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# **International Trade and Guidelines on Equivalence and Mutual Recognition**

by

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# Foreword

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This report deals with equivalence and mutual recognition as tools to facilitate trade. During the last couple of decades a large number of equivalence agreements and Mutual Recognition Agreements (MRAs) have been negotiated, both bilaterally and multilaterally. Subsequently, several international guidelines have been produced to give advice on how to utilize these tools. This report gives a comparative empirical analysis of a sample of such guidelines in order to strengthen the basis for assessing the need for further guidance on these issues, particularly in relation to the WTO (World Trade Organization) and the United Nations food standards body Codex Alimentarius Commission. The comparison of international guidelines made in this report can be seen as a supplement to earlier work on the issue of equivalence and mutual recognition conducted at the Norwegian Agricultural Economics Research Institute (c.f. Elvestad 2002; Veggeland and Elvestad 2004).

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Norwegian Agricultural Research Economics Institute,  
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# Abbreviations and definitions

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- **ALOP:** Appropriate Level of Protection
- **APEC:** Asia-Pacific Economic Cooperation
- **ASEAN:** Association of South East Asian Nations
- **CAC:** Codex Alimentarius Commission
- **CCFICS:** The Codex Committee on Food Import and Export Inspection and Certification Systems
- **Conformity assessment procedures:** Any procedure used, directly or indirectly, to determine that requirements are fulfilled. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.
- **Conformity assessment system:** A system that has its own rules of procedure and management for carrying out conformity assessment.
- **Designated bodies:** A body appointed by a Member State, with responsibility to identify and monitor conformity assessment bodies
- **Equivalence determination:** A process involving judgements of whether two measures (such as food safety measures), although they are different, can achieve equivalent levels of protection or of other stated objectives.
- **EU:** European Union
- **Good manufacturing practise (GMP):** A practise related to the proactive steps that are taken to ensure that products are safe, pure, and effective. This requires a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. This in turn, protects the consumer from purchasing a product which is not effective or even dangerous.
- **Good regulatory practice (GRP):** A regulatory approach aimed to reduce regulatory burdens and improve the quality (for instance with regard to consistency, transparency, clarity and equity) and cost-effectiveness of regulatory systems. The use of GRP may contribute to reducing barriers to trade.
- **HACCP:** Hazard Analysis and Critical Control Point
- **IEC:** International Electrotechnical Commission
- **IPPC:** International Plant Protection Convention

- **ISO:** International Organization for Standardization
- **ISPM:** International Standards for Phytosanitary Measures
- **MRAs:** Mutual Recognition Agreements
- **OIE:** World Organization for Animal Health
- **SPS Agreement:** (the WTO) Agreement on the Application of Sanitary and Phytosanitary Measures
- **TBT Agreement:** (the WTO) Agreement on Technical Barriers to Trade
- **WTO:** World Trade Organization



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# Executive Summary

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## **Purpose of the report**

The purpose of the report is to provide an overview of international guidelines dealing with the application of equivalence and mutual recognition as trade facilitating tools, focusing on the main aspects and application areas of these guidelines. The aim is furthermore to get a better understanding of both existing relevant guidelines and the possible need for development of further guidance in this area. The report focuses in particular on the potential for applying equivalence and mutual recognition in relation to food trade, and relates this to discussions taking place in the WTO and the Codex Alimentarius Commission (CAC). The report seeks to increase the knowledge about relevant guidelines and thus provide a better basis for decisions on whether to move the work on these issues further in the relevant international forums dealing with trade facilitation.

## **Methods, selection of guidelines and the report structure**

The report is based on a comprehensive study of mainly public documents, including the original guideline documents available from the international organizations that have issued them. In addition to the analysis of the documents, we base our assessments on interviews with national civil servants dealing with issues of equivalence and mutual recognition and our own participation in CAC meetings where these issues have been discussed.

We selected a wide variety of guidelines for inclusion in the study. Our main concern is with facilitation of global food trade. We have therefore studied guidelines developed in the three standardisation bodies mentioned in the WTO's SPS Agreement, which deals with food safety and animal and plant health. Second, we have studied ISO guidelines. ISO is considered to be a relevant international standardization body under the WTO's TBT Agreement and is furthermore potentially relevant for all sectors. Third, we have studied guidelines developed and applied by important regional economic co-operations, such as the APEC and the ASEAN. Finally, we have included some guidelines developed by powerful economic actors in international trade, such as the United States and the EU.

We apply six main categories for comparing and analysing the documents covering the main elements dealt with in the guidelines: 1) purpose and scope of the guidelines, 2) pre-negotiation assessments, 3) core elements included in an equivalence or mutual recognition agreement, 4) confidence-building measures, 5) methods and procedures for achieving and maintaining recognition, and 6) institutional set-up for securing implementation. These categories are used as chapter headings to structure the analysis of the guidelines in the study.

The report consists of three main parts. Chapter 1 is an introduction and presentation of the main issues being raised in the report. Chapter 2 classifies the different guidelines and explores the specific contents of the guidelines according to the categories chosen for the study. In Chapter 3 we assess the need for more guidance on these issues in the food sector and the need for further work in the CAC and the WTO.

## **Main findings and conclusions**

Our study of guidelines on equivalence and mutual recognition shows that there are a large variety of different guidelines applied within international trade. In the SPS area, in particular, there are a large number of well advanced guidelines available from both international standardisation bodies and in connection with bilateral and regional agreements. In the SPS area there are guidelines covering both inspection and control procedures/conformity assessment and specific product requirements. The situation in the TBT area is somewhat different. There are several guidelines dealing with unilateral or bilateral (mutual) recognition of conformity assessment, e.g., Codex guidelines, ISO guidelines, APEC guidelines and national guidelines applied by the United States. However, there is not much guidance on how to establish equivalence of either specific technical product requirements or TBT related production or process methods. Thus, the work in the TBT area has not moved as far as the work in the SPS area. However, there are many references in international guidelines to the *relevance* of equivalence and mutual recognition for other specific requirements than food safety or health, i.e. for TBT measures. Furthermore, many of the procedures and techniques described in SPS guidelines should also be relevant for the TBT area. The main difference is related to the objective basis for comparisons of measures. The main basis for comparing SPS measures is a defined Appropriate Level of Protection (ALOP). For TBT measures the basis for comparisons will vary depending on the specific measures to be compared, but a number of possible parameters could be identified, e.g., different performance criteria such as degree of environmental and consumer protection.

Thus, our preliminary conclusion is that there is still a potential for the development of general international guidelines on TBT measures in the food sector dealing with the process of achieving equivalence and/or mutual recognition of both specific technical requirements and conformity assessment systems. Taking into account the complications following the lack of *one* objective basis for comparison with regard to TBT measures (since there are no direct parallels to the ALOP for SPS measures), we see no reason why guidelines could not be developed for TBT measures in line with the way the existing SPS guidelines have been developed and designed.

## **Recommendations**

Our survey of international guidelines shows that there are already many relevant guidelines to take into consideration in relation to the work in the WTO and the CAC. In the SPS area, the work on further guidance was promoted on the basis of

an initiative taken in the WTO's SPS Committee. Such an initiative was not taken in the TBT area. Thus, there seems to be a need for more information-sharing and discussions in this area. Furthermore, it is still not clear if it is worth the effort to spend the same amount of time and resources in the TBT area on developing more international guidance. However, our survey shows that equivalence and mutual recognition certainly are relevant trade facilitating tools in *both* the SPS and TBT areas. Thus, a first step in enhancing the discussions could be to invite relevant parties with extensive experience from equivalence and mutual recognition agreements, such as the United States, Canada, the EU and APEC, in a process of *sharing their experiences on the value of guidelines* for their own work on equivalence and mutual recognition.

Finally, there is one more point worth mentioning. Many of the guidelines underline that the application of international standards, such as HACCP and standards developed by CAC, OIE, IPPC and ISO, enhances the process of judging equivalence and achieving mutual recognition. The point is that international standards contribute first, to harmonizing national regulatory systems and measures, and second, to providing parameters upon which these systems and measures can be evaluated. Thus, international harmonization creates confidence between trade partners and increased compatibility between regulatory systems. International harmonization facilitates the application of mutual recognition and equivalence. At the same time, international guidelines on *how* to apply mutual recognition and equivalence enhance harmonization. Consequently, international guidelines dealing with equivalence and mutual recognition could have a double role in facilitating trade; by promoting acceptance of different measures and systems as equivalent and by promoting processes of harmonization. These factors should also be taken into consideration when discussing good regulatory practise in general and trade facilitation in particular, in international forums such as the WTO and the Codex Alimentarius Commission.



# 1 Introduction

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## 1.1 The purpose of the report

In this report, we make a comparative empirical analysis of a sample of international guidelines on equivalence and mutual recognition. We also refer to documents and policy frameworks provided by members of the WTO when relevant for the discussion on international guidance. However, these documents are not necessarily included in our systematic presentation and discussion.

In a report published in 2004, in which we studied the application of equivalence and mutual recognition in trade arrangements, we drew the following conclusion (Veggeland and Elvestad 2004: 67):

“An evaluation of existing international work could be a first step in the direction of coordinating 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.”

Thus, the comparison of international guidelines presented in this report can be seen as a supplement to our earlier work on equivalence and mutual recognition (see Elvestad 2002; Veggeland and Elvestad 2004). Based on that earlier work, this report has two main purposes. First, by studying international guidelines we intend to identify their core elements and by doing so, showing alternative means of facilitating trade through equivalence and recognition activities. Second, we intend to show the variation in the types of existing guidelines. By comparing these guidelines we intend to strengthen the basis for making an assessment of the further

need for guidance in the trade facilitation work in the food sector in general, and in the ongoing discussions on these issues in the WTO and the CAC in particular.

During the last couple of decades, a large number of equivalence agreements and MRAs have been negotiated, both bilaterally and multilaterally. Subsequently, several international guidelines containing recommendations on how to utilize equivalence and mutual recognition as trade facilitating tools have been developed.

In this report, our main concern is with facilitation of global *food* trade. Thus, we study guidelines developed in the three international standardizing bodies referred to in the WTO SPS Agreement: CAC, OIE and IPPC. The SPS Agreement is particularly important with regard to the reduction of trade impediments caused by non-tariff barriers in world trade (e.g. trade restrictive national food regulations). Furthermore, WTO members can fulfil their obligations under the SPS Agreement by basing their national measures on standards and related texts developed in CAC, OIE and IPPC. We also study guidelines from one of the most influential standardizing bodies internationally, namely ISO. ISO's guidelines are potentially relevant for all product sectors, including the food sector. Furthermore, ISO is considered a relevant standardizing body under the TBT Agreement. Thus, not following relevant ISO standards could have implications under WTO rules.

