

VI - E.E.C. QUALITY POLICY AND LIABILITY FOR FAULTY PRODUCTS. INSURANCE.

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PART I - THE NEW APPROACH TO TECHNICAL HARMONIZATION AND STANDARDIZATION

The Community's policy for the removal of technical barriers to trade is based on two guiding principles:

- where possible, mutual recognition of product legislation and standards and the means of assessing conformity to them, and
- where necessary, the harmonization of technical legislation by means of reference to European standards.

The preferred path is that of "mutual recognition", whereby Member States of the Community are required to accept on their territory products legally produced and/or marketed in other Member States, unless there are compelling reasons relating to the protection of human or animal health or safety, or the protection of the environment or the consumer, which require the imposition of technical specifications. The Commission has powers to challenge Member States which do not apply the principle of mutual recognition before the European Court of Justice, and the Court has in a series of judgements since 1979 tended to take an extensive view of the obligations of the Treaty in this matter. Individuals may bring to the commission complaints concerning the application of mutual recognition by Member States, irrespective of the place of manufacture of the products concerned.

The European Court of Justice has made clear in recent years that Member States are required under Article 30 of the Treaty to accept on their territory any product, including one originating outside the Community, which has been legally marketed in another Member State. The only qualification to this general rule of "mutual recognition" is that where a Member State considers

that essential public policy considerations (such as the protection of health and safety, the consumer interest or the environment) demand that specific technical requirements are met, it may impose those requirements provided that it can demonstrate that they are necessary to achieve the objective in question and are proportionate to that objective. Whenever specific requirements are imposed by law, however, test data generated in another Member State must generally be recognized for the purposes of obtaining mandatory certification in the importing Member State.

Harmonization of technical legislation within the Community is still necessary in cases where Member States have legitimately imposed technical requirements on products for public policy reasons, and conflicting national legislation restricts the free movement of products within the Community. This harmonization through EEC Directives is intended to be limited to these "difficult" cases, however, and not pursued across-the-board.

The EEC Council of Ministers adopted a new approach to technical harmonization and standardization in a Resolution of 7 May 1985 (Official Journal of the European Communities, No. C 136, 4.6.85, pp. 1-9). This New Approach constitutes a set of general principles which should apply in those areas where public authorities have the obligation to protect the health and safety of citizens but where the carrying out of such obligations has led to barriers to trade. It should only cover industrial sectors which are capable of being covered by standardization, and is designed to deal with wide ranges of products sufficiently homogeneous to allow common "essential requirements" to be defined rather than with individual types of products.

This means that manufacturing industries, at first sight, are better suited to fulfil these criteria. Moreover, the Council Resolution of 1985 itself states that the New Approach should concentrate mainly on those areas in which there is a lack of Community legislation without calling into question Community regulations that are already well advanced (such as for motor vehicles, pharmaceuticals, metrological instruments or foodstuffs).

The Resolution lays down a number of fundamental principles on which the new approach will be based, which are worth quoting directly:

- "(EEC) legislative harmonization is limited to the adoption ... of 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 Community:
- the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives ... is entrusted to organizations competent in the standardization area,
- these technical specifications are not mandatory and maintain their status of voluntary standards,
- but at the same time national authorities are obliged to recognize that products manufactured in conformity with harmonized standards ... are presumed to conform to the essential requirements established by the Directive. (This signifies that the producer has the choice of not manufacturing in conformity with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive.)"

Some of the implications of these principles need drawing out.

The Council clearly distinguishes between the function of **EEC legislation**, which is to lay down essential requirements in terms of public policy objectives (these requirements may also include provisions concerning the means of demonstrating conformity to them), and of **European standardization**, which is to develop detailed technical specifications representing one way (but not the only way) to meet the essential requirements. Detailed technical specifications are,

therefore, as a general rule to be removed from the legislative domain and transferred to the voluntary domain.

The European standards which are developed on the basis of the essential requirements of an EEC Directive represent only one option open to manufacturers in order to demonstrate conformity to those requirements; other options, such as conformity to national standards or to no standards at all may be chosen, but in that case the manufacturer will have to prove, usually by third party certification, that his product conforms to the essential requirements. The essential requirements of a Directive should be sufficiently clear to allow for direct demonstration of conformity to them. The advantage of following European standards is that this constitutes a "fast track" to the EEC market, in so far as it always gives rise to accelerated procedures for demonstration of conformity to essential requirements, often without further third party testing.

