The Machinery Directive, gains and challenges for the New Approach

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The European Commission set work going to revise the Machinery Directive in 1997. Much to the confusion of the Member State representatives on the Directive Standing Committee, it said it would not be going with the "very liberal" conclusions of the Molitor Group. The Commission's proposal came before the Council in January 2001 and began its passage through parliament[1]. Over 70 amendments were tabled. The Commission presented its amended proposal to Parliament and the Council in February 2003[2].

Is Europe a stalled technocratic system or a living and growing organism, getting a bold and imaginative grip on the many inconsistencies inherent in a complex social process ? Have the barriers to trade really come down ? Or have they just assumed another guise with required product safety standards that are still low and different in each Member State ? Does machinery, for example, move more freely now and is it safer than in the pre-Directive days ? Is there any way of implementing the Directive that goes beyond local interests to find a general consensus on the "right" way to interpret all its "mandatory" rules and the specific "voluntary" technical standards ? Is there agreement on the role of third-party certifiers : should they be given more independence or allowed more freedom of enterprise ? Why are some Member States so lukewarm about effective, consistent transnational market surveillance ? What determines the state of the art : technical development or protectionism towards strategic knowledge ? Do we foster user protection and their involvement in design, or go on making operators' lives less secure and cutting down workers' rights of participation in an unregulated market ?

On 13 and 14 June 2002, the TUTB called a meeting of machinery experts in the International Trade Union House in Brussels to present a research methodology on all these issues and discuss how to put it in place. The project fell into the following stages :

- forming a partnership between the players : European trade unions (the TUTB), government departments (French Ministry of Work, Finnish Ministry of Social Affairs), a public research institute (ISPESL in Italy) and a tripartite body (KAN, Germany);
- setting a common objective, i.e., collecting source data for a descriptive and comparative reality-check through a purpose-developed questionnaire submitted to institutional, social and technical experts in various States;
- open cross-checking with other partners not directly involved in the research on practical issues arising with the application of Directive, with special reference to woodworking machinery;
- producing deliverables in the form of suggestions to the Commission and Member States for setting up a "machinery system" that is more lined up with the Treaty principles.

A first version of the survey report by the TUTB's Stefano Boy, and Sandra Limou of Robert Schuman University in Strasbourg, was handed out to the workshop participants. The discussions launched straight into an assessment of how effective the New Approach Directive/standards system was and how far it was delivering improved, harmonized safety-by-design of machinery. The focus here was on the role of the certification bodies and the practical problems they have with manufacturers. The key importance of worker/union participation and the inseparability of market and social protection rules was stressed during the debates, along with the difficulties facing more effective market surveillance. It concluded with a review of gains and areas of uncertainty in the system in view of the ongoing legislative revision.

The June 2002 workshop was a major milestone in the methodology developed by the TUTB. Cross-checking the survey findings with other actors from different EU Member States bore out and expanded the scope of some of the conclusions. The final report *The Implementation of the Machinery Directive. A delicate balance between market and safety* explaining the approach in its entirety will be published in 2003[3].

Machinery Directive and harmonized standards

Hydraulic car lifts of the type used in garages are one of the few kinds of lifting equipment where work has to be done under the lifted load. The immense risk to the operator is clear to see. The weight of cars is not uniformly distributed : the heaviest part - the engine - is normally at the front. This means that a car lift must be able to withstand the load whichever way the car is driven onto it. This is what harmonized standard EN 1493 thinks - but not the market. Lighter (and cheaper) lifts, certified by notified bodies, are available where the user has to drive the car onto the lift in one specific direction. Loading the other way round - as is almost bound to happen one day - could cause the lift to collapse. In this particular case, the European standard is "sound", but manufacturers are placing machinery on the market that is

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[1] See "Revision of the Machinery Directive", *TUTB Newsletter*, No 17, June 2001, pp. 5-11.
[2] COM (2003) 48 final, of 11 February 2003.
[3] See p. 8.

not up to prescribed safety standards, and third party certifiers are colluding in that.

Sometimes, the harmonized standard itself may be "unsound", so machinery manufactured to it will not satisfy the Directive's essential requirements. EN 692 on mechanical presses - challenged by France in 1997 - and EN 708 on agricultural machinery - on which the United Kingdom invoked the safeguard clause in 1998 - are cases in point.

In yet other cases, there is no standard, so machinery will be designed and placed on the market after going through the regulatory certification procedures, based on the manufacturer's own interpretation of the Directive's essential requirements. This is the general rule, and it is only through market surveillance that machinery not in conformity with Directive 98/37/EC[4] can be identified, modified and if need be, taken off the market.