We also study guidelines developed between countries participating in economic regional co-operations: APEC, ASEAN and the EU. Here we study both guidelines for facilitating food trade and guidelines for facilitating trade in other product sectors. We furthermore study a selection of national guidelines/frameworks, in particular those developed by the United States. Thus, we assume that guidelines developed in different contexts and for different purposes may still be of relevance and have value across sectors and levels. Furthermore, we assume that guidelines applied bilaterally and by regional economic partners, may be of relevance for trade relations globally, e.g. for the work in the WTO and CAC. In addition to the guidelines mentioned above, we also present elements of other guidelines and frameworks when relevant for our discussion (see Section 2.2 for a complete overview of the guidelines).

## 1.2 The structure of the report

In Chapter 2, we first provide an overview of the different types of guidelines included in the study. The main focus of Chapter 2, however, is to analyse and compare the main elements of the documents. In order to structure the analysis, we use five main categories to organize the content of the guideline documents (see the introduction to Chapter 2). Finally, we summarize our comparative findings.

Based on the empirical investigation in Chapter 2, we make an assessment in Chapter 3 of the relevance of the different guidelines with regard to the need for further guidance in the food sector, and for further work on developing guidelines in the CAC and the WTO.



# 2 A Comparison of International Guidelines

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## 2.1 Introduction

This chapter is designed both to provide an overview of relevant international guidelines and to provide an in-depth presentation of the content of these guidelines. However, the different guidelines vary with regard to the elements included and the documents furthermore give several overlapping recommendations. Thus, we decided to construct suitable categories covering the core elements of the guidelines to structure the analysis and presentation, instead of introducing the individual guidelines one by one. However, we initially categorize each of the guidelines according to type (see Table 2.2). At the end of the chapter (see Section 2.8) we treat each guideline individually for the purpose of summing up the similarities and differences of the guidelines in the study. After reading through all the documents and discussing what we considered to be the main elements of the guidelines, we ended up with the categories listed in the table below (Table 2.1). These categories are identical with chapter headings used in this chapter.

**Table 2.1 Categories for analysis of guidelines**

<b>Categories of analysis</b>	<b>Chapter heading</b>
1. Purpose and scope	2.3
2. Pre-negotiation assessments	2.4
3. Guidance on the elements of agreements	2.5
4. Methods and procedures for achieving and maintaining recognition	2.6
– General confidence building measures	2.6.1
– Procedures for determination of equivalence and demonstration of conformity	2.6.2
– Procedures for continued confidence	2.6.3
5. Institutional set-up for ensuring implementation	2.7

## 2.2 An overview and classification of international guidelines on equivalence and mutual recognition

In Table 2.2 we have classified the guidelines in terms of type of document based on three kinds of criteria: level (global, regional or national), governmental or non-governmental, and finally, general, sectoral or specific. We study seven different guidelines that are global in scope. In fact, the WTO has developed a guideline related to services on the establishment of mutual recognition agreements/arrangements in the accountancy sector. This guideline can be used both at the governmental level as well as in the private sector. However, five of the global guidelines we study are related to the food sector and/or sanitary/phytosanitary measures; all of the guidelines of the Codex Alimentarius Commission (CAC), the guide from the International Plant Protection Committee (IPPC) and the guide from the World Organization of Animal Health (OIE). In addition, the International Organization for Standardization (ISO) has developed a general guideline for the private sector in relation to mutual recognition of conformity assessment results that is also included in this study.

We also study three examples of regional guidelines. The Association of Southeast Asian Nations (ASEAN) has developed a general guideline for the establishment of MRAs in different sectors. The Asia-Pacific Economic Cooperation (APEC) has developed several guidelines of interest. Here, we study the guideline/framework document on Food MRAs and one of the non-food guidelines, namely the framework for the development of MRA for Telecommunications Equipment.<sup>1</sup> In addition, we study guideline documents from the United States and the EU. United States has developed a guideline for the judgement of equivalence of foreign meat and poultry regulatory systems and a guideline on mutual recognition of good manufacturing practises (GMPs). The EU has a

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<sup>1</sup> The APEC model Mutual Recognition Arrangement on Automotive Products and the APEC Mutual Recognition Arrangement on Conformity Assessment of Electronical and Electronic Equipment are two other such framework documents.

prepared a document containing guiding principles in relation to MRAs. In addition, we included national documents on MRAs submitted by Canada and Japan to the TBT Committee of the WTO. These two documents cannot be considered as real guidelines, but we nevertheless included them in the study since they give relevant advice on the subject.

**Table 2.2 Type of Guidelines**

<b>Guideline*</b>	<b>Level</b>	<b>Governmental/ Non- Governmental</b>	<b>General, Sectoral or Specific</b>
ISO 2002	Global	Non-Governmental	General
WTO 1997	Global	Gover./Non-Gov.	Sectoral/Accountancy Sector
CAC 1997	Global	Governmental	Sectoral/Food
CAC 1999	Global	Governmental	Sectoral/Food
CAC 2003	Global	Governmental	Specific/Sanitary, food safety
IPPC 2004	Global	Governmental	Specific/Phytosanitary
OIE 2003	Global	Governmental	Specific/Sanitary, animals
APEC 1996	Regional	Governmental	Sectoral/Food
APEC 1998	Regional	Governmental	Specific/Telecom. Equipment
ASEAN 1998	Regional	Governmental	General (Sector neutral)
EU 2000	National	Governmental	Sectoral/Industry
USA 1997	National	Governmental	Sectoral/Health
USA 1999/2003	National	Governmental	Specific/Meat and Poultry
<i>Canada 2001</i>	<i>National</i>	<i>Governmental</i>	<i>General</i>
<i>Japan 2003</i>	<i>National</i>	<i>Governmental</i>	<i>General</i>

\* The whole reference/title of the document is found under "References".

## 2.3 Purpose and scope

The primary purpose of applying the tools of equivalence and mutual recognition in trade agreements<sup>2</sup> is to facilitate trade, i.e. to reduce trade barriers caused by differences in regulatory systems. Moreover, guidelines on equivalence and mutual recognition have been developed to assist the parties to draw up agreements and to establish equivalence and/or mutual recognition. In the following sections, we look more closely at the purpose and scope of a selection of these guidelines.

The purpose of **ISO/IEC Guide 68:2002(E)** is to provide guidance "...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" (ISO 2002: 1). The objective of conformity assessment is to provide confidence for users that requirements applicable to products, services

<sup>2</sup> In this report "agreements" include both formal and informal agreements, voluntary arrangements, memoranda of understandings and other schemes put in place to regulate trade relations between two or more parties.

and systems have been met. Such confidence contributes to market acceptance and thus facilitates trade.

The scope of the agreements covered by the ISO Guide is limited to activities related to “...the conduct of unregulated marketplace transactions extending across borders from one country to another” (ibid.). Thus, the Guide does not specifically address transactions of *regulated* goods and services. However, the Guide could nevertheless be of relevance for agreements that address governmental requirements. The guidance provided in the ISO Guide is introductory and general in nature.

The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) has issued several guidelines containing elements of equivalence and mutual recognition. **The CCFICS guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems** “...provide a framework for the development of import and export inspection and certification systems consistent with the Principles for Food Import and Inspection and Certification”.<sup>3</sup> The guidelines are furthermore intended to “...assist countries in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs” (CAC 1997). The guidelines deal with the recognition of equivalence of inspection and/or certification systems and not with specific food product standards.

The **CCFICS guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems** provide “...practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems” (CAC 1999). Such agreements include both legally binding agreements and less formal arrangements such as memoranda of understandings. The guidelines mention three purposes that the agreements covered by the guidelines could have:

- 1) provide enhanced means of assuring that exported products conform to importing country requirements;
- 2) eliminate duplication of activities and use collective resources more efficiently and effectively;
- 3) provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with requirements.

Generally, the agreements are supposed to be means of ensuring that importing country requirements are met with minimal trade impediments. The CCFICS guidelines on equivalence agreements cover both bilateral and multilateral agreements and trade in one or both directions between trading partners. An equivalence agreement is furthermore supposed to cover control and certification systems related to any aspect of food safety or *other relevant requirements for food* (!). Thus, in

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<sup>3</sup> These principles are to be found in CAC document: CAC/GL 20-1995; equivalence is one of the principles dealt with in this document (CAC 1995).

principle the guidelines are relevant for control systems related to both SPS and TBT measures as defined under the WTO.

The purpose of the **Codex Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems** is stated in the second paragraph of the preamble (CAC 2003):

“...in order to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement)”.

The Codex guidelines on the judgement of equivalence of sanitary measures further state in paragraph 3 that equivalence also serves to minimize the costs of regulation to governments, industry, producers, and consumers. The scope of the guidelines is stated in Section 2: For the purpose of determining equivalence the measures “...can be broadly characterized as infrastructure; programme design; implementation and monitoring; and/or specific requirements”. According to the CCFICS, these guidelines should be read in conjunction with CAC/GL 34-1999 (c.f. CAC 1999).

Equivalence is one of the general principles described in International Standards for Phytosanitary Measures (ISPM) No.1,<sup>4</sup> issued by the Secretariat of the International Plant Protection Convention (IPPC). In May 2004 a draft ISPM titled **Guidelines on the Concept of Equivalence of Phytosanitary Measures and its Application in International Trade** was sent out for country consultation. The further development of these Draft Guidelines was still pending for comments by IPPC members when we prepared this report. However, we nevertheless make some comments on the preliminary design of the guidelines.

The IPPC guidelines describe both “...the principles and requirements that apply to the concept of equivalence of phytosanitary measures” and “a procedure for equivalence determinations in international trade” (IPPC 2004). According to the guidelines, “...equivalence generally applies to cases where phytosanitary measures already exist for a specific pest associated with a trade in a specific commodity”. The guidelines state that equivalence may be applied to an individual measure, a combination of measures, or integrated measures in a systems approach. Furthermore, “...evaluation for equivalence of phytosanitary measures may not be limited to an assessment of the measures alone, but may also involve consideration of aspects of the export certification system”. Thus, both specific requirements and conformity assessment systems are covered. The draft ISPM standard also sets out in more detail the situations in which the guidelines for equivalence are relevant: They could apply in situations

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<sup>4</sup> The full name of this standard is “Principles of plant quarantine as related to international trade”.

“...where an importing contracting party has a phytosanitary measures in place, or is proposing a new measure, and an exporting contracting party proposes an alternative measure to achieve the importing contracting party’s appropriate level of protection/acceptable level of risk. The alternative measure is then evaluated for equivalence.”

The **OIE guidelines for equivalence** are included as Section 1.3.7 in the Terrestrial Animal Health Code (OIE 2003). The OIE guidelines recognize that “...significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*” (Article 1.3.7.1). The same article further states that the guidelines are to “...assist OIE Member Countries to determine whether sanitary measures arising from different animal health and production systems may provide the same level of animal and human health protection.” The OIE guidelines are relevant when equivalence applies to the level of specific measures or on a systems-wide basis, to specific areas of trade or commodities, or generally.