It should also be underlined that the harmonized European standards developed by the European standards bodies are voluntary technical specifications which are custom made to reflect the legally-imposed essential requirements. In other words, they are to be specific to EEC legislation, although based as closely as possible upon international standards.

The consequences of the new approach are far-reaching for EEC and non-EEC manufacturers alike.

- Whereas the principle of mutual recognition will in most cases mean that conformity to any standard in any Member State gives the right of access to the entire EEC market, when there is a Community Directive, that right is guaranteed to every product which is in conformity with the requirements of the Directive.
- The restriction of the task of EEC legislation in this area to laying down essential requirements, together with the more recent revision of the EEC Treaty to allow for the adoption of common technical legislation by weighted majority vote, has dramatically speeded up the rate of technical harmonization. A single set of essential requirements for all twelve Member States of the EEC has already been agreed for some important sectors of industry (pressure vessels, toys, building products, machinery) and Commission proposals have been presented to the Council for others (protective equipment, gas appliances, medical devices).
- The new approach introduces an unprecedented flexibility in the conditions of compliance with EEC legislation. Instead of facing many different mandatory technical specifications, a non-European manufacturer may choose between following harmonized European standards, which gives immediate access to the entire EEC market, or alternative specifications which, after independent certification, may also confer the right of access to the market. (There may still be differences for some time to come between national standards in matters which are not covered by EEC legislation, but as European standardization progresses these differences will become less important.)

The new approach gives added importance to the process of European standardization and to agreements for the acceptance of test data and certificates of conformity. These issues are dealt with in the following sections.

PART II - THE EUROPEAN STANDARDIZATION PROCESS

a) European, national and international standards

Any explanation of European standards-making must address the preliminary questions, "Why is European standardization necessary? Why introduce a new level of activity between international standardization and national standardization?"

The answer is that European standardization promotes the use of international standards within Europe. The original motive for the creation of the two main European standards bodies, the European Committee for Standardization (CEN) and the European Committee for Electro-technical

Standardization (CENELEC) was to agree uniform application of international standards by the member national standardization bodies. That is still an essential part of their function today. Indeed, the internal rules of CEN and CENELEC, by making the transposition of standards agreed at European level obligatory, even in cases where agreement has been achieved through a majority vote instead of consensus, have reinforced the implementation of international standards within Europe.

International standardization work, whether in the form of existing international standards or of ISO/IEC working documents, is the starting-point for European standardization. Only where international standards do not exist, and are unlikely to emerge for the foreseeable future, do the members of CEN/CENELEC decide to harmonize their standards on any other basis. In fact, CEN/CENELEC have agreed to consult ISO/IEC before starting on new work in order to see whether the same work could be carried out at the international level instead. The results of CEN/CENELEC work are always communicated to the international standards bodies, and further development of international standardization is taken into account at the European level.

In general, European standardization has a good record of following international standardization. A greater proportion of European standards are based upon ISO/IEC standards than is the case for other major international trading partners, such as the United States or Japan. This is particularly true in the electrotechnical area. The commitment to achieve an integrated market within the European Community will have the effect of further reducing the number of national deviations from international standards which have been maintained in one or other Member State.

In other words, European standardization does not represent "additional" activity alongside international and national standardization. Rather, it is a substitute for one of the existing levels, that is, national standardization. The prospect of a single European market has made the idea of further national standardization largely irrelevant to European industry, a notion which is reinforced by the qualified majority voting system adopted by the European bodies.

Stronger European standardization reduces the risks of national deviation from agreed international standards; it reinforces international discipline in standardization at the regional level. This is good news for non-European as well as European exporters. Even where European standards are not in line with international standardization results, or where such results do not exist, the creation of a common set of specifications for eighteen countries is a very positive step.

b) The growing demand for harmonized European standards

The volume of European standardization has begun to increase rapidly in recent years because of two factors: the demand for harmonized standards to accompany EEC technical harmonization Directives (the legislative component) and a more spontaneous growth in interest in European standards from European industry itself with a view to benefitting more fully from the internal market (the voluntary component).

The legislative component of European standardization is represented by requests made by the European Commission to the European standards bodies for the adoption of harmonized European standards either in areas covered by new approach Directives or in subjects which are critical to the Community's industrial policy, particularly in the new technologies. In the former category (areas covered by EEC Directives), European standards have already been developed for electrical equipment, simple pressure vessels and toys and standardization work has started on building products, machines, personal protective equipment, electro-magnetic compatibility and gas appliances.

