COMMISSION OF THE EUROPEAN COMMUNITIES

COM(89) 209 final - SYN 208
Brussels, 24 July 1989

A GLOBAL APPROACH TO CERTIFICATION AND TESTING

Quality measures for industrial products

(Communication from the Commission to the Council)

Proposal for a

COUNCIL DECISION

concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives

---

(presented by the Commission)

A GLOBAL APPROACH TO CERTIFICATION AND TESTING

Quality measures for industrial products

(Communication from the Commission to the Council)

(2)

INTRODUCTION

Regulation, standardization and the various structures for evaluating the conformity of products to the regulations and standards together constitute some of the key elements in the organization of quality. That organization itself, which is the result of both legislative acts or regulations and consensual measures, has a profound influence on individual behaviour on a particular market and means that, in order to have access to that market, each manufacturer has to ensure that his products conform to the level of quality of which this organization is the expression.

In order to be effective the work on completing the internal market must have as its goal the gradual establishment of a common market organization, with its own level of quality, by acting *inter alia* on three of its distinguishing features: regulations, standards and structures for the assessment of conformity.

In its resolution of 7 May 1985 on a new approach to technical harmonization and standards, the Council laid the foundations for a policy geared to that objective. That resolution also states explicitly that this policy must be accompanied by a policy on the assessment of conformity and calls on the Commission to give this matter priority.

The memorandum and draft proposal for a decision annexed to this communication are the response to that request.

II THE OBJECTIVES OF A GLOBAL APPROACH TO THE ASSESSMENT OF CONFORMITY

In each national market the structures for conformity, inspection and testing meet specific needs expressed by the legislator and by the behaviour of buyers, users and consumers. Consequently, manufacturers must subject their products to a system of multiple checks according to the markets on which they intend to sell the products.

Where these barriers to trade are the result of binding regulations, they must be removed

- either, through directives based on Article 100a of the Treaty, by harmonizing these regulations and by requiring the authorities of each Member State to recognize proofs of conformity issued in other Member States;

- or by applying the doctrine sanctioned by the Court with regard to the obligations arising out of Articles 30 to 36 of the Treaty and under which a product lawfully produced and marketed in one Member State must, in principle, be admitted to the markets of the other Member States.

Where, on the other hand, these obstacles are the result not of legal requirements but of the free play of market demand - i.e. there is no direct or indirect influence from the public authority - the means for the gradual removal must be sought on the one hand in the harmonization of voluntary standards laying down criteria for the operation of national conformity structures and, on the other, in measures to promote agreements between these structures to bring them gradually towards the establishment of common systems of certification and testing.

There is a danger, however, that action taken on these three levels - namely harmonization of regulations, mutual recognition of national regulations and the approximation of structures within a system of voluntary certification - might be ineffective in practice unless they solve the same problem and satisfy the same needs, that is to say the need to create the conditions which will enable confidence to grow and become fundamental to the operation of mutual recognition.

The necessity for a global approach to certification, inspection and testing thus arises out of this basic need to create conditions that are conducive to confidence and, to that end, to bring the structures and procedures involved in these activities more closely into line.

III THE MEASURES NECESSARY FOR THE IMPLEMENTATION OF THE GLOBAL APPROACH

A start has already been made on some of the measures under this global approach since the resolution of 7 May 1985 on the new approach and these must now be further developed and placed in the context of an overall policy. They relate to three different levels of action.

A. Action on the basic structures

The basic structures for the evaluation of conformity are the bodies responsible for certification and inspection of the testing laboratories, and the manufacturers' quality systems. The aim is to make these structures as homogeneous, transparent and credible as possible throughout the Community, since this is a precondition for the proper functioning of conformity assessment, both compulsory and voluntary.

To this end the Commission took steps, as it had announced in its White Paper on completing the internal market[1], to encourage the drafting of technical guidelines setting out the criteria to be used when evaluating the competence of operators in the field of conformity assessment.

At present these guidelines (drawn from ISO documents) have been transposed into European standards (EN 29000 and EN 45000) and are therefore applicable in all Member States of the Community. The decision to give these guidelines the status of European standards rather than that of binding Council Directives was dictated by the nature of the subject matter, which does not lend itself well (except in special cases such as pharmaceuticals, chemicals or pesticides where there is a close link with human health) to being imposed as such on the economic system. This is an area that requires fairly sophisticated expertise which all operators will eventually have to acquire, but which will demand of them a considerable effort of adjustment and learning which cannot simply be imposed by law.

1 Doc. COM (85) 310, 14.6.1985, para 78

Legislation, however, can serve as a powerful instrument to assist this development nevertheless by introducing a presumption of conformity with the provisions of the Directives on conformity assessment for operators who can demonstrate that they are applying these standards (a practice that is well-known part of the new approach); in other words for manufacturers who apply the standards governing the management of quality assurance (EN 29000) and to certification bodies and accredited laboratories in accordance with the EN 45000 series standards.

The Commission therefore calls on the Member States to promote the implementation of these standards both in their regulations and in private certification systems, and to introduce accreditation systems based on these standards.

The Commission is also studying measures, including budgetary measures, to be envisaged for the development of certification and testing structures in those Member States or specific sectors of industry where delays are liable to jeopardize the smooth functioning of Community regulations.

B. Action on regulations

The conformity assessment procedures in Community regulations must take account of the considerable progress made and the new mechanisms available (quality assurance, accreditation, standardized assessment criteria and so on).

A global approach which involves drawing up a set of modules for the various operations is designed to allow the Community legislator to lay down the most appropriate procedures in the harmonizing directives, using what has already been done in the field of European and international standardization as a basis. The fundamental principles of the modular approach are as follows:

- the Directives must define the limits of the choice of procedures open to the manufacturer for ensuring compliance with the essential requirements;

- the affixing of the CE mark on the products is the tangible sign of their conformity to Community rules. No other mark of conformity to Community rules is allowed to be used, although voluntary marks of conformity to standards are compatible with the CE mark. The Commission will be submitting a proposal for a Directive on the use of the CE mark and will be examining carefully the case for a possible coexistence of the CE mark and national voluntary marks.

- the bodies involved in the conformity assessment procedures are designated by the Member States and notified to the Commission and the other Member Sta$s in accordance with the common assessment criteria . The fact that these accredited bodies conform to European standards (EN 45000) gives rise to a presumption of conformity with those criteria.

As far as non-harmonized national regulations are concerned, all the steps taken or advocated under point A above are intended to give full effect to the principle of mutual recognition; their aim is that the certification bodies and laboratories that are authorized to attest that the products conform to national regulations should be designated or accredited according to objective criteria of transparency and competence and that the operation of such bodies should also satisfy the same criteria. In other words, their purpose is to ensure that the requirement of mutual recognition is applied in full without any possibility of this being contested by the national authorities.

Similarly, it can be argued that the harmonization of conformity assessment procedures, as advocated by the modular approach, will inevitably exert an influence on the procedures laid down in non-harmonized national regulations. Moreover, Directive 83/189 is the appropriate instrument for making sure that this is done in a systematic way.

C. The need for a European infrastructure for certification and testing

The measures set out in point A above relate to the mechanisms which can help to generate the necessary confidence in the competence of operators in the field of conformity assessment. This confidence is essential if mutual recognition is to work. In areas which are not covered by the aims of Article 36 and which would be described as activities carried out privately on a contractual basis, mutual recognition cannot be imposed by law. Consequently, the efforts to remove barriers to trade that arise from the existence of national voluntary certification arrangements will have to be accompanied by incentives for cooperation between organizations and laboratories at European level - as was the case in fact with standardization - with a view to the establishment of joint systems for certification and the recognition of test results.

This has led to a call from several quarters for a flexible and non-bureaucratic structure, in Europe, to be set up under the aegis of the Commission within the existing European standardization infrastructure (CEN/CENELEC).

The Commission will also look into the possibility of a directive coordinating the statutes of these bodies, particularly as regards questions of liability and insurance which are likely to have a bearing on their cooperation agreements.

IV. CONCLUSION

This communication contains the main elements of the memorandum (set out in annex 1) which elaborates on all the components of a European policy in the field of conformity assessment which, if carefully and properly assembled, will provide the Community with one of the basic essentials for progress towards an overall quality policy, indispensable to any industrial policy and inherent in the very concept of an internal market.

The measures recommended can be summarized as follows:

a) The Council:

- is to adopt the modules for the various phases of the conformity assessment procedures, which are to be used in the technical harmonization directives, and the criteria governing their use in those directives;

- is to encourage the Member States to promote on a wide scale the use of standards EN 29000 and EN 45000 so as to harmonize to the greatest possible extent the criteria for the evaluation of quality systems and of certification, inspection and testing bodies, making use of the instrument of accreditation;

b) The Commission

- is to prepare, on the basis of the guidelines set out in the attached memorandum, a proposal for a Directive on the use of the CE mark which it intends to put before the Council by the end of 1989;

- will give mandates to CEN/CENELEC to supplement the standards on the evaluation of the competence of operators in the area of conformity assessment (EN 29000 and EN 45000);

- is to continue its action in cooperation with the groups concerned with a view to expediting the completion of a suitable infrastructure for certification and testing, within the organization of European standardization.

- will take appropriate steps to strengthen the role of the Community Bureau of Reference (BCR) in the fields of standardization and cooperation between testing laboratories;

- will examine the questions of liability and insurance and related problems associated with the different statutes which certification,

inspection and testing bodies may have, with a view to drawing up, if appropriate, a proposal for a Directive;

- is to seek to ensure that the Treaty rules on competition are observed by certification, inspection and testing bodies when they conclude recognition agreements or choose partners for such agreements or, more generally, exercise their normal activities;

- shall seek to ensure that Member States observe the principle of mutual recognition both in the context of harmonized rules and in the context of national regulations;

- shall study measures, including budgetary measures, to be envisaged for the development of the certification and testing structures where there are serious delays;

c) The Council and the Commission will work for the implementation of a coherent and open policy towards non-Community countries in the field of conformity assessment. Since the global approach is based to a large extent on what has already been achieved in international standardization, it provides the appropriate basis for the conclusion of mutual recognition agreements at international level.