APEC (Asia-Pacific Economic Cooperation) provides a framework for the application of a voluntary mechanism to facilitate trade by entering into mutual recognition agreements involving conformity assessment systems (**APEC Food MRA**) (c.f. <http://www.apec.org/apec.html>). The general provisions and framework for how to enter into sectoral mutual recognition arrangements are included in an umbrella arrangement, which is the primary mechanism in the APEC context for promoting confidence in each other’s conformity assessment systems. The purpose of the arrangement is to provide guidelines for the APEC members in developing sectoral arrangements for specific foods, food products and sectors. Members are encouraged to use the arrangement to

“...facilitate extension of bilateral arrangements to include other member economies and to attain a high degree of commonality in arrangements on the conformity assessment of foods and food products which member economies might develop and implement” (Section 1, paragraph 1.7).

Appendix B of the APEC umbrella arrangement sets out in more detail the guidelines for the development and administration of sectoral arrangements. The sectoral arrangements may apply to an entire conformity assessment system, parts of the system, or to specific inspection or testing components.

The purpose of the **APEC Framework for the Development of MRA for Telecommunications Equipment** is to

“...streamline the Conformity Assessment Procedures for wide range of telecommunications and telecommunications-related equipment and thereby to facilitate trade among the Parties. It provides for the mutual recognition by the importing Parties of Conformity Assessment Bodies and mutual acceptance of the results of testing and equipment certification procedures undertaken by those bodies in assessing conformity of equipment to the importing Parties’ own Technical regulations” (APEC 1998: 1. Purpose of the Arrangement).

The APEC arrangement does not constitute an acceptance of the standards or technical regulations of a party by the other parties, or mutual recognition of the equivalence of such standards or technical regulations. The arrangement is not a legally binding document, but it shall be used to assist member economies in developing and concluding MRAs in the area of telecommunications equipment. This should be done in two phases or modules. The first phase or module is the mutual recognition of test results (Annex B) and the other module is for mutual recognition of certification (Annex C). Mutual recognition of test results is defined as *mutual recognition of test results from exporting economies based on importing economies' established procedures*, while working toward a common basis for recognizing testing laboratories. Mutual recognition of certification is defined as mutual recognition of certification by authorized bodies in other economies, so that the designated *conformity assessment bodies from each economy can certify products to the other economies' requirements*. It could also be mentioned that the APEC Telecommunication MRA has two basic principles related to trade facilitation. The first principle is to attain the minimum number of technical regulations and administrative procedures among the member economies to reduce non-tariff barriers to trade. The second principle is the mutual recognition of conformity assessment, seeking to limit the number of modules to reduce costs and time for conformity assessment such as testing and certification.

The WTO guideline for recognition of qualifications in the accountancy sector is also a non-binding document. The title **Guidelines for Mutual Recognition Agreements or Arrangements in the Accountancy Sector** indicates that the participants may be governmental as well as non-governmental. However, the guidelines are first and foremost intended to be used by governments with the objective of making it easier to negotiate agreements on mutual recognition of professional qualifications in the accountancy sector. According to the WTO, the guidelines shall serve as effective means of facilitating the movement of accountants across borders and of avoiding the emergence of new disparities between recognition regimes around the world. MRAs should specify the conditions to be met for recognition in the territories of each party and the level of equivalence between the parties (WTO 1997: 4).

ASEAN (Association of South East Asian Nations) has developed a framework for mutual recognition agreements: **ASEAN Framework Agreement on Mutual Recognition Agreements** (c.f. <http://www.aseansec.org/home.htm>). The purpose of the framework is clearly formulated in the introduction:

“...to deepen and broaden cooperation on Standards and Conformance in ASEAN and to provide a basis for developing and implementing MRAs in specific product sectors (...) to facilitate the realization of the ASEAN Free Trade Area”.

The ASEAN framework includes specific guidance for mutual recognition of *conformity assessment procedures*.

The European Commission has prepared a Commission Staff Working Document with the title **Guiding Principles on and a Vade mecum for the management of agreements on mutual recognition of conformity assessment** (European Commission 2000). The purpose of the Guiding Principles of this document was to

“...contribute to a better understanding, by the Member States policy-makers and representatives, of the principles guiding the preparation, negotiation and implementation of Mutual Recognition Agreements” (European Commission 2000: 3).

The purpose of the Vade mecum of the document was to be used by “...the Members States representatives and experts participating in all consultation and information procedures on MRAs” (ibid.). In 2003, the Commission revised the Staff Working Document with regard to the Vade Mecum. Thus, a separate document (Vade Mecum) on the management of Agreements on mutual recognition on conformity assessment was issued (European Commission 2003). However, because the purpose of this report is to map the variation of principles, elements and methods etc. for applying equivalence and mutual recognition, we have chosen to consider both of the Commission documents in our presentation.

Negotiating MRAs is one of the four elements of the EU’s external trade strategy and through such agreements the EU aims at reducing the costs of testing and certification in other markets (European Commission 2000: 4). For the EU, MRAs are “agreements between the EU and third countries on the mutual recognition of the conformity assessment of industrial products” (European Commission 2000: 6). Thus the EU guidelines cover conformity assessment procedures and are furthermore primarily restricted to industrial products.

The United States has developed several guidelines covering the application of equivalence and mutual recognition, e.g., “A Plan That Establishes a Framework For Achieving Mutual Recognition of Good Manufacturing Practices Inspections” (USA 1997) and “Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems” (USA 1999, 2003).<sup>5</sup> Furthermore, the United States has negotiated several MRAs, *inter alia*, seven MRAs on conformity assessment with the European Union (see: <http://europa.eu.int/comm/enterprise/international/indexb1.htm>).

The purpose of the U.S. guidelines for **Equivalence of Foreign Meat and Poultry Food Regulatory Systems** is to

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<sup>5</sup> The Food Safety and Inspection Service (FSIS) of the U.S. Department for Agriculture issued in 2003 a revised guide on the “Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems” which replaced the 1999 document on this issue. However, the evaluation process described in the 2003 document was essentially unchanged from the 1999 version, although it was expanded in certain areas (USA 2003: 2). Thus, in this report we cite both of these documents.



“...present the evaluation process FSIS applies to initially determine and periodically verify whether foreign meat and poultry food regulatory systems are equivalent to U.S. domestic regulatory programs” (USA 2003: 2).

The aim of this evaluation is to decide whether countries are eligible to export meat and poultry products to the United States and thus ensure that U.S. standards are upheld while at the same time facilitating trade in meat and poultry products. The guidelines furthermore cover evaluation of *systems*.

The U.S. **Framework For Achieving Mutual Recognition of Good Manufacturing Practices Inspections** applies only to mutual recognition of good manufacturing practices (GMP) inspections. The document summarizes the activities involved in the exchange of GMP information and presents the key considerations and factors that go into the approach to arrangements with other countries regarding such activities. The U.S. Food and Drug Administration (FDA) furthermore focuses on its role to maintain, strengthen and safeguard domestic public health and to strive “toward a common ground internationally on regulatory systems (including GMPs), criteria for the collection and assessment of inspection information, appropriate enforcement procedures” (USA 1997:1). Thus, the FDA seems to focus more on the goal of upholding national standards than on the goal of facilitating trade. In addition, through mutual recognition arrangements the FDA seeks to make more efficient use of scarce resources.

## 2.4 Pre-negotiation assessments

The first step towards an agreement in the field of equivalence and mutual recognition should be to perform some form of preliminary assessment to determine whether to undertake negotiations. Some of the guidelines and framework documents explicitly describe elements that should be considered before deciding to start consultations. In the following, we shall treat some of the most important elements of such pre-negotiation assessments according to the guidelines. The question on pre-negotiation assessment was especially treated in CAC 1999, EU 2000, Canada 2001 and Japan 2003. The elements described below are drawn from these documents and summarized as follows:

### a) Identifying needs, making a cost-benefit analysis

The first step in the process towards an agreement would be to assess the actual need for trade facilitation. What is the nature and scope of problems? Is there a clear potential for facilitating trade? How would an ideal solution of negotiations look like?

Trade barriers in the market concerned must be “significantly burdensome” to warrant the use of resources:

“The effect (of mutual recognition of conformity assessment) especially increases when exporters face a heavy burden of foreign conformity assessment such as complexity of the

regulations or associated procedures, the difficulty to foresee the results of conformity assessment, and/or lack of sufficient number of competent certification bodies/laboratories” (Japan 2003:2).

On the other hand, trade volumes between the potential partners must be significant to make negotiations worthwhile. The potential economic benefits of an agreement should be demonstrated, making sure they can justify the estimated costs associated with developing and maintaining the agreement. None of the guidelines describe in detail how to carry out this kind of cost-benefit analysis. However, it could be mentioned that the European Commission has been working on a specific methodology for econometric assessments of MRAs to cover this aspect (EU 2000).

### **b) Choosing appropriate tools, deciding on scope**

It is vital to decide what kind of trade facilitating tool to apply. It is necessary to check what tools or methods can be used. If the main problem is high costs of adapting to different national standards and regulations, harmonisation or recognition of equivalence of rules and standards would be the appropriate tools. If problems are primarily related to product approvals, priority should be given to the mutual recognition of conformity assessment procedures (Elvestad 2002). The possibility of combining different trade facilitating tools should also be assessed.

In addition, priorities concerning the scope of an agreement must be carefully considered. Should an agreement cover just one product or several products or product categories? Should it be sector specific or should one opt for a multi-sector agreement? Sector specific agreements are more common, since complex multi-sector agreements are time consuming and resource demanding to negotiate and implement. Step by step approaches including one sector at a time may be an alternative.

### **c) Sufficient system/measure compatibility**

Successful conclusion and implementation of agreements seems to be contingent on a certain level of compatibility between the regulatory measures or systems of the parties concerned. For instance, it may be difficult to conclude an agreement if regulatory schemes differ in principal elements such as the subject responsible for certification (e.g. government certification versus private third party certification). Identification of similarities and differences between measures or systems should therefore be an integral part of the pre-negotiation assessment. It is also important to make sure that potential partner institutions have a comparable level of technical skills, infrastructure and staff competence. If regulatory “cultures” are too different, it may be problematic to reach an agreement. Basing national measures on international standards is one way of facilitating such compatibility.

#### **d) Sufficient resources and support**

Another important element of the preparations is to identify and allocate sufficient resources to cover consultations, negotiations as well as the implementation of potential agreements. The necessary infrastructure, manpower, and economic and administrative resources must be in place. Furthermore, all parties involved should have a will to invest a quite extensive amount of time and resources in the process. In order to accommodate the negotiation process, it may be necessary to consider making internal changes. It is vital to seek support from all decision makers to ensure commitment to the work. The support of key players may be fundamental for achieving successful outcomes of negotiations.