Machinery on the special Annex IV list (which covers only about 5 to 10 % of all machinery placed on the market), must be certified by a notified body, sometimes after a type-examination.

Cases of non-conformity abound. For example, instruction handbooks are often not in the user's own language (Tuiri Kerttula, Ministry of Social Affairs, Finland), do not set out safe operating requirements and give no warning about residual risks (Uli Bamberg, KAN). But, disappointingly, we are still nowhere near having a common market surveillance strategy at European level.

Standards have to comply with the Directive's essential requirements, but often that is not made clear in the standard itself. As Emilio Borzelli (ISPESL), stressed, standards may go further than the Directive requires, either by adding advanced design details which, contrarily, permit a wide range of technological solutions, or by spelling out appropriate tests. But they can also fall short of the Directive by adding unnecessary restrictions on designers that do not improve safety and overly-vague tests that prevent them being assessed.

The level of standards for woodworking machinery is seen as satisfactory to very satisfactory (Uli Bamberg) especially by comparison with other standards (Emilio Borzelli), although they have their own shortcomings. A flawed standard that can be produced relatively quickly will often be preferred to no standard at all. But this means making provision to revise it if machines are found to be unsafe in use. Unfortunately, (Emilio Borzelli) standards bodies get no feedback from users that can kick-start this process. This issue will be considered elsewhere. The KAN made the useful suggestion that if there are no information channels, then at least testing should be prescribed as part of the design process (Uli Bamberg).

Standards may also clash. EN 708, EN 704 and EN 632 are cases in point. They set different dimensions for similar safety devices, notwithstanding the safeguard clause invoked by the United Kingdom against the first of them (Phil Papard, HSE). But they may also serve no useful purpose at all, adding nothing to the Directive's provisions or being obsolete when published due to long framing processes and technological advances. Finally, standards may be a major but daunting challenge for the safety assessment and harmonization of machinery control software, glossed over in Annex I (Tuiri Kerttula).

Some of the Directive's definitions (interchangeable equipment, safety components) and Annex I provisions may be unclear, incomprehensible as translated, at variance with national traditions, or clearly flawed (Pascal Etienne), like the requirements on emissions (noise, vibrations, pollutants, etc.), or may not match up with the Work Equipment Directive (Phil Papard). So, the Machinery Directive (article 3.4.3, Annex I) only requires that where there is a risk of self- propelled machinery rolling over, it must be fitted with anchorage points allowing it to be equipped with a rollover protective structure (ROPS) instead of requiring it to actually be fitted with ROPS as such or prescribing effective designed-in stability. This makes it the user's responsibility to evaluate the machinery and install safety devices if need be.

But there are also failings if not loopholes in the provisions of the Directive itself, and by the same token in the standards. Pascal Etienne (Ministry for Work) pointed out that this is especially so with ergonomics, which barely rates a mention in Annex I. The essential requirements and standards focus mainly on mechanical and electrical risks, although there is now a smattering of ergonomic design standards (Harald Riekeles, CEN). It is true to say that ergonomic considerations may be disparate and that as a subject area, ergonomics does not always come with an overall approach in terms of concepts and instruments that can be easily used by mechanical or electrical engineering designers with no special ergonomics training. The TUTB's guide (Ringelberg, Koukoulaki, 2002) on risk assessment for musculoskeletal disorders in machinery design could therefore be invaluable in helping lift these limitations so that the ergonomics input stops being thought of as just rounding off sharp edges on machines !

Even so, as Theoni Koukoulaki (TUTB) stressed, more deep-rooted resistance to ergonomics is often to be found stemming from the general lack of acceptance that final users must be part of the equipment design process, feeding in elements which in shop-floor practice have been found to ensure operators' physical and mental well-being.

Standards and legislation therefore stand in a wide variety of relationships to one another.

[4] Codified version of the Machinery Directive.

The contents of the standard will depend equally on the expertise of the standards developers, behind them the interests of each national mirror group, and also the dialogue with the CEN consultants mandated by the Commission to assess its compatibility with the Directive. But the final deliverable also depends on the involvement of each Member State, which checks whether the standard is in line with the Directive (and - it is well-known - with its own national interests). So, each country influences the interpretation of the Directive according to its own openness to trade, commercial interests or policy strategy.

The time taken by DG Enterprise to bring out the very useful guidance/comment documents on the Machinery Directive (1999) and the New Approach (2000) show the complexity of the issues which are holding back the process. No-one, however (T. Kerttula), feels that sound guidance on how to apply the Directive can be more effective than changes to the legislation.

