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IMPLEMENTING POLICY FOR EXTERNAL TRADE IN THE FIELDS OF STANDARDS AND CONFORMITY ASSESSMENT: A TOOL BOX OF INSTRUMENTS

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SUMMARY

All governments make regulations. When such regulations relate to things that are traded, there will be an effect on trade with other countries, since foreign suppliers will need to comply with the importing country's rules. Consequently, there have been substantial efforts to reduce the impact on trade of national or regional regulation. Regulations may serve legitimate ends, but at the same time efforts are necessary to ensure that regulation should not be more trade-restrictive than necessary to achieve such ends. The application of the principle of proportionality ought to ensure the necessity and effectiveness of the measures undertaken in comparison to the objective pursued.

The experience of the Commission in trade facilitation has led to the view that a broad variety of measures can be applied to accomplish it. 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 supervision practices, and an appropriate level of technical and administrative infrastructure.

Different measures are available to the Community and its trading partners to bring these ideal conditions closer. Measures such as regulatory co-operation (to make regulatory and market surveillance systems more compatible); harmonisation (to create single technical rules); mutual recognition agreements (to eliminate costs arising from unnecessary duplication of certification requirements); support for the development of international standards (to create compatibility and interoperability of products and, eventually, to provide a common technical basis for rules); and the development of codes of conduct and technical assistance (to provide support for the setting-up of a quality infrastructure in third countries), are all actions that can be used effectively to facilitate trade.

The Community should work towards achieving an optimal mix among these measures. This paper examines them in some depth, together with examples where appropriate, in order to facilitate future choices.

INTRODUCTION

There has in recent years been a renewed interest in international co-operation in the areas of standards, conformity assessment, and the elimination of technical barriers to trade (TBT).

The purpose of this paper is to examine questions concerning technical rules and requirements for products, and their effect on trade. The effectiveness of measures for rendering rules less trade-restrictive, while pursuing legitimate regulatory objectives such as the protection of health and safety, consumer protection and information, and protection of the environment, will also be considered. The analysis is intended 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.

With the increasing recognition of the impact of technical rules on trade in goods, a number of mechanisms to lessen this impact have been identified. They could be further exploited in order to offer a variable response, adapted to the needs and opportunities that present themselves in each specific situation. The choice of instrument will depend on the characteristics of the markets, the regulatory environment and technical infrastructure in the countries or regions concerned, the nature of the products, and the willingness on the part of industries and regulators to make use of such different instruments.

SCOPE

What follows is intended to deal with issues of external trade in industrial products. However, the issues raised here may have implications for trade in other areas – for example, services, and agricultural products – since the issues are often similar, even though existing regulatory modalities are generally different.

In other words, the concepts developed here may be useful in other areas, on the understanding that their application, if any, to those areas would depend on the specific regulatory framework in each case.

BACKGROUND: POLICY OBJECTIVES AND CURRENT ACTIVITIES OF THE COMMUNITY

The Community's trade objectives can easily be summarised: first, to reduce technical barriers in external markets and to prevent the emergence of new ones; and second, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international and European practice. Achievement of both objectives will mutually facilitate trade and market access.

The general principles of EC external trade policy in this area are set out in the 1996 *Communication from the Commission on the Community External Trade Policy in the fields of Standards and Conformity Assessment* [1] The Communication rests on two assumptions:

(a) that the impact on trade of product standards and means of determining conformity with them appears to be increasing, thereby giving rise to technical barriers to trade, and demanding greater attention and action than in the past; and

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[1] COM(1996) 564 final of 13.11.1996.

(b) that the completion of the single market has placed the Community in a position to pursue a more outward-looking trade policy in this field.

At the same time, other developments in the Community's legal framework have propelled the EU towards improving the effectiveness of regulatory authorities in protecting an ever-increasing number of public policy interests such as health and safety, the environment, and consumers' interests. In this respect, it is worth mentioning the application of the principle of proportionality and the recent Commission Communication on the precautionary principle [2], where the Commission considers that the principle has a scope to cover measures for protection of human, animal and plant health in addition to environmental aspects.

The internal market itself has developed from a largely trade facilitation mechanism to one that marries trade facilitation with a high level of protection of public interests, as defined in the EC Treaty. The policy towards standards and conformity assessment in external trade set out in the Communication was endorsed by the Council [3], which has also reaffirmed other aspects of this policy, for example, the importance of coherence in international standards, and the creation of standards-receptive regulatory models [4].

The trade objectives have so far been pursued through a four-fold strategy, comprising:

(a) Reliance on the WTO, notably the Agreement on Technical Barriers to Trade;

(b) Conclusion of bilateral (inter-governmental) agreements to reduce barriers and the cost of trade, which have so far consisted in the conclusion of Mutual Recognition Agreements (MRAs) for conformity assessment, certificates and marking, which are intended to reduce the costs of testing and certification in other markets, notably those of major trading partners;

(c) Technical assistance to ensure that other countries' regulatory regimes are transparent and trade-friendly, and that an appropriate infrastructure in the areas of testing and certification is being put into place;

(d) Regulatory co-operation, aiming at harmonising regulations with trading partners, achieving a common understanding of "best regulatory practice" (BRP), and promoting recourse to it, including increased transparency in regulations and standards, international standardisation, and the harmonisation of regulations amongst trading partners.

THE MECHANISMS OF TECHNICAL REGULATION AND THEIR RELATIONSHIP WITH TRADE

The main elements that govern the placing on the market of goods can be identified for the purposes of this paper, as:

(a) Technical regulations (laws) applying to the characteristics of products;

(b) Standards (drawn up by consensus), whether for voluntary application or incorporated into the legal framework in some way or other;

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2 COM(2000) 1 final of 2.2.2000.

3 Council conclusions of 26 June 1997, OJ C 8 of 11.1.2001, p.1-3.

4 Council resolution of 28 October 1999, OJ C 141 of 19.5.2000, p. 1-4.

(c) Certification requirements, determining how compliance with regulations is to be determined, including marking and similar procedures;

(d) Testing procedures for the actual determination of compliance, and related aspects, such as good laboratory practice, laboratory accreditation, and metrology;

(e) Market surveillance (including, where appropriate, product liability aspects).

