KAN Kommission Arbeitsschutz und Normung

CIOP PIB

DGUV Deutsche Gesetzliche Unfallversicherung Spitzenverband

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# Technical regulations, standards and conformity assessment methods within the TTIP:

## The issue of mutual recognition

### A. Standards

Product standards must continue to constitute a reliable technical point of reference for all stakeholders. They will otherwise fail to support the legislation consistently and without contradictions in its function of preventing distortions in competition and contributing to the high level of safety called for in the Treaty on the Functioning of the European Union (TFEU).

The German Social Accident Insurance (DGUV), the Central Institute for Labour Protection – National Research Institute (CIOP-PIB) in Poland and the Commission for Occupational Health and Safety and Standardization (KAN) in Germany are closely and actively involved in the development of European and international standards, since they constitute the basis for safe and healthy work equipment and personal protective equipment. Standards are an important prevention instrument with a major role in preventing occupational accidents and diseases. With the experience they have gained in companies and their work in standardization in the interests of safe and healthy products, these institutions are mindful of the challenge of creating global standards for products and thereby of fostering international trade whilst at the same time assuring a high level of worker safety.

In the view of the DGUV, CIOP-PIB and KAN, the existing high level of protection for work equipment (such as machinery) and protective equipment in Europe could be at risk should the TTIP result in the EU and the USA mutually recognizing each other's product requirements. The reason for this is not for example that the USA has lower standards for safety and health; rather, it is a result of differences in the legal, safety and standardization philosophies, and the different functions of product standards within these philosophies. The approaches differ fundamentally in a number of ways. For example:

**a) Hierarchy of protective measures**

A clear hierarchy of protective measures applies in the EU. A technical solution to a safety problem that can be achieved according to the state of the art always takes precedence over organizational solutions such as training or information measures. It follows that in the EU, inherently safe products are of exceptionally high importance for the safeguarding of safety and health at work.

Employers in the USA have greater freedom to use obsolete and possibly even unsafe working equipment and instead to counter the risk by means of training or other organizational measures. This lowers the pressure on the US to formulate solutions presented in principle by the state of the art in standards that are of decisive importance for product manufacturers.

Specific examples include large construction and agricultural machines such as excavators and combine harvesters. In Europe, the 2006/42/EC directive requires the use of technical protective measures, such as a greater field of vision or more effective shrouding of dangerous parts of the powertrain. Incorporating these necessary technical protective measures into ISO standards is however extremely difficult, not least owing to the strength of the US manufacturers' lobby.

**b) No contradictions in the body of standards**

Under the rules governing European standardization, no more than one standard may exist for a given subject of standardization. In addition, all European standards must be adopted unchanged in the body of standards of the EU Member States, and conflicting national standards must be withdrawn. The resulting freedom from contradictions of the European body of standards thus underpins the free movement of goods within Europe.

Conversely, the system in the USA is characterized by considerable diversity. The number of recognized standards institutes runs into the hundreds. For the same subject, for example for a machine, these institutes may produce standards containing alternative or even contradictory provisions. Whereas in Europe, the principle applies of "one subject of standardization – one standard", standards in the USA are also in competition with each other. Product manufacturers and product users, such as employers, must (or may, depending on the point of view) ultimately arrive at a combination of a certain product safety level and organizational requirements at the workplace which is suitable for their own specific situations. The greater freedom for manufacturers is thus accompanied by a higher selection effort (higher transaction costs) for users, particularly SMEs.

By contrast, work equipment and other products may be placed on the market in the EU only if they comply with the state of the art, which in turn is generally reflected in the European standards. Users then need only concern themselves with the residual risk.

**c) Demonstrating the equivalence of levels of protection as a criterion for mutual recognition**

Demonstrating the equivalence of levels of protection that are based upon different approaches may prove extremely difficult. Even on the assumption that two systems that are different but both highly developed should yield approximately the same level of protection, mutual recognition of standards can by no means necessarily be extrapolated. This can be demonstrated with reference to the following examples:

- **Firefighters' clothing**
  Individual members of fire crews in the USA are often assigned permanently to a particular vehicle and therefore to a particular task such as fire control or rescue. Accordingly, the NFPA standard makes provision for seven different types of firefighters' clothing, each for a specific emergency duty.

In Europe, members of fire crews are to be available for universal duty if at all possible. For this reason, only two different forms of protective clothing are generally used, which provide protection during all standard duties. For a given specific hazard, the highly specialized protective clothing provided for by the NFPA standard may well be subject to stricter requirements than those set out in the CEN standards. The latter however offer a high overall level of protection against all hazards typically encountered during emergency duties. Since the various forms of protection may impact negatively upon each other in some cases, a good compromise between them is sought in the firefighters' interests. From a European perspective, this affords the firefighters better protection, since the various emergency duties often overlap, and the special, duty-specific clothing used in the US may well provide better protection for one hazard, but poorer protection for another.

Consequently, whereas firefighters' clothing to NFPA standards is generally unsuitable from a European perspective, US fire services would also consider the protective clothing to CEN standards unsuitable, since it fails to satisfy the strict US requirements, which are geared to specific situations.

The NFPA standards, which are those most frequently applied in the USA, are therefore incompatible with the firefighters' clothing system described in the CEN standards, owing to differences in the way that fire service duties are organized. If both requirements had to be accepted mutually, the form of protective clothing that is less suitable in the respective case could enter use on both sides of the Atlantic.

