Agriculture 2003).

The Task Force had its second meeting in October 2003. On the agenda for this meeting was the need for exploring models and mechanisms of equivalence and mutual recognition.²² A presentation on this topic was made at the meeting, and a discussion paper based on this presentation was subsequently published.²³ The paper presents examples and models with regard to harmonization, mutual recognition and equivalence from other industries and seeks to learn from their

²¹ See IFOAM (2002a, 2002b).

²² See UNCTAD homepage: http://r0.unctad.org/trade_env/test1/openF1.htm

²³ Sasha Courville and David Crucefix (2004): *Existing and Potential Models and Mechanisms for Harmonization, Equivalency and Mutual Recognition*. Discussion Paper, March 2004. ITF, UNCTAD & FAO.

experience and identify models and/or components that may be applied to organic trade (Courville and Crucefix 2004: 2). We will highlight some of the important issues discussed in the paper.

Courville and Crucefix (2004) stress that there is a strong linkage between harmonisation of standards and equivalence of conformity assessment procedures. They further point out that *equivalence is likely to be a required tool* in convergence of organic standards *even if some harmonisation is achieved*. Japan, EU and United States all have mechanisms in place for facilitating trade in organic food through equivalence assessments and/or one- and two-way recognitions of conformity assessment procedures. However, Courville and Crucefix point out the difficulties in applying and maintaining these mechanisms in practise. They thus see the need to explore further the elements that could enter into different trade facilitating models and mechanisms with regard to organic food.

Mutual recognition would be the simplest step towards reducing possible “over-regulation”. The end point of such negotiations could be that conformity assessment bodies in the exporting country would be competent to verify compliance of organic producers to the standards of the importing country and that this recognition would be based on the approval by the authorities in the exporting country. Further, a basis for developing equivalence could be international standards, e.g., Codex standards for Organic Production. However, Courville and Crucefix point to the fact that few national regulations refer to Codex standards and guidelines and that there is thus little common structure to commence the process. With other words, in order to facilitate negotiations on equivalence and mutual recognition, there is a need for some convergence to have taken place, e.g. through international standardization. Otherwise, some complicated equivalence would have to be made while standards evolve. Nevertheless, if the involved parties would focus on what are *common* regulatory objectives in national regulations, i.e. the essential elements, equivalence agreements could easier be reached in the spirit of EU “New Approach.”

Courville and Crucefix discuss the possibility of combining the elaboration of a common international standard – a Basic Standard – with the acceptance and recognition of a fixed number of regional standards. Different regional organic standards could thus be recognized as equivalent as long as they share some main characteristics of the Basic Standard. The process thus requires equivalence assessments. Moreover, it allows for (necessary) variations related to agroecology or stage of development of organic agriculture, while at the same time rationalizing the number of organic production standards and avoiding a one-size-fits-all standard. Moreover, approved regional standards could replace many of the existing private standards.

IFOAM has already launched a mechanism to recognize approved regional standards, but this process has until now taken place in isolation from government regulations. As an intergovernmental body, the Codex Alimentarius Commission could however provide the legitimacy necessary for linking such mechanisms to arrangements and agreements involving governments and national regulations. With fewer standards around the world, equivalence assessments would be much

easier. However, this requires co-operation and co-ordination of the private and public sector (i.e. through combining the strengths of the private based IFOAM and the government based Codex). The setting up of an international forum where both private and public sector actors could meet is one way of enhancing such co-operation and co-ordination.

Courville and Crucefix underline that complete harmonisation is not only hard, but in the context of organic standards it is undesirable. Equivalence will therefore with certainty be part of the trade facilitation process with regard to organic food. To harmonise at least some core values will however facilitate the process of judging equivalence. Thus, in the view of Courville and Crucefix some harmonisation of rules is desirable. Equivalence judgements will nevertheless be needed to maintain regional and even national appropriateness of organic standards. The processes of harmonisation and equivalence assessments are thus strongly interlinked.

3.2.2 Examples of mutual recognition and equivalence of organic foods

There are a few examples of actual agreements involving mutual recognition and equivalence with regard to organic food. One recent example is a recognition agreement between Japan and United States from March 2002.²⁴

Recognition Agreement between the United States and Japan

The agreement replaces and expands upon a temporary agreement that allows U.S. plant-based organic food ingredients to be exported to Japan and sold as organic. The Japanese Ministry of Agriculture, Food and Fisheries (MAFF) has officially recognised that the United States Department of Agriculture's (USDA) national organic standard for the production, handling and processing of plant-based organic agricultural products meets the requirements of the Japanese agricultural standard.

However, the agreement stipulates that three substances allowed under the U.S. organic standard, should not be used in raw or processed organic food exported to Japan. USDA envisions verification of the non-use of these substances by an accredited certifying agent (ACA) to be based on a paper review (audit) and visual examination (on-site) process. In order to facilitate acceptance of the product, a compliance statement declaring the applicable prohibitions must be entered into the remarks section of the export certificate. The compliance statement for Japan is, "Products covered under this export certificate are not known to be produced with alkali-extracted humic acid, lignin sulfonate and potassium bicarbonate".

The U.S.–Japan agreement was based on an examination of equivalence of the organic products grading system in the United States to that in Japan. The examination resulted in a statement by the MAFF that the grading system of organic agricultural products and food processed from organic agricultural products (referred to as "organic products") in the U.S., which is stipulated in the National Organic Program, is equivalent to the grading system of organic products under the

²⁴ See information on this agreement on the homepages of the U.S. Department of Agriculture's Agricultural Marketing Service: <http://www.ams.usda.gov/nop/>

Japanese Agricultural Standard. In order to maintain equivalence, MAFF wanted to confirm that the U.S. government had the following intentions²⁵:

- In case the U.S. side amends the above-mentioned Program, to notify the Japanese side of the contents of the amendment in advance;
- To provide the Japanese side, upon request, with as much information as practicable, including whether the inspection and certification system on organic products is properly implemented in the U.S.;
- In case the Japanese side notifies in advance the U.S. side of its inspection plan on the Registered Foreign Certification Organizations in the U.S., to cooperate in such inspection, as much as practicable; and
- To take necessary action to prevent the use of the following substances in organic products which will be exported to Japan:(1) alkali extracted humic acid (2) lignin sulfonate (3) potassium bicarbonate.

The exception of the three substances means that Japan has only accepted the U.S. system as partially equivalent. However, the U.S. is considering a general ban of the three substances, so that producers only have to conform to one set of rules and avoid the demand for any additional documentation when exporting to Japan. Thus, a harmonization process is in practice taking place with regard to the two countries' rules for organic foods. The agreement has been notified to the WTO Committee on Technical Barriers to Trade (TBT Committee) (WTO 2002a).

USDA recognitions and equivalence determinations

The USDA is working with several governments with the aim of recognizing their ability to assess and accredit certifying agents as meeting the requirements of the U.S. National Organic Program (NOP). Currently, such co-operation is taking place with Canada, Denmark, Israel, New Zealand, Spain and the United Kingdom.

The USDA has already determined that a number of foreign government conformity assessment programs are sufficient to ensure conformity with the NOP. These determinations allow organic certification organizations in good standing to apply the NOP technical standards to certify operations that produce or handle agricultural products that will be sold, labelled or represented as organic in the United States. Production or handling operations certified by an organization that is recognized under these determinations may only use the USDA organic seal on their products when those products have been produced and handled in accordance to the NOP regulations. Thus, these agreements are for all practical means compliance agreements, but still based on equivalence determinations for the conformity assessment procedures. As of 2 December 2002, the following foreign government conformity assessment programs were recognized as sufficient: New Zealand (two programs), Quebec (six programs), United Kingdom (one program) and Denmark (one program).

²⁵ See letter from MAFF to USDA, dated February 6, 2001. Available online at: <http://www.ams.usda.gov/nop/NOP/TradeIssues/JapanTranslation.pdf>

In the United States, an equivalence determination is facilitated at the formal request of a foreign government. USDA is currently working with the governments of India, Japan, Australia and the European Union to determine whether their organic certification programs are equivalent to the technical requirements and conformity assessment system of the U.S. National Organic Program.

EU regulations²⁶

The access of third countries to the European Organic Food Market is generally based on a concept of equivalence. The EU regulations on organic production are set out in Council Regulation (EEC) No. 2092/91 and its amendments. Article 11 of this regulation specifies the requirements for importing products from countries outside the EU. The provisions apply to all processed and unprocessed food products from plants or animals and to wild products. Three methods are used for meeting the requirements for importing organic foods into the EU.

