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Background information to the EUROSHNET “CRACOW MEMORANDUM”

– Standardisation for Safe Products –

CONTENTS

Background

A STANDARDISATION

1. Towards harmonised European Standards guaranteeing a higher level of safety and legal security
 - 1.1. The requirements of Single Market Directives
 - 1.2. The content of the existing harmonised European Standards
 - 1.3. Benefits of legally more robust standards
2. Towards technically more robust harmonised European Standards
3. Towards European and International standards preserving a high level of safety

B TESTING AND CERTIFICATION

1. How could the risks of discrepancies in the certification decisions be minimised?
 - 1.1. Participation in the European Coordination of Notified Bodies
 - 1.2. Development of an effective and consistent market surveillance policy

C RESEARCH AND STUDIES IN SUPPORT OF STANDARDISATION

1. The importance of research and studies
2. Normative research and studies

Background

The New Approach and the current CEN standardisation and CE certification processes, although not perfect, have proved extremely useful and have enhanced the safety level of the products placed on the EU market. The present Memorandum does not question the New Approach system and its recent revision by the European Commission*. Nor does it question the many procedures on which its operation is based, or the major achievements such as the A, B, and C standards scheme developed in the machinery field. Instead, it aims to point out areas where progress can be made such that the quality of harmonised standards is further improved, in particular regarding the key European objective of “ensuring the highest possible level of safety for users of products circulating freely in the EU”.

The New Approach aims to eliminate the obstacles to the free movement of goods in the European Union. According to Article 95 of the Treaty establishing the European Community, the approximation of the laws is based, as regards safety and health, environmental protection and consumer protection, on a high level of protection, taking account in particular of any new developments based upon scientific facts. This general provision means that harmonised European standards which support the internal market directives are to be developed not only to facilitate the free marketing of the products, but also to ensure a high level of protection with respect to the safety and health of European citizens in their private and professional capacity. It also means that the standards must be regularly updated in step with evolution of the state of the art.

Past crises such as those involving asbestos, contaminated blood, severe acute respiratory syndrome (SARS), BSE and bird flu have led to greater public sensitivity to aspects of safety and health. The increasing risk of prosecution and punishment for faults leading to severe accidents or even disasters should encourage those in charge in commerce, policy and administration to be increasingly vigilant in this respect.

New rules have emerged for maintaining personal safety and security, such as the precautionary principle. The essential idea in this case is that those responsible should address problems by taking effective and commensurate prevention measures rather than waiting for scientific certainty. The precautionary principle, which is already recognised in various international agreements, such as the SPS agreement on health and phyto-sanitary measures, has been extended to consumer protection. In February 2000 the European Commission issued a Communication on the precautionary principle in which it adopted a procedure for the application of this concept. In September 2000 a solemn resolution concerning this principle was adopted by the European Council.

Harmonised European standards should therefore be robust on both the legal and technical levels. In turn, the products should be safe and in actual conformity with the provisions of the relevant directives: in other words, their quality should be such that they ensure safety and health on the one hand and minimise the risk of litigation on the other. Harmonised European standards should generate a high degree of confidence not only among the market players but also among all other stakeholders (European and national authorities, social partners, consumers, notified bodies, manufacturers, OSH organisations, etc).

* Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products

A. STANDARDISATION

1 Towards harmonised European Standards guaranteeing a higher level of safety and legal security

1.1 The requirements of single market directives

- Risk analysis is considered as a preliminary stage, a tool for the identification of the relevant essential requirements that are applicable to a given product.
- The manufacturer of a product must identify the essential requirements of the relevant directives that apply to the product in question, list the requirements in the technical files, and consider them in the design and production phase of the product.
- Most directives require the manufacturer to draw up and sign an EC declaration of conformity specifying expressly that the product satisfies all the relevant provisions of the directive.
- New Approach Directives usually grant the presumption of conformity to a product complying with a harmonised European standard in respect of the essential requirements that are actually covered by that standard.

1.2 The content of the existing harmonised European standards

In order for harmonised European standards to constitute a reliable technical reference for all stakeholders and to support legislation consistently and free of contradictions, they should cover all the essential requirements that are applicable to the products concerned or, where relevant, refer to other existing harmonised standards each covering a part of the essential requirements.

