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**UNECE FORUM ON MARKET SURVEILLANCE
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**Information on the Use of Harmonized Standards
in the Machinery Sector in the EU**

This background paper was prepared by Mr. Harald Riekeles, Rapporteur of the CEN for the Machinery Safety Sector.

It is presented for **information** to delegates and is reproduced in the form and language in which it was received by the secretariat.

Harmonised standards according to the European Technical Directives are voluntarily applicable standards which specify the mainly general wording of essential requirements in EU directives. Their application allows the manufacturer to assume the conformity of his product with the requirements dealt with; makes it easier to place the product on the market, may relieve the product from third party certification and supports market surveillance as criterion for the assessment of a product.

In 1985 the basis for Technical Directives in Europe was given by the New Approach of the European Community in order to realise the political aim of a uniform single European market:

- EU Directives with compulsory essential requirements which are to be transposed into national law by the member states;
- Harmonised European Standards (EN) in order to specify the essential requirements but the application of which is voluntary.

Importance of Harmonised Standards

Their importance for market access and market surveillance is described in the corresponding articles of EU directives according to the New Approach - for example in the Machinery Directive 98/37/EC in article 4 (1) and 5 (2) - and in the definition of the term "harmonised standard".

Article 4

- (1) Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of machinery ... which comply with this Directive.

Article 5

- (2) Where a national standard transposing a harmonised standard, the reference for which has been published in the Official Journal of the European Communities, covers one or more of the essential safety requirements, machinery constructed in accordance with this standard shall be presumed to comply with the relevant essential requirements.

According to the principles of the New Approach, harmonised standards are technical specifications which were elaborated by an European standards organisation under a mandate given by the EU commission and are listed by the commission under reference to the corresponding directive(s) in the Official Journal of the European Communities (OJEC). For the user (of standards) it is said in the foreword of the standard that it was elaborated under a mandate of the EU commission. The listing of EU directives specified in the standard is given in its last annex (annex Z).

Because of the presumption of conformity defined for example in article 5 (2) of the Machinery Directive the manufacturers have a very great interest to use not only European standards EN, but harmonised ENs. If an authority has the opinion that a product is not in line with the essential requirements of the relevant directive(s), although the manufacturer has the opinion that it is fully in line with the relevant harmonised standard(s), it has to offer evidence - not the manufacturer.

If a member state has the opinion that the provisions of the standard are not sufficient or are in contradiction to the essential requirements of the directive, it has to initiate a safeguard action against the standard. The consequence can be the deletion of this standard from the Official Journal or a restriction of its presumption of conformity which can have an effect on the products launched on the market from that time on.

If a product is not or only partly produced according to harmonised standards, the market surveillance can use the standards' content as criterion for the assessment of a product, but it can not be used as demand. The status or category, which can be different from directive to directive, of the available standards for a certain field have to be considered.

Structure and presumption of conformity of standards for machinery safety

Because of the complexity and size of the work programme for machinery safety it was agreed in the beginning to have a standards system (type A, type B and type C standards). This should prevent double work and develop a logical system to have a fast standards development procedure and an easier cross-reference between the different standards.

The systematic structure distinguishes three types of standards:

- Type A standards (basic safety standards) giving basic concepts, principles for design and general aspects, that can be applied to machinery;
- Type B standards (group safety standards) on particular aspects (e.g. safety distances, surface temperature, noise) or a kind of safeguard which can be used across a wide range of machinery (e.g. two-hand controls, interlocking devices, pressure sensitive devices, guards);
- Type C standards (machine safety standards) with detailed safety requirements for a particular machine or group of machines which can provide requirements different from the type A or B standards.

Although according to the Machinery Directive all harmonised standards have a presumption of conformity, it has been seen to be different in practice: The presumption of conformity regarding a product is only given by a type C standard, and only for the scope defined!

If there is no type C standard for a product available, type C standards of similar products and hazards can be taken into consideration. Even not yet ratified standards like draft standards (prEN) are useful, as they show the consensus achieved within the Technical Committee in the European or international field.

Only if there is no type C standard available for a machine or there are significant hazards not dealt with, the provisions of the relevant basic and group standards type A and B give help in order to fulfil the corresponding essential safety requirements for the specific machine or give criteria for assessment by market surveillance.

The publications in the OJEC until 15 June 2002 list 375 harmonised standards to the Machinery Directive 98/37/EC. Thereof are:

- 79 basic standards (type A) and group standards (type B) for safety aspects and safeguards
- 206 product standards (type C) for machines and machine groups, including 27 standards for machines according to annex IV of the Machinery Directive (if these are applied completely the obligatory EC-type examination of annex IV-products does not apply).
- 90 type C standards for certain components like chains, conveyor belts and for machine specific aspects or equipment like noise measurement, braking equipment.

For the Lift Directive 95/16/EC there are listed 3 type C standards.

The total work programme of standards for machinery and lifts safety includes today 750 projects, including 130 type A and B standards.

Regarding the electromagnetic compatibility there are about 20 harmonised standards for machines and -assemblies listed in the OJEC to the EMC directive 89/336/EEC (with amendments) including:

- 4 product specific ENs for lifts, escalators, agricultural machines, sewing machines
- 4 generic standards which give the presumption of conformity instead of a product standards.

Standard's content

Type C standards shall deal with one or more essential safety requirements of the relevant EU directive(s). Normally - for standards for machines of annex IV this is a necessity - they include all hazards known by the standardizers under consideration of the essential requirements of the

Machinery Directive as well as all other directives relevant for the machine. They describe concrete solutions with the presumption of conformity as well as the basis for verification or inspection.

The clause Scope defines the machine(s) with its limits and gives information whether a certain hazard is dealt with or not. In this last case the standard is not faulty, but intentionally incomplete. For the hazard in question the manufacturer has to assess additionally the risk himself.

In particular, the clause list of hazards indicates the hazard analysis done by the standardizers (corresponding to the requirement in annex I, preliminary observation 3). There, the standardizers list all known significant hazards. But the designer has to check whether there will be additional hazards generated by his machine and has to take the necessary safety measures.

The clause Safety requirements and/or measures is the heart of a safety product standard. The provisions are indicated as results or as means, e.g. as constructive solutions. The described state of the art has a special meaning for machines where it may not be possible to meet the objectives as indicated in the Machinery Directive (annex I, preliminary observation 2).

In the clause, "Information for use", the requirements for the marking as well as the significant specifications for the information for use of the machine are indicated (directive requirements annex I, 1.7.3 and 1.7.4). The standards shall indicate the residual risks which cannot be reduced by design measures and advice the manufacturer on protective measures to be taken by the user or operator for the minimisation of the residual risks, such as wearing of personal protective equipment.

Summary

Harmonised Standards form the manufacturers' keys to the European Single Market – and constitute the basis for a rational market surveillance.

The manufacturer can choose whether or not to refer to harmonised standards. If he chooses not to follow a harmonised standard, he has the obligation to prove in his Technical File that his product is in conformity with the essential requirements of the relevant directive(s) by the use of other means of his own choice (e.g. by means of other technical specifications such as purely national standards).

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