Further requests will be made for harmonized standards for medical devices and electro-medical equipment. Commission requests for other standards have mainly concerned the information technology sector, although requests have also been made for the programming of standards work on advanced ceramics and in the transport, energy and water supply sectors. (A list of Commission standardization requests to European standards bodies is given in annex 1.) The recent transmission to the Council of the proposal for a directive covering telecommunications equipment will also call for more European standards requests from the Commission.

A Commission request for a European standard is intended to accelerate standardization work in areas of high priority. The acceptance of such a request by the European standardization bodies imposes a "standstill" on all related national standardization work, thereby making technical expertise available for European work.

The Commission does not intervene in the drawing up of the standards, except to recall, where appropriate, the essential requirements of an EEC Directive and to refer to relevant international standards. It asks for the European standards to be completed within a certain period, in return for which it pays for the additional resources in the CEN/CENELEC Secretariat which will be needed for carrying out the standardization request. The participation of the member national standards bodies in the work requested by the Commission remains their own financial responsibility.

At present, because of the high demand for European standards related to Directives before the end of 1992, approximately half the annual budget of CEN/CENELEC is accounted for by Commission standards requests. This percentage is likely to decline as the Community's legislative programme for 1992 is completed and as European standardization undertaken at the initiative of the private sector gathers momentum.

EEC manufacturers are becoming more interested in European standardization as other obstacles to intra-Community trade recede under the Community's 1992 programme. It is becoming recognised that a single standard across Europe makes economic sense. Sectors in which initiatives have been taken by industry in recent months to promote such European standardization include processed foods and advanced industrial ceramics; some thought is also being given to European standardization in the biotechnology field.

The Community has also set up under Council Directive 83/189/EEC(1) an information system on national standardization activity, managed by the European standardization bodies, which is intended to promote a greater awareness among national standardization bodies of each other's work and to provide a procedure whereby work of common interest may be transferred from the national to the European level.

c) The procedures of European standardization

There are three European standardization bodies:

- the European Committee for Standardization (CEN)
- the European Committee for Electro-technical Standardization (CENELEC)
- the European Telecommunications Standardization Institute (ETSI)

Although their procedures for the final agreement upon standards are practically identical, the membership and working methods of ETSI is rather different from that of CEN/CENELEC and will be treated separately.

CEN/CENELEC

The members of CEN and CENELEC are the eighteen national standards organizations or electro-technical standardization committees of the EEC and EFTA countries. The work of the two European standardization bodies is organized through national delegations, each national member body being responsible for the representation of national interests at the European level and for consultation at national level concerning proposals for a new European standard. The standards prepared by CEN and CENELEC are based as far as possible on the consensus of the parties concerned in member countries.

The usual objective of European standardization in the CEN/CENELEC framework, as already indicated previously, is the harmonization of existing national standards. Under CEN/CENELEC rules, member standardization bodies are required to modify their national standards to conform to

European standards adopted under the CEN/CENELEC voting procedure, even in the case of those members which, in the absence of consensus, may have voted against a proposed European standard. The process is therefore one of an international negotiation, at a regional level, between the authors of existing national standards, the outcome of which binds the parties concerned.

This explains why CEN and CENELEC do not provide for the direct participation of interested parties in their work except through their national standardization bodies. All interested parties are given the opportunity to influence work at the European level by participation in the establishment of consensus at the national level. Direct participation by interested parties at the European level would be unmanageable as long as the European standardization process involved negotiating the convergence of existing national standards. European-level professional organizations or industrial associations may, however, be given observer status for European standardization of particular interest to them.

The normal process for adoption of a European standard is as follows:

- new work items are proposed by a member body (or by the Commission, EFTA or a European-level industrial federation).
- agreement to proceed is given by the Technical Bureau of CEN/CENELEC;
- in the case of a reference document (such as an international standard) a preliminary questionnaire is sent to members; if approved, CEN/CENELEC proceeds to a formal vote (see below), if not, the item is referred to a technical working group;
- in the absence of a reference document, or if valid objections against implementation of international standards are expressed, the work item is allocated to a Technical Committee for preparation of a draft;
- on completion of the draft, a six-month public enquiry is conducted in each member country;
- comments received are analysed by the Technical Committee, before a formal vote (two-months procedure) on a draft European standard;
- if adopted, the European standard is then published in each member country as a national standard.