•

• •

The Commission proposes to the Council that it

- approve the broad lines of the global approach to the assessment of conformity in respect of industrial products set out in its memorandum in annex to this communication (Annex I);

- adopt the proposal for a Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, and the criteria governing their use in those directives (Annex II);

ANNEX I

COMMISSION MEMORANDUM ON A GLOBAL APPROACH TO CERTIFICATION AND TESTING

Instruments of quality for industrial products

CHAPTER I

INTRODUCTION

The adoption by the Council of Directive 83/189/EEC on 28 March 1983[1] laying down a procedure for the provision of information in the field of standards and technical regulations constituted a watershed in terms of the Community's attitude towards the elimination of technical barriers to trade and led to the approval by the Council of its Conclusions on Standardization[2] on 16 July 1984, and its Resolution of 7 May 1985[3] on a new approach to technical harmonization and standards.

These three texts laid the foundation for a policy intended to make national activity in this area more transparent, to substantially reinforce European standardization and to streamline Community legislative techniques through greater recourse to European standards and the restriction of legislative texts to the "essential requirements" for the protection of the general interest, in particular health and safety or the protection of the consumer and of the environment.

The Council Resolution of 7 May 1985 clearly states "that the new approach will have to be accompanied by a policy on the assessment of conformity" and calls on the Commission to give this matter priority.

---

(1) OJ No. L 109, 26.4.1983

(2) OJ No. C 136, 4.6.1985 p.2

(3) OJ No. C 136, 4.6.1985, p.1

Testing and certification issues in past Community legislation have almost exclusively been restricted to the determination of common technical specifications for products, as these were the main object of the national regulations which had to be harmonized in order to eliminate barriers to trade.

In many Member States, however, as in many other countries in the world, there is a growing move towards ensuring the level of safety of a product by means of measures to improve and to control the quality of the product itself as well as the quality and competence of the suppliers, the testing laboratories, and the certification and inspection bodies. Under this approach, measures designed to ensure the product's safety and quality can be taken at a number of different stages in its development and can relate to the product itself, to the manufacturing process or to the controls applied to either.

That is why the Council called on the Commission to draw up a policy not simply restricted to certification, i.e. the action of certifying the conformity of a product or service to a given specification, but enlarged to include conformity assessment, which covers a much wider field, involving testing (and calibration), quality systems, certification and accreditation. Moreover, the national systems for ensuring the safety of products put on the market are in some instances extremely divergent, ranging from full confidence in the manufacturer (manufacturer's declaration) to reliance on inspection at the place of installation or during the use of products. (In the foodstuffs area the distinction between pre-market and market controls is not made as the systems of control cover both).
This memorandum is a response to these broader terms of reference and attempts to bring together all the different elements which, when carefully and properly assembled, will give the Community as a whole a comprehensive quality policy which is an indispensable part of any industrial policy and fundamental to the very concept of an internal Market.

To begin with it is necessary to circumscribe the notion of quality. For ISO (8402 - 1986) quality is 'the totality of features and characteristics of a

product or service that bear on its ability to satisfy stated or implied needs". Over and above the commercial connotations of quality which are expressed in terms of excellence, it is clear that the ISO definition is a generally acceptable one, both for the private and legislated sectors. Using this definition as a basis, quality organization relates to the elements and instruments to be developed in order TO ascertain and control identification, transparency and observance of these properties and characteristics, thus ensuring fairness of transactions and an informed choice by the consumer, in accordance with the binding rules and voluntary standards applied.

Consequently, under Community legislation, quality is associated with the essential requirements, inasmuch as quality can only be equal to or higher than the level of these essential requirements in the Community since any product failing to satisfy them is, by definition, prohibited. Outside the field of legislation where there is no need to legislate since the products do not present any dangers, it is clear that the concept of quality remains linked to the ability of the product to meet the needs of users and consumers, in other words, the needs of the market.

The purpose of this memorandum is to establish a doctrine on the assessment of the conformity of products to the requirements set down in legislation or other technical specifications. In this sense it is just one basic component of a quality policy which must also include others.

CHAPTER II

THE ROLE AND IMPORTANCE OF TESTING, CERTIFICATION AND INSPECTION

1. Basic concepts

Just as the process of testing is an integral part of product design and development,and continuous surveillance and testing are an essential part of ongoing production so as to ensure conformity with the original design, prototype or model representative of the projected series.

Metrology and calibration provide the basic language for the measurement which is fundamental to testing, while quality systems, certification and inspection procedures provide the final demonstration of quality, i.e. quality in the sense of conformity to product requirements.

All of these elements can be found either in private systems (i.e. used for commercial reasons) or in systems imposed by public authorities for the purpose of ensuring a proper level of safety.

These activities are carried out at varying stages :

- before production, in the course of the development of a prototype or model;

- during production, either as surveillance of the products or as surveillance of the production processes ;

- after the manufacturing process but before the marketing of the product;

- after the initial marketing of the product. This can include spot

checks on the market and inspection after installation and during use of given types of products.

The procedures may be undertaken either by competent and properly equipped manufacturers themselves, or by specialist third parties, i.e. testing laboratories and certification bodies. These laboratories and bodies can, in turn, be evaluated as to their technical competence by a third party (accreditation body) and hence be accredited, as can in-house testing laboratories which are separate from production or commercial divisions of a company. Increasingly industry is using quality systems (with the object of ensuring that products conform to a model or to a technical specification) and where these are certified by a third party the credibility of that manufacturer is enhanced insofar as quality and product safety no longer solely depend on product certification for verification. The competitiveness of his industrial production is improved and the costs associated with lack of quality (rejects, recalls, customer guarantees, etc) are reduced.

2. The private and public sectors

Companies are now voluntarily investing, substantially, in quality systems and other in-house techniques because they improve efficiency, cut costs, and establish a reputation for reliability. Alternatively a company may entrust systematic or sample product testing to an independent body (third party). In either case the concern is for quality and cost saving - and the decision as to the appropriate technique to apply is a voluntary one.

Mandatory testing, certification and inspection are generally imposed by public authorities in order to ensure that certain public interests such as health, safety, consumers or the environment are effectively protected.

Testing, certification and inspection however, are not always based solely on such considerations; they can also be an integral part of a national industrial policy intended to promote goods both nationally and

internationally. The reasoning behind such policies is that the reputation of certain certification marks represents a strong commercial advantage in international trade. Nevertheless, it should be underlined that the proportion of products which come under mandatory systems in the Member States remains small compared to the total quantity of products on the market.

3. The role of testing laboratories, certification and inspection bodies

Their is an important role in ensuring conformity, building confidence and protecting public interests. The competence and quality of such bodies varies, as does their distribution among Member States. It has been estimated that there are over 10.000 testing laboratories and 1.000 certification bodies in Europe of varying capacity, legal status and reputation. In the less industrially developed regions of the Community, the presence of competent bodies is small. If they are to become an essential part of the structure of the internal market, the Community will have to see to it that this gap is filled.

4. Product liability

Council Directive 85/374/EEC of 25 July 1985[5] on the approximation of the laws, regulations and administrative provisions of the Member States concerning product liability makes manufacturers liable for damage caused by defective products. This directive clears the manufacturer of his liability if he proves "that the defect is due to compliance of the product with mandatory regulations issued by the public authorities" i.e. when he has no discretion whatsoever as to how to proceed. In most cases Community technical regulations do not affect such liability because they leave the manufacturer a choice as to the specification to be applied. Under the new approach Directives the economic operator is not obliged to follow the European standards referred to in the Directives. He also has some choice

(5) OJ No. L 210, 7.8.1985, p. 29

as to the methods for demonstrating conformity to the Directive. Testing, certification and inspection may diminish the risks and hence the likelihood of damages (which in turn reduces the insurance cost), but do not affect the liability of the manufacturer.

This Directive therefore puts responsibility on the supplier to produce safe products, through the pressure which the costs liability places on him after an accident due to a defective product.

Testing, certification and inspection activities place the emphasis on preventing as far as possible the putting on the market of unsafe products and thus avoiding damage being caused. These two elements can therefore be seen as complementary in ensuring an adequate level of safety, whether the testing, certification and inspection activities are mandatory or voluntary.

Community safety policy therefore places responsibilities on the manufacturer through product liability (within the limits set out in Directive 85/374/EEC) and in the form of the obligation imposed by the technical legislator to take certain preventive measures.

5. National practices

Certain Member States in some industrial sectors rely on the manufacturer to ensure conformity to mandatory safety requirements, whilst others require third party intervention. The choice of mechanisms to be applied and the procedures for applying them vary from Member State to Member State and from sector to sector as does the use of voluntary or mandatory certification. This variation is due to the relative importance attached to the manufacturers, to the strength or weakness of national testing, certification and inspection infrastructures, to national political traditions in respect of the role of legislation, and, before 1985, to different national attitudes towards product liability. It is an expression of divergence between the Member States not as to the results to

be obtained but rather as to the techniques which should be used in order to reach the desired end.

The Council of Ministers in its Conclusions of 16 July 1984 recognized "that the objectives being pursued by the Member States to protect the safety and health of their people as well as the consumer are equally valid in principle, even if different techniques are used to achieve them."

In the past, the impossibility of accepting this divergence of practice and, more importantly, the difficulty of demonstrating that different testing, certification and inspection techniques could lead to a level of safety acceptable in legal and political terms, even though the technical results may not be identical, have hampered the development of Community legislation.

