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Memorandum on health and safety standardization in support of "New Approach" Directives - Application in the field of machinery

Memorandum on health and safety standardization in support of "New Approach" Directives - Application in the field of machinery

Memorandum zur Normung im Bereich Sicherheit und Gesundheit in Ausfüllung von Richtlinien nach der "Neuen Konzeption" - Anwendung im Bereich Maschinen

Mémoire sur la normalisation en matière de santé et de sécurité destinée à appuyer les directives "Nouvelle Approche" - Application au domaine des machines

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English version

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on
health and safety standardization
in support of
"New Approach" Directives -
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This CEN REPORT has been established by the CEN/BT Working Group 60 and has been approved by CEN on 1993-01-18.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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1 INTRODUCTION

This Memorandum has been prepared by CEN/BT/WG 60, in response to CEN/BT Resolution 14/1991.

It is primarily intended to give standardizers¹ a clear understanding of the role of standards in relationship to the European directives made under the "New Approach"².

Several directives with a health and safety dimension have been adopted or are in preparation under the "New Approach", such as the "Machinery directive" 89/392/EEC (including its amendment relating to the specific risks due to mobility and ability to lift loads), the directive 89/686/EEC relating to the design of personal protective equipment (known as "PPE directive"), the directive on toys, the directive on gas appliances, the directive on simple pressure vessels, etc. Others have been proposed, relating to pressure equipment or equipment used in potentially explosive atmospheres. Each of these directives is – or will be – supported by harmonized standards.

The "Machinery directive" has given rise to a large programme of standards with a structure and hierarchy intended to aid the production of effective standards. This programme has also yielded valuable information on the management of such programmes and the need for identifying and setting priorities. The experience gained in this programme has been used in this Memorandum to illustrate and to help solve :

- general problems of standardization in relation to the New Approach (see sections 3 to 5),
- problems of standardization arising specifically from the field of machinery safety (see section 6 "Machinery-related issues", which deals notably with the "A,B,C hierarchy of standards", as created for machinery design.

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The basic approach described in sections 3 to 5 of this Memorandum can be applied in the field of other directives.

Separate Memorandum dealing with specific issues for each directive may be prepared at a later time.

¹ For the purposes of this Memorandum, standardizers include all those taking part in the preparation of standards, e. g. :

- chairmen, conveners, secretaries and members of technical committees (TCs), sub-committees (SCs) and working groups (WGs);
- manufacturers and users of products and their representatives;
- public authorities;
- testing, inspection and certification bodies.

² The present Memorandum should not be confused with the Vademecum (or Guide) being prepared by the EC Commission. This Vademecum concerns the "New Approach" in general – not limited to standardization issues – and is intended for all parties concerned by the application of the "New Approach", and not only for standardizers. Examples of issues dealt with in the Vademecum are the use of safeguard clauses, the role of notified bodies, the technical file, the role of standards, etc. It is of interest to public authorities, industry, standardization organizations, interested parties, etc.

The first parts of this Vademecum have been made available at the end of 1992.

NOTE

The "Machinery directive" was made under Article 100 A of the EEC Treaty and deals with the design and construction of machinery.

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The use of machinery is subject to several directives made under Article 118 A which relate to health and safety at work – notably the directive 89/655/EEC concerning the *minimum safety and health requirements for the use of work equipment by workers at work*.
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It is important that standardizers are aware of the existence of these "use" directives. Machines manufactured to harmonized standards mandated under the "Machinery directive" will be subject to the "use" directives after being put into service.

Table 1, page 4, shows the main features of the Article 100 A and 118 A directives and of the associated standards, if any.