## **2.5 Guidance on the elements of agreements**

Several of the guidelines present lists of relevant elements to be included in agreements (APEC 1998; ISO 2002; ASEAN 1998; CAC 1999; CAC 1997; WTO 1997). After reviewing the documents, we believe that the different elements can be grouped into four categories; introductory elements, substantive elements, implementation elements and closing elements:

#### **a) Introductory elements**

Most guidelines suggest that agreements should include a title and provisions regarding the purpose or objective of the agreement in the beginning of the document. The parties or signatories to the agreement should be stated. The introductory part of the document should also define the scope of the agreement, and important definitions may be presented.

#### **b) Substantive elements**

The guidelines differ somewhat concerning what elements they recommend to include with regard to the substantive obligations of agreements. This is perhaps not very surprising taking into account how the guidelines vary with regard to purpose and scope. For instance, the WTO “Guidelines for Mutual Recognition Agreements or Arrangements in the Accountancy Sector“ specify that agreements should include elements concerning qualifications (education, experience) and government licensing of the accountancy sector (WTO 1997: 4a, 4b). However, some of the guidelines give more general recommendations regarding mutual recognition or equivalence provisions. For instance, both the ASEAN guideline (ASEAN 1998, article 4) and the Codex guideline (CAC 1997, article 15) give general advice to list relevant legislative framework and administrative procedures pertaining to conformity assessment procedures or technical regulations. The Codex “Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems” has in fact a special annex describing the “Contents of Equivalence Agreements”. Point 6-12 of the annex deals with the substantive obligations of the parties. The Codex guideline,

e.g., lists equivalence findings as one of the elements, meaning a statement of the control system or parts of systems that have been found to be equivalent. In addition, the annex recommends including a description of the methods and procedures used to verify compliance, plans for continuing verification, lists of the criteria used to determine if the products meet relevant standards when using certificates, listing of procedures used for testing and/or certification, and procedures used to determine the compliance of products. The ASEAN “Framework Agreement on Mutual Recognition Arrangements” recommends sectoral MRAs to include a list of the Designating Bodies, the procedures and criteria used when listing conformity assessment bodies and a statement of the scope of the conformity assessment and relevant procedures for which each has been accepted.

### **c) Implementation elements**

All of the guidelines that specify elements to be included in agreements point to the need for provisions with regard to implementation of the obligations made. Several of the guidelines recommend the establishment of joint committees or similar institutional arrangements to facilitate implementation of the agreement. Elements related to the designation of liaison officials or points of contact for the exchange of information between the parties are also recommended. Several of the guidelines also mention provisions in relation to dispute resolution between the parties as an important element in agreements.

### **d) Closing elements**

Provisions specifying the date of entry into force of the agreement as well as provisions related to duration or determination of agreements are mentioned in several of the guidelines as relevant elements. Decisions regarding the possible revisions, modifications and amendments of the agreements should also be included. Signatures should be the final element of the agreement.

## **2.6 Methods and procedures for achieving and maintaining recognition**

Trust and confidence is vital if the parties are to accept measures differing from their own as equivalent or to allow various aspects of control activities to be performed by others. Through different kinds of co-operative measures, the parties can gain trust and be confident that the measures and systems of the other party are effective and can be relied upon.

However, it takes time to develop a solid foundation of knowledge and trust between the parties. It is therefore important to start to focus on measures promoting confidence as early in the process as possible. Confidence-building measures may in fact be a precondition for starting specific procedures for judging equivalence and achieving recognition. For instance, in the MRA between the EU and the U.S. there is a transition period with special procedures and programmes

for confidence-building aiming at giving the parties a fundament to make judgments concerning the equivalence of Conformity Assessment Bodies (CABs). However, confidence-building measures are also important supporting mechanisms set up to maintain recognition.

In the initial phases of negotiations, lack of confidence can be devastating and lead to a break down of negotiations. Furthermore, lack of trust can cause rejection of requests for recognition and result in the withdrawal of recognitions previously given to one of the parties. Consequently, it is important to secure adequate knowledge, understanding and trust of each other's systems through all phases of the process.

In the following paragraphs, we first look at some general confidence-building measures described in some of the guidelines that may be especially important in the initial phases of negotiations. However, these measures can be applied in all phases of the process. Second, we look at the more specific procedures described by the guidelines related to the actual process of judging equivalence or achieving recognition. Finally, we describe some of the specific mechanisms related to maintaining trust and recognition according to the advice given by the guidelines.

### **2.6.1 General confidence-building measures**

Where trade is already established between parties, experience provides knowledge about the other party's systems, thus making up an essential part of the confidence developed between the parties. This knowledge and experience can be very valuable, assisting in the evaluation of equivalence, and strengthening confidence between the parties (IPPC 2004, 3.6). In addition to the knowledge gained through practical experience, a fundamental element in confidence building is to formally exchange information on regulations and administrative procedures to promote familiarity of each other's systems.

For instance, the Codex "Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems" emphasises the need to facilitate the consultative process by exchange of information. The guideline provides a comprehensive list of information that could be exchanged, for instance legislative texts, documentation on control programs and operations, decision criteria and action, facilities and equipment, laboratories, inspection, audits, alert systems etc. (CAC 1999, Section 7). The ASEAN Framework Agreement on Mutual Recognition Arrangements encourages member states to strengthen and enhance existing cooperation efforts in confidence building, *inter alia*, through an exchange of information and joint training (ASEAN 1998, article 3.5). Exchange of personnel or joint training and exercises are mentioned in several guidelines as good ways to promote familiarity with the principles and practices concerned. The APEC Food MRA (APEC 1996, I:3) also underlines the importance of allowing on-site visits as a confidence-building measure. Most guidelines also point to joint audits as an appropriate tool for building trust. It follows, that the results and conclusions from audits should be exchanged. Joint seminars and workshops may represent important arenas where key players can get to know

each other and develop valuable relations. Such events may of course be very useful means to elucidate specific problems or issues.

Engaging in technical co-operation can also be a way to familiarise with each other's regulatory systems. If the systems are too unequal, engaging in capacity building can also help to develop institutional structures and pave the way for improved trust between the parties. Another way of increasing trust and confidence can be to set up a pilot study or design a trial programme to test specific elements, identifying difficulties and allowing for adjustments before entering into an agreement (CAC 1999, section 8).

The APEC Telecommunication MRA guideline sums up the issue of confidence-building in this way:

“Confidence-building can be facilitated in various ways, including through technical co-operation and assistance which can help to develop institutional structures on measurement, testing and other conformity assessment skills, and also by means of courses, seminars, personnel exchanges, inter-comparisons, joint audits and the like. Such technical cooperation and assistance can help to develop a greater familiarity with other Parties' requirements and a greater commonality approach” (APEC 1998, introduction).

## 2.6.2 Procedures for determination of equivalence and demonstration of conformity

First, it is necessary to make a distinction between the process of determining equivalence and the process of demonstrating conformity. Equivalence determinations include comparisons between two or more measures against some common denominator (e.g., appropriate level of protection (ALOP), specific objectives, relevant international standards etc.). Demonstration of conformity simply means that the parties utilize different methods to demonstrate conformity to whatever requirements are set out in an agreement. Thus, demonstration of conformity may or may not include equivalence determinations. In the following, we present different procedures for the determination of equivalence and demonstration of conformity described in international guidelines.

### a) Demonstrating conformity and achieving recognition

The ISO Guide 68: 2002 (ISO 2002) suggests several methods for demonstrating conformity and thus achieving importing country's recognition of exporting country's conformity assessment systems (c.f. Article 5.2). The *direct method* is based on a peer assessment where each of the potential signatories is evaluated by, or on behalf of, all the others. The involved bodies often set up a team to carry out the assessment of conformity. This method is chosen when confidence between the parties can be created through direct contacts. The ISO Guide furthermore refers to proficiency testing as a possible means, where applicable, of demonstrating equivalency of performance.

According to the *indirect method*, the recognition of assessment results is provided by external assessment systems. A commonly relied upon method is accreditation of participants by accreditation bodies using equivalent procedures. Arrangements

among the accreditation bodies used for recognizing each other's work may subsequently support the arrangements among conformity assessment bodies. An alternative is letting the participants be assessed by one or more bodies (e.g. certification bodies), which often will be specified in the agreement. It is important to stress that these bodies are not the same as those conducting conformity assessment activities covered by the arrangement. Furthermore, the bodies are selected for their competence only.

The direct and indirect methods are not mutually exclusive. Thus, the ISO Guide 68 refers to an example involving an international arrangement in which eligibility to participate can be demonstrated either directly (i.e. the body is assessed) or indirectly (i.e. by virtue of acceptance of participants from a regional grouping).

ISO Guide 68 underlines that regardless of the methods used to demonstrate conformity, the bodies participating in such assessments should have equivalent competence and operate in an equivalent manner.

The APEC Food MRA contains a number of provisions on recommended methods to demonstrate conformity, first of all in the "APEC Food MRA: Supplementary Material", but also in the Appendix B: "Guidelines for the Development and Administration of Sectoral Arrangements" of the APEC Food MRA (APEC 1996). Section 1 of Appendix B contains provisions concerning the development of sectoral arrangements and states the need for confidence-building activities leading to recognition of different national conformity assessment systems. Such a process could include peer review of the exporting country's conformity assessment system by the competent authority of the importing country. It is underlined that the provisions of a sectoral agreement should be consistent with WTO rules, in particular the SPS and TBT agreements, and with Codex standards and related texts, in particular those developed by CCFICS.

"APEC Food MRA: Supplementary Material" stresses the importance of exchange of information between member economies. Article 4.1 states that members should "...establish a system for the uniform and systematic exchange so as to provide assurance and engender confidence in each other and to demonstrate the efficacy of the programs controlled". Exporting members should notify on conditions that may adversely impact on the risk status of foods covered by a sectoral arrangement (Article 4.2). Importing members should inform of verification activities, including such information as the number of consignments imported, the number inspected, the total numbers of failures to comply with standards, the reason(s) for failures, and changes in requirements (Article 4.3). Exporting members should ensure "...the implementation of the controls necessary to assure importing Parties that their requirements are complied with" (Article 5.2.1). The exporting Party should furthermore (c.f. Article 5.2.2):

- identify the points within the production, processing etc. where hazards may occur, and thus should be subject to control to ensure the compliance with the requirements of the importing Party (critical control points)
- ensure that mechanisms are put in place to control the points where hazard may occur

- verify that these mechanisms are being implemented and are effective
- ensure that mechanisms are in place to minimise adverse changes and ensure that product complies with the relevant requirements.

Article 5.2.3 further suggests that members should consider the use of internationally accepted methodologies, such as HACCP (Hazard Analysis and Critical Control Point), as an integral component of their assessment and export inspection program. Article 5.4 states the need to ensure that mechanisms (e.g. certification, electronic information exchange, coding systems etc.) are in place for the provision of assurance that products have (or have not) been exported. Article 5.5 states that the exporting Party should implement systems to ensure that the integrity of the product exported is maintained after assurance. Article 5.5 includes provisions on compliance programs. The exporting Party should design and implement such programs to verify that the conformity assessment system provided for in a sectoral arrangement is correctly and consistently implemented (Article 5.6.1). Non-compliance during audits should be rectified in accordance with a set of “standard resolutions” (Article 5.6.2) and the results of the audits should be documented and made available to the importing Party on request (Article 5.6.3).

