

# COMMISSION OF THE EUROPEAN COMMUNITIES

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## Technical harmonization and standards: a new approach

(Communication from the Commission to the Council and to the  
European Parliament)

## S U M M A R Y A N D C O N C L U S I O N S

### I. Presentation of the approach: motivations and criteria

This new approach is presented on the basis of the finding that a revision is needed of the methods and procedures regarding technical harmonization in the Community to realise the objective of the completion of the Internal Market.

The new approach follows guidelines laid down by the European Parliament in its resolution of 16 October 1980 and conforms to those drawn up by the Council during its session on 16 July 1984.

### II. Outline of a directive concerning the approximation of Member States' legislation for the elimination of technical barriers to trade using the "general reference to standards" approach

This outline of a directive concerning the approximation of Member States' legislation involves the development of a general approach which the Commission intends to apply, according to the legislative requirements of sectors or groups of products as well as of categories of hazards, in drawing up proposals for directives based on Article 100 of the EEC Treaty.

The outline is not claimed to be a final legal text but it does provide in summary form a pattern for a directive on which the Commission could subsequently graft firm proposals. The text of this chapter therefore consists of a description of the contents of the directive and a paragraph by paragraph commentary.

### III. Priority sectors or areas to which the approach should initially be applied

The analysis of these sectors has been carried out in the light of the experience of over 15 years of activity in the field of technical barriers to trade. The choice of priority subjects takes into account both the need to make up for lost time and the opportunity to profit from what can be considered to be favourable conditions. As the word "priority" suggests, the choice of these areas does not imply the exclusion of other areas or sectors to which the approach could be applied in the future.

### IV. Conclusions

The Commission envisages starting this work without delay in order to translate into concrete terms this new approach so that the Community may progress towards the realisation of the Internal Market for industrial products, progress which has to date been seriously hampered by the Community's burdensome decision-making procedures. The Commission awaits from the other Community institutions to which this communication is addressed, an unequivocal political commitment concerning the criteria and principles of this approach and criteria for the choice of priority areas to which the approach will be applied.

**Part One**

Presentation of the approach: motivations and criteria

1. The discussion in the Council and the adoption of Council directive 83/189/EEC on 28 March 1983 marked an awareness on the part of all parties concerned - the Commission, Member State administrations, standardization bodies, industry - of the need to begin an in-depth consideration of the criteria, principles and procedures which had, since 1969, guided work on the elimination of technical barriers to trade.

In 1969 the Council acting on a Commission proposal, adopted a series of resolutions which to a certain extent defined policy in this area both for the procedures and the work programmes. The procedures and work programmes were subsequently updated in 1973. However since this significant effort was made to produce a policy framework for Community activity on technical harmonization, no new consideration as a whole has ensued to check whether the chosen approach remained valid in all sectors and in the light of experience over the years.

2. This need to proceed to a revision of the policy was also made clear by the detailed factual findings which industry has repeatedly brought to the attention of the Commission.

While work on technical harmonization has doubtless led to important results in certain areas (there are currently 177 Council directives, amended by 56 Commission directives) it is necessary to point out that:

- in certain industrial sectors results remain almost negligible in the face of the multiplicity of technical rules and standards abounding in all countries;

- even in the cases where directives have been adopted, they too often cover only certain aspects while other factors continue to obstruct the existence of a true internal market;
- the technological evolution is now too rapid for harmonization procedures and the decision making processes of the Council to hope to be even able to reach an objective which seems destined to become increasingly remote rather than nearer to attainment;
- these procedures have reached a degree of lengthiness<sup>1</sup> which deprives of all credibility policies based on guidelines which in certain respects have clearly been overtaken;
- while the optional method of harmonization, which was generally followed, had the advantage of facilitating the seeking of compromise in the Council, it proved too often inadequate for the realisation of a true internal market the benefits of which need to apply to all sectors of the economy: industry, workers, user and consumers;
- finally the root of most of these problems probably derives from a poor distribution of the respective roles between the public authorities on the one hand and the standardization bodies on the other. The authorities too often allocate to themselves competences in the area of detailed definition of technical specifications of products which belong more naturally to the standardization organizations.

