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# On the Safety of Machinery – What does the New Machinery Directive Say?

Due to changed requirements and procedures for determining conformity, the new EC Machinery Directive directly affects agricultural machinery. It also impacts the related safety standards. Following the political mandate to simplify the legal regulations in the EU, the revision of the EC Machinery Directive has been completed after a period of ten years. The new EC Machinery Directive 2006/42/ EC was published in the Official Journal of the European Union on 9 June 2006 and came into force on 29 June 2006. The Member States are obliged to transpose this Directive into national law by 29 June 2008, and to apply it with effect from 29 December 2009. Until then, the existing EC Machinery



Fig. 1: EC Maschinery Directive 98/37/EC and 2006/42/EC

Directive 98/37/EC remains valid. *Figure 1* provides an overview of the essential changes.

# **Inclusion of tractors**

Probably the most significant change affecting agricultural machinery in particular is the partial inclusion of tractors within the scope of the Directive. Whereas previously tractors were completely excluded from the EC Machinery Directive, 2006/42/EC applies to tractors with regard to risks that are not recorded by the EC type-approval procedure 2003/37/EC. This means considerably higher costs. The manufacturer must carry out a risk assessment for the entire tractor, not only with respect to the risks not covered by 2003/37/EC. In addition, the expenditure for documentation is considerably increased.

According to the grounds for consideration, the EC Machinery Directive is no longer to be applied when the previously unrecorded risks are covered by the EC type-approval procedure. In this connection, the European Commission established an ad hoc working group that identified a total of 6 technical matters for which adaptations to the EC type-approval procedure are required [1].

# Risk assessment instead of hazard analysis

In the new EC Machinery Directive, the former hazard analysis is replaced by a risk assessment. The risk assessment includes a risk analysis and a risk estimate. For the risk analysis, in determining the limits for the machinery, in addition to proper use any reasonably foreseeable misuse is also to be taken into account. Moreover, the hazards relating to the machinery and the associated hazardous situations and events are to be ascertained, and the risk elements are then to be determined within the framework of the risk estimation. The concluding risk evaluation is then to assess whether the measures taken are sufficient in order to reduce risks. This assessment is effected primarily by means of a qualitative evaluation. Whereas accident occurrence was previously a decisive factor for the evaluation of a protective measure, in the case of risk assessment, it is no longer decisive. This also means that an absence or a low occurrence of accidents is not to be equated with a low risk.

# Other significant changes

For fixed guards the requirement has been added that their fastenings shall remain attached to the machine or to the guard after removal of the guard. Whereas previously in the case of self-propelled machinery subject to tipping over and/or rollover risks or hazards due to falling objects it was sufficient to provide the machinery with anchorage

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points for rollover protective structures (ROPS) and/or falling-object protective structures (FOPS), in future ROPS and/or FOPS are to be installed. Like drive shaft guards, ROPS and FOPS are classified as Annex IV machinery, and are thus subject to the same procedures for assessing conformity. In accordance with the existing EC Machinery Directive, Annex IV machinery is to be subject to an EC type-examination. In addition to the EC type-examination, the new EC Machinery Directive provides for a full quality assurance procedure as an alternative.

## Marking and instruction handbook

Concerning the requirement of marking the year of construction on the machine, there is a clarification to the effect that this is to be done 'openly', and that pre- or post-dating is prohibited. In future, the instruction handbook must contain the EC declaration of conformity. Moreover, there is a change with respect to the labelling of the instruction handbook. The original instruction handbook, which is to be delivered with the machine and for which the manufacturer assumes responsibility, is to be marked as 'Original instructions'. If a translation in the language of the user country is required and if the manufacturer does not assume responsibility for this translation, this translation is to be marked as 'Translation of the original instructions'. In this case both the translation and the original instructions are to be delivered with the machine. In addition, the new Machinery Directive contains requirements concerning the information provided in sales literature, which must not contradict the information in the instruction handbook. In particular, information on emissions must correspond to that contained in the instruction handbook.

#### Declaration of conformity and declaration of incorporation

For the declaration of conformity, there is an additional requirement that the name and address of the person authorised in the EU for documentation is to be stated. The manufacturer's declaration that was previously required for partly completed machinery is replaced by a declaration of incorporation. In particular, this declaration of incorporation must contain information concerning which requirements of the EC Machinery Directive are fulfilled.

