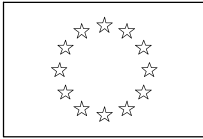

EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach
Standardisation

Vademecum on European Standardisation

Part IV

European standardisation in the International Context

Chapter 4.1

The external dimension of the Internal Market - Overview

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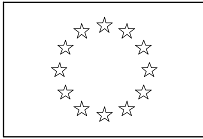

EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach
Legislative coordination and simplification; mutual recognition

Brussels, 31 July 2003

The External Dimension of the Internal Market

When exporting goods to foreign countries, industry and suppliers need to comply with technical regulations, conformity assessment procedures and certification requirements. These regulations normally serve legitimate ends (protection of health, consumers, environment, safety and so on). However, sometimes they might be more trade-restrictive than necessary to achieve such ends. This is why any regulatory measures concerning products should be proportionate to the objective pursued. This is the main principle that ensures both EC internal and international trade in goods. The Commission has identified the following variety of measures that could facilitate international trade in products between the EU and third countries. All these measures have three main objectives: preventing and reducing the effect of regulatory technical barriers, supporting varying degrees of regulatory convergence and promoting the EU regulatory approach, notably the internal market philosophy.

Mutual Recognition Agreements. Mutual Recognition Agreements (MRAs) are treaties established between the European Community and governments of third countries that *have a comparable level of technical development* and a compatible approach concerning conformity assessment. These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports concerning industrial products issued by the conformity assessment bodies (CABs) of one of the parties of the *agreement in conformity with the legislation of the other party*. Their objective is to facilitate international trade by reducing approval costs of industrial products and simplifying their placing on the market. MRAs are also a tool for regulatory convergence. As far as the EU is concerned, their legal basis stems from Article 133 (Common Commercial Policy) of the EC Treaty and they normally include a framework agreement, along with annexes that (normally) cover several sectors.

So far the EC has signed 7 MRAs, with Japan, Switzerland, the USA, Israel, Australia, New Zealand and Canada.

MRAs should also bring additional benefits, such as the elimination or reduction of duplicate testing, improved regulatory transparency, increased co-operation between the regulators of both parties and a reduction of the risk that conformity assessment will be used to protect domestic markets.

These benefits are particularly relevant for small and medium-sized enterprises (SMEs) which may lack the resources to access the regulatory system of a distant third country. MRAs can enable them to test and certify their products locally.

However, a few Member States, some industry representatives and stake-holders have criticised some MRAs because, in some sectors, they have not yet produced the expected increase in trade.

Other trade facilitating instruments. This experience has led to the view that other measures can be applied to facilitate trade. Indeed, conditions for open trade include 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 an appropriate level of technical administrative infrastructure.

The Commission has identified a "tool box" of instruments to bring these conditions closer in a working paper produced on 28 September 2001. These measures include ***regulatory co-operation, harmonisation, recognition of equivalence, partial or voluntary reduced or less formal types of mutual recognition, international standardisation and technical assistance***. The selection of the right instrument depends on the characteristics of the markets, the regulatory environment in the third country concerned, and the willingness on the part of industries, regulators and other stakeholders to achieve the agreed objectives[1].

Regulatory coo-operation means reciprocal understanding of regulation, transparency (e.g. WTO TBT agreement, ASEM best regulatory practice, EC-Mexico FTA, MERCOSUR, TEP regulatory guidelines, UNECE recommendations on standardisation) seminars, training sessions, joint visits, surveys and information gathering.

International standardisation implies using international standards as a basis for technical regulation (e.g. UNECE WP 29 for motor vehicles).

Recognition of equivalency leads to free trade of products assessed against different regulations that have the same objectives (e.g. EU-US marine safety equipment agreement).

Partial or voluntary reduced or less formal types of mutual recognition includes agreements in some specific sectors such as Good Laboratory Practice (GLP) or Good Manufacturing Practice (GMP), co-operation in the field of accreditation, subcontracting, voluntary co-operation of laboratories and certification bodies, co-operation in the development of standards.

Technical Assistance means, for example, raising awareness of the WTO-TBT agreement, preparing recipients for membership and building up the related infrastructure.

Harmonisation denotes drawing-up common rules. The international promotion of the so-called EC New and Global Approach (NGA) to technical regulation plays a huge role in trade facilitation. The advantages of this "regulatory system" are still not well enough known outside the EC. Indeed, it would be the ideal regulatory approach for large decentralised countries, federal countries or members of economic areas (e.g. MERCOSUR) whose regions or states have their own technical specifications. Essential requirements could be made compulsory for the entire territory and regional standards

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[1] See document SEC (2001) of September 28, 2001 "Implementing Policy for External Trade in the Fields of Standards and Conformity Assessment: a Tool Box of Instruments".

made voluntary. Furthermore, it would facilitate trade with third countries, as the New Approach is based on the notion of "essential requirements", which are more easily negotiable than detailed technical specifications. This is why recent bilateral agreements signed with some candidate countries for EU membership are almost completely founded on the New and Global Approach.

These bilateral agreements, known as PECAs (Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products), can be considered as the major instrument of the pre-accession strategy in the field of the free movement of goods. They are a specific type of mutual recognition agreement, based on the approximation of the legislation of the candidate country for EU accession with that of the EC and the development of the appropriate implementation infrastructure in the areas of standardisation, conformity assessment and market surveillance. PECAs create an enlarged internal market for products in certain industrial sectors prior to accession and represent a recognition of progress made in preparation for full participation in the EC internal market. As such, they are of great political and economic significance to the countries concerned. PECAs are also important to the EU in extending the benefits of the internal market using a sectoral approach, on the basis of the sectors identified by the candidate countries.

The Community has made a success of PECA negotiation and implementation, effectively 'exporting' the New Approach to third countries. To date, PECAs have been signed with six acceding countries (the Czech Republic, Hungary, Latvia, Lithuania, Slovenia and the Slovak Republic) and have entered into force. New sectors should be added as negotiations proceed. A PECA has been signed with Estonia and awaits the completion of the ratification procedures. A PECA-type agreement has been initialled with Malta. Formal negotiations on PECAs are ongoing with Poland and have been requested by Bulgaria and Romania.

Based on the experience gained from PECA negotiation, DG Enterprise believes that the EC should explore the possibility of extending the application of the model to other third countries. However, it is necessary to adapt the PECA model to a new context, bearing in mind that countries concerned are not, at this time, candidates for EU membership. The Commission is developing the concept of a 'ring of friends' with a view to promoting stability and prosperity in neighbouring countries following the next enlargement in 2004[2]. This process should address the issue of the expansion of the internal market to these countries and the adoption of common regulatory structures wherever possible. Particular attention should be paid to the advantages for third countries of adopting established common principles, within the context of existing WTO objectives. There is also a political advantage in binding the markets of third countries more closely to that of the EU.

Preliminary contacts with Mediterranean and western Balkan countries demonstrate a keen interest in cooperating with the EC in the furtherance of these key economic and political objectives. The next steps will be to engage in extensive preliminary dialogue with the countries concerned and to carry out detailed analysis of the framework conditions necessary to embark on a successful round of negotiations. Given that the

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[2] COM (2003) 83 final, Communication from the Commission to the European Parliament and the Council, Annual Policy Strategy for 2004, pp. 7-8.

degree of political leverage that can be exerted by the EC is less than that used with candidate countries, the conclusion of final agreements is likely to be a medium- to long-term process.

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