With regard to the obligations of the importing Parties, the APEC Food MRA Supplementary material stresses the importance of transparency; importing Parties should ensure that

“...requirements for the safety, fitness for purpose and labelling of imported products are documented in English and made available to the exporting Party” (Article 6.1).

Furthermore, Article 6.2.1 states that the importing Party can confirm that provisions are met through mechanisms such as verifying the degree to which the exporting Party’s conformity assessment system meets the importing Party’s requirements, reviewing the exporting Party’s compliance/audit program, export system audits including on-site checks, checks of consignments at an appropriate frequency, and post-market surveillance.

Article 6.3.1 states that when the importing Party designs an inspection program, it should

“...recognise the pre-export conformity assessment procedures carried out by the exporting Party as providing the basis for ensuring that food products comply with their requirements (...).”

Thus, the import inspection requirements should be reduced to an appropriate level.

Article 6.3.2 states that imported products

“...can be subjected to routine import inspection, as a part of the importing Party’s monitoring and verification program as appropriate”.



But these should be designed to minimise delays at the point of entry. Furthermore, products identified for inspection and/or testing should be released as soon as possible (Article 6.3.3). Article 6.4 spells out the actions that should be taken in the event of non-compliance with agreed provisions.

Thus, the APEC Food MRA provides detailed and extensive guidance on how to demonstrate conformity and thus achieve recognition of exporting Party's conformity assessment procedures.

The "ASEAN Framework Agreement on Mutual Recognition Agreements" is less detailed than the APEC Food MRA on the methods to demonstrate conformity (ASEAN 1998). However, some of the provisions contain some guidance on the methods to be used. According to Article 6 ("Listing of conformity assessment bodies") each Designating Body<sup>6</sup> specified in a Sectoral MRA should identify conformity assessment bodies that could be listed in a Sectoral MRA. Three alternative ways of demonstrating the technical competence of the conformity assessment bodies are suggested:

- accreditation by an accreditation body that is a signatory to a regional or international MRA, which is conducted in conformance with the relevant ISO/ECE Guides,
- or participation in regional/international mutual recognition arrangements for testing and certification bodies, which are conducted in conformance with the relevant ISO/ICE Guides,
- or regular peer evaluations conducted in conformance with relevant ISO/IEC Guides.

Thus, ISO/IEC standards are the core yardsticks by which the competence of the conformity assessment bodies is evaluated. The Designated Body shall ensure that the conformity assessment bodies have adequate knowledge of the applicable technical regulations. Article 7 and Article 8 contain provisions on the basis for the possibility of suspension and removal of listed conformity assessment bodies. Article 9 ("Verification of technical competence and compliance of conformity assessment bodies") states that designating bodies should ensure that identified conformity assessment bodies will be available for verification of technical competence and compliance when required by the relevant Joint Sectoral Committee set up under an agreement. A request for verification should be justified in an objective and reasoned manner. Article 10 ("Monitoring of conformity assessment bodies") furthermore states that designating bodies should ensure that conformity assessment bodies are capable and remain capable of assessing conformity of products or processes. Thus, they should perform monitoring by means of regular audit or assessment.

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<sup>6</sup> Designating Body is defined as a body appointed by a Member State to a Sectoral MRA, with responsibility to identify and monitor conformity assessment bodies as specified under the Framework Agreement and the Sectoral MRAs (c.f. ASEAN Framework Agreement, Article 1).

The ASEAN Framework Agreement is thus primarily focused on the demonstration of compliance with regard to the acceptance, listing and performance of conformity assessment *bodies*.

With regard to negotiation of MRAs, the document “Guiding Principles on and a Vade mecum for the management of agreements on mutual recognition of conformity assessment” states that “...the preparation of a single model agreement appears to be difficult, if at all possible (...)” (European Commission 2000: 12). Hence, the EU has not developed one standardised approach to MRAs. The framework for MRA negotiations thus tends to be designed on a case-to-case basis. Nevertheless, the document “Guiding Principles on and a Vade mecum...” contains recommendations on both the decision-making procedure in the Community in relation to conformity assessment bodies (pp. 19-21) and the procedure for designation of conformity assessment bodies under MRAs with non-member countries (Annex 1). In the EU, a Member State designating body can assess and determine that a conformity assessment body (CAB) within its own territory fulfils the requirements of the other Party in an MRA and has the capacity to operate according to those requirements (European Commission 2000: 19). The designating body should establish a complete technical file to this effect, and the designation should include a clear statement that it has assessed and determined that the conformity assessment body in question fulfils the requirements of the other Party according to the terms of the MRA (*ibid.*).

On the other side, EU members can contest a designation by the other Party in an MRA, or consider that verification is necessary. In such cases, they should inform the European Commission services, giving an objective reason for this (European Commission 2000: 20). It is the responsibility of the Commission to inform the other Party. The “Guiding Principles...” underline the importance of information exchange through all these processes:

“The MRAs encourage and require the Parties to exchange information on a number of issues, for example, on the procedures used to verify the compliance of CABs with the requirements set out in the sectoral annexes, implementation of legislation, regulations and administrative provisions referred to in the annexes etc. The Parties are also required to notify each other of changes to the legislation referred to (...)” (European Commission 2000: 20).

Annex 1 contains further details on the procedure for designation, e.g., the kind of information included in submissions, what units to communicate with etc.

The EU document “Guiding Principles on and a Vade mecum...” thus contains some guidance on how to demonstrate conformity under an MRA, but the number of and details in the general provisions are limited. The reason for this is that the EU to a large extent has provided separate negotiating frameworks for its many MRAs.

The Codex “Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification System” includes an Annex providing “Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification

Systems of an Exporting Country” (CAC 1997). Such procedures are also essential with regard to demonstrating conformity (and equivalence) in a process where two countries aim at establishing an equivalence or mutual recognition agreement. The guidelines state that assessment and verification should primarily concentrate on “...effectiveness of the inspection and certification system in operation in the exporting country rather on specific commodities or establishments” (CAC 1997: 19).

The subject of assessment and verification could be an exporting country’s inspection and certification infrastructure, or a specific inspection and certification regime applied to a single producer or group of producers. The guidelines suggest a plan for conducting the audit that should cover, *inter alia*, the subject and scope of the audit, the date and place of the audit, the identity of the auditors, the language in which the audit will be conducted and the report issued, a schedule of meetings with officials and visits to establishments, and confidentiality requirements. The guidelines further suggest that an opening meeting should be held with representatives of the exporting country where the auditor will be responsible for reviewing the audit plan.

The Codex guidelines furthermore provide recommendations regarding the examination, which comprise a document review of a national food inspection and certification system, an on-site verification to check on compliance with information contained in the documentary material, and a follow-up audit. The guidelines also suggest a checklist of elements to evaluate (CAC 1997: 21):

- legislation and policy;
- establishment structure and working procedures;
- the adequacy of inspection and sampling coverage and product standards;
- sampling plan and results;
- certification criteria;
- compliance action and procedures;
- reporting and complaint procedures;
- training of inspectors.

After the examination has been performed, a closing meeting should be held where the auditor presents the findings of the audit. A draft report is then forwarded to the appropriate authorities in both countries for comments, which subsequently should be included in a final report. We should note that the described procedures in these guidelines could be equally relevant for assessments based on judgements of equivalence of inspection systems as well as for assessments based on determinations of strict conformity with the importing country’s requirements (see below under “Judging equivalence and achieving recognition”).

The Codex “Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems” does not clearly distinguish between the initial confidence-building measures and the procedures for determining equivalence (CAC 1999). Furthermore, the guidelines

do not go into detail on the actual procedures for judging equivalence. However, section 7 of the guidelines presents important elements of the consultative process involved in the development of an equivalence agreement. The importing country should make available the texts of its relevant control measures and identify the objectives of these measures. The exporting country should provide information that demonstrates that its control system achieves the importing country's objectives, whether these are objectives related to food safety measures (appropriate level of health protection) or objectives related to other relevant requirements for food. The guidelines state that the development of equivalence agreements is facilitated by the use of Codex standards, recommendations and guidelines by both parties. Thus, equivalence could be achieved by evaluating the exporting country's measure against a Codex text (related to both 'food safety' and 'other requirements').

Information exchange is considered to be vital to the consultative process. The guidelines suggest that information could be exchanged on legislative framework, control programs and operations, decision criteria and action, facilities, equipment, transportation, and communication, laboratories, systems for assuring competent and qualified inspection, audit procedures, and details of any rapid alert systems. The participating countries should furthermore identify a process for jointly considering differences in measures and/requirements.

## **b) Judging equivalence and achieving recognition**

The CCFICS guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CAC 2003), the guidelines on the concept of equivalence of phytosanitary measures and its application in international trade (IPPC 2004), and the OIE guidelines for equivalence (OIE 2003), all go into detail on the actual process of judging equivalence. These guidelines are quite similar in design and share some core elements with regard to the recommended steps for how to judge equivalence. We will explore these elements further in the following sections.

All guidelines include accepted level of protection (ALOP) as a core basis for comparison between different measures. They furthermore point to the basic principle, that importing countries should recognize that measures different from their own may be capable of achieving the ALOP they have set themselves. However, it is the responsibility of the exporting country to objectively demonstrate that it can achieve the importing country's ALOP.

The ALOP should primarily be stated in the form of quantitative risk assessments, but if this is not possible, qualitative descriptions should be taken into account. It is up to the importing country to specify as precisely as possible an objective basis for comparison, the reason and purpose of its own measure and its relationship to the ALOP, the level of control achieved by the measure, and any additional relevant information.

The guidelines underline that in order to facilitate judgement of equivalency, countries should base their measures on relevant international standards and related

texts (i.e. standards and related texts elaborated in Codex, OIE and IPPC, respectively). Thus, international standards could be used as yardsticks by which different measures can be evaluated.

The extent of equivalence determination depends on the importing country's prior experience, knowledge and confidence regarding food control measures in the exporting country. Furthermore, determination of equivalence of specific requirements cannot be seen in isolation, but must be seen in relation to the entire food control and production system of the exporting country (c.f. conformity assessment). Thus, the CCFICS guidelines (CAC 2003) include infrastructure, administrative systems, enforcement systems, and provisions for certification, in the categorisation of sanitary measures associated with food inspection and certification systems (Section 5, paragraph 13). The OIE guidelines (2003) state that in many instances "...a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health and production system" (Article 1.3.7.4). The Draft IPPC guidelines Guide (2004) state that in some circumstances, a determination of whether a proposed measure achieves the ALOP, "...may need to be considered in relation to relevant components of an exporting contracting party's phytosanitary system" (Article 3.9).

