Setting Standards: Strategic Advantages in International Trade

Michelle Egan

Among the most important technical barriers to trade are the different standards, testing and certification measures for products and services. Efforts to co-ordinate these within Europe – including the EU’s increasing reliance on private sector standards bodies – are now underway. The EU’s single market has not only integrated national markets, but has also shaped trading principles at the international level. The EU has exported its trade principles to third country markets and European companies have gained strategic advantages in influencing standards both internally within Europe and externally at the international and transatlantic level. Firms should invest resources and actively participate in setting standards to protect and increase their competitive advantage.

Standards are becoming “the new guns in global competition” (Cargill, former Standards Director of Netscape). Over 25,000 firms as well as consumer organisations, trade unions and others are involved in setting standards in the EU alone. The output of standards has increased – and firms have increasing responsibility in shaping them. They are important for business strategies and resource allocation (Table 1, overleaf). Yet they often get little attention even among public affairs or management units within companies, let alone from top management. Perhaps because they are often so technical, standards, certification and testing are usually handled by specialist middle managers: usually an engineering unit or R&D division.

Not only have EU firms become more engaged in standard-setting in Europe; they have also used this opportunity to exercise “first mover advantage” in shaping markets outside the EU. Trade disputes are driving demands for a deeper understanding of the relationship between standards and trade, and the approach employed in internal market harmonisation by the EU deserves greater attention as it has provided a driving force for other international agreements. Most standards used to be developed at the national level. But this is no longer the case. In the EU, new regulatory strategies have been adopted, especially since the 1980s (Falke 1996). When European
standards are implemented or transposed to the national level, any competing national standards have to be withdrawn. Any firm outside the EU has to abide by EU standards as well as local national standards if it wants to access the EU market, as many a US company has discovered to its cost. The development of EU standardisation has particular implications for Central and Eastern European (CEE) countries planning to join the EU. US companies increasingly complain that the EU has too much influence on the standards-setting process worldwide. Mandatory regulations are imposed by governments on the characteristics of a product or its production process to meet policy objectives – health and safety requirements, for example. Standards are voluntary specifications emanating from market forces. While lacking the force of law, standards may also hinder commerce because firms, customers and suppliers will not accept products and services that do not conform to local standards or certification marks (Sykes 1995). Standards and regulations are increasingly at the forefront of trade disputes. Higher standards are often challenged as disguised protectionism and lower standards characterised as social or environmental dumping.

Managing these technical barriers is not easy either for governments or for companies. Increasingly, however, both recognise the benefits of a level playing field and have mounted co-ordination efforts. These can have significant implications for business policy and strategy, providing opportunities for new high-value-added activities, and promoting innovative products or new production processes as firms seek to capture the benefits of a single set of manufacturing standards and practices. However, measuring the efficiency gains from removing barriers is difficult. It needs an in-depth knowledge of the structure of individual industries, including the relationship between market demand and price, and the shape of the cost curve (CEPS 1992). Few quantitative assessments of the dynamic effects of removing barriers have been made, beyond an ad hoc reduction in trade costs (for exceptions, see Brenton et

Table 1

Benefits of Standardisation

- Reduce costs through simplification of large-scale production processes
- Provide production information and facilitate buyer-seller relationships
- Promote market information and confidence by signalling product quality, or compatibility of products or components
- Reduce liability and insurance costs
- Enable firms to exploit economies of scale
- Reduce costs of learning if certain items are standardised
- Facilitate competitive corporate strategy, efficient management and effective commercial decisions if firms adopt quality standards and quality assurance schemes to enhance product reputation.

Disadvantages of Standardisation

- Reduced product variety
- Costs of compliance through product re-design, and registration or certification costs to meet necessary standards
- Locking in a particular technology that may be obsolete or sub-optimal (for example, QWERTY keyboard). This is especially problematic for products with short technical life-cycles

Source: Based on Pelkmans (1987), CEPS (1992) and Egan (2001)

EU market is still fragmented. Particularly in some sectors, the differences in regulations, standards, testing and certification requirements discourage competition and cross-border trade (EC 1996). These technical barriers affect businesses' production, sales, marketing, and R&D policies through their impact on product redesign and production reorganisation (Table 1). Research by the European Commission (EC) has estimated that about 80% of intra-EU trade is influenced by technical barriers to trade.

These technical barriers include both mandatory regulatory or legislative requirements established by governments and non-mandatory requirements such as standards and certification marks established by trade and industry federations, professional and scientific associations (EC 1998). Mandatory regulations are imposed by governments on the characteristics of a product or its production process to meet policy objectives – health and safety requirements, for example. Standards are voluntary specifications emanating from market forces. While lacking the force of law, standards may also hinder commerce because firms, customers and suppliers will not accept products and services that do not conform to local standards or certification marks (Sykes 1995). Standards and regulations are increasingly at the forefront of trade disputes. Higher standards are often challenged as disguised protectionism and lower standards characterised as social or environmental dumping.

