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Trade Facilitation through Equivalence and Mutual Recognition: The EU Model

Frode Veggeland

SeMM
Centre for Food Policy

NILF
Norwegian Agricultural
Economics Research Institute

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Author	Frode Veggeland
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About NILF

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Foreword

This report deals with the EU's work on trade facilitation in general and the application of the principles of equivalence and mutual recognition in particular. Both the EU's work on facilitating trade between its Member States and between the EU and third countries is explored. The EU has through its custom union, common trade policies and its work on establishing a single European market, acted as an entrepreneur in exploring different trade facilitating tools. Thus, it is possible to talk of an EU "model" of trade facilitation. This model includes a variety of tools. However, in this report only two trade facilitating tools are highlighted, namely equivalence and mutual recognition because these have been high on the agenda in several international bodies in recent years. The report looks at both the EU's work internally on applying these tools and its international work, both bilaterally and towards the WTO and Codex Alimentarius Commission.

The 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; Elvestad and Veggeland 2005).

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Ivar Pettersen
Director

Abbreviations and definitions

- **CAB:** Conformity Assessment Body (Checks whether traded products comply with existing requirements.)
- **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 conformity assessment body**: A conformity assessment body accepted (e.g. by a Party to an MRA) as being competent to test/certify/mark in accordance with agreed/prevailing legislative requirements.
- **DG SANCO:** Santé et protection des Consommateurs (The European Commission's Directorate General for Health and Consumer Affairs)
- **EC:** European Community (The EC changed name to the EU when the Maastricht Treaty establishing the European Union entered into force on 1 November 1993. However EC continues to exist as Pillar One of the EU, which encompasses economic, trade, and social policies ranging from agriculture to education.)
- **EEC:** European Economic Community (the former name of the EC)
- **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 (For reasons of simplicity we use the name European Union (EU) throughout the report even when EC or EEC is the formally correct name.)
- **FDA:** United States Food and Drug Administration
- **GATT:** the General Agreement on Tariffs and Trade (Signed in 1947 and was the predecessor to WTO.)
- **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 ineffective or even dangerous.

- **IPPC:** International Plant Protection Convention
- **MRAs:** Mutual Recognition Agreements
- **NTBs:** Non-tariff Trade Barriers
- **OIE:** Office International des Epizooties (World Organization for Animal Health)
- **PECA**: Protocol on European Conformity Assessment
- **SPS Agreement:** (the WTO) Agreement on the Application of Sanitary and Phytosanitary Measures
- **TBT Agreement:** (the WTO) Agreement on Technical Barriers to Trade
- **TEP:** the Transatlantic Economic Partnership
- **U.S.:** United States
- **USDA:** the United States Department of Agriculture
- **USTR:** the United States Trade Representative
- **VEAs:** Veterinary Equivalency Agreements
- **WTO:** World Trade Organization (Established in 1995 as a successor to GATT.)

Contents

Executive Summary

This report explores how equivalence and mutual recognition have been applied by the European Union (EU) in order to facilitate trade. The EU is of particular interest in this area because it has been in the forefront internationally with regard to applying these tools, both in its internal market project and in its external trade relations.

The report includes an empirical mapping of EU's experience with applying equivalence and mutual recognition as trade facilitating tools. The aim here is to increase the understanding of how these tools can be relevant and important in a wider global context, in particular with regard to food trade. Furthermore, based on this experience some of the challenges that countries are faced with when applying these tools are highlighted thus allowing some assessments of the prospects of and difficulties in achieving trade facilitation through these means.

Chapter 2 includes an account of some of the regulatory approaches that the EU has pursued in its attempts at realising an internal market, from the adoption of common rules, to mutual recognition and the "Better Regulation" programme included in the Lisbon strategy. Chapter 3 discusses EU's rules for third-country relations. Furthermore, some of EU's mutual recognition and equivalence agreements are explored. In addition to these, Chapter 3 includes an account of one-way judgements of equivalence included in EU's rules for imports of organic food and fishery products. Chapter 4 presents EU's work and positions on equivalence and mutual recognition in the WTO and the Codex Alimentarius Commission. Chapter 5 includes an assessment of the EU's experience with mutual recognition and equivalence. Finally, in Chapter 6 some conclusions and final remarks are made.

EU's institutional framework possesses some characteristics, which indicate that it is easier for the EU to facilitate trade between its Member States than it is to facilitate trade between countries in many other international settings. EU's comprehensive legal framework and its relatively strong institutions to enforce common rules, give it a strong regulatory capacity and thus make it a special case with regard to how trade can be facilitated between nation states.

Thus, one has to have lower expectations with regard to facilitating trade in many other international settings. The experience of the EU certainly show that equivalence and mutual recognition may be useful trade facilitating tools and that these tools could be used and could have a positive effect in trade relations between certain countries. However, there are many problems attached to this. For example, developing countries will in many cases have problems achieving equivalence and/or recognition of their conformity assessment systems because of inadequacies in infrastructure and regulatory capacity.

Furthermore, even when these tools are applied between countries with similar levels of development and regulatory capacities, many problems can arise. These tools may therefore in many cases be costly to apply in practise. Thus, one has to

carefully consider whether it is worth the effort to enter into processes of judging equivalence and seeking mutual recognition.

Therefore, it seems important to consider on a case-by-case basis whether these tools should be applied. Furthermore, increased activity of international standardization bodies, active country participation in these bodies, and widespread adherence to international standards, will enhance the application of equivalence and mutual recognition, as well as enhance harmonization.

Finally, in many cases equivalence and mutual recognition (and harmonization) will initially not be the most (cost) effective trade facilitating tools. Often, softer approaches such as regulatory dialogue, information sharing etc., may be easier to initiate and maintain. It may take a long time to reach the goal of removing trade barriers by using these approaches, but they may still be more effective in the long run, not least because they may more effectively lead to harmonization. The EU has for some years used soft approaches with the aim of facilitating trade, but only as a supplement to other approaches such as MRAs.

One example of an alternative approach is the regulatory dialogue that has been established between the EU and the U.S. The two parties have agreed on "Guidelines for Regulatory Cooperation and Transparency" under the Transatlantic Economic Partnership (TEP) and in 2004 they furthermore set out a roadmap for this co-operation. The roadmap outlines a range of specific regulatory cooperation activities the parties jointly intend to pursue. It includes: specific sectoral co-operation, such as co-operation on food safety, pharmaceuticals and auto safety regulation; horizontal initiatives, such as a regular informal dialogue on regulatory policy issues and practices of mutual interest; identification of resources and mechanisms to promote exchanges of U.S. and EU regulatory experts in specific areas/projects, and seminar/workshops where regulators can exchange views and raise awareness of regulatory activities, priorities and approaches on issues of mutual interest. The European Commission has established such regulatory dialogues with several other countries and has in fact stated that it will increase its attention and efforts towards the use of such approaches to regulatory compatibility.

This report thus points out some of the difficulties involved in applying equivalence and mutual recognition as trade facilitating tools in bilateral trade relations. Furthermore, it highlights the possible benefits of making greater efforts on so-called soft approaches to harmonization. As indicated above, by entering into regulatory dialogues and by sharing experiences more actively, regulatory authorities could contribute to building sufficient confidence and trust thus enhancing closer and more formalized co-operation such as, for example, MRAs and equivalence agreements. These "softer" regulatory co-operation efforts, which take place without the need to negotiate formal agreements, may subsequently lead to a gradual harmonization of regulatory systems thus enhancing the work on removing regulatory trade barriers.

1 Introduction

1.1 The main research questions

Over the years, there has been an increased focus, both in academic literature and in discussions in international trade fora, on trade barriers caused by trade restrictive national regulations and product standards (Vogel 1995; Sykes 1995, 1999; Egan 2001). An important question has been: How can trade be facilitated without compromising legitimate regulatory objectives such as health and environmental protection? This report highlights two trade-facilitating tools: equivalence[1] and mutual recognition—and focuses on one of the most powerful economies where these tools are applied, namely the European Union (EU).[2]

The report's purpose is thus twofold. First, I empirically map EU's experience with applying equivalence and mutual recognition as trade facilitating tools. My aim is to increase the understanding of how these tools can be relevant and important in a wider global context, in particular with regard to food trade. Second, based on EU's experience I explore the challenges that countries are faced with when applying these tools. My goal here is to make some assessments on the prospects and difficulties in achieving trade facilitation through these means.

This report is based on documents, reports, academic literature and a number of interviews with officials from the European Commission's DG SANCO[3], DG Trade, DG Agriculture and DG Enterprise; officials from the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA); officials

[1] The terms "equivalence" and "equivalency" are used interchangeably throughout the report.

[2] For reasons of simplicity I use the acronym EU (and not EEC: European Economic Community or EC: European Community) throughout the report.

[3] DG SANCO is the acronym for the Directorate General for Health and Consumer Affairs.

from delegations to the Codex Alimentarius Commission, and former officials of the Secretariat of Codex.

1.2 Equivalence and mutual recognition as trade facilitating tools

Mutual recognition and equivalence can be used as tools to remove technical trade barriers caused by differences between regulatory systems.[4] These tools can thus function as both alternatives and supplements to harmonization. "Harmonization" means that two or more rules are replaced by one common rule, whereas "determination of equivalence" means that the involved parties accept that rules are different as long as it is possible to determine that the rules fulfil some commonly stated objective in a satisfactory way. Thus, the concept of equivalence refers to the "likeness" (not "sameness") of different rules with regard to some pre-determined parameter. Outside the EU, the principle of mutual recognition is most often applied through so-called Mutual Recognition Agreements (MRAs). These agreements allow two or more trading partners to accept that a commodity can be traded freely between/among them even though differences in their regulatory systems continue to exist. Normally, MRAs are designed to let trading partners accept each other's conformity assessment systems in order to avoid that traded products will be subject to unnecessary and overlapping testing (by conformity assessment bodies in both the exporting and importing country). In the EU, the application of the mutual recognition principle guarantees free movement of certain goods and services without the need to harmonise Member States' national legislation. Thus, goods which are lawfully produced in one Member State cannot be banned from sale in the territory of another Member State, even if they are produced to technical or quality specifications which are different from those applied to the importing state's own products.

1.3 The EU Model: applying the concepts

The theme of this report is what I have chosen to call the EU "model" of applying equivalence and mutual recognition as trade facilitating tools. The EU is a well-advanced regional economic co-operation entity, and the member countries have throughout EU's history faced challenges in achieving two goals: removing trade barriers between themselves and promoting common trade policies towards third countries.

One important means of achieving these goals has been to elaborate one common set of rules, i.e. to harmonize national rules. Another important means has been to remove regulatory trade barriers through the principle of "mutual recognition", which was introduced in the EU in the 1970's. In the EU context,

[4] See Veggeland and Elvestad (2004) for a more comprehensive explanation of mutual recognition and equivalence.

this principle ultimately implies that any national regulation with reasonable policy goals, such as environmental conservation, health, safety and so on, will be tolerated within the Single European Market. The principle of "mutual recognition" has together with the principle of equivalence also been applied in the EU's work on reducing regulatory trade barriers in its third-country relations.

Thus, the EU stands out as both an important testing ground for achieving free trade internally between different countries, *inter alia*, through mutual recognition, and as one of the pioneers of trying out mutual recognition and equivalence as a supplement to harmonization and/or unilateral conformity in its third-country trade relations.

1.4 The structure of the report

The remainder of this report is structured as follows: Chapter 2 includes an account of different regulatory approaches that the EU has followed in its attempts at realising the internal market, from the adoption of common rules to mutual recognition and the Lisbon strategy. Chapter 3 discusses EU's trade with third countries. I provide an overview of EU's rules for third-country trade relations and of EU's mutual recognition agreements. Furthermore, I present examples of how the EU has applied equivalence and mutual recognition in its third-country relations within specific policy sectors. In Chapter 4 I present the EU's work and positions on equivalence and mutual recognition in the WTO and the Codex Alimentarius Commission. In Chapter 5 I make an assessment of the EU's experience with mutual recognition and equivalence. Finally, I present some conclusions and final remarks in Chapter 6.

2 Realisation of the internal market

2.1 Background: harmonization of rules within the EU

In the period between the Treaty of Rome, which entered into force in 1958, and the Single European Market initiative, which was launched in 1985, the European Commission sought to address numerous obstacles to trade through an ambitious programme of regulatory harmonization (Egan 2001: 61). The Member States' roles in setting their own regulatory standards were thus challenged in a number of different areas covered by the EU aquis.[5] Due to complex and contradictory pressures of domestic interests, and subsequently a widespread opposition to many EU regulations among the Member States, the harmonization programme that was followed in the 1960s and 1970s ran into big difficulties in establishing common regulations and removing trade barriers. Thus, in most sectors, attempted harmonization efforts were commonly perceived to have largely failed.

Attempts at harmonizing food regulations were also perceived to have failed (O'Rourke 1998). The Treaty of Rome did not explicitly mention food regulations. Furthermore, it did not originally mention the goals of consumer protection and public health, which traditionally are the core goals of national food regulations. Thus, based on the Treaty of Rome, food regulations were for many years mainly about removing trade barriers and establishing a functioning common market. This is reflected in the original Article 3 of the Treaty, which says that the EU's activities should include:

[5] EU aquis: EU laws, practices, principles and obligations.

- the elimination, as between Member States, of customs duties and of quantitative restrictions on the import and export of goods, and of all other measures having equivalent effect;
- the establishment of a common customs tariff and of a common commercial policy towards third countries;
- the approximation of the laws of Member States to the extent required for the proper functioning of the common market;

Thus, based on the Treaty, until the amendment to Article 3 via the Single European Act in 1985 and the Maastricht Treaty in 1991, food regulations were part of the wider EU harmonization programme aimed at removing trade barriers and creating a well-functioning market. However, provisions on public health and consumer protection were implemented in the EU by first the Single European Act and then the Maastricht Treaty (cf. in particular Article 95 and Articles 152–153 of the Treaty of Rome), thus laying down the basis for more coherent food policies and regulations at the EU level.