Approval of third countries

Commission Regulation (EEC) No. 94/92 lays down detailed rules for implementing the arrangements provided for in Council Regulation (EEC) No. 2092/91. It requires the EU authorities to evaluate and approve a third country's organic standards and its organic inspection system as *equivalent* to the EU requirements. Where other countries' inspections are carried out by private certifiers the EU will evaluate the exporting country's system for accrediting private certifiers. Approved countries appear on a list annexed to Commission Regulation (EEC) No. 94/92. The list may specify approved regions, production units, or inspection bodies within the country. The EU provides formatted tables for enabling comparison of third country standards against those of the EU. The information must include types of products intended for export; rules of production; rules on the inspection system and a description of how it is organised; and any available reports on the effectiveness of the implementation of production and inspection rules. This Third Country list of approved exporters was initially considered to be the main route for import of organic products. However, by 2003 – twelve years after the regulation was published – only eight countries were on the list and most products moreover enters instead under the importer derogation (see below), which is a process which relies on document review by Member State administrations; a considerable more costly process (Courville and Crucefix 2004).

Member state authorisation of products – the importer derogation

EU rules allow Member States to authorise an importer to import products from a country not included in the Article 11 list of Council Regulation (EEC) No. 2092/91 (cf. amendments of Council Regulation (EEC) No. 2083/92). In order to do this, the importer must furnish the Member State with sufficient evidence to show that the imported product was produced according to organic production rules *equivalent* to EU standards. Further, it must be proved that the inspection

²⁶ See Commins and Wai (2002).

measures are *equivalent* to EU inspection requirements as well as permanently and effectively applied. Moreover, the certification body must operate in compliance with ISO/IEC Guide 65. It is important to notice that Member States and even regional authorities tend to implement this provision differently with respect to the nature of evidence that must be supplied. A majority of the imported organic products are currently entering the EU according to this method.

Commission approval of third country's inspection body

A recent amendment to Council Regulation 2092/91 has provided a mechanism under which certification organisations approved in EU countries could be approved for certifying imports from third countries. The amendment allows the Member State to assess a third country's inspection body (certification body) and request the Commission to approve it. It can then be added to the Article 11 list.

The EU rules for market access of organic products from third countries do not require identical procedures, sameness or structural congruence of the foreign regulatory systems. Third countries are given access to the EU market while at the same time being allowed to develop their own organic food production and certification systems. Thus, the EU rules are based on determination of equivalence. However, the foreign systems must achieve comparable effectiveness. Moreover, the burden of demonstrating equivalence is on the exporting country. Nevertheless, equivalence is already a tool that is much used under EU rules in order to facilitate trade in organic products between the EU and third countries.

3.3 Mutual recognition and equivalence in agreements covering seafood trade

Based on our survey of trade agreements, Canada stands out as a country that has been active in using equivalence and mutual recognition as trade-facilitating tools in the food sector. This is especially true for fish and seafood production where Canadian authorities have negotiated so-called equivalence agreements and memoranda of understanding/mutual recognition agreements with eight countries: Australia, Ecuador, Iceland, Indonesia, Japan (two agreements), New Zealand and the Philippines.²⁷ A short presentation of the relevance of these arrangements for technical measures is included in annex III of this report. We will look closer at how the concept of equivalence is applied in three of the arrangements: Canada/Australia, Canada/New Zealand and Canada/Thailand.

The Memorandum of Understanding between Australia and Canada was signed in June 1993. The Agreement implies that the Australian Quarantine and Inspection Service and the Canadian Department of Fisheries and Oceans will monitor fish and fish products for export to the other party for compliance with the applicable standards for fish and fish products. The parties will recognize export

²⁷ The full text of these agreements can be found on the website of the Canadian Food Inspection Agency: www.inspection.gc.ca/.

certificates issued by the participating agencies, thus minimizing the requirements for further inspections and analysis. The certificates will ensure that the exporter meets the importing country requirements.

Beyond that, the Agreement leaves inspection with the exporting country without any additional inspection and analysis on arrival. The parties thus mutually accept each other's food control and inspection systems as equivalent in order to ensure compliance with applicable regulations and standards. The Agreement thus combines a required compliance of the regulations/standards of the importing country with a judgement of equivalence of conformity assessment procedures.

The Equivalence Agreement between Canada and New Zealand was signed in April 1996. In this agreement, equivalence is defined as "the recognition that the exporting country's regulatory and technical measures achieve the level of health protection desired by the importing country". The definition further specifies "these measures may be acceptable even if they are not identical to those used by the importing country".

The emphasis on health protection indicates that equivalence is meant for sanitary measures only. However, Article 8.1 states that "each party will recognise as equivalent the other Party's inspection and control systems governing the processing, packaging, handling or export of fish and fishery products, in accordance with Annex A." Thus, judgements of equivalence are also performed on conformity assessment systems. Further, as indicated by the purpose and scope of the Agreement, these systems apply to both sanitary and technical measures. Each Party will provide the other Party with reasonable efforts for the purpose of auditing continued equivalence of the inspection and control systems.

Annex A to the Agreement further specifies the meaning of equivalence and equivalence assessment. It clearly states that equivalence judgements apply to food safety measures (sanitary measures), but that "request for equivalence may be considered in relation to inspection and control systems, parts of the system, or in relation to specific inspection requirements."

Annex A further describes the process of equivalence assessment, stipulating assessment of competent authorities and their performance in relation to control programs and assurances, as well as legislation and powers in place to ensure that domestic and importing Party requirements are met. The criteria for equivalence assessments also relate to performance verification, i.e., reviewing compliance/audit programs, verifying efficacy of the total program in meeting the requirements of the importing Party, and on-site checks at the request of the importing Party and necessary following requests for equivalence.

The equivalence agreement between Canada and Thailand was signed in April 1997. An important objective of the Agreement is "to establish a process for recognizing and maintaining equivalence of the fish and fishery products inspection and control systems" of the two countries. For the purposes of the Agreement equivalence is defined as "the capability of different inspection systems to achieve the same objectives" (Article 1a). Article 4 deals with recognition of equivalence. According to this provision, the parties recognize each other's fish and fishery

products inspection and control systems insofar as the recognition process is conducted in accordance with the procedures outlined in Annex II to the Agreement.

Article 4.3 states that “where differences exist in product standards and labelling requirements, the exporting Party will require the establishments identified in Annex III to comply with the product standards and labelling requirements of the importing Party.” Thus, in this Agreement a compliance requirement for non-harmonized technical measures is combined with a judgement of equivalence for the conformity assessment systems (food and inspection control).

The procedures for recognition of equivalence are laid down in Annex II to the Agreement. The determination of equivalence is based on the assessment of the following criteria with regard to the existence of a national fish and fishery products inspection and control system of Canada and Thailand: legislative framework, governmental structures (including identification of the main objectives addressed by the inspection and control systems), adequate resources/tools, appropriate implementation of mandate, training for inspectors and laboratory personnel, inspection and sampling plans, certification systems and enforcement history.

Annex II also spells out the criteria for the assessment of:

- The identification of fish processing establishments: seafood processors should have adopted a system of controls that prevent the occurrence of food-safety hazards or other regulatory infractions exported to the other party, and
- Ability to perform audit procedures on the inspection control system: laboratories should demonstrate that they have consistently acceptable performance through programs that include, *inter alia*, adequate quality-assurance controls, and,
- Verification of equivalence: each Party should verify the equivalence of systems to meet import requirements; the verification may include side-by-side comparison, review of compliance history or compliance audit.

Canada has thus a number of agreements in place that include equivalence of conformity assessment procedures applicable to technical measures. Moreover, these agreements specify the criteria on which equivalence assessments are based.

3.4 Mutual recognition arrangements in The Asia-Pacific Economic Co-operation

The Asia-Pacific Economic Co-operation (APEC) is the premier forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region.²⁸ APEC has a membership of 21 economic jurisdictions,²⁹ a population of

²⁸ See APEC website: <http://www.apecsec.org.sg/>

²⁹ The members are: Australia, Brunei Darussalam, Canada, Chile, People’s Republic of China, Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, United States of America, Vietnam.

over 2.5 billion and a combined GDP of 19 trillion US dollars, accounting for 47 percent of world trade.

APEC has established a multilateral arrangement (MRA) called the APEC Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products (“the APEC Food MRA”). The Food MRA consists of an umbrella arrangement, which contains the general provisions that apply to all products and sectors that are covered by the MRA, and guidelines for the elaboration of sectoral arrangements (Appendix B). Sectoral agreements are in practice the implementation of elements pertaining to specific foods or food product sectors.

The APEC Food MRA is “a voluntary mechanism designed to facilitate trade by minimising food inspection controls at the point of entry into importing economies on the basis of assurances provided through pre-export conformity assessment (...)” (APEC undated 2). Determination of equivalence of conformity assessment systems could thus be a core element of sectoral arrangements under this framework.

The umbrella arrangement encourages participants to enter into a process of confidence building and closer co-operation, which may lead to participation in specific sectoral arrangements. The umbrella arrangement is thus a framework for entering into specific mutual recognition agreements. The APEC Sub-Committee on Standards and Conformance (SCSC) is the appropriate forum for review and discussion of the arrangement. The sectoral arrangements are supposed to be based on the principles and guidelines set out in Appendix B to the umbrella arrangement.