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Most of the research in this area tends to consider the trade effects on particular markets or industries, focusing on case studies of specific disputes over products like compact disks, high definition television, or third generation mobile telephony (Pelkmans 2001, Lembke, forthcoming).

The importance of technical barriers can also be judged from the trouble firms take to avoid them. At the least, they complain to their trade associations and governments. For example, within Europe, there have been complaints against the ban on sales of recycled packing in Denmark, and the German preference for refill quotas for beverages. The case of the toy industry shows how standards can still create problems even within the single market (see box). Examples of troublesome issues for EU exporters to third countries are the extensive health declarations the US requires on timber packaging, additional certificates for electrical appliances in Saudi Arabia, and restrictive kosher certification requirements for exports to Israel. For US exporters to the EU, a cause célèbre is the US gas appliance manufacturer Dormont.

Like other forms of trade protection, many of these requirements favor domestic producers over foreign competitors. For example, the specification of building tile thickness by the French standards body AFNOR hindered Italian and Spanish competitors, and was compounded by the refusal of French insurance companies to provide coverage to tiles that did not meet national standards (CEPS 1992).

Companies’ actions in securing agreement on collective outcomes in the standards arena show us how important these trade differences are to firms, and how these institutional arrangements, beyond those normally associated with governments, influence industrial development and regulatory policy-making.

Under pressure to reduce public intervention in markets, governments have limited the resources they devote to regulatory standards, and have increasingly harnessed private sector resources to further public policy goals. While this form of self-regulation has become increasingly prominent at the European level, and has received some attention in that context (emphasising regulatory structures rather than firm activities), research on international bargaining and negotiation still tends to focus on state strategies rather than private or quasi-private mechanisms of market governance.

Continued complaints from industrialists including members of the American Chamber of Commerce to UNICE and the European Roundtable of Industrialists about industry standards, export licenses and certification practices increased pressure on the EC to act, in three ways:

- To proactively prevent new technical barriers to trade from arising;
- To harmonise regulations through a “reference to

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**Complying with Toy Standards**

The toy directive was the first new approach directive to promote Europe-wide toy standards. A small British toy company found itself with major compliance problems by including pipe cleaners in its modelling kits. Having produced such kits for many years, the company contested the decision and sought compensation for lost sales. Despite the fact that it had sold 260 million kits without incident, it was forced to recall tens of thousands of its products from store shelves. Reflecting not only the difficulties of coordinating European standards, but also different compliance policies followed by national authorities, the company complained to the British Toy and Hobby Association.

Further problems concerning toys resulted from the insistence of German authorities that German food laws apply to toys. Toys would be subject to toxological tests designed to ensure that plastics used for cooking containers, which are also used for toys such as model kits, needed to meet German specifications. German authorities sought to have their standards promoted at the European level. Six standards for toys were finally agreed including safety, flammability, chemical properties, and age-warning labels. All six standards developed by CEN Technical Committee (TC 52) and CENELEC Technical Committee (TC 61) have been adopted, but not without significant controversy.
The Case of Dormont

Dormont is a small manufacturer of flexible gas appliances connectors and related plumbing supplies in rural Pennsylvania. Its experience in dealing with standards and certification issues in Europe has been raised in Congressional Hearings. The Wall Street Journal and several US trade publications have also featured articles on this small company’s experience.

Dormont developed an innovative gas appliance connector in the 1970s made of steel rather than brass. The product allowed commercial kitchens to put their cooking equipment on castors or wheels to facilitate cleaning and service. Used by a number of companies including McDonald’s, the product became the American standard for metal connectors for movable gas equipment. Dormont sold over 35 million of these stainless steel gas connectors for both residential and commercial food service markets.

Hoping to influence standards in Europe, especially as American fast food companies were expanding throughout Europe, Dormont found itself shut out of national markets. National standards bodies in Europe adopted gas connectors with different design criteria. Dormont complained that their competitors were deliberately writing rules to exclude its product which conformed to necessary safety standards. When McDonald’s refused to accept Dormont products in Britain and France, including the newly opened Euro-Disney, the company sought certification and approval to meet national requirements. Told that they met performance and safety criteria, but did not meet design criteria, Dormont was refused the French certification approval, followed by a similar decision to refuse certification in Germany.

With orders pending, Dormont’s effort to meet design and certification marks in each national market was cumbersome and expensive. The company then chose to gain product approval under the newly adopted gas appliance directive. This would allow it to seek product approval from notified bodies in Britain and Belgium that would certify that Dormont met European standards. However French authorities declared that the European certification mark (CE) issued by the British Standards Institute (BSI) was unacceptable. The European Commission informed Dormont that gas connectors fell outside the scope of the gas appliance directive, and member states were free to adopt their own design standards since this product was not covered by the new approach directive on gas appliances. The argument that the gas distribution system of each member state was sufficiently different to warrant individual standards for gas connectors has thwarted the efforts of Dormont to market its product on a European-wide basis. Those involved in trade issues on both sides of the Atlantic are familiar with the Dormont case, and there is a substantial correspondence on what has become something of a cause célèbre.

