

EUROPEAN STANDARDISATION

∞ PROPOSALS TO MAKE THE SYSTEM MORE EFFICIENT ∞

UNICE DISCUSSION PAPER

In spite of all endeavours towards making the internal market operate at full efficiency, technical barriers to trade still pose serious problems as regards the free movement of goods in the European Union.

Technical barriers to trade arise because differences in national regulations or standards impede the free movement of goods. National technical regulations can be very effective obstacles to commerce when they have the force of national law behind them. Governments, industry or firms in one state can use them to keep out products from other countries, usually citing public interest – health, safety, environment – as a reason for doing so. Occasionally, this is with justification, often not.

National regulations which impose technical specifications can be an enormous headache for outside producers. The latter often have to re-design, re-package and re-label their products and go to the expense of obtaining duplicate testing certificates to satisfy local health and safety requirements.

I. TECHNICAL HARMONISATION AND STANDARDS

1. The "traditional" approach

Article 30 of the 1957 Treaty of Rome establishes the principle that all national initiatives resulting in unjustified barriers to trade are illegal. Article 100 authorised^d the Council of Ministers to issue directives for the approximation of national laws or regulations when necessary. Only little progress, however, was made. From the sixties to the mid-eighties the Commission presented harmonisation directives in all areas in which application of the principle of mutual recognition had been fruitless. However, in spite of the Commission's sustained efforts, this initiative turned out to be a failure. This was due in particular to the fact that the practice of incorporating detailed technical specifications in directives had given rise to long delays because unanimity was required in the Council.

The slow pace of the legislative process for adopting directives meant that the number of barriers to trade was not reduced, far from it. On the contrary, the number increased as it was easier and faster for the member states to work out new rules or make a standard mandatory than it was for the EU to harmonise the rules.

Furthermore, the preparation of directives was overtaken by technical progress, new production methods and new national requirements on health, safety, prevention of pollution and protection of consumers and citizens.

In 1979 the European Court of Justice handed down its judgment in the famous “Cassis de Dijon” case, in which it confirmed the principle of free movement based on the fundamental notion that products manufactured and marketed in compliance with the law in one member state should be allowed to be placed on the market anywhere in the Common Market. On the other hand, the European Court of Justice ruled that provisions necessary to satisfy mandatory requirements relating to (inter alia) public health, could be upheld.

It then became clear that, if the provisions of the Treaty of Rome were to be translated into reality and the Single Market established, the decision-making process for adoption of harmonisation directives had to be changed radically.

This is why, in the early eighties, the Commission started considering a new strategy for harmonisation which resulted in the publication in 1985 of the White Paper “Completing the Internal Market”. The White Paper contained 282 proposals intended to give the Treaty real meaning at last, and the date of 1 January 1993 was set for completion of the Single Market programme.

These proposals were adopted together with the Single European Act in 1986 which meant that removal of barriers to trade could from then on be adopted by majority voting.

2. *The “New Approach”*

As mentioned above, together with the programme for completing the internal market, the Commission proposed a new and more efficient procedure for harmonising technical regulations, in order to deal with technical barriers to trade in the light of the “Cassis de Dijon” Court ruling.

However, as early as 1985, in a communication dated 31 January, the Commission presented to the Council a completely new approach for dealing with technical harmonisation and standardisation. The Council approved this so-called “*New Approach*” in its resolution dated 7 May 1985.

The New Approach is based on four principles:

- (i) Legislative harmonisation is limited to adoption of the essential safety requirements (or other requirements in the general interest) with which products put on the market must conform, and which should therefore enjoy free movement throughout the Union.
- (ii) The task of drawing up the harmonised standards needed for producing and placing on the market products which conform to the essential requirements established by the directives is entrusted to CEN, CENELEC, and ETSI.
- (iii) The technical specifications are not mandatory and retain their status as voluntary standards.

- (iv) National authorities are obliged to recognise that products manufactured in conformity with harmonised standards are deemed to conform with the “essential requirements” established by the directive, and consequently to ensure that they may be placed on the market.