### Impacts on safety standardisation

The essential safety requirements of the EC Machinery Directive are put into concrete

Table 1: ISO and EN Safety Standards
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ISO-Norm ISO Standard	Teil-Titel Part title	EN-Norm EN Standard
ISO 4254-1	Gemeinsame Sicherheitsanforderungen Common safety requirements	EN 1553
ISO 4254-5	Kraftbetriebene Bodenbearbeitungsgeräte Power-driven soil-working machines	EN 708, EN 708 A1
ISO 4254-6	Pflanzenschutzgeräte Plant protection equipment	EN 907
ISO 4254-7	Mähdrescher, Feldhäcksler, Baumwollerntemaschinen Combine harvesters, forage harvesters, cotton harvesters	EN 632
ISO 4254-8	Mineraldüngerstreuer Solid fertilizer distributors	EN 14017
ISO 4254-9	Sämaschinen Seed drills	EN 14018
ISO 4254-10	Kreiselzetter und Kreiselschwader Roatry tedders and rotary rakes	Bisher keine EN
ISO 4254-11	Sammelpressen Pick-up balers	EN 704
ISO 4254-12	Kreiselmähwerke und Schlegelmäher Rotary mowers and flail mowers	EN 745

form by means of so-called 'harmonised' standards. These are developed by the CEN under a mandate from the European Commission, and are published in the Official Journal of the European Union. These standards thereby have a presumption of conformity, i.e. if a machine conforms to such a standard, it is presumed that the requirements of the Machinery Directive have also been fulfilled. There are now more than 600 harmonised standards cited in the Official Journal of the European Union concerning the existing EC Machinery Directive. Due to the changes in the new Machinery Directive, a review and, if necessary, a technical adaptation of these standards is required.

Here the CEN provides three possibilities. The first possibility is a formal adaptation (referred to as a 'simple amendment'), where the standard is changed only so that it refers to the new rather than to the existing Machinery Directive. The second possibility is a formal adaptation with additional technical changes that are limited in extent. The third possibility is the complete revision of a standard. For the approximately 30 safety standards for agricultural machinery developed to date, the Technical Committee responsible for agricultural machinery standardisation, CEN/TC 144 'Tractors and machinery for agriculture and forestry', has decided to perform only a formal adaptation. This ensures that these standards will maintain their status as harmonised standards in the transition from the existing to the new Directive.

This decision is to be welcomed, particularly in light of the fact that the internationally-oriented agricultural machinery industry requires globally valid legislation and hence also internationally valid safety standards. Since the European safety standardisation for agricultural machinery can be regarded as almost completed, it has therefore

been agreed to carry out the revision of EN safety standards jointly at the CEN and ISO in accordance with the so-called Vienna Agreement. This permits the simultaneous development of a European (EN ISO) and an international (ISO) standard with the same standard number and identical contents. Here the existing EN standard remains valid until the publication of the new EN ISO standard. The joint revision is also carried out in light of the fact that in the case of the ISO, in the standard series ISO 4254, comprising nine parts, there were likewise safety standards that required revision. Figure 2 provides an overview of the relationships between the existing EN and ISO standards.

While the previously existing standard series ISO 4254 applied to tractors and machinery for agriculture and forestry, the new series of standards applies only to agricultural machinery. For this reason, ISO 4254-2 (Anhydrous ammonia applicators, withdrawn), ISO 4254-3 (Tractors, in future ISO 26322-1 Standard tractors and ISO 26322-2 Narrow-track and small tractors) and ISO 4254-4 (Forestry winches, replaced by ISO 19472) are not included in the overview. So far ISO 4254-1 has been concluded, and in the meantime EN 1553 has been replaced by EN ISO 4254-1. ISO 4254-7 will be concluded shortly and the other parts are still in process. The standards in the new series ISO 4254 are adopted as EN ISO standards with the same standard number and unchanged contents, and thus replace the existing EN standards.

# Literature

[1] Schauer, A.: Sicherheitstechnische Anforderungen an Traktoren aus Sicht der Industrie. LANDTECHNIK 63 (2008), H. 5, S. 270 -271