The Commission had two choices: total or optional harmonisation. The two have very different trade and technology effects. In the case of total harmonisation, all products must meet the standards set out in the Directives or laws. This extensive regulatory action forces member states to permit goods that comply with a Directive to be freely marketed and to prohibit the sale of goods not complying with the Directive. In effect, European regulation becomes the exclusive standard by which products can access the domestic market.

Alternatively, the Commission could choose optional harmonisation. This more flexible strategy allows for
the parallel existence of both Community and national regulations. Optional harmonisation allows products that comply with the Directive to be sold across the Community, but allows firms that wish to sell their products only in their home market to continue to use national standards. This was particularly attractive for small firms producing solely for domestic markets, since total harmonisation would have required them to use new standards without any compensating advantages.

While recognising the importance of removing barriers to trade, member states often made clear that the ambitious program of regulatory harmonisation should not go too far – particularly when harmonisation challenged national regulatory standards. Member states were anxious to ensure that their own domestic industries were not put at a disadvantage. In this formative period, and as the Commission sought to establish its own legitimacy as an actor in the regulatory process, harmonisation addressed only a small number of trade barriers. The limited results were due in part to the veto powers of the individual member states in the Council of Ministers, but also reflected the Commission’s own difficulties in selecting the most appropriate harmonisation strategy.

The Commission was unable to stem the growing number of national regulations that undercut efforts to harmonise differences in national regulatory regimes (Egan 2001a). The institutional strains of enlargement and the impact of two severe recessions in the 1970s also contributed to the loss of momentum. As national governments adopted measures to combat the national impacts of the economic downturn, the growth of impediments to trade included every conceivable device short of tariffs and quotas. The policy of harmonisation was increasingly regarded as a regulatory mismatch, where the policy instrument chosen was ill-suited to deal with the political and economic realities of the problem at hand (Breyer 1982).

New Instruments of Regulatory Policy

In various surveys in the 1980s, firms gave high priority to problems of standards, testing and certification. Acknowledging the need for regulatory reform, the Commission adopted a policy in the mid-1980s based on four fundamental principles or “approaches”:

- mutual information requirements;
- mutual recognition;
- the new approach; and
- the global approach.

Mutual information

The need to prevent member states from adopting national regulations without regard to their consequences for EU internal market liberalisation led the European Commission to adopt a mutual information directive to function as an “early warning mechanism” (Council Directive 83/189). Member states and national standards bodies were required to notify other interested parties if they were to introduce new standards or regulations. This proactive strategy was backed by a “standstill” policy in which member states were asked to refrain from introducing new regulations so that the EC could assess the potential restrictive effects of national action upon the single market, initiate infringement against them for failure to comply with the Directive, and request them to stop their activities if Community-wide action was to be taken instead. The obligation on standards bodies worked the same way.

This provided opportunities for work at the national level to be transferred to the European level to prevent the development of multiple national standards from acting as technical barriers to trade. Though aimed at early notification of potential trade barriers, compliance has been problematic: national standards and regulations continue to proliferate. The sheer volume of notifications, as well as the need to process and evaluate them in a set time-period has been difficult. However, it has allowed the EC to intervene to seek revisions of licensing and marking requirements, specific ingredients or materials, limits on usage of certain products, or approval arrangements that could be discriminatory.

Mutual recognition

The principle of mutual recognition emerged as an alternative to detailed harmonisation. Although the
concept of mutual recognition was in fact written into the original EU Treaty of Rome to allow for mutual recognition of professional qualifications, it was not used in relation to products and services. This changed as a result of several legal cases in which the European Court of Justice ruled on the extent to which national restrictions to trade were the least restrictive means to ensure health, safety, environmental and other public policy objectives. Dassonville in 1973 and Cassis (Rewe) in 1979 are the most widely-cited examples.

The Court ruled that member states must demonstrate that their regulations were not disguised protectionism or more restrictive than necessary. Exceptions to free trade were limited, since the requirement of free movement of goods was one of the fundamental rules in the Treaty. Hence, the Court argued in the Cassis case that there was no valid reason why products lawfully produced and marketed in one member state should not circulate freely within another member state.

The Commission seized on mutual recognition as a new strategy to promote market access, since the idea that many national regulations were broadly equivalent reduced the need for extensive harmonisation. It expanded this framework from products to all other areas, and treated services as essentially subject to the same policy of mutual recognition of national laws.

As a core principle of the single market program, mutual recognition is based on the idea of regulatory equivalence or compatibility. Conceding that many standards and regulations at the national level were in fact “approximate” or similar in nature, the Commission concluded that harmonisation was not in effect necessary in all cases. Freedom of trade could take place without extensive intervention under the principle of mutual recognition. Mutual recognition does assume a degree of prior regulatory convergence or harmonisation. Without this, the product or process must be subject to some form of co-ordination or harmonisation before circulating in the Community.