In anticipation of, but subject to, the acceptance by Parties to the GATT Agreement on Technical Barriers to Trade of the EEC's proposal in the Uruguay Round for the establishment of a code of good practice for standardizing bodies, CEN/CENELEC already follow certain principles of that code.

Interested parties in the European standardization process, including those outside the Community, are informed about progress and can make their views known at a number of stages in the procedure.

New CEN/CENELEC work items are publicised in the newsletters of their member bodies and in a monthly Review of Activities published by CEN/CENELEC. CEN/CENELEC are prepared to receive from non-European standardization bodies that are members of ISO/IEC written contributions which are relevant to the proposed work.

During preparation of the draft European standard, interested parties within Europe can be associated through their national standards bodies with the coordination of national positions and may assist those bodies in the discussions at European level.

A draft European standard, once agreed at the technical level, is published for comment by each of the member bodies of CEN/CENELEC; copies of the draft standard are also made available to ISO/IEC, and through them to the relevant national member bodies of those organizations. ISO/IEC member bodies may address comments on the draft to the CEN/CENELEC Central Secretariat.

CEN/CENELEC are prepared, if comments are important enough and if a technical discussion might be advantageous, to organize meetings between the ISO/IEC member organization and the relevant technical body in CEN/CENELEC.

In their contacts with other standards bodies CEN/CENELEC will seek similar information and opportunities for comment to those they are willing to grant themselves.

ETSI

As indicated above, ETSI has a different kind of membership and different working methods to CEN/CENELEC. Membership is open to all relevant organizations with an interest in telecommunications standardization which belong to a country within the geographical area of the European Confederation of Posts and Telecommunications Administrations (CEPT), that is, administrations, network operators, manufacturers, users and research bodies. These members may participate directly in standardization work organized at the European level. The process of consultation, public enquiry, voting and publication of a European Telecommunications Standard is practically identical to that followed by CEN/CENELEC, and is carried out by the national standardization body member of CEN.

One distinguishing feature of ETSI is that non-European organizations concerned with telecommunications may be invited to participate as observers in the technical work of the organization. An agreement has also been concluded between ETSI and ANSI, the United States standardization body, on the exchange of information about their respective standardization work.

PART III - MUTUAL RECOGNITION OF TESTS AND CERTIFICATION INSIDE AND OUTSIDE THE EEC

Agreement upon a common set of technical specifications in the form of European standards is the first step towards the removal of technical barriers to trade within the Community. Another equally important step is mutual recognition by the EEC Member States of the procedures used to assess the conformity of a product to a standard, ranging from a manufacturer's declaration through quality assurance systems to independent testing and certification. Without such recognition, a manufacturer can be faced with serious delays and costs in introducing his product onto the market, even if he has followed a given standard.

The Community is developing a comprehensive policy to deal with the issue of recognition of tests and certificates, which confers clear rights for manufacturers, whether of Community or non-Community origin, throughout the Community market. In this regard the Commission transmitted to the Council a comprehensive communication on 24 July 1989 relating to a Global Approach to testing and certification(2), which formed the basis for a Council Resolution on this subject on 21 December 1989(3).

In cases where several Member States may have legitimately imposed technical regulations and differences in national legislation seriously affect intra-Community trade (see part I), the Community normally chooses to harmonise technical legislation by an EEC Directive. Each Directive then lays down a procedure to be followed for assessment of conformity of products and each Member State is required to allow the marketing of any product designated (usually by the "CE" Mark) as being in conformity with the requirements of the Directive.

The same rules apply whatever the origin of the product. In the absence of an EEC Directive, the right to "mutual recognition" applies to any product which has been admitted into free circulation on the territory of the Community. In the case of an EEC Directive, non-Community products have access to the certification system laid down in the Directive on the same footing as Community products, in conformity with the principles of the GATT Agreement on Technical Barriers to Trade. Where, for instance, a manufacturer's declaration accompanied by the maintenance of a technical dossier is sufficient for a Community manufacturer to obtain the "CE" mark, the same goes for a non-Community manufacturer. Where, on the other hand, the Community manufacturer has to submit his product for type examination by one of the "notified bodies" indicated for a given Directive, so does the non-Community manufacturer (or his authorized representative in the Community). Both must follow the same procedure and both have the same rights.

As far as recognition by the Community of non-Community test reports or certificates of conformity is concerned, this will depend upon the conclusion, case by case, of mutual recognition agreements between the Community and the non-Community partners concerned.