Sectoral agreements involve “the acceptance by an importing Party that foods and food products imported under the provisions of those arrangements conform with its legislative, regulatory and administrative requirements on safety, fitness for purpose and truth in labelling” (Article 1.2). Technical as well as sanitary measures are thus covered. The basis for acceptance is the exporting Party’s conformity assessment systems, which the importing Party has recognised for the purpose of a specific sectoral arrangement.

In effect a participant in an MRA on conformity assessment recognizes the conformity assessment procedures of the other(s) as being equivalent (APEC undated 1). However, under the APEC Food MRA this is not a precondition for participation in such arrangements (Article 1.4). Still, the arrangements are expected to provide the members with confidence in each other’s conformity assessment systems and thus reduce the need to reassess the exporting products when entering the importing Party’s market. If the conformity assessment systems are judged to be equivalent, the products can be assessed prior to export as to their conformity with the importing countries’ requirements. Thus, for duplicate assessments to be avoided equivalence will necessarily play an important part of the MRAs.

We have so far not been able to come up with examples of sectoral agreements being negotiated under the framework of the APEC Food MRA. However, in order to facilitate trade in food between the APEC members, there is an ongoing effort for the inclusion of more economies in the Food MRA, the achievement of

common food related goals of the APEC food system, and the promotion of the use of sectoral MRAs between the members (APEC undated 3).

3.5 India's work on food agreements involving recognition and/or equivalence³⁰

The Export Inspection Council of India (EIC), which is the Official Certifying Body of India, is currently working with various governments for the signing of MOUs or MRAs on conformity assessment in the food sector. These agreements will result in the acceptance of the EIC certification of food exports. The Indian conformity assessment procedures will thus be determined to be equivalent to the procedures of the importing country in question.

Arrangements are already in place with the Australian Quarantine and Inspection Service (AQUIS) for, *inter alia*, fishery products, tea, spices and cashew nuts. The agreement covering Indian seafood imports follows an AQUIS assessment of India's export controls that have found that the controls are equivalent to Australia's systems. In addition it has confirmed that seafood products imported from India consistently have met Australia's requirements over many years. Shipments of Indian products such as frozen prawns and fish will now be accepted on the basis of certification, minimising entry fees and making entry processing more efficient. The agreement is based on both India's compliance with the rules of Australia and an equivalence assessment of the Indian conformity assessment system for seafood exported to Australia.

India has also signed an agreement with Sri Lanka to cover more than 80 items, which have been under their import control. The recognition of EIC's export certification following this agreement will avoid duplication of inspection, sampling and tests at two levels – at the exporting and importing ends. It will also minimise and even eliminate rejection at the point of entry with the accompanying high costs of recall. Further, such an arrangement would also take care of problems resulting from variation in quality due to production by small farmers or enterprises. The agreement can thus lead to reduction of trade impediments caused by technical/quality measures. The Additional Secretary of the Indian Department of Commerce, Mr L.V. Saptharishi, has actually underscored the need for the food industry to pay serious attention to the "quality aspects" in the WTO regime and thus in world trade.³¹

³⁰ Part of the information on India's work on MOUs/MRAs is based on a letter dated 8 July 2003 from the director of EIC, Ms. Shashi Sareen, to the authors of this report. See also the website of AQUIS: <http://www.affa.gov.au/content/output.cfm?ObjectID=9DA3A020-A043-45A9-BD56B82D9FE9DA6D>

³¹ See presidential address delivered by Mr. Saptharishi in a seminar on "WTO Regime and Export Certification in Food Sector", organised by EIC, and referred to in a release from the Press Information Bureau of the Government of India, 20 November 2002. Available online at: <http://pib.nic.in/archieve/lreleng/lyr2001/rnov2001/20112001/r2011200110.html>

EIC is further negotiating an agreement with Singapore to cover all food and agricultural products as well as non-food areas. In addition, dialogue is on with a number of other countries such as Canada, Japan and South Korea for signing MOUs/MRAs on conformity assessment in the food sector.

3.6 Examples of mutual recognition and equivalence in non-food arrangements

3.6.1 The Mutual Recognition Agreement between the European Community and the United States³²

The European Community (EC)³³ has signed MRAs with seven countries – all on non-food areas: Australia, New Zealand, Canada, Israel, Japan, Switzerland and United States.³⁴ These agreements all cover mutual recognition of conformity assessment procedures. We will take a closer look at one of these agreements – between the EC and the United States – with an emphasis on how equivalence assessment of conformity assessment systems is being handled.

The MRA between the EC and the United States was signed in 1997. It consists of a general framework and six annexes covering mutual recognition of conformity assessment in specific sectors: telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical good manufacturing practises and medical devices.

The two parties recognize that “...mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards **equivalent** to the assurance offered by the Party’s own procedures” (emphasis by author). Article 3.3 of the Agreement further states the need for conformity assessment procedures utilized to “...assure conformity to the satisfaction of the receiving Party, with applicable legislative, regulatory and administrative provisions of that Party, equivalent to the assurance offered by the receiving Party’s own procedures”. However, unless specified in a sectoral annex, the MRA do not entail the mutual recognition of standards or technical regulations (cf. Article 4).

In Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs), equivalence of the regulatory systems means systems that are “...sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled” (Article 1.1). It is clearly stated that equivalence does not require that the respective regula-

³² Available online on the websites of the United States Food and Drug Administration: <http://www.fda.gov/oia/mrapage.htm> and the European Commission, DG Enterprise: <http://europa.eu.int/comm/enterprise/international/indexb1.htm>

³³ Here, we use the name European Community (instead of the European Union) because this is the name that is used in the agreement itself.

³⁴ See website of the European Commission, DG Enterprise: <http://europa.eu.int/comm/enterprise/international/indexb1.htm>

tory systems have identical procedures. The provisions of the Annex govern the exchange between the Parties' official GMPs inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems. Equivalence assessment is thus a cornerstone of the Annex.

Article 6 of the Annex on Pharmaceutical GMPs spells out in detail the procedures for equivalence assessments. The parties are supposed to establish and communicate to each other draft programmes for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. If necessary, these programmes will be carried out for post- and pre-approval inspections and for various product classes or processes. The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities.

Equivalence is established by having in place regulatory systems covering the long list of criteria for assessing equivalence for post- and pre-approval referred to in Appendix 4, and a demonstrated pattern of consistent performance in accordance with these criteria (Article 9). The Parties shall document insufficient evidence of equivalence in sufficient detail to allow the authority being assessed to know how to attain equivalence. In order to achieve continued equivalence the parties will perform monitoring activities including review of the exchange of inspection reports, performance of joint inspections and conductance of training sessions (Article 15).

The annex on medical devices also has provisions on equivalence. For the purposes of this Annex, equivalence means that Conformity Assessment Bodies (CABs) in the European Community are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner **equivalent** to those conducted by the Food and Drug Administration and vice versa (Article 2) (emphasis by author). Confidence building between CABs is an essential part of the process of determining equivalence. The CABs that have participated in confidence building activities will be determined to be equivalent provided they have "...demonstrated proficiency through the submission of a sufficient number of adequate reports (Article 9).

As mentioned earlier, the EC has signed MRAs with a number of other countries. These agreements do not entail mutual recognition of the equivalence of standards or technical regulations, as is the case for the MRA with United States. Thus, in these bilateral trade agreements the use of mutual recognition is reserved for conformity assessment procedures (including GMPs and CABs).

3.6.2 The Trans-Tasman Mutual Recognition Arrangement³⁵

The Trans-Tasman Mutual Recognition Arrangement (TTMRA) involving the Australian Parties (the Commonwealth of Australia, six states and two territories) and New Zealand was signed in 1998. The objective of the Arrangement is to

³⁵ See website of the Australian Department of Foreign Affairs and Trade:
http://www.dfat.gov.au/geo/new_zealand/

remove regulatory barriers to the movement of goods and service providers between Australia and New Zealand and to thereby facilitate trade. TTMRA is an umbrella arrangement laying down the principles for the elaboration of specific sectoral agreements.

In respect of goods, the basic principle in the TTMRA is that a good that may be legally sold in Australia may also be legally sold in New Zealand, and vice versa. Exemptions are made for certain products and for the protection of public health and safety and the environment. This way of applying the principle of mutual recognition of goods resembles the EU application, as illustrated by the “Cassis de Dijon” case described in Chapter 1 of this report. Legislation implementing the TTMRA overrides any law, with certain exceptions, that regulates the manufacture or sale of the goods, including product standards, packaging and labelling and conformity assessment requirements. Thus, in this context equivalence is not really an issue. The good produced according to the standards and regulations of one country is accepted without reservations into the market of the other country.

Cooperation programmes under the Arrangement are assumed to have three possible outcomes: 1) Continued operation of mutual recognition because requirements applying in each country are perceived to be adequate from a regulatory point of view, 2) Cooperation leads to harmonisation or closer alignments of regulatory requirements, which once again will lead to the application of the mutual recognition principle, 3) Parties seek an agreement to have a good added to the list of permanent exemptions.