**Safety marking**

For liability reasons, every possible situation must always be indicated in the USA as it is manifested in a particular case. Since a duty to provide instruction does not exist in the USA, signs must often serve as a substitute. The result is a plethora of different signs geared to the applicable situations. Mandatory and prohibitory signs are often combined within a single sign.

By contrast, the view of the EU is that a more general sign enhances recognizability and therefore also safety. The principle of separation of mandatory and prohibitory signs is strictly followed. Mandatory signs are marked blue, prohibitory signs red. In the European view, this also enables mandatory and prohibitory signs to be recognized as such even unconsciously. This further avoids a bewildering and inconsistent plethora of signs.

For valid reasons, different philosophies for safety markings have therefore been adopted on each side of the Atlantic. The respective philosophy must however be applied consistently. Mutual recognition of safety signs from the opposing system is not possible, since the signs pursue different objectives in each case.

**Personal protective equipment for protection against fault arcs**

Electricians are exposed to a hazard of fault arcs which may occur for example when live circuits are broken (as is the case when live fuse links are inserted or

removed). Under such conditions, extreme heat is generated within fractions of a second which may have a devastating impact upon the employee.

Facility must exist for clothing for protection against the effects of fault arcs to be tested and evaluated reliably and reproducibly. For historical reasons, two different approaches have emerged in Europe and North America. Broadly speaking, the method set out in European standards makes provision for two protection classes, each of which presents a defined minimum standard of protection. The method used in the US leads to a very broad and more finely subdivided spectrum of characteristic values in accordance with which a 50% probability exists that second-degree burns will not occur (severe pain but with complete recovery, possibly with scarring).

These test results must enable users to select suitable protective clothing for the specific application. The test method and selection procedure must therefore not be independent of each other, but mutually compatible. Besides the complex test methods, correspondingly different (and complex) selection procedures have been developed for the protective clothing.

Leaving aside the issue of compatibility with the European statutory framework, mutual recognition of the product standards would lead to users on both sides of the Atlantic having to get to grips with selection procedures for which virtually no expertise exists.

### B. Conformity Assessment

From an occupational safety and health perspective, external conformity assessment bodies must be involved during the products' development and where appropriate also during their manufacture when products associated with high risk are placed on the market. The importance of this involvement of independent test and certification bodies is shown by experience in the field: a substantial proportion of the tested products fail to satisfy the essential health and safety requirements of the European legislation when first tested. Conformity assessment performed by independent conformity assessment bodies assists in identifying non-compliant products and preventing them from being placed on the market. This strengthens fair competition, increases purchasers' confidence in the products, and eases the burden upon market surveillance authorities.

Conformity assessment procedures are based in particular upon provisions governing products and test methods formulated in standards. Technical harmonization thus represents an important step, not least for alignment of conformity assessment arrangements. Without technical harmonization, conformity assessment procedures lead to different results. This impairs functioning of the market, or leads to higher costs of information and selection for users.

⇢ **Example: respiratory masks**

In the EU, respiratory masks serving as life-saving personal protective equipment must be tested by a notified body before being placed on the market. This includes testing of the mask's leaktightness. Users rely upon these third-party tests having been passed.

In the USA, such third-party testing is not mandatory; instead, companies are obliged by OSH regulations to check the leaktightness of respiratory masks each time before use.

Safe use of the masks can be assured by either approach. However, if masks from the USA were to be placed on the market in the EU without the performance of third-party testing and users were to have no way of knowing that third-party testing of the leaktightness had not been performed, the consequences could be fatal.

For alignment in the area of conformity assessment, common principles must also be found for the work of the conformity assessment bodies (including provisions governing the bodies; conformity assessment procedures; joint application and further development of test methods and methods for the interpretation of product requirements; coordination and pooling of experience). The existing international standards of the ISO/IEC 17000 series are not of themselves sufficient to cover the regulatory requirements, and must be supplemented, as provided for in Europe by Decision 768/2008/EC.

Conversely, the mutual recognition of conformity assessment results and of conformity assessment bodies is not expedient.

### C. Principles: Statutory Provisions

Product safety is governed by European statutory provisions. European legislation and standardization are closely linked, since European Single Market directives under Article 114 of the TFEU set out essential safety requirements for consumer products and work equipment only in largely abstract form. In order for these essential safety requirements to be met, use is made of harmonized European standards detailing the product property requirements set out in the legislation. As soon as the title of such a harmonized standard, developed against the state of the art, has been published in the Official Journal of the European Union, users of the standard may claim presumption of conformity, i.e. that products satisfying the standard also satisfy the essential requirements of the Single Market directives covered by it, thereby reversing the burden of proof. Voluntary application of the standards considerably simplifies satisfaction and testing of products with respect to the essential safety requirements formulated in the Single Market directives. The context explained above illustrates that the **foundations of the New Approach/New Legislative Framework would be at risk if standards and specifications were to be recognized mutually.**

The DGUV, CIOP-PIB and KAN therefore reject mere mutual recognition of European and US statutory provisions, standards/specifications and conformity assessment methods, on the grounds that this would not be expedient. The high level of protection demanded by the EU treaties for the trade in products must not be compromised. At the same time, standards and specifications must continue to support the essential health and safety requirements of the EU Single Market directives under the rules of the New Legislative Framework.

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