Unfortunately, this aim has not yet been reached by all harmonised standards. In many areas, existing standards fail by a wide margin to cover all the applicable essential requirements. In some cases, the requirements in question are not merely administrative but, in fact, essential requirements relating to the safety and health of operators.

Documents developed by notified bodies in support of the EC type-examination process and regularly updated within the framework of the quality assurance systems highlight such deficiencies in standards without ambiguity.

To compensate for the lack of certain specifications or measurement methods in standards, the experts in notified bodies who carry out examinations must on occasion supplement their technical reference document with data taken from other existing national or international standards and from the recommendations of the European Coordination of Notified Bodies, or introduce “expert statements” based upon their own laboratory and field experience.

For example, the analysis of a support document for the examination of dimension saws (one of the most widely used woodworking machines sold on the market), carried out by INRS, showed that out of a total of 353 technical items to be checked on these machines, only 66% could be checked on the basis of EN or EN/ISO standards, 32% on the basis of direct expert statement and 2% on the basis of national or ISO standards.

A major risk exists that owing to inadequate knowledge, some manufacturers and indeed some notified bodies will simply apply the incomplete content of harmonised standards rather than referring to additional data where needed. If all notified bodies were to apply a rigorous approach, greater confidence in product safety would be generated, at least for products subject to EC type examination.

Many products however are subject to a simple EC declaration of conformity by the manufacturer, without an independent notified body being involved. Were these products to be designed and manufactured solely according to the content of harmonised standards which have not been prepared carefully and which fail to cover all relevant essential health and safety requirements, a major risk to safety and health would exist. It is not universally understood that by reference to harmonised European Standards, a CE certified product benefits from the presumption of conformity only for the EHSRs that are actually covered by the standards concerned.

Standards developers should therefore bear in mind that if harmonised European Standards are to constitute a reliable technical reference for all stakeholders and are to support legislation consistently and free of contradictions, they must cover all essential requirements applicable to the product concerned, where relevant by reference to other existing harmonised standards. The mere comment that certain EHSRs are not covered in a standard is disappointing for the user of the standard and may lead to unsafe products, cause market distortions and be the source of new barriers to trade.

1.3 Benefits of legally more robust standards

All stakeholders should be aware that identification of the EHSRs that are applicable to a product and that are covered or not covered by a standard is **a major factor for clarification and transparency**. Only in this way can the exact scope of the presumption of conformity associated with a harmonised standard be defined. Transparency is in the interest of all the parties involved, but is especially advantageous and important for manufacturers and notified bodies. For their own legal security, manufacturers and notified bodies should in any case distinguish between the essential requirements covered by the standard and those that are not. Where existing harmonised European standards fail to cover all applicable EHSRs, in fact, manufacturers and notified bodies must not only apply these standards but must also use other relevant technical specifications and test methods in order to assess the conformity to the EHSRs not covered in the standard. Transparency is also of specific interest for public authorities, due to the upstream and downstream roles they play when checking that standards and products comply with the Community legislation and in particular with the applicable EHSRs.

Should a standard fail to state clearly the requirements which it covers and those which it does not, a lack of transparency is created which may result in different interpretations and ultimately disputes concerning the conformity of products with the requirements of the directive. Transparency is one means of preventing certain manufacturers and notified bodies from merely applying the standard without considering whether it does in fact take account of all essential requirements applicable to the product concerned.

The lack of reference data in standards (objective assessment methods of the actual risks and corresponding specifications) covering all essential requirements that are applicable to a given product leads to differences between the methods used to assess the safety and conformity of products that are candidates for CE marking. This sometimes also leads to non-assessment of essential health and safety requirements which are not addressed in the harmonised standards. These discrepancies and breaches are likely to be detrimental to the safety of users. Transparency in harmonised European standards is an important means of contribution to a high level of safety called for by the EU Treaty and of contribution to fairness of competition.

The standards developers and certifiers are doing their utmost on the technical level to meet the needs of the market players. What is still lacking, however, are guidelines and close monitoring by the European Commission and CEN/CMC on strategies regarding compliance with the essential health and safety requirements of the directives and the quality of the content of the European standards.