Because of all these difficulties and because of the ensuing lack of Community legislative activity, the circulation of goods takes place on the basis of Article 30 of the EEC Treaty, as interpreted by the Court of Justice.

It is now well known since the "Dassonville" decision (case 8/74), and even more so since the "Cassis de Dijon" decision (case 20/78) and the abundant jurisprudence which followed, that the application of national commercial regulations to imported products is to be considered as a measure having equivalent effect to quantitative restrictions, except when the Member State in question can demonstrate that the measures are necessary in order to satisfy "imperative requirements" or can be justified by one of the

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<sup>1</sup> The 15 directives making up the "package" adopted by the Council on 17 September 1984 had an average age of 9 1/2 with a maximum of 12 years.

derogations set out in Article 36. As the national courts and the European Court (Article 30 is directly applicable) decide on a case by case basis, the absence of Community legislation thus leaves to the judiciary the responsibility of deciding on questions which normally fall to the responsibility of the legislator. The ensuing uncertainty is highly detrimental to economic operators.

It thus became more and more necessary to make a selection of those standards which could create a right to the presumption of equivalence to the existing regulations within the Community vis à vis the safety objectives pursued and to organize the conditions in which this presumption can be reversed, as the jurisprudence in question leads in fact to a sort of presumption of equivalence.

3. At the Internal Market Council on 26 October 1983 the Commission had already stated that to a large extent the delays and difficulties encountered in the harmonization activities resulted from the procedure of harmonizing precise and detailed technical construction specifications in statutory texts rather than from an obligation of performance. There is only one sector, that of low voltage electrical equipment, for which the latter technique has been followed with success.

Basing itself on this conclusion, the Commission then envisaged a gradual move towards basing further legislative efforts on the formula of the Low Voltage directive, experience of which had proved favourable. Safety provisions would be established to which products would have to conform, while the task of defining technical characteristics of products would be left to European, and if necessary, national standards.

In the sectors for which this approach should be feasible the conditions for application of these guidelines should be:

- recognition by all member countries of the Community of the equivalence of objectives pursued by their technical regulations and standards concerning in particular the health and safety of their citizens;
- the existence of certification bodies and laboratories which ensure confidence between the authorities concerned;

- the establishment of procedures ensuring that authorities in the Member States have efficient safeguards for the protection of the health and safety of their citizens.

4. The Council on 16 July 1984 set out general principles for a European standardization policy<sup>2</sup>. This represented an important step in the process of consideration and revision which the Community has to pursue in order to definitively bring about the creation of the internal market for industrial products. The Council stated notably "that the objectives being pursued by the Member States to protect the health and safety of their people as well as the consumer are equally valid in principle even if different techniques are used to achieve them." It recommended the "extension of the Community practice in matters of technical harmonization of entrusting the task of defining the technical characteristics of products to standards, preferably European but if necessary national, where the conditions necessary for this purpose, particularly as regards health protection and safety, are fulfilled."

5. The Commission has meanwhile pursued its work, assisted by a group of Senior Officials Responsible for Standardization Policy in the Member States, and in consultation with interests in industry and standardization circles. The most opportune approach has been to draw up an outline for a directive concerning the approximation of Member States' legislation for the elimination of technical barriers to trade using the "general reference to standards approach".

The following are the four fundamental principles on which the outline is based:

- legislative harmonization is limited to the adoption, by means of directives under Article 100 of the EEC Treaty, of the essential safety requirements (or other requirements in the general interest) with which products put on the market must conform, and which should therefore enjoy free circulation throughout the Community,

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<sup>2</sup> By the term "standardization policy" is understood all activity, whether in the public or private sector, which relates to the definition of technical specifications of products and certification procedures.

- the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the directives, while taking into account the current state of technology, is entrusted to organizations competent in the standardization area,
- these technical specifications are not mandatory and maintain their status of voluntary standards,
- but at the same time national authorities are obliged to recognize that products manufactured in conformity with harmonized standards (or, provisionally, with national standards) are presumed to conform to the "essential requirements" established by the directive. (This signifies that the producer has the choice of not manufacturing in conformity to the standards, but in this event, that he has an obligation to prove that his products conform to the essential requirements of the directive.)

