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(Information)

COUNCIL

COUNCIL RESOLUTION

of 7 May 1985

on a new approach to technical harmonization and standards

(85/C 136/01)

THE COUNCIL,

in extension of its conclusions on standardization, approved on 16 July 1984 (Annex I);

emphasizes the urgent need to resolve the present situation as regards technical barriers to trade and dispel the consequent uncertainty for economic operators;

emphasizes the importance and desirability of the new approach which provides for reference to standards — primarily European standards, but national ones if need be, as a transitional measure — for the purposes of defining the technical characteristics of products, an approach outlined by the Commission in its communication of 31 January 1985, which follows certain guidelines adopted by the European Parliament in its resolution of 16 October 1980 and forms part of the extension of the Council's conclusions of 16 July 1984;

aware that the new approach will have to be accompanied by a policy on the assessment of conformity, calls on the Commission to give this matter priority and to expedite all its work in this area;

approves the guidelines encapsulated in the list of principles and main elements to be embodied in the main part of the Directives (Annex II to this resolution);

calls on the Commission to submit suitable proposals as soon as possible.

ANNEX I

CONCLUSIONS ON STANDARDIZATION

Approved by the Council on 16 July 1984

The Council believes that standardization goes a long way towards ensuring that industrial products can be marketed freely and also towards creating a standard technical environment for undertakings in all countries, which improves competitiveness not only on the Community market but also on external markets, especially in new technology.

It recognizes 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.

Accordingly, the Council adopts the following principles for a European standardization policy:

— agreement by the Member States to keep a constant check on the technical regulations which are applied — whether *de jure* or *de facto* — on their territory so as to withdraw those which are obsolete or unnecessary;

— agreement by the Member States to ensure the mutual recognition of the results of tests and the establishment, where necessary, of harmonized rules as regards the operation of certification bodies;

— agreement to early Community consultation at an appropriate level, in accordance with the objectives of Directive 189/83/EEC where major national regulatory initiatives or procedures might have adverse repercussions on the operation of the internal market;

— 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;

— a very rapid strengthening of the capacity to standardize, preferably at European level, with a view to facilitating on the one hand harmonization of legislation by the Community and on the other industrial development, particularly in the field of new technologies, since this could in specific circumstances involve the Community in introducing new procedures to improve the drawing up of standards (e.g. standardization bureaus, *ad hoc* committees). The adoption of European standards would be submitted to the European standardization bodies for approval.

In high technology sectors particularly, subjects should be identified where common specifications and standards will make for efficient exploitation of the Community dimension and the opening of public works and supply contracts so that the decisions required in this connection may be taken.

ANNEX II

GUIDELINES FOR A NEW APPROACH TO TECHNICAL HARMONIZATION AND STANDARDS

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

— legislative harmonization is limited to the adoption, by means of Directives based on 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 movement throughout the Community,

— the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives, while taking into account the current stage 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 with the standards but that in this event he has an obligation to prove that his products conform to the essential requirements of the Directive.)

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 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 assisted 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 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 technical separate Directives for each product. The scope of Directives according to the 'general reference to standards' formula should encompass wide product categories and types of risk.

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.

OUTLINE OF THE PRINCIPLES AND MAIN ELEMENTS WHICH SHOULD MAKE UP THE BODY OF THE DIRECTIVES

A. JUSTIFICATIONS

Amongst the traditional principles justifying a Directive the following aspects should be emphasized:

— Member States have the responsibility of ensuring safety on their territory (in the home, at the workplace, etc.) of persons, domestic animals and goods, or the respect of other essential protection requirements in the general interest such as health, consumer or environmental protection etc., with regard to the hazards covered by the Directive itself (1);

— 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 the Directive, in accordance with the guidelines which the Commission, after consultation of the Member States, has signed with these bodies (2).

(1) For reasons of convenience and ease of drafting 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 hazard.

2. The object of the Directive will be specified in each sphere of application according to the types of hazard (safety, health, environmental, 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 defined in such a way that a consistent approach to the action is ensured, and that the proliferation of Directives on specific products is avoided. Moreover, it should be noted that the enacting terms of such a Directive 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 placing on the market

The products covered by the Directive may be placed on the market only if they do not endanger the safety of persons, domestic animals or goods when properly installed and maintained and used for the purposes for which they are intended.

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.

   Appropriate solutions could be envisaged in order to take account of the need to support, in some Member States, a harmonious move towards the introduction of a system of binding regulations, in order in particular to ensure the establishment of appropriate certification infrastructures.

   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, which is to leave to the trade the choice of the means of attestation of conformity and thus to prohibit Member States from setting up any system of control prior to placing on the market (except, of course, in cases where 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 covered by 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. They should be so formulated as to enable the certification bodies straight away to certify products as being in conformity,

having regard to those requirements in the absence of standards. The degree of detail of the wording will depend on the subject matter. If the basic requirements for safety are observed, the general clause in point II can be applied.

2. Amendments to these requirements can be made only by means of a new Council Directive under Article 100 of the Treaty.