Table 1 : Main features of the "New Approach" system (based on Art. 100 A of the EEC Treaty) compared with those of the instrument adopted on the basis of Art 118 A

| | "New Approach" to technical harmonization and standards (Scope of the present Memorandum) | Instrument adopted on the basis of Art. 118 A of the EEC Treaty (Out of the scope of the present Memorandum) |
|---|--|--|
| Basic article in the EEC Treaty | Article 100 A (see annex A) | Article 118 A (see annex A) |
| CEC/DG in charge of the task | DG III Internal market and industrial affairs | DG V Employment, industrial relations and social affairs |
| Aims | <ul style="list-style-type: none"> • Design and construction (or manufacturing) of safe products • Removal of technical barriers to trade | Progressively higher levels of occupational health and safety by means of harmonizing legislation |
| Beneficiaries of safety requirements and specifications | Persons and, where appropriate, domestic animals and property | Workers |
| "Covered" activities | DESIGN, CONSTRUCTION/MANUFACTURING, PLACING ON THE MARKET and PUTTING INTO SERVICE of PRODUCTS/EQUIPMENT for professional and non-professional purposes | USE of PRODUCTS/EQUIPMENT at work |
| Expression mode | ESSENTIAL REQUIREMENTS established by DIRECTIVES and TECHNICAL SPECIFICATIONS in the form of HARMONIZED STANDARDS | MINIMUM REQUIREMENTS established by DIRECTIVES (known as "social directives") |
| Comments | <ul style="list-style-type: none"> • Harmonized standards give presumption of conformity with essential requirements (see 3.2.2). • The essential requirements take as a basis a high level of safety. • Member States shall neither adopt nor keep conflicting national regulations and further specifications. | <ul style="list-style-type: none"> • Standards may be developed, except for the establishment of limit values of exposure for workers. • The "social directives" may refer explicitly to standards (e. g. standards for measuring methods). • Each Member State is left free to fix more stringent requirements under these directives, provided they are compatible with the Treaty. |

2 DOCUMENTS TO WHICH REFERENCE IS MADE IN THIS MEMORANDUM

| Document | Part of the document... | ... quoted/ referred to/ reproduced in : |
|---|------------------------------|--|
| • EEC Treaty | Articles 100 A and 118 A | Annex A |
| • Council Resolution of May 7th 1985 on a new approach to technical harmonization and standards | Extract from Annex II | 3.2.1, Annex B |
| • Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery (amended by directive 91/368/EEC) | | Introduction, 5.3.1, 6.1, 6.3.2.4, 6.4, 6.5 |
| • Council directive 89/655/EEC of 30 November 1989 concerning the minimum health and safety requirements for the use of work equipment by workers at work | | Note, p. 3 |
| • EN 414 "Safety of machinery – Rules for the drafting and presentation of safety standards" | Numerous references | 4.1.3, 4.1.4, 5.4, 6.2, 6.2, 6.3 |
| • EN 45 020 : 1991 (ISO/IEC Guide 2) "General terms and their definitions concerning standardization and related activities" | 3.2 1.4 | 4.1.1 4.1.2 |
| • EN 292 "Safety of machinery – Basic concepts, general principles for design - Part 1 : Basic terminology, methodology - Part 2 : Technical principles and specifications" | Note 2 of 6.1 of EN 292-1 | 4.1.2, 6.1 |
| • EN 60204-1 : 1992 "Safety of machinery – Electrical equipment of machines – Part 1: General requirements" | | 6.1 |
| • CEN/CENELEC Internal Regulations – Part 2 : "Common rules for standards work" | | 4.2.1 |
| • CEN/CENELEC Internal Regulations – Part 3 : "Rules for the drafting and presentation of European Standards (PNE-Rules)" | | 4.2.1, 4.1.4, 5.4 |
| • CEN/CENELEC Memorandum 4 "General Guidelines for cooperation between the Commission of the European Communities (CEC) and the European Free Trade Association (EFTA) and the European standards institutions" | | 5.3 |
| • EFTA-EC "Luxembourg declaration" | | Annex E |
| • European Economic Area (EEA) Agreement | Summary | Annex D |
| • Document CENELEC/TC 44X N 22 C "Guidance for Sectoral Committees and Working Groups – Electrotechnical aspects of machinery safety – Revision 4" | | 6.6.2 |
| • "Safety of machinery – Guidance for the drafting of the noise clauses of safety standards" (Document prepared by CEN/TC 211) | | 6.6.1 |
| • "Rules for the drafting and presentation of a noise test code" (Document prepared by CEN/TC 211) | | 6.6.1 |
| • Reminder to some essentials for CEN work in the field of machinery safety (Edition 1 : 1992-01-14) | | Annex F |