The introduction of the New Approach has changed the contents of directives radically. Directives no longer spell out detailed specifications of a technical nature, but give an outline of the characteristics a safe product must have. These characteristics are called “*essential requirements*” because they include all that is necessary for the protection of the public interest (safety of these products, health protection, etc.). Detailed technical requirements, in contrast, are left out.

Instead of these detailed technical specifications, the directives based on the New Approach include a reference to European standards. These standards, if published in the Official Journal, carry a presumption of conformity, thereby obliging the member states to grant free movement to all products that conform to them. If a national authority finds such a product to be unsafe, it has the obligation to trigger the so-called “*safety clause*”.

As mentioned above, European standards are developed by the European standardisation organisations (CEN, CENELEC and ETSI) and are based on a mandate given by the Commission in accordance with Directive 83/189/EEC.

Harmonised standards, however, are not compulsory. They are an optional technical guideline. A manufacturer is free to opt for other specifications. However, if he does so, he will bear the burden of proof that his products are in conformity with the relevant essential requirements. In some cases, he will need certification by some independent testing body that his products conform to the essential requirements.

Clearly, the advantage for a manufacturer of opting for harmonised standards is that national authorities are obliged to recognise that his products are deemed to conform to the essential requirements.

Products which satisfy the essential requirements of a directive can be identified by the CE mark affixed to them. The use of CE marking was harmonised in 1993 (the so-called “Global Approach”). The CE mark also indicates that the products comply with the appropriate conformity assessment procedures laid down in the relevant directive. The CE marking shows that the product is accompanied by a declaration of conformity.

Compared to the total number of products on the market, the number of products covered by the New Approach directives is relevant. To date, 19 “New Approach” directives, which cover around 20 per cent of intra-Community trade, have been adopted.

Consumer preference for a product's characteristics, qualities, etc., cannot be changed or removed by means of directives. National authorities are simply obliged to ensure the free movement of industrial products in the internal market and therefore consumer requirements do not represent a barrier to trade in this regard.

3. The standardisation procedure in CEN

The standardisation procedure in CEN consists of three steps:

- start of the standardisation work,
- preparation of the standard,

- adoption as a European standard.

More than 10,000 European standards are in preparation. The Commission has requested several thousands of standards based on mandates in conformity with the New Approach to technical harmonisation and standardisation. Many standards are not expected to be ready for adoption before the end of the century.

As shown in figure 1, the present procedure for developing European standards is both slow and inefficient.