Governments prescribe technical rules that apply to products; for a variety of reasons, such rules may relate to the characteristics of the products, and may also make provision for the certification that the product in fact complies with those technical rules. Of course, rules are adopted for legitimate purposes: the protection of safety and health, the environment, and so on; but they can also be misused as means of erecting protective barriers around the domestic market. For this reason the WTO TBT Agreement calls for technical rules and certification procedures not to be more trade-restrictive than is necessary for the objective being pursued, to be transparent and non-discriminatory, and for the use, where appropriate, of international standards. There remains, however, a need for further progress in its practical implementation.

CONDITIONS FOR OPEN TRADE

A fully-developed common market between two or more territories will have the characteristics that any product lawfully placed on the market in one territory will be equally freely marketed in the other, and conversely, that products that may not be lawfully placed on the market in one territory may not be so placed in the other. The obvious example is provided by the EU internal market. The recommendations of the TBT Agreement go some way towards achieving the situation described above. It must be borne in mind, however, that the concepts contained in the TBT Agreement cannot approach the situation of a common market, in the absence of a strong institutional framework to support it, that is, of legislative and administrative bodies such as the Council, the Parliament and the Commission, and judicial control such as that exercised by the European Court of Justice.

With this in mind, the most desirable situation, compatible with the provisions of the TBT Agreement, would imply the following.

1. Compatibility of approach

Approaches to product regulation should be compatible, if not identical, at least within defined product sectors. Where sophisticated systems of product regulation have emerged, there may be imbalances with less sophisticated systems (for example, with developing countries).

2. Coherence of regulation

Technical requirements (regulations) for specific products should be the same, or recognised as equivalent for the purpose of fulfilling the same regulatory objectives.

3. Coherence of standards

Standards, where they have either a regulatory impact or a major market impact, should be the same, or technically equivalent, or at least be recognised as fulfilling the same technical objectives not conflicting with each other.

This should perhaps be explained: standards, *strictu sensu*, are voluntary-compliance documents, drawn up in principle by a consensus of those who will use them, to reach technical objectives such as reducing unnecessary variety and providing known means of specification and levels of performance. Sometimes, as with the EU's New Approach and public procurement legislation, reference is made to them in laws; in many other cases, although entirely voluntary, standards in effect have some prescriptive force because they provide a fundamental reference for market participants.

4. Transparency and impartiality of regulation and standards

Both standards and technical regulations should be transparent and available to those who will use them, be based on recognised international work wherever appropriate, and not be such as to favour the products of one party over those of another.

5. Appropriate level of regulation

Technical regulations, and standards with regulatory or quasi-regulatory force, should be only as stringent as is necessary for the achievement of legitimate public policy aims (such as those set out in Art. 95 (3) of the EC Treaty for a high level of protection of health, safety, environmental protection and consumer protection), taking account of new scientific developments. The TBT Agreement provides that regulations and standards shall not be more trade-restrictive than necessary to fill a legitimate objective.

6. Transparency and impartiality in obtaining certification

Certificates, where required, must be available by procedures that are the same whatever the nature and nationality of the entity seeking them.

7. Recognition of certificates

Certificates, where required, must be recognised by all authorities impartially as giving access to the market. As a consequence of this, there must be transparency as to the nature of the bodies issuing the certificates and guarantees as to the quality of certificates. Where appropriate (for example, when certificates are granted by independent certification and assessment bodies rather than directly by public authorities), there will be a requirement for agreement on accreditation or other assessment of certification bodies, and on relevant metrology requirements.

8. Compatibility of market surveillance

Market surveillance procedures - both before and after sale - must work in practice. That is, they should be effective, compatible and impartial, and not favour the products of one entity over those of another.

9. Development of infrastructure

A country must have the capacity and infrastructure necessary to make the relevant systems work, including the capacity for regulation. The necessary certification bodies, standards bodies, laboratories and other facilities must exist and be sufficiently effective.

Imbalances between developed and developing economies may result in barriers to trade, for example where producers in developing economies cannot meet other countries' more sophisticated product regulations, or where developing countries' governments must rely on

ex ante rules for market access because they do not possess sufficient resources for effective *ex post* market surveillance. It will be difficult for developing countries to participate in this kind of co-operative trade facilitation measure until they have reached an adequate level of regulatory sophistication. The roles of technical assistance and capacity-building initiatives are important in this area.

WORKING TOWARDS THE IDEAL: A DIVERSITY OF MEASURES

The 1996 Commission Communication on *Community external trade policy in the field of standards and conformity assessment*, already mentioned above, formulates two "basic objectives", as follows.

"First, to reduce or prevent the emergence of new standards and conformity assessment barriers for industrial products in other markets. Secondly, to promote where possible, the adoption overseas of standards and regulatory approaches based on, or compatible with, international and European practices, in order to improve the market access and competitiveness of European products."

Sometimes the adoption of Community practice is complete. For example, the countries of the European Economic Area (EEA) have adopted all the *acquis communautaire* as it relates to the trade in goods. Countries that are candidates for accession to the EU have also committed themselves to adopting all the elements of the European system (since their intention is to become Member States, this will be necessary at the time of their accession in any case).

For other countries though, it may not be commercially profitable, or politically desirable or practical, to achieve such complete alignment in all the areas of the *acquis*. Other instruments are being explored by the Community and by other countries, such as mutual recognition agreements (MRAs). However, it has become increasingly clear that MRAs represent only one of a series of instruments, and that all trade facilitation instruments have implications for their practical implementation that need careful consideration.

Some tools for addressing each of the issues indicated above can be identified: for Nos.1, 5 and 8, regulatory co-operation; for No.2, harmonisation of regulation, international regulation, and recognition of equivalence; for Nos. 3 and 4, harmonisation of standards, international standardisation and recognition of equivalence; for Nos. 6 and 7, mutual recognition agreements, and for Nos. 8 and 9, technical assistance programmes (See Table 1 for a summary).

These elements are not, of course, entirely separate, and for that reason the correlations set out in Table 1 should be regarded as merely indicative. For example, harmonisation and regulatory co-operation are closely linked, and international standardisation has strong links both with regulation and with certification. The choice of measures will need to take coherence into account, together with other factors such as the level of trade between the parties and the technical infrastructure in those countries. It should also be remarked that all these instruments can be applied bilaterally, regionally or multilaterally.