Mutual recognition also requires a high degree of transparency in terms of how testing and certification bodies are accredited by national authorities so that they are deemed equivalent, as well as assuming a high degree of mutual trust between regulators for mutual recognition to work in practice.

New approach
Where regulatory compatibility or equivalence cannot be assumed, the EU acknowledged the need for harmonisation of legally-binding requirements. To prevent further legal impediments to market access, the Commission promoted two harmonisation strategies: the old approach and the new approach.

The old cumbersome method of detailed product or component legislation continued in key high-risk areas such as pharmaceuticals, foodstuffs, chemicals and motor vehicles (Pelkmans 1987). In other areas, a new approach reorganised the roles and responsibilities of the public and private sectors. The new approach restricted EU regulations to “essential requirements” for product safety, with responsibility given to private bodies to develop specific standards that would conform to these requirements.

No single organisation encompasses all aspects of standard-setting in Europe. Through a contractual agreement with the main European standards bodies, the European Telecommunications Standards Institute (ETSI), Comité en Normalisation (CEN) and Comité en Normalisation Electrotechnique (CENELEC), these bodies were delegated the responsibility for negotiating the technical details to enable firms to meet the essential requirements. While European standards retain their voluntary, non-binding status under the new approach, conformity to the standards developed by these bodies is often the easiest way for firms to prove that they meet the relevant mandatory “essential requirements”. Moreover, public authorities are obligated to accept that products manufactured in accordance with European standards meet the essential requirements of the European Directives or laws.

Global approach
Even where standards and regulations have been mutually recognised or harmonised, exporters often had to comply with national level certification requirements because of a widespread reluctance to accept the conformity assessment tests and certificates of partner countries. This meant that many technical barriers would remain in place even if European
standards were collectively agreed. The global approach sought to address the problem by providing common ground rules or compatibility among testing and certification bodies, if third party (independent) assessment is required by EU directives. The global approach is thus a co-ordinated system of mutual recognition of conformity assessment within Europe.

The EU gave some scope for regulatory flexibility by allowing different mechanisms or modules for testing and certification, depending on levels of risk involved, the characteristics of the product, and the nature of the production process. Ranging from manufacturers’ self-declaration to full quality assurance and independent verification by an approved body, the global approach provides a strategic and coherent policy towards testing and certification (Council Decision 90/683/EU). However, EU member states have the right to independently choose the bodies (known as notified bodies) under their jurisdiction that are technically competent to provide product approval and apply the necessary CE Mark signifying that products should be allowed to be marketed freely across Europe. Responsibility for monitoring these bodies (testing labs, certification agencies, verification and inspection bodies) rests with the member states, who must then “notify” these public or private bodies to the EU. Since the notified bodies are expected to be equivalent, the EU proposed harmonising of accreditation rules or standards (on which the notification is based) to provide assurances of equivalence across member states.

**Outcomes**

The most visible outcome has been much faster adoption of standards at the European level. Over the past decade, the average development time within ETSI has dropped from 45 to 28 months, and CEN from 135 to 75 months. This has been achieved by greater co-ordination between national and European activities, increased use of qualified majority voting rather than consensus to avoid extensive delays and gridlock, and enhanced monitoring of work in progress by the European standards bodies (Egan 2001a, EC 1999).

These reforms have been joined by a growing recognition that the standards bodies have different functions. ETSI is mainly concerned with proprietary technologies and intellectual property rights, working to co-ordinate firms at the pre-standardisation stage. CENELEC focuses on electrical and electronic standards subject to significant international co-ordination efforts, including in information technology and medical devices. CEN is concerned with horizontal standards that cut across many sectors and industries, as well as standards development in new areas such as ergonomics, food irradiation and environmental management. This makes the CEN development process more innovative but also more protracted, given the greater number of industries affected by CEN standards.

Although European standards bodies are independent, they have memorandums of understanding with the Commission to meet the requirements of the new approach. The bulk of their activity over the past decade has concerned the single market, but the demand for standards can come from three sources: national standards bodies; European bodies (CEN, CENELEC, ETSI, the EU and EFTA); and scientific bodies, professional organisations, and commercial associations. The bulk of the demand for European standards has come from the Commission. Standardisation activities related to the New Approach have already covered a wide range of industries, from “Explosive for civil uses” to “In vitro diagnostic medical devices” (EC 1998, COM/98/291). While several types of standards are produced, the most critical are collectively-agreed European standards (ES) which all the national standards bodies are required to implement. European Pre-standards (ENV) are increasingly adopted as prospective standards (especially by ETSI) in areas where there is rapid change and innovation. While the former focus on health and safety requirements, the latter provide guidance for manufacturers focusing on compatibility and intellectual property rights.

