

New Machinery Directive soon on track?

After four years of discussion under seven presidencies (Sweden, Belgium, Spain, Denmark, Greece, Italy, Ireland, The Netherlands), the Competitiveness Council of 24 September 2004 reached a political agreement on the proposal for a directive on technical harmonisation of machinery and amending Directive 95/16/EC¹. Once the text has been finalised, the Council will formally adopt its common position at a forthcoming meeting, and forward it to the European Parliament for second reading.

This article looks at the new published text² against current Machinery Directive 98/37/EC, and what if any progress has been made over the Commission's first proposal issued in 2000³.

Confirmations and extensions

The **scope** of the Directive has been extended to construction site hoists (intended for lifting persons or persons and goods) and portable operated impact machinery designed for industrial purposes only (marking guns, fixing tools, stunning pistols). Safety components are now designated as "machinery" and regulated through a series of definitions and an annexed *indicative* list that the Commission can update, whereas the initial proposal provided an *exhaustive* list for safety components. The Directive is also clearly now applicable to partly completed machinery. A new set of definitions clarifies the meaning of *placing on the market, manufacturer, authorised representative, putting into service, and harmonised standard*.

Market surveillance is referred to by name for the first time in the Machinery Directive. Recital 8 underlines its importance by requiring a new legal framework to be put in place for it. The new article 4 re-visits article 2 of Directive 98/37/EC and supplements it with the requirement that in order to be placed on the market and put into service, machinery must *satisfy the relevant provisions of the directive*. Three new sub-paragraphs address the need to take into account *partly completed machinery*, and make sure that authorities monitor conformity of machinery through *dedicated bodies with defined tasks, organisation and powers*. Finally, there are new provisions on *confidentiality* in the treatment of information covered by professional secrecy, and *cooperation* between Member States in exchanging information and experience to ensure that the Directive is applied uniformly.

The need to distinguish between **actions against machinery and standards** is introduced in Recital 9. The two distinct procedures – now dealt with in article 10 (standards) and article 11 (machinery) – have changed little from Directive 98/37:

- Member States will now take action against *machinery* that is likely to compromise the health

and safety of persons not only when used in accordance with its intended purpose, *but also under conditions which can reasonably be foreseen* [Art. 11, (1)].

- A Member State that takes action (against *machinery*) must immediately inform not only the Commission, *but also the other Member States* [Art. 11, (2)].
- Where a Member State has taken action against *machinery* on the basis of alleged shortcomings in harmonised standards, the Commission – in the light of the opinion of the 98/37/EC Committee – will now *decide* (and not *inform*) what action to take against the harmonised standard(s) involved (Art. 10).

A new article (9) describes the action to be taken against **potentially hazardous machinery**. If a harmonised standard does not entirely satisfy the essential health and safety requirements (EHSRs) it covers, the Commission or a Member State may ask for measures to be taken at Community level against all machinery designed in accordance with the defective standard(s). If the Commission thinks that the action taken by a Member State against a machine is justified, the Commission or a Member State may ask for measures to be taken at Community level against all machinery that presents the same design risk(s). The Commission can adopt the necessary measures at Community level on the basis of consultation with the Member States and other interested parties about what measures it intends to take against potentially dangerous machinery.

Actions to be taken before **machinery is placed on the market and put into service** are now drawn together in a new article (5) that introduces *conformity assessment* and condenses the existing provisions of Directive 98/37 in particular concerning:

- The need to satisfy the EHSRs in Annex I.
- The need to ensure the availability of the Technical File.

Article 5 also underlines the need to supply *instructions*.

Further information:

- The ETUC calls for a revision of the Machinery Directive. Consultable on: <http://tutb.etuc.org/uk/newsevents/files/Machinerydirective.pdf>.
- Tozzi, Giulio Andrea, The Machinery Directive, gains and challenges for the New Approach, *TUTB Newsletter*, No. 21, June 2003, p. 3-7.
- Boy, Stefano, Revision of the Machinery Directive, *TUTB Newsletter*, No. 17, June 2001, p. 5-11.