Certification : the weakest link

For some machines - those in the Annex IV list - an expert third party is required to test a specimen and assess its conformity with the Directive (manufacturers rarely use the other two options offered by the Directive). The workshop participants were broadly agreed that the Annex IV list of machinery was inconsistent and flawed, and in need of revising. But there was no consensus (U. Bamberg) about the relevance of the module H procedure - total quality assurance - included in the draft revision of the Directive and stressed by Martin Eifel (DG Enterprise). Dietmar Reinert (BIA) also expressed strong misgivings about the system, querying the expediency of extending third party notification to non-Annex IV machinery.

Certification body assessments are generally acceptable enough, but in some instances examinations have been found to be scaled down or made easier because they are not profitable - the rates applied have to keep the organization competitive (or increase its market share). Another issue is that there is no time limit on the certificates awarded in most countries, so that solutions overtaken by developments may remain valid even when obsolete.

Notified bodies should be testers rather than consultants to clients, which is not always the case in some States. Their role is understandably quite difficult given the limitations of manufacturers, many of whom may not know how to translate the Directive into nuts and bolts (and not just for Annex IV machines) and therefore are after expertise more than certifications.

The Directive does not lay down a single compulsory procedure for approving notified bodies. Limits have been set and guarantees provided in some but not most countries (D. Reinert). Notification is hardly ever revoked, if at all, even in the event of repeated mistakes or evident dormancy - which may show that notification is used only as a benchmark for improved action in other areas.

The lack of consistency in the technical assessments made by these bodies was also mentioned. National coordinations and a European coordination of notified bodies have been set up to narrow the worst gaps, but D. Reinert (BIA) spoke for most workshop attendees in saying that because participation in these was voluntary, involvement remained at a very low level.

Social partner participation : a missing link

Social partner participation in running the system is very patchy, and there is often too little involvement by unions and employers, especially at national level. Manufacturers and employers - often lumped together under the same label - are coping, not always successfully, with changes in their own identity. Manufacturers are increasingly turning into support service suppliers, sub-assembly and quasi-machinery producers, complex system assemblers, or mere users of machinery control software. They are often at the borderline of where the Machinery Directive applies and so lack the minimum protection of a transparent set of rules. Franck Gambelli (ORGALIME) clearly described the hard choice between further undermining regulatory systems in order to "release" resources and developing the ability to plan sufficiently far ahead not to get bogged down in an unregulated, shambolic development.

For the workers, Laurent Vogel (TUTB) stressed the improvements made to work equipment by the New Approach. He emphasized the crossover between the "Product" and "Social Protection" Directives and criticized the failure to set up a systematic feedback of experience such as by requiring manufacturers to collect data on the use of their products.

Some national authorities have set up procedures with the unions to feed back workers' knowledge into machinery design, but such initiatives are still few and far between : the hazard flagging sheets operated by workplace health and safety committees in France; the work analysis methodology developed with woodworking machinery operators in Italy and Sweden; the tripartite body set up to monitor standards (the KAN) in Germany.

Information can also be fed back directly from the workface into European level discussions; the CEN Consultants would like to receive it (Detilloux). The case of truck mixers reported by the TUTB on information received from the Italian construction unions is a positive example which reignited the discussions on the standard before it was adopted by CEN.

Regrettably, trade union involvement in the national mirror groups is still too low and, in most countries, just nominal. Not only does the revision of the Directive not improve this - it makes it worse. L. Vogel pointed out the alarming fact that the Commission's proposal for a revision of Directive 95/16/EC has simply scrapped the recital stressing, albeit in very general terms, the need for employers and employees to have an influence on the standardization process. Also, nothing new has been added to article 5.3 of the Directive, which lays down national and European procedures for the social partners to monitor the standardization process[5].

A mixed pattern of market surveillance

The Machinery Directive has only been on the books for ten-odd years. It is quite a complex system to implement in full. Also, some countries with a well-established tradition of prevention, like Sweden, Denmark and Finland, joined the European Union after the adoption of Directive 89/392/EEC and so had no direct hand in framing it. But they still had to adapt very quickly to the new elements introduced into their systems. In Sweden, for instance, the Labour Inspectorate ran a large-scale campaign in 1996, two years after the Directive entered into force, to check how it was being implemented. Half of the 3,000 machines vetted were found not to be in regulation order (including 175 Annex IV machines), (Lennart Ahnström).

It is only recently that larger numbers of "new" machines have begun appearing in workplaces and accident reports have started coming in. The authorities that carry out preventive inspections and accident investigations have begun identifying various types of CE-marked machine that are dangerous and non-conforming. Official action in the field often leads to action by central government departments in charge of coordinating market surveillance (a term which does not feature in the present Directive, but is included in the proposal for a new directive). Also, the first cases involving manufacturers and their disputes with their purchasers over injuries caused by their products are now being decided.