Table 1.
An indicative list of tools for addressing regulatory issues

This table is intended to suggest measures that might be appropriate in each case; it is not exhaustive and the correlations set out are not mutually exclusive.

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

REGULATORY CO-OPERATION [5]

As has already been indicated, regulations, standards and conformity assessment procedures serve legitimate objectives, such as protection of safety and health, the environment, the promotion of quality, the control of unnecessary diversity in products, and the protection of consumers from deceptive marketing. On the other hand, they have a very substantial potential to impede trade. One purpose of regulatory co-operation is to reconcile these aims. Thus the objective quoted above, "to reduce or prevent the emergence of new standards", should be understood as being applicable where such standards constitute unnecessary [6] obstacles to trade.

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5 In line with the Commission Communication, this encompasses both multilateral initiatives for harmonising regulatory requirements and mandatory standards and for developing best practice in conformity assessment, and bilateral co-operation with the EU's trading partners in developing technical regulations, harmonising standards and regulatory reform.

6 It is assumed that the trade impact of regulation that is necessary to achieve the objectives of the regulation is proportional, and is compatible with the TBT Agreement (Art.2.2: "...technical regulations shall not be more trade-restrictive than is necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.").

The co-operative mechanisms that emerge will inevitably differ in the light of the nature of the products, historical factors (the previously existing structure of regulation), the compatibility of regulatory systems, and the extent of the will to open trade.

Regulatory co-operation is typically an informal process during which regulators consult with each other during various stages of the regulatory process. Such co-operation can be based on bilateral, regional or multilateral arrangements, and is often encouraged by industry willing to see governments agree on common solutions.

The major instrument already achieved in this area is, of course, the WTO TBT Agreement. In prescribing notification of proposals for technical regulations and standards programmes, and calling upon its signatories and their standards bodies to base technical rules, standards and certification requirements on international standards wherever possible, the TBT Agreement represents a major step forward. However, the breadth of its scope, and the number of its signatories, means that for practical reasons there must be a certain amount of "lowest common denominator" in its regulatory approach. It should also be observed that there is considerable scope to improve its implementation. Some progress has been made in two "triennial reviews" of the TBT agreement; however, other issues remain unresolved.

Bilateral, regional and inter-regional initiatives in this area also offer potential for advance. For example, principles on best regulatory practice agreed in the context of ASEM set out some useful guidance for consultation; an exchange of information is foreseen under the FTA between the EC and Mexico; and certain forms of co-operation are envisaged between the Community and the countries of Mercosur. Such initiatives could be regarded as a first step to the achievement of regulatory co-operation.

Particular mention should be made of *best regulatory practice:* efforts to establish a common understanding of the basic principles of good ways to regulate, such as exchanging information on trade issues, transparency in programmes, clarity of rules, fitting the regulatory approach to the objective of the regulation, and the like.

Another important element of regulatory development is transparency. The European Commission places great importance on the issue: bringing the legislator closer to its citizens and getting them fully involved in the process is a key priority. While the principles of transparency (such as public consultation and public access to official documents) are generally shared, the ways these principles are implemented differ widely. When regulators in different countries co-operate, it is therefore important that they are aware of each other's systems of addressing transparency aspects and their impact on the regulatory process.

Two further points should be made. First, agreements on paper need to be backed up by concrete implementation. Second, the EU itself should continue to be flexible in its regulatory system for trade in goods where mutual advantage can be gained by opening trade.

Practical measures in regulatory co-operation

The experience of the EU in the area of free movement of goods within the internal market has shown that many obstacles stem from lack of understanding of legal and market requirements. Removing such obstacles would be facilitated by the development and distribution of information on certification, accreditation and standardisation procedures. It is therefore useful to organise exchanges of information and institutional experience and specific requirements for sectors or product categories. Seminars, training sessions, joint visits, audits, surveys and information gathering can also contribute to the objective.

This can lead to an indirect "bench-marking" process whereby regulatory authorities are made familiar with other authorities' experience, and amend their regulatory practice as a result. The identification of good regulatory practices can also lead to regulatory transparency and enhanced market access. The EU is pursuing this line in bilateral fora such as the Transatlantic Economic Partnership (TEP) with the USA and in multilateral fora such as ASEM.

HARMONISATION

At the outset, it is perhaps necessary to underline the difference between harmonisation and international standardisation, though obviously they have strong similarities. In general, *harmonisation* may be regarded as the drawing up of common or identical rules by a group of authorities, with the intention that the mandatory rules governing a product or service shall be the same among them. *International standardisation* (in its broadest sense, i.e. including the drawing up of technical specifications by public authorities) has as its aim the elaboration of a common set of requirements at international level, with the involvement of those who have a legitimate interest in them: governments, economic entities such as industry, and users, without the intention that mandatory rules and technical practice should always be the same.

This distinction is necessary, for it must be recognised that international standards are not universally used, despite the call for their use in the TBT agreement as a basis for national and regional regulation and standardisation where appropriate. The coherence of regulations and of standards can be achieved through harmonisation, which has already proved its usefulness in the context of the EU internal market. Harmonisation, both of rules and of standards, has the advantage that it is clear that the rules are the same, and a supplier placing a product on the market can therefore be confident that the same rules are applicable whatever the jurisdiction.

Some international regulatory harmonisation is already in place. Organisations such as the Codex Alimentarius Commission, ICAO, IMO, and the like are already active in international rule-making on an inter-governmental basis.

Harmonisation, however, is a "maximal" option, that is not always practical or even desirable, for example because of its potentially high cost. Harmonisation of rules requires regulatory adaptation, either through bringing one party's rules into alignment with another's (as is the case with the applicant countries) or through the development of entirely new rules. Such procedures are costly, both in administrative terms and for suppliers of products that must conform. In addition, attempts at harmonisation can run into political problems; for example, different regulatory systems may not be compatible, and administrations may not wish to bring their regulatory systems into line with what may be perceived as alien requirements, or may encounter difficulties in persuading their legislatures of the expediency of doing so.

