European directives, standards and procedures in the international context

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Going international : where do we move from ?

Since first being set up, the TUTB has worked to gain a better grasp of the decision-making mechanisms of both Community institutions and standard-making bodies, in order to increase the trade union influence on both legislation and technical work that affect the health and safety of workers.

As part of that, the TUTB has over the years kept under review two main elements of the European health and safety regulatory context : one is the balance between the essential requirements that products have to meet under the New Approach directives to be regarded as safe, and the voluntary standards that translate them into technical specifications ; the other is the balance between the two distinct legislative frameworks dealing with the working environment and products moving within the internal market.

The TUTB keeps track of both things in terms of the interlock between them : on the one hand, an effective squaring away of standards and legal requirements, and on the other hand, two legal spheres that regulate work equipment that is fully integrated into the workplace. Inevitably, this approach leads the TUTB to look at the balance between market demands and the protection of workers' health and safety.

The New Approach to technical harmonisation

In Europe today, free movement of goods is regulated by a legislative system characterized by a number of distinctive aspects : detailed Essential Health and Safety Requirements (EHSRs) are laid down in directives with obligations placed on manufacturers ; "mandates" are issued by the European Commission, requesting standardization bodies to draw up *harmonised* standards as an aid to interpretation of the legislative provisions ; draft versions of these standards are made available at national level for public comment before approval ; assessments are carried out by "consultants" in charge of checking the compliance of draft standards with the mandates issued by the European Commission ; a facility exists for objecting to draft standards that are thought not to deliver the EHSRs, and a safeguard clause exists to address failings identified at a later stage. The European legislature maintains control of the final outcomes, as the references of these standards must be published in the *Official Journal* for them to have legal effect (presumption of conformity). Finally, a policy for the revision of standards is in place to maintain their quality over time.

In other words, Europe has mechanisms for ensuring the quality of technical work that affects the working environment. Additionally, the legislative context includes Directives that oblige Member States to take measures to enable both sides of industry to have an input – at national level – into the process of preparing and monitoring health and safety standards. Admittedly, participation of societal stakeholders is only specifically mentioned in the Machinery Directive[1]. This provision reflects the fundamental principle that health and safety are central to workers' rights : the TUTB has over the years fought to get this principle written into the European legislative framework and the supporting voluntary standardization programme.

In connection with this, the TUTB handles two different communication flows : information gleaned from our observation of European standardization work on health and safety matters is channelled through to our affiliates in order to identify priorities and develop technical proposals, while information collected on workplaces is filtered and ultimately passed on to EU institutions in order to improve the quality of their health and safety-related activities.

The issue here is that the work equipment market is a global fact : this raises the question of what might happen to the European model, its dynamics and trade union involvement when moving up to the international scale.

Going international : where do we move to ?

The international dimension of standardization is central to the current debate within the trade union movement. As global trade increases, so does the use of international standards to enhance market access and facilitate trade. The fact of the matter is that the world of standardization is a patchwork quilt, a mixed bag of organisations with different structures and vocations and methods of standards development. Much remains to be done to achieve a coherent system.

[1] Article 5(3).

The TUTB is very alert to the growing focus on the WTO Agreement on Technical Barriers to Trade (the TBT Agreement as it is known), and the ways in which Member States and EU institutional actors consider themselves bound to observe the provisions of WTO agreements. A complex set of issues are being raised as to how the policy- and law-making process in the European Union is affected by the EU's membership of the WTO.

One major complication is that the TBT Agreement requires Member States to use *international standards* as a basis for their regulation, but neither defines what standards are nor lays down any concrete obligation as to how standards should be used in technical regulation.

The question arises as what scope this leaves the New Approach for further development. The TUTB – and it is not the only one – believes this bears close scrutiny, and is closely monitoring the ongoing discussions on the role of the New Approach within the enlarged Europe and beyond, as well as the scope for extending the *essential requirements* concept to the global level. The essence of the New Approach - combining the flexibility of a voluntary method of consensus-based agreements with the certainty of legislative control - is not, in principle, up for discussion.

What remains controversial is not only what organisation might assume the task of framing international essential requirements (i.e., identifying common regulatory objectives to align legal requirements in countries with different fundamental cultural and societal concerns), how, and using what instruments ? Questions also arise about how international voluntary standards might recognize and support the essential requirements, and what international forum would monitor the interaction between them.