The difference is that now Europe is supposed to operate as a barrier-free single market in which warnings and bans issued in one country should be immediately harmonized and disseminated to all EU countries. But the finding is that more often the issue is resolved by the national authority getting the manufacturer to make changes to all the machinery sold by him in-country without necessarily involving the rest of Europe, or worse, restricting action to the specific machine identified as dangerous !

The Directive does not require information on national approaches to be directly communicated to the other States, so a machine judged dangerous in one country could perfectly well be sold and used "as is" elsewhere. This is at odds with the rules of what is supposed to be a single market where safety is meant to be maximized and consistent and constraints minimized and identical everywhere in Europe !

It is clear, though, that the information and assessment procedure as laid down in the Directive - i.e. via the safeguard clause, which involves an assessment by the Commission and may require expertise - has created major hold-ups, because it is only after this extremely slow-moving procedure that information can be disclosed in all Member States. This means that several years may elapse before action is taken on machinery that meanwhile may cause other harm. The fact that only one case has gone through the procedure so far (Italian power presses seized by France) raises questions about the efficiency of the system.

The national authorities have taken initiatives, like the Machex network set up by SLIC (the European Senior Labour Inspectors Committee) to address the issues of safety of machinery in the workplace (L. Ahnström), or work out common practices for simpler administrative procedures (ADCO) on market surveillance - particularly essential with new member countries joining the EU (P. Papard).

The Commission, whose December 2001 consultative document on the New Approach put some pertinent questions, took a keen interest in the debate hosted by the TUTB (M. Eifel). Major resources need to be put into this area by States and the Commission's DG Enterprise as a matter of urgency. The recent Commission Communication (May 2003) aimed at improving the application of the "New Approach" Directives trails a series of steps in the right direction.

An incomplete score sheet

Fragmented and inherently poor data make it hard to give a full picture of what the Directive has done for health and safety.

Notwithstanding steady improvements, national and European accident statistics (Eurostat) remain patchy (e.g., most accident records have nowhere in them to specify what machine caused the accident) so that incriminated machinery cannot be identified.

The data also provide reactive information - notifications after accidents happen - rather than proactive safety assurances to prevent incidents occurring (near-misses are not accounted for). Does the fact that Germany has no record of accidents with band saws not fitted with emergency stopping devices - even though prescribed by the Directive - make this an unnecessary obligation ?

Accidents prove that there is a continuing risk from machinery, whether from misuse or poor design.

[5] The TUTB has joined with the Swedish SALTSA Programme to set up another research project aimed at taking stock of trade union participation in standardization work and proposing a methodology for a participatory approach by workers in machinery design. The project consolidated report will be published in 2003 and the next number of the *TUTB Newsletter* will be a special issue on the results of the seminar held in Brussels in June to present and discuss the report.

Useful information and particulars of the causes of accidents and the incidence of poor equipment design have been collected by the authorities in France and Italy, and through surveys in the United Kingdom, Sweden, Finland and Denmark. Successfully run market surveillance campaigns, and nascent cooperation between authorities signal major opportunities for improving the system (Pascal Etienne described a long series of such schemes).

Gains and challenges

Even though harmonization is clearly not being walked the way it is talked, the New Approach's regulatory and standards process has achieved undeniable results in design, and these were forcefully brought out at the workshop (Jean-Paul Lacore). Safety integration, the 3-step method, the complementarity between product design and operator safety are all concepts gaining wider acceptance among the new generation of designers, although not always as quickly as might be wished. More needs to be done to speed up this process through training schemes, some of which have already produced results.

But also (K. O. Hansen, Danish government representative), effective political agreements are needed to steer through the revision of the Directive and develop exchanges on its implementation through joint campaigns, inter-country exchange visits of inspectors, and ongoing dialogue with manufacturers.

The way to improve cooperation and avoid duplication of efforts, argued the KAN (U. Bamberg), is to set up a rapid information exchange system with immediate notification of emergencies, common databases on hazardous products, national and European cooperation groups for each Directive.

The twin-track approach (design-protection) is a locked-in gain for Europe's workers that trade unions want to see raised up to the international level as an original approach to which workers' representatives have been major contributors. The system's kingpin standard – EN 292 - has just undergone a long and arduous revision and will be published as a joint European and international standard (EN ISO 12100). It will be a litmus of how far the European model stands apart from or is part of the global trend to deregulation. Might not the real issue of debate be between the proponents of social regulation as the basis of the free market and advocates of purely voluntary rules underpinned by powerful international economic interests unimpeded by regional or social "barriers"? ■