The first EU food directive was concerned with colours in foodstuffs and was adopted by the Council of Ministers in 1962. However, in the following years the adoption of food regulations was a slow, fragmented and piecemeal process, as was the case in many other sectors. Furthermore, the EU did not succeed in creating a genuine European Food Law that put consumer and health interests to the fore. Instead, food regulations were to a large degree based on commercial interests on the one side and on protecting Member States' domestic interests on the other.

Thus, EU's harmonization efforts in the food sector, as well as in most other sectors, ran into difficulties. However, a new momentum was created at the end of the 1970s when a new method of facilitating trade gained importance, namely the principle of mutual recognition. Moreover, the Single European Act and the plans for the realisation of the internal market that followed in the 1980s were to a large degree precisely about removing technical barriers to trade. Such trade barriers had continued, despite the ongoing harmonization efforts, not only in the food sector, but also in most other product sectors.

2.2 Cassis de Dijon and the principle of mutual recognition

As already indicated, harmonization of regulatory measures was for many years the EU's main instrument for removing trade barriers. However, based on the slow and limited progress of harmonization, the European Commission introduced alternative methods of trade facilitation at the end of the 1960s.

In the "General Programme for the removal of technical obstacles to trade", which was adopted by the Council in 1969, the EU proposed different ways to deal with trade barriers, including the new principle of mutual recognition (Egan 2001: 69). Table 2.1 lists the different methods for eliminating trade barriers that were proposed and the conditions assumed to be necessary to carry them out.

Table 2.1 Methods to eliminate barriers to trade[6]

Category	Conditions
Total harmonization	Compliance mandatory Options for local deviations prohibited Counteracts all NTBs[7]
Optional harmonization	Compliance optional in local markets Local differentiation preserved For interstate commerce—mandatory compliance
Mutual recognition	Mutual approval of marketing conditions Need high degree of mutual credibility and trust
Reference to standards	Harmonized standards Used as alternative to regulations

Thus, the methods of both mutual recognition and reference to standards were introduced as alternatives and supplements to harmonization. The category "Reference to standards" indicates that instead of developing detailed regulations, regulators could focus on directives which cover only some core horizontal issues. The technical details could thus be covered by references to harmonized standards, which are developed by international standardization bodies. This is a method which became increasingly important following the later introduction of the "New approach to technical harmonization" (see below).

In addition, with the intention of removing regulatory trade barriers more effectively, the European Commission was given the right to engage in administrative rule-making, including the right to modify and update regulations. The Commission was nevertheless subject to oversight by committees composed of representatives from the Member States.

The new methods for eliminating barriers to trade also provided greater regulatory flexibility in the process. The "General Programme" did not however, advance the process of removing trade barriers much further. First, only a fraction of the technical barriers was included in the programme. Second, the EU ran into the same problem, i.e. slow progress in adopting new rules, which characterized the old harmonization programme, even though new and more flexible methods had been introduced. Third, faced with this slow progress, the EU compromised in allowing Member States to push their particular domestic interests to the front and to place a range of products and production processes on import prohibition lists. These prohibitions were moreover often based on political rather than scientific or technical considerations.

Hence, part of the process became counter-productive by allowing a system where certain Member States prohibited products and production processes at the national level, even though these were acceptable in other Member States. Moreover, the regulatory strategy of harmonization was still the dominant method pursued, and as Michelle Egan (2001: 82) has noted, this method "...proved

[6] Table 2.1 is taken from Egan 2001:70.

[7] NTB = Non-tariff Trade Barriers.

ineffectual because it was viewed as increasingly inappropriate at addressing the widespread effects of non-tariff barriers".

Thus, the EU's failed efforts to remove technical barriers to trade in the 1970s can be characterized by the term "eurosclerosis", a term which, *inter alia*, has been used to describe a European integration process that seemed to loose steam.

However, at the end of the 1970s things began to change. An important turning point regarding the work on removing non-tariff trade barriers, including technical barriers to food trade, was the Cassis de Dijon case. Even though the principle of mutual recognition had been introduced to the EU as early as the late 1960s, it was the rulings in the Cassis de Dijon case that really made the principle an important part of EU's regulatory approach.

The Cassis de Dijon case was about a French liqueur—*Cassis*—which was prohibited for import into Germany on the basis of a German statutory provision fixing a minimum alcoholic content for similar liqueur products produced and marketed in Germany (Egan 2001: 95). The provision stated that to be marketed as wine-spirits these products needed to have a minimum alcohol content of 32 per cent; however, *Cassis* had an alcohol content of only 15–20 per cent.

The case was brought to court and the European Court of Justice ruled that the German provision constituted a measure having an effect equivalent to a quantitative restriction. The Court further argued that "...there is no valid reason why, provided that they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other member state" (Egan 2001: 96). The burden of proof to show non-discrimination thus fell on the *importing* country, i.e. the German government in this case. The Court assumed in the *Cassis* case that national standards in Germany and France were sufficiently equivalent to be mutually recognized as acceptable. The key passage of the judgement is the following (c.f. European Court of Justice 1979):

> In the absence of common rules, obstacles to movement within the community resulting from disparities between the national laws relating to the marketing of a product must be accepted in so far as those provisions may be recognized as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer.

The ruling thus stated the importance of the principle of mutual recognition and simultaneously indicated that harmonization would only be necessary when national regulations were not sufficiently equivalent (Egan 2001: 96).

In a series of cases following the *Cassis* judgement the European Court of Justice has considered the validity of member state laws restricting trade in foodstuffs. The rulings in these cases have followed the *Cassis* judgement by reviewing the purpose, reasonableness, and application of national regulations (Egan 2001: 99).

The *Cassis* judgement has thus paved the way for a regulatory approach in the EU where emphasis is put on harmonizing only those requirements that can be referred to as essential (c.f. health and consumer protection, etc.). Trade barriers caused by other regulatory disparities should to the extent possible be solved by

applying the principle of mutual recognition unless derogation is available under EU law, which, in the case of food products, means on public health grounds. This regulatory approach gained considerable influence in connection with the Single European Market Programme that was launched in the mid 1980s.

2.3 Technical Regulations and the Single European Market Programme

The idea of mutual recognition swiftly became part of European policy-makers new strategy to promote market access and greatly influenced the design of the Single European Market Programme (Egan 2001: 107). The European Commission used the *Cassis* judgement in promoting a doctrine based on the principles of mutual recognition and equivalence of regulations and standards. The Commission argued that member state governments could not take an exclusively national view-point because many national regulations were broadly equivalent (ibid.).

The basic idea of the new doctrine was that importing countries *in principle* should allow imports of all products from other Member States as long as the products had been lawfully produced and conformed to the rules of the exporting country. Importantly this strategy aimed to promote free trade in general and the Single Market Programme in particular and thus to create a new momentum in the European integration process.

The Single European Market Programme involved the adoption of a series of new EU regulations. The programme was launched in 1985 by the Single European Act and gave the Commission a mandate to provide a comprehensive package of proposals to complete the internal market by 1993 (Egan 2001: 113). Non-tariff trade barriers (NTBs) were treated as one of the issues that had to be addressed in order to obtain a well-functioning internal market. NTBs included the specifications of products, the use of different health and safety standards, environmental regulations, and quality control (Egan 2001: 114).

Furthermore, the Single European Market Programme signalled the active use of the principle of mutual recognition. This is clearly illustrated in the following passage taken from the "White Paper on the Completion of the Internal Market" under *Part Two: The Removal of Technical Barriers* (European Commission 1985):

> 57. The elimination of border controls, important as it is, does not of itself create a genuine common market. Goods and people moving within the Community should not find obstacles inside the different Member States as opposed to meeting them at the border.
>
> 58. This does not mean that there should be the same rules everywhere, but that goods as well as citizens and companies should be able to move freely within the Community. Subject to certain important constraints (see paragraph 65 below), *the general principle should be approved that, if a product is lawfully manufactured and marketed in one Member State, there is no reason why it should not be sold freely throughout the Community. Indeed, the objectives of national legislation, such as the protection of human health and life and of the environment, are more often than not identical. It follows that the rules and controls developed to achieve these objectives, although they may take different forms, essentially come down to the same thing, and so should normally be accorded recognition in all Member States, not forgetting the possibi-*

lities of cooperation between national authorities. What is true for goods is also true for services and for people. If a Community citizen or a company meets the requirements for its activity in one Member State, there should be no valid reason why those citizens or companies should not exercise their economic activities also in other parts of the Community. (author's emphasis).

This shows that mutual recognition (and implicit equivalence) was an important part of the work on removing technical trade barriers within the EU with the aim of realising the internal market.

2.4 The New Approach, the Global Approach and the Food Sector

The New Approach to technical harmonisation and standardisation was laid down in connection with the Single European Market Programme and established the following principles (European Commission 2000a: 7):

- Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.
- The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards.
- Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.
- Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements.

The New Approach calls for only essential requirements to be harmonised and thus requires that it be possible to distinguish between such essential requirements and technical specifications. Implicit in this approach therefore is the concept of equivalence whereby the applied technical specifications are allowed to differ as long as the essential requirements are met.

In addition to the principles of the New Approach, the Commission saw the need for laying down the conditions for reliable conformity assessment procedures across national borders (European Commission 2000a: 8). Important in this respect were the building of confidence through competence and transparency, and the setting up of a policy and framework for conformity assessment. Thus, in 1989 the EU adopted the Global Approach to certification and testing, which included the following principles for EU's policy on conformity assessment (ibid.):

- A consistent approach is developed in Community legislation by devising modules for the various phases of conformity assessment procedures, and by

laying down criteria for the use of these procedures, for the designation of bodies operating these procedures, and for the use of the CE marking.

- The use of European standards relating to quality assurance (EN ISO 9000 series), and to the requirements to be fulfilled by conformity assessment bodies operating quality assurance (EN 45000 series) is generalised.
- Setting up of accreditation systems and the use of inter-comparison techniques are promoted in Member States and at Community level.
- Mutual recognition agreements concerning testing and certification in the non-regulatory sphere are promoted.
- The differences of existing quality infra-structures (such as calibration and metrology systems, testing laboratories, certification and inspection bodies, and accreditation bodies) between Member States and between industrial sectors are minimised by programmes.
- International trade between the Community and third countries is promoted by means of mutual recognition agreements, cooperation and technical assistance programmes.

The Global Approach was completed by a Council decision in 1993, which included general guidelines and detailed procedures for conformity assessment used in New Approach directives. According to this decision conformity assessment is based on (ibid.):

- manufacturers' internal design and production control activities;
- third-party type examination combined with manufacturers' internal production control activities;
- third-party type or design examination combined with third-party approval of product or production quality assurance systems, or third-party product verification;
- third-party unit verification of design and production; or
- third-party approval of full quality assurance systems.

It is important to note that the New Approach *has not* been applied in sectors where EU's legislation was well advanced prior to 1985, including, *inter alia*, the foodstuffs and veterinary sectors. In these sectors the "old approach" of developing detailed, mandatory regulations has prevailed. Thus, the legislation in these sectors has not been based on the principles of the New Approach. Nevertheless, the development of EU's food law has some resemblances to the New Approach.

First, over time, the EU has concentrated its food legislation work on developing horizontal rules. These horizontal rules are based on requirements and objectives that are relevant across different product groups, i.e. based on the essential requirements and objectives of consumer and health protection. Thus, the work on vertical rules, dealing with product specific requirements based on political and commercial considerations, has been downgraded.

Second, many of EU's food regulations refer to international food standards, which specify the details that enable EU members to fulfil their obligations under EU law. Codex Alimentarius Commission standards are particularly important. An example of this is paragraph 4 in Commission Directive 2004/45/EC of 16 April 2004. This Directive is an amendment to Directive 96/77/EC, which lays down specific purity criteria on food additives other than colours and sweeteners:

> (4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Third, mutual recognition is widely applied in non-harmonized areas of the food sector, as is the case for the New Approach.

Thus, even though the New Approach first and foremost is relevant for the sectors that were only slightly harmonized prior to 1985, it may nevertheless be seen as a broader approach to regulatory work, and one that is also relevant for other sectors in the EU where the "Old Approach" (regulative harmonization) still dominates, such as the food and veterinary sectors.

2.5 The soft approach to better regulation: the Lisbon strategy

EU's Lisbon Strategy was launched in 2000 when the European Council agreed to the goal of making the EU "the most competitive and dynamic knowledge-driven economy by 2010" (European Council 2000). The Lisbon Summit called for a new method of "open coordination", which was an approach that would serve as an alternative to traditional forms of EU policy formulation by involving, *inter alia*, active use of target setting and benchmarking.

In the renewed Lisbon Strategy—"Partnership for Growth and Jobs"—which was launched in the spring of 2005, a broad programme called "Better Regulation" was the centrepiece of the European Commission's agenda (European Commission 2005).[8] The objective was to make sure that regulations be used only when necessary and that the burdens they impose be proportionate with the aims. The Commission highlighted three tools and processes that would be utilized to achieve this objective:

- Withdraw or modify pending legislative proposals
- Simplify existing legislation
- Use impact assessment and public consultation to ensure better quality in the development of new policy proposals

So far the "Better Regulation" programme has resulted in a large number of proposals for EU laws being withdrawn and an initiative being taken to perform a

[8] See also homepage of DG Enterprise: http://europa.eu.int/comm/enterprise/regulation/better_regulation/

broad consultation with Members States and stakeholders on regulatory quality. Furthermore, a process of simplifying existing legislation has been initiated, starting with the most regulated sectors, such as cars, industrial waste and construction, followed by sectors such as pharmaceuticals, cosmetics and foodstuffs.