Requests for standards are examined by the European standards bodies. They then go before specially-formed technical committees. These are the workhorses of standardisation. The European standards bodies often rely on drafts produced by international standards bodies, national standards bodies, or specialised trade federations. This allows them to base their work on existing documents, and to assess the degree of consensus or agreement that already exists across national standards bodies. Draft standards are then
circulated for comments among the technical committee assigned the task of co-ordinating a specific standard. Members of the specific technical committees can raise questions about specific aspects of the proposal, seek amendments and propose changes to the draft document.

The Role of Firms
The ability of firms to influence the standard-setting process varies considerably depending on factors which include resource allocation and credibility. Currently it is estimated that over 25,000 firms as well as consumer, trade union and other industrial organisations are involved in some way in European standard setting. Although this masks some variation in level of commitment, firms find themselves both pressuring and pressured in the standards-setting process. Organisational norms are crucially important in understanding business ability to influence the process. The various technical committees allow those with significant expertise to exercise considerable influence in shaping outcomes. Although consensus is the key operating principle, firms acknowledge that they engage in both co-operation and competition within standards committees. While every effort is made to accommodate disagreements, “the interplay of reputation, credibility, and the ability to generate a coalition of common interests is a key determinant of the standards setting process” (Foray 1994, p269).

The success of firms depends heavily on their ability to participate, often at both the national and European level, and to keep abreast of new technological developments or production changes resulting from standardisation. European standards must be ratified at the domestic level where a single opinion to accept or reject a negotiated European standard must be taken by national standards bodies. Though opposition must be unusually strong, organised or widespread to derail a negotiated standard, it can happen. Perhaps the most spectacular example is the rejection of draft European standards for plugs and voltages. Despite negotiations spanning 18 years, British and German opposition on the grounds of safety blocked any agreement. In most cases, once national positions are reached, a vote is taken at the European level based on a complicated weighted voting system that gives a blocking power to minorities: it requires a simple majority, at least 25 votes in favor, no more than 22 votes against, and no more than three national standards bodies opposed.

While the weighted voting allows the major standards bodies in Britain, France, Germany and Italy to exercise the biggest influence, the rules do ensure that once a standard is agreed, any differences in assessment or technique at the national level are no longer acceptable. The most important change has been the growing public-private co-ordination in setting the rules for European-wide market access. The regulators and the regulated are in this case the same, and the rules that govern their behavior are adopted voluntarily (Haufler 1998). Consequently, the shift in regulatory instruments has given firms a more direct influence in the decision-making process. Some firms remain standards users rather than standards developers relying on their trade associations, national standards bodies and supplier relationships to keep them informed about new standards. But even those firms that play no more than a marginal role in the standards process generally recognise that standards-setting is intended to facilitate international exchange of goods and services, enhance the reputation of the industry, and reduce the costs of doing business.

Testing and Certification: Stumbling Blocks
Having achieved some progress in addressing divergent standards, the European Commission has promoted a similar strategy of public-private co-ordination on testing and certification practices. A multitude of these stem from different regulatory practices and private sector business preferences. The EC has used the concept of mutual recognition as a core integration tool. It established a forum to promote quality assurance in the private sector, build confidence across member states, and enhance co-operation and equivalence. Since 1990, the European Organisation for Testing and Certification (EOTC) has been the mechanism to co-ordinate testing and certification practices to help exporters avoid unnecessary duplication in the importing country. Recently renamed the European Organisation for Conformity Assessment, EOTC was designed to promote the general recognition of technical competence between conformity assessment bodies through cross-border sectoral agreements.
Though EOTC has promoted mutual recognition agreements, progress slowed down as some national members lost confidence in the project and withdrew their membership (Gaddes 2000, Journal of Commerce 1997). Faced with financial difficulties, EOTC has struggled to regain members and push forward with private sector efforts to co-ordinate certification and accreditation practices based on common criteria or standards. While agreements have been reached in several sectors such as quality assurance and low voltage, the Commission has continued to express concern (EC 1999). This concern was particularly acute in foodstuffs, electrical engineering, construction and motor vehicles, financial services and professional qualifications (recognition of diplomas). The problems are due to lack of information on the legislation and verification procedures of other member states, as well as misunderstandings about the principle of mutual recognition.

Though rapid increases in the number of European standards lend support to the claim that the single market is improving market access, business will be hampered by the continued restrictions on conformity assessment unless greater attention is paid to equivalence issues on testing and certification. To ensure better compliance, the European Court of Justice has stated that European member states have an obligation to include mutual recognition in national regulation, thereby formalising a legal commitment to mutual acceptance of testing and certification practices. Market surveillance is a key factor in ensuring that the actions taken to promote the single market tackle constraints on trade.

Beyond the EU: Shaping Global Markets

The issue of market access for third country products and services was not initially addressed by the EU until pressure from their trade partners about openness and transparency of European standardisation forced them to stress their commitment to principles of non-discrimination. However, the growth of EU standardisation has in fact shaped entry requirements in third country markets as European technical expertise and other institutional resources committed to standards negotiations at the European level have resulted in a strategic spillover effect.