The chances of getting in the international sphere what has been achieved in Europe by trade unions' continuous struggle for an "ideal" standardization model which supports work equipment regulation (cooperation between industry, workers, consumers and authorities with a delicate balance of interests between all the actors involved, producing a consensus that gives credibility to the results) probably remain slim.

The TUTB has repeatedly voiced concerns about what "consensus" means in the European standardisation model: more specifically, a fundamental issue is whether the "national consensus" brought into the CEN system reflects a "balanced" representation of all interests concerned in the standardisation process. In fact, as each national standardisation organisation can only take a uniform national position in the voting, societal stakeholders strive to exercise their influence through the national standardisation work and as members of the national "mirror committees".

As improving European societal stakeholders' involvement in the standardisation process is arguably a precondition for its "accountability", the TUTB will keep the debate alive on whether the WTO accepted principles supporting international standards (Transparency, Openness, Impartiality and Consensus, Effectiveness and Relevance, Coherence, Development dimension) will ultimately deliver an adequate representation of societal interests. Regrettably, in many countries outside the EU, the formal rights of social groups to participate differ profoundly, while in many others they are non-existent.

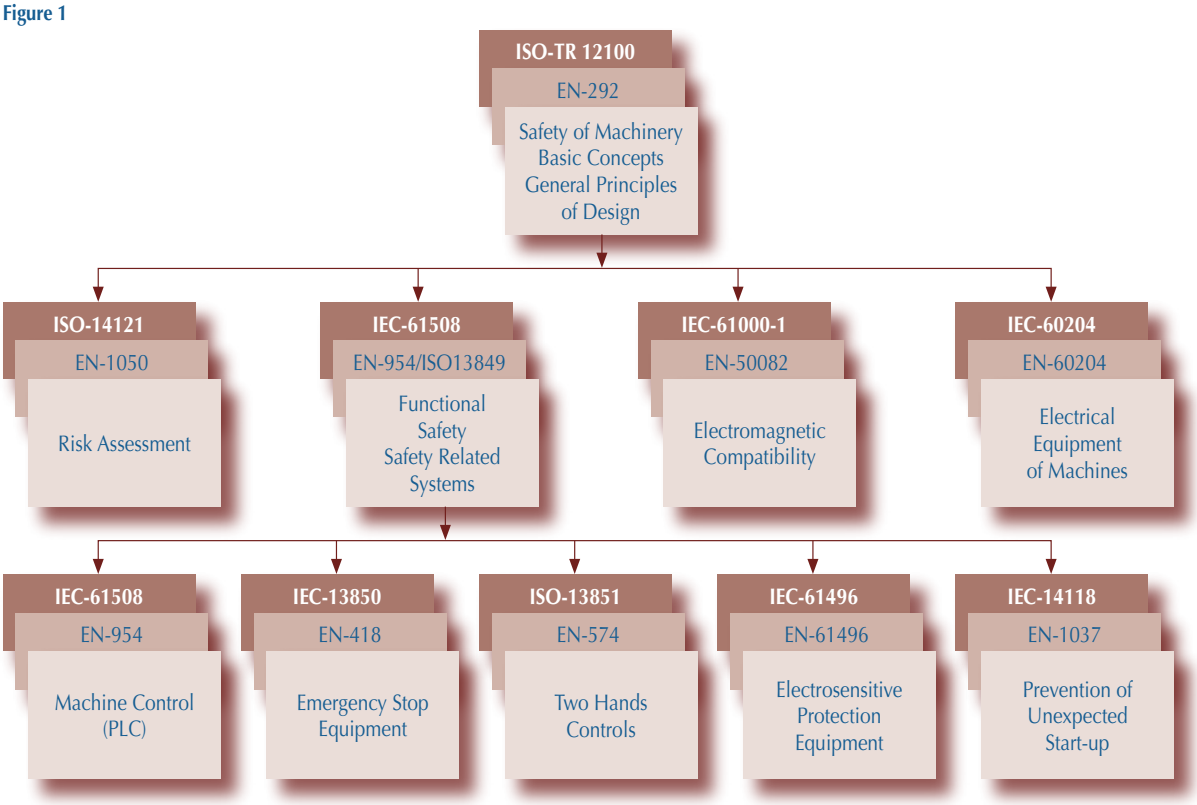
The interplay between CEN and ISO

As global distribution of products becomes the norm, work equipment manufacturers and end-users increasingly look to global machinery safety requirements when designing equipment. Unlike the electrotechnical sector, the interplay between European and international standardisation has been less developed in the mechanical engineering sector.