The "Better Regulation" programme involves close co-operation between the European Commission, the Member States and other relevant stakeholders and consists of a wide range of approaches to improve the regulatory quality and performance in Europe. One of the new elements that the "Better Regulation" programme emphasizes is a more flexible and open approach to regulatory co-ordination. The exchange of best practises and peer reviews, the search for good indicators to assess regulatory quality (c.f. benchmarking), and the active use of consultations and constructive dialogue with all stakeholders in order to decide on the proportionality of regulations, are some of the "softer" means that the EU will encourage in order to create a better regulatory culture and climate in Europe.

The renewed Lisbon strategy thus introduces a supplement to the "Old" and "New" approaches by, *inter alia*, seeking to change the regulatory environment through "softer approaches".

2.6 Summing up the EU model for realising an internal market through trade facilitating tools

The EU model of realising an internal market is characterized by comprehensive efforts to harmonize national regulations and standards while limiting to the extent possible the harmonization efforts to essential requirements and horizontal rules (such as hygiene rules). These efforts are combined with an active use of the principle of mutual recognition which allows national regulations and standards to differ as long as they fulfil the same core objectives. Inside the internal market the application of the principle of mutual recognition is thus first and foremost relevant in areas which have not been harmonised.

Furthermore, the EU has moved to become more flexible in its approach towards regulative co-operation and harmonization, c.f. the open method of co-ordination, benchmarking and voluntary co-operation and communication programmes, which are all inherent parts of the Lisbon strategy. The EU has thus established a set of complementary regulatory approaches to create a better regulatory environment and a well-functioning internal market. However, it is important to note that even though new regulatory approaches have been introduced, technical harmonisation through the development of mandatory regulations is still a core activity of the EU.

3 EU's trade with third countries

3.1 Introduction

One important aspect of the European integration process is the development of common trade policies towards third countries (Meunier 2005). These policies also include different tools to reduce the problem of trade barriers caused by the Member States' different technical regulations, standards and conformity assessment procedures. Thus, the EU has included in its policies on third-country trade relations the application of equivalence assessments and mutual recognition as tools to reduce the problem of regulatory trade barriers.

3.2 "A toolbox of instruments": EU approaches to third-country trade relations in the regulatory field

The main legal basis for EU's common commercial policy is Article 133 of the EC Treaty. Articles 25–27 lay down the provisions for a customs union and Articles 28–31 of the Treaty set out the provisions on the prohibitions against quantitative restrictions. In line with these provisions, the EU has adopted common rules and procedures for exports from and imports into the internal market. Furthermore, the European Commission has been given the task of negotiating trade agreements on behalf of the EU (Meunier 2005). This task is, however, based on a mandate decided by the Council.

EU's common trade rules also include procedures for administering and implementing trade arrangements, and procedures for information and consultation which are to be followed before implementing protective and punitive trade

measures. Furthermore, the EU has a common external trade policy in the fields of standards and conformity assessment (European Commission 1996, 2000b, 2001a, 2003). The EU's objectives for external trade policy in the regulatory field can be summarised simply in two categories (WTO 2002b:4):

- The first category includes the promotion of EU's commercial and export interests, namely the reduction of technical barriers in external markets and the prevention of the emergence of new ones.
- The second category includes the promotion of EU's policies and concepts as accepted by its constituents, namely the encouraging of trading partners to adopt standards and regulatory approaches based on, or compatible with international and European practises.

As will be illustrated in the next chapter, the separation of these two categories of objectives has also had an impact on how the EU organizes its external representtation in the area of regulatory policies.

The European Commission issued in 2001 a Commission Staff Working Paper in which it presented a broad variety of measures that, based on its experience, it viewed as useful in accomplishing trade facilitation (European Commission 2001a). The Commission foresees that in a fully-developed common market any product lawfully placed on the market in one territory would be equally freely marketed in the other territories. Of course, the EU itself has come a long way in achieving this through its internal market.

However, there is no global parallel to EU's strong institutional framework which can be used to support the development and maintenance of a fully-fledged global common market. Thus, a less ambitious agenda should be set. Accordingly, the Commission refers to a series of important conditions/issues for facilitating global trade. The Commission furthermore links these conditions/issues to relevant trade facilitating tools that can be used to address them. This linkage is presented in an indicative list which however, is not exhaustive and which furthermore contains elements that are not mutually exclusive (European Commission 2001a: 9) (see Table 3.1)[9]:

[9] See also Veggeland and Elvestad (2004: 25) where the same table is presented and commented upon in connection with a description of the work of the WTO TBT Committee on the issue of mutual recognition.

Table 3.1 The European Commission's list of tools for addressing regulatory issues

No.	Issues	Some tools for addressing them
1.	Compatibility of approach	Regulatory co-operation
2.	Coherence of regulation	Harmonisation
3.	Coherence of standards	Recognition of equivalence
4.	Transparency and impartiality of regulation and standards	Mutual Recognition Agreements
5.	Appropriate level of regulation	Partial, voluntary, reduced or less formal types of mutual recognition
6.	Transparency and impartiality in obtaining certification	International standardisation
7.	Recognition of certificates	Technical assistance
8.	Compatibility of market surveillance	Regulatory co-operation
9.	Development of infrastructure	Harmonisation

The European Commission concludes that the selection of the right tool depends on several different factors, including the characteristics of the markets, the regulatory environment in the third country or region concerned, and the willingness of the involved industries, regulators and other parties to achieve the agreed objectives (European Commission 2001a: 22).

Only two of the tools mentioned by the European Commission will be discussed further in this report, namely, mutual recognition agreements and recognition of equivalence. The reason for drawing attention to only these two tools is that they have been placed high on the agenda of several international fora in recent years, e.g. the WTO and the Codex Alimentarius Commission.

3.2.1 EU's approach to Mutual Recognition Agreements

The EU has been in the forefront internationally with regard to negotiating so-called Mutual Recognition Agreements (MRAs). These agreements lay down the conditions under which the EU and the third country concerned would accept conformity assessment procedures as being in conformity with the legislation of the other party to the agreement. Conformity assessment procedures include test reports, certificates and marks of conformity issued by conformity assessment bodies (CABs) in the countries involved. MRAs are thus first and foremost "...instruments that facilitate market access by reducing costs and time associated with obtaining product approvals" (DG Trade 2006).

In general, MRAs do not imply regulatory convergence nor do they imply that regulations imposed on products by the Parties are to be brought into alignment. However, there are some exceptions to this. One example is the EU's MRA with Switzerland which deals with mutual recognition of certification in areas where the EU and Switzerland have the same regulations. Another example is the EU-U.S. MRA on marine equipment, which has as a precondition that both Parties use internationally agreed conventions as the underlying regulations that are subject to mandatory certification.

To this date the EU has negotiated seven so-called "traditional" MRAs, which are those agreements that provide for the recognition between trading partners of test results and mandatory certificates for certain industrial products.[10] These "traditional" agreements furthermore cover only products that are subject to mandatory certification.

- Australia (OJEC L 229 of 17/08/98)
- New Zealand (OJEC L 229 of 17/08/98)
- Canada (OJEC L 280 of 16/10/98)
- United States (OJEC L 31 of 4/02/99)
- Israel (OJEC L 263 of 9/10/99)
- Japan (OJEC L 284 of 29/10/2001)
- Switzerland (OJEC L 114 of 30/04/2002)

In addition to these agreements, the EU has negotiated yet another MRA with the U.S. on Mutual Recognition of Certificates of Conformity for Marine Equipment, which was adopted by the Council in 2004. It is important to note that the EU has chosen to establish MRAs only with governments of third countries which are on *a comparable level of technical development as the EU* and moreover have a comparable approach concerning conformity assessment (European Commission 2000: 63). In principle, these agreements are supposed to include all the conformity assessment requirements of the parties necessary to obtain full market access. Moreover, the agreements function in such a way that the traded products are evaluated in the country of production against the regulatory requirements of the importing country (ibid.).

The MRAs comprise framework agreements, which lay down the essential principles, and sectoral annexes, which specify the details, such as scope and coverage, regulatory requirements, lists of designated conformity assessment bodies etc. As already noted, EU's MRAs are confined to conformity assessment procedures and are thus not based on the necessity that the parties accept each others' technical regulations and standards, or that they consider as equivalent each other's legislation in the fields concerned.

Nevertheless, MRAs presuppose the existence of a comparable level regarding the protection of health, safety, environment or other public interests (c.f. essential requirements). Furthermore, MRAs may pave the way for a more harmonized system of standardization and certifications and more regulatory coherence and transparency between the involved parties.

The main objectives of MRAs are to remove trade barriers caused by duplicate testing, certification etc. and thus to improve market access and increase trade. EU's experience shows however, that MRAs can be costly and difficult to maintain and that improvements in market access are not guaranteed. I will come back to this experience later.

[10] See homepage of DG Enterprise and Industry (http://www.eu.int/comm/enterprise/international) and DG Trade 2006.

3.2.2 Facilitating new EU memberships: PECAs

In addition to negotiating MRAs with third countries, the EU has also used mutual recognition of conformity assessment as a tool in and important step of the accession process of new EU members. These agreements are called "Protocols on European Conformity Assessment" (PECAs) and are related to the implementation of EU's technical regulations in candidate countries (European Commission 1998). PECAs are quite similar to MRAs. However, there are some important differences. The most obvious difference is of course that candidate countries eventually will become EU members and thus that they will be bound to implement all relevant EU legislation concerning conformity assessment as well as product regulations and standards.

Thus, under a PECA the Conformity Assessment Bodies (CABs) will necessarily check compliance with EU rules, and these rules will eventually become the legislation of the candidate country. Under an MRA CABs will check whether the exported products comply with the importing country's requirements. However, in contrast to PECAs there is no prerequisite that these requirements become part of the exporting country's legislation.

The practical result of both MRAs and PECAs is that the Designating Authorities of the contracting Parties must ensure that suitable CABs can operate in accordance with the criteria and procedures of the other Party's regulations as specified in the text of the Agreement. However, as already indicated, in the case of PECAs the criteria used will also be identical to the EU directives, which furthermore are supposed to be implemented in the corresponding candidate countries' legislation. PECAs are thus transitional arrangements, where the aim is to accommodate and incorporate the conformity assessment systems of new members into EU's common regulatory framework.

3.2.3 EU's approach to equivalence assessments

Equivalence is one of the trade facilitating tools applied by the EU in its third-country relations. However, as noted by the European Commission, although a powerful tool, this mechanism can be technically complex in practise, which explains why it is relatively little used (European Commission 2001a: 12). Equivalence assessments mean that the objective of a regulation must be set out. Then agreement must be reached on the equivalence of two or more regulations/conformity assessment procedures, i.e. agreement that they be able to accomplish the same objective. Finally an agreement must be reached about their mutual acceptability. This process must be very detailed, i.e. it must be carried out on a sector-by-sector and case-by-case basis. Furthermore, the need for substantial revision or updating means that a new determination of recognition and equivalence is necessary. For these reasons, the European Commission realizes that the principle of equivalence cannot be considered generally applicable.

Thus, in practise there is not *one* EU approach to equivalence, but many approaches depending on the sectors and products involved. Furthermore, equivalence assessments have been more widely used in the area of sanitary and phyto-

sanitary measures (SPS measures), where health protection normally is the core objective, than in the area of technical regulations and standards (TBT measures), where a whole range of objectives are involved.

Thus, in the SPS area it is easier to identify a parameter against which different regulations can be assessed. But even in this area, it has proven hard to reach agreement on equivalency, and to maintain such agreement over time. Nevertheless, the EU has some experience both in determining equivalence for specific product groups, such as in the organic food area, and in reaching more comprehensive equivalence agreements, such as in the veterinary area. To date, the EU has in place veterinary equivalency agreements (VEAs) with the U.S. (1999), Canada (1998), New Zealand (1996) and Chile (2002). Furthermore, negotiations are ongoing with Australia and Mercosur (Argentina, Brazil, Paraguay and Uruguay).

In the following sections, I present some examples of EU's application of both equivalence and mutual recognition.

3.3 Examples of the EU's application of equivalence and mutual recognition

3.3.1 Trade in organic food

Organic farming represented only around 3 percent of the total EU utilised agricultural area in 2000, but has nevertheless developed into one of the most dynamic agricultural sectors in the EU.[11] The organic farm sector grew by about 25 percent a year between 1993 and 1998 and is estimated to have grown by around 30 percent a year since 1998. As a result of increased consumer awareness of and demand for organically grown products tens of thousands of farms have been converted to this system. Furthermore, the demand for organic products has also led to increased imports, both directly for consumption and as inputs for EU's organic food processing industry. A significant proportion of the increased imports come from developing countries.

The EU rules on organic farming came into force in 1992 and contain, *inter alia*, provisions governing trade in organic products with third countries. The EU rules furthermore include provisions on the application of equivalence assessments as tools to facilitate trade in organic products. For the time being, these rules are mainly relevant for *imports* into the EU.

Article 11 of Council Regulation (EEC) No 2092/91 provides an equivalency regime for organic products imported from third countries (European Commission 2004: 28). This provision states that it must be demonstrated that imported organic products are produced and inspected in accordance with prevailing standards and are subject to inspection arrangements that are *equivalent* to those which are applied

[11] See homepage of DG Agriculture: http://europa.eu.int/comm/agriculture/qual/organic/

to organic production in the EU. The equivalency regime covers thus both product and production requirements and conformity assessment procedures.

The EU had in operation until 2006 two different systems for imports of organic products concerning assessment and determination of equivalency (ibid.):

- **First,** Article 11(1) states that for imported organic products to be marketed as organic in the EU they must originate from a third country that appears on a list drawn up by the European Commission. Until 2003 this list included eight third countries and nine more applications were then assessed.[12]
- **Second,** Article 11(6) states that Member States can on a case-by-case basis and upon the request of an importer authorise the marketing in the EU of a consignment of imported products as organic. This second system was derogated from the first system and was supposed to be in operation until 31 December 2005. The majority of the imports of organic products, originating in 92 countries, passed through this second system. The number of import authorisations under the system rose from 599 in 1998 to 1248 in 2002.