2 Towards technically more robust harmonised European standards

In order to be considered legally robust standards, test methods and specifications should be immune to challenges by technical experts such as OSH experts, consumers associations, or testing laboratories. This means that where test methods and technical specifications are laid down in harmonised European Standards, the standards should in particular:

- reflect the current state of the art, in other words correspond to the highest level of safety and ergonomics that can reasonably be expected from a product;
- be regularly updated to take into account the continual evolution of the state of the art;
- contain test methods and specifications allowing manufacturers and testing laboratories to assess the actual performance of products objectively with respect to ergonomics and safety and to give reproducible, repeatable results.

To meet these fundamental objectives, all stakeholders have made efforts to improve the completeness and consistency of the existing standards. The quality of machinery and PPE placed on the EU market for example is now generally acceptable. Nevertheless, the legal robustness of the standards is not yet so completely assured that product and standard liability litigation can be ruled out entirely.

Ample scope still exists for the elimination of gaps and deficiencies in certain existing standards and for improvements to the existing situation for the benefit of manufacturers and consumers. Many deficiencies and imperfections identified by the users of standards must be considered if the existing standards are to be improved. To quote for example: *the absence of objective test methods to assess all applicable health and safety requirements, the lack of validation of the reproducibility and repeatability of some test methods, the lack of consideration for ergonomic aspects, the poor quality of the instructions for use supplied by manufacturers ...*

3 Towards European and international standards preserving a high level of safety

The founding of the World Trade Organisation (WTO) and the subsequent adoption of the WTO Technical Barriers to Trade Agreement (WTO/TBT) have placed obligations on organisations to ensure that the international standards that they develop, adopt and publish in support of global trade are globally relevant.

Global Relevance is the characteristic of an ISO standard through which "it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world". Ideally, an ISO standard should represent a single international solution that applies to all countries and can be applied by all countries.

The main criteria for globally relevant standards are that they must:

- effectively respond to regulatory and market needs (in the global marketplace);
- respond to scientific and technical developments in various countries;
- not distort the market;
- have no adverse effects on fair competition;
- not stifle innovation and technological development;
- not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions;

- be performance-based as opposed to design-prescriptive.

The development and adoption of an international standard that fails to meet these requirements is therefore open to the charge of creating a barrier to free trade.

The WTO/TBT agreement recognises that no country should be prevented from taking measures that are necessary for the protection of safety and health, at the levels it considers appropriate. Such measures shall not however be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction upon international trade. Nevertheless, the agreement does not define any legal framework setting out the safety objectives to be met.

The agreement encourages countries to apply international standards where appropriate, whilst recognising their right to determine the level of protection they deem suitable to allow them to comply with legitimate objectives, provided that such measures are not implemented in an arbitrary or discriminatory manner. At European level, the adoption of common EN ISO standards whenever possible is actively encouraged by CEN.

Within this context, one of our main challenges is to preserve the specific characteristics of European standards, namely their compatibility with the requirements of the European Directives and a high level of safety, emanating from Article 95 of the Treaty instituting the European Community.

B. TESTING AND CERTIFICATION

Maintaining and strengthening the credibility of the legislative framework established at Community level will be of vital importance in the coming years. This means ensuring that the enforcement of the New Approach directives is both effective and equivalent: in other words, that the same rules apply to all and that fair competition can develop within a transparent system.

This ideal objective is still far from being reached, despite the considerable effort put into eliminating the ambiguities contained in the legislative texts and harmonised standards, resolving differences in interpretation, and even coordinating the practices of the notified bodies.

Today, it is necessary to put more effort into preventing the insidious development of regional initiatives, national peculiarities from forming new protectionist barriers on the one side, and the market from becoming too open to the influx of non-conforming and safety-deficient products on the other. Verification by Member States of the products placed on the European market is probably the most effective way of maintaining and improving confidence in the system in general and in CE marking in particular. This is in the interest not only of consumers, public authorities, manufacturers, importers and distributors, but also of notified bodies. In this respect the new “Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products” (Regulation (EC) No 765/2008) is highly appreciated.