Finally, harmonisation does not imply mutual recognition of certificates. It is one thing to set out rules that are identically the same, or technically compatible; it is another to accept that products conform with the rules. Even when the rules of two countries are the same, the acceptance of certificates of conformity with them by one country is based on that country's trust in the conformity assessment procedures of the other. In effect, therefore, to achieve full compatibility in regulated areas, harmonisation of regulations and standards will need to be matched with mutual recognition of certificates of conformity, and market surveillance mechanisms on the parties' territories must allow for the placing on the market of goods that conform to the commonly agreed rules.

RECOGNITION OF EQUIVALENCE

Even where regulations or standards differ, progress towards mutual opening of markets may be possible if they are recognised as equivalent. Where the regulation in each territory has the same regulatory objective as that in the other, and the two sets of regulations both actually fulfil this objective, the authorities can agree to regard them as equivalent. Then, they can agree that products conforming to the other party's regulations (where necessary, including relevant conformity assessment and certification procedures) can be placed on the market in the territory of either party as though it conformed to the rules in force there.

While potentially a powerful tool, and one recommended by the WTO TBT Agreement, this mechanism can be technically complex in practice, which perhaps explains why it is little used. First, the *objectives* of a regulation have to be set out (this is done for EU legislation), then they have to be agreed as being equivalent, and finally agreement has to be reached on their mutual acceptability. This is a complex process, not least because it has to be done in detail, sector by sector; in addition, any substantial revision or updating (for example, to take account of technical progress) is likely to make a new determination and recognition of equivalence necessary. For these reasons, this relatively simple principle cannot be considered of general applicability. Where it can be applied, however, it is a valuable instrument of trade facilitation while fully respecting the regulatory autonomy of the parties.

Where harmonisation is considered feasible, it is generally considered as a better tool than equivalence. Nevertheless, harmonisation risks being a longer process than recognition of equivalence. Moreover, there may be non-technical reasons why harmonisation is not an option, where equivalence would help achieve a very similar result in terms of trade facilitation. On the other hand, where technical regulations differ radically, in particular in terms of the objectives they seek to achieve, it is likely that a determination of equivalence will not be possible and that harmonisation will prove unfeasible.

With recognition of equivalence (which can be mutual or unilateral), a country accepts that imported products that meet the applicable technical requirements of the exporting country are placed on its market as if they met its own applicable technical requirements. Recognition of equivalence of standards may be envisaged in situations where no relevant international standards exist or their completion is not imminent. As an interim measure until suitable international standards are developed, standards originating from other trading partners could be accepted as equivalent even though these standards are different from the domestic ones.

Recognition of equivalence does not imply, *per se*, recognition of conformity assessment. It does make sense, however, to combine the two, both in terms of trade facilitation and in terms of regulatory efficiency. Together with recognition of conformity assessment, recognition of equivalence of technical regulations ensures that a product needs to comply with only one set of technical requirements and is tested and assessed only once, by the public or private conformity assessment bodies that are most familiar with the requirements against which the product is being assessed.

In order to achieve this result, however, two sets of conditions must be fulfilled.

First, the technical regulations must be equivalent in their regulatory objectives. This can be determined either if the objectives are set out explicitly, or if they can be determined in detail from the regulations themselves. The objectives should be very similar, if not identical, and the requirements of each set of regulations should be capable of meeting the regulatory objectives of the other. These conditions are more likely to be met, in practice, when the two

sets of technical regulations are based on very similar standards or the same standard (for instance, international standards).

Second, the two parties must have confidence in the conformity assessment infrastructure of the other party, in terms of technical competence, honesty, impartiality, independence, etc., of the conformity assessment bodies of the other party.[7].

Case study: instances of equivalence

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

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

MUTUAL RECOGNITION AGREEMENTS

Mutual Recognition Agreements are agreements on the mutual recognition of conformity assessment of regulated products. Through an MRA, each importing party is given the authority to test and certify products against the regulatory requirements of the other party, in its own territory and prior to export. In cases where countries require mandatory third-party certification of specific products, each importing party agrees, by the terms of the MRA, to recognise the tests, certificates and approvals issued by agreed conformity assessment bodies of the exporting party, and the products can be exported and placed on the other party's market without undergoing additional procedures. The mandate received in 1992 by the European Commission on MRA and the following 1994 and 1998 negotiating directives authorised negotiations on a bilateral basis. This has made possible the MRAs currently in place, and (with a supplementary mandate) the Transatlantic Economic Partnership (TEP) actions with the United States. The mandate from the Council to the Commission to negotiate mutual recognition agreements indicated the objective that the third countries concerned will conclude with the EEA EFTA States parallel agreements equivalent to those to be concluded with the Community. The system of parallel agreements protocols formally grants the third country concerned the same market access throughout the European Economic Area for products covered by the mutual recognition agreements.

MRAs do not require or presuppose harmonisation of each party's technical requirements, or recognition of their equivalence. Each party is free to set its own regulations or standards, though the partners to an MRA must obviously have concepts for product testing and

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[7] It is worth pointing out the difference between recognition of conformity assessment in the contexts of equivalence and of MRAs. In both cases, the parties must have confidence that the conformity assessment bodies of the other party (public or private) present certain characteristics: adequate qualifications and training of their personnel, impartiality, independence from vested interests, technical competence to carry out tests, etc. Under an MRA, the conformity assessment bodies of the exporting party must also understand the requirements of the importing country and be competent to assess products for conformity with such requirements. Under equivalence the conformity assessment bodies of an exporting country assess the conformity of a product with the requirements of that country; thus, they do not need technical competence additional to what they need in the domestic context.

approval that are broadly compatible, and each party must have comparable - or at least mutually acceptable - systems of certification and underlying technical infrastructures. Once established, the MRA will need to be maintained, for example by keeping lists of recognised certification bodies, and the standards or rules against which they must certify.

The benefits arise from removal of duplicated inspection or certification. Where a product intended for two markets may have to be assessed twice (when technical requirements or standards are different), the assessment would be cheaper when carried out by the same body. The time to market is reduced since contacts between the manufacturer and the conformity assessment body, and a single assessment, speed up the process. Even where the underlying regulations are harmonised, for example on an international standard, the need for recognition of certificates remains, and in such cases the benefit will be clear: the product is assessed once against the commonly accepted standard instead of twice.