In December 2005 the European Commission presented a proposal for a new Council Regulation on organic production and labelling of organic products. This regulation will amend Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

The proposal recommends that the second system of the equivalency regime will cease to exist. If the new regulation is adopted, the equivalent guarantees will be provided by third-country authorities or certified EU-approved control bodies only. Thus, EU Member States will have their authority reduced regarding determining whether imported products can be marketed as organic. The first system involving a 'community list of third countries' will however be maintained.

The proposed new regulation further states that equivalency assessments can be based on either relevant international standards (Codex Alimentarius standards) or on the Community regulations. It is thus clearly stated that imported products can be marketed as organic in the EU, even though they have been produced according to requirements that differ from EU legislation. However, the products must have been produced, controlled and inspected under conditions that are sufficiently equivalent to the corresponding requirements stated in either EU rules or the Codex standards.

[12] The eight countries that appeared on the list were Argentina, Australia, Costa Rica, Czech Republic, Hungary, Israel, New Zealand and Switzerland. Since then, the Czech Republic and Hungary have become EU members and are thus no longer considered as third countries. The nine applications that were assessed were from Chile, Colombia, Dominican Republic, Guatemala, India, Japan, Tunisia, Turkey and the United States of America.

3.3.2 The Veterinary Equivalency Agreement between the EU and the U.S.

After six years of negotiations, the EU and the U.S. finally signed the Veterinary Equivalency Agreement (VEA) on July 20, 1999. The framework and wording of this agreement are quite similar to those found in EU's agreements with New Zealand and Canada (USDA Foreign Agricultural Service 2005).The equivalency agreement between the EU and Chile is, however, somewhat different; thus, I will first briefly comment upon some of the specificities of that agreement.

Contrary to EU's other equivalency agreements, the EU-Chile VEA is not an independent document but is set out in an annex of a more comprehensive Association Agreement between the two parties (ibid). The EU-Chile VEA also includes some elements that are not found in the other VEAs, such as animal welfare standards. The agreement is explicitly linked to the WTO's SPS Agreement and thus specifies in a more formal way than the other agreements the deference to the provisions of that agreement. Furthermore, it does not, whereas the other agreements do, contain a comprehensive list of individual products and equivalency ratings attributed to each product (ibid.). Rather the EU-Chile VEA only includes guidance for the *process* of determining equivalency. Thus, the other VEAs are more detailed with regard to identifying specific products traded between the contracting parties and the status of equivalency ratings for those products.

The VEA between the EU and the U.S. is a particularly important agreement for the facilitation of international trade, especially because of the extensive trade volume that exists between the two parties. The EU and the U.S. are the leading participants in international trade, accounting between them for about 37% of world merchandise trade and 45% of world trade in services (European Commission 2001b: Chapter 1, A5).

The VEA covers two-way trade in various animal products, including fishery products, valued at about $3 billion annually (Becker 1999). It includes a list of all the individual products that are covered by the agreement, and each of the products is assigned a level of equivalency for the respective requirements attached to it. The rankings are listed in Table 3.2 below (USDA Foreign Agricultural Service 2005: 5):

Table 3.2 Equivalency Rankings under the EU-U.S. VEA

Ranking categories	Implications for trade
Yes (1)	The importing Party agrees that the exporting Party's measures achieve the importing Party's appropriate level of sanitary protection.
Yes (2)	The importing Party agrees that the exporting Party's measures, with the special conditions set out, achieve the importing Party's appropriate level of sanitary protection.
Yes (3):	Equivalency agreed in principle, subject to satisfactory completion of the actions. Pending completions, trade shall occur on the basis of the special conditions set out.
NE:	Not evaluated (NE). Trade shall occur on the basis of compliance with the importing Party's requirements.
E	Still evaluating. Trade shall occur on the basis of compliance with the importing Party's requirements.

Yes 1 is the highest degree of equivalency that can be achieved under the agreement and implies that trade can occur without impediments caused by the requirements evaluated (c.f. full equivalency). The other two rankings involving agreed equivalence (Yes 2 and Yes 3) set out special conditions for trade to occur. Table 3.3 lists the occurrence of different types of equivalency rankings under the veterinary agreement (USDA Foreign Agricultural Service 2005: 5).

Table 3.3 Equivalency rankings for traded products under the EU-U.S. VEA

	Yes 1	Yes 2	Yes 3	E	NE	Total
EU exports to the U.S.	30	36	11	17	32	126
U.S. exports to the EU	4	8	10	21	82	125

The total of rankings for the EU is not the same as that for the U.S. given the unique breakdown of commodities (i.e. classification of products) by the two parties. Table 3.3 shows that the EU has achieved considerably more of the two highest equivalency rankings (Yes 1 and Yes 2) than the U.S. However, one has to be cautious in putting too much weight on this finding. Information about the relative trade significance of each product is needed in order to make a more comprehensive evaluation. The number of equivalency rankings does not say anything about the value or quantity of trade in these products. Furthermore, because of the structure of the agreement it is difficult to estimate accurately the trade implications of the agreement's equivalency rankings.

USDA's Foreign Agricultural Service has nevertheless made some attempts at determining the trade impact of the EU-U.S. VEA (USDA Foreign Agricultural Service 2005). It has compared data on trade in all the products covered by the VEA from the year the agreement went into effect (1999) against data on trade in all such products for every year up to and including 2004. The data shows that in

the period 1999–2004 the trade of such products from the EU to the U.S. and vice versa *increased in value*:

Table 3.4 Value of trade in all products covered by the VEA between the EU and the U.S.

	U.S. exports to the EU	EU exports to the U.S.		
	1999	2004	1999	2004
Trade value all products	$2,635 billion	$3,039 billion	$2,261 billion	$3,066 billion
Trade value Yes 1 products	$239,251 thousand	$391,144 thousand	$145,028 thousand	$154,892 thousand

Thus, the value of trade in all such products has increased in the period 1999–2004 for both parties to the agreement. The data further indicate a clear increase in the value of trade in the products with the highest equivalency ranking (YES 1 products). Table 3.4 shows a clear increase in U.S. exports to the EU. This is largely caused by increased exports of high value Yes 1 products such as fish.

However, when we look at trade volume measured in *quantities*, the picture changes somewhat. This is partly caused by the fact that fluctuations in exchange rates affect fluctuation in trade value and thus disturb the total picture. As for U.S. exports, quantities increased significantly in only a very few categories, namely live animals, fish, dairy products and bird eggs, products of animal origin NESOI[13], and raw hides and bovine skins. The increase in the value of EU exports to the U.S. is not reflected by a corresponding increase in the quantity of exports. However, there has been an increase even in export quantities in the categories of meat and edible meat offal, food preparations NESOI, and Casein.

Thus, for important YES 1 products such as fish products from the U.S. and meat and edible meat offal products from the EU, the positive effect of the VEA on trade seems to hold, even when exports in such products are measured in quantities.

However, according to officials of both the European Commission and the U.S., handling the veterinary agreement has not been an easy endeavour.[14]

- First, the negotiations were difficult and time-consuming, lasting more than six years.
- Second, the parties did not succeed in including in the agreement one of the most important traded products between the parties, namely poultry. Because of strong disagreement over hygiene requirements for poultry production, trade in this product has been more or less halted until now, despite the fact that the VEA originally was supposed to solve the problem

[13] NESOI = Not Elsewhere Specified Or Indicated

[14] Interviews conducted with officials of the European Commission's DG SANCO and the U.S. Mission to the European Union, Brussels, October 2005.

by including this product category. The dispute was even brought to the WTO and for many years it was subject to consultations between the parties under WTO procedures.

- Third, it is difficult to uphold equivalency determinations over time, due to changes in circumstances and the fact that national requirements continuously are updated.
- Fourth, it has proved difficult to perform new equivalency determinations under the agreement. Determination of equivalency has been performed for only two new product categories since the agreement went into force in 1999.
- Fifth, differences in how the sanitary and phytosanitary area is being organized in the EU and the U.S. have also caused some problems regarding the administration of the equivalency agreement.

In the following sections I will elaborate further on the last point. Both EU and U.S. officials have stressed that it is important with regard to how and whether the equivalency agreement works. How policies are organized and handled nationally may generally have important repercussions for both the negotiation process and the follow-up of equivalency agreements.

In the EU all VEAs are administered by the European Commission's DG SANCO. This is in accordance with the implementation of major reforms in EU's food regulation in recent years whereby responsibilities for food safety policies have ended up as the responsibility of DG SANCO (see also next chapter). Hence, because the primary responsibility for the sanitary and phytosanitary area and VEAs is placed in DG SANCO, the other parties to EU's VEAs (the countries themselves) only have to relate to one single authority regarding follow-up of the agreements (USDA Foreign Agricultural Service 2005: 4).

With regard to *monitoring* the sanitary equivalency of a product traded between the EU and the U.S., there is a delineation of responsibility according to whether the product is being imported or exported (ibid.). The primary responsibilities for EU exports to the U.S. lie with the individual member state involved in the exportation. These responsibilities include the control of production requirements and the issuing of health certificates. EU Member States must either conform to the standards of the importing country, or alternatively base the exports on possibly agreed equivalency determinations with this country.

The Member States have also retained important tasks and responsibilities with regard to imports, but in this area they are primarily charged with complying with EU regulations. The EU has a comprehensive set of harmonized legislation which regulates imports of food and veterinary products from third countries and is enforced through customs and border inspections (ibid; Ugland and Veggeland 2004). Thus, in this area national customs and food inspection authorities act as agents of the European Commission, which is the supreme authority for regulating imports into the Single European Market (Ugland and Veggeland 2006).

The structure of the U.S. regulatory systems stands out in stark contrast to EU's single authority structure (USDA Foreign Agricultural Service 2005: 4). Depending

on the product being traded, responsibilities for domestically produced as well as imported veterinary products, encompass nine agencies:

- U.S. Department of Agriculture (USDA)
- Animal and Plant Health Inspection Service (APHIS)
- Department of Interior (DOI)
- Fish and Wildlife Service (FWS)
- Food and Drug Administration (FDA)
- Food Safety Inspection Service (FSIS)
- Department of Commerce (DOC)
- National Marine Fisheries Service (NMFS)
- Agricultural Marketing Service (AMS).

Thus, there are big differences between the EU and U.S. regulatory systems. EU's system is characterized by a demarcation of responsibilities along the lines of imported vs. exported products as well as by a horizontally integrated food safety system where all the primary responsibility for food imports and for consumer and health protection is placed within a single agency, DG SANCO. Furthermore, in line with this structure there is a clear separation of, on the one side, the quality, technical and commercial aspects of food regulation and, on the other side, the health and consumer protection aspects. The U.S. system is more fragmented and characterized by a number of different agencies with jurisdiction over different products. Thus, demarcation of responsibilities in the U.S. runs along the lines of the products being traded.

This creates a mismatch between the EU and U.S. systems, which sometimes lead to communication problems as well as to problems with maintaining trust and confidence in each other's systems.[15] Furthermore, due to a similar mismatch, similar problems have occurred under yet another important agreement between the EU and the U.S., namely the Mutual Recognition Agreement (MRA) of 1998.

3.3.3 The MRA between the EU and the U.S.

The MRA between the EU and the U.S. was signed in 1998 and that same year a three years transitional phase was inaugurated by an exchange of letters under the agreement (Horton 1998: 723). The agreement was the result of several years of activities involving the European Commission and the relevant U.S. regulatory agencies, in particular the FDA, aimed at establishing mutual recognition of one another's inspections.

At the behest of the European Commission, talks with the relevant U.S. regulatory agencies were initiated as early as 1992 and it was clear early on that mutual recognition could be applied only to product testing (c.f. conformity assessment); it could not be applied to the setting of product standards (Steffenson 2002). The MRA does not, therefore, acknowledge the equivalence of the Parties'

[15] Interviews with EU and U.S. officials.

standards but rather the competence of the Parties to conduct conformity assessment tests (ibid.).

The establishment of the EU-U.S. MRA can be viewed as a policy transfer from the EU to the transatlantic marketplace because the principle of mutual recognition has been most developed and the use of MRAs has been most extensive within the internal market (ibid.) (see also chapter 2 of this report). Furthermore, as already indicated, the talks were *initiated by the EU*.

The MRA negotiations were carried out between the European Commission and the Office of the United States Trade Representative (USTR) and included conformity assessments for drugs and medical devices, telecommunications, electromagnetic compatibility, electrical safety and recreational craft. The basis for the agreement was the slogan and principle "approved once, approved everywhere" (Egan 2001: 185). In order to facilitate the negotiations of the MRA some controversial issues were taken off the table. For instance the negotiations on pharmaceuticals focused mainly on the exchange of inspection reports concerning compliance with Good Manufacturing Practises (GMPs)[16] (Egan 2001: 189).

The assumption is that an MRA may contribute to considerably reducing transaction costs, which, as in the case of VEAs in the veterinary area, is potentially of great benefit to both the EU and the U.S. because of the large volume of trade involved. An MRA including telecommunications and recreational crafts was considered to be particularly advantageous to the U.S. whereas an MRA including pharmaceuticals was considered to be particularly advantageous to the EU.

The negotiated MRA can thus be viewed as a "balanced package" comprising several sectoral annexes and taking both Parties' interests into consideration. It is furthermore important to note that the agreement was facilitated by the fact that the EU and the U.S. already had harmonized parts of their requirements in advance, for instance some of the GMPs for pharmaceuticals (Horton 1998: 723). Nevertheless, it was realized that considerable confidence-building work and harmonization was needed in order for the follow-up of the agreement to be effective.

The EU-U.S. MRA consists of an umbrella/framework agreement and six individual annexes (see table 3.5).