In the case of products that are subject to government regulation, the Council Resolution of 21 December provided that the Community would endeavour to promote international trade in regulated products in particular through mutual recognition agreements, while ensuring that

- the competence of the third country testing and certification bodies is and remains on a par with that required of their Community counterparts;
- the mutual recognition arrangements are confined to reports, certificates and marks drawn up and issued directly by the bodies designated in the agreements;
- in cases where the Community wished to have its own bodies recognised, the agreements establish a balanced situation with regard to the advantages derived by the parties in all matters relating to conformity assessment for the products concerned.

For products which are not subject to government regulation, mutual recognition agreements may be freely concluded by private parties; for those which are regulated, such agreements will be negotiated between the Community and the authorities of the non-Community countries.

This issue of mutual recognition agreements was one of the subjects dealt with in the Commission's Communication to the EEC Council of Ministers on a "global approach" to quality assurance, testing, and certification, in which a number of new initiatives are proposed for Community policy in this field. The main proposals, which have already been broadly endorsed by the Council in its Resolution of 21 December 1989, will benefit non-Community as well as Community industry. They include:

- i) a clear and coherent philosophy for the use of conformity assessment procedures in future EEC technical Directives. The Commission has proposed a so-called "modular" approach, which will give a reasonable degree of flexibility or choice to European industry while safeguarding the overriding need for safety (each Directive will provide for one or more alternative procedures taken from the "modules", or model procedures, already laid down by the Council, according to the level of risk of the product concerned);
- ii) the promotion of coordinated national accreditation systems for testing and certification bodies, in order to provide objective verification of their independence and competence on the basis of commonly-agreed criteria in conformity with ISO/IEC results;
- iii) the development of greater transparency in all aspects of testing and certification in Europe (definitions, rules, criteria and standards);
- iv) the establishment of a new organizational framework in Europe for testing and certification arrangements in the private sector (European Standards bodies have existed for over 20 years, but no similar structure exists for testing and certification);
- v) Community-funded assistance to less-favoured Member States, where necessary, in order to help them set up or reinforce their own infrastructure for testing and certification.

The global approach will give new impetus to the principle of mutual recognition and help to turn it into reality in the coming years. Greater objectivity, flexibility and homogeneity within the Community in the testing and certification area will benefit both intra-Community and international trade.

PART IV - CONCLUSIONS

The New Approach to technical harmonization and standardization, adopted by the Community nearly four years ago, is now making itself felt. Important pieces of Community product legislation are already in place and progress is rapid on the remaining issues. The underlying principle of the approach - reliance on the private sector for the development of technical specifications - is now generally accepted, even for the most politically sensitive products. The same principle is now being extended to the field of conformity assessment through the "global approach" described in Part III of this paper.

The Community's policy has transformed the prospects for European standardization. Alongside the significant volume of work that has been entrusted to the European standardization bodies by the Commission for legislative purposes, the private sector is now taking matters into its own hands and setting its own priorities for European standardization. We are witnessing an explosion in European standardization activity, as the possibilities of the 1992 programme become more widely understood. This phenomenon should be, and generally is, welcomed by the Community's international partners. The more progress is made towards a common set of European standards, based whenever possible on international standards, and towards a common approach towards conformity assessment, the more economic and profitable trade with the Community will become for its international partners.

The Community understands that the process of negotiating technical convergence within the European economy interests its international partners, and that it must make every effort to conduct the process in an open way. Information is already available and opportunities to influence the European debate exist; the Community will continue to make improvements where appropriate. Discussions are still going on in the GATT Uruguay Round negotiations on the subject of improving the transparency of the functioning of non-governmental standardizing and certifying bodies on a multilateral basis. While the Community cannot offer its partners "a seat at the table", it is ready to explain itself and to listen to other points of view. Above all, through its fundamental commitment to international standardization, it intends to avoid any unnecessary fragmentation of the international economy.

The Community hopes that its commitment to coordination and transparency of standardization activity, participation in international standardization and implementation of international standards will be more widely shared by its partners, and that cooperative efforts can be made to work more effectively towards international standardization. This will be one of the challenges of the 1990's.

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- (1) Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, Official Journal of the European Communities No L 109
 - (2) "A Global Approach to Certification and Testing"; COM(89)209 final, 24 July 1989
 - (3) Not yet published in the Official Journal of the European Communities. What does this mean for products originating from outside the Community?