Other benefits include increased transparency (all procedures have to be clearly laid down); furthermore, contacts between regulators may lead to some harmonisation, and transparency in procedures ensures greater predictability, which makes it easier for companies better to plan their market strategies.

Multilateral mutual recognition arrangements

Internationally in recent years multi-lateral agreements or arrangements have begun to be concluded, either at government level or by regional organisations. The underlying rationale is to extend to a larger number of trade partners the benefits of easier market access. However, because of the involvement of a large number of parties, these arrangements often lead to increased complexity (owing to the wider range of differences in each system).

The contents of this type of MRA are often different in nature, involving either a limited number of sectors or partial recognition leading to a lower level of trade facilitation. This is the case for most of the existing multilateral arrangements on mutual recognition, where the scope is generally limited to acceptance of test reports performed by a laboratory in the territory of one party by the other parties, based normally on the use of commonly agreed or international standards.

Case study: the APEC MRA

The Asia-Pacific Economic Co-operation (APEC) MRA represents the best known example outside the EU of a multilateral agreement. APEC [8] has given its support, through the Osaka Action Agenda, to the development of multilateral and bilateral mutual recognition arrangements in the APEC region. There are four sectors.

(a) The *APEC Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products* (APEC Food MRA) consists of a framework arrangement (the "Umbrella Arrangement") and separate implementation arrangements (Sectoral Arrangements). The Sectoral Arrangements involve the acceptance by an importing party that foodstuffs conform with that party's requirements.

(b) The *APEC model Mutual Recognition Arrangement on Automotive Products* is not an arrangement in its own right, but a template or *pro-forma* to be used by member

[8] APEC, established in 1989 in response to growing interdependence among Asia-Pacific economies, began as an informal dialogue, but has since become the primary regional vehicle for promoting open trade between its 21 member economies.

economies in entering into bilateral arrangements. Each party guarantees that products exported under the arrangement comply with the list of harmonised standards specified in the arrangement. The harmonised standards will be based on the equivalent UN/ECE standards.

(c) The *APEC Mutual Recognition Arrangement on Conformity Assessment of Telecommunication Equipment* (APEC Tel MRA) comprises a framework arrangement and two conformity arrangements (one relating to test reports and the other relating to certificates). Member economies are free to participate in whichever of the conformity arrangements best suit their regulatory régime.

(d) The *APEC Mutual Recognition Arrangement on Conformity Assessment of Electrical and Electronic Equipment* (APEC Electrical MRA), like the Tel MRA, deals with the recognition of test reports and certificates; however, the provisions are contained within a single document.

Selecting an MRA: a review of experience

The costs and benefits of MRAs have to be regarded in the light of political and commercial competition aspects. The Commission's experience is that MRAs are only worth negotiating in the following circumstances:

(a) where certification systems are not too different in principle and in practice; and

(b) where there are substantial, functioning regulatory, standards and certification infrastructure and market surveillance infrastructures and capacities, that are comparable and compatible with those of the EU; and

(c) where trade between the parties is sufficient to justify the cost involved in setting them up; and

(d) where the trade that is being liberalised offers some opportunities to open markets to EU industry as well as to that of the third country, since political support from industry is evidently necessary if trade liberalisation measures are to gain support.

MRAs do not remove some serious technical barriers to trade. In some sectors, certification activities are subject to restrictive government control. There may be technical regulations that for political or other reasons are not susceptible to modification. There may be market sectors in which, although products are in theory not subject to mandatory certification, it is inevitable in practice, for example for market reasons (customers may demand certified products even though uncertified products may be lawfully placed on the market).

MRAs cannot resolve such issues. They are a trade facilitation tool, for use when the potential partners have paved the way by bringing their systems close enough to make MRAs workable, while either not addressing questions of harmonisation, or accepting that harmonisation is too remote an objective to be practicable within any reasonable time-frame.

PARTIAL, VOLUNTARY, REDUCED OR LESS FORMAL TYPES OF MUTUAL RECOGNITION

Mutual recognition agreements require confidence on the part of each party, that the systems for certifying products in the other are effective and can be relied upon to deliver an appropriate level of protection. This confidence may take some time to establish, since the authorities of each party are effectively placing part of the task of enforcement of technical

rules in the hands of bodies over whom they have no direct control (though they may be said to have a degree of indirect control through their relations with the authorities of the other party), and resistance to this is understandable where a product may present a potential hazard.

In effect, the parties to an MRA have agreed to share some degree of control over their home markets in the relevant product area in exchange for the other party doing the same. At early stages in the operation of such an agreement, they may be unwilling to surrender a part of their discretion to regulate their own markets.

In addition, if one party lacks the necessary technical infrastructure for an MRA, this may not be the most appropriate instrument, for it requires comparable levels of technical infrastructure. A country with a more developed infrastructure may be able to deliver the requisite certificates to another country, but if the latter has a less developed certification infrastructure, its conformity assessment bodies may well not have the capacity to deliver certificates that can be relied upon by the other party. On the other hand, the less developed partner may have strict rules regarding control at import that substitute for the lack of an effective market surveillance mechanism.

Mutual recognition can be broken down into a number of elements, which the classical MRA includes as a package. However, if it is regarded as premature to conclude an MRA, or if the political willingness or technical resources for doing so are wanting, it may be possible to identify certain elements that can be applied separately, on a stand-alone basis or as part of a group of measures that fall short of a complete MRA. An "MRA by steps" might consist of an umbrella agreement with phased supplementary agreements to achieve regulatory co-operation, mutual recognition, or other objectives. Political willingness to reach an MRA might be helped by a "package" approach in which each side can gain a part of its wants in exchange for concessions from the other.

For example, in the pharmaceutical sector, good manufacturing practice (GMP) or good laboratory practice (GLP) may be treated as part of an MRA; but they could be the subject of a stand-alone agreement (one on GLP has been reached with Israel). The traceability of measurement standards offers another area for co-operation. If the measurement standards used by laboratories on the territory of one party are regarded as acceptable by the other, it will facilitate the acceptance of test results.

Accreditation

One area particularly susceptible to development is accreditation: one of the more common means by which a body is recognised as competent in certification, testing and associated functions. In general, certification bodies are accredited to grant certificates of conformity by an accreditation body in their own country or region. The certification may be based on testing by accredited test laboratories, similarly accredited to carry out tests for their own country or region.