When entering into the process of determining equivalence the importing country should make available details of measures. The exporting country should then review all applicable measures of the importing country. To facilitate the determination of equivalence the parties should use an agreed process for information exchange of relevant information.

The guidelines by CAC, OIE and IPPC all suggest a sequence of steps to facilitate the determination of equivalence. The involved parties are requested to follow these steps in a cooperative manner in order to reach agreement.

The exporting country should identify the relevant measure of the importing country for which it suggests an alternative measure, and request the reason and purpose for it.

The importing country subsequently provides the reason and purpose and other relevant information. Moreover, it should specify the objective basis for a comparison between its own measure and the alternative measure proposed by the exporting country.

On the initiative of the exporting country, the two countries should enter into a dialogue concerning the objective basis for comparison. The exporting country should then demonstrate that the application of an alternative measure achieves the objective (ALOP) of the importing country. It presents this in a submission to the importing country based on a risk assessment or other relevant methodology as appropriate.

The importing country reviews the submission and uses this as a basis to determine whether the exporting country's measure achieves the importing country's objective (ALOP). Any concerns should be notified to the exporting country, including the reasons for these concerns.

The exporting country should respond by providing further information, modifying its measure or taking other appropriate action.

The importing country should notify the exporting country of its judgement and provide the reasoning for its decision, should the judgement be that the alternative measure is not equivalent. Finally, attempts should be made to resolve any differences of opinion over a judgement.

Figure 2.1 shows a flow chart for the sequence of steps involved in the determination of equivalence. This figure is presented in the CCFICS guidelines on the judgement of equivalence of sanitary measures (CAC 2003), but is just as relevant for the sequence of steps presented in the OIE (2003) and IPPC (2004) guidelines.

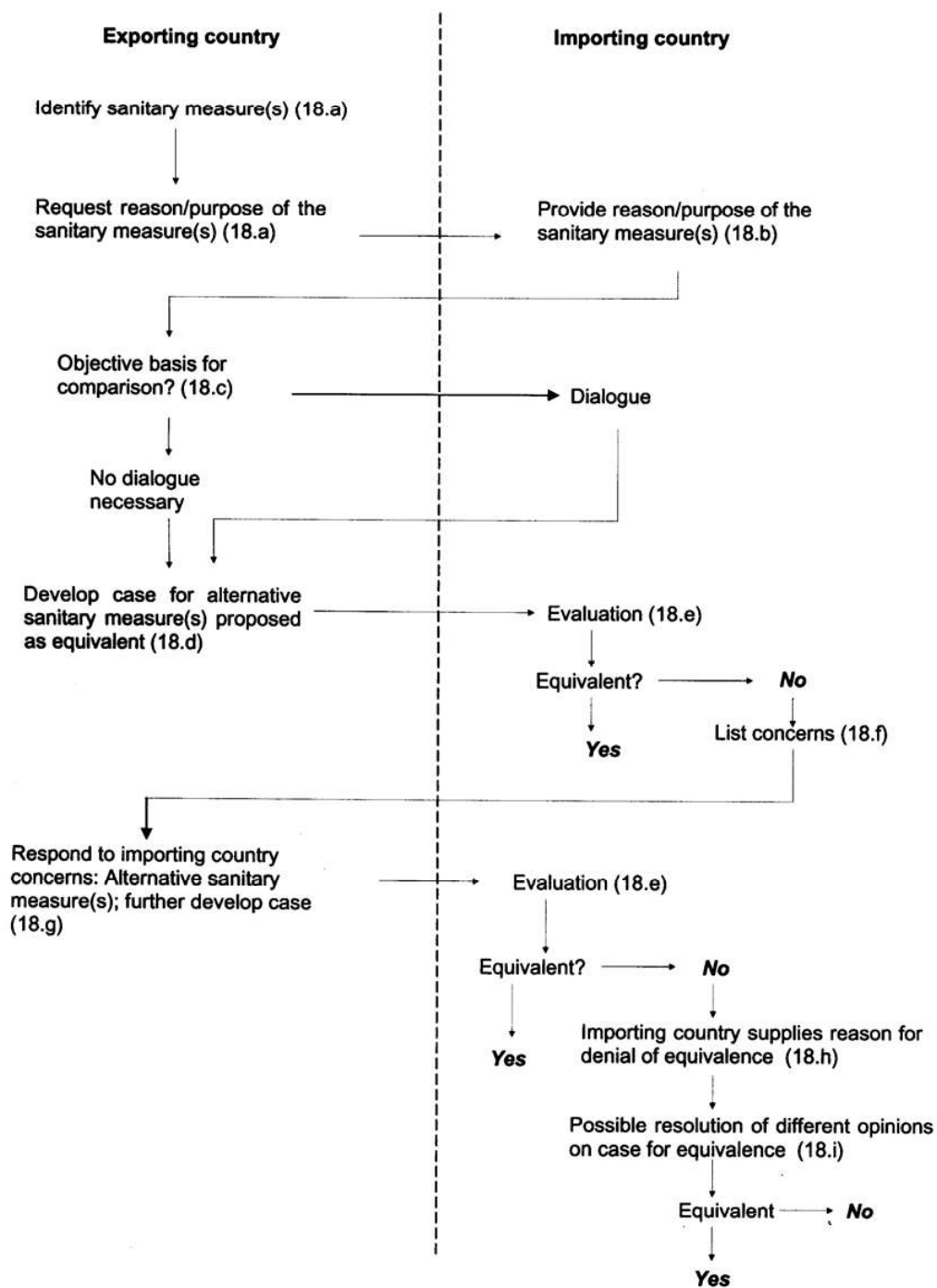


Figure 2.1 Sequence of steps for the determination of equivalence

According to the guidelines “Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems”, the U.S. Food Safety and Inspection Service conducts two types of equivalence evaluations (USA 2003: 10):

- to initially determine whether a foreign food regulatory *system* is equivalent in the case of a country that is not eligible to export meat or poultry products to the United States and;
- to determine whether an *individual sanitary measure* is equivalent in the case of a country that has already established its equivalence and is requesting that FSIS recognizes an alternative method of eliminating or abating a particular food safety hazard.

The two types of evaluations envisage different methods for the judgement of equivalence. However, the elements regarding the judgement of equivalence of an *individual sanitary measure* are quite similar to the elements included in the guidelines from CAC, OIE and IPPC. Thus, here we confine ourselves to present how FSIS evaluates system equivalence.

Any country can apply for eligibility to export meat or poultry products to the United States, and the application process begins with a letter to FSIS from a foreign government asking for approval to export its products (USA 2003: 11). FSIS responds by returning a package containing questionnaires designed to collect detailed information about the foreign regulatory system, examples of completed questionnaires, and copies of relevant U.S. laws and regulations. The package aims at providing the applicant country with information about the level of sanitary protection that FSIS deems appropriate and thus about the expectations that FSIS anticipates in an equivalent foreign system (ibid.).

When the FSIS receives the application, it conducts an initial document analysis to compare the foreign inspection system with measures that FSIS applies domestically. In many cases, further information or clarification is needed. Upon completion of the document analysis, the FSIS decides whether the foreign food regulatory system either meets all U.S. requirements in the same or equivalent manner, or if it cumulatively provides the same level of protection attained domestically. A satisfactory completion of this step is followed by on-site audit of the foreign food regulatory system. Initial equivalence audits are conducted by a multidisciplinary team of experts. The audit scope may include country laws and regulations, test results, testing methodologies and special U.S. import requirements such as HACCP programs (USA 2003: 12). During audit, FSIS correlates foreign program documentation with actual observations of program delivery. The goal of the audit is to *verify* that the foreign food regulatory system has implemented all the elements that FSIS found to be equivalent during document analysis.

When document analysis and on-site audit have been satisfactorily completed, FSIS proposes to add the country to the list of eligible exporters. Upon the receipt of public comments, the FSIS then finally decides about system equivalence based on all available information. The FSIS does not, however, conduct food inspections in the foreign country or certify foreign establishments. After a foreign system has



been judged to be equivalent, FSIS relies on the foreign country to perform its own inspections and certifications.

The establishment of initial equivalence through completion of document analysis, on-site audit, and final rulemaking are pre-conditions for a foreign country to export meat or poultry products to the United States. Moreover, this is a time-consuming endeavour; the whole process from application to completion may require three to five years.

On the basis of the guidance from FSIS, it is interesting to note that the way equivalence of systems is evaluated in many ways resembles the CAC procedures for conducting an assessment by an importing country of inspection and certification systems of an exporting country (c.f. CAC 1997). Thus, we see that evaluations of system equivalence may be intertwined in the process of demonstrating conformity.

### **2.6.3 Procedures for continued confidence**

The competence and capabilities of the conformity assessment systems or the equivalence of measures are not only evaluated in the initial phases of trust building and in the actual judgement processes. Several of the guidelines also underline the importance of establishing procedures to ensure continued confidence and ways of dealing with non-compliance and lack of trust.

For instance, in the Codex “Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems” the parties are encouraged to establish procedures to periodically audit and verify that equivalence continues to exist after the conclusion of an equivalence agreement (CAC 1999, see section 7).

The draft guidelines of the ICPM (“The Interim Commission on Phytosanitary Measures”) include verification procedures to ensure continued confidence:

“After the recognition of equivalence and to provide continued confidence in the equivalence agreements, contracting parties should implement the same review and monitoring procedures as other phytosanitary measures. These may include assurance procedures such as audits, periodic checks, reporting of non-compliance and other forms of verification” (IPPC 2004:3.10).

Another example of such procedures can be found in the document of the United States Department of Agriculture, Food Safety and Inspection Service (FSIS) describing “the Process for Evaluating Equivalence of Foreign Meat and Poultry Food Regulatory Systems”. This document has a special section about verification of “Continuing Equivalence”. FSIS utilizes a three-part evaluation process to verify that foreign food regulatory systems continue to be equivalent. The first part consists of a document analysis reviewing laws, regulations and implementation policies of an export country’s food regulatory system. The second part is yearly on-site audit, and the third part is continuous port-of-entry re-inspections of products shipped from export countries (USA 1999).

In accordance with “the ASEAN Framework Agreement on Mutual Recognition Arrangements”, Conformity Assessment Bodies (CABs) should be monitored by means of regular audits or assessments to ensure that they remain capable of properly assessing conformity assessment of products or processes. Nevertheless, the parties have the right to contest the technical competence or compliance of accepted CABs and suspend or remove bodies from the list of accepted CABs if they fail to maintain the necessary confidence (ASEAN 1998, Articles 6-10). Also “the APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment” gives guidance with regard to situations where one of the parties experiences the need to contest technical competence and to limit or withdraw recognition (Article 8: Verification of Conformity Assessment Bodies). “The APEC Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products” also focuses on how to proceed to verify continued compliance and how to react in situations where deficiencies undermine confidence (Section 4 Verification of Compliance with Sectoral Arrangements and Section 5 Suspension or Termination of Arrangements). With regard to minimising the cost of maintaining confidence in conformity assessment systems, sharing of information, joint audits, proficiency testing or other activities to enhance conformity are recommended (APEC 1996:Section 3,5c).