Extracts of official documents inserted into the text are printed in *italics*

3 OVERALL APPROACH AND LEGAL BACKGROUND:

3.1 The European market

The Member States of the European Community agreed in 1987 that :

"The Community shall adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992".

and that :

"The internal market shall comprise an area without internal frontiers, in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the EEC Treaty" (article 8 A inserted into the EEC Treaty by the European Single Act of 1987).

Standards play a key role in the completion of the European market .

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3.2 The "New Approach"

In the past, Member States imposed a wide range of obligations on business in the interests of safety, consumer protection and the like. However well justified, these obligations gave rise to technical barriers to trade because of differing requirements and procedures in different Member States.

The traditional solution was to adopt Directives setting out the detailed requirements a product must satisfy in order to be entitled to be sold freely throughout the Community. This was a slow process, because of the detailed nature of the requirements and the need for unanimity required by Article 100 of the EEC Treaty.

The "New Approach to technical harmonization and standards" introduces new methods for technical rule making at the level of the European Community.

Its primary purpose is to remove the technical barriers to trade referred to above. It is set out in a resolution adopted on the 7th May 1985 by the Council of Ministers of the European Communities. This resolution emphasized *"the importance and desirability of the new approach which provides for reference to standards – primarily European Standards – ...for the purposes of defining the technical characteristics of products..."*.

Additionally, it stresses that the free movement of goods has to be ensured *"without lowering existing and justified levels of protection in the Member States"*.

The new Article 100 A introduced into the EEC Treaty by the European Single Act replaces unanimity by qualified majority in the voting procedures.

The **four fundamental principles for this new approach** can be summed up as follows (see in Annex B the part of the Council resolution of 7 May 1985 which defines those principles) :

Directives contain essential safety requirements or other requirements in the general interest (all referred to hereafter as "essential requirements");

Harmonized standards set out technical provisions that allow compliance of the products with the essential requirements;

The technical provisions set out in harmonized standards are not mandatory; applying them is a means of meeting the corresponding essential requirements;

A product complying with the provisions of a harmonized standard the reference of which has been published in the Official Journal of the EC is presumed to comply with the corresponding essential requirement(s).

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3.2.1 Role of "New Approach" directives in the field of health and safety

Many of the non-tariff barriers to trade which the New Approach is designed to remove have their justification in the protection of health and safety. There is thus a close relationship between the directives setting out general requirements on manufacturers and health and safety.

Usually, the field of application of a New Approach directive is a large range of products and hazards generated by those products. In a few cases, adopted or proposed directives focus on a physical phenomenon (e. g. electromagnetic radiation, pressure...) which may be a hazard in itself, or which may generate a hazard.

This means that a product may have to comply with (some of) the requirements of more than one directive.

New Approach directives set out the obligations (essential requirements) which the relevant product must fulfill before it is put on the market, and fix the procedure(s) for the EC declaration of conformity of the relevant product with respect to the hazards covered by the directive.

In paragraph B.III of its Annex II, the Council Resolution of 7 May 1985 states that :

"The essential safety requirements... 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."

It is the responsibility of the manufacturer, his authorized representative established in the Community, or the person placing the product on the market, to ensure that the product complies with the relevant directive(s).

The "CE" mark expresses the compliance with the requirements of directives and not with the provisions of standards.

3.2.2 Role of standards in the "New Approach"

Products must comply with the essential requirements when they are put on the market. It is for the manufacturers to determine how their products should be designed and constructed/manufactured in order to comply with the essential requirements, and they may choose to implement different techniques for this purpose.