The increasing development of contacts and agreements between accreditors is a reality and this can certainly play a relevant role as a support to trade facilitation activities in the area of conformity assessment.

However, there is no *a priori* reason why accreditation should be so limited; and, in theory, a system or arrangement could be set in place by which laboratories on the territory of one party were accredited by the accreditation body of the other party to grant certificates of conformity

with the other party's technical rules. This would make it possible to extend the area in which certificates of conformity are accepted, and in general would facilitate trade by making certification administratively easier to obtain. But such an arrangement would need to be carefully designed, and would in any case require a similar degree of trust between parties. This is perhaps a matter to be explored further in the light of experience with the existing MRAs.

Voluntary agreements between accreditors, certifiers, and test laboratories are already increasingly being set up. They take account of common experiences, and create networks for interchange of information, technical work and practices. Such activities are applied on a voluntary basis by non-governmental parties, though governments can play a role in supporting and facilitating agreements. Support can be provided directly, by promoting or financing exchange of information and organisation of events, or indirectly, by establishing or recognising a role for the existing schemes in bilateral or multilateral agreements.

In addition, there is already a whole range of sub-contracting agreements in existence between testing laboratories and certification bodies. In such cases, while the leading organisation keeps the responsibility for whole or part of the conformity assessment, the partner laboratory carries out most of the product testing. This type of agreement is also very common at international level, between organisations located in different countries.

Case studies: examples of accreditation activities [9]

At the regional European level, EA (European Accreditation) members can apply for peer-group evaluation of their activities. Successful members may sign the appropriate multilateral agreement (MLA) for accreditation as certification body, laboratory or inspection body under which they recognise and promote the equivalence of each other's systems and of certificates and reports issued by bodies accredited under these systems. EA promotes the recognition and acceptance in all the MLA countries of certificates and reports issued by organisations accredited by national accreditation bodies who have signed the MLA. The EA MLA aims at achieving a uniform level of competence of the accredited bodies involved and to diminish or eliminate the need for multiple assessments.

The developing system of multilateral mutual recognition agreements between laboratory accreditation bodies within ILAC (International Laboratory Accreditation Co-operation) based on peer reviews enables accredited laboratories world-wide to achieve a form of international recognition, and allows their test data accompanying exported goods to be more readily accepted on overseas markets.

Similarly, the IAF (International Accreditation Forum) is establishing multilateral mutual recognition agreements globally based on the equivalence of conformity assessment body accreditation programmes operated by accreditation body members, verified through peer review among those accreditation body members. The primary function of both ILAC and the IAF is to develop voluntary world-wide recognition by setting programmes with common criteria for accreditation and conformity assessment, which contribute in the elimination of non-tariff barriers to trade. This effectively reduces costs for both the manufacturer and the importers, as it reduces or eliminates the need for products to be re-tested in another country.

[9] EA (European Accreditation) is an organisation of national accreditation organizations in Europe. ILAC (International Laboratory Accreditation Co-operation) unites laboratory accreditors at world level; IAF (International Accreditation Forum) is its analogue for certification bodies.

> The IECEE-CB Scheme is a multilateral agreement among participating certification organisations in many countries. Countries that are members of the International Electrotechnical Commission IEC, may join the Scheme and can designate National Certification Bodies CB. The scheme uses Certification Bodies Test Certificates to attest that product samples are in compliance with the requirements of relevant IEC standards and with the declared national deviations existing in various member countries. The Scheme is therefore based on the use of international IEC standards, and the transparent exchange of information of any deviation from those standards that can be nationally applied. A manufacturer utilising a CB test report issued by one of the member certification organisations can obtain easy national product certification in all other countries of the scheme.

Co-operation on the development of standards

Co-operation on the development of standards is also of value, for though in general standards tend to enshrine existing technical practice, it will be economically beneficial for technical practices to converge.

While measures of this kind fall short of actual harmonisation, nonetheless they serve to build up confidence and develop an environment that is, over the medium to long term, conducive to the convergence of technical rules. Once confidence has been built up, more elements of mutual recognition and convergence can be introduced, if necessary sector by sector.

INTERNATIONAL STANDARDISATION

In addition to the harmonisation of regulatory requirements, international standardisation has become important as a means of establishing technical requirements at the international level, in principle for voluntary application. The classical international standards bodies IEC and ISO have been established for many years, and have established a position at the world level. Particularly in the case of the IEC, it may be said that internationalisation of the technical practice in the area it covers (the electrotechnical sector) has been a substantial success, at least in some areas (for example, the standards according to which electrical equipment is built are much the same across the world).

As mentioned above, the WTO TBT agreement gives a certain priority to international standards – where they exist - as a basis for technical regulation (by governments) and for national and regional standardisation (by recognised standards bodies at the national and regional levels). But this is by no means an absolute requirement, and can be deviated from where appropriate where the WTO Member has a legitimate reason for doing so. Such reasons, however, must relate to the legitimate objective of the regulation or standard. Of course, if international standards are lacking, WTO Members are free to standardise or regulate as they see fit.

International standardisation has some advantages: a single solution agreed across the global economy will open trade to the extent that it unifies technical practice, provides a globally accepted reference, and promotes the economic benefit that derives from the elimination of divergent though technically equally valid solutions while leaving room for competition of diverging products.

Nonetheless, there continue to be problems with the international standards system as it has evolved. One is the proliferation of bodies: the OECD and the WTO have both identified a large number of organisations that draw up technical specifications for international use, for

example, IEC, ISO, ITU, OECD, UN-ECE and OIE all made presentations at a WTO meeting on the subject. New bodies continue to emerge, such as GHTF, W3C and IETF [10]. In some cases, the members of these bodies are governments; in others, standards bodies; in others, industry federations or even individual commercial enterprises. Although the position in this respect remains not entirely clear, some basic principles for the development of international standards have emerged from the WTO Triennial Review of the TBT Agreement and it is to be hoped that they can now be developed further.

Furthermore, there is some difficulty in establishing timely responses to regulatory needs. The international standardisation process can be painfully slow (typically four or five years from proposal to publication); and priorities do not always appear to be set by the needs of international trade. As a result, even the EU, which is the leading participant in international standardisation, and has a strong commitment to it, has made relatively limited use of international standards as the basis for technical legislation and the opening of trade.