[16] Good Manufacturing Practise: 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 ineffective or even dangerous.

Table 3.5 The MRA between the EU and the U.S.[17]

	The MRA Framework Agreement: operational since 1998					
Annexes	Telecommunications	Medical devices	Electromagnetic compatibility	Electrical safety	Recreational craft	Pharmaceuticals
Operational since:	2000	Not in operation	2000	1998	2000	2001
No. of CABs designated:	11 EU CABs 16 US CABs	0	54 EU CABs 29 US CABs	EU obligations suspended	1 US CAB	Not applicable

As illustrated by Table 3.5, only three of the sectoral annexes are really in operation. There is significant trade under the Annex on telecommunications and the Annex on electromagnetic compatibility, which are both in full operation and under which a considerable number of CABs have been designated (DG Trade 2006). However, the EU adopted in 2004 new rules in the field of electromagnetic compatibility that imposes no third-party certification obligations on manufacturers. This means that the Annex will be needed only for the EU's access to the U.S. market and not vice versa.

The Annex on recreational craft is in operation with one designated CAB, but new EU rules also in this area mean that either the Annex has to be either revised or it has to be dropped altogether.

The operation of the Annex on pharmaceutical GMPs awaits the FDA's presentation of an implementation plan.

The EU's obligations under the Annex on electrical safety remain suspended due to the position of the U.S. Occupational Safety & Health Administration (OSHA).

The Annex on medical devices has not become operational yet due to problems with regard to the acceptance of CABs, which can subsequently be listed under the MRA.

The EU-U.S. MRA thus illustrates both some of the problems and some of the benefits with regard to applying and maintaining MRAs as trade facilitating tools.

Mutual recognition is a concept which has been particularly well developed within the EU and which furthermore has been successfully transferred to both EU's own third-country relations and even to other bilateral and multilateral trade relations. This transfer of ideas from the EU is clearly evident in the EU-U.S. MRA, which was negotiated on the EU's initiative.

The EU experience furthermore shows that comprehensive MRAs are often difficult to negotiate and that they moreover presuppose from the outset some compatibility between the Parties' regulatory systems. Thus, MRAs seem to be most relevant as a trade facilitating tools when applied between Parties with relatively well developed bureaucratic infrastructures and regulatory systems. Nevertheless, the operation of the EU-U.S. MRA shows that even in such cases many problems will arise.

[17] See DG Trade 2006.

The experience with the EU-U.S. MRA also shows that asymmetries between regulatory systems—even between well-developed ones such as the EU and U.S. systems—represent big challenges with regard to creating sufficient trust and confidence in Parties' different approaches to regulation and in Parties' abilities to perform satisfactorily inspections and controls.

The regulatory systems of the EU and the U.S. show asymmetries in that responsibilities and authority are differently located and distributed between governmental and private agencies. Furthermore, in the U.S. the large number of involved agencies—all with superior authority in their respective area of competence and all with their own regulatory cultures and ways of seeing and doing things—creates a fragmented system which makes it difficult to uniformly implement regulatory changes. The U.S. regulatory agencies furthermore have a tradition of carrying out their tasks relatively independently of ministerial control, which may cause problems for the designation of CABs and for the acceptance of other Parties' methods of product approvals.

The EU regulatory system is less fragmented and thus characterized by a more active and consistent hierarchical control. However, the multilevel decision-making process of the EU and the need for approval of the Council in a large number of decisions imply a lack of flexibility and time-consuming amendments to agreements with third countries.

Thus, differences in the characteristics of these two regulatory systems create anomalies that complicate negotiations, amendments and maintenance of the MRAs.

As already indicated, the operation of MRAs is furthermore complicated by the fact that changes in the relevant legislation of one of the Parties may require amendments to and revisions of the MRA itself. Thus, MRAs need to be continuously updated through new negotiations and discussions, which may prove difficult and time-consuming and may even lead to a situation where parts of the agreement are suspended or dropped altogether, as has occurred in the EU-U.S. MRA.

Thus, even though the EU and the U.S. spent significant time and resources in preparations, and eventually succeeded in negotiating a framework MRA, its operation in specific sectors, i.e. the sectoral annexes, has proven very difficult, *inter alia*, because of the factors mentioned above.

Partly because of such problems, the European Commission has stated that it does not foresee further negotiations on "traditional" MRAs, even though there is a certain amount of evolution in existing MRAs, *inter alia*, through amendments (DG Trade 2006).

Instead the European Commission aims at establishing less ambitious and less comprehensive regulatory agreements. It furthermore wants to explore some of the softer approaches to better regulation, i.e. by being more active in entering into regulatory dialogue and formal and informal regulatory cooperation with third countries.

3.4 Summing up EU's model for third-country trade relations

The EU has a number of trade facilitating tools that are being used in its third-country trade relations. An important characteristic of EU's "model" of trade facilitation is the extensive use of the principles (tools) of equivalency and mutual recognition. The EU has been a pioneer in applying these tools to external trade and has furthermore been active in transferring them to a global setting. Thus, the EU has negotiated a number of equivalency agreements and MRAs with third countries and has therefore been one of the key initiators and contributors to the work on equivalency and mutual recognition in international bodies such as the WTO and the Codex Alimentarius Commission. Furthermore, the EU model and the EU experience with applying this model have been important in setting the global agenda and moving it forward in international negotiations and discussions.

It is important to note however that requirements for compliance with EU rules still dominate EU's third-country trade relations, particularly those regarding trade in food and veterinary products.

4 The EU's work on equivalence and mutual recognition in the WTO and the Codex Alimentarius Commission

4.1 Introduction

As illustrated in Chapter 3, the EU has been active in promoting and transferring the principles of equivalence and mutual recognition in both bilateral and global settings through negotiations on bilateral trade agreements in particular. Furthermore, the EU has also pursued these issues in relevant international fora such as the WTO and the Codex Alimentarius Commission. In this chapter, I will explore further the role EU has played in these two international bodies regarding the understanding and application of the principles of equivalency and mutual recognition. First however, I will describe how the EU organizes its representation of common positions in international bodies in order to demonstrate the EU's capacity for transferring its "trade facilitation model". I particularly focus on food policies, an area where the international discussions on trade facilitation and equivalence in particular, have been extensive.

4.2 Organizing the EU's external representation

Since its very beginning, the European Economic Community (EEC) has been a single actor in trade policy (Meunier 2005: 5). Thus, the EEC, later the EC

(European Community),[18] was a full member of the GATT and is presently a full member of its successor, the WTO.[19] This implies that the EU representatives, normally the European Commission, speak on behalf of all the Member States in this forum. The EU Member States are also members of the WTO and are represented in WTO meetings, but they are not allowed to speak on those matters that are within the competence of the EU institutions.

The WTO's SPS Agreement and TBT Agreements both entered into force in 1995. The SPS Agreement covers measures aimed at protecting public health through food safety, and measures aimed at protecting animal and plant life, and health. The TBT Agreement covers technical regulations, standards and conformity assessment procedures. Both agreements are relevant for the food sector. The SPS Agreement is relevant for food safety measures particularly, such as rules for food additives. The TBT Agreement is relevant for all product groups, including food. Examples of TBT-related food regulations and standards are rules for labelling, packaging, and organic food production.

Both agreements state that WTO members can fulfil their obligations by basing national rules on recognized international standards. The SPS Agreement explicitly refers to three international standardization bodies: Codex Alimentarius Commission for food safety standards, OIE (World Organization for Animal Health) for animal health standards and IPPC (International Plant Protection Convention) for plant health standards. The TBT Agreement refers more generally to relevant international standards.

Thus, due to both agreements the work in international standardization bodies has achieved higher status and attracted more attention from all WTO members, particularly because of the possible consequences of ending up in WTO disputes if trade-restrictive national food regulations disagree with recognized international standards (Veggeland and Borgen 2005). Thus, regarding food policies, coordinating the activities taking place in meetings of the SPS and TBT Committees, and in international standardization bodies, has become more important. Below, I will focus on the EU's representation on the SPS Committee and in Codex, because these fora are of particular relevance for the food sector.

When the SPS Agreement came into effect in 1995, the European Commission's DG Agriculture was initially responsible for the SPS area and thus headed the EU delegation to SPS meetings and acted as "enquiry point" under the agreement. Thus, for some years the DG Agriculture spoke and acted on behalf of the EU in SPS Committee meetings. After a while DG Trade also became part of the delegation on a regular basis.

DG Enterprise/Industry is enquiry point under the TBT Agreement and has headed the EU delegation to TBT Committee meetings. DG Trade is also part of this delegation. DG Enterprise/Industry is thus a core player regarding both the work on new approach standardisation, technical regulations and the use of the mutual recognition principle internally in the EU, and the work on aspects

[18] For simplicity's sake we use the term European Union (EU) even when EC or EEC is formally the correct term.

[19] WTO succeeded GATT in 1995.

regarding technical trade barriers in third-country relations, including MRAs. DG Enterprise/Industry is thus heavily involved in areas that are also relevant for the food sector, i.e. non-SPS aspects of technical regulations and standards. DG Trade is responsible for aspects regarding the promotion of EU's export interests.

The Codex Alimentarius Commission was established in 1963 and thereafter DG Agriculture and DG Enterprise/Industry normally met as EU's representatives in Codex meetings. However, until 2003 the EU only had observer status in this forum whereas the EU Member States had full participatory rights. Thus, it was a representative from one of the Member States who spoke on behalf of the EU on those areas covered by EU law.

In 2003 through a vote, the Codex Commission agreed on the accession of the EU to full-member status in Codex. After the Council of the European Union on 17 November 2003 decided that the EU should become a member of Codex the European Commission began acting on behalf of the EU Member States. Thus in Codex, as is the case in the SPS Committee, the Commission now speaks and acts on behalf of the Member States in areas covered by EU law.[20] However, in contrast to the situation in the SPS Committee, the Member States are allowed to take part in discussions at Codex meetings. Furthermore, representatives of the Secretariat of the Council of Ministers may occasionally also attend both WTO and Codex meetings.

It was not until 6 October 2005 that the EU became a Contracting Party to the IPPC. It is still not a member of OIE, but through an exchange of letters in 2004 it has established official relations with the OIE and participates in OIE meetings as an observer.

After the BSE crisis hit the EU in the mid-1990's the EU implemented extensive institutional reforms of the European Commission, including reforms of the Commission's external representation of EU's food policies. DG SANCO took over the leading and coordinating role in EU's food safety work, both within the Commission and the Council and in on-the-spot co-ordination meetings in WTO, Codex and other international fora where the EU is represented. Thus, today DG SANCO acts as both enquiry point under the SPS Agreement and as contact point for Codex matters. Because Codex is a decision-making body, a formalized set of procedures for co-ordination between the EU Member States, involving DG SANCO, has been put in place in a Council working group.

The SPS Committee, however, is not a decision-making body. Nevertheless, DG SANCO has chosen to initiate co-ordinating meetings with the EU members before SPS Committee meetings. The co-ordinations involved take place in a Commission working group. DG SANCO is furthermore responsible for co-ordinating and following up OIE and IPPC issues within the EU as well as in the meetings of the respective international bodies. The EU has thus responded on the

[20] The EU has established a set of complex procedures for guiding voting by the European Commission and the EU member states should vote in Codex whereby their voting will depend on whether the issues on the agenda are within the Community competence, Member State competence or a mixed competence. However, I will not go further into these procedures here.

international level by giving main responsibility for EU work on international food policies to DG SANCO, which subsequently also takes the lead in the EU's SPS work, including related activities towards Codex, OIE and IPPC.

Today, DG SANCO heads the EU Delegation to the SPS Committee and DG SANCO delegates normally attend meetings together with delegates from DG Trade. As a rule, the two DGs share the SPS work between them in the following way: DG SANCO has the main responsibility for EU's SPS work and speaks on those matters that are related to explaining EU's food safety policies, sharing EU's experiences in the food safety area with other WTO members, and defending EU's SPS measures that are challenged by other WTO members. DG Trade becomes involved when the EU raises trade concerns regarding other WTO members' SPS measures, i.e. on issues regarding external trade.

This division of labour in the SPS area illustrates EU's attempts at separating institutionally the responsibilities for issues based on food safety and health objectives from issues based on EU's commercial and trade interests. Thus, DG SANCO is supposed to work towards the SPS Committee within the single mandate of health and consumer protection whereas DG Trade is supposed to take care of the trade mandate of promoting market access for EU's exports. Generally, the division of labour between DG SANCO, DG Enterprise/Industry and DG Trade illustrates EU's attempts at creating a coherent and consistent regulatory system where, to the extent possible, designated agencies are given clearly defined and sole responsibility for promoting specific objectives such that they (the agencies) will not easily come into conflict or duplicate efforts.

The EU has responded to the developments in international food regulations (and other international product regulations) in several ways:

- First, it has itself carried out extensive reforms in its regulatory framework. In the food policy area, these reforms have been largely motivated by other factors, especially the BSE crisis, but have nevertheless been adjusted to the international developments.
- Second, the EU has become a full member of other relevant international bodies such as the Codex and the IPPC in the same way that it is a full member of the WTO. Furthermore, in some cases the European Commission has established formal relations with other relevant international bodies, although it has not joined them, e.g. OIE.
- Third, the EU has made an effort at clarifying the responsibilities for different regulatory areas according to the objectives that it seeks to achieve. Thus, responsibilities for all food safety activities have been placed under the responsibility of DG SANCO, which works under the single mandate of promoting health and consumer objectives. DG SANCO is also responsible for coordinating food policies internally before bringing them before the SPS Committee and the meetings of Codex, OIE and IPPC. The responsibility for the non-SPS area (the TBT area) of food regulation is however left to DG Enterprise/Industry.