Being first to develop a standard that may be adopted by other countries, regions, or international forums is a big potential advantage. Because firms often follow the market leader, creating a bandwagon is crucial in the standards-setting process. Attracting a critical mass of users more quickly than rival standards may be achieved through licensing, early adoption, subsidising initial users, and forming strategic alliances. Although markets can be effective in setting standards, they are sometimes imperfect, and institutional frameworks are necessary as alternative co-ordinating mechanisms to resolve collective action problems. Precisely for this reason, the institutional arrangements to deal with varying standards in market economies have assumed increasing importance beyond the Community marketplace (Table 2).

The EU’s “first mover advantage” is growing. EU standards are now being “exported” or promoted at the regional, international and transatlantic level.

Central and Eastern Europe: The Pressures of Enlargement

Trade in industrial products between the EU and Central and Eastern Europe (CEE) is now subject to few tariff restrictions. These countries need to meet the requirements of accession in other ways too. Among the most important are technical barriers to trade. The Europe Agreements provide for each of the CEE candidate countries to harmonise their laws with EU single market legislation, and the EU accession process requires that the applicant states adopt the legal and institutional framework in existence, known as the acquis communautaire. Currently, there are

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<th>Table 2</th>
<th>Levels of Standardisation and the Main Standard-setting Institutions</th>
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<td><strong>National Standards Bodies</strong></td>
<td>British Standards Institute (BSI-UK), Deutsches Institut für Normung (DIN-Germany), Association Française de Normalisation (AFNOR-France), American National Standards Institute (ANSI-US)</td>
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<tr>
<td><strong>Regional Standards Bodies</strong></td>
<td>Comité en Normalisation (CEN), Comité en Normalisation Electrotechnique (CENELEC) and European Telecommunications Standards Institute (ETSI)</td>
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<td><strong>International Agreements promoting use of international standards</strong></td>
<td>Technical Barriers to Trade Agreement and Sanitary and Phytosanitary Agreement (World Trade Organisation)</td>
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more than 200 Directives concerned with placing products on the market to be adopted by CEE applicants (Benton 2001, p270). They must also meet necessary standards, testing and certification practices to ensure that their institutional framework matches the EU.

Though the CEE bodies are generally “affiliates” within CEN, CENELEC and ETSI, rather than full members, they will be expected to replace national standards with EU standards where appropriate. Recognising the tremendous task involved, the Commission has provided substantial funding and resources to establish standards infrastructures in CEE (Egan 2001a). Progress in this area has been more rapid than in testing and certification. Without progress on both fronts, incongruent conformity assessment and market surveillance procedures will effectively prevent EU-wide market access for applicant countries. Technical barriers will persist if CEE testing and certification bodies are not mutually recognised as equivalent to those in Western Europe.

The Commission has proposed mutual recognition agreements called Protocols on European Conformity Assessment (PECA) with applicant states. Negotiations have begun with Hungary, Poland, the Czech Republic and, more recently, with Latvia, Lithuania, Estonia and Slovenia to try to reach agreement on Protocols relating to European conformity assessment (www.dti.gov.uk/strd/conformi.htm). These will provide market access and acceptance of their testing and certification bodies as being equivalent to those in the EU, speed up their alignment to Community legislation, and eliminate technical barriers to trade. The Commission expects to ratify the PECAs with Hungary and Czech Republic in 2001, and then with other states such as Poland so that products approved by the designated bodies in these applicant states will have freedom of movement throughout the EU. The PECAs have been primarily concerned with sectors where technical regulations have been harmonised under the new approach, such as electrical safety, machinery, and medical devices (Benton et al, p271). Other products will presumably have access to the single market after accession, but there is not yet sufficient equivalence in terms of standards, testing and certification practices within the applicant countries to meet EU requirements. What this means is that for the time being, industrial products entering those countries that have not signed PECA agreements require companies to undergo testing by local testing bodies to demonstrate their conformity with national standards.

For non-CEE companies, closer alignment of CEE product approval practices with the EU will reduce the costs of accessing multiple markets. However, moving from their traditional centrally-regulated system to a producer-based self-regulated system of standards and conformity assessment has proved difficult for many CEE countries, as illustrated by the case of Poland (Preston and Michonski 1999).

EU versus US
The increased disputes over standards brought to the World Trade Organisation (WTO) over the past five years mainly concern trade in agricultural products, and include some high profile cases such as the dispute between the US and EU over beef hormones. There is also rising tension between the EU and US over genetically-modified organisms (Egan 2001b). Preventing disputes has led to the adoption of two accords, the Technical Barriers to Trade (TBT) and Social and Phytosanitary (SPS) Agreements, as part of the WTO. These are aimed at promoting international trade by referring to international standards of the relevant international organisations as the basis for harmonisation or mutual recognition of national standards (Victor 1999).