In addition, there is still no established mechanism by which governments can call upon the international standards bodies (as distinct from inter-governmental bodies) to draw up international standards that can then be used in support of a common regulatory structure. Work towards devising a mechanism to do this is under way in the context of the UN Economic Commission for Europe. However, it is at a preliminary stage, and support at the world level is yet to be sought.

In short, it may be said that international standardisation offers a potential route towards commonality in the regulatory environment. This is to an extent demonstrated by the experience of the EU in using regional standardisation as a tool for the development of its own internal market. At present, however, the effectiveness of international standardisation is somewhat limited, though active efforts are being made to pursue it within international standards bodies, and to improve alignment of national standards on international ones in a number of fora. In general, Europe is strong in international standardisation, and this tool offers Europe an opportunity to promote its system. To this end, the Council has requested the Commission to develop guidelines for a European standardisation policy in the international context. [11]

TECHNICAL ASSISTANCE

The aims of technical assistance

Technical assistance offered by the EU in the context of programmes whose main objective is to pursue targets based on broad EU objectives, the partner country's policy agenda, analysis of the partner country's situation, and the activities of the major partners. Particularly in the case of developing countries, the system of trade preferences is not the only element to favour the development of exports. Technical assistance to develop the supply side is necessary;

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[10] OECD: Organisation for Economic Co-operation and Development. ITU: International Telecommunications Union. UN-ECE: United Nations Economic Commission for Europe. OIE: Office International des Epizooties. GHTF: Global Harmonization Task Force. W3C: World Wide Web Consortium. IETF: Internet Engineering Task Force. All these organizations – and many others – make specifications, standards or technical regulations (the difference is not always entirely clear) at the global level.

[11] Council Resolution of 28 October 1999, OJ C141 of 19.5.2000, p. 1-4.

technical assistance in the field of standards and conformity assessment can contribute to ensuring that requirements for products are met.

In this context, the type of assistance will depend upon the situation and the level of development level of the recipient country. In addition, the results of that assistance should be sustainable with the recipient's own resources.

Technical assistance actions can aim at reducing TBTs; and raising awareness of TBTs and the need to reduce them; helping recipients to fulfil EU requirements; at preventing the export of unsafe products; at the preparation of agreements to reduce TBTs; at preparing recipients for membership of the WTO; at helping recipients to implement the TBT agreement effectively; at preparing recipients for MRAs or free trade agreements; at gaining support for the EU approach; at building up necessary institutions and other facilities; and at the encouraging economic and social development of the recipient country. This list is not exhaustive: there may be other reasons for technical assistance.

Such programmes can help developing countries to develop a regulatory, standards and conformity infrastructure; to encourage the adoption by developing countries of international and European standards, to improve their infrastructure and set up accreditation and standardizing systems, and to train officials in developing technical regulations and standards. It is in the interest of both the Community and the third country in question to be helped to produce better quality or safer products, so that developing countries' products can be traded with developed countries in full compliance with relevant requirements for the protection of health, safety, etc. The Community also has an interest in promoting consumer demand in third countries for high-value Community products.

Some partner countries have now reached a stage of economic and industrial development where basic infrastructures - such as a functional standards body, a range of basic industrial standards, and testing laboratories - are in place. Assistance may therefore be directed towards areas such as improving the regulatory regime for specific sectors, refining the infrastructure necessary for mutual recognition agreements to be concluded, and promoting European and international regulatory approaches, including approaches to conformity assessment. Where technical conditions are met, mutual recognition can be one of the objectives. The Community's own single market experience may provide a relevant model for many areas of the world considering regional systems.

Types of technical assistance

Independently of what assistance is provided, the recipient has to have the capability and motivation to take advantage of and apply the results of the assistance. Two most effective methods are "learning by doing", and exchanging experiences in practical work. When the recipients' needs and priorities are not clear, assistance for assessment of the situation might be a good starting point. Support for investment requires that necessary structures and resources are in place.

Assistance might take the form of assessment of the situation in the country, enabling developing countries to assess their needs and priorities; information seminars and workshops; awareness conferences and campaigns; training courses, including training trainers; "hands-on" training in European public and private organisations; participation in the work of international organisations; regional co-operation activities; expert advice; institution-building (creating and reinforcing relevant organisations); and investment.

Where the aim of the assistance is to reduce technical barriers to trade, EU policy is to spread the European approach to reconciling regulatory and trade objectives. Accordingly, assistance may focus on the New and Global Approaches; harmonisation of legislation and regulations; standardisation, accreditation, inspection, testing and certification (and conformity assessment in general); marking, metrology and market surveillance. Target groups include public authorities (including customs services), standardisation accreditation and conformity assessment bodies, economic operators, including manufacturers and trade organisations, testing laboratories and consumer groups.

Delivering technical assistance

EC technical assistance is usually provided as grants, though there may be a requirement for the recipient to pay a share of the investment (typically 25 %). EU financing of the assistance may be through multi-annual programmes with projects and sub-projects, or as single projects. Agreements for assistance can be made at different levels, for example, government to government, region to government, region to region, private organisation to private organisation, or within multinational private organisations.

In deciding on technical assistance, it is necessary to take into account such factors as: co-ordination with other assistance projects, completed, existing or planned; the possibility of pooling resources for funding; the possibilities of regional co-operation, and other bilateral and international assistance; the state of existing institutions and other facilities; whether the recipient is member of WTO TBT, and where appropriate, its fulfilment of its obligations under the TBT Agreement and other TBT problems; the long term (about five-year) infrastructure strategy, the priorities and realism of present development plans and proposed projects, including financing and human resources; the sustainability of the results of proposed assisted activities; the management of such activities, and political considerations.

Case studies: some EU technical assistance projects

(a) A project on *Standards and Conformity Assessment for a non-candidate Eastern European country* is intended to facilitate the transition to a market economy, and integration of the country and its companies into the global economy. Assistance will be provided to help bring about a significant reduction in the number of products subject to compulsory pre-market third party certification; where appropriate, to introduce manufacturer's declarations of conformity; to help draft horizontal legislation, in particular on conformity assessment and product safety; to help in consolidating the distinction between compulsory technical regulations and voluntary standards; to help in any matter related to compliance with the WTO TBT agreement (in particular, the operation of the Enquiry Point); to cover organisational matters within the standardisation body, and between it and other organisations involved in activities in the field; and to acquaint officials with the implications of the move towards EU and international systems of standardisation and conformity assessment.