In order that this system may operate it is necessary:

- on the one hand that the standards offer a guarantee of quality with regard to the "essential requirements" established by the directives,
- on the other hand that the public authorities keep intact their responsibility for the protection of safety (or other requirements envisaged) on their territory.

The quality of harmonized standards must be ensured by standardization mandates, conferred by the Commission, the execution of which must conform to the general guidelines which have been the subject of agreement between the Commission and the European standardization organizations. In so far as national standards are concerned their quality must be verified by a procedure at Community level, and managed by the Commission, assisted by a Standing Committee composed of officials from national administrations.

At the same time safeguard procedures must be provided for, under the management of the Commission, advised by the same Committee, in order to allow the competent public authorities the possibility of contesting the conformity of a product, the validity of a certificate or the quality of a standard.

In order to ensure the coherent operation of these new directives the Commission envisages the creation of only one Standing Committee "general reference to standards" competent to assist the Commission in the management of all the directives of this type, instead of setting up a Committee for each directive. It would, moreover, be called upon to work in close liaison with the Standing Committee set up by directive 83/189/EEC (information procedure for technical standards and regulations).

6. In following this system of legislative harmonization in each area in which it is feasible, the Commission intends to be able to halt the proliferation of excessively technically detailed product by product directives. The scope of directives according to the "general reference to standards" formula should encompass wide product categories and types of hazards.

The Community could on the one hand, therefore, complete the extremely complex undertaking of harmonizing technical legislation and on the other hand promote the development and application of European standards. These are essential conditions for the improvement of the competitiveness of its industry.

## Part II

### Outline for a directive on the harmonization of the laws of the Member States in order to eliminate technical barriers to trade through the "general reference to standards" approach

This outline provides the principles and main elements which should make up the body of the directives.

#### A. JUSTIFICATIONS

Amongst the classical principles for the justification of the directive the following aspects should be underlined:

- Member States have the responsibility of ensuring safety on their territory (in the home, at their place of work etc.) of persons, domestic animals and goods, or the respect of other essential requirements of collective importance such as health, consumer or environment protection etc., with regard to the hazards covered by the directive itself;<sup>(1)</sup>

- the national provisions ensuring such protection must be harmonized in order to ensure the free movement of goods, without lowering existing and justified levels of protection in the Member States;

- CEN and CENELEC (one or the other, or both according to the products covered by the directive) are the competent bodies to adopt European harmonized standards within the scope of this directive, in accordance with the guidelines which the Commission, after consultation of the Member States, has signed with these bodies<sup>(2)</sup>.

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(1) For practical editorial purposes the rest of this document refers only to safety.

(2) For specific sectors of industrial activity other competent European bodies for the drawing up of technical specifications could be involved.

1. In this outline a general approach is developed which should be applied according to the needs for legislation by Directives based on Article 100 of the Treaty relating to sectors or families of products as well as types of hazards.
2. The object of the Directive will be specified in each application according to the types of hazard (safety, health, environment, consumer protection, etc.) and should the need arise to the circumstances (in the home, at the place of work, under road traffic conditions, during leisure activities, etc.).
3. Where appropriate, it should be stated that the Member States may make provision, in accordance with Community law, for national regulations concerning the conditions for use of products covered by the scope of the Directive.
4. Concerning the objective mentioned in the second principle, it is obvious that it is carried into effect by the very adoption of the directive under Article 100 of the Treaty, as the essential safety requirements contained in it are of such a nature as to ensure the pursuit of such an objective.

## B. MAIN ELEMENTS

### I. Scope

Definition of the range of products covered, as well as the nature of the hazards it is intended to avert.

The scope should be drawn up in such a way that a coherent approach to the action is ensured, and that the proliferation of directives on specific products is avoided. Moreover, it should be noted that the legal provisions of the directive under consideration do not preclude the possibility of several directives being adopted on one and the same product according to the various types of hazard associated with that product (for example, mechanical safety of a machine on the one hand and pollution by that machine on the other hand).