Unavoidably, there is a margin of appreciation between the essential requirements and their practical application, case by case, to product design. It is the role of harmonized standards to assist manufacturers in this respect.

Compliance with national standards implementing harmonized standards, the reference of which has been published in the Official Journal of the European Communities, creates a presumption of conformity with the essential requirements to which these standards relate.

It is therefore expected that the main method by which manufacturers will show that their products meet the relevant essential requirements set out in the directives will be by designing and constructing/manufacturing according to the relevant standard (or standards).

3.3 EC - EFTA - EEA

The European Community (EC) and the European Free Trade Association (EFTA) made in 1984, at a meeting between Ministers in Luxembourg, a joint declaration (see Annex E) - known as the Luxembourg declaration - with a view to continuing, deepening and extending cooperation within the framework of, and beyond the Free Trade Agreements concluded earlier. This cooperation has later developed in numerous fields of mutual interest, especially in the field of the "New Approach", as described in 3.2.

A further step was taken when the explanatory talks between the parties started in 1989, followed by formal negotiations concluded in 1992. This resulted in the European Economic Area (EEA) Agreement between EC and EFTA (see Annex D), according to which the single market is widened to embrace also the EFTA countries, provided that they implement the relevant EC legislation.

At the beginning of 1992, EFTA was preparing for a revised internal structure to be better in accordance with the requirements of the recently concluded EEA Agreement. Consequently, it might be misleading to give references to the EFTA structure in parallel to the references made to the EC and CEC structure. It should however be emphasized that the EC and CEC functions either correspond to similar EFTA functions or cover the EFTA needs by means of EFTA-EC cooperation.

4 STANDARDS

4.1 Fundamental nature of standards - Basic statements

4.1.1 Definition (3.2 of EN 45 020 : 1991, equivalent to ISO/IEC Guide 2)

"Standard : Document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Note : Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits."

4.1.2 Taking into account the state of the art when preparing standards³

Subclause 1.4 of EN 45020 : 1991 provides with the following definition :

State of the art

Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.

Note 2 of 6.1 of EN 292-1 provides with the following statement :

“As absolute safety is not a fully attainable state, the objective to be met when designing a machine is the highest possible level of safety taking into account the state of the art.”

The state of the art determines the constraints – including cost constraints – placed upon actual construction and use of the machine. The means employed to meet a safety objective which are acceptable according to the state of the art at a particular time, are no longer acceptable when developments allow the next generation of the same machine to be safer, or allow the design of a different and safer machine for the same purpose.”

All technical provisions expressed in standards should preferably have been previously validated by practical application, referring to data or experts recognized by all parties concerned.

Given the specific nature of harmonized standards, standardizers must ensure that such standards reflect the highest possible level of safety taking into account the state of the art (see above Note 2 of 6.1 of EN 292-1).

Updating of the technical provisions must reflect technical progress (improvement in existing technologies and development of new technologies).

Difficulties met in the standardization process often reveal an important need for technical research.

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4.1.3 Taking into account users' experience when defining the intended use of a product

Standardizers must make sure that, when they define the foreseeable conditions of use of a product (intended use of a product⁴), practice and experience of users (employers and employees, consumers) are also taken into account, using all related data (e. g. accident/near-accident reports, surveys, scientific and medical reports) and expertise and including awareness of Article 118 A directives (see also NOTE on page 3 of this Memorandum and 5.2.g of EN 414).

The technical provisions must take into account all foreseeable conditions⁵ of use of the product at all phases of its “life”

For a definition of “use”, see Paragraph 1.1.2 (c) of Annex 1 of the “Machinery directive”

³ See the 11th recital (“Whereas...”) of the “Machinery directive”

⁴ Subclause 3.12 of EN 292-1 defines the intended use of a machine.

⁵ Subclause 5.2 “Systematic assessment of hazardous situations” of EN 292-1 provides guidance in this matter as far as machinery is concerned.