In this way the EU has enhanced its capacity for coordinating its work on international regulations in general and on food regulations in particular. Furthermore, the EU has enhanced its capacity for promoting coherently and consistently its regulatory work internationally. This is particularly true for the food sector where the EU has established a food regulation system which creates coherency between how this policy area is integrated within the EU and how it is represented and promoted within the WTO and the three standardization bodies: Codex, OIE and IPPC. The EU's external representation of food policies has thus become integrated institutionally in a way that enhances the promotion of common and coherent EU food policies in the international arena. EU's external representtation furthermore involves attempts at insulating the promotion of food safety policies from the parallel promotion of EU's trade and commercial interests (c.f. the division of labour between DG SANCO and DG Trade in the SPS Committee).

4.3 The EU's work on equivalence and mutual recognition in the WTO

The EU is an important player in the WTO (and was likewise in GATT before that), and has acted as a collective entity in trade policies ever since 1957 when the Treaty of Rome was signed and the EU gained exclusive competence to negotiate and enter into international trade agreements (Meunier 2005).

From 1995, when the SPS Agreement and TBT Agreements came into force, the EU has actively promoted its regulatory policies and approaches in the WTO context, including the use of trade-facilitating tools such as equivalence and mutual recognition. The discussions and submissions on these issues have mainly taken place in the TBT Committee, where DG Enterprise/Industry co-ordinates EU's positions in advance and leads the EU delegation, and the SPS Committee, where DG SANCO co-ordinates the positions and leads the EU delegation.[21]

4.3.1 The EU and the TBT Committee

The TBT Agreement has three main provisions which deal with mutual recognition and equivalence and which are all assumed to be useful tools to facilitate trade under the agreement:

- **Article 2.7 on equivalence of technical regulations:** "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."

[21] See Veggeland and Elvestad (2004) for a more comprehensive presentation of the discussions in the TBT and SPS Committees on equivalence and mutual recognition over the years.

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

- **Article 6.3 on the conclusion of MRAs: "**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 TBT Committee has initiated work to clarify how these provisions can be understood and applied in practise, but the work has proved difficult. Discussions on how to determine equivalence for technical regulations (c.f. Article 2.7) has been particularly hard to move forward. The TBT Committee has for many years repeatedly invited Members to exchange views on their experiences in the implementation of Article 2.7, which relates to equivalence of technical regulations. Still, it has seemed very difficult to identify practical examples of how such equivalence determinations have facilitated trade.

Greater progress has been made in the discussions on the other two provisions, namely articles 6.1 and 6.3. Several Members stress that these provisions touch upon elements that have proven to be important trade facilitating tools in many product sectors. Article 6.1 deals exclusively with the recognition of conformity assessment by central government bodies. Compared to Article 2.7, it provides greater details on the means of implementation. In fact, mutual recognition of the equivalency of conformity assessment procedures is included as a core element in many MRAs, whereas mutual recognition of the equivalency of the technical regulations seldom is.

In line with Article 6.3 of the TBT Agreement the Members have been requested to notify the TBT Committee of MRAs in which they take part. Up until 2005 about 40 MRAs concerning the results of conformity assessment procedures had been notified to the Committee (WTO 2005:18). About half (46 percent) of these notifications were from the European region (ibid.: 19). Thus, with regard to equivalence and mutual recognition, the main focus of the TBT Committee seems to have become MRAs and conformity assessment procedures. As we will see, this is also in line with the approach taken by the European Union in this field.

The most comprehensive submission which the EU has made to the TBT Committee in this field is the communication from the European Commission

entitled "A Policy Framework for the Facilitation of Trade in the Fields of Standardization and Conformity Assessment: A Toolbox of Instruments" (WTO 2002b), which is actually identical to the working document (European Commission 2001a) of the Commission presented earlier in this report. This submission covers many areas relevant to the regulatory work on trade facilitation.

The European Commission stated that the objective of submitting this document to the TBT Committee was to "…share with other WTO Members the European Community's experience in external trade in the fields of standards and conformity assessment, and present a framework for our future work in this area" (WTO 2002a).

In its communication the Commission underlines that its experiences have led to the view that a broad variety of measures can be applied to accomplish trade facilitation and furthermore it refers to several important (ideal) conditions for open trade (WTO 2002b: 3):

- Compatibility of approach
- Coherence of regulations and standards
- Transparency of rules
- Appropriate levels and means of regulation
- Impartiality in certification
- Compatibility of market surveillance measures and supervision practises
- Appropriate level of technical and administrative infrastructure.

The Commission explains that the EU applies a variety of measures together with its trading partners, including equivalence and mutual recognition agreements, to bring about these ideal conditions. The Commission furthermore intends in its submission to the TBT Committee to "..facilitate the identification and development of priorities for action in the field, in such a way as to be as effective and cost-efficient as possible" (WTO 2002b: 4).

The Communication was intended to deal with issues of external trade in industrial products, but the Commission stresses that the issues that are raised may also have implications for trade in other areas, for example agricultural products, where the issues are often similar although existing regulatory modalities are generally different. The Commission nevertheless emphasizes that it is important to note that the application of concepts to areas or sectors will depend on the specific regulatory framework existing in each case. Of course, this is also true when applying the concepts in cases concerning states with divergent regulatory frameworks.

In the following sections I will point out some of the elements of the document "Implementing Policy for External Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments" (European Commission 2001a) relevant to the TBT discussions (see also Chapter 3 of this report). The Commission states in this document that it is important to bear in mind that the concepts contained in the TBT Agreement cannot be applied to global markets in the same manner that they are applied to EU's internal market. The main reason

for this is the absence of a strong institutional framework at the global level to support applying them in such a manner (WTO 2001b:6). In other words, the fact that the WTO lacks strong legislative and administrative bodies—such as the Council of the European Union, the European Parliament and the European Commission—and judicial control—such as that exercised by the European Court of Justice—makes it important to apply a different mix of trade facilitation tools than the mix which is used by the EU itself. The trade facilitating tools envisaged by the Commission are listed in Table 3.1 of this report.

Several important points are worth mentioning with regard to the European Commission's inputs into the discussions in the TBT Committee.

First, the Commission seems to be somewhat reserved as to applying the concept of equivalence of technical regulations under the TBT Agreement (c.f. Article 2.7). It recognizes that when it can be applied, it can be a valuable instrument of trade facilitation, but also states that because of the complexities involved the principle of equivalence cannot be considered to be of general applicability.

Second, the Commission seems to be positive towards the work in the TBT Committee on clarifying how to achieve and apply mutual recognition of the equivalency of conformity assessment procedures (c.f. Articles 6.1). As an active negotiator on MRAs, the EU has also seen the relevance of the TBT Agreement's Article 6.3 on how to enhance the establishment of such agreements. However, the EU's own experience has highlighted the many problems with maintaining viable MRAs. The European Commission has thus become more sceptical about the applicability of this tool, particularly in cases involving trade with developing countries. The Commission has planned to share its experience with MRAs with the Committee. Thus, with regard to the work in the TBT Committee, the Commission seeks to promote regulatory approaches that are based on and compatible with European practises and experiences.

4.3.2 The EU and the SPS Committee

The SPS Committee's work on trade facilitating tools, particularly equivalence, has produced more concrete results than the TBT Committee's work on these issues. The SPS Agreement does not explicitly refer to mutual recognition, but instead refers to bilateral and multilateral agreements on the recognition of equivalence (see below). The agreement has one main provision dealing exclusively with equivalence, namely Article 4 entitled "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 Committee has for many years discussed the implementation of Article 4. These discussions resulted in the "Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures", which the SPS Committee adopted in 2001 and which subsequently has been revised several times.[22] Inputs from WTO members regarding their experiences with equivalence recognition have been important for these discussions.

The EU was one of the WTO Members that made submissions on this issue. In 2002 the EU submitted a document to the SPS Committee which described the application of equivalence to inspection and certification systems in its imports of fishery products (WTO 2002c). The objective of the document was to provide other WTO Members with a practical example of how the EU has applied the principle in its day-to-day work regarding trade relations with third countries, in particular towards facilitating trade with WTO Members which are developing or less developed countries.

The principle of equivalence is reflected, *inter alia*, in Articles 10 and 11 of the EC Council Directive 91/493/EEC. Article 10 says that "…provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products", whereas Article 11 elaborates on the specific import conditions that need to be fulfilled. It is important to note that the EU stresses that the purpose of the Directive is to describe the system rather than the individual measures, and that the EU has always emphasized the prerequisite need for an equivalent system before considering product equivalence (WTO 2002c: 2). Thus, the EU views that the discussion on the application of equivalence in line with Article 4 of the SPS Agreement first must concentrate on equivalence determinations regarding food inspection and certification systems. This is also reflected in EU's own work on these issues. The EU has in practice concentrated much of its work on equivalence determinations on different aspects of food inspection and certification systems, for example regarding imports of fishery products.

The first conditional step of determining equivalence according to EC Council Directive 91/493/EEC is to make documentary evaluations of the inspection system of the exporting country. Import conditions are furthermore adapted to the particular situation in the third country based on the equivalence of the inspection and certification system. The exporting country should issue a health certificate to follow the consignment in order to provide assurance that the inspection of the fishery products has been performed in an equivalent way to the EU's standards. The same procedure applies to a listing of approved establishments and auction or wholesale markets registered and approved by the competent authority. When the

[22] An account of the work on equivalence in the SPS Committee, including the Committee's Decision on this issue, is given in Veggeland and Elvestad (2004: 17-21).

sufficient guarantees have been provided to establish an equivalent system of inspection, the products concerned can be exported.

The EU approach to recognizing the equivalence of inspection and certification systems for fishery products has led to a reduction in the frequency of physical controls at border inspection posts: from 100 percent physical control to 50 or 20 percent, depending on the risk level. Furthermore, from 1991 up until 2002, 62 third countries had been recognized as having implemented equivalent systems of inspection and certification for fishery products and hence, in principle, had achieved better access to the EU market.

The EU has generally been active in contributing information to the SPS Committee on its experiences in applying equivalence. EU's contributions through submissions and participation in the Committee's discussions, illustrate that on this issue, EU emphasizes the work on the equivalence of food inspection and certification systems more than the work on product equivalency. This is also reflected in the EU's work with Codex.

4.4 The EU's work on equivalence in the Codex Alimentarius Commission

The principle of equivalence has been on the agenda in Codex for many years, particularly in the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS). Equivalence is even included as one of the Codex Commission's main principles for food import and export inspection and certification (Codex Alimentarius Commission 1995):

> **Equivalence**
> 12. Countries should recognize that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

CCFICS has furthermore produced several guidelines where the principle of equivalence is included as an integral part.[23] The "Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems" (Codex Alimentarius Commission 1997) includes a whole section on the application of equivalence in connection with accreditation. The "Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems" provides practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems (Codex Alimentarius Commission 1999).

Finally, there are the "Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems" (Codex

[23] See also Elvestad and Veggeland (2005) for a presentation of these guidelines.

Alimentarius Commission 2003). These guidelines, which were adopted by the Codex Commission in 2003, were developed on the basis of a request from the WTO's SPS Committee for the Codex to provide guidance with regard to the practical understanding and application of equivalence as indicated in Article 4 of the SPS Agreement. The EU has been actively involved in this work and I will thus make a short presentation on the EU's written contributions to the work on these guidelines.[24]

In its comments a Discussion Paper[25] that was presented at a CCFICS meeting in February 2000, the EU stated that it could agree in principle to further work on the draft guidelines. However, its condition for agreeing to do so was that the EU Member States be actively involved in the development of the text and that other relevant Codex committees be consulted prior to redrafting.

In its comments to the proposed Draft Guidelines[26] that were presented in December 2000 the EU clearly expressed its will to focus the work on the *systems* of food inspection and certification, rather than on the measures themselves. Accordingly, the EU wanted to limit the scope of the guidelines by changing the wording "Sanitary measures involved in the determination of equivalence" to "Sanitary measures *related to inspection and certification systems*" (author's emphasis).

In its comments to a Codex Circular Letter CL 2001/25-FICS distributed in 2001, the EU stated that it supported the Draft Guidelines, but made some comments on the scope and definition of sanitary measures. The EU meant that the scope was too narrow and that the document should include judgement of equivalence for all food safety issues, and also some of the hazards that are not covered by the SPS Agreement's definition of food safety, such as food allergens. The same comments were made by the EU in 2002 with regard to a Codex Sircular Letter CL 2002/8-FICS.

At the end of 2002 the final Draft Guidelines were presented. This time the EU only made one short comment, namely that it supported the present document on the Draft Guidelines. These Guidelines were subsequently adopted by the Codex Commission in its meeting in July 2003.

Parallel to the work on the "Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems", CCFICS has also considered developing "Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems". Initially, this work was meant to take place in parallel with the development of the guidelines on sanitary measures. A document containing proposed draft guidelines on technical regulations quite similar to the guidelines on sanitary measures was thus presented to the committee. However, the CCFICS members soon realized that it would be a more complicated process to develop

[24] This presentation is simply based on EU's Codex position papers, which are to be found on the homepage of DG SANCO: http://europa.eu.int/comm/dgs/health_consumer/

[25] "Discussion Paper on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems".

[26] "Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems".

guidelines on the equivalence of technical regulations. Furthermore, Codex had not received a request from the WTO to provide guidance in the area of technical regulations; it had received such a request concerning sanitary measures. The work on guidelines for equivalence of technical regulations was thus slowed down, whereas the work on guidelines for equivalence of sanitary measures sped up.

CCFICS put the proposed guidelines for equivalence of technical regulations away and decided to focus on discussion papers instead. The aim was to explore further whether it was worth spending time and resources on developing guidelines in this area. Because of the reluctance of several Codex members to proceed, CCFICS decided at its meeting in December 2003 that the work on these guidelines should temporarily be halted.