6. Community legislative techniques

Almost all EEC Directives adopted to date, apart from new approach Directives and the "Low Voltage Directive"(5), provide for the operation of the mutual recognition of certificates on the basis of a single assessment technique for a given product and on certificates being issued by or under the direct responsibility of public authorities. Certification and the mutual recognition thereof were considered to be within the purview of public administration. Directives did not, therefore, lay much emphasis on the technical competence of the bodies involved.

The Council Resolution of 7 May 1985 on the new approach to technical harmonization made a clear distinction between the function of the essential requirements (mandatory) and that of standards (voluntary), underlining the notion that a product manufactured in conformity with

(5) OJ No. L 77, 26.3.73, Council Directive of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

harmonized standards is presumed to conform to the essential requirements established by a Directive. This distinction is particularly important in the present context, in that one of its consequences is to leave the manufacturer a degree of flexibility in demonstrating conformity to the Directive. If he follows the harmonized standards he may use a simplified procedure, whereas if he manufactures directly to the essential requirements, for whatever reason, third party intervention is required to ensure conformity with the Directive.

Thus the Council Resolution itself introduces the approach whereby there may be different ways of evaluating the conformity of a product to Community technical legislation. However, this is only a first step in addressing to the necessities of the internal Market in this sphere of activity.

CHAPTER III

THE OBJECTIVES OF A GLOBAL APPROACH

The activity of assessing the conformity or products to the technical specifications which define their level of quality is a response to a need expressed either

- by mandatory regulations, or
- by the market.

In the first case, the proofs of conformity are laid down by the public authority which requires the manufacturer - for reasons which may bear on the protection of health, safety, the environment, etc - to adduce those proofs before the products are placed on the market.

In the second case they are required by the purchasers when concluding commercial transactions, and are therefore contractual in nature.

In both cases - regardless of whether they are mandatory or voluntary - the various types of proof of conformity (marks, certificates, test reports, etc) must be provided by suppliers wishing to sell their goods on a particular market.

Given the liability aspects, which can be an extremely important factor in the assessment of conformity, it is natural that the person demanding the proof of conformity (be it the public authority or the purchaser) should at the same time demand the soundest possible guarantees of competence and credibility, both in technical terms and in terms of professional ethics, from those adducing that proof.

The result of this is that in each national market the structures for conformity, inspection and testing meet the specific needs expressed by the

legislator and by the behaviour of buyers, users and consumers. Consequently, manufacturers must subject their products to a multitude of controls depending on the markets on which they intend to sell them.

Where these barriers to trade are the result of mandatory regulations, they must be removed

- either by means of directives based on Article 100a of the Treaty, through the harmonization of these regulations and through the requirement on the authorities of each Member State to recognize proofs of conformity issued in other Member States;

- or by applying the doctrine sanctioned by the Court with regard to the obligations arising out of Articles 30 to 36 of the Treaty and under which a product lawfully produced and marketed in one Member States must, in principle, be admitted to the markets of the other Member States.

Where, on the other hand, these obstacles are the result not of legal requirements but of the free play of market demand - i.e. there is no direct or indirect influence from the public authority - the means for their gradual removal must be sought, on the one hand, in the harmonization of voluntary standards laying down operating criteria for the national conformity structures and, on the other hand, in measures to promote agreements between these structures to bring them gradually towards the establishment of common systems of certification and testing.

There is a danger, however, that action taken on these three levels - namely harmonization of regulations, mutual recognition of national regulations and the approximation of structures within a system of voluntary certification - might be ineffective in practice unless they solve the same problem and satisfy the same needs, that is to say the need to create the conditions to enable confidence to grow and become fundamental to the operation of mutual recognition.

The necessity for a global approach to certification, inspection and testing thus arises out this vital need to create conditions conducive to confidence and, to that end, to bring the structures and procedures involved in these activities, more closely into line.

The next chapter sets out the various measures, some of which have already been initiated since the Resolution of 7 May 1985 on the new approach and which now need to be further encouraged, developed and, in particular, placed within the context of a comprehensive policy. It comprises four sections dealing respectively with :

- action to be taken on basic structures (the operation of which is instrumental in determining the results of both mandatory and voluntary certification) in order to make them as homogeneous, transparent and credible as possible throughout the Community;

- the measures necessary to facilitate mutual recognition under the procedures for assessment of conformity laid down in the harmonizing directives based on Article 100a of the EEC Treaty;

- The impact of these actions on the implementation of the Court's case-law concerning mutual recognition of national regulations;

- initiatives to be promoted to assist cooperation between national certification and testing structures.

CHAPTER IV

THE NECESSARY MEASURES TO IMPLEMENT THE GLOBAL APPROACH

Section One : BUILDING CONFIDENCE THROUGH COMPETENCE AND TRANSPARENCY

Paragraph 3 of Article 100a of the Single European Act sets out the principle that, with respect to industrial products, health and safety legislation as well as the protection of the environment and the consumer shall be based on a high level of protection. This can be achieved amongst other means by ensuring a high level of quality of the products themselves, through appropriate European standardization and the promotion of the use of quality management systems by manufacturers. Improvements in the competence, capacity and quality of the testing laboratories and of the certification and inspection bodies will also contribute. But confidence in the new systems will only be developed if the systems not only work properly but are seen to work properly. Thus transparency and competence are both equally essential in order to generate confidence.

Transparency and competence of quality structures are also a necessary condition for the success of a Community industrial policy as a whole, since testing, certification and inspection constitute the foundations of any industrial activity. The development of a Community market in these areas will reduce unnecessary costs both for economic operators and for the public authorities by limiting the number of certifications, tests and multiple inspections. It will also lead to an improvement in the competitiveness of European products both on the Community market and on world markets. It must be recognized, however, that the reduction of testing, certification and repetitive inspection for many products will no doubt be offset by additional voluntary demand for these services as manufacturers and consumers attach greater importance to quality. This is seen as a particularly important factor in maintaining or even enhancing the competitive position on the world

markets of an industry established in countries with high costs.
Consumers and users will find themselves faced with fewer administrative costs passed on in the price of the products and will have a greater choice of products,on a more resilient and innovative market, in which the safety considerations will have been catered for effectively but without artificial or arbitrary constraints.

1. European standards

The Community policy for the reinforcement of European standardization was formally initiated in 1983 with the adoption of Directive 83/189/EEC laying down inter alia a procedure for the provision of information on national standardization programmes and draft standards and the mechanism by which the Commission, after consulting the Standards and Technical Regulations Committee, can give mandates to the European standardizing bodies to draw up European standards for Community purposes and in particular to ensure compliance with the essential requirements. The effect of such standardization orders is to impose a formal standstill on all national work covered by the European mandate.

To date, several standardization programmes have been or are being drawn up under this system, in particular in areas covered by new approach activities (such as toys, pressure vessels, construction products, machines, personal protection equipment) and by the Community policy in information technology and telecommunications. Most of this standardization work relates to product specifications.

European standardization also has an important role to play in helping to open up procurement contracts which traditionally impose national technical specifications on suppliers. The Community has already amended the existing Directives on public procurement to require reference to European standards where they exist, and the Commission has recently transmitted to the Council proposals which adopt the same approach in respect of the hitherto excluded sectors (water, energy supply, transport

and telecommunications). These proposals will require the adoption of a great number of European Standards, and work is underway to prepare new mandates for the European standards bodies to draw up appropriate standardization programmes.

European standardization activities are also expanding and will have to expand still further in order to reduce divergencies between national standardisation in those areas which do not come under EEC regulations.

It must also be emphasized that European standardization will be easier in future insofar as it is no longer necessary to impose a single European technical solution in a European standard except, possibly, where questions of interoperability and compatibility are involved. In view of the separation in the new approach between the level of safety to be obtained and the means by which it can be obtained, European standards can recognize the technical validity of a number of technical solutions as long as they are capable of giving the desired result : conformity to the essential requirements. Thus a greater degree of flexibility can be introduced into European standardization.

More emphasis will, however, have to be given to drawing up common test methods and to addressing testing and conformity assessment issues in order to reinforce the effectiveness of product standards. Many current European product standards are posing problems for testing laboratories, certification and inspection bodies alike, because they have been drawn up for the purposes of the manufacturing processes and techniques and not specifically for that of facilitating demonstration of conformity.

The Commission has already recognized this problem and is proposing to modify its framework contracts with CEN and CENELEC in order to take it on board. These considerations will be incorporated into future standardization mandates. The need for greater interaction between the preparation of standards and testing, certification and inspection must also be kept in mind in the context of the establishment of the European Organisation for Testing and Certification referred to below, as proper

Input into standards activities will also help to ensure that European standards become more comprehensive and effective.

2. Criteria to guarantee technical competence

a) The manufacturer

Besides using European standardization as a means of improving the quality and acceptability of products, it is necessary to enhance confidence in the ability of the manufacturer to supply quality products. This confidence cannot be simply imposed either upon public authorities or consumers; it depends primarily upon the attitude of the manufacturer himself, i.e. it must be earned !

The international and, recently, the European standardization bodies have drawn up appropriate instruments to assist the manufacturer who wishes to obtain a consistent product quality through the proper management of his quality systems. They are enshrined in the EN 29000 series of standards on quality assurance techniques (the common CEN and CENELEC implementation of the ISO 9000 series), which contain the general rules relating to quality assurance models and the general rules applicable to the different industrial sectors.

Quality assurance techniques should play an important role in developing quality consciousness in the Community, but can also contribute towards conformity assessmentin in both the voluntary and the mandatory areas. Although these techniques cannot be made mandatory as such because each specification is linked to the characteristics of the production unit, they may be presented as a complement to the more conventional method of product certification.

Quality assurance techniques are an integral part of the design and operation of a production unit. As an investment in modern management techniques, quality assurance can play an important role in reducing the

number of non-quality products, hence reducing the number of rejects at the end of the production line. This leads to a better quality image for the manufacturer and his products and to a reduction of his costs (rejects, controls by third parties etc).