The Agreement on technical cooperation between ISO and CEN (Vienna Agreement), formally approved in 1991, was one result of the pressures to integrate the Single European Market into the emerging global marketplace. To avoid duplication or divergence of activities, and to promote the use of international results whenever possible, CEN and ISO agreed to work on developing and adopting identical ISO and CEN standards, with the drafting work done once only within one organisation, and a parallel approval procedure for drafts in both organisations. The Agreement recognizes the singular needs of the "mandated" standardisation work supporting European legislation : in particular, for standards mandated under European Directives (under the New Approach), CEN may be assigned "leadership" in drafting them. However, the Vienna Agreement does not rule out giving "leadership" of mandated work to ISO : in this case, as Consultants are still required to assess draft standards, a negative assessment of the ISO work may ultimately lead to a joint decision to withdraw the project from the Vienna Agreement so as to allow ISO and CEN to finalize separate standards (see figure 1, p. 18).

To give an idea of the figures, under the Agreement between ISO and CEN, 2362 ISO standards have been adopted by CEN (at June 2003) of which 910 were developed under ISO's and 222 under CEN's leadership, while 1230 were the product of ex post adoption of existing ISO standards. It is worth mentioning that the ISO standards adopted by CEN are then adopted by all the CEN member countries as their own national standards, with concurrent cancellation of any previously existing national standards that are found to be in conflict.

Figure 1



Source : From *New Global Regulatory Process For Machinery Safety* – Frost Controls Inc.

Interestingly, the CEN Technical Board has recently decided to assign the ISO leadership of all future work on revisions and amendments of ISO/CEN-developed standards : this decision – although consistent with the recognized primacy of international standardisation enshrined in the Vienna Agreement and confirmed by the WTO in the Code of Good Practice – brings new challenges to the complex relation between standards and legislation. And the TUTB's experience in the CEN and ISO arena so far bears out the level of that complexity.

Diverging views on "designing for safety"

Over the past three years, the TUTB has monitored the revision of three fundamental safety standards : EN 292:1991[2] *Safety of machinery – Basic concepts, general principles for design – Part 1: basic terminology, methodology – Part 2 : technical principles and specifications* ; EN 1050:1996 *Safety of machinery – Principles for risk assessment* ; and EN 954:1996 *Safety-related parts of control systems – Part 1: General principles for design*. As these standards lay down basic safety concepts to be used across a wide range of work equipment, their revision has provided the TUTB with valuable insights into the complex process of reaching international consensus on core principles of machinery safety in an increasingly global market.

The CEN and ISO cooperation brings together a large number of technical experts from all over the world to (endeavour to) agree common technical solutions to identified problems. This process reveals widely differing conceptions of work equipment safety, which are the product of diverse historical national approaches to health and safety regulation. Different safety philosophies have therefore emerged over the years, and crucial elements like risk perception, risk–damage causality, state of the art, human-technology interaction among others all remain sticking points where different views confront one another.

The divergences between those who espouse the view that machinery users must be protected against their own mistakes, and those who contend that priority must be given to worker education and training to address contingencies during machinery use, have inevitably shaped the debate around the *reasonably foreseeable misuse* issue.

Admittedly, there is no unanimity in CEN and ISO about how safety standards should deal with foreseeable misuse. If reasonably foreseeable misuse must be taken into account[3], a decision must be taken on whether and to what extent this should be done at the product design stage or whether other protective measures are needed, or whether safety information should suffice. Some experts argue that it would be very difficult to detail reasonably foreseeable misuses and prohibited applications in C-type standards, and

[2] The new standard was adopted at the end of 2003 as EN ISO 12100-1:2003.
[3] As required by EN 292-1:1991, 3.12 (now EN ISO 12100-1:2003).