### II. General clause for the placing on the market

The products covered by the directive may be placed on the market only if they do not endanger safety of persons, domestic animals and goods when properly installed and maintained, and used in applications for which they were made.

1. The directives would provide for total harmonization as a general rule. Consequently, any product placed on the market falling within the scope of the directive must be in conformity with the requirements of the directive. In certain specific conditions, optional harmonization for certain products may prove to be opportune. The outline directive, however, is drawn up with a view to total harmonization.

Point II therefore represents a general clause setting out the responsibilities of the Member States in relation to the placing of goods on the market.

2. In order to respect the general principle on which the outline directive is based, namely leaving to the professionals the choice of the means of attestation of conformity and which prohibits Member States setting up any system of prior control to the placing on the market (except, of course, in cases where the prior control is required by specific directives for special sectors, as is moreover clearly provided for in Point VIII), it is obvious that the national authorities in order to acquit themselves of their responsibilities set out in this clause must be allowed to exercise control on the market by way of spot checks.
3. In certain cases, in particular with regard to the protection of workers and consumers, the conditions set out in this clause may be strengthened (foreseeable use).

### III. Essential safety requirements

Description of the safety requirements which are essential for the application of the general clause in Point II with which all products falling within the scope of the directive must conform.

1. The essential safety requirements which must be met in the case of products which can be put on the market shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced. If the basic requirements for safety are observed, the general clause in Point II can be applied.
2. The amendments to these requirements can only be made by means of a Council directive pursuant to Article 100 of the Treaty.

### IV. Free circulation clause

Obligation for the Member States to accept the free circulation of products which conform to the requirements of Point III under the conditions set out in Point V.

Free movement will be ensured in the case of products declared to conform to the protection requirements laid down in the directive, without as a general rule, preventive verification of compliance with the requirements set out in Point III, it being understood that the note 2 of Point II also applies in this case.

The interpretation to be given to this provision should not have the consequence that third party certification is to be used systematically.

#### V. Means of proof of conformity

1. Member States shall presume to be in conformity with the requirements of Point III, products which are accompanied by one of the means of attestation described in Point VIII declaring that they are in conformity with:

- (a) the harmonized standards adopted by the European standards body which is particularly competent within the scope of this directive, when these standards are adopted in accordance with the guidelines agreed between that body and the Commission and the references of which are published in the OJEC; such publication is moreover also carried out by the Member States;
- (b) or as a transitional measure, and insofar as harmonised standards do not exist in the field covered by such standards, national standards referred to in paragraph 2.

2. Member States shall communicate to the Commission and to the other Member States the text of those national standards which they consider to meet the provisions of Point III. In accordance with the procedure laid down in para. 2 of Point VI, the Commission shall notify the Member States of the national standards which enjoy the presumption of conformity with the requirements of Point III.

The Member States are required to have the references of these standards published. The Commission will see to it that they are also published in the OJEC.

3. Member States shall accept that the products for which the manufacturer has not applied any standard (because of absence of a standard as laid down in paras. 1a) and b) above or for other exceptional reasons), are considered to be

in conformity with the provisions of Point III, when their conformity is demonstrated by one of the means of attestation set out in Point VIII paragraph 1a) and b).

1. Only those means of attestation provided for in Point VIII necessarily carry presumption of conformity.
2. The presumption of conformity is constituted by the fact that the conformity of a product to harmonized or national standards is declared by one of the means of attestation set out in Point VIII. When the product is not in conformity with a standard, because the standards do not exist, or because the manufacturer, for example in cases of innovation, prefers to apply other manufacturing criteria of his choice, conformity to the requirements of Point III is declared by the means of an attestation delivered by an independent body.
3. In cases under Point V § 1 and § 3 Member States will therefore have the right, for the presumption to operate, to request at any time one of the means of attestation set out in Point VIII.
4. The drafting and adoption of the harmonized standards mentioned in para. 1a) by the CEN and CENELEC, these bodies being generally considered to be the "European standards bodies which are particularly competent", and the obligation relating to transposition into national standards, are governed by these two bodies' internal rules and their regulations relating to standards work. The internal rules of CEN and CENELEC are in the process of being harmonized.