All *TUTB Newsletters* are consultable on : <http://tutb.etuc.org> > *TUTB Newsletter*.

¹ European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts.

² Council of the European Union, Doc 12509/04, ENT 123, CODEC 1017, 17 September 2004.

³ COM(2000) 899 final.

On **conformity assessment**, the procedure for machinery **not listed in Annex IV** remains the same, but changes have been made to that for machinery **listed in Annex IV**. More especially, where such machines are designed to harmonised standards that cover all the applicable EHSRs, the manufacturer can declare the machine as compliant with the Directive *without having to submit a copy of the Technical File to a Notified Body*. And yet, the Commission's first proposal did require the Technical File for Annex IV machinery to be checked by Notified Bodies in every instance. In all other cases, manufacturers of Annex IV machines can follow a *full quality assurance procedure*, as an alternative to EC-type certification.

The **EC declaration of conformity** must now contain the *name and address of the person authorized to compile the Technical File*, who must be established in the Community, as well as *where and when the declaration was made*.

Annex V of Directive 98/37 (the EC declaration of conformity) has now gone, and its main content – the description of the **Technical File** – has become part a) of the new Annex VI, with the following added particulars:

- *Operational issues* must be carefully explained.
- *Risk assessment* must be documented: in particular, *residual risks* must be indicated.
- The reports and results from the manufacturer's research and tests – to determine the safe design for his product – must be *included in the Technical File*.

Significantly, the new text not only no longer requires the Technical File to be kept available for inspection on the manufacturer's premises for inspection, it makes clear that it does not even have to be located in the territory of the European Community.

The duties of Notified Bodies (NBs) when carrying out the **EC type-examination** (new Annex X) have also been clarified. In particular, they are now required to distinguish those design solutions that are in accordance with harmonised standards from those that are not, and in the latter case, to take special care over the examination. Validity of the EC-Type examination certificate is dealt with in a new paragraph (9) of new Annex X. For one thing, NBs are reminded of their responsibility for ensuring that certificates remain valid when modifications and/or the state of the art might imply that a certificate is no longer valid. But also, manufacturers must ensure that machinery *meets the state of the art*: they must ask the NB to *review the validity* of the certificate every five years. If the certificate is not renewed, the manufacturer can no longer place the machine concerned on the market.

There are new provisions on the **Notified Bodies**. The Council has gone further than the Commission's

first proposal – which clarified elements like *staff, means* and *access to equipment* as pre-conditions when assessing the competence of NBs – by adding provisions for *suspending or withdrawing* certificates, and announcing Community initiatives for the exchange of experience between notified bodies and the national authorities in charge of their appointment, notification and monitoring. Two new paragraphs have been introduced in the minimum criteria to be taken into account by Member States for notifying bodies. One stresses the importance of NBs participating in *co-ordination* activities, and in European *standardization*, the other the need to ensure that customers' files and dossiers do not go astray if an NB ceases its activities.

Two new recitals (17 - 18) reaffirm the *significance* of **CE marking**, the prohibition on *misleading* third parties with similar marking, and the need for CE marking to be affixed next to the name of the *person* who has taken responsibility for it.

The **presumption of conformity** has undergone only minor rewording in the Council text; an intermediate text (September 2003) which came out of the debate in the Council Working Party on Technical Harmonization included the *conditions* on which the references of harmonised standards would have been published in the *Official Journal*. These required the list of EHSRs relevant to the machine concerned, those fully covered by the standard (and by which paragraph) and those only partly covered or not at all.

The new text addresses some major concerns voiced by the European trade union movement

The TUTB levelled a number of criticisms⁴ at four main changes made by the Commission's first proposal concerning *partly completed machinery*, *ergonomics*, *controls*, *instructions*, and *risk analysis*. The new Council text seems to address these concerns of the European trade union movement.

The provisions on **partly completed machinery** introduced by the Commission proposal have been tightened up to make it subject to a specific *procedure*.