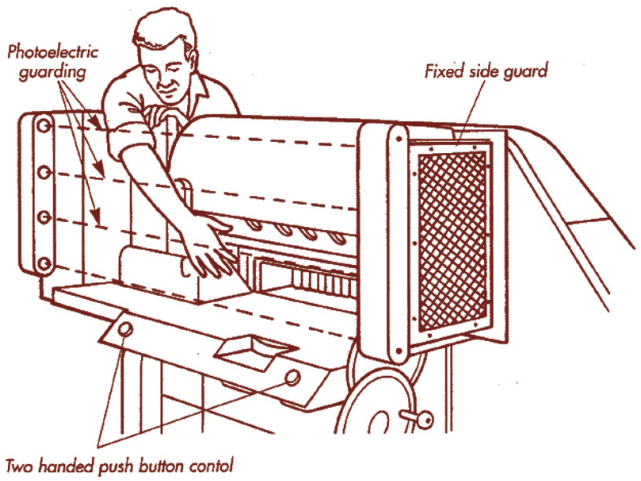
fundamental questions remain about how far the standard should go in illustrating potential risk uses. Others experts contend that manufacturers may fight shy of specifying foreseeable misuses for fear of limiting the use of their equipment.

Machinery misuse may be attributable to designers' failure to anticipate the design's vulnerability to operators knowingly taking a risk-benefit gamble : a case in point is one of the most common operator "errors" - interventions on machines which are running (see figure 2). A range of incidents may occur during machine operation : as manufacturing systems are increasingly under the pressure of productivity, operators may feel impelled to take action themselves in cases of equipment/process malfunction. When facing such dilemmas, operators are aware of the trade-offs between production and repair/maintenance requirements. A barrier – fitted to prevent (part of) the operator's body intruding into a hazard area – may be by-passed to gain in productivity and/or quality, as the operator may prefer to "watch" inside the machine to check the material quality and/or prevent overload and jamming. So, operators may see lessening the consequences of a production stoppage as overriding the risk to their own health. This problem is particularly acute whenever "barriers" protecting operators are included in the final stage of design rather than as the result of an inherently safe design approach, because safety "add-ons" very often hinder performance and functionality.

Machinery misuse may also be due to designers' failure to anticipate that the design may be capable of being used in unintended ways : a case in point is where flawed design of the working area of refuse collection vehicles results in recesses or projections that operators may find usable as foot- or hand-holds, thus assuming hazardous postures that may bring them into contact with compaction mechanisms.

CEN and ISO experts have at times voiced concerns about the difficulty of dealing with foreseeable misuse in C-type standards covering *families* of machines : one such is earth-moving machinery standards that cover equipment with a wide range of functions and characteristics, making it nigh-impossible to illustrate all misuses to be avoided. On the other hand, where the misuse is well-known to the industry, there is general agreement on the need for a redesign. Here, manufacturers' role in standard work is crucial : they have an intimate knowledge of their equipment to feed into standards, but if they are unaware of the real conditions in which machinery operates, incidences of misuse will be beyond their ken and will never appear in safety standards. The recent TUTB Machinery Project has shown that surprisingly many designers are quite out of touch with workplaces, and left to their own devices, may have little idea of the realities of the environment in which their machines are used. By contrast, diligent manufacturers follow-up their

Figure 2



Source : *A Guide to Practical Machine Guarding*, Queensland Government, Australia

equipment through direct contact with customers, or sales and after-sales service networks.

In conclusion, it is clear that not all irrational uses should be taken into account when framing standards, but a decision is still needed on how much foresight is required of the manufacturer and where the limits of legitimate users' expectations lie. And that involves a difficult compromise between hazard avoidance, technical possibilities and economic constraints.

There has been robust debate among CEN and ISO experts around a number of basic machinery design aspects, including the relationship between hazard, hazard situation, hazardous event and injury or damage to health, safety functions, fail-safe condition, risk assessment and reduction, and inherent design measures. Discussions on the meaning of the so-called "3-step method" by which designers will make the best possible use of, successively, *inherent design* measures, then *safeguarding* measures, and finally *information for use* (see figure 3), have been complemented by different views expressed on what *inherent design measures* mean when applied to control systems. In this connection also, the concept of *machine* has been revisited, in particular as regards the traditional schematic demarcation between the *control system* and the *operative part*.