In the face of world competition, in particular from countries such as Japan and the United States where quality has become an integral part of the production process in certain important mass production sectors, the recourse to quality assurance techniques must be one of the main objectives of a Community industrial policy. By providing for the possibility of using quality assurance in the demonstration of conformity either to an approved model or to standards, as an alternative to more conventional product certification based only on product testing, Community legislation will be encouraging investment in quality on the part of the manufacturer and will allow him to reduce the costs incurred by product certification. In the past, the obligation to use certification has led manufacturers, on occasion, to reduce internal production controls to a bare minimum, thus placing the burden of finding rejects on the third party. Such a situation is economically second-best.

Promoting voluntary use of quality assurance techniques not only makes economic, industrial and commercial sense; it also helps to ensure that the products placed on the market are safe.

CEN and CENELEC should therefore consider the framing of a standardization programme, drawing on the practical experience of economic operators in the implementation of these standards.

b) Testing laboratories, certification and inspection bodies

Experience of the implementation of Community Directives under the old approach, the restrictions placed on the free movement of goods by national legislation and attempts at cooperation agreements between

bodies and laboratories in the field of voluntary certification have highlighted one of the main problems, namely the lack of adequate information concerning the operation and competence of these bodies as well as the lack of means for demonstrating their competence.

Such uncertainty can only be avoided if appropriate criteria are used for evaluating these bodies on the grounds of technical competence and independence and applied throughout the Community. Criteria have been developed over recent years in international fora such as ISO, IEC and ILAC (International Laboratory Accreditation Conferences), and in November 1987 CEN and CENELEC were mandated by the Commission to adopt a set of criteria, developed by Commission working groups, as European Standards before the end of 1988.

These documents are at present being processed as the EN 45000 series of European standards for the operation and evaluation of testing laboratories and certification bodies undertaking product certification, quality system assessment and so on. Once they have been formally adopted as European Standards, they will be accepted in all the Member States and this acceptance will ensure their implementation (since any diverging national standard must be withdrawn), without there being any need to provide for mandatory across-the-board application, which would be contrary to the philosophy of the new approach. Conformance to these standards will help to reinforce the position of Community producers wishing to export to other Community countries, especially when the test reports and certificates concerned are based on harmonized European standards.

The more these criteria are used, both in Community and in national legislation, the more confidence is likely to develop. This will encourage the private sector to use the selfsame criteria when operating outside mandatory systems so as to reinforce the credibility of their activities and thus reduce the possibility of disputes. Member States should commit themselves to promoting the use of the EN 45000 series as widely as possible.

It has to be pointed out that the EN 45000 series is incomplete since it does not yet cover all conformity assessment activities. It will be necessary, in particular, to establish criteria for the inspection bodies and for the bodies responsible for accrediting the certification and inspection bodies. Standardization mandates to this end will be issued shortly to CEN/CENELEC.

Lastly, the implementation of these standards and the operation of the existing mutual recognition agreement between bodies clearly shows that it will also be necessary to look into the issues of liability and insurance, as well as related questions concerning to the various types of status such bodies may have.

c) Good Laboratory Practice (GLP)

Good Laboratory practice guidelines (GLP) follow the same logic as the EN 45000 series of standards, i.e. they define a level of performance for laboratories. GLP guidelines have been developed for specific use in the field of chemicals (not only chemicals but also pharmaceuticals, food additives etc....) and first originated in the OECD. They were adopted by the Council in Directives 87/18/EEC and 87/19/EEC of 18.12.86[6] for testing of chemical products, pesticides and pharmaceuticals.

These mandatory provisions represent a departure from the general philosophy of the new approach, which is based on the principle that standards are voluntary. It is explained by the special features inherent in this sector with regard to the protection of human health and by the fact that the regulations in this area are largely based on the old approach.

(6) OJ No. L 15, 17.1.87, p. 29
OJ No. L 15, 17.1.87, p. 31

Within the Community, the principles of GLP should be seen as a particular sectoral application of criteria governing the operation of laboratories, and their future evolution should be examined in this context rather than in isolation. There is a move at international level towards a review of the OECD GLP guidelines in order to separate those criteria which can be considered as being general (and which are therefore covered by the EN 45000) from those which relate specifically to chemical analysis testing laboratories. The object of such a move is to show that all testing laboratories conform to the same basic criteria, with specific supplementary requirements being drawn up for particular industrial sectors (such as GLP for chemicals).

3. Transparency

Technical competence and transparency must be taken together if mutual confidence is to be achieved. Transparency means access to information as well as openness of operation.

a) Information procedures for technical specifications

Directive 83/189/EEC of 28 March 1983 established two information procedures which ensure transparency as to national activities in the field of draft standards (operating between the national members of CEN and CENELEC) and in the field of draft technical regulations (operating between the Member States and the Commission). Both procedures concern not only product specifications but also product-related issues such as testing, certification and inspection requirements.

Information on draft standards is fed into the Integrated Standardization Information System database (ISIS) in CEN and CENELEC, which is accessible to member standards bodies for further distribution to interested parties. Discussions are underway between the Commission and the European standards organizations to promote more direct and wider access to the information by European industry.

b) PROMOLOG-CERTIFICAT

The above information will be complemented by the end of 1990 by the CERTIFICAT database which the Commission is developing with AFNOR and CEN and which will contain information on all certification systems and procedures in Europe, both mandatory and voluntary, including the relevant technical specifications and the bodies and laboratories involved. Thus, in spite of the lack of harmonization, the economic operator will have the means of knowing what is expected of him and how he can go about placing his product on his targeted market.

It is intended that CERTIFICAT be merged with the integrated standardization information system (ISIS) at a later stage, and may also be expanded to contain a directory of testing laboratories in Europe.

c) Transparency of conformity to technical competence criteria

Greater confidence will be generated if this competence and quality are transparent, i.e. can be demonstrated.

- Certification of manufacturers' quality systems

The manufacturer has always had the possibility of asking a third party to test or certify his products. However, there is a growing awareness on the part of manufacturers of the value of quality assurance techniques and, at the same time, of the need to be able to demonstrate to purchasers that these techniques have been properly applied. Consequently, private certification of quality systems have developed in many parts of the Community.

Such a development should be encouraged, all the more so as the standards used by all these systems are mainly based on the abovementioned ISO 9000 series of standards which has been recently adopted at European level as the EN 29000 series. There is thus a

common standard throughout Europe on which third party certification of quality assurance can rely.

The development of private certification systems based on the same European Standards will be a step towards reducing the multiplicity of separate and different audits which manufacturers are often required by their various buyers to undergo. This should not only encourage large and small firms to make more systematic use of quality systems, but also reduce considerably the costs of such systems, especially for small and medium-sized enterprises which are often sub-contractors for bigger firms.

The more the various national certification systems in this area are made coherent and compatible, the easier it will be to ensure mutual recognition and acceptance of certificates and the more accessible and acceptable quality systems will become throughout the Community.

- Intercomparisons

Testing laboratories and certification bodies can demonstrate their competence and efficiency by taking part in "Round Robin" tests (the same product is tested, in turn, by all the participating bodies and the results compared), or in proficiency testing programmes (i.e. by means of interlaboratory test comparisons). Such techniques are important today and will no doubt be used even more in the future in mutual recognition agreements. The Commission's Community Bureau of Reference (BCR) has been carrying out a programme of work in this area for a number of years which should be expanded beyond scientific circles into the industrial arena. A reinforced BCR programme in this area, more directly designed to reflect current industrial priorities than hitherto, would have the objectives of helping to develop transparency, to improve the quality of the laboratories and to prepare testing material for input into the European standardization process.

- Accreditation

Accreditation entails laboratories, certification and inspection bodies being assessed and audited at regular intervals as to their technical competence against published technical criteria by a third party. As a third party assessment technique, it is therefore an important instrument for the generation and maintenance of confidence in these bodies, just as certification is for products. The EN 45000 series of standards includes the technical criteria for the operation and assessment of testing laboratories as well as those to which the accreditation bodies for testing laboratories themselves should conform. They also include the criteria for certification bodies.

In the field of testing laboratories there are already eight accreditation networks in the Community either in operation or in development phase at the national level (but not operated by the public authorities). This development should be extended to the rest of the Community and cooperation between the various national networks reinforced and stimulated, a process which will be helped by the adoption and implementation of the EN 45000 series of standards.

Mutual recognition agreements between national networks, based on the EN 45000 series, standardized test methods and the inclusion of interlaboratory test comparisons and proficiency testing for the implementation of these agreements in conjunction with mutual audits, appears to be the next logical step towards promoting greater competence and quality in testing and certification in the Community. It is the Commission's belief that creating a "network of the national networks" would be the most efficient means of achieving the necessary degree of trust between them. A more formal structure at Community level may be necessary, in the future, to oversee the mutual recognition agreements in order to ensure consistency between the agreements and to cement the bonds created by them. However, in view of the proposals concerning an overall European infrastructure for testing and certification, (see below), the Commission does not feel that it is appropriate to encourage the setting up of a Community accreditation body which would unnecessarily lengthen the chain of responsibility and add unnecessary administrative and bureaucratic burdens without providing additional confidence.

In the field of certification and inspection bodies accreditation techniques should be more widely applied. At present only three national accreditation systems for such bodies exist in the Community (Netherlands, Portugal and the UK). The extension of accreditation to this area would help mutual recognition, facilitate the drawing up of Community legislation, and reduce the need for more arbitrary national designation, which can have the effect of discriminating against national bodies which can demonstrate their competence. As is mentioned in Section Two of this chapter, the Commission has every intention of encouraging more systematic recourse to the technique of accreditation by inviting Member States, wherever possible and appropriate, to notify for the purposes of EEC legislation only those bodies which are accredited to EN 45000 or those which can demonstrate by any other means that they conform to these standards (e.g. by providing documentary evidence).