The TUTB said that the Commission proposal lacked a clear obligation to carry out a risk assessment even on partly completed machinery, to make the job of final assemblers responsible for the overall risk assessment of complex machinery easier. The improvement made is that manufacturers of partly completed machinery must now compile the *technical documentation* described in part B of the new Annex VI, especially on risk assessment. This closely resembles the *Technical File* for machinery. Also, partly completed machinery can only be placed on the market if accompanied by a *declaration of incorporation* indicating, among other things, *what EHSRs*

⁴ Cf. TUTB Newsletter, No. 17, *op. cit.*

have been applied and fulfilled, and by detailed assembly instructions, now considered so important that they are dealt with in a separate annex (V).

The **Annex I** changes made by the Commission proposal appear to be endorsed. Provisions on machinery *handling*, for example, have been expanded with a focus on *transportation* hazards, while provisions on *stability* have been finessed. Interestingly, the need to avoid *overturning, falling or uncontrolled movements* has been extended to transportation, assembly, dismantling, scrapping and any other action involving machinery. By contrast, some modifications criticized by the TUTB have been revisited. The new paragraph on **ergonomics** has been enriched with references to the *work rate, operators' concentration, space of movements, man-machine interface*. The paragraph on **controls** has reinstated the deleted paragraphs on *errors in the control system logic*, while a number of new provisions have been introduced. The express references to *hardware & software faults, human error, unexpected start-up, changes in machinery parameters, stopping, pieces ejection, efficiency of protective devices, coherency of control systems of assembly of machinery, cableless control* are cases in point. The need to avoid machinery starting up when persons other than the operator acting on the start command are in the danger zone has also been underlined. The provisions on **instructions** have been supplemented and clarified. On top of what was required by Directive 98/37/EC, instructions must now include a general description of the machine, with descriptions and explanations, details on assembly, installation and connection, details on stability during the whole machinery life-cycle, details on the operating methods to be followed in case of accidents or breakdowns, and details of how to safely carry out maintenance tasks. Finally, the Council text removes the uncertainties of the Commission's first proposal concerning the role of *risk analysis*, by making *risk assessment* central to the manufacturer's duties. Significantly, paragraphs 1 and 2 of the General Principles of Annex I introduce *risk assessment* and *risk reduction*, taking advantage of the fundamental harmonised standard EN ISO 12100 *Safety of machinery*, published in 2003.

Other important improvements over the first Commission proposal include:

- *Principles of safety integration* have been added, with express references to *operability* and *reasonably foreseeable misuse*.
- Provisions concerning *noise* and *vibrations* have been incorporated, with a suggestion that machinery

emission be assessed by reference to comparative emission data for similar machinery. This concept is re-introduced in the provisions on instructions. This does justice to the activities promoted by KAN and INRS in support of European research on quantifying machinery emissions.

Finally, the recital stating that the *EHSRs must be complied with to ensure that machinery is safe* has been reinstated (Recital 10-b), thus providing an adequate introduction to Recital 19 requiring manufacturers to carry out a risk assessment for machinery they wish to place on the market.

The TUTB's general view

Generally, the Council text consolidates most of the *directions* introduced by the first Commission proposal, with a focus on ensuring legal certainty for users. Positive aspects include the focus on the needs of *consumers*, included for the first time in the Machinery Directive. These are now to be found in Recital 3, reminding Member States about their responsibility for ensuring health and safety on their territory, and in Recital 11, emphasizing the need to take consumers into account when designing and constructing machinery.

Also positive is the recognition given that *traceability* of documentation is important. Manufacturers must keep the EC declaration of conformity and declaration of incorporation for a period of at least 10 years from the last date of manufacture. Also, Member States must take steps to see that affected customers' files and dossiers do not go astray if NBs cease their activities.

A third positive aspect is the focus on the whole lifecycle of machinery, with special emphasis on *operational* health and safety issues: significantly, the Directive's provisions now address *purposes which can reasonably be foreseen* in addition to the purposes intended by the manufacturer.

Finally, the Council text reflects a desire for better communication among all stakeholders affected by the Machinery Directive, as envisaged in the recent publications concerning the improvement of the implementation of the New Approach Directives and the Community strategy on health and safety at work. ■

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