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FEM IT information paper on:

**Implementation of the new Machinery Directive
2006/42/EC and**
- availability of harmonised standards for Industrial Trucks
- dealing with EC declaration of conformity

The revision of the Machinery Directive and its publication as 2006/42/EC¹ in 2006 also brought about changes to some 600 harmonised standards. All these harmonised standards had to be checked for conformity to the new directive and amended according to three categories:

- Type 1: simple amendment of standard (editorial changes, update of major horizontal standards and addition of an Annex (ZB) referring to 2006/42/EC)
- Type 2: technical amendment (Type 1 and technical modification)
- Type 3: revision of the standard

For all three types of amendments "deadlines" were set up, stating when the amendments of the standards should be completed. 30th May 2009 was fixed as a final deadline. Until this date all standards have to be submitted to the CEN Management Centre for harmonisation. This is necessary, because from 29th December 2009 the current Machinery Directive 98/37/EC becomes invalid and will be replaced by the new Machinery Directive 2006/42/EC. At this point all harmonised standards referenced in the Machinery Directive 98/37/EC will lose their presumption of conformity, unless they or their subsequent standards have received harmonisation through the new Machinery Directive 2006/42/EC.

Standardisation in the field of Industrial Trucks

In the area of Industrial Trucks it has also been decided to establish standardisation at an international level (ISO and CEN) according to the Vienna Agreement. This became necessary, as all manufacturers are global players and time was too short to produce a worldwide standard by the end of May 2009. However time showed that this undertaking also had its

¹ The New Machinery Directive; "A tool to uncover the changes introduced by the revised directive"; i.e. available under: <http://hesa.etui-rehs.org/uk/publications/pub43.htm>

difficulties. For example in some cases it became necessary and unavoidable to create individual parts of the standard for European and Non-European countries. This alone involved considerable extra work for the members of the working groups. Nevertheless no effort was spared to revise the relevant safety standards according to the requirements of the new Machinery Directive 2006/42/EC and to finalise new standardisation projects. Unfortunately, the necessary processes in standardisation didn't produce the anticipated success in all cases. Parts of the standardisation projects have been finalised to a stage where only publication of the standard is still outstanding. In other cases the standardisation projects are still in the voting phase.

Consequently, manufacturers of Industrial Trucks might have to work partly with "non-harmonized" standards from 29th December 2009. They will face the situation of applying the requirements of Annex I of the new Machinery Directive 2006/42/EC without a full set of harmonised standards.

Reminder: Risk assessment and harmonised standard

The design construction of a product must meet the requirements of Annex I (Essential Health and Safety Requirements) of the new Machinery Directive 2006/42/EC with effect from 29th December 2009.

One task for the manufacturer is to apply a risk assessment on the design construction. Depending on whether or not a harmonised standard is existing, this task takes more or less effort. The draft Guidelines for the new Machinery Directive include a helpful clarification:

§164 Risk assessment and harmonised standards

The process of risk assessment is facilitated by the application of harmonised standards, since C-type standards for machinery identify the significant hazards that are generally associated with the category of machinery concerned and specify protective measures to deal with them. However the application of harmonised standards does not dispense the machinery manufacturer from the obligation to carry out a risk assessment.

A manufacturer who applies the specifications of a C-type standard must ensure that the harmonised standard is appropriate to the particular machinery concerned and covers all of the risks it presents. If the machinery concerned presents hazards that are not covered by the harmonised standard, a full risk assessment is required for those hazards and appropriate protective measures must be taken to deal with them.

Furthermore, where harmonised standards specify several alternative solutions without defining criteria for choice between them, the choice of the appropriate solution for the machinery concerned must be based on a specific risk assessment. This is particularly important when applying B-type standards – see comments on Article 7 (2).

Paragraph 2 of the Guideline text clarifies, that "If the machinery concerned presents hazards that are not covered by the harmonised standard, a full risk assessment is required **for those** hazards and appropriate protective measures must be taken to deal with them."

Implicitly this means, that for risks covered by the harmonised standard, no risk assessment is necessary. Mentioning the hazard and referring to the appropriate chapter of the relevant harmonised standard is sufficient.

Bearing in mind the advantage of using harmonised standards, this paper clarifies the status of the standardisation for Industrial Trucks. Moreover, it is meant to indicate how manufacturers can best handle the situation if the relevant standardisation project might not be finished in time.