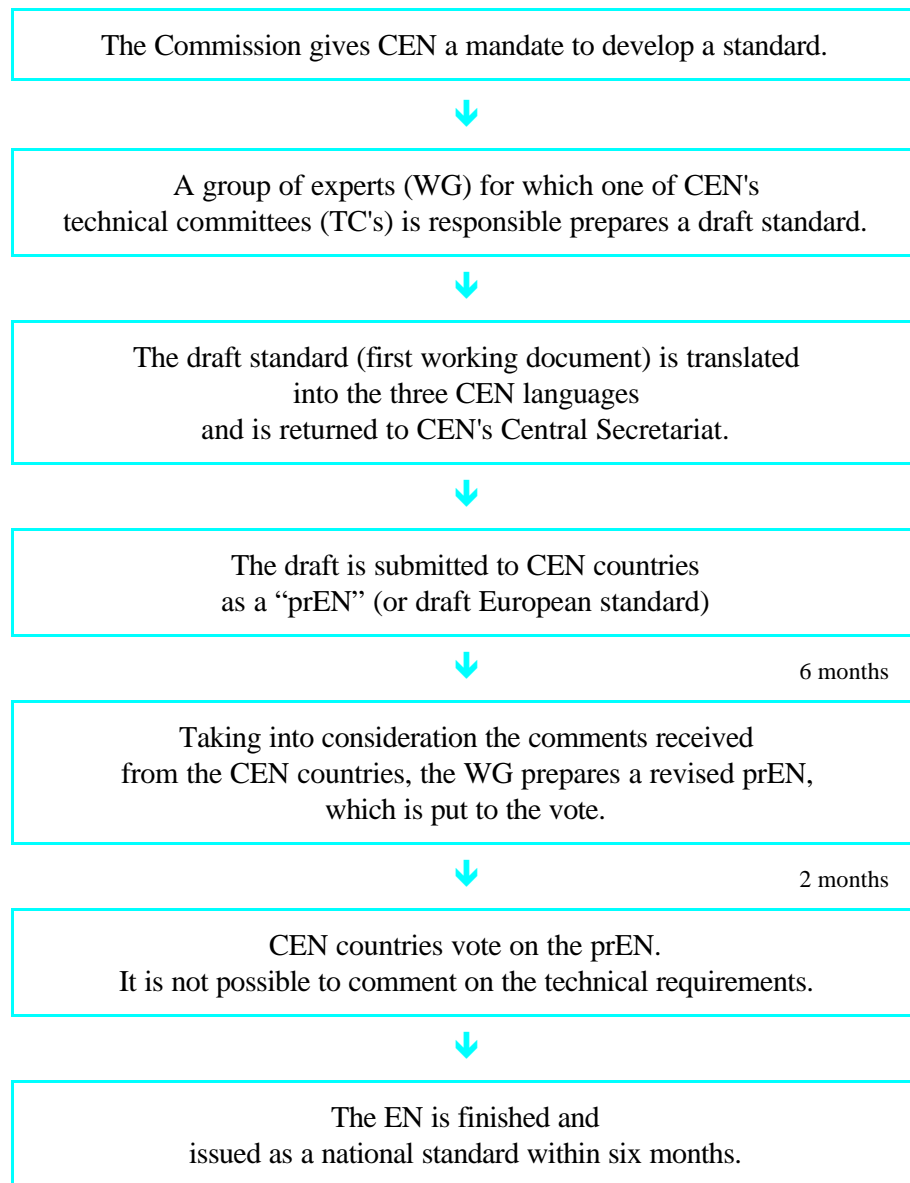


Figure 1: The standardisation procedure in CEN

Despite sustained efforts to make the standardisation process in Europe more efficient, industry has become increasingly critical of the time it takes for standards to be brought to the market. Industry's

growing frustration resulted in CEN's decision to use electronic means of communication in connection with the voting procedure, as of October 1996.

For industry, it is important that the process of preparing European standards be as efficient as possible. It is not satisfactory that the time to develop a standard is clearly more than four years. This creates disadvantages for European industry in relation to international competition and disturbs the functioning of the internal market. By way of example, under the Machinery Directive, 710 standards had been mandated by the end of 1997, of which 168 have been ratified, whilst 315 are awaiting approval.

Another example of an area with great problems is the Construction Products Directive where not a single product standard has been adopted. The directive came into force in 1991. The proposals put forward by the SLIM I team have not led to much change in this respect.

In addition to the efficiency of the standardisation process itself, external factors have to be addressed. Important prerequisites are timely and precise mandates as well as timely publication of ratified standards in the Official Journal. For example, of the 168 machinery standards ratified by 1997, only 122 were actually published in the Official Journal. In many cases and for a variety of reasons, it takes more than three months to publish a standard. Furthermore, the use of the safeguard clause by national authorities should be looked at

II. UNICE PROPOSALS TO MAKE THE SYSTEM MORE EFFICIENT

In order to make the preparation of standards more efficient, UNICE has considered various proposals for enhancing the efficiency of the European Standardisation process.

UNICE is aware of the Strategy Review currently under way within CEN as well as the discussions taking place in the Council on these matters and wishes to contribute effectively to this exercise. The aspects mentioned below should be examined in detail in this process.

As the international dimension of standardisation is becoming increasingly important, UNICE would like to extend the debate to the question of how the interface between European and international standardisation can be structured in an efficient manner.

1. The regulatory framework has to be optimised. At national level, heavy regulation prevents standardisers from reaching a consensus. The Construction Products Directive is a good example.

☞ *UNICE asks the Commission to discuss ways of reducing the regulatory burden of national legislation in this field.*

In some areas, mandates are issued with much delay and lack clarity. This makes the technical work of drafting a standard more difficult.

☞ UNICE proposes that ways of delivering timely and precise mandates be identified.