The EU made several contributions to the discussions on guidelines for the equivalence of technical regulations. In 2000 the EU stated that a document on Proposed Draft Guidelines[27] had still not reached a sufficient degree of maturity. Specifically, the EU thought that it did not clearly reflect the fact that equivalence of technical regulations must be based on the results of the assessment of a *system* of food inspection and certification (author's emphasis). Furthermore, the EU thought that the document did not sufficiently reflect the provisions of the WTO's TBT Agreement. The EU wanted thus to focus on systems and conformity assessment and did not see the need for or relevance of including in such guidelines the methodologies for comparing technical regulations per se.

In its comments to the discussion paper on the guidelines for the equivalence of technical regulations that were presented in 2002, the EU reiterated its view that CCFICS should focus on the equivalence of inspection and certification systems, which is within its mandate, and not on the equivalence of technical TBT regulations, which in the opinion of the EU is not within CCFICS' mandate. The EU thus wanted to focus on conformity procedures. The EU further stated that it should be considered whether it is more appropriate to have a common (universal) approach for all kinds of inspection and certification systems or a more graduated approach taking into account the specificity of each system.

The comments that the EU made in 2002 were repeated in 2003 when a new discussion paper was presented to CCFICS. Again the EU stressed the need to focus on conformity procedures and not technical regulations and referred to the definition of technical regulations in the WTO's TBT Agreement, which does not include an inspection and certification component. The EU stated that it recognised that there is some need for practical guidance on judgement of equivalence of conformity assessment procedures. However, the EU suggested that Codex first should consider whether this issue is already sufficiently covered by Codex Committees and other relevant International Agencies.

The EU nevertheless concluded that the CCFICS has a role to play in providing guidance to Codex Members in determining the equivalence of the competence of conformity assessment bodies. However, before initiating this new work the EU felt the need to consider whether the existing Codex guidelines (c.f. Codex Alimen-

[27] "Proposed Draft Guidelines on the Judgement on Equivalence of Technical Regulations associated with Food Inspection and Certification Systems".

tarius Commission 1997) cover the need for guidance in the determination of equivalence. The EU did not see the need for a new separate text dealing specifically with conformity assessment bodies, but meant instead that the existing guidelines should be amended, if necessary, in order to take into account specific needs related to these bodies. Regarding mutual recognition, the EU pointed out that this issue was not in the terms of reference of the CCFICS and that the Codex Commission therefore should establish a clear mandate.

The EU was thus one of the few Codex members that was positive about CCFICS' doing at least some work on guidelines for the judgement of equivalence of technical regulations associated with food inspection and certification systems. Still, CCFICS decided that the work should be put on hold.

4.5 Summing up the EU's international activities on equivalence and mutual recognition

The EU has proven to be an active player with regard to establishing accepted international principles and guidelines on the application and understanding of equivalence and mutual recognition as trade facilitating tools. There have furthermore been important internal reforms in the organization of EU's regulatory activities, which have given the European Commission quite some leeway in promoting EU's regulatory policies in international fora. The EU seems to view the international work as a natural extension of the work that has been done within the EU. Thus, partly based on its experience with the internal market, the EU has actively promoted ideas and approaches for facilitating trade internationally. This is particularly true for the food sector, where the European Commission participates on behalf of the EU in several international bodies (such as the SPS Committee, Codex, IPPC and OIE), and where the EU as a major global food exporter and importer has introduced alternative tools to facilitate market access for EU exporters while at the same time allowing exporters to the EU better access to the EU market.

The EU has thus had great influence in shaping how trade facilitating tools such as the principles of equivalence and mutual recognition can be understood and applied in practise. The EU's experience is furthermore important as a basis for deciding which trade facilitating tools should be used in different contexts internationally.

5 An assessment of the EU's experience in applying mutual recognition and equivalence

5.1 Introduction

The EU stands out as an international entrepreneur with regard to negotiating MRAs as well as applying the principles of equivalence and mutual recognition. Furthermore, the EU has shown itself to be an influential actor on the world stage with regard to sharing experiences and providing guidance on how these trade facilitating tools can be used in practise. Thus, the experience of the EU is of particular interest when assessing the prospects of and difficulties in applying these tools. In this chapter I will thus summarize some of the core characteristics of EU's "trade facilitation model", point out some of the factors which have contributed to shaping this model, and finally make some assessments of EU's experience with applying different trade facilitating tools in a global setting.

5.2 EU's "trade facilitation model": some core characteristics

This report is not aimed at describing in depth all the approaches and tools that the EU applies in order to facilitate trade. Instead, it has focused on *some* of the important elements of what can be called the EU "model". I have identified some core characteristics of this model, which are important to understanding how the EU has approached trade facilitation in the regulatory field.

The level of integration in the EU is greater than in other regional economic co-operations. An important aspect of the EU integration process has been the creation of strong common institutions. Thus, the EU has a large capacity for both developing and enforcing common (harmonized) rules and policies and for acting with a single voice in a global setting. The existence of a strong executive (the European Commission) compared to what exists in other international organizations is particularly important in order to understand *how* the EU has managed to facilitate trade both between its Member States and between the EU and third countries.

The European Commission separates the management of the internal market from the management of external trade relations. The experience with the establishment of a single European market has nevertheless highlighted some of the pitfalls and possibilities attached to applying different trade facilitating tools. This experience is also relevant in a wider international context. The work on the single European market has been an important testing ground for applying different approaches towards removing trade barriers. This work and this experience have also influenced discussions on trade facilitation in international fora.

The establishment of the single European market created a need for the EU to strengthen and further develop common approaches and policies in the field of external trade. The European Commission thus made several important initiatives in the 1990s and later.

The Commission was in forefront internationally with regard to negotiating equivalence agreements and MRAs. In this way, the EU managed to set an example concerning how these trade facilitating tools could be used. Thus, the EU influenced the work on these issues in the WTO and other relevant international fora such as the Codex. The EU furthermore gained influence on other countries' regulatory systems through its bilateral trade agreements. Several observers have noted that the bilateral agreements have been catalysts for the EU's transfer of its regulatory policies, including the principle of mutual recognition, to the other parties to the agreements, and that this transfer has been greater from the EU to other countries than vice versa (Nicolaodis 1997; Shaffer 2002; Steffenson 2002).

There are several important elements that characterize the EU's "trade facilitation model". First, the EU has had extensive experience both negative and positive, with harmonizing rules between Member States with the aim of facilitating trade. Second, the EU model gradually included the application of the principle of mutual recognition. Subsequently this resulted in the establishment of the "new approach" to standardization within the internal market and the "global approach" in its third- country relations, which complemented and supplemented harmonization as a trade facilitating tool. Third, based partly on its experience from the work within the internal market, the EU has applied and tested a complex mix of different trade facilitating tools in its third-country relations.

In some respects, the EU has thus acted as an entrepreneur with regard to applying the principles of equivalence and mutual recognition in a global setting. Furthermore, the EU has been active in participating in the discussions on regulatory issues taking place in international bodies such as the WTO and Codex.

This active involvement can be explained by, *inter alia*, its experience from the European integration process described above, as well as the European Commission's high level of competence in the fields of trade and regulatory policies. Furthermore, the Commission has acquired more competence from the EU Member States on these issues than on many other issues. Thus, the regulatory work taking place in international bodies where the Commission has gained access has been viewed by some EU officials as a possible extension of EU's own regulatory policies. This has furthermore necessitated an active strategy towards developing strong, common EU positions, which again has enhanced EU's international influence in the regulatory field.

5.3 The EU's experience: some assessments

Although the EU has made use of different trade facilitating tools in its third country trade relations, not all of its experience in applying these tools has been positive. Below, I will first make some assessments of EU's experience with Mutual Recognition Agreements (MRAs) and Veterinary Equivalency Agreements (VEAs). Then I will make a short assessment of the use of equivalence as a supplement and complement to EU's import regime for third countries. Finally, based on the EU experience I summarize the prospects of and difficulties in applying equivalence and mutual recognition in a global context. I also briefly comment upon an alternative approach to trade facilitation, which has gained increased attention from the EU in recent years due, *inter alia*, to the experienced problems and limits of formal agreements.

5.3.1 EU and bilateral trade agreements

The EU has realized that there are clear limitations with regard to applying both equivalence agreements and MRAs. Such comprehensive agreements are often costly to negotiate and maintain. They normally necessitate some prior harmonization before negotiations can start. Negotiations are normally initiated with partners that have a comparable level of development to the EU's; despite this, the agreements may be very difficult to implement in practise. Another aspect is that it has proven difficult to measure precisely the trade benefits derived from the agreements. In fact, comments by officials of both the EU and the U.S. indicate that the costs are sometimes perceived to exceed the benefits.

Thus, based on its experience with existing agreements the European Commission is not currently interested in negotiating more traditional MRAs. The experience with VEAs shows many of the same difficulties. In practise it has proven difficult to perform equivalence determinations within these agreements, which is partly why the European Commission often chooses to refer to them as "veterinary agreements" instead of as "equivalence agreements". As is the case with the MRAs, to negotiate and maintain VEAs demands that the parties have relatively advanced levels of infrastructure and of administrative and regulatory capacity.

Thus, some of the EU's experience with regard to MRAs and equivalence agreements are quite discouraging. Such comprehensive agreements demand that the parties spend significant time and resources in order to negotiate, maintain and update them. Furthermore, it seems to be difficult for developing countries to be allowed to enter into negotiations on such agreements. This is clearly reflected in EU's traditional MRAs, which have only been negotiated with advanced developed countries (Australia, New Zealand, Canada, United States, Israel, Japan, and Switzerland). VEAs have been negotiated with either advanced developed countries (United States, Canada, Australia) or advanced developing countries (Chile, Mercosur).

Based on the EU experience it is possible to identify some important points with regard to the prospects of and difficulties in applying comprehensive MRAs and equivalence agreements. Some of these points can be summarized as follows:

- ***Trade volume matters***: The basic objective of MRAs and equivalence agreements is of course to facilitate trade. A certain volume of trade between the parties in products important for both parties should thus exist before the parties enter into negotiations. Both the MRA and the VEA between the EU and the U.S. are clear examples of agreements that *potentially* could have a big trade facilitating effect because of the large amount of trade involved. Thus, the agreements should in effect give something in return for the resources spent on negotiations and administration. However, these returns may not necessarily be of an economic nature, but rather could be of a political nature.

- ***Political salience and political will matter***: EU officials have pointed out that trade agreements can be mainly driven by political will and political salience, in which case they would not necessarily bring significant economic returns. However, the agreements can nevertheless be important because of their political effect, either through the establishment of a generally closer economic relationship with a preferred country or through closer regulatory co-operation and dialogue more specifically. Political returns from establishing formal relationships with trading partners through MRAs and equivalence agreements could thus be an extra incentive, and sometimes a prerequisite, for entering into negotiations.

- ***Balanced agreements are necessary:*** Trade agreements should include sectors and products that are of interest to both parties. For example, there was much discussion between the EU and the U.S. on which sectors to include in an MRA. Initially, a large number of sectors were placed on the negotiation table, but only a few ended up as part of the MRA; some were of special interest to the U.S. and some were of special interest to the EU.

- ***Level of development matter:*** As already indicated, the parties' levels of development matter when deciding to enter into negotiations on bilateral trade agreements. A sufficient infrastructure and regulatory capacity must be

in place in order for MRAs and equivalence agreements to work properly. This is of utmost importance because of the fact that these agreements presuppose that the parties trust and have confidence in each other's regulatory systems. Verification and the assurance that systems can "deliver" are therefore needed in order to establish viable agreements.

- *Political institutions and regulatory frameworks matter*: The EU's experience clearly shows that the political institutions and regulatory frameworks of the parties to MRAs and equivalence agreements affect the way these agreements work. The EU-U.S. MRA is a good example of this. The MRA was negotiated by the European Commission and the U.S. Trade Representative with the assistance of the relevant regulatory agencies. However, when the MRA came into operation the EU experienced problems because it had to deal with a large number of U.S. agencies, each of which had full responsibility for different parts of the agreement. Each agency furthermore had its own regulatory culture and its own clear views on the best way to regulate. The U.S. for its part had to deal with only the European Commission, but nevertheless experienced problems when changes or amendments to the agreement were needed, because this demanded a formal decision by the Council of the European Union. Thus, organizational asymmetry and divergent regulatory cultures may cause problems in negotiating and maintaining trade agreements.

5.3.2 The EU's import regime and the use of equivalence

The EU has also applied equivalence on a unilateral basis. In the fisheries sector, the EU on its own initiative evaluates the equivalency of other countries' inspection and certification systems in order to determine if their systems are at an equivalent level which would allow them to export to the EU market. The approved inspection and certification systems are then put on the EU's list of approved systems. The fishery products that are inspected in the exporting countries having approved facilities must however comply with EU food regulations. These rules that allow for such one-way equivalency judgements facilitate trade by making it easier for countries to export fishery products to the EU. At the same time the administrative burden on the EU's own inspection service is relieved because inspections are done by the exporting countries.

EU's rules for organic food also include one-way equivalence judgements, but these equivalence judgements are performed for both product regulations and for inspection and certification systems. Countries that are allowed to export their organic foods to the EU as a result of such one-way equivalence judgements are put on a list of approved countries.

Equivalence judgements concerning organic foods are performed at the request of the exporting country. EU officials have stated that it is easier to determine equivalence for those countries that base their national rules on the same international standards as the EU uses. For example, with regard to organic food the most relevant standards would be Codex standards. The EU may accept as equivalent the

imports of organic foods from countries which base their national regulations on relevant Codex standards.

Though not being widely used, such one-way equivalence judgements under the EU's import regime are of some significance in facilitating trade in certain sectors and in certain situations.

5.4 Learning from the EU experience: the prospects of and difficulties in applying equivalence and mutual recognition

Because the EU possesses certain characteristics, the EU can facilitate trade relatively easily between its Member States; on the other hand, it is much harder in many other international settings for the countries involved to facilitate trade amongst themselves. For example the EU possesses a comprehensive legal framework and relatively strong institutions to enforce common rules. This gives it a strong regulatory capacity and thus makes it a special case with regard to the methods used to achieve trade facilitation.