Even though equivalence is not explicitly mentioned in the TTMRA, it may still play a role in the process of accepting the other party’s conformity assessment procedures. For example, the 1988 Memorandum of Understanding Between the Governments of Australia and New Zealand on Technical Barriers of Trade, which still applies, states that “...each Government will endeavour to ensure that relevant authorities in its country accept test results provided and certificates of conformity with technical regulations and requirements issued by competent and authorised bodies of the other country”.³⁶ The provision further states that “it is recognised that prior consultations may be necessary to arrive at mutually satisfactory understandings between relevant bodies in this regard”. Thus, arrival at mutually satisfactory understandings could involve equivalence assessments. However, Australia and New Zealand are moving towards both uniform standards and certification practices also in this area, *inter alia*, through the establishment of the Joint Accreditation System – Australia and New Zealand (JAS-ANZ).

The TTMRA includes, with certain exemptions, all goods including food. However, food is less relevant than many other goods because of the establishment of the joint food regulatory agency, the Australia-New Zealand Food Authority (ANZFA), in 1995. ANZFA has contributed to the harmonization of Australian and New Zealand food standards, which consequently automatically have been mutually accepted for entering the markets of the two parties. The Australia–New

³⁶ See website of the Australian Department of Foreign Affairs and Trade http://www.dfat.gov.au/geo/new_zealand/anz_cer/anz_cer.html

Zealand Food Standards System includes the development of technical measures related to, e.g., packaging and labelling.

For the food standards that have not yet been harmonized, a form of mutual recognition still applies. In addition, the TTMRA underpins the harmonization process to assure that other technical barriers do not exist. The possible inability to harmonize should therefore not result in regulatory barriers to the trade of food products between the two countries.

Equivalence is not explicitly a big issue in the TTMRA, although it may play a significant role in connection with the process of recognizing each other's conformity assessment procedures under a sectoral arrangement. Thus, equivalence assessments *are* being performed in order to attain mutual recognition of the regulatory systems. New Zealand has described the TTMRA as a move to create mechanisms for regulatory cooperation that in practice has provided a useful platform for the pursuit of equivalence, as it allowed regulators to share experiences and establish mutual confidence (WTO 2003b: 3). Besides, Australia has signed several other agreements (e.g. with the EU) where equivalence of conformity assessment is an issue.

The TTMRA illustrates two important points. First, that mutual recognition of technical measures takes place in co-operating arrangements outside the EU where the concept was developed (cf. the "Cassis de Dijon doctrine"). Second, mutual recognition (including equivalence) can both facilitate and complement harmonization processes.

3.7 The process towards equivalence acceptance and mutual recognition – conditions for success

In the following sections we look at the *process* towards achieving equivalence and/or mutual recognition and some of the conditions for successful co-operation between different regulatory systems. Some central questions are asked: What considerations should be made before entering into negotiations on agreements involving equivalence and mutual recognition? How should one go about when setting up trade arrangements that include mutual recognition and equivalence assessments?

Based on the empirical examples presented above, we thus explore some important issues to be considered when deciding on converging regulatory systems. As mentioned in chapter 2, some countries have developed special policy frameworks in relation to the process of developing agreements on equivalence and mutual recognition (e.g. Canada, EU and Japan). Further, suggestions for considerations to be made in these processes can also be extracted from academic literature on the subject (e.g. Nicolaodis 1997; Horton and Hastings 1998). In this section we will try to summarize some of the main points of these "recipes". These elements may be of interest to consider in the further work on guidelines on equivalence and mutual recognition in the TBT area.

3.7.1 Cost-benefit analysis

Before entering into negotiations involving equivalence assessments of regulatory systems, countries have to analyse the associated costs and benefits. Establishing equivalence is both complicated and time-consuming. Countries should thus consider carefully whether they should spend the efforts to entering into negotiations.

First, a fundamental prerequisite is that serious trade problems exist and that these problems can be resolved through this kind of agreement. Further, there should be a sufficient volume of trade in specific sectors between the parties involved, in order to justify the high administrative costs. In addition, there should be a clear potential for tangible economic benefits as a result of the agreement. The benefits from the potential agreement should be demonstrated and alternative trade facilitating measures must be considered. It is important that the preparatory work involve a thorough evaluation of what is the most appropriate regulatory tool to use for resolving the trade problems at hand.

3.7.2 Compatibility of regulatory systems and resources available

A certain degree of symmetry between the parties' regulatory systems should exist before starting negotiations. For instance, sound and effective regulatory infrastructure calls for three basic elements: food law and accompanying regulations (i.e. a legislative and administrative base), qualified trained staff to deal with programmes, and performance provisions and well-equipped analytical laboratories and other facilities (Malik 1997). Underlying compatibility in the regulatory systems of the trading partners will make negotiations easier and the potential for reaping gains greater. If the technical competence of the two parties is different there will be need for a step-by-step approach. In such situations progress could be made by first initiating technical co-operation to bring the levels of competence more in line.

The generally long-term nature of the negotiations makes it very important to assure sufficient resources for negotiation and implementation. There should be a political will to put time and efforts into the tasks at hand. Further, there should be a will to make compromises among the people employed in regulatory agencies. The support from key players is fundamental for a result-oriented process. To closely consider and take into account the interest of stakeholders is a prerequisite for obtaining successful outcomes of negotiations.

3.7.3 Scope of the agreements

One way of designing mutual recognition/equivalence agreements is to make an effort to include all possible elements and products, i.e. to make the scope as broad as possible. This is however a risky endeavour considering the time and resources needed to maintain equivalence for all the products and procedures included, and to solve the problems that will arise during the operation of such agreements. A less risky way is to follow the example of, e.g., APEC, United States, EU and Australia and start negotiating an umbrella arrangement that lays down the general principles that can be used to guide subsequent sectoral agreements on specific products or product groups. Equivalence (of measures or conformity assessment

procedures) can thus be established on a case-to-case basis. Moreover, it is easier to start equivalence assessments on a few and less complicated elements of the regulatory systems (e.g. test results or Good Manufacturing Practises – GMPs) and then move on to more complicated elements.³⁷ Differences between the systems will gradually be reduced through continuous equivalence assessments thus leading up to a process where national regulatory systems are harmonized.

3.7.4 Building capacity and trust

A critical lesson to be learned from the examples of harmonisation, equivalence and mutual recognition, is that regulatory convergence between parties is a process over time that requires information exchange, mutual learning, training and trust building. For example, the U.S. FDA has made some efforts in order to overcome its mistrust of European Conformity Assessment Bodies. In the process of establishing the US-EC MRA sectoral annex on medical devices, the U.S. FDA organized a “joint confidence building program” including seminars, workshops, joint training exercises and observed inspections (Shaffer 2002: 22).

Confidence between the parties is thus an important condition for making it possible to establish and maintain equivalence. This is particular important with regard to the conformity assessment systems. The negotiating parties should thus start the process with information sharing and visits to each other’s facilities. Further, if necessary the parties can assist each other in building capacity into the systems, making the system of the exporting country capable of performing the conformity assessments required by the importing country (based on equivalence assessments). Joint training and inspections, or exchange of personnel could be effective means of strengthening mutual confidence. Lack of trust between the parties can be devastating for the potential to reach agreement and achieve the results wanted. The importance of building confidence should thus not be underestimated.

3.7.5 Learning from experience

The gradual process of establishing mutual recognition and equivalence under a general trade framework gives regulatory agencies useful experience in dealing with complicated discrepancies between national systems. Further, they may be more or less forced into a situation where compromising is an important part of the game. Thus, people working inside the regulatory systems may learn from experience the best way to solve trade problems resulting from discrepancies in regulatory traditions and systems. Moreover, it is important for regulatory agencies to search for information on how such trade arrangements work for other products and other countries, and to evaluate their own arrangements in order to make the necessary adjustments along the way. Sometimes, maintaining equivalence may be too costly

³⁷ It interesting to note that the TBT Committee, in its Triennial Review, concluded that in its further work would focus on the Member’s experiences with equivalence of GMPs (See Annex I of this report).

weighed up against the benefits. In those situations, going back to the outset or speeding up the process of harmonizing the systems can be better options.

3.8 A short assessment of the empirical findings

After the comprehensive presentation of examples in the preceding sections, it is time to make some preliminary assessments of the empirical data.

There are many examples of arrangements involving equivalence assessments of conformity assessment procedures. These arrangements often cover conformity assessment of both sanitary/phytosanitary and technical food measures. Some of the basic elements of equivalence assessments of conformity assessment procedures in the food sector generally seem to be quite similar to the principles of assessments being performed in non-food sectors. The same goes for judgement of equivalence for technical standards and regulations. It is therefore worthwhile to *look more careful at the experiences from non-food sectors* when considering how equivalence and mutual recognition can apply in food trade arrangements.

One should note, nevertheless, that equivalence assessments are perceived to be more relevant for some products and measures than for others. The decision on whether such assessments should be performed thus has to be done on a *case-to-case basis*. As we will come back to later in this report, this is even more so for TBT measures than for SPS measures, because of the vast variety of different regulatory objectives that may be linked to the former type of measures (cf. the TBT Agreements' more open-ended provisions on what constitutes a legitimate objective).