## 2.7 Institutional-set-up for ensuring implementation

In order to assist the implementation of agreements, several of the guidelines recommend establishing joint committees. The “Guiding Principles on and a Vademecum for the management of agreements on mutual recognition of conformity assessment” prepared by the European Commission especially stresses the role of joint committees in the implementation of MRAs. In fact, all EU MRAs have set up a joint committee.<sup>7</sup> The role of these committees is to supervise the functioning of the agreements and to take decisions allocated to them under the MRAs such as adopting lists of CABs. In addition, the joint committees are important forums for discussing and resolving divergent views and problems. Decisions regarding amendments to the agreements are other important tasks of the committees (EU 2000).”The ASEAN Framework Agreement on Mutual Recognition” recommends that all sectoral MRAs should have a Joint Sectoral Committee (JSC) responsible for the effective functioning of the MRA. The JSC should comprise of one official representative designated by each member state to the arrangement (Article 5.1). The JSC should particularly be responsible for (ASEAN 1998, Article 5.2, 5.3):

- a) listing, suspension, withdrawal, removal, reinstating and verification of Conformity Assessment Bodies,
- b) amending transition arrangements,

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<sup>7</sup> A joint committee is also set up to effectively implement the APEC telecommunication MRA (APEC 11).

- c) providing a forum for discussion of issues that may arise concerning the implementation
- d) considering ways to enhance the operation of the sectoral MRAs.

The decision of the Joint Sectoral Committees shall be made by consensus. The joint committees can be viewed as institutions for amicable settlement of differences and disputes. However, ASEAN has a Dispute Settlement Mechanism that could be used if consultations within the framework of joint committees fail.

According to the ISO/IEC Guide 68, MRAs should identify contact personnel or point of contact responsible for the consecutive updating and exchange of all types of relevant information between the parties (Article 4.11). For instance, in the APEC Food MRA the term “Liaison Officer” is used to designate the persons responsible for the communication with the other party on all matters related to administration and implementation (APEC 1996).

The WTO “Guidelines for Mutual Recognition Agreements or Arrangements in the Accountancy Sector” have a specific provision regarding mechanisms for implementation (WTO 1997: 5). Provision 5 of the agreement has a long list of elements to be included to ensure implementation, for example procedures to be used to monitor and enforce the agreement, mechanisms for dialogue and administrative co-operation and means of arbitration for disputes under the agreement.

## 2.8 Summing-up the guidelines

**The ISO guideline** is not a very comprehensive document. Instead of treating issues like general requirements, for instance for inspection bodies, laboratories, certification/registration bodies and quality systems, the guideline refers to other ISO documents. However, the document provides good guidance with regard to what elements to include in agreements and to the necessary institutional set-up. The ISO guideline deals with demonstration of conformity, but it is not very specific with regard to describing the actual procedures. Nevertheless, the ISO guideline presents a list of several internationally recognized principles for providing confidence in conformity assessment results.

The strengths of **the WTO guideline** in terms of general value seem to be the parts describing the elements of agreements and the mechanisms for implementations. The mutual recognition provisions of the guideline are very specific with regard to criteria relevant for the accountancy sector. Much of the guidance included in the guideline is thus not particularly relevant for other sectors.

**The CAC 1997 guideline** has a section on recognition of equivalence that is very general in nature. This explains the bracket in the column for procedures for determination of equivalence in Table 2.3. In addition, the CAC 1997 includes a specific annex providing; “Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country” or in other words determination of conformity.

The CAC 1997 also includes a section on equivalence agreements; listing certain provisions that may be included in equivalence agreements on a general basis.

In contrast, **the CAC 1999 guideline** describes most relevant aspects of establishing agreements but does not go into specifics on how to judge equivalence/determine conformity. However, in spite of its title: “Guidelines for the Development of Equivalence Agreements...”, the overall goal of the guidelines is to “provide an enhanced means of assuring that exported products conform to importing country requirements” (Section 3.1). This seems to imply that the kind of agreements this guideline promotes may include both judgements of equivalence as well as elements related to determination of conformity (with the requirements of the importing country), even though the procedures for doing so are not described in the guideline. The strengths of the CAC 1999 guideline are especially related to the provisions on pre-negotiation assessments and all the provisions covering the different aspects of confidence building as well as the list of elements of agreements.

**The CAC 2003 guideline** focuses solely on the determination of equivalence of sanitary measures associated with food inspection and certification systems. Judgement of equivalence is also the main focus of the **IPPC 2004** and the **OIE 2003** guidelines. However, these guidelines have a slightly broader scope, including not only equivalence of measures but also recognition of systems or parts of systems. The IPPC guideline also includes some provisions focusing on confidence building.

The regional guidelines **APEC 1996, APEC 1998 and ASEAN 1998** do not treat the process of judging equivalence, but focus on all aspects of building confidence and reaching agreement on the recognition of conformity assessment. The APEC 1996 and the ASEAN 1998 guidelines include provisions on implementation and institutional set-up. Both the APEC 1998 and ASEAN 1998 have provisions on which elements to include in agreements.

The national guidelines or framework documents **EU 2000, Canada 2001 and Japan 2003** deal particularly with pre-negotiation assessment. However, the EU 2000 also has interesting elements related to both demonstration of conformity and institutional set-up. **USA 1997** deals with mutual recognition of Good Manufacturing Practises Inspections and is primarily related to public health safeguards. **The USA 1999 and 2003** documents deal with evaluating the equivalence of foreign meat and poultry food regulatory systems. The documents give particular guidance on how to judge equivalence as well as how to maintain confidence in the equivalence of foreign regulatory systems.

Table 2.3 provides an overview of the guidelines indicating how they relate to the five main categories presented in this chapter (c.f. sections 2.3-2.7). An ‘X’ means that the guideline deals with the element in a relatively substantial way. In principle, if a guideline has no ‘X’ it means that the guideline does not treat the element. However, some guidelines with no ‘X’ may treat the element in question, but not directly or in a superficial manner.

**Table 2.3 Main elements of the Guidelines presented in this study**

<b>Guideline</b>	<b>Pre-negotiation Assessments</b>	<b>General confidence Building -</b>	<b>Procedures for determination of equivalence</b>	<b>Procedures for demonstration of conformity</b>	<b>Procedures for Continued confidence</b>
ISO 2002				X	
WTO 1997					
CAC 1997			(X)	X	
CAC 1999	X	X	(X)	(X)	X
CAC 2003			X		
IPPC 2004		X	X		X
OIE 2003			X		
APEC 1996		X		X	X
APEC 1998		X		X	X
ASEAN 1998		X		X	X
EU 2000	X			X	
USA 1997	X	X	X		
USA 1999/2003			X	X	X
<i>Canada 2001</i>	X				
<i>Japan 2003</i>	X				

**Table 2.3 (cont.) Main elements of the Guidelines**

<b>Guideline</b>	<b>Institutional set-up/ implementation</b>	<b>Elements of Agreements</b>
ISO 2002	X	X
WTO 1997	X	X
CAC 1997		X
CAC 1999		X
CAC 2003		
IPPC 2004		
OIE 2003		
APEC 1996	X	
APEC 1998		X
ASEAN 1998	X	X
EU 2000	X	
USA 1997		
USA 1999/2003		
<i>Canada 2001</i>		
<i>Japan 2003</i>		



# 3 Summary and conclusions

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## 3.1 Introduction

Based on our survey of international guidelines on equivalence and mutual recognition we will in this last chapter make some assessments; first, with regard to the potential for further guidance in the food sector and second, with regard to further guidance in the WTO and the CAC.

## 3.2 Relevance of selected guidelines for further guidance

In this report we have presented a number of international guidelines that provide guidance on how to apply equivalence and mutual recognition as trade facilitating tools. What lessons can be drawn from the different guidelines with regard to the need for further guidance in the food sector?

Table 3.1 shows if the guidelines are focused on giving advice in relation to the general process of making agreements or if they are limited to giving guidance on how to judge equivalence or determine conformity. Furthermore, the table intends to characterize the subject matter of the guidelines. Do the guidelines treat equivalence or recognition of conformity in relation to specific measures, whole systems or specific results produced by the systems? This classification facilitates the assessment of both the relevance for the food sector and the possible need for more guidance.

**Table 3.1 Scope of the Guidelines**

<b>Guideline</b>	<b>Guidance on Agreements or judg./determ.</b>	<b>Subject</b>
ISO 2002	Agreement	Recog. of conformity assessment results
WTO 1997	Agreement	Recog. of qualifications and licensing (measure/system)
CAC 1997	-	Recog. (of equiv.) of insp./certif. systems
CAC 1999	Agreement	Recog. (of equiv.) of insp./certif. systems
CAC 2003	Judgement	Recog. of equiv. of measures
IPPC 2004	Judgement	Recog. of equiv. of measures/parts of syst.
OIE 2003	Judgement	Recog. of equiv. of measures or syst.
APEC 1996	Agreement	Recog. of conf. ass. of systems/parts of syst.
APEC 1998	Agreement	Recog. of test results and cert.
ASEAN 1998	Agreement	Recog. of conf. ass. procedures/syst.
EU 2000	Agreement	Recog. of conf. ass. procedures/syst.
USA 1997	Agreement	Recog. of conf. ass. procedures
USA 1999/2003	Judgement	Recog. of equiv. of measures/syst.
<i>Canada 2001</i>	<i>Agreement</i>	<i>Recog. of conf. ass. procedures/syst.</i>
<i>Japan 2003</i>	<i>Agreement</i>	<i>Recog. of conf. ass. results</i>

The “triples” CAC 2003, IPPC 2004 and OIE 2003 are all confined to dealing with judgement of equivalence. Also, the United States guideline is restricted to the judgement of equivalence (on meat and poultry regulatory systems). All the other documents are mainly focused on giving some kind of guidance on how to establish agreements. However, these guidelines may also include provisions on, for instance, how to determine conformity as part of the process of reaching an agreement. It should be noted that the CAC 1997 first and foremost is a guideline on how to develop import and export inspection and certification systems consistent with Codex principles and does not really say much about how to achieve equivalence and recognition. This explains the hyphen line in the column for agreement/judgement under this guideline.

Many of the guidelines presented are explicitly designed for the food sector. This is particularly true with regard to SPS measures, i.e. measures related to food safety, animal health or plant health. These guidelines cover both specific product and process requirements and different elements of the food and inspection systems (i.e. conformity assessment procedures). Thus, the three CAC guidelines (1997, 1999, 2003), the OIE guidelines (2003) and the guidelines that are being developed by IPPC (2004), seem to cover much of the need for guidance. In addition, the ISO Guide (2002) and related ISO texts can provide further guidance with regard to mutual recognition of conformity assessment results.