Thus, one has to set a lower ambition level with regard to facilitating trade in many other international settings. The experience of the EU certainly shows that equivalence and mutual recognition may be useful trade facilitating tools and that these tools could be used in and could have a positive effect on trade relations between many countries internationally. However, there are many problems attached to this; for example, developing countries will in many cases have problems with achieving equivalence and/or recognition of their conformity assessment systems because of inadequacies in their infrastructures and regulatory capacities.

Furthermore, even when applied between countries with comparable levels of development and regulatory capacity, many problems can arise. These tools may therefore in many cases be costly to apply in practise. Thus, one has to carefully consider whether it is worth the costs and efforts to enter into processes of judging equivalence and seeking mutual recognition.

Therefore, it seems important to consider on a case-by-case basis whether these tools should be applied. Furthermore, increased activity by international standardization bodies, active country participation in these bodies, and widespread adherence to international standards will enhance the application of equivalence and mutual recognition, and will enhance harmonization.

Finally, in many cases equivalence and mutual recognition (or harmonization) will initially not be the most (cost) effective trade-facilitating tools. In these cases softer approaches such as regulatory dialogue and information sharing etc. may be more efficient. It may take a long time to reach the goal of removing trade barriers by using these approaches, but they may still be more effective in the long run, particularly because they may more easily lead to harmonization. The EU has for some years used these softer approaches to facilitate trade, but only as a supplement to other approaches such as MRAs.

One example of an alternative approach is the regulatory dialogue that has been established between the EU and the U.S. The two parties have agreed on "Guidelines for Regulatory Cooperation and Transparency" under the Transatlantic Economic Partnership (TEP) and furthermore set out a roadmap for this co-operation in 2004. The roadmap outlines a range of specific regulatory cooperation activities which the parties jointly intend to pursue including: specific sectoral co-operation, such as co-operation on food safety, pharmaceuticals and auto safety regulation; and horizontal initiatives, such as a regular informal dialogue on regulatory policy issues and practices of mutual interest; identification of resources and mechanisms to promote exchanges of EU and U.S. regulatory experts; and seminar/workshops where regulators can exchange views and raise awareness of regulatory activities, priorities and approaches on issues of mutual interest.

The European Commission has established such regulatory dialogues with several other countries and has in fact stated that it will increase its attention and efforts towards the use of such approaches to achieve regulatory compatibility.

6 Conclusions and final remarks

6.1 EU's experience summarized

The EU has been in forefront internationally with regard to applying and promoting the principles of equivalence and mutual recognition. One of the important factors explaining this position is the EU's unique work on realising an effective and well-functioning internal market and thus facilitating trade between Member States, which from the outset had different regulatory cultures and practises. EU has thus gained valuable experience with applying a mix of different trade-facilitating tools, including harmonization and mutual recognition in particular.

The EU has also applied a mix of trade-facilitating tools in its third-country trade relations. However, the mix of tools used in these relations is different from that which is used internally, particularly because the EU and its partners (the other parties) in such bilateral trade agreements do not have strong common institutions to enforce the agreements between them, such as the EU institutions (European Commission, European Court of Justice etc.) which enforce the EU's own rules for the internal market. Thus, regarding external trade, the EU has to a large degree applied rules which imply that exporters to the EU must comply with EU standards in order to gain market access to the EU. These rules are, however, supplemented with *inter alia*, the use of mutual or unilateral (one-way) recognition of conformity assessment procedures and judgements of equivalency.

The EU's experience shows that judgements of equivalence are easier when the two parties involved base their national rules on the same international standards. Thus, an active involvement in international standardization bodies becomes paramount in facilitating regulatory co-operation. Furthermore, the EU has little

experience with judgements of the equivalence of product standards or regulations, at least not within the framework of equivalence agreements or MRAs. Thus, the EU's focus is on judgements of the equivalence of regulatory systems, particularly food inspection and certification systems. This is also true for EU's rules on the imports of fishery products, which include judgements of the equivalence of fish inspection and certification systems. However, the EU's rules on the imports of organic food include judgements of equivalence of the technical product regulations in addition to inspection and certification systems.

All of the EU's MRAs are about the recognition of conformity assessment systems, and some of them also include equivalence judgements. However, equivalence of product standards and regulations is not included.

Thus, mutual recognition and equivalence seem to be most relevant and easiest to apply with regard to the approval of systems or parts of systems for conformity assessment, including certification and inspection. Furthermore, it seems to be easier to apply these tools on a case-by-case basis adapted to specific contexts than to include them in general and comprehensive formal agreements.

6.2 Transferring the EU's ideas to a global setting

The EU's experience in applying mutual recognition and equivalence is discouraging in some respects and promising in others:

First, the EU's experience indicates that it is important not to set the ambition level too high with regard to how much trade facilitation can be achieved by applying these tools.

Second, a gradual approach towards regulatory co-operation seems to be the most effective in preparing the ground for the removal of regulatory trade barriers through equivalence, mutual recognition or ultimately some kind of harmonization.

Third, the EU's experience indicates that it may be wise to focus on equivalence of regulatory systems, including conformity assessment procedures, before making efforts to determine equivalence for a wide variety of product standards and regulations.

Fourth, the EU's experience highlights the importance of international standardization work which subsequently may facilitate the use of equivalence and mutual recognition and bring different regulatory systems closer together. International standards are well suited as a basis for determining equivalence and furthermore make the process of determining equivalence less complicated and potentially less time-consuming. It is also easier to achieve mutual recognition of conformity assessment systems when they are based on the same international guidelines and standards.

6.3 Some final remarks: the way forward

This report has explored the EU's experience with equivalence and mutual recognition and pointed out some of the limitations to applying these tools in bilateral

trade relations. Furthermore, it has highlighted the possible gains from spending more efforts on so-called soft approaches to harmonization. By entering into regulatory dialogues and by sharing experiences more actively, regulatory authorities could contribute to building sufficient confidence and trust thus enhancing closer and more formalized co-operations such as, for example, MRAs and equivalence agreements. These "softer" regulatory co-operation efforts, which to take place do not require formally negotiated agreements, may subsequently lead to a gradual harmonization of regulatory systems thus enhancing the work on removing regulatory trade barriers.

Sources

Becker, Geoffrey S. (1999): *U.S.-European Union Agricultural Trade: The Veterinary Equivalency Agreement*. CRS Report for Congress RS20242. Congressional Research Service, United States.

Codex Alimentarius Commission (1995): *Principles for Food Import and Export Inspection and Certification*. CAC/GL 20-1995.

Codex Alimentarius Commission (1997): *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*. CAC/GL 26-1997.

Codex Alimentarius Commission (1999): *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems*. CAC/GL 34-1999.

Codex Alimentarius Commission (2003): *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems*. CAC/GL 53-2003.

DG Trade (2006): *Mutual Recognition Agreements Newsletter No.1*. February 2006

Egan, Michelle P. (2001): *Constructing a European Market: Standards, Regulation and Governance*. Oxford: Oxford University Press.

Elvestad, Christel (2002): *Equivalence and Mutual Recognition Agreements in Relation to Technical Measures*. NILF Working Paper 2002-36. Oslo: Norwegian Agricultural Economics Research Institute.

Elvestad, Christel and Frode Veggeland (2005): *International Trade and Guidelines on Equivalence and Mutual Recognition*. NILF Report 2005–1. Oslo: Norwegian Agricultural Economics Research Institute.

European Commission (1985): *Completing the Internal Market: White Paper from the Commission to the European Council (Milan, 28–29 June 1985)*. COM(85) 310, June 1985

European Commission (1996): *Community External Trade Policy in the fields of Standards and Conformity Assessment*. Commission Communication COM (96) 564 def. of 13/11/96

European Commission (1998): *Implementation of Mutual Recognition Agreements on Conformity Assessment (MRA) and Protocol on European Conformity Assessment (PECA)*. Brussels, 24 July 1998. DG III/B/4/GM D(98).

European Commission (2000a): *Guide to the implementation of directives based on the New Approach and the Global Approach*. Downloaded from the homepage of DG Enterprise January 16, 2006: http://europa.eu.int/comm/enterprise/newapproach

European Commission (2000b): *Commission staff working document. Guiding Principles on and a Vade mecum for the management of agreements on mutual recognition of conformity assessment*

European Commission (2001a): *Implementing Policy for External Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments*. Commission Working Paper SEC(2001) 1570 of 28/09/01

European Commission (2001b): *Doing business in the Unites States of America. Facilitating conformity assessment. Guide to the mutual recognition agreement between the European Community and the Unites States of America*. European Commission, March 2001.

European Commission (2003): *Vade Mecum. On the management of Agreements on mutual recognition on conformity assessment*. Commission of the European Communities, Brussels, April 2003, DG Trade/F/2. Revision 1.

European Commission (2004): *European Action Plan for Organic Food and Planning*. Commission Staff Working Document. Annex to the Communication from the Commission [COM(2004)415final]. Brussels, 10 June 2004 SEC(2004) 739

European Commission (2005): *Common Actions for Growth and Employment: The Community Lisbon Programme*. Communication from the Commission to the Council and the European Parliament COM(2005) 330 final, Brussels, 20.7.2005.

European Council (2000): *Presidency Conclusions Lisbon European Council 23 and 24 march 2000*. Downloaded from European Union online, January 20, 2006: http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/ec/00100-r1.en0.htm

European Court of Justice (1979): *Judgment of the Court of 20 February 1979. - Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein. - Reference for a preliminary ruling: Hessisches Finanzgericht - Germany. - Measures heaving an effect equivalent to quantitative restrictions*. - Case 120/78.

Horton, Linda (1998): "Mutual Recognition Agreements and Harmonization", *Seton Hall Review,* Vol 29 (Book 2): 692–732.

Meunier, Sophie (2005): *Trading Voices. The European Union in International Commercial Negotiations*. Princeton and Oxford: Princeton University Press

Nicolaodis, Kalypso (1997): *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*. Jean Monnet Working Papers No.7/97. New York University School of Law.

Nicolaodis, Kalypso and Gregory Shaffer (2005): "Transnational Mutual Recognition Regimes: Governance without Global Government", *Law and Contemporary Problems*, Vol. 68 (3–4): 263–318.

O'Rourke, R. (1998): *European Food Law*. Bembridge: Palladian Law Publishing.

Pollack, Mark A. and Gregory C. Shaffer (eds.) (2001): *Transatlantic Governance in the Global Economy*. Rowman & Littlefield Publishers, Inc.

Shaffer, Gregory (2002): *Managing U.S-EU Trade Relations through Mutual Recognition and Safe Harbour Agreements: "New" and "Global" Approaches to Transatlantic Economic Governance?* EUI Working Papers No. 2002/28. Robert Schuman Centre, European University Institute.

Steffenson, Rebecca (2002): *The EU's Exportation of Mutual Recognition: A Case of Transatlantic Policy Transfer?* RSC No. 2002/73, Transatlantic Programme Series. EUI Working Papers. Firenze: European University Institute.

Sykes, Alan O. (1995): *Product Standards for Internationally Integrated Goods Markets*. Washington, D.C.: The Brookings Institution.

Sykes, Alan O. (1999). "The (Limited) Role of Regulatory Harmonization in International Goods and Services Markets", *Journal of International Economic Law*, Vol. 2(1): 49–70.

Ugland, Trygve and Frode Veggeland (2004): "Towards an Integrated Approach? Food Inspection Reforms in Canada and the European Union", *Policy and Society*, Vol. 23(4): 104–124.

Ugland, Trygve and Frode Veggeland (2006): "The European Commission and the Integration of Food Safety Policies Across Levels". In Morten Egeberg (ed.): *The Multi-Level Union Administration: On the Transformation of Executive Politics within the European Union*. Palgrave Macmillan. Forthcoming.

USDA Foreign Agricultural Service (2005): *The US-EU Veterinary Equivalency Agreement: Content and Comparison. EU-25 Trade Policy Monitoring*. GAIN Report E35219. United States Department of Agriculture, Foreign Agricultural Service.

Veggeland, Frode and Christel Elvestad (2004): *Equivalence and Mutual Recognition in Trade Arrangements. Relevance for the WTO and Codex Alimentarius Commission.* NILF Report 2004–9. Oslo: Norwegian Agricultural Economics Research Institute.

Veggeland, Frode and Svein Ole Borgen (2005): "Negotiating International Food Standards: The World Trade Organization's Impact on the Codex Alimentarius Commission," *Governance,* Vol. 18(4): 675–708.

Vogel, David (1995): *Trading Up. Consumer and Environmental Regulation in a Global Economy*. Cambridge, Mass. And London, England: Harvard University Press.

WTO (2002a): *A Policy Framework for the Facilitation of Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments*. Communication from the European Commission. Committee on Technical Barriers of Trade, 8 March 2002. G/TBT/W/173

WTO (2002b): *A Policy Framework for the Facilitation of Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments*. Communication from the European Commission. Committee on Technical Barriers of Trade, 19 April 2002. G/TBT/W/173/Add.1

WTO (2002c): *A Practical Example of Implementation of the Principle of Equivalence*. Submission of the European Communities. Committee on Sanitary and Phytosanitary Measures, 12 March 2002. G/SPS/GEN/304

WTO (2005): *Preparation of the Fourth Triennial Review: Conformity Assessment Procedures*. Background Note by the Secretariat, 26 October 2005.

Interviews

Interviews with officials from the European Commission's DG SANCO, DG Trade, DG Agriculture and DG Enterprise, officials from United States' Food and Drug Administration and Department of Agriculture, officials from delegations to the Codex Alimentarius Commission and with former officials of the Secretariat of Codex. The interviews were conducted in July 2003, October 2005, and February and March 2006.