4 Mutual Recognition and Equivalence of Technical Measures: Some Critical Points

4.1 Introduction

Based on our presentation of actual trade arrangements and a review of documents and literature, we will in this chapter pinpoint some critical issues regarding the use of mutual recognition and equivalence assessments. First, we make some clarifications with regard to the *concepts* of equivalence and mutual recognition in a TBT context. Then we look at the *application* of the concepts on technical regulations and standards in connection with the work on achieving equivalence and/or mutual recognition through co-operation between different regulatory systems.

4.2 Clarification of central concepts

4.2.1 Regulations and standards vs. conformity assessment procedures

We have shown in this report that equivalence assessments can be performed on both rules (regulations, standards) and conformity assessment systems (accreditation, certification, test results, etc.). In order to reduce redundant testing and certification requirements, conformity assessment procedures can be used by the *exporting party* either to check the products against the rules of the importing party (cf. compliance), or to check the products against national rules, which in advance have been harmonized or deemed equivalent and/or mutually recognized. Duplicate

inspections, tests and controls when entering the importing country can thus be avoided.

- The judgement of equivalence of conformity assessment procedures is thus about two or more parties accepting (mutually or unilaterally) each other's verification procedures as equivalent in order to ensure that the traded products actually comply to whatever rules are in force.
- The judgement of equivalence of rules, on the other hand, is basically about accepting each other's products as equivalent. This means that some diversity in national rules is upheld while at the same time ensuring that the rules in question do not seriously undermine (e.g. through requirements regarding labelling or quality features) nationally stated regulatory objectives.

Thus, even if rules are harmonized, deemed equivalent or mutually recognized, trade impediments can persist because of a lack of convergence between conformity assessment systems (cf. duplicate inspections, tests, control etc). There is thus a need for some sort of mutual recognition and/or equivalence of conformity assessment systems for the products to be allowed freely into the market of the importing country. In an ideal situation, convergence between rules and conformity assessment should be pursued simultaneously. Alternatively it could be wise to establish equivalence/mutual recognition of conformity assessment before negotiating equivalence of rules.

The presented examples in this report seem to indicate that it is easier to establish equivalence of conformity assessment than for rules. However, these issues are strongly interrelated, and it could therefore be interesting to look more carefully at those products where full harmonization through international standardization is not relevant or even desirable, and where equivalence thus could be particularly relevant as a trade-facilitating tool.

4.2.2 Equivalence assessments vs. mutual recognition

The two concepts – equivalence and mutual recognition – often emerge together in processes involving convergence of different regulatory systems. However, in this report we have tried to illustrate that equivalence and mutual recognition describe occurrences at different levels. When *evaluating* different regulatory systems the key concept is equivalence assessments, i.e. the process of judging the conformity assessment procedures and/or rules of another country to be *equivalent* to national conformity assessment procedures and/or rules. If equivalence is established, the parties can mutually recognize each others systems, e.g. through entering into MRAs. The concept of mutual recognition has furthermore been mainly reserved for the recognition of conformity assessment procedures.³⁸ However, in practise, equivalency of rules may also be part of a broader MRA, as for instance is the case in the Trans-Tasman Mutual Recognition Arrangement between New Zealand and Australia. Thus, equivalence assessments are the practical task of achieving

³⁸ The EU also applies the concept of mutual recognition to rules (cf. the “Cassis De Dijon” case and the “New Approach”).

acceptance for regulatory diversity whereas mutual recognition is achieved when equivalence assessments are put into a broader co-operative framework.

4.3 Application of equivalence on technical food regulations and standards

The application of equivalence and mutual recognition is in its infancy. There are only a few food agreements that include equivalence assessments of technical measures and conformity assessment. However, in world trade there are serious trade impediments caused by differences in national regulatory systems and measures. As a matter of fact, quality requirements and other technical measures have been pointed out as a bigger problem for world trade than sanitary measures. The work on harmonizing quality requirements has gradually been given a lower priority in the CAC and the EU, as well as in many other organizations and countries.

Thus, in order to reduce trade problems caused by such measures, there is a need for considering other trade-facilitating tools (cf. mutual recognition and equivalence). Moreover, new controversial issues, e.g. biotechnology, organic production, animal welfare and other environmental concerns, have been placed high on the international food agenda. Even though some of these issues contain elements relevant for the sanitary and phytosanitary area, they are first and foremost relevant for the TBT area.³⁹ Thus, the discussion on technical measures as trade barriers will probably be even more important in the years to come. Further, dealing with these issues is a relevant task for both the CAC (cf. ensuring fair practices in food trade) and the WTO (cf. facilitating trade).

The discussions in both the TBT Committee and in particular the CCFICS, illustrate that there are some problems concerning the application of equivalence on TBT related food regulations and standards. In the SPS area at least some progress has been made in providing international guidance and clarifying the position of equivalence under the WTO framework. The discussions in the TBT area are characterized by uncertainty and scepticism among the members of the WTO and the CAC. We will pinpoint some of the conditions underlying this uncertainty and scepticism and make some assessments on the implications of these conditions for pursuing equivalence in a TBT context.

4.3.1 ALOP vs. other legitimate objectives

Under the SPS Agreement the way to make equivalence assessments is to compare different SPS measures to see if they can achieve the same appropriate level of protection (ALOP). Moreover, the legitimate objectives of the agreement are protecting human, animal or plant life or health. The agreement further refers to risk assessment techniques as preferred ways to determine appropriate levels of protection. With the risk of oversimplification, one could therefore claim that the SPS Agreement has some relatively clear parameters to be used in equivalence

³⁹ And thus also relevant for the TBT Agreement of the WTO.

assessments: *Based on risk assessments, the task is to determine whether two different measures are capable of ensuring the same appropriate level of protection for human, animal or plant life or health.*

Under the TBT Agreement, however, the task of identifying the relevant parameters is more difficult. The agreement includes a long non-exhaustive list of possible legitimate objectives (Article 2.2). The TBT Agreement says that one should take account of the risks of non-fulfilment of the objectives and it further refers (once again) to a non-exhaustive list of relevant elements of consideration. Such elements are available scientific and technical information, related processing technology or intended end-uses of the product. When making judgements of equivalence of TBT measures the parties thus have to identify the relevant objective among a large number of possible legitimate objectives, then decide what is necessary to fulfil this legitimate objective, and finally to find a way to measure the risks of non-fulfilment.

The TBT Agreement is therefore relatively open-ended with regard to how equivalence assessments can be performed in concrete situations. However, this does not necessarily imply that such assessments are impossible or irrelevant. On the contrary, the inherent characteristics of TBT measures allow for a pragmatic approach to equivalence, which actually could enhance the use of this as a trade-facilitating tool. One could argue that health concerns ensured by SPS measures in most instances can be considered more vital or essential than, e.g., concerns related to quality or product information ensured by TBT measures. Thus, it should be easier to accept differences in relation to, for instance, labelling of quality properties than in relation to, e.g., maximum level of aflatoxins in food.

The open-ended character of the TBT measures suggests that it is important to consider on a case-by-case basis whether equivalence is relevant. For instance, the process of establishing equivalence becomes more complicated when a TBT measure is based on product requirements in terms of design or descriptive characteristics instead of performance (see below).

4.3.2 Performance criteria vs. descriptive characteristics

A measure establishing an appropriate level of health protection based on a risk assessment constitutes a performance criterion, which allows more easily for an equivalence assessment to be performed. The requirements of TBT measures, however, are often stated in terms of descriptive characteristics, which often are difficult to clearly separate from the regulatory objectives they are supposed to fulfil. Examples of this include the requirement that a cheese must contain exactly 17.5% fat and the requirement that the word “Sardine” can be used as a trade description for canned sardines only when the species *Sardina pilchardus* is used in production.

With regard to the second example, because there exists a Codex standard on canned Sardines and Codex standards have been deemed as relevant standards under the TBT Agreement, the countries no longer have full freedom in deciding how to use the trade description “Sardines”.⁴⁰ The Codex standard states the condi-

⁴⁰ See for example Hauser (2003).

tions under which the name “Sardines” can be used. According to the standard, the name “Sardines” can be used for “Sardine-like” fish species other than *Sardina pilchardus*, but only in combination with another name (e.g., Chilean Sardines). The relevant “Sardine-like” fish species are included in a list, which may be revised by the Codex Committee on Fish and Fishery Products to even include more species.

The Codex standard could thus be described as a move towards equivalence, insomuch that the standard allows for variation as to product characteristics (i.e. different fish species used in the production) as long as the consumers are informed of this variation through the labelling of the product. Further, the Codex work on deciding which species can be included on the list of “Sardine-like” species, can be said to involve some sort of equivalence assessments. The whole logic of defining fish species as “Sardine-like” is parallel to the logic of equivalence, which is precisely about defining “likeness”. Even though the Codex standard (in combination with the TBT Agreement) to a great extent may “solve” the trade problems caused by different regulations on canned sardines, some problems persist, such as the details on how precisely the “Sardine-like” canned Sardines should be labelled. Again, such problems could be solved by equivalence agreements.