4. Community support for the development of certification and testing structures

Delays in the development of infrastructures for certification and testing, inspection, accreditation and quality management in certain sectors of industry or in certain countries may seriously hamper the implementation of this policy of harmonizing structures and procedures. In particular this may prove a real obstacle to the putting into effect of certain Community directives.

The Commission is studying measures, including budgetary measures, which might help to make up the delays in the development of these infrastructures.

Section Two : NEW LEGISLATIVE TECHNIQUES FOR CONFORMITY ASSESSMENT

1. Basic orientations

The previous chapters have dealt with basic instruments applicable to both the voluntary and the regulatory areas, whether national or Community. Their development, taken in conjunction with the growing experience in the drawing up of New Approach Directives should allow such Directives to be more effective in protecting collective interests whilst avoiding undue bureaucracy.

The Council Resolution of 7 May 1985 showed the way by accepting that there could be more than one means of proof of conformity to a Directive. It provided for presumption of conformity to a Directive on the basis of a European harmonized standard, or, during a transitional period, of national standards which had been submitted and recognized as equivalent under a Commumnity control procedure. When the manufacturer complies with these standards, the directives are there to allow him to make use of simplified certification mechanisms.

When the product does not conform to a standard, however, either because the standards do not exist or because the manufacturer, for example in the case of innovation, prefers to apply other manufacturing criteria of his own choice, the assessment of conformity to the essential requirements must involve a third party, either by certification or by third party testing.

The Resolution therefore introduced the fundamentally new principle that Directives should as far as possible leave it to the manufacturers themselves to choose one of the two methods for assessing conformity.

The Council Resolution recognized, however, that it had not provided all the answers on conformity assessment and that the New Approach needed to be accompanied by a comprehensive policy on such issues.

2. Conditions for a coherent approach

In view of the considerable progress made towards the development of conformity assessment procedures and techniques in the private sector, a coherent approach can now be put forward on their use in future legislation at Community level ("modular approach").

Taking as a starting point that the objective is to ensure the protection of the general interest, the Council Resolution of 7 May 1985 laid down the general principle that there may be different technical means of achieving similar, if not "identical", results. In other words the Community legislator may, when laying down in a directive the essential requirements to be met, decide that different conformity assessment mechanisms will afford an adequate guarantee that this requirement will be met and that the economic operators may, within the conditions set out in the directive, choose the most appropriate from among those mechanisms. Such an approach entails redefining conformity assessment in such a manner as to allow the legislator to evaluate the consequences of each of the mechanisms so that

the system can be applied with flexibility and various mechanisms are capable of giving an acceptable result.

In future, therefore, Community legislation should, as a general rule, avoid fixing only one conformity assessment procedure for a given product. It should confine itself to laying down the essential requirements to be met and to determining the different means for assessing conformity and the conditions in which these can apply.

The modular approach thus provides a means of spreading the burden of conformity assessment more flexibly over the entire production process, adapting it to the needs of each individual operation. This should in particular enable the legislator to obtain the desired level of safety without having unnecessarily to burden the economic operators, and especially the small and medium-sized businesses, with excessively onerous conformity assessment procedures.

It is clear that this objective is the first parameter which must be taken into consideration in the choice of conformity assessment procedures. However, other parameters must also be taken into consideration, such as :

- appropriateness of the methods to the type of risk and to the sensitivity of consumers and users to the risk which a product or group of products may present. For instance, sterile products may require different solutions from those reserved for simple pressure vessels;

- appropriateness of the methods to the infrastructure of the sector of activity; for example, it might be inappropriate to choose third party intervention on products in an area where appropriate bodies do not exist;

- appropriateness of the procedures to the characteristics of the products themselves - for example, some products using advanced technology lend themselves less well to tests on the finished product (cf. data-processing equipment or sterile products). In such cases, one can apply

methods based on the application of quality assurance on production.

- appropriateness of the procedures to the rate of production of a product - for example, it is not necessarily practicable to impose assessment methods adapted to mass production when a large proportion of the production is based on small series. Nor is it practicable to provide for verification of individual units when the product is mass-produced.

3. The modular approach

The modular approach subdivides conformity assessment procedures into a number of operations (modules) which differ according to :

- the stage of development of the product, (e.g. design, prototype, full production),

- the type of assessment involved (e.g. documentary checks, type-testing, quality assurance, inspection, etc.),

- who carries out the assessment (the manufacturer or various third parties).

These separate operations or "modules" can be combined to form a complete procedure. In one directive several alternative modules can be applied to the same function provided that a degree of equivalence between their results is obtained, (i.e. they all ensure that the product meets a given technical specification or affords a given level of safety).

Such a modular approach allows the procedures to be more easily evaluated in relation to both the burden on the manufacturer and the desired end result, and therefore facilitates the choice of the appropriate modules for a particular sector or product to be incorporated in the Directive.

Conformity assessment procedures normally come into play at two levels in

(7)

the manufacturing process : the design stage and the production stage. The procedures have therefore been subdivided into modules addressing each of these two levels. However, some modules which only relate to the production stage may be applied on their own without the intervention of a module at the design stage (although it seems that this is exception). Some modules, on the other hand, automatically cover both the design and production phases and so constitute full procedures in their own right.

4. The modules

A detailed description of the modules, guidelines for their use and a summary table are attached in annex.

The functions of each of the modules are summarized below :

- Module A : EC Declaration of Conformity

This module covers both the design and production phases. The manufacturer declares that the products concerned satisfy the requirements of the Directive. He establishes technical documentation explaining the design, manufacture and operation of the product as well as the assessment of conformity with the Directive. This technical documentation is available to the public authorities for inspection for a specified period of time. The manufacturer affixes the CE mark to the products and draws up a written declaration of conformity.

In certain specific cases, Directives may require the EC declaration of conformity to be accompanied by the obligation for a test or series of tests to be carried out on one or several specific aspects of a product, either by the manufacturer in the presence of a third party, or directly by the third party.

Directives may also provide for random product checks to be carried out by or under the responsibility of a notified body. In such cases the

directives set out the general rules for the carrying out of the checks.

- Module B : EC Type Examination

This module only relates to the design phase and must be accompanied by a "production module". A notified body ascertains and attests that a product specimen, representative of the production envisaged meets the provisions of the Directive which apply to it. It will examine the technical documentation and perform or have performed those tests only which are necessary to demonstrate conformity to the provisions of the Directive.

These tests should be restricted, by the notified body, to what is absolutely necessary for demonstrating conformity. In order to ensure a consistent interpretation of what is necessary, the European Organisation for Testing and Certification or, in its absence, the Commission, will establish close links between the notified bodies. The notified body shall issue an EC type examination certificate. The CE mark is not affixed during this phase.

- Module C : EC declaration of conformity to type

This module relates to the production phase only and cannot be carried out alone : it must follow the issuance of an EC type examination certificate. The manufacturer satisfies himself that the products concerned are in conformity with the type as described in the EC type examination certificate and meet the requirements of the Directive that apply to them, and makes a declaration to that effect. The manufacturer affixes the CE mark to the products and draws up a written declaration of conformity.

Directives may provide for random product checks to be carried out by or under the responsibility of a notified body. In such cases the Directives set out the general rules for carrying out the checks.

- Module D : EC declaration of conformity to type (production quality assurance)

This module relates to the production phase only and cannot be carried out alone : it must follow the issuance of an EC type examination certificate. The manufacturer satisfies himself that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the Directive that apply to them and makes a declaration to that effect.

He operates an approved quality system for manufacturing, final production inspection and testing (such as described in EN 29002) and is subject to EC surveillance. He affixes the CE mark to the products and draws up a written declaration of conformity. The CE mark is accompanied by the identification symbol of the notified body which carries out the EC surveillance.

- Module E : EC declaration of conformity (product quality assurance)

This module relates to the production phase only. It is normally carried out in conjunction with an EC type examination, but may, in special cases, be carried out alone. The manufacturer satisfies himself that the type as described in the EC type examination certificate or with the essential requirements (when EC type examination is not required under the Directive that apply to them and makes a declaration to that effect. He operates an approved quality system for final product inspection and testing (such as described in EN 29003) under which all products are individually examined and appropriately tested. He is subject to EC surveillance and affixes the CE mark to the products and draws up a written declaration of conformity. The CE mark is accompanied by the identification symbol of the notified body which carries out the EC surveillance.

- Module F : EC verification

This module relates to the production phase only. It is normally carried out in conjunction with an EC type examination, the notified body checks and attests that the products are in conformity with the technical documentation (when EC type examination is not required under the Directive) or with the type as described in the EC type examination certificate and, in both cases, that the products satisfy the requirements of the Directive that apply to them. The manufacturer may choose (within the limits set by the Directive) statistical verification provided he takes all the necessary measures to ensure that the manufacturing process guarantees homogeneity of production as well as conformity to the technical documentation or to the type as described in the EC type examination.

The notified body or the manufacturer, according to the provisions of the Directive, affixes the CE mark to the products and draws up a written certificate of conformity. The CE mark is accompanied by the identification symbol of the notified body.

- Module G : EC Unit Verification

This module relates to both the design and production phases. It is normally used for unit production or production in small series. The notified body checks and attests that individual products are in conformity with the requirements of the Directive that apply to it. The notified body affixes the CE mark to the products and draws up a written certificate of conformity. The CE mark is accompanied by the identification symbol of the notified body.

- Module H : EC declaration of conformity (Full Quality Assurance)

This module relates to both the design and production phases. The manufacturer ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. He operates an

approved quality system for design, manufacture and final product inspection and testing (such as described in EN 29001). The Directive may, in certain cases, require the manufacturer to request a notified body to examine and approve the conformity of the design to the requirements of the Directive. He is subject to EC surveillance and affixes the CE mark to the products and draws up a written declaration of conformity. The CE mark is accompanied by the identification symbol of the notified body which carries out the EC surveillance.