In other areas, the need to publish harmonised standards in the Official Journal creates difficulties if publication is delayed.

☞ *UNICE asks the Commission to speed up this process and commit itself to publishing harmonised standards within two months of completion of the voting procedure. Member states should not hold back the publication of standards in the Official Journal, especially if they have participated in the standardisation work. The safety clauses should be used only as a means of last resort and their legality promptly decided by the Commission.*

☞ *In addition, the Commission should, in UNICE's view, ensure timely translation of the titles of the standards in all Community languages.*

- 2.—Regarding the standardisation procedures, UNICE is well aware that time is needed to build consensus. On the other hand, the publication of standards must be sufficiently timely to gain market acceptance. UNICE shares the view that maximum industry participation is necessary to draft good European Standards. Efficiency is the main factor to attract industry participation. Additional formal requirements or political interventions are counterproductive.

UNICE notes that the CEN Optimisation process is well under way and wishes to see results in the near future. In the view of UNICE, CEN should generally give priority to standards needed for the functioning of the Single Market. Wider use of IT as well as QM structures, combined with better education of the participants, notably the chairmen, should be considered. Thereby, better coordination and monitoring could be assured. At technical level, wider use of project teams in the standardisation process could be looked into further.

☞ *Consequently, the Commission should continue to follow a policy of co-operation and dialogue with standardisation bodies, as well as with industry, on ways of improving efficiency.*

3. Translation of working documents into German and French is another area in which preparation of the standard can be optimised. At present, the French and German standardisation bodies, AFNOR and DIN, translate the working documents from the English. Good translations are essential to the quality and acceptance of European standards. Nevertheless, time limits have to be strictly observed and the necessary resources assigned to this task.

☞ *UNICE asks CEN to assure timely translation.*

4. The mandate which the Commission gives CEN can be compared to an order. When it comes to "placing its order", the Commission could enter into some kind of piece-work contract. For each mandate an order form is worked out specifying the details for the preparation of standards, including time limits and financial matters.

☞ *UNICE asks the Commission to co-operate with CEN in developing realistic timescales for mandated work, taking into account the TCs' annual work programmes. This should be accompanied by more efficient procedures within the Commission. For certain areas, mandates for a longer term could be a good idea. Automatic linkage between mandates and financing should be discouraged to avoid the development of standards with no market relevance.*

5. CEN is in the process of developing and testing new deliverables. For instance, it has introduced the CWA (CEN Workshop Agreement). UNICE – being aware of the more limited legitimacy of these deliverables – welcomes this development with regard to the growing need for flexibility and will closely monitor acceptance of this new product.

☞ *UNICE asks the Commission to enter into a dialogue with all interested parties on the relevance of new deliverables in Community legislation.*

6. The added value of European standardisation for industry depends very much on the interface with international standardisation. International standardisation has the difficult task of creating a level playing-field for business to act globally. European standardisation bodies can provide valuable services by co-ordinating European views, especially with regard to the European legal framework.

UNICE would nevertheless recall that efficient input at international level is arranged via national standardisation organisations. Were European participation and representation in the international standardisation process to be left exclusively to the European standardisation organisations in their own right, there is a risk that this would strongly diminish European influence and hamper acceptance of international standards.

Currently, the Dresden Agreement covering the electrotechnical sector is the benchmark for cooperation between the European and international levels.

☞ *Whilst much remains to be done to make international standardisation more efficient, UNICE asks the Commission to promote the use of international standards throughout the world, in particular in the U.S. In this respect, a strong interface is needed with the Transatlantic Business Dialogue.*

☞ *By contrast, UNICE would discourage the Commission from bypassing international standardisation by promoting European standards as internationally acceptable in their own right.*

On the contrary, many industrial sectors could benefit if direct use of international standards in Europe were to be made easier, thereby avoiding the time-consuming task of transposing them into European standards. UNICE understands that the WTO Agreement on Technical Barriers to Trade obliges members to use international standards as widely as possible.

☞ *Consequently, UNICE encourages the Commission to launch a wide debate with all interested parties on possibilities for giving the relevant international standards a broader role in the European legal context.*