The “Sardines” example illustrates that even though a TBT measure in the outset is based on a strict product requirement in terms of product characteristics, it is possible to find mechanisms to avoid unnecessary trade impediments. This can be done either through international harmonization, equivalence or mutual recognition, or through a combination of all three.

When a TBT measure is based on strict requirements on design and product characteristics, there are basically only two ways of solving the problem of determining equivalence. The requirements have to be relaxed either in terms of more flexibility in the design itself (e.g., allowing a cheese to include a fat percentage in the interval of 15–20%) or by defining a performance criterion (e.g., appropriate consumer information) under which different product characteristics can be judged equivalent as to achieve this “appropriate information”.

This same logic also applies to TBT measures based on requirements in terms of processes and production methods (PPMs). To give an example: There are a number of different standards and regulations for the production of organic food. Thus, different criteria are used in different countries to define a food product as “organic”. In determining equivalence, the involved parties thus either must agree on some key requirements of processes and production methods to be similar, or to define a performance criterion (e.g. environmentally sustainable) under which equivalence could be judged.

4.3.3 Private vs. governmental initiatives

There is one last point to be made with regard to the application of equivalence on technical food regulations and standards, namely the link between private and governmental initiatives. The TBT Agreement encourages agreements for mutual recognition of conformity assessment procedures for both governmental and non-governmental applications. However, the Agreement applies directly to the former (Article 6.3) and influences only indirectly on the latter (Article 8.2). The

Agreement applies directly to governmental regulations (Article 2) and more indirectly to standards (Article 4 and “Code of Good Practise”). The TBT Agreement is thus relevant for both governmental and non-governmental conformity assessment bodies and for both mandatory governmental regulations and voluntary private standards.

Both public and private actors are thus involved in the elaboration and application of measures, which are covered by the TBT Agreement. This mix of private and governmental activities and responsibilities creates a complex picture and has a potential for creating confusion among the member states of the WTO and the CAC. As the examples from the organic food sector illustrate, there is a need to map the variety of both relevant private and governmental international standards and guidelines for mutual recognition and equivalence of conformity assessment.

A reduced number of relevant reference points for the TBT Agreement could also enhance the efforts made to converge different regulatory systems through harmonization or/and equivalence (cf. the SPS Agreement, which refers to only three relevant standardizing bodies). Because the TBT Agreement covers a wide range of products, this must be done on a sector-to-sector basis. For example, with regard to organic food, there exist a large number of private and semi-private standards in addition to a Codex standard – both on the international and regional level. This variation may create co-ordination problems resulting in trade barriers. Thus, the TBT Committee, which deals with both governmental regulations and private standards, could play a role in facilitating trade through promoting co-ordination of standardization efforts. Equivalence is relevant in the process of reducing the number of relevant international standards (“different standards are deemed equivalent”). A reduced number of reference points may simplify the process of determining equivalence between different national regulatory systems.

In the SPS area, governments are often strongly involved in defining the measures, mainly because all SPS measures concern essential requirements in terms of health protection. As stressed several times, a larger variety of objectives are linked to TBT measures. The TBT Agreement furthermore covers a wider spectrum of products and measures than the SPS Agreement. The TBT Agreement thus also affects a larger variety of actors – public and private sectors as well as different industries. Co-ordination between private and governmental initiatives is thus even more relevant and important in the TBT context.

4.4 Some final remarks on achieving equivalence and mutual recognition

There are some important differences between SPS and TBT measures, some of which also have consequences for the work on achieving equivalence and mutual recognition. First of all, at first sight equivalence assessments in the TBT area are more complicated and less clear-cut. We nevertheless believe there are no principal reasons why such assessments cannot play an important role in the TBT area. There is therefore a big *potential* for applying both equivalence and mutual recog-

dition on TBT measures. However there are many good reasons to carefully watch one's step when searching for methods and mechanisms to achieve this. As emphasised earlier in this chapter, some key factors to remember in such endeavours are the open-ended character of the TBT Agreement, the problem of identifying legitimate objectives separate from the TBT measures themselves, the need to separate performance criteria from design and product characteristics, and the need to sort out the relevance and importance of both private and governmental initiatives in providing relevant standards and guidelines. In the next chapter we address the implications of these factors for further work on international guidance.

5 Assessments and Concluding Comments

5.1 Introduction

In this chapter, we make some final assessments regarding how equivalence and mutual recognition may be utilized as trade-facilitating tools in a TBT context. Based on our empirical and conceptual presentations in this report, we also propose some possible ways of pursuing the work on international guidance with regard to these issues.

5.2 How relevant are equivalence and mutual recognition as trade-facilitating tools in a TBT context?

The variety of national technical food measures (i.e., other measures than sanitary and phytosanitary measures) is generally perceived to cause big problems for traders, producers and consumers. In such a context, equivalence and mutual recognition (in addition to harmonization) can be useful tools in order to facilitate trade and ensuring fair trade practices in the food sector.

With regard to both food and non-food agreements, it is hard to come up with many good examples of equivalence assessments being performed on technical regulations and standards. This illustrates the complicated (or perceived complicated) process of comparing such measures with the aim of determining equivalence. We nevertheless have identified a few areas where such equivalence assessments are being discussed and tested out.

Of special interest is the organic food sector where an interesting process is going on with the aim of enhancing the use of equivalence and mutual recognition,

together with harmonisation, as trade-facilitating tools. This happens on a bilateral and multilateral basis with regard to conformity assessment as well as regulations and standards. Moreover, the three biggest trading countries in organic food, Japan, United States and the EU, all apply these tools today. The organic food sector thus represents an example where equivalence assessments and mutual recognition of technical regulations and standards are perceived as relevant and potentially important for facilitating trade. We argue moreover that there are no good reasons why equivalence assessments should not be just as relevant for a wide range of other food products.

5.2.1 SPS and TBT work on equivalence as parallel or separate “paths”?

The work on equivalence and mutual recognition takes place in two different committees in the WTO – the SPS Committee and the TBT Committee. In their efforts to clarify these concepts under the respective agreements, the two committees naturally have followed different paths. First of all, the provisions on equivalence and mutual recognition are different in the two agreements. Secondly, SPS measures *are* different from TBT measures. Thirdly, the TBT agreement covers a wider range of measures and product sectors, as well as governmental and non-governmental bodies and governmental regulations and private standards. In the CAC, however, the work on guidelines on the judgement of equivalence of both sanitary measures and technical regulations associated with food inspection and certification systems has been carried out in the same committee, namely the CCFICS. Initially, the CCFICS’ work on guidelines for sanitary measures was parallel to the work on guidelines for technical regulations, which was also reflected in early drafts. However, after a while the work on equivalence of technical regulations was halted, whereas the work on sanitary measures progressed, resulting in the adoption of new guidelines in 2003. Thus, the work on equivalence of SPS and TBT related measures, respectively, has followed different paths in the CAC. However, although there are good reasons for separating the TBT and the SPS work on equivalence, also in the CAC, we argue that many of the basic principles and arguments that apply to the SPS area also apply to the TBT area. In both areas, factors such as cost-benefit considerations, confidence building and information exchange, enter into the co-operative work as important conditions. Further, in both areas, the difficult but nevertheless feasible task is to specify two or more different measures and the regulatory objectives they are meant to fulfil, and on this basis evaluate the “likeness” of the measures. Thus, in principle, the potential for applying equivalence to TBT measures is at least as good as for SPS measures.

5.2.2 Thresholds for achieving equivalence: a pragmatic approach

So then, what are the thresholds for achieving equivalence, and are these in fact higher for TBT measures than for SPS measures? As we discussed in chapter 4, one important threshold is defining the regulatory objectives and based on these, setting the level (e.g. minimum protection level) that measures must reach. We argued that this exercise might be considered to be more complicated for TBT measures than for SPS measures. However, the argument could also be turned around. For SPS

measures, health protection is the central legitimate regulatory objective. This objective is inherently linked to essential requirements and just as importantly, national core interests. Hence, if the set level of appropriate health protection differs strongly the threshold for achieving equivalence will be very high.

Many TBT measures, however, are not necessarily linked to such essential requirements or core interests. Instead they may be a result of tradition, taste or even accidental circumstances. The above-mentioned “Sardines case” serves as an example of this. Thus, in many situations, there is not really very much at stake for states with regard to relaxing the measures and negotiating equivalence.

One should note, nevertheless, that equivalence assessments are perceived to be more relevant for some products and measures than for others. The decision on whether such assessments should be performed thus has to be made on a *case-to-case basis*. This is even more so for TBT measures than for SPS measures, because of the vast variety of different regulatory objectives that may be linked to the former type of measures (cf. the TBT Agreements’ more open-ended provisions on what constitutes a legitimate objective). We argue therefore that a more pragmatic approach is appropriate when applying equivalence to TBT measures.