Indeed, the relationship between the operator, the equipment with which he works and the physical environment in which this "man-machine system" operates has dramatically evolved in the last two decades. Not only the operator-machine interface, but also the allocation of function is increasingly changing: as automation processes proceed more smoothly, manning levels can be reduced, sometimes drastically, and therefore costs can be contained and productivity increased.

However, automation brings a number of problems with it that are perceived in different ways by designers around the world. Among them, *task allocation* :

Figure 3 : Protective measures taken by the designer

Step 1 : Inherent design measures

Step 2 : Safeguarding and complementary protective measures

Step 3 : Information for use
- at the machine
  - *warning signs, signals*
  - *warning devices*
- in the instruction book

Source : EN 292:1991 Safety of machinery – Basic concepts, general principles for design – Part 1: basic terminology methodology – Part 2 : technical principles and specifications

the human operator is often required to monitor the performance of largely automated systems, initiate and coordinate key stages of system operation and respond to any malfunctions that cannot be handled automatically. This may result in problems when things go wrong and the operator has to intervene : by moving the operator from active control to passive monitoring he will invariably start to run behind the process. And if, for whatever reason, human intervention is required, the speed and quality of that intervention will almost certainly be poor.

These comments on automation cannot be dissociated from reflections about the increasing use of programmable electronic (PE) technology to improve safety and increase productivity. Although PE provides many benefits, accident data show that it adds a level of complexity that, if not properly taken on board, may jeopardize workers' safety. Experts agree that it is no longer conceivable to design work equipment without asking the following question : what will happen if safety control systems and components fail ? This question is crucial when integrating PE technology in work equipment, as it shows unique failure modes that are different from mechanical systems or hard-wired electronic systems traditionally used in machinery design. On computer-controlled machines, visible and identifiable malfunctions in traditional electromechanical components are now being replaced by a new category of "intangible" faults in electronic modules and systems resulting from software errors, bus connection failure, sensing device malfunctions. Here, CEN and ISO machinery experts take different approaches to integrating microprocessors, embedded controllers, programmable logic controllers (PLCs), and associated software in machinery. In particular, differences of opinion remain on how to validate the designer choices : validation involves defining a list of faults which will be "injected" directly into the equipment to be tested, or used as a basis for failure mode and effect analysis (FMEA). Such a list represents a benchmark to help designers in the choice of technical solutions "resistant" to those faults. Now, a list of faults is straightforward for simple components like transistors, but not for complex components like microprocessors made up of millions of "gates" : all failure modes may simply not be known. The conclusion is straightforward : where the hardwired technology is replaced by another more complex, less mature and entrenched technology, the question arises whether the same level of safety will be achieved or not.

These reflections on the complexities of dealing with the safety of work equipment surround the TUTB's conviction that more opportunities must be explored for collaborative work between engineers, employers, workers, manufacturers, researchers and governments who can contribute to better health and safety through consideration of design issues. In particular, designers typically enjoy few opportunities to experience operations at first hand, and only a minority of operators spend the time in a design office that can help them understand how a design embodies a designer's intentions. Participatory design seems to us a valuable example of cooperative work.

Participatory design : the way ahead ?

Against this complex background stands the TUTB's commitment to exploring new pathways to deliver the aim of putting workers' knowledge to best use in improving the working environment. In particular, what information can be extracted from the working environment to help improve the design of work equipment ? A second related question is the use of this information to improve harmonised standards : the TUTB is thinking around developing a *tool* that incorporates end-user data and makes it readily understandable by standard makers, public bodies, and all interested stakeholders.

The TUTB-SALTSA Conference has shown that participatory design – supported by appropriate research efforts – could be a methodological delivery system for this data and to formally organize the tool, which could in turn be part of the knowledge base that guides standard revision work, market surveillance initiatives, and Community initiatives to strengthen the legislative framework.

Participatory design is an innovative field and a method for involving workers in analysing and redesigning their own job. Participation is thought to legitimize the ideas and experiences that workers have accumulated in doing their jobs, which they can draw on to suggest their own solutions to work-related safety problems.

What participatory design sets out to do is to provide a context in which design experts can gain the practical understanding they need for successful design : end-users possess this knowledge but lack the insights designers and manufacturers have into new technical possibilities : bringing designers and end-users together is the first step towards that goal. By involving end-users in developing and implementing technology at the workplace, a more intensive and creative use of their knowledge and experience can ultimately make the difference between a safety and health proactive, rather than entirely market driven, design.