5. The notified bodies

The idea underlying the new approach is that it is desirable to limit direct involvement by the public administrations to that which is absolutely necessary to ensure compliance with the essential requirements (as is made clear in the general clause concerning placing on the market which appears in all the Directives). This principle is fully consistent with the fact that the authorities are still required to be responsible for surveillance of the market and of the use of the products;

The various modules provide for the involvement of bodies at different levels (type-examination, product surveillance, approval of quality assurance, verification). The purpose of the Directives is to define the general criteria which these bodies must satisfy in order to be deemed competent. It is the task of each Member State to designate them and notify them to the Commission and to the other Member States. Where the notified bodies can demonstrate that they satisfy the criteria laid down in the European standards (EN 45 000 series); for example, the fact that are accredited means that are presumed to comply with the criteria laid down in the Directive.

If they are unable to demonstrate that they meet the criteria, it is then up the Member States to provide the Commission with equivalent proof.

This approach makes it possible to distinguish between the act of designation and the act of recognition of competence, the first being the acknowledged power of the authorities to choose and the second ensuring that this choice is objective and transparent.

6. The CE mark

The present situation concerning the affixing to products of Community marks in Directives is unsatisfactory and confusing. Community Directives have provided for a number of different Community marks over the years, which do not always have the same significance. Such confusion is not conducive to an organised market.

With the preparation of the first directives under the new approach provision was made for a single Community mark and it should therefore be adopted for all future comprehensive Community legislation. It should have the following shape in all language versions :

Application of the CE mark should be determined by the following criteria :

- The mark should be reserved exclusively to indicate, for control purposes, conformity to directives which are comprehensive in nature and therefore replace completely all national legislation relating to its scope;

- The mark should signify or indicate that the product and/or the manufacturer comply with the essential requirements and that the manufacturer (importer) or third party has carried out the relevant conformity assessment operations so that the product may be placed on the market without restriction;

- The mark should be affixed on the product, but specific Directive may allow the CE mark to be affixed to the packaging or the accompanying documentation;

- The mark should relate to all the essential requirements which concern a given product. If the product is covered by several Directives, the affixing of the mark will signify conformity to all the Directives involved. The person responsible for affixing the mark must ensure that all the Directives have been complied with. (These two requirements considerably reduce the problems of overlapping between Directives).

- The mark should not indicate the directives and/or standards to which a product conforms. The test reports and certificates should contain such information (in an appendix, where appropriate).

- The CE mark should not signify conformity to a particular conformity assessment procedure, even though it has to be affixed at the production phase of the assessment procedure only and not at the design phase.

- Although the CE mark will not indicate that a particular procedure has been followed, it is advisable that when a third party is involved in one

of the modules of the production phase of a conformity assessmentprocedure, that third party should affix its stamp/mark/seal next to the CE mark to so indicate.

- The mark should also be accompanied by the last two digits of the year in which it is affixed.

- Since the CE mark is a sign of conformity to legislation, the natioanl marks of conformity to European or national standards therefore remain compatible. These national marks of conformity to standards cannot, howecre, indicate conformity to Comunity legislation;

- The CE mark is therefore the only mark which can indicate conformity to the comprehensive Community Directives which replace all national regulatons on the subject. This means that the CE mark replaces all national marks indicating conformity to national regulations, which are no longer allowed (such as the GS mark in Germany).

The Commission intends to propose a Directive to the Council which will set down the conditions governing the use and protection of the mark and which will clear up some of the confusion which has crept into recent legislation of this issue.

It will also closely monitor market developments in connection with the coexisence of the CE mark and voluntary national marks which eventually would lose their reason to exist if they did not provide a further element of quality in addition to that provided by Community legislation.

Section Three : THE IMPACT OF A GLOBAL APPROACH ON THE IMPLEMENTATION OF MUTUAL RECOGNITION OF NATIONAL REGULATIONS

In its judgment in the "Cassis de Dijon" case the Court of Justice held that any product lawfully produced and marketed in a Member State must, in principle, be admitted to the market of every other Member State.

The significance of the words "in principle", as emphasised by the Commission in its communication on the subject published in OJ No C 256, 3.10.1980, p. 2, comes from the fact that the Court accepts no exceptions to this rule, except under very strict conditions. Barriers to products originating in other Member States are only admissible if they are necessary to satisfy mandatory requirements, serve a purpose in the general interest and are essential for the purpose to be attained.

Experience has shown that it can sometimes be very difficult to demonstrate that a requirement is neither necessary nor in the general interest, nor essential when, say, the protection of helth and safety is at issue.

This difficulty is even more evident when, in addition to securing recognition of the equivalence of national regulations, it is a matter of establishing the credibility of proofs of conformity to those regulations or, rather, the credibility of those providing those proofs(1).

The object of all the measures undertaken and advocated in Section One of this chapter is to ensure the full implementation of the principle of mutual recognition; they seek to create a situation where the certification bodies and laboratories that are authorized to attest the conformity of products to national regulations are designated or accredited according to objective criteria of transparency and competence and where the operation of such bodies also meets these criteria. Thus, the aim is to make mandatory mutual recognition fully applicable, with no possibility of this being disputed by the national authorities.

Similarly, the harmonization of conformity assessement procedures as advocated under the modular approach will inevitably have an influence on the procedures laid down in non-harmonized national regulations. Directive 83/189 is the appropriate instrument to ensure that this is done in a systematic way.

(1) In its judgment of 17 December 1981 in the "Biologische Producten" case, the Court stressed that the national public authorities are not entitled unnecessarily to require tests to be carried out that have already been performed in another Member States. The need to repeat tests therefore appears to imply lack of confidence in the person or body performing them.

Section Four : THE NEED FOR A NEW EUROPEAN ORGANISATION FOR CERTIFICATION AND TESTING

The measures set out in Section One of this chapter are to do with the mechanisms that can serve to generate the necessary confidence in the competence of operators in the field of conformity assessment. That confidence is essential in order for mutual recognition to work. In areas which are not covered by the provisions of Article 36 and which involve private activities carried out on a contractual basis, mutual recognition cannot be imposed by legislation. Consequently, the only way to eliminate certification systems is through cooperation at European level between bodies and laboratories - as has been done in the case of standardizaton activity - inorder to establish common systems for certification and the recognition of test results.

A need was therefore felt in various quarters for a flexible and non-bureaucratic structure in Europe which would draw the various elements together and constitute a focal point for all interested parties.

Such an infrastructure must be able to provide information, experience, and a framework within which appropriate structures and agreements for the different industrial sectors can be negotiated. It should also provide a coherent environment capable of reassuring consumers, users and public authorities that the requisite levels of quality and safety are being met.

Apart from a few isolated sectoral agreements, such as the CCA, CECC and HAR within CENELEC and two CENCER systems within CEN, there is at present an institutional vacuum at European level in the testing, certification and inspection field, which is in sharp contrast to the situation in respect of standardization. The Community's immediate task is to ensure that this vaccum is filled.

In line with the separation of responsibilities between the private and public sectors required by the new approach, this task should be assigned to the

private sector rather than to the public authorities, political control of the national and Community authorities must not be affected.

In January 1988 the Commission services published a consultative document on the future organisation in this field, in order to gather reactions to the basic conditions which they considered were indispensable to the launching of such a project.

On this basis the Commission decided to organize a large-scale Symposium in Brussels in June 1988 on the theme of organising testing and certifiction for Europe, which brought together some 800 participants.

The Symposium conclusions confirmed the need for such an infrastructure if the achievement of the internal Market is to have any real significance for the free movement of goods within the Community.

Such an infrastructure would also provide the common technical basis that is indispensable for the negotiation of mutual recognition agreements with non-Community partners.

The existence of such an infrastructure could also play an important role in facilitating the administration of EEC legislation, by providing a common technical basis for future the Directives for the regulated sectors.

In accordance with the broad guidelines agreed in consultation with the representatives of national governments and confirmed by the Symposium conclusions, the Commission asked CEN/CENELEC to establish the necessary contacts with all the interested parties, in order to draw up a list of priority areas where sectoral work should be started, to make proposals on how the sectoral committees could be organized, and to reflect on appropriate ways in which the coordinating structure could be supported by CEN/CENELEC.

Since the Symposium in June 1988, work has gone on within CEN/CENELEC to devise appropriate answers to these questions. This has led to the formulation of a proposal for a more general restructuring of testing,

certification and inspection activities at European level round the present CEN/CENELEC structure, whilst ensuring a certain degree of autonomy for these activities from the conventional standardizing activities of these organisations.

The Commission considers that it has a responsibility in this matter for properly discharging the supervisory functions conferred on it by the Treaty in resspect of any activity liable to have a bearing on the completion of the internal Market

CHAPTER V

EXTERNAL ASPECTS OF THE GLOBAL APPROACH

The adoption by the Community of the global approach, which provides clear and objective means of assessing the competence and responsibilities of testing, certification and inspection bodies, should considerably facilitate the relations between the Community and its international partners in this area. The strengthening of confidence through the structures to be established within the Community will in turn generate greater confidence in dealings with the non-Community countries, either through the relevant international organizations or on a bilateral basis.

1. Guiding principles

The starting point for the Community is, of course, its commitments in GATT under the Agreement on Technical Barriers to Trade. The Community will continue to grant non-discriminatory access to its conformity assessment procedures to products originating in third countries. Under Community law any product, including one originating in a third country, which has been lawfully marketed in one Member State will be able to circulate freely within the Community as a whole. The reinforcement of mutual confidence resulting from the adoption of the global approach will enable this free movementto operate more effectively for products subject to conformity assessment procedures, for both third country and Community goods.