5.2.3 The role of developing countries

This report has not focused much on the role of developing countries. Nevertheless, at this point we think it is useful to make a few comments on the issue. The process of negotiating equivalence and mutual recognition between regulatory systems is difficult for many developing countries because of, *inter alia*, insufficient administrative resources and weak technical infrastructures. Some of these problems are reduced by capacity building programmes initiated by the WTO and the United Nations, but many obstacles persist. These problems do not however, imply that equivalence and mutual recognition are not important mechanisms also for developing countries. On the contrary, regulatory requirements of developed countries often have particular negative effects on trade with developing countries, mainly because of the difficulties for these countries in living up to the high standards of developed countries. Equivalence, mutual recognition as well as international standardization, could thus be beneficial for the developing world – insomuch that trade impediments caused by unnecessarily strict regulatory requirements are reduced. As the presentation in Chapter 2 of this report on the work in the TBT committee illustrates, several developing countries – such as Egypt, Columbia and Thailand – are in favour of further exploring the potential for using equivalence and mutual recognition in trade facilitation. At first sight, the most relevant topic is equivalence of conformity assessment – not least because with regard to several types of requirements, especially health requirements, developed countries would not be willing to accept what they consider to be inferior rules of developing countries. However, we argue that equivalence of technical regulations and standards actually have a potential of being accommodated by some developed countries and thus could be important for developing countries. This could at least be possible in situations where the measures are not linked to essential require-

ments or core state interests and consequently where developed countries could be more willing and have less to lose on negotiating equivalence.

5.3 Comments on pursuing the work on international guidance

There is no clear-cut answer to how to pursue the work on international guidance for the judgement of equivalence of technical measures and conformity assessment. Moreover, the question of whether or not to pursue the work must be based on an assessment of the possible benefits and costs of spending time and resources on this work. We will nevertheless make some suggestions for possible strategies for continued progress. These suggestions are based on our observations presented earlier in this report.

5.3.1 Co-ordinated efforts by international organizations

We have observed that the activities of many international organizations are relevant for the work on equivalence and mutual recognition of technical regulations and standards and conformity assessment in the food sector, e.g. WTO, CAC, ISO, and IFOAM.

Presently, there is an important process going on in the TBT Committee of the WTO with regard to discussing these issues. The WTO is important for the process of these efforts. In line with the TBT Agreement's reference to the relevance of other appropriate international standardizing bodies, the WTO can take initiatives to link the work of these organizations to the operation of the TBT Agreement. This was actually done when ISO was encouraged to develop guidelines for arrangements for the recognition and acceptance of conformity assessment results (see Chapter 2.2.4 of this report). The TBT Committee works on clarifying the provisions of the TBT Agreement, including the provisions on equivalence of technical regulations (Article 2.7), equivalence of conformity assessment (Article 6.1) and MRAs (Article 6.3). However, most of the practical work on developing guidelines on technical issues must take place outside the TBT Committee, e.g. in ISO or the CAC.

To what extent is the CAC the right forum for discussing the issues of equivalence and mutual recognition of technical measures? When mutual recognition merely involves compliance with other states' sets of requirements, it is difficult to see what role standardization bodies like Codex Alimentarius can play. However, mutual recognition may involve a two-way (or multiple way) determination of equivalence (e.g. of conformity assessment) and is thus relevant for the Codex work on this issue (Gascoine 1999).

For the time being, however, work on guidelines for the judgement of equivalence of technical measures seems to be a non-starter in the CAC. The issue has temporarily been taken off the agenda, but stays on as a work priority through the reference to this work in the Medium Term Plan and Strategic Framework for 2003–2007 (see Annex II). In any case, the CAC remains as *the most* important

international food standardizing body and thus has a natural role to play in the discussions on equivalence and mutual recognition of food measures.

One place to start in pursuing the work is to evaluate the already existing relevant CAC guidelines, e.g., Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26–1997) and Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34–1999). Based on such evaluations it would be easier to consider the actual need for developing new guidelines on equivalence of technical measures, including conformity assessment procedures.

Further, internationally, it may be useful to evaluate the activities of other international bodies concerning both their application of the concepts of mutual recognition and equivalence of technical measures and conformity assessment procedures, and the possible need for additional international guidance. Examples of relevant work of other international organizations are: IFOAM's work on standards for organic food, and ISO's work on quality requirements (ISO 9000), environmental challenges (ISO 14000) and conformity assessment in general (ISO Development Manual 2 for conformity assessment, ISO/IEC Guide 68:2002: "Arrangements for the recognition and acceptance of conformity assessment results").

An evaluation of existing international work could be a first step in the direction of co-ordinating different international standards and guidelines (intergovernmental and private) with the aim of reducing the complexity and getting a clearer picture of both existing relevant standards and guidelines, and the possible need for further development. The relevance of this work for the CAC is actually stated in the Statutes of the CAC. Article 1(b) of the Statutes says that one of the purposes of the CAC is: "promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations."

5.3.2 Co-ordinated national initiatives

The experiences from the work on guidelines on equivalence of sanitary measures illustrate that there is also a need for co-ordinated national initiatives in order to move the work forward. This is especially true for intergovernmental organizations such as the WTO and the CAC. When some of the leading countries, e.g., the United States or the EU, are passive or resistant to continuing the work on certain issues, the process tends to halt. Thus, in order to progress the work, it is of utmost importance to provide convincing information and arguments (if these exist) in cooperation with other willing states.

With regard to the issue of equivalence of technical measures there is another problem, namely that the states themselves are not necessarily co-ordinated in their inputs to international organizations. An illustration of this is New Zealand's inputs to the TBT Committee and the CCFICS on the relevance and importance of equivalence of technical regulations. In the WTO, New Zealand is one of the most active and progressive states in promoting equivalence as a trade-facilitating tool with regard to technical regulations, conformity assessment as well as voluntary standards. New Zealand has consequently provided several examples of these

mechanisms being applied by the New Zealand government in negotiations with other states. In the CCFICS, however, New Zealand has supported the efforts to move the issue off the agenda.

One possible explanation for this seemingly inconsistent behaviour is that the TBT Committee and the CCFICS delegates are not the same persons. The delegates that meet in the TBT Committee are often diplomats. Moreover, a variety of people from different parts of the national regulatory systems are involved in TBT work. The CCFICS work, however, is dominated by food, health and veterinary regulators. Thus, there may exist a “translation” problem with regard to convincing members of the CAC in general and the members of the CCFICS in particular, that the TBT Agreement is relevant for food regulations and standards. Further, there also seems to be a problem in convincing members of the CAC that the discussion on equivalence and mutual recognition in the TBT Committee is relevant for the food sector (and thus the CAC) in addition to other product sectors.

One important challenge is thus to find good arguments for the relevance of technical measures for the work on facilitating food trade. Furthermore, it would be necessary to reduce the scepticism among many of the member states of WTO and CAC in order to move the work on international guidance forward.

5.3.3 Information sharing and confidence building at the international level

As the previous sections illustrates, there is still a need for further clarification on a number of issues regarding equivalence and mutual recognition with relevance for technical regulations, standards and conformity assessment. Moreover, confidence building, including sharing and exchange of information, remains a crucial issue. This applies both to the process of negotiating equivalence and mutual recognition agreements, and to the process of discussing and co-ordinating these TBT-related activities internationally. Thus, further work could include co-ordinated analysis of available information on equivalence and mutual recognition of TBT measures. These efforts could include identification and sorting out of some core elements of equivalence assessments, which could provide the basis for proceeding with the work. Such efforts could take place on a bi- and multilateral basis as well as in the TBT Committee. One could also arrange workshops and have presentations on the relevance of equivalence and mutual recognition for technical measures in general and technical food measures in particular. Discussions could also take place in appropriate fora where representatives of intergovernmental, private as well as semi-private international organizations could meet. Such joint efforts involving sharing of information could contribute to confidence building and further clarification on the role of equivalence and mutual recognition in a TBT context.

5.4 Harmonization, equivalence and mutual recognition as complimentary tools

We have provided some examples of equivalence and mutual recognition being applied in food trade arrangements. However, there is considerable variation as to *how* the concepts are applied. Further, there are few reports of “success stories”. On the contrary, the resources and time needed for entering into and maintaining mutual recognition and equivalence arrangements are often considered to outweigh the benefits.

Many countries nevertheless choose to sign such agreements, and the agreements obviously seem to contribute to the reduction of trade barriers, at least with regard to conformity assessment systems, which is what most equivalence and mutual recognition agreements seem to concentrate on. Another interesting observation is that trade arrangements involving equivalence and mutual recognition also can lead to a harmonization process between the parties, i.e., a process where different regulatory systems converge. Moreover, some prior convergence between regulatory systems, e.g. by applying the same or similar international standards, seems to enhance negotiations on equivalence and mutual recognition agreements. Mutual recognition and equivalence are thus important trade-facilitating tools, but nevertheless should be studied and applied in combination with international harmonisation and standardization.