A participatory approach to re-design can take many forms, there is no single model. Participatory design may be structured around a team or task-force, mostly consisting of worker and management representatives provided with ergonomic inputs and training.

As participatory design supports an integrated interplay between technological, organisational

and worker-related factors in the design process, it can be a promising means of easing the tensions between the two dominating policy objectives : regulating free movement of equipment and the working environment. The dual dimension of essential requirements laid down by Community legislation and national occupational safety and health requirements in fact form the specific backcloth to the CEN and ISO's initiatives on work equipment health and safety matters. The TUTB argues that these two regulatory elements can be reconciled by identifying and implementing mechanisms to feed back information on the use of work equipment to design and manufacturers : it remains to be seen which procedure in the CEN & ISO system would better promote participatory design experiences, with the aim of integrating *safety* and *design* into a coherent *safe design* culture. ■

International standards and occupational safety

New links between regulatory requirements and voluntary standards

In the past 20 years, two major developments in the area of harmonization of technical regulations and facilitation of trade have introduced new links between regulations and voluntary standards : the Agreement on Technical Barriers to Trade, now signed by some 147 countries in the context of the World Trade Organization, and, in Europe, the New Approach to harmonization of technical regulations. Both have given a new impetus to international standardization, particularly in the area of safety standards. The "Vienna Agreement" between ISO and CEN, in force for some twelve years now, has enabled a good synergy between the regional and international levels, and helped ensure that the construction of the EU internal market does not result in the building of a so-called "Fortress Europe".

Indeed, technical obstacles to trade often relate to diverging regulatory requirements. The level of safety that consumers and workers are entitled to expect must not be lowered in order to overcome these obstacles. Standardizers must ensure that this does not happen when regulators refer to their standards so as to facilitate international trade. They have therefore paid growing attention to associating all stakeholders with their work, operating transparent consensus-building procedures and designing both product and generic standards and guides to incorporate safety requirements.

The longstanding involvement of ISO in safety at work and ergonomics

ISO has a long record of involvement in ergonomics and safety of industrial machinery and protective equipment : ISO/TC 159 *Ergonomics* has published some 50 International Standards, from basic methodology for designing safe machines through carrying out risk assessment, to standards dealing with particular aspects of machine safety. Recent developments of particular interest have been the revision of ISO 6385 *Ergonomics in the design of work systems*, the extension of ISO 10075 to all aspects of ergonomic principles related to mental workload, and new standards related to the *human-system interaction in the IT field* interface. ISO/TC 94 *Personal safety – Protective clothing and equipment*, ISO/TC 199 *Safety of machinery*, as well as ISO/TC 23 *Tractors and machinery for agriculture and forestry* and ISO/TC 127 *Earth-moving machinery* are all deeply involved in safety related standards, often collaborating with CEN in the context of the Vienna Agreement.

Taking user experience into account in standards development and implementation

The experience of users is paramount when developing safety standards to ensure the efficient incorporation of safety principles in the design of equipment and the workplace, all the more so as the tendency nowadays is to prefer performance over design standards, if only not to hinder innovation.

This can be done in various ways :

- by ensuring the participation of representatives of workers' organizations as well as of research and technical institutes involved in safety at work, at least in the activities of the ISO national mirror committees and whenever possible at the international level ;
- by developing general guidelines on the incorporation of safety elements in standards, as illustrated above in relation to the work of ISO/TC 159 ;
- by encouraging the participation of workers' expertise at the conformity assessment level, where the actual implementation and interpretation of standards may be tested, validated and improved.

International standards : reconciling adequate safety and international trade

Owing to their global reach and acceptance, and because they are based on a consensus involving all stakeholders, International Standards are the modern way to address the complexity of today's technologies, as well as to reconcile the quest for adequate safety and the facilitation of international trade. ISO has recently launched a broad consultation through its national members and main international partners to capture expectations in regard to ISO for the coming decade. Involvement of stakeholders is one of the central issues, and participants in this workshop are invited to actively take part in this consultation through their national ISO member. ■

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This paper is based on the presentation given by Alan Bryden, Secretary General of ISO, at the Conference panel discussion.