As regard recognition by the Community of non-Community declarations, tests, reports, certificates or marks of conformity, the GATT Agreement on Technical Barriers to Trade does not lay down binding obligations, although its Article 5.2 requires parties "where possible" to accept such

declarations, tests and certificates from other parties, subject to bilateral negotiations to ensure "a mutually satisfactory understanding". The Community is prepared, in accordance with this undertaking, to conclude agreements for mutual recognition of tests, reports, certificates and marks provided that the following conditions are met :

- The **technical competence** of the non-Community partner is adequate:

  The Community will be concerned to ensure that tests or inspections carried out by a non-Community body will offer the same guarantees as those located within the Community. This would normally require the use of common evaluation criteria (EN 45000 series) based on international standards, and would be further facilitated by the use of common standards or technical regulations for the products concerned. It would also be necessary to ensure that both sides offered equivalent safeguards with regard to the continued technical competence of their testing, certification and inspection bodies.

- The mutual benefits flowing from the agreement are **equivalent** and **guaranteed in an identical manner**. The Community will wish to be satisfied that the practical results of any agreement, in terms of ease of access to the market, are the same for both sides; for instance, it would be difficult to accept that one party to the agreement did not reduce its administrative requirements in respect of conformity assessment for placing products on the market as a result of the agreements.

- **The agreement is limited** to the testing, certification and inspection activity of designated bodies. Since these arrangements are based upon confidence in particular bodies, their scope needs to be carefully defined. They cannot be automatically extended to include third parties by further agreements on mutual recognition without the consent of the parties to the original agreement.

2. Procedures

The parties involved in the negotiation of mutual recognition agreements and the procedure for such negotiations will differ according to whether the products concerned are subject to government regulation or not.

a) Products subject to legislation

International agreements between governments on the mutual recognition of test reports or certificates, although they seek to ensure that the public policy objectives of technical legislation are achieved, are primarily intended to promote international trade, and therefore are a matter of common commercial policy under Article 113 of the Treaty. The negotiation and conclusion of such agreements with third countries for products subject to lawfully enforced conformity assessment systems is therefore the responsibility of the Community.

Moreover, the obligation for Member States under Community law to accept products, including third country products, lawfully marketed in another Member State means that the conditions of access to an integrated Community market cannot be determined by agreements with third countries concluded by individual Member States. In this context, the technical bodies within the new European Organization for Testing and Certification will need increasingly with time, to draw up common codes of practice or rules for conformity assessment.

It follows that mutual recognition agreements for products subject either to Community or national technical regulations will be negotiated by the Commission on behalf of the Community, advised by representatives of the Member States in the normal way. (Negotiations of this kind are due to be opened shortly for example, in respect of the mutual recognition of Good Laboratory Practice verification between the Community and OECD member countries). In the case of products not subject to Community legislation, any Member State wishing to benefit

from a mutual recognition agreement must inform the Commission which will then obtain negotiating directives from the Council for a Community-level agreement with the third country concerned. The Commission recognizes that this activity will represent a considerable additional demand on its resources and intends to explore with the Member States ways in which national technical expertise can be made available to the Community for these negotiations.

b) Products not subject to legislation

Where, in the absence of legislation, testing, certification or inspection bodies outside the Community wish to participate in voluntary mutual recognition agreements under the global approach, they should be permitted to do so provided that they fulfil the same conditions of competence as their counterparts in the Community. The participants in the Community agreements can satisfy themselves that this is the case, and establish their own rules for the extension of the agreements.

Proposal
for a Council Decision

concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission(1),

In cooperation with the European Parliament(2),

Having regard to the opinion of the Economic and Social Committee(3),

---

Whereas the introduction of harmonized methods for the assessment of conformity and the adoption of a common doctrine for their implementation is , likely to facilitate the adoption of future technical harmonization directives the placing on the market of industrial products and thus be conducive to the completion of the internal market by 31 December 1992;

(1) OJ No C
(2) OJ No C
(3) OJ No C

HAS ADOPTED THIS DECISION

Sole Article

The modules for the various phases of the procedures for conformity assessment which are to be used in the technical harmonization directives relating to the marketing of industrial products will be chosen from among those listed in the annex to this Decision and in accordance with the criteria set out therein.

For the Council

THE PRESIDENT

ANNEX TO THE PROPOSAL FOR
A COUNCIL DECISION

Conformity assessment procedures
in the technical harmonization Directives

---

1. General guidelines

The principal guidelines for the use of conformity assessment procedures in technical harmonization Directives are the following :

a) the essential objective of a conformity assessment procedure is to give to the users, consumers and public authorities, the assurance that products placed on the market conform to the various requirements expected of them as these are expressed in the provisions of the Directives;

b) conformity assessment can be subdivided into modules which relate to the control of the design phase of products or to the control of their production phase; in certain specific cases these two functions are so inseparable they must be combined to constitute a module (e.g. modules A, G and H);

c) as a general rule a product should undergo a control in both phases before being able to be placed on the market if the results are positive;

d) there are a variety of modules which cover the two phases in a variety of ways. The Directives shall set the range of possible choices which can be considered by the Council to give the public authorities the acceptable level of safety they seek, for a given product or product sector;

e) in setting the range of possible choices open to the manufacturer, the Directives will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and importance of production etc...

f) the Directives will set out the requirements governing the conditions in which the manufacturer makes his choice as to the most appropriate modules for his production;

g) the Directives should, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring an acceptably high level of protection, as laid down by the essential requirements; the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the Directive concerned;

h) notified bodies should be encouraged, whenever possible, to apply the modules without undue burden for the economic operators in order to ensure consistent interpretation and application of the modules. The European Organisation for Testing and Certification or, in its absence, the Commission will organise close cooperation between the notified bodies;

i) whenever Directives provide the possibility for the manufacturer to use quality assurance techniques, they must also wherever possible provide for the possibility of recourse to product certification;

j) for the purposes of operating the various modules, Member States shall notify only competent bodies which comply with the requirements of the Directives; bodies accredited to apply the EN 45000 series or which can produce documentary evidence that they conform to the EN 45000 series shall be considered to conform to the requirements of the Directives. Member States which do not notify accredited bodies shall be invited to produce the documentary evidence that they conform to the requirements of the Directive;

k) lists of notified bodies shall be published by the Commission in the OJEC and constantly updated;

l) the CE mark (accompanied, wherever appropriate, by the identification symbol of the third party involved in the control of the production phase) shall be affixed to show that the production phase has been carried out satisfactorily only having regard to the requirements of the Directives.

II - Modules for conformity assessment

Explanatory notes

Specific directives may allow the CE mark to be affixed to the packaging or the accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) shall cover either individual or several products and shall either accompany the product(s) covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

References to articles refer to the standard paragraphs of Annex II B of the Council Resolution of 7 May 1985 (OJ N° C 136/1 of 4 June 1985), and which have become standard articles in the New Approach Directives.

The development of computerized telecommunications as a means / of publication of certificates issued by notified bodies / is envisaged within INSIS.
Specific directives may use modules A, C and H with additional sections containing supplementary requirements (which figure in the boxes in the modules).

Modules C and D are designed to be used in combination with module B (EC type examination). Modules E and F will also normally be used in combination with module B; however, in special cases (for example when dealing with certain products of very simple design and construction) they may be used on their down.

Module A : EC declaration of conformity

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in paragraph 3 and he or his authorized representative established within the Community shall keep it for a period ending at least 10 years(1) after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

   Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

3. The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   The documentation shall contain so far as relevant for assessment:

   - a general description of the product
   - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
   - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product
   - a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential

requirements of the directive where the standards referred to in Article 5 have not been applied
- results of design calculations made, examinations carried out, etc
- test reports.

4. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in paragraph 2 and with the requirements of the directive that apply to them.

(Possible supplementary requirements)

For each product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf(2). The tests shall be carried out in the presence of a notified body, chosen by the manufacturer, or by that notified body.

A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in article 5, or equivalent tests, shall be carried out to check the conformity of the production output with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform the notified body shall take appropriate measures. The product checking shall use the following elements: (Relevant elements shall be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etcetera.)

Module B : EC type examination

1. The EC type examination is that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production planned, meets the provisions of the directive that apply to it.

2. The application for the type examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body.

   The application shall include :

   - the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition
   - a written declaration that the application has not been lodged with any other notified body
   - the technical documentation, as described in paragraph 3.

   The applicant shall place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called "type"(3). The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   The documentation shall contain so far as relevant for assessment:

   - a general description of the type
   - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 5 have not been applied
- results of design calculations made, examinations carried out, etc.
- test reports.

4. The notified body shall,

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the directive;

4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have been applied effectively;

4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.

5. Where the type meets the provisions of the directive, the notified body shall issue an EC type examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer,

conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

The relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

6. The applicant shall keep the notified body that has issued the EC type examination certificate informed of any modification to the approved product.

Modifications to the approved product must receive additional approval from the notified body that issued the EC type examination certificate where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type examination certificate.

7. Each notified body shall publish periodically the relevant information concerning

- the applications for EC type examination received
- the EC type examination certificates and additions issued
- the EC type examination certificates and additions refused
- the EC type examination certificates and additions withdrawn

8. The other notified bodies may receive copies of the EC type examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

Module C : EC declaration of conformity to type

1. This declaration of conformity is that part of the procedure whereby the manufacturer ensures and declares that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the type as described in the EC type examination certificate and with the requirements of the directive that apply to them.

(Possible supplementary requirements)

A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in article 5, or equivalent tests, shall be carried out to check the conformity of the production output with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform the notified body shall take appropriate measures.

The product checking shall use the following elements:

(Relevant elements shall be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etcetera.)

Module D : EC declaration of conformity to type (production Quality Assurance)

1. This declaration of conformity is that part of the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and

declares that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for EC surveillance.