IV. **Free movement clause**

Obligation on the Member States to accept, under the conditions referred to in point V, the free movement of products which conform to points II and III.

1. Free movement will be ensured in the case of products declared to conform to the protection requirements laid down in the Directive, without recourse as a general rule to prior verification of compliance with the requirements set out in point III, it being understood that 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 systematically required by the sectoral Directives.

2. The actual aim of the Directives in question is to cover all essential requirements, but in the exceptional case of cover proving incomplete, it would always be possible for a Member State to act under Article 36 of the Treaty.

V. **Means of proof of conformity and effects**

1. Member States shall presume to be in conformity with points II and 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 standardization body which is particularly competent within the scope of this Directive, when these standards are adopted in accordance with the general guidelines agreed between that body and the Commission and the references of which are published in the *Official Journal of the European Communities;* such publication should, moreover, also be carried out by the Member States;

   (b) or as a transitional measure, and in so far as harmonized 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 the text of those national standards which they consider to meet points II and III. The Commission shall forthwith forward this text to the other Member States. In accordance with the procedure laid down in paragraph 2 of Point VI, the Commission shall notify the Member States of the national standards which enjoy the presumption of conformity with points II and III.

   Member States are required to publish the references of these standards. The Comission shall also ensure that they are published in the *Official Journal of the European Communities.*

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 paragraphs 1 (a) and (b) above or for other exceptional reasons, are considered to be in conformity with points II and III, when their conformity is demonstrated by one of the means of attestation set out in point VIII, paragraph 1 (a) 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 points II and III is declared by the means of an attestation delivered by an independent body.

   3. In cases under point V, paragraphs 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 paragraph 1 (a) 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 ruled out that the harmonized standards referred to in paragraph 1 (a) will 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 when drawing up a frame of reference for standardization after consultation with the Member States.

5. In the selection of national standards, due considereration will be given to any practical difficulties arising from that selection.

   National standards are selected only on a transitional basis. Accordingly, when a selection decision is made, the relevant European bodies will in principle be sent instructions to draft and adopt the corresponding European standards within a given period of time and under the conditions stated above.

VI. **Management of the list of standards**

1. Where a Member State or the Commission considers that harmonized standards or drafts thereof do not fully satisfy points II and III, the Commission or the Member State 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 shall, in the light of the committee's opinion, notify the Member States of the necessity of withdrawing or not withdrawing the standard from the publication referred to in point V, paragraph 1 (a). It shall 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, paragraph 2, the Commission shall consult the committee. After the committee has given its opinion, the Commission shall, within a given period, notify the Member States whether the national standard in question should or should not enjoy presumption of conformity and, if so, be subject to national publication of its references.

   If the Commission or a Member State considers that a national standard no longer fulfils the conditions for presumption of conformity to the safety requirements, the Commission shall consult the committee. In the light of the opinion of the committee, it shall notify the Member States whether or not the standard in question should continue to enjoy presumption of conformity and in the latter case be withdrawn from the publications referred to in point V, paragraph 2.

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

VII. **Safeguard clause**

1. Where a Member State finds that a product might compromise the safety of individuals, domestic animals or property, it shall take all appropriate measures to withdraw or prohibit the placing on the market of the product in question or to restrict 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) non-compliance with points II and 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. The Commission shall consult the Member States concerned as soon as possible. If the Member State which has taken measures intends to maintain them, the Commission shall refer the matter to the committee within a specified period. Where the Commission, after consultation of the committee, finds that the action is justified it shall, also within a given period of time, inform the Member State in question and point out to the other Member States that (all else being equal) they are also obliged to prevent the product in question from being placed on the market.

3. Where failure of the product to comply with points II and III results from a shortcoming in the harmonized standards or in the national standards, the consequences shall be 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 inform 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.

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 expiry of the Community examination procedure, because in such cases the general rules of the Treaty apply.

VIII. **Means of attestation of conformity**

1. The means of attestation referred to in point V which the trade 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) declaration of conformity issued by the manufacturer or his agent based in the Community. This may be coupled with the requirement for a surveillance system;

(d) other means of attestation which could possibly be determined in the Directive.

2. The choice by trade and industry between these different means may be limited, or even removed, 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. It must be borne in mind that the certification bodies designated by the Member States for cases (a) and (b) will have to intervene in particular in the absence of standards and where the manufacturer does not observe standards (see point V, paragraph 3).

2. The bodies referred to in paragraph 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 for believing 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 comunicate these data constitutes sufficient reason to doubt the presumption of conformity.

4. 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 member of the trade to prove, by any means he sees fit within the framework of a dispute or court proceedings, the conformity of the product with points II and 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 convened 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 carry out the tasks entrusted to it by virtue of the foregoing points.

2. Furthermore, any question regarding the implementation of a Directive may be submitted to the committee.

The tasks of the committee shall be 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.

Criteria for choosing the priority areas 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 based on 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 be 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 manufacturing industry (which appears at first sight better to fulfil 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 a stroke, with the adoption of a single Directive, all the problems concerning regulations for a very large number of products, without the need for frequent amendments or adaptations to that Directive. 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.