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Interviews with people employed in national administrations, FAO and the CAC Secretariat.

Annex I: The Third Triennial Review of the WTO Agreement on Technical Barriers to Trade (text on Equivalence and Mutual Recognition)⁴¹

On equivalence:

12. At the Second Triennial Review, the Committee reiterated the importance of giving positive consideration to accepting as equivalent technical regulations of other Members as provided for under Article 2.7. The Committee also noted that, as an interim measure until suitable international standards were developed, in some cases, standardizing bodies or regulators in some Members had chosen to accept as equivalent standards originating from other Members, even though these standards differed from their own, on the basis that such standards fulfilled their objectives.

13. For the Third Triennial Review, the Committee notes that equivalency can be an element of good regulatory practice (and is also relevant to conformity assessment as foreseen under Article 6.1). Moreover, it should not detract from the development of international standards. In considering equivalence, Members must have regard to their general obligations, including those with respect to transparency and non-discrimination.

Recommendations

14. The issue of good regulatory practice is important, evolving, and worthy of further discussion in the TBT Committee. To further its work on good regulatory practice, the Committee agrees to:

- Invite Members to exchange experiences related to the identification of elements of good regulatory practice at the domestic level;
- continue its exchanges on Members' experiences and focus its discussion, on, *inter alia*, choice of policy instruments, mandatory versus voluntary measures, and the use of regulatory impact assessments to facilitate good regulatory practice; and to
- initiate a process of sharing experiences on equivalency in the Committee particularly with regard to how the concept is implemented in practice.

⁴¹ See WTO (2003f).

On Mutual Recognition Agreements for the Acceptance of Conformity Assessment Results (MRAs)

38. The Committee notes that, under Article 6.3 “Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of Agreements for the mutual recognition of results of each other's conformity assessment procedures.” Mutual Recognition Agreements (MRAs) are one of the approaches foreseen to facilitate the acceptance of conformity assessment results. The Committee notes, as indicated under Article 6, that appropriate confidence building measures, including accreditation, could facilitate the acceptance of conformity assessment results without entering into MRAs.

39. The Committee notes that MRAs can be negotiated between governments with respect to specific regulations, or can be voluntary arrangements between domestic and foreign conformity assessment bodies. The Committee notes that while MRAs can be a useful approach to facilitate acceptance of conformity assessment results, there may be difficulties faced in their negotiation and implementation. There are various considerations for the conclusion of effective MRAs between governments, such as: a sound regulatory infrastructure, and a sufficient volume of trade in specific sectors between the parties involved to justify the high administrative costs and the generally long-term nature of the negotiations. The following factors may also need to be taken into consideration in the establishment of MRAs: tangible economic benefits; interest of stakeholders; support from key players; underlying compatibility in the regulatory systems of the potential MRA parties; and sufficient resources for MRA negotiation and implementation. Moreover, a step-by-step approach may be useful to conclude an MRA, in particular, where the technical competence of the two parties is not equivalent. In this respect, progress could be made by means of technical cooperation to obtain mutual benefits.

Recommendations

Work Programme

40. With a view to improving Members' implementation of Articles 5–9 of the Agreement and promoting a better understanding of Members' conformity assessment systems, the Committee agrees to the following work programme to:

- Exchange information and experiences on existing conformity assessment procedures and practices, the use of relevant international standards, guides and recommendations, and the participation of Members in national, regional and international accreditation schemes;
- exchange information and experiences and hold a workshop on SDoC covering issues such as: the regulatory authorities, sectors and suppliers which use SDoC; the surveillance mechanism, liability law and penalties used to ensure that products comply with requirements; the incentives for suppliers to comply with requirements; and the legislation that underpins the relationship between buyers and sellers;

- invite representatives from relevant international and regional accreditation fora to provide information on their operation and the participation of Members, in particular, developing country Members, in their systems. Moreover, users, such as certification bodies, should also be invited to share their experiences in this respect; and to
 - hold a workshop on the different approaches to conformity assessment, including on the acceptance of conformity assessment results.
41. The Committee will take stock of the progress made on this Work Programme and reflect it in its Annual Report to the Council for Trade in Goods.

Annex II: CAC's strategic framework 2003–2007, Objective 1: Promoting Sound Regulatory Framework⁴²

7. In many countries, effective food control is undermined by the existence of fragmented legislation, multiple jurisdictions and weaknesses in surveillance, monitoring and enforcement. Sound national food control and regulatory systems are essential to assuring the health and safety of domestic population as well as assuring the **safety and quality of foods** entering international trade. While the establishment of regulatory framework is fundamentally a national responsibility, the CAC and its parent bodies, the FAO and WHO, have a strong interest in promoting national regulatory systems that are based on international principles and guidelines and address all components of the food chain. The development of sound food control and regulatory infrastructure including human resources is particularly important for developing countries as they seek to achieve higher levels of food safety and nutrition and will require high level political and policy commitment as highlighted in the report of the 1999 Melbourne Conference on International Food Trade Beyond 2000. An effective food control system is critical in enabling all countries to assure the safety of their foods entering international trade and to ensure that imported foods conform to national requirements. Successful negotiation of bilateral **mutual recognition and/or equivalence** also depends on the ability of countries to assure each other of the integrity of national regulatory systems.

8. The priorities for the CAC in the development of international standards and related texts will be to:

- **provide essential guidance** for member countries through the continued development of international standards and guidelines **relating to food safety and hygiene, nutrition, labelling and import/export inspection and certification systems and for the practical application of the concepts of equivalence and mutual recognition** ; and
- promote the development of national food control systems based on international principles and criteria for the reduction of health risk along the entire food chain.

(emphasis by the authors of this report)

⁴² See: “Strategic Framework of the Codex Alimentarius Commission for 2003-2007”.

Annex III: Canada's memoranda of understanding/mutual recognition agreements involving seafood⁴³

1. Memorandum of Understanding Concerning the Inspection and Certification of Fish and Fishery Products Traded between Australia and Canada

Under the Agreement the Australian Quarantine and Inspection Service and the Canadian Department of Fisheries and Oceans recognizes the principle of equivalency in connection with ensuring that imported and exported products are safe and wholesome, are not tainted or decomposed or fraudulently presented. Thus, we see that non-safety objectives are mentioned, which indicate that technical food measures are covered.

2. Memorandum of Understanding Regarding the Inspection of Fishery Products between Ecuador and Canada

The Agreement covers labelling and Good Manufacturing Practices (GMPs), including assurance of good quality, and is thus relevant for technical measures and conformity assessment.

3. Memorandum of Understanding Between the Canadian Food Inspection Agency and the Directorate of Fisheries of Iceland

The Agreement involves exchange of information on technical measures/conformity assessment procedures and other measures that may cause impediments to trade.

4. Arrangement on the Mutual Recognition of Fish and Fishery Products Inspection and Control Systems Between the Canadian Food Inspection Agency and the Directorate General of Capture Fisheries of the Department of Marine Affairs and Fisheries of the Republic of Indonesia

The Agreement defines consumer protection as “the requirements that exists with respect to the acceptable quality or proper identification of fish and fish products”. Thus, it is relevant for technical/quality requirements.

5. Memorandum of Understanding Between the Japan Canned Food Inspection and the Department of Fisheries and Oceans of Canada

⁴³ The full text of these agreements can be found on the website of the Canadian Food Inspection Agency: www.inspection.gc.ca/.

The Agreement includes provisions to determine compliance of labelling and is thus relevant for technical measures/conformity assessment.

6. Cooperation Program on Export of Raw Oyster Products Between the Ministry of Health and Welfare of Japan and the Canadian Food Inspection Agency

The purpose and scope of the Agreement is to facilitate the export of raw oyster products from Canada to Japan in a manner that “ enhances public health and protects consumers from unwholesome oysters and from false, misleading or deceptive labelling practices (..) Thus, the Agreement is relevant for technical measures.

7. Equivalency Arrangement on Control Measures for the Safety and Quality of Fish and Fishery Products Between the Government of New Zealand’s Ministry of Agriculture and Ministry of Health and the Government of Canada’s Department of Fisheries and Oceans.

Technical measures are covered by the objective of the Agreement, which is to “facilitate bilateral trade in fish and fish products in a manner that protects public health, and protects consumers from unwholesome fish and fishery products and from false or misleading or deceptive labelling practices”.

8. Memorandum of Understanding Regarding the Inspection of Fish Products Between the Department of Health, Bureau of Food and Drugs, of the Government of the Republic of Philippines and the Department of Fisheries and Oceans of the Government of Canada

The Agreement is relevant for technical measures/conformity assessment through the inclusion of, *inter alia*, GMPs and labelling.

9. Agreement Between the Government of Canada and the Government of Thailand on the Equivalence of Fish and Fishery Products Inspection and Control Systems

The Agreement is relevant for technical measures/conformity assessment through the inclusion of provisions on processing and proper identification, including labelling.