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include :

- all relevant information for the product category envisaged
- the quality system's documentation
- an undertaking to carry out the obligations arising from the quality system as approved
- an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness
- if applicable, the technical documentation of the approved type and a copy of the EC type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type as described in the EC type examination certificate and with the requirements of the directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (4).

The assessment team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2. or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance

4.1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and shall provide it with all necessary information, in particular

- the quality system documentation
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall periodically (5) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

Module E : EC declaration of conformity (product Quality Assurance) (6)

1. This declaration of conformity is that part of the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned [are in conformity with the type as described in the EC type examination certificate and] satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for EC surveillance.

2. The manufacturer shall operate an approved quality system for final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include :

- all relevant information for the product category envisaged

- the quality system's documentation

- an undertaking to carry out the obligations arising from the quality system as approved

- an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness.

- if applicable, the technical documentation of the approved type and a copy of the EC type examination certificate.

3.2. Under the quality system each product shall be examined and appropriate tests as set out in the relevant standard(s) referred to in article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

- the examinations and tests that will be carried out after manufacture

- the means to monitor the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard(7).

The assessment team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2. or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance

4.1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage, and shall provide it with all necessary information, in particular

- the quality system documentation
- the technical documentation
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall periodically (8) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

Module F : EC verification (6)

1. The EC verification is that part of the procedure whereby a notified body checks and attests that the products concerned / are in conformity with the type as described in the EC type examination certificate and / satisfy the requirements of the directive that apply to them.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products [with the type as described in the EC type examination certificate and] with the requirements of the directive that apply to them.

3. The EC verification may be carried out, at the choice of the manufacturer, by examination and testing of every individual product as specified in paragraph 4, or by examination and testing of the products on a statistical basis as specified in paragraph 5(9).

4. Verification by examination and testing of every individual product

4.1. All products shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in article 5 or equivalent tests shall be carried out in order to verify their conformity with [the type as described in the EC type examination certificate and] the requirements of the directive that apply to them.

4.2. The notified body shall affix the CE mark to each approved product and draw up a written certificate of conformity. The CE mark shall be accompanied by the identification symbol of the notified body.

5. Statistical verification

5.1. The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures homogeneity of each lot produced.

5.2. If appropriate the manufacturer may affix the CE mark to each product(10) during the manufacturing process. The CE mark shall be accompanied by the identification symbol of the notified body responsible for the statistical verification.

5.3. All products shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in article 5, or equivalent tests, shall be carried out to ensure their conformity

with the relevant requirements of the directive and to determine acceptance or rejection of the lot.

5.4. The statistical procedure shall use the following elements:

(Relevant elements shall be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etcetera.)

5.5. If a lot is accepted the notified body shall draw up a written certificate of conformity. All products in the lot may be put on the market except those products from the sample that were found not to be in conformity.

If a lot is rejected the notified body or the competent authority shall take appropriate measures to prevent the putting on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification.

Module G : EC unit verification

1. The EC unit verification is the procedure whereby a notified body checks and attests that the product concerned is in conformity with the requirements of the directive that apply to it. The notified body shall affix the CE mark to the product and draw up a written certificate of conformity. The CE mark shall be accompanied by the identification symbol of the notified body.

2. The product shall be examined and appropriate tests as set out in the relevant standard(s) referred to in article 5, or equivalent tests, shall be carried out to ensure its conformity with the relevant requirements of the directive.

3. Technical documentation shall be made available to the notified body and shall contain, so far as relevant for the assessment:

   - a general description of the product
   - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
   - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product
   - a list of the standards referred to in article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in article 5 have not been applied
   - results of design calculations made, examinations carried out, etc
   - test reports.

Module H : EC declaration of conformity (full Quality Assurance)

1. This declaration of conformity is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for the EC surveillance.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

- all relevant information for the product category envisaged
- the quality system's documentation
- an undertaking to carry out the obligations arising from the quality system as approved
- an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness.

3.2. The quality system shall ensure compliance of the products with the requirements of the directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality,

- the technical design specifications, including standards, that will be applied and, where the standards referred to in article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the directive that apply to the products will be met,

- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out,

- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard(11).

The assessment team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2. or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance

4.1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular

- the quality system documentation
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification repports of the personnel concerned, etc.

4.3. The notified body shall periodically(12) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4 Additionally the notified body may pay unexpected visits to the manufacturer. During such visits full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

(Possible supplementary requirements)

Design examination

1. The manufacturer shall lodge an application for examination of the design with a single notified body.

2. The application shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   It shall include

   - the technical design specifications, including standards, that have been applied,
   - the necessary supporting evidence for their adequacy, in particular where the standards referred to in article 5 have not been applied in full. This supporting evidence shall include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

3. The notified body shall examine the application and where the design meets the provisions of the directive that apply to it shall issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the product's functioning.

4. The applicant shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design.

Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of the directive or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC design examination certificate.

5. The notified bodies shall publish periodically the relevant information concerning
   - the applications for EC design examination received
   - the EC design examination certificates and additions issued
   - the EC design examination certificates and additions refused
   - the EC design examination certificates and additions withdrawn

Foot-notes

(1) Specific directives may change this period

(2) If this option is used in a specific directive the products concerned shall be specified, together with the tests to be carried out.

(3) A type may cover several product variants provided that the differences between the variants do not affect the level of safety and other performance requirements of the product.

(4) This harmonized standard shall be EN 29002, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(5) In specific directives the periodicity may be specified.

(6) When this module is used without module B :

- it shall be completed (between paragraphs 1 and 2) by paragraphs 2 and 3 of module A, to introduce the need for technical documentation ;
- the text in brackets shall be deleted.

(7) This harmonized standard shall be EN 29003, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(8) In specific directives the periodicity may be specified.

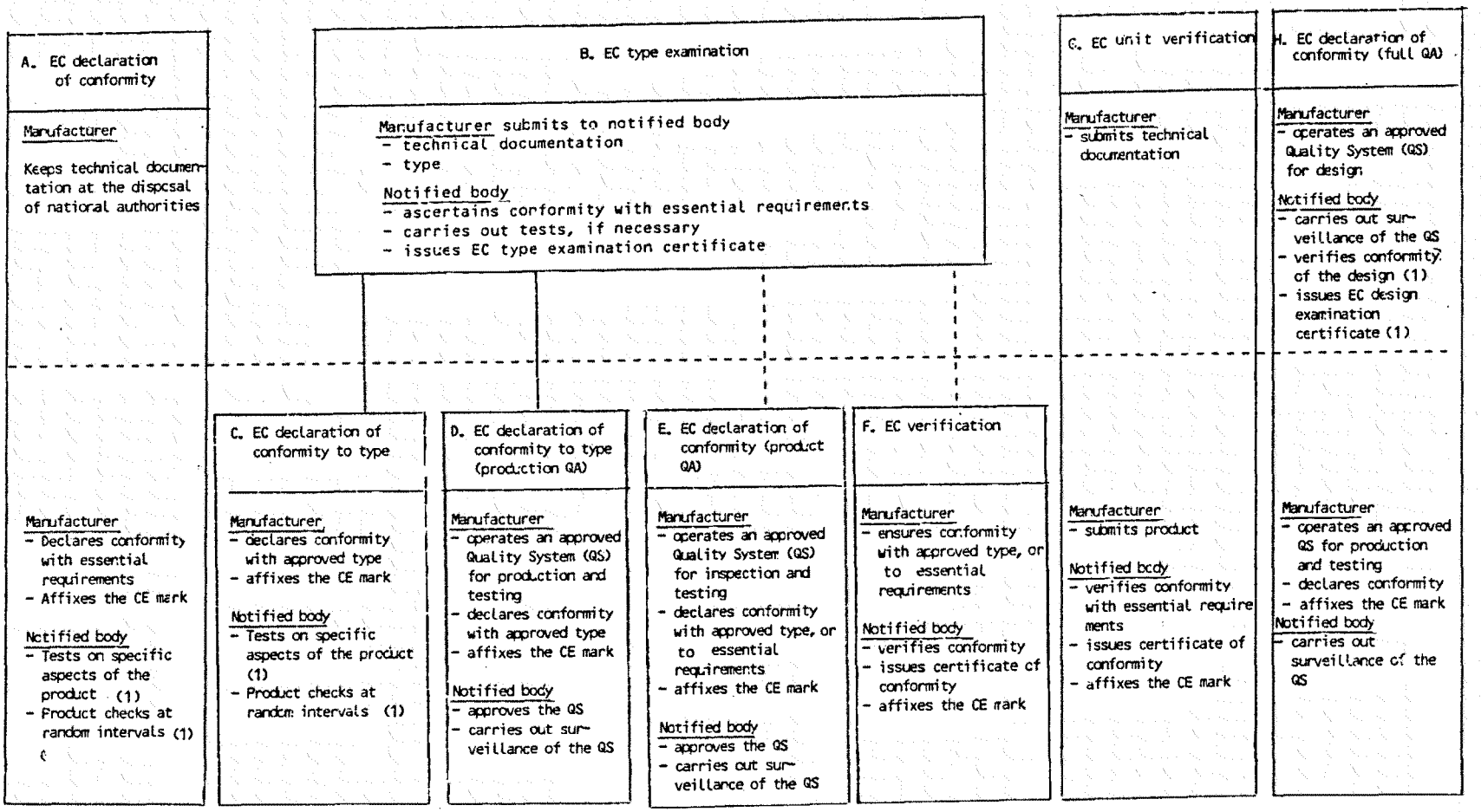
(9) In specific directives the choice of the manufacturer may be limited.

(10) Specific directives may specify that the CE mark shall be affixed by the notified body.

(11) This harmonized standard shall be EN 29001, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(12) In specific directives the periodicity may be specified.

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION



(1) supplementary requirements which may be used in specific directives