However, it is not impossible that the harmonized standards referred to in para. 1 be prepared outside CEN and CENELEC by other bodies which may assume these functions in particular areas; in such cases adoption of the harmonized standards shall be submitted for approval by CEN/CENELEC. In any case, the drafting and introduction of the harmonized standards referred to in Point V must be subject to the guidelines agreed between the Commission and these organizations. The guidelines deal in particular with the following principles and conditions:

- the availability of suitable staff and technical infrastructure at the standards body which the Commission mandates to proceed with standardization;
- the association of public authorities and interested circles (in particular manufacturers, users, consumers, unions);
- the adoption of harmonized standards and their transposition into national standards or, at least, the annulment of diverging national standards under conditions approved by the Commission set out in a mandate for standardization, after consultation with the Member States.

## VI. Management of the lists of standards

1. Where a Member State or the Commission has reason to believe that harmonized standards or drafts thereof do not fully satisfy the requirements of Point III, the Commission shall bring this to the attention of the Committee (Point X) setting out the reasons. The Committee shall give an opinion as a matter of urgency.

The Commission may, on the basis of the Committee's opinion, notify the Member States of the necessity of withdrawing the standard from the publication referred to in Point V 1a. It will inform the European standards body concerned and, if necessary, give it a new or revised mandate.

2. On receipt of the communication referred to in Point V 2, the Commission will consult the Committee. After the Committee has given its opinion, the Commission may, within a certain period, notify the Member States that the national standard in question should enjoy presumption of conformity and have its references appear in a national publication.

If the Commission considers that a national standard does not fulfil the conditions for presumption of conformity to the safety requirements, it may, after consulting the Committee, notify the Member States that the standard in question should no longer enjoy presumption of conformity and thus be withdrawn from the publications referred to in Point V § 2.

As indicated above (see notes to Point V § 2) the Member States have the power to decide which of their national standards may be considered to be in conformity with the provisions of Point III and thus be subject to the Commission confirmation procedure.

## VII. Safeguard clause

1. Where a Member State finds that a product does not conform to the provisions of Point III, it shall take all appropriate measures to prohibit the placing on the market of the product in question or impede its free movement even if it is accompanied by one of the means of attestation referred to in Point VIII.

Within a given period of time, and only when the product in question is accompanied by one of the means of attestation provided for in Point VIII, the Member State shall inform the Commission of such a measure. It will indicate the reasons for its decision and in particular whether the non-conformity results from:

- a) the non-respect of the provisions of Point III (when the product does not conform to any standard);
- b) incorrect application of the standards referred to in Point V;
- c) a shortcoming in the standards themselves.

2. Within a given period of time, the Commission shall submit the cases under b) and c) above to the Committee. Where the Commission, after consultation of the Committee, finds that the action is justified it shall, also within a given period of time, give confirmation to that effect to the Member State in question and inform the other Member States that they are also obliged to prevent the product in question from being placed on the market.

3. Where the non-conformity of the product to the requirements of Point III results from a shortcoming in the harmonized standards or in the national standards, the consequences are those set out in Point VI;

4. Where the non-conforming product is accompanied by a means of attestation issued by an independent body or by the manufacturer, the competent Member State shall take the appropriate measures against the author of the attestation and informs the Commission and the other Member States.

5. The Commission shall ensure that all Member States are kept informed of the progress and of the outcome of this procedure.

1. This Point describes the consequences when recourse by a Member State to the safeguard clause appears to be justified. It does not give any indication on the consequences when recourse does not appear to be justified after the expiry of the Community examination procedure, because in such cases the general rules of the Treaty apply.

2. In all cases, referral to the Committee does not necessarily imply a procedure for the formulation of an opinion. In many cases, as the experience of the "Low Voltage Directive" shows, problems can be solved by bilateral contacts between the Commission and the Member State which has had recourse to the safeguard clause.

VIII. Means of attestation of conformity

1. The means of attestation referred to in Point V which the professionals may use are:

- (a) certificates and marks of conformity issued by a third party
- (b) results of tests carried out by a third party
- (c) manufacturer's declaration of conformity
- (d) other means of attestation which could possibly be determined in the directive.