However, the situation is quite different with regard to TBT related food measures. In this area we find a number of relevant guidelines, but these are often narrower in scope than the SPS guidelines. Many of the guidelines only cover



certain aspects of the mutual (or unilateral) recognition of conformity assessment systems, e.g., test results, designation of accreditation bodies or certification. We find no detailed guidance on how to determine equivalence for specific TBT requirements, even though according to both the WTO and the CAC, this is considered to be a potentially important area for the work on trade facilitation (see below). The EU, which is in forefront with regard to applying equivalence and mutual recognition as trade facilitating tools, has stressed the importance of achieving equivalence both for product requirements and for conformity assessment procedures:

(...) the results of the assessment of conformity with the requirements of one Party would be recognised as equivalent to the results of an assessment of conformity with the requirements of the other Party. The pre-condition to achieve this is a determination of equivalence between the two Parties' regulatory requirements, in terms of both product requirements and conformity assessment procedures. (European Commission 2000:7).

The European Commission also indicates how such equivalence determinations of TBT measures could be performed:

Equivalence between technical regulations and standards of the two Parties would mean, in general terms that the regulatory requirements of one Party (including product standards, test methods and the choice of conformity assessment procedures) are capable of fulfilling the regulatory objectives of the other Party and vice-versa. In other words, if one Party prescribes a given standard in order to achieve a given level of let's say performance, safety or environmental protection, the standard of the other Party must be capable of ensuring the same level of performance, safety and protection and vice-versa. (ibid.).

These citations illustrate the most crucial difference between determining equivalence for SPS measures vs. determining equivalence for TBT measures, namely the objective basis for comparisons. The main basis for comparing SPS measures is a defined level of protection (c.f. ALOP). For TBT measures the basis for comparisons will vary depending on the specific measures to be compared, but a number of possible parameters could be identified, e.g., performance or environmental protection. And, as the European Commission indicates, this difference between the SPS and TBT area does not mean that equivalence determinations could not be performed for TBT measures. On the contrary, there is a considerable potential for equivalence determinations in the TBT area (Elvestad 2002; Veggeland and Elvestad 2004). Moreover, such equivalence determinations will often be a pre-condition for equivalence determinations of conformity assessment procedures and thus for facilitating food trade.

Thus, our preliminary conclusion is that there still is a potential for the development of general international guidelines on TBT measures in the food sector, covering the process of achieving equivalence and/or mutual recognition of both specific technical requirements and conformity assessment systems. Taking into account the complications following the lack of *one* objective basis for comparison with regard to TBT measures (c.f. no direct parallel to the ALOP), we see no

reason why guidelines could not be developed for TBT measures in line with the way the existing SPS guidelines have been designed.

### 3.3 Relevance of international guidelines for further work in the WTO and the Codex Alimentarius Commission

In Table 3.2 we try to characterize the guidelines with regard to whether they address sanitary and/or phytosanitary measures (SPS measures) or technical measures (TBT measures). Some guidelines cover both types and some guidelines are purely SPS or TBT relevant. Of special interest for the food sector, for example, is the CAC 1999 guideline that states that the guideline “may relate to any aspect of food safety or other relevant requirement for food” (Section 4). The term “food safety” implies that the scope of the guideline is SPS measures, but the phrase also points to relevance of other relevant requirements for food – or in other words that TBT measures are also included. Another guideline related to food that covers both SPS and TBT measures is the APEC guideline on Food MRAs. The guideline defines its scope pertaining to: “...acceptance of...requirements on safety, fitness for purpose and truth in labelling”. Requirements on safety are synonymous with SPS measures, while fitness for purpose and truth in labelling are related to TBT measures.

**Table 3.2. Guidelines in relation to sanitary (SPS) and/or technical measures (TBT)**

<b>Guideline</b>	<b>SPS /TBT</b>
ISO 2002	TBT
WTO 1997	TBT
CAC 1997	SPS/TBT
CAC 1999	SPS /TBT
CAC 2003	SPS
IPPC 2004	SPS
OIE 2003	SPS
APEC 1996	SPS/TBT
APEC 1998	TBT
ASEAN 1998	TBT
EU 2000	SPS/TBT
USA 1997	SPS/TBT
USA 1999/2003	SPS (TBT)
<i>Canada 2001</i>	<i>SPS/TBT</i>
<i>Japan 2003</i>	<i>SPS/TBT</i>

The Codex guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CAC 2003), as well as the

OIE guidelines (2003) and the IPPC Draft guidelines (2004), were actually developed on the basis of discussions and initiatives taken by the WTO SPS Committee (Veggeland and Elvestad 2004). The basis for the work on SPS guidelines was the provisions on equivalence in the SPS Agreement, in particular Article 4:

*Equivalence*

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.

The SPS Agreement's definition of a sanitary or phytosanitary measure includes end product criteria, processes and production methods as well as testing, inspection, certification and approval procedures. Thus, both specific product requirements and conformity assessment procedures are covered by the definition and thus by all the provisions of the Agreement. Thus, the developed SPS guidelines also include both specific product requirements and conformity assessment procedures.

The situation is not as straightforward with regard to the TBT area, not least because the TBT Agreement provides different definitions for technical regulations, standards and conformity assessment procedures. Thus, in contrast to the SPS Agreement, separate provisions apply to specific product requirements and conformity assessment. This may explain why guidance on the equivalence of TBT related measures and systems is more fragmented than for SPS measures.

The members of the TBT Committee have for many years discussed how to apply the TBT Agreement's provisions on equivalence and mutual recognition; Article 2.7 for equivalence of technical regulations, Article 6.1 for equivalence and recognition of conformity assessment procedures, and Article 6.3 on MRAs:

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:

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.

The discussions in the Committee resulted in statements that were included in the Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, which, *inter alia*,

“...reiterated the importance of giving positive consideration to accepting as equivalent technical regulations of other Members as provided for under Article 2.7” (WTO 2003:3).

Furthermore, the TBT Committee specified that equivalency can be an element of good regulatory practice (and relevant to conformity assessment as foreseen under Article 6.1) and agreed to

“...initiate a process of sharing experiences in the Committee particularly with regard to how the concept is implemented in practice” (*ibid.*).

The Committee noticed that

“...MRAs can be negotiated between governments with respect to specific regulations or can be voluntary arrangements between domestic and foreign conformity assessment bodies” (WTO 2003: 7).

However, it was also noted that, as indicated under Article 6,

“...appropriate confidence building measures, including accreditation, could facilitate the acceptance of conformity assessment results without entering into MRAs” (*ibid.*).

The TBT Committee is prioritising work on both equivalence and mutual recognition. As a matter of fact, the ISO Guide on Arrangements for the Recognition and Acceptance of Conformity Assessment Results (ISO 2002) was developed after members of the TBT Committee requested such guidelines to be developed (Veggeland and Elvestad 2004: 21-22). Thus, ISO provided guidelines for recognition and acceptance of conformity assessment results relevant for the *private sector*.

However, the TBT Committee has not made similar requests for guidelines to be developed by intergovernmental standardization bodies such as the CAC. This is one of the reasons why the work on the Codex guidelines on the judgement of equivalence of technical regulations associated with food inspection and certification systems was halted at the CCFICS meeting in December 2003 (CAC 2003b, 2003d; Veggeland and Elvestad 2004). One of the conclusions from this meeting was that CCFICS

“...decided not to pursue work on the judgement of equivalence of technical regulations...at the current time...” (CAC 2003d: 11).

However, CCFICS decided that it might return to this issue at a future meeting. Furthermore, the reference to judgement of equivalence of technical regulations was kept in the Medium-Term Plan 2003-2007 (*ibid.*).

One of the problems with developing guidelines for judgement of equivalence for technical regulations is the difficulty of gathering many good examples of how such equivalence determinations have facilitated trade. Furthermore, facing the lack of good examples, many countries are sceptical of spending time and resources on developing such guidelines.

However, as our presentation of guidelines has illustrated, many guidelines already include provisions relating to both TBT and SPS measures and provisions related to both specific product requirements and conformity assessment procedures. A good example of this is the CAC “Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems” (CAC 1999), which states that an equivalence agreement covering control and certification systems may relate to food safety *or other relevant requirement for food*, and that the scope of requirements to be addressed can include, e.g., health and safety, quality assurance systems, labelling and consumer fraud (CAC 1999: 25, 27). Thus, according to these guidelines, CAC clearly sees the relevance of equivalence determinations for both TBT and SPS related measures.

Our survey of international guidelines on equivalence and mutual recognition thus shows that there are already many relevant guidelines to take into consideration for both the WTO and the CAC. With regard to equivalence agreements covering determination of equivalence of conformity assessment procedures associated with TBT measures, much guidance is already provided by existing guidelines, i.e. CAC 1997 in combination with CAC 1999 and ISO 2002. However, at the present time, more work could be done, in particular with regard to guidelines on equivalence of specific technical regulations.

### 3.4 Final remarks

Many of the guidelines surveyed in this report, including the CAC guidelines, cover both TBT and SPS related measures. Moreover, regional economic co-operations, such as APEC, have developed detailed and useful guidelines containing elements of equivalence determinations and demonstrations of conformity in the context of MRAs. These guidelines are relevant for both TBT and SPS related measures. However, the guidelines referred to in this report vary to a large degree, according to the scope of the guidelines and the elements that are included in the guidance, e.g., equivalence of systems, parts of a systems, specific measures, combination of measures etc. This is particularly true with regard to TBT measures in general and conformity assessment systems in particular. Thus, there seems to be a need for general and comprehensive guidelines containing guidance on the application of equivalence and mutual recognition in the TBT area. However, before considering spending time and resources on such work, a first step could be to invite relevant

parties with extensive experience from equivalence and mutual recognition agreements, such as the United States, Canada and APEC and EU countries, in a process of sharing their *experiences on the value of guidelines* for their own work on equivalence and mutual recognition.

Finally, there is one more point worth mentioning. Many of the guidelines underline that the application of international standards, such as HACCP and standards developed by CAC, OIE, IPPC and ISO, enhances the process of judging equivalence and achieving mutual recognition. The point is that international standards contribute first, to harmonizing national regulatory systems and measures, and second, to providing parameters upon which these systems and measures can be evaluated. Thus, international harmonization creates confidence between trade partners and increased compatibility between regulatory systems. International harmonization facilitates the application of mutual recognition and equivalence. At the same time, international guidelines on *how* to apply mutual recognition and equivalence enhance harmonization. Consequently, international guidelines dealing with equivalence and mutual recognition could have a double role in facilitating trade; by promoting acceptance of different measures and systems as equivalent and by promoting processes of harmonization. These factors should also be taken into consideration when discussing good regulatory practise in general and trade facilitation in particular, in international forums such as the WTO and the Codex Alimentarius Commission.

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