Within the context of the EC type examination, notified bodies must assess the conformity of the products submitted to them for examination with respect to the essential requirements applicable to the product. Since they are responsible for their decisions when carrying out this assessment, they are empowered to use any appropriate technical references. The notified bodies' fees, in turn, are determined by the effort invested in testing and certifying a product.

Indeed, under the current very competitive circumstances, the least conscientious manufacturers might be inclined to have their products tested and certified by the least stringent and thus least expensive notified body. In order to avoid losing too many customers and becoming victims of their probity, the most conscientious organisations and manufacturers might in turn adapt their practices to the level of their least demanding competitors, and thus contribute to a downward spiral in quality and safety.

The divergence currently observed both by manufacturers and by Member States between notified bodies in their practices and fees (which may reach a ratio of 10 to 1) highlights the fact that, to a certain degree, this risk has become a reality. The development of such disparities could detract from the quality of the certification system in Europe and, in time, possibly jeopardise the single market itself.

1 How could the risks of discrepancies in the certification decisions be minimised?

1.1 Participation in the European Coordination of Notified Bodies

Besides appealing to their sense of responsibility, coordinating and encouraging the exchange of experience between notified bodies could also be a solution. The European Coordination of Notified Bodies has invested considerable effort in this respect. Since the Coordination does not have any legal powers, however, its effectiveness remains limited. In addition, notified bodies are obliged neither to participate in the structure (except where the national notifying authorities have established specific requirements for this purpose), nor to apply the recommendations developed by the European Coordination of Notified Bodies.

The difficulty in obtaining clear statements at short notice from the Standing Committees in response to regulatory questions raised by the Coordination of Notified Bodies is clearly not a motivating factor for the active participation by notified bodies in the latter's structure. Enhancing the status of this coordination and making the active participation of notified bodies mandatory offers a promising solution to the problem. In its revision of the New Approach, the Commission has developed legislation to improve the situation. A major step forward can be expected from the new "Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (Regulation (EC) No 765/2008).

Nevertheless, additional efforts are needed to make the European Coordination of Notified Bodies more attractive and dynamic and to encourage a greater number of notified bodies to participate in it and to take its decisions on board. The European Coordination should not only deal with specific technical matters, but also develop a global process for progress in order to enhance the credibility of the European certification structure.

1.2 Development of an effective and consistent market surveillance policy

Surveillance of the European market is a major regulatory factor, one which did not fall within the responsibility of the Commission, having remained until now with the Member States. The general rules on market surveillance will benefit from being harmonised and made transparent without necessarily being uniform. This is in the interest not only of consumers, public authorities, manufacturers, importers and distributors, but also of notified bodies. Here too, major improvements can be expected from the new "Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (Regulation (EC) No 765/2008). Market surveillance actions accompanied by appropriate media coverage ought to encourage notified bodies to provide a service of irreproachable quality and to participate actively both in inter-laboratory tests and in the work of the European Coordination. This would lend them greater credibility and spare them seeing their measurement results and decisions challenged by others, made public and even brought before the courts on occasions. National authorities do not always possess the necessary technical competence to carry out inspections internally. As a result, they must call upon experts, competent external laboratories, and, more particularly, notified bodies. The involvement of notified bodies in inspections would be very positive. In the wake of the exceptional peak of activity which accompanied the enactment of the directives, the overall workload of the notified bodies is now in sharp decline. The additional activity generated by market surveillance would provide these bodies with a workload allowing them to maintain and consolidate their level of competence. Maintaining this level is also vital for the Member States themselves within the context of market surveillance; indeed, they need credible and reliable laboratories to carry out technical surveys with indisputable conclusions.

C. RESEARCH AND STUDIES IN SUPPORT OF STANDARDISATION

1 The importance of research and studies for the generation of sound knowledge

The existing set of European standards was produced within a short timeframe in the nineteen-nineties, and has been improved progressively in step with evolution of the state of the art and by elimination of flaws and deficiencies identified by the users of the standards (manufacturers, market surveillance authorities, notified bodies). Certain complex problems still await resolution. These concern not only new products involving high technology, but also more "conventional" aspects such as the evaluation of ergonomic issues or the operational safety of electronic safety devices.