2. The choice of the professionals between these different means may be limited, or even suppressed, according to the nature of the products and hazards covered by the directive.

3. National bodies authorized to issue marks or certificates of conformity shall be notified by each Member State to the Commission and to the other Member States.

- 1. The appropriate means of attestation will be established and expanded in the specific directives taking into account the special requirements of their scope.
- 2. The bodies referred to in para. 3 must carry out their duties according to recognized international practices and principles and especially in accordance with ISO Guides. The responsibility for the control of the operation of these bodies lies with the Member States. Questions concerning the carrying out of tests and certification may be put before the Committee set up under Point IX.
- 3. With regard to the manufacturer's declaration of conformity, the national authorities have the right to ask the manufacturer or the importer to communicate the data relating to the tests carried out concerning safety etc. when they have good grounds to believe that a product does not offer the degree of safety required in all respects. Refusal on the part of the manufacturer or the importer to communicate these data constitutes sufficient reason to doubt the presumption of conformity.
- 4. Another of the means covered by para. 1d) could consist for example in the manufacturer's declaration of conformity coupled with a system of production surveillance.
- 5. The determination of a limitative list of means of attestation only concerns the system of presumption of conformity but cannot have the effect of restricting the possibility for a professional to prove by any means at his disposal within the framework of a dispute or court proceedings, the conformity of the product with the requirements of Point III.

#### IX. Standing Committee

A Standing Committee shall be set up chaired by a representative of the Commission and consisting of representatives appointed by the Member States who may avail themselves of the help of experts or advisers.

The Committee shall be convoked by its Chairman either on his own initiative or at the request of a Member State.

The Committee shall draw up its own rules of procedure.

#### X. Tasks and operation of the Committee

1. The Committee shall be consulted by the Commission on harmonized and national standards in accordance with Points V and VI.
2. The Committee shall have submitted to it all cases arising out of the measures adopted by the Member States under Point VII 1b) and c) and shall be consulted by the Commission on the outcome to be given to such cases.
3. The Committee may be consulted on all questions arising out of Point VIII.
4. Any question regarding the implementation of this directive may be submitted to the Committee.

The tasks of the Committee are concerned with the implementation of the directive. The object of the consultation of the Committee prior to the publication of the references of the national standards is more to provide for a forum for the discussion of the objections which the Commission or a Member State may formulate, than to carry out a systematic examination of the entire contents of the standards.

### Part III

Priority areas or sectors in which this approach could initially be applied

1. The need to find a new approach to the harmonization of technical regulations, based on "general reference to standards" and following the lines described earlier, is the outcome of a number of conditions (outlined in the first part of this Communication) backed up by the experience already acquired by the Community. Consequently it is a general principle, the validity of which will have to be assessed in practical terms in the various areas in which it will be applied.

The Council took a similar view in its "Conclusions" of 16 July 1984 when it confirmed the general need for an extension of the "general reference to standards" practice, but only provided the necessary conditions were fulfilled, i.e. as regards the obligation on public authorities to protect the health and safety of their citizens.

2. Before the priority areas in which this approach should initially be applied can be chosen, it is therefore necessary to establish a number of selection criteria to be taken into consideration, criteria which cannot be taken separately:

(a) Since the approach calls for the "essential requirements" to be harmonized and made mandatory by directives under Article 100 of the Treaty, the "general reference to standards" approach will be appropriate only where it is genuinely possible to distinguish between "essential requirements" and "manufacturing specifications". In other words, in all areas in which the essential requirements in the public interest are such that a large number of manufacturing specifications have to be included if the public authorities are to keep intact their responsibility for protection of their

citizens, the conditions for the "general reference to standards" approach are not fulfilled as this approach would have little sense. In the light of this statement areas involving safety protection certainly appear to have priority over those involving health protection (which applies to the scope of Directive 83/189).