(b) *A project on Standards and Quality in an Asian least developed country* has the objective of contributing to efforts in the country's transition to a market economy. The specific purpose is to improve quality at institutional and enterprise level. Assistance is provided to strengthen the quality structure of industry; encourage and facilitate the understanding and use of standards and technical regulation by industry, particularly in the context of exports; provide industry and regional centres with well based and reliable metrology and calibration services; provide companies with internationally recognised and accepted testing and product certification services; improve the quality of products through introduction of a quality management system

based on international standards and certification; and establish a national accreditation scheme for laboratories and certification bodies.

(c) A South American regional programme provides technical support to countries in the region for activities and co-operation in the quality infrastructure field. It includes financing participation of technical experts in international meetings and knowledge transfer from Europe. "Sub-projects" cover training of quality auditors and quality trainers; assistance to SMEs to obtain quality certification according to ISO 9000; assistance to set up national information and notification systems in the participating countries; support to the participating countries for developing regional standardisation activities and applying the European INES system; assistance to develop certification and accreditation systems according to international models; creation of consistent legal and industrial metrology and reinforcing capabilities in these fields in the participating countries; and reinforcing regional information centres for SMEs in the field of standardisation and quality.

These three examples contain a variety of components; however, all contain the characteristic elements of support for information and training, development of legislation and regulations and implementation by setting up and improving procedures and developing organisations.

When the development of the basic quality infrastructure has progressed, technical assistance for specific issues such as participation in international work, solving trade problems and support for investment become more widespread. It should be recognised that despite the existence of typical patterns, the situation of each potential recipient is unique.

IMPLEMENTING SYSTEMS

It is not sufficient to make agreements; there must be reasonable confidence that they will be adhered to. Experience has demonstrated that if the capacity, or the political will, to implement an agreement is missing, then the agreement itself will remain merely words; and a well-intentioned agreement that goes beyond the ability or willingness of any party to implement it will do more harm than good, since the entire concept will become discredited.

Consequently, any agreement to facilitate trade should be accompanied by genuine readiness, capacity and willingness to implement it. This implies, among other things, that the relevant bodies (for example, legislative or governmental entities) in both parties to a negotiation ought to be involved in it, and there should be a reasonable expectation that they can and will implement the results. Ultimately, agreements of this type depend upon the commitment of the parties to carry them out, and it is better to determine what can realistically be delivered, rather than to agree an ambitious programme, only to find that what can be agreed on paper cannot be implemented on the ground.

CONCLUSION: SELECTING THE RIGHT INSTRUMENT

Analysis of trade facilitation measures in the area of technical regulation, conformity assessment and certification shows that a range of instruments is available. Selection of the right instrument will depend on the characteristics of the markets, the regulatory environment in the third country or region concerned, and the willingness on the part industries, regulators and other parties to achieve the agreed objectives.

In any case, the sectors in question should offer clear opportunities to facilitate access by EU industry to foreign markets; at the same time it should guarantee the functioning of the EU

internal market without undermining its principles. Trade facilitation measures can also be used to promote the regulatory approaches experienced in the EU, which have proved their advantage in the establishment of the single market. Different sectors will often have different needs. For example, if there is an established corpus of international rules already in place (the example of marine equipment has already been quoted), then harmonisation and / or equivalence can be based on such rules.

Particular characteristics of the partners to an agreement

Asymmetries in requirements between the partners may be an obstacle in particular sectors. They may arise from differences in regulatory practice, for example, *ex ante* certification, active market surveillance by governmental agencies, or *ex post* product liability based on the aggrieved customer's right to sue the supplier. They may also arise from fundamental differences in technological practice. Such problems may not easily be reconcilable by recognition of certificates or common standards, particularly if one party maintains a more liberal régime than another. One avenue to explore in this direction is the possibility of *multi-sectoral agreements*, possibly involving different instruments. But this will require a substantial degree of administrative sophistication, and will clearly be more difficult to accomplish than a simple mutual agreement in a single sector.

If several trading partners have economies that are well integrated with one or more other local partners, then a further problem may arise in making an agreement with one, without making agreements with all of them. If trade between the EU and a particular country is facilitated, for example through an MRA, and if the partner country is a regional trading centre, full of goods being exported or imported elsewhere, then goods in the partner country originating from its local partners will enter the European market on the back of the MRA, though the local partners have made no similar agreement with the EU, and therefore EU exports to these countries will not enjoy the same advantages. "Rules of origin" or similar provisions are likely to be ineffective, because the EU will have no means, and the partner country no incentive, to enforce them. The decision to conclude an agreement with such countries must bear this risk in mind; either the possibility of facilitating trade on an asymmetrical basis "through the back door" will have to be tolerated, or agreements with such trading centres may have to depend on the ability to make agreements with all of the local partners.

An approach to identifying the tool to use

The EU is already actively engaged in a substantial number of activities, in all of these areas, some of which have been described in detail above. As well as the MRAs in place or planned, there are other activities, such as the ASEM dialogue on standards (as part of ASEM's Trade Facilitation Action Plan) and the Transatlantic Economic Partnership. Through agreements with the European standards bodies, the EU is a major supporter of international standardisation, and is active in the WTO Technical Barriers to Trade (TBT) Committee.

Future trade facilitation activities should continue to make use of all the various tools that are available. A *systematic approach* to identifying the tool to use might be based upon an assessment of the potential for increased trade; the nature of the barriers (different standards, certification procedures, market surveillance capacity, etc.); the political will among the parties to reach a solution (for example, if a government agency in a particular country is known to be systematically uncooperative, it may not be worth the effort if the agency's co-operation is needed in another sector); the desire among economic operators for an agreement; and the relative regulatory capacities of the parties.

At the same time, factors other than trade will need to be taken properly into account. For example, where regulation has a legitimate aim such as safety, any moves intended for trade facilitation must leave the necessary level of protection in place. Furthermore, the parties to an agreement may find it politically necessary to maintain a degree of regulatory autonomy.