Research and standardisation are inter-dependent for at least two main reasons:

- The development of high-quality standards requires scientific information which provides an objective basis for negotiations between interested parties;
- Standardisation can be a highly effective route for the exploitation of research results. It is a particularly effective way of promoting and optimising work results at international level.

This route is frequently neglected by researchers, who are often only vaguely familiar with the standardisation process and its importance, particularly for the prevention of occupational accidents and diseases. They often consider "standardisation" to be less demanding than "science", and have difficulties negotiating technical compromises on the basis of their own scientifically validated results.

The word "standardisation" may also inspire fear. For some, it may evoke the authoritarian application of coercive measures and even restrictions upon creative freedom of expression.

It is indeed very difficult to quantify the social and economic impacts of standards with regard to the involvement of OSH experts and researchers in the standardisation process. Nevertheless, the significance of standards for OSH is without question in consideration of the diversity of the political, technical and personal benefits. These include:

- Standardisation serves as a bridge between the scientific domain and the regulatory and economic framework.
- Standards provide a direct contribution to safer and healthier products and workplaces by integrating the consideration of health and safety requirements at the design stage.
- Standards contribute to the best possible balance between health and safety requirements, technical possibilities, and economic demands.
- Standards offer the possibility to establish universally recognised specifications for design, performance and related information on conditions of use, maintenance, etc.
- Experts derive inestimable benefit from the pooling of knowledge, different cultural approaches, and the intense exchange of ideas that takes place in standardisation groups.
- Standardisation offers experts an unparalleled opportunity to update their knowledge on an ongoing basis, which helps them to shake off prejudices that are harmful to efficiency and provides them with an efficient means of monitoring the latest technological developments.
- Participation in standardisation provides researchers with technical and scientific recognition at European and international level and increases the reputation of the institutions involved.
- Involvement in the standardisation process facilitates networking with other members of a standards committee and stimulates trans-national collaborative research, which is often a pre-requisite of European Commission funding.

In its Communication to the Council, the European Parliament and the European economic and social committee "towards an increased contribution from standardisation to innovation in Europe"

(COM/2008/0133 final), the Commission underlined the importance of standardisation for innovation in Europe.

2 Normative research and studies

Research and studies that can be used to develop a new standard or improve existing standards are termed “normative research”. Aiming at the resolution of technical and scientific problems, they can assist in the creation of a robust and valid standard. Two types of normative research and studies have been considered at EU level up to now:

- **Pre-normative research and studies (PNRS)** likely to support future trends in standardisation (i.e. work anticipating future standards).
- **Co-normative research and studies (CNRS)** interacting with ongoing and/or planned standardisation activities, usually proposed by technical committees to further the progress of items in their agreed work programme (such as the development of new or improved test methods, or inter-laboratory tests to improve their reproducibility).

Ten research projects of a pre and co-normative nature have been carried out during the past 20 years with the political support of CEN/STAR (Standardisation and Research) and the financial support of the European Commission within the R&D framework programmes.

In practice, a third major type of normative research and study exists. This type is termed “post-normative research and studies”; such studies are not funded by the Commission, but for the most part carried out by OSH institutes at their own expense.

- **Post-normative research** is carried out when the standards are already in application. The aim is to evaluate and check their relevance in consideration of the products' actual conditions of use. In these projects, the situations found at workplaces are evaluated, in order for the actual acceptability level and efficiency to be established of, for example, the PPE used or the safety devices fitted to machines. Post-normative research assists in improvement of the quality of the existing technical specifications and test methods included in the standards, some of which are somewhat empirical in character and have not always been sufficiently validated. Efficiency and comfort characteristics that have been established in the laboratory often remain quite theoretical. Therefore, products may nevertheless prove to be unsatisfactory when used at the workplace even though they attained positive results in the tests for which provision is made by the standards.

People involved in standardisation and certification activities are untiring in their efforts and do their utmost to improve the quality of European standards. Thanks to their watchfulness, flaws and deficiencies in the content of standards have been identified and progressively resolved. Encouraging though this situation is, safety and health problems still await resolution with the support of researchers. In fact, this is a lengthy process involving cross-cooperation and the mobilisation of all experts concerned over a period of years. We should also work towards progress at European level, in particular to decrease the fragmentation of normative research activities and to improve awareness and integration between the research and standardisation communities.