- (b) If "general reference to standards" is to be possible, the area concerned must be covered by, or capable of being covered by, standardization. Areas which are inherently ill-suited to standardization work are certainly the areas referred to in (a) above where the need for regulations is felt unanimously throughout the Community. In other areas there is a standardization capacity or potential and in the latter case the Community should encourage it in close cooperation with both the industry concerned and the European standards bodies, whilst ensuring that the interests of consumers are taken into account.
- (c) The progress of technical harmonization work in the Community under the general programme established by the Council resolutions of 1969 and 1973 varies greatly from one industrial sector to another. In the manufacturing industry (which appears at first sight to best meet the abovementioned criteria) most of the directives adopted concern three areas: motor vehicles, metrology and electrical equipment.

The new approach will therefore have to take this state of affairs into account and concentrate mainly on other areas in which there is a lack of Community activities (e.g. many engineering products and building materials) without calling into question regulations that are already well advanced (for example those referring to motor vehicles). The case of electrical equipment is different: this is the only area to have been

tackled by a directive of the "general reference to standards" type and should certainly be included in the priority areas for all such products not yet covered, in view of the extremely important part played in this area by international and European standardization.

- (d) One of the main purposes of the new approach is to make it possible to settle at one stroke, with the adoption of a single directive, all the problems concerning regulations for a very large number of products<sup>1</sup>, without the need for frequent amendments or adaptations to that directive<sup>2</sup>. Consequently in the selected areas there should be a wide range of products sufficiently homogeneous to allow common "essential requirements" to be defined. This general criterion is, however, based mainly on practical and labour-saving considerations. There is nothing to prevent a single type of product, in certain cases, from being covered by the "general reference to standards" formula if all the abovementioned criteria are met.
- (e) Finally mention should be made of one criterion that the Commission, in agreement with industry, has always regarded as essential. There must be grounds for considering that the existence of different regulations does in practice genuinely impede the free movement of goods. In some cases, however, even if these grounds are not obvious, a directive may appear necessary to protect an essential public interest uniformly throughout the Community. Whereas technical manufacturing specifications are bound to become obsolete as technological progress is made.

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<sup>1</sup> The "low voltage" Directive 73/23/EEC defining the essential safety requirements for electrical products and referring to CENELEC standards is currently based on around one hundred EN and HD. If the Community had had to follow the approach adopted in the "motor vehicles" framework directive, for example, it would probably have needed about one hundred directives under Article 100!

<sup>2</sup> One of the main features of the "essential requirements" that have to be defined is the fact that they remain valid for long periods.

3. It is the Commission's intention to initiate the procedures leading to the submission of practical proposals and it will start on the necessary work at the earliest opportunity, selecting the following areas<sup>3</sup>:

(a) Mechanical engineering

This work will have to find solutions for areas in which harmonization has already been started (pressure vessels, gas appliances, construction plant, lifting appliances) and areas in which there are no directives such as machine tools and other types of machines.

(b) Building materials

One specific area appears to merit priority: the fire resistance of building materials and components.

(c) Electrical appliances

Two areas should be chosen: active and passive protection against disturbances by conduction and radiation, the essential requirements for which apply to an ever-increasing market for industrial products, especially in information technology, and electromedical equipment, only covered to a very limited extent by the recent Council Directive 84/539/EEC, which should be subjected to a thorough study.

4. The choice of of these three areas does not mean that in the near future further work may not appear necessary to meet other requirements (e.g. labelling for the information of consumers) or to cover other areas.

The Commission considers that all these activities should be carried out with strict attention to priorities and criteria but also in a great spirit of pragmatism as it is in the light of experience and the successes achieved that the procedure will be streamlined and simplified.

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<sup>3</sup> Not necessarily in order of priority.

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The Commission requests that the European Parliament and the Council approve the orientations set out in this Communication, especially on the following points:

- the urgency of putting right the present situation in the field of technical barriers to trade and of clearing the uncertainty for the economic operators which stem from that situation;
- the new approach consisting in asking general references to standards;
- the four fundamental principles on which the outline directive is based (cf. especially Part I, paragraph 5);
- the selection criteria which have to be taken into consideration in order to determine those fields in which the new approach should be applied as a priority (cf. especially Part III, paragraph 2).