Though the agreements are designed to limit the use of standards as disguised barriers to trade, and ensure that national standards are reasonable and no more trade restrictive than necessary, their main aim is to promote harmonisation of national standards. The Codex Alimentarius has attracted the most political attention because it focuses on food safety standards, and has made more extensive use of risk assessment procedures that have to account for the precautionary principle. But other international standards bodies are playing an equally significant role in shaping trade rules. In fact, the strategic importance of the main international standards bodies, the International Standards Organisation (ISO), International Electrotechnical Commission (IEC) and the International Telecommunications Union, has increased as the TBT Agreement (known as the standards code) encourages all standards bodies to participate in preparing international standards and promotes positive consideration of mutual recognition.
In addition, the international standards bodies have also increased their profile in response to developments within the EU. These international standards bodies bring together 133 national bodies in numerous technical committees and working groups. Different interests have made collective action difficult. The scope for agreement is often affected by differences in standards between advanced industrialised states and newly-industrialising states. The results often seem to be the lowest common denominator standards that encourage a "race to the bottom" among competing national standards. Because international standards are voluntary, not mandatory, participants may adopt national standards that are stricter than international standards. Exceptions to these harmonisation efforts have in practice hindered the effectiveness of international standards bodies. So, in order to strengthen their position, the international and European standards bodies have adopted formal understandings – known as the Lugano and Dresden Agreements – to co-ordinate their activities and avoid duplication. For the EU, the practice of considering whether international standards are suitable for adoption as European standards is meant to ensure that international standards are not neglected (Woolcock 1993). Furthermore, these agreements allow the international standards bodies the opportunity to comment on proposed European standards in progress, and also to provide a “fast track” for European standards to be considered as international standards. Today more than 70% of European electrotechnical standards are based on world standards.

This influence is reinforced by the decision-making process in international standardisation that allows each country one vote. Other advanced industrial states have complained that the European countries have a disproportionate voting bloc within the international standards bodies, as well as substantial presence on critical working groups and technical committees. European industry dominates many committees, investing considerable time and energy in reaching consensus. About 60% of secretariats at the ISO and IEC are held by European members, whilst North Americans hold about 30% of ISO and 20% of IEC.

Some American companies have argued that international standardisation is not responsive to their interests, although there has been a substantial American presence in specific sectors such as medical devices and heavy equipment. Concerns about waning American influence have prompted Congressional hearings, and suggestions from both government and industry leaders for radical reform of the international standards process (US Congress 1998). This is mainly focused on internal decision-making where draft standards are voted by qualified majorities of national members, providing EU member states along with the CEE applicants substantial influence en bloc in the approval process.

Poland: The Problems of Compliance

Efforts to align Polish standards and conformity assessment with the EU reveal some sharp differences in principle and practice, notably the dominance of third-party certification for many products that are self-certified in the EU and the bias towards detailed and prescriptive technical regulations in Poland. Research undertaken for British companies found a range of certification problems, including supplementary certification beyond that required in the EU for products such as ceramics and electrical products (Preston and Michonski 1999).

While the Polish standards body has been looking to adopt EU standards, the gap between the EU and Polish system is still large (EC 1997). The Commission estimated that 80% of Polish standards were purely national, and less than 3% were European. The negotiations have shifted towards greater regulatory alignment, focusing on implementing EU product liability and sectoral new approach directives, rather than seeking mutual recognition of conformity assessment practices. The Polish regulatory preference for extensive mandatory third party certification is judged by the EU to be incompatible with the internal market. The emphasis on technical assistance to improve the operations of conformity assessment and accreditation bodies, while also promoting harmonised standards, illustrates the EU's impact in shaping the markets of the accession countries, and exporting its trade principles to CEE.
As a result, arguments between the US and EU about technical standards are increasing. American firms have complained that Europe’s efforts to win international acceptance of many European standards in areas such as quality management, environmental management and mobile telephony could be used to discriminate against American firms. Criticism by American firms partly reflects the decision-making process within international standardisation, but also reflects different philosophies. American firms prefer standards set by the market whereas European firms have increasingly set standards – especially in telecommunications and information technology – through institutionalised industry co-operation (Tate, forthcoming, and Financial Times, Jan 20 1999). Because international standardisation has resulted in some spectacular failures (such as OSI open systems interchange and JAVA), American companies have turned to alternative institutional mechanisms of co-ordination. Pushing for ad hoc standards consortia among business alliances is one indication of the alternative steps American companies have taken. Some companies with proprietary technologies are also reluctant to participate in international standardisation, preferring to compete rather than co-operate.