Designing Industrial Trucks according to standards

When designing Industrial Trucks the means to fulfil the requirements of Annex I of the Machinery Directive must at least be equivalent to the level of safety in the technical standards giving the state-of-the-art.

In regards to the new Machinery Directive 2006/42/EC, EN version of ISO 3691-1 together with EN version of ISO 3691-7 will be the state-of-the-art for the safety of Industrial Trucks. The standards therefore will cover the requirements of Annex I and will provide presumption of conformity once the EN versions of ISO 3691-1 and ISO 3691-7 are referenced in the European Official Journal - (OJEU).

In the event that a reference in the OJEU is not possible by 29th December 2009, manufacturers of Industrial Trucks might be faced with two separate scenarios at the date of implementation of the new Machinery Directive 2006/42/EC (29th December 2009):

Scenarios:

1. Published EN versions of ISO 3691-1 and ISO 3691-7 exist apart from being referenced in the European Official Journal.
2. No published EN versions of ISO 3691-1 and ISO 3691-7 exist.

Scenario 1. Published EN versions of ISO 3691-1 and ISO 3691-7 exist apart from being referenced in the OJEU

- The EN versions of ISO 3691-1 and ISO 3691-7 have been finalized and published but not referenced in the OJEU which means the standards are published following;
 - A positive vote on the standards
 - A positive assessment by the CEN-Consultant is given
(If the design construction of an Industrial Truck is in accordance with the published standards, the Industrial Truck is considered to fulfil the requirements of Annex I of the new Machinery Directive 2006/42/EC, ensured by the positive assessment of the CEN-Consultant)

Taking this into account there is no reason that the standard should not be considered and referenced in the technical file prior to the formality of entering the OJEU as a harmonised standard.

Consequently, manufacturers will have the freedom to simplify their risk assessment for a hazard which is covered by the EN version of ISO 3691-1 and ISO 3691-7, if they apply the standard on their particular Industrial Truck, by referring to the standard.

As soon as a published standard is referenced in the OJEU it achieves the so-called "presumption of conformity". This gives the presumption of conformity to all machines built according to the standard concerning the EHSR's covered by the standard.

Scenario 2. No published EN versions of ISO 3691-1 and ISO 3691-7 exist.

The standard is either still under revision or in the voting phase. Here the emphasis has to be put on timely completion of the projects.

As already indicated in this paper the manufacturer has to fulfil the requirements of the new Machinery Directive 2006/42/EC and especially Annex I (Essential Health and Safety Requirements).

The manufacturer has to do a full risk assessment and to design and build the machine accordingly.

They have to consider the state-of-the-art when doing so. They can use for example draft standards such as ISO/FDIS 3691-1 to refer to the state-of-the-art in the assessment.

However, a draft or non harmonised standard may change between the time the machine was designed and the standard published with the result that subsequent design changes may be required.

Clarification to harmonisation of standards:

Harmonisation of a standard: A standard referenced in the official journal of the EU together with the Directive it relates to, confirms that the standard achieves "presumption of conformity"

Industrial Trucks and EC declarations of conformity

The new Machinery Directive will be implemented on 29th December 2009 without any transitory period. For the manufacturers, it is difficult to ensure that the EC declaration of conformity will have the reference to the applicable directive when the lift truck will be put on the market due to uncertainty of the date of sale.

In regard to how to deal with the EC declaration of conformity and the uncertainty of the date of placing finished machinery in stock on the market, the recommendation of the European Commission reads as follows²:

"Therefore it is recommended that in cases where the manufacturer cannot be certain on what date the Industrial Trucks will be placed on the market, providing the Industrial Trucks comply with both the current and the new directive, the manufacturer may establish an EC declaration of conformity referring to Directives 98/37/EC and 2006/42/EC.

The Directive 98/37/EC should be removed from the EC declaration of conformity after the 29th December 2009."

In the case of referencing to both directives, the EC declaration of conformity can be drafted as follows: "This EC declaration of Conformity is referring to Machinery Directive 98/37/EC until 28 December 2009 and to Machinery Directive 2006/42/EC from 29 December 2009".

² http://ec.europa.eu/enterprise/mechan_equipment/machinery/faq2006-42-ec.pdf