Mutual recognition agreements were considered a priority

Attempts at Transatlantic Agreements

European companies cannot ignore the pressures from the US since the credibility of international standards depends on their usage in domestic markets. As a result, efforts have been made to accommodate American concerns through two distinct bilateral agreements. In the first instance, the European and American standards bodies exchange information on draft standards in progress. This allows companies on both sides of the Atlantic to keep abreast of any developments that could have adverse effects on their manufacturing process. Though American companies have argued that this is inadequate since some regional standards do not reflect the broader needs of global markets, their reactive posture is in part driven by the diverse, decentralised nature of American standardisation. American standards bodies are often competing with one another, and are divided between the public and private sectors. Federal agencies including the Department of Defense, Food and Drug Administration and Department of Transportation are involved in standard-setting, along with a range of trade associations, such as the American Society for Testing and Materials (ASTM) and Institute for Electrical Engineers (IEE), that are often fiercely independent from the main umbrella organisation, the American National Standards Institute. This makes co-ordination across agencies and interest associations extremely difficult.

In Europe, with only three major standards bodies, the standardisation process appears much more co-ordinated and less fragmented. In many cases, private sector standards in the US are international in application but are not “approved” within the international standards bodies. This lack of formal recognition shifts the advantage to the Europeans, who have actively co-operated with international standards bodies.

The US and EU have also sought to ease trade tensions through a second bilateral agreement that transfers the mutual recognition principle to the transatlantic level. Concerned at an EU proposal to transfer to Europe all notified bodies that provide independent testing and certification, American companies were anxious to avoid duplicate conformity assessment requirement. The global approach provided for reciprocity and mutual access by promoting the possibility of mutual recognition agreements with third countries.

Mutual recognition agreements (MRAs) are sectorally-specific arrangements that allow for testing and certification practices to be mutually recognised and accepted without further product surveillance. This avoids double-testing, and reduces costs and red tape in marketing products in their respective markets. Pushed by multinational business, through the Transatlantic Business Dialogue, mutual recognition agreements were considered a priority. For American exporters, the idea was to extend the “certified once, accepted everywhere” concept prevalent in Europe and gain the benefits of regional market access. European companies strongly supported the negotiations, since they gave them the opportunity to push for reform of the American system of standardisation – with its myriad state and local as well as private sector standards bodies.

Negotiations produced convergence as the American government agreed to grant their testing and certification bodies the same kind of “notified body”
status that exists in Europe. This is likely to streamline the American system and pave the way for mutual recognition of conformity assessment in areas that account for $41bn in bilateral trade.

So far, six sectors – pharmaceuticals, medical devices, electromagnetic compatibility, electrical safety, telecommunications and recreational marine craft – have MRAs. Negotiations have stalled in service sectors like insurance, architecture and engineering services. However, continued advocacy of MRAs as part of the EU trade agenda has provided a powerful incentive for other countries, such as Australia, Japan, Canada and Switzerland, to negotiate them. More needs to be done to induce greater reliance on testing and certification conducted in the country of export, since MRAs have experienced operational difficulties in practice reflecting the need to build greater confidence and incentives to accept their counterpart’s testing and certification regime (Egan 2001a, 2001b).

**What Firms Need to Do**

The institutional arrangements that have emerged in Europe to deal with varying standards – CEN, CENELEC and ETSI – have assumed increasing importance both regionally and globally. European standards bodies are shaping standards in Central and Eastern Europe in the context of the current EU accession negotiations. They are also shaping the worldwide standards agenda by co-ordinating their activities with international standards bodies. This has generated substantial concern in the US, leading to considerable pressure and lobbying for US access to and influence on European standards setting. Rebuffed in these efforts, American firms have sought alternative means to ensure that they are not at a competitive disadvantage in terms of their standards, testing and certification practices. This has resulted bilateral agreements on mutual recognition of testing and certification requirements (although not the underlying standards themselves).

In many cases, agreement on rules governing market access may depend more on the negotiating dynamics of firms than on the policies of governments. In this changing regulatory climate, it is therefore important to recognise the increasing influence of international agreements on corporate strategy. Firms need to use all available channels – national, regional and global – to access information, reduce uncertainty and influence the changing regulatory landscape. The best strategy requires multiple channels of information about work in progress that can be garnered from direct participation in technical committees, membership of industry associations and national standards bodies, and monitoring of new mandates for standardisation at the regional and international level.

Successfully influencing both regional and international markets requires an organisational capability to co-ordinate strategic alliances, and monitor activity in different forums. It is also crucial to establish a reputation for being positive, since this creates a climate of trust within committees. The demand for standards has increased in response to the EU single market program, and supply of standards has also improved due to internal reforms within the European standards bodies. Decision-making has speeded up.

The growing links between national, regional and international bodies means that firms must also think about the interactions between these different levels. Once certain policy options are chosen, other standards may be rendered obsolete, with big consequences for those that did not jump on the bandwagon. International standards are proliferating and the private sector now plays a big role in the creating these common rules for market access. This means firms need to get involved in the frequently arcane business of standards-setting if they are to avoid losing competitive advantage. If they do not get involved, their competitors are likely to set standards, and define the way products are tested and certified.

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RESOURCES


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