Machinery Directive 2006/42/EC

- your guide to the new Machinery Directive

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Introduction
A new Machinery Directive comes into effect on the 29th December 2009. The Machinery Directive is known as ”Machinery” (2006/42/EC), and replaces the previous Directive ”Machinery and other technical apparatus” (98/37/EC). Although both Directives are similar to a certain extent, there are naturally a number of changes that affect you as a machine manufacturer and importer.

The most important differences are simplification and elucidation. The Directive shall be easier to use and understand. A number of changes also concern basic health and safety requirements, for example in the fields of: ergonomics, control systems, stability, protection, noise, vibration, user instructions and sales support material.

There is no transitional period between the new and the old Machinery Directives. The transition comes into effect on the 29th December 2009.

The intention of this guide is to highlight the differences between the old and the new Directives, and also to give you some concrete ideas for safer machinery.

Background
The 2006/42/EC Directive governs the requirements that machinery must meet before it can be released onto the market, or put into operation inside the European Union, Iceland, Norway and Liechtenstein. The Member States of the EU are obliged to incorporate the Directive into their legislature.

History
The Machinery Directive has previously undergone a number of name changes . It was originally known as 89/392/EEC, since when subsequent changes to the Directive have implied new names. For example, 91/386/EEC, 93/68/EEC and most recently 98/37/EC.

This new Directive (2006/42/EC) was officially published on the 9th June 2006 as the third change in legislature for the Machinery Directive. The Member Countries of the European Union have since then had time to implement the Directive into their legislature.

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Scope of the Directive
The 2006/42/EC Machine Directive is valid for the following products:
- machinery
- interchangeable equipment
- safety components
- lifting accessories
- chains, ropes and webbing
- removable mechanical transmission devices
- partially completed machinery.

Exceptions
Some changes concerning exceptions:
- The new Machinery Directive has no provision for the exclusion of hand-driven machinery.
- Medical equipment is nowadays completely covered by the Directive for Medical Equipment.
- The Machinery Directive does not cover weapons, including firearms.
- The implication of means of transport is more clearly defined in the new Directive.

The following products are now completely covered by the Low Voltage Directive (LVD):
- Household appliances intended for domestic use.
- Audio and video equipment.
- Information technology equipment.
- Ordinary office machinery.
- Low-voltage switchgear
- Electrical motors.
- Connection devices and equipment, and transformers.

A more detailed list, including exceptions, can be found under Article 2.

Assessment of Conformity
A significant change concerns machinery listed in Annex 4, in particular respect of dangerous machinery. If the machine has been manufactured in compliance with the harmonised standards published in the European Union's official journal, and if the standards encompass all the health and safety requirements, the Machinery Directive gives the manufacturer the option to self-certify the machine. Thus the CE marking does not need to be inspected by a notified body.

Market Surveillance
This new Machinery Directive is more specific concerning Member States' obligation to organise market surveillance. The obligation comprises a collaborative effort for maintaining market surveillance and respect for safety and transparency. The Directive has been produced with the help of material from the General Product Safety Directive. This has enabled a discussion within the European Commission, the purpose of which being to limit the machinery's market position based on its category.

Certification
A manufacturer that had previously performed type inspections of his own machinery based on the prevalent Machinery Directive must submit the certification to a Notified Body as a new application for certification. This must be done in order to enable the release of the machinery onto the market after the 29th December 2009.

The manufacturer must follow one of the procedures in Annex 12 (3) and (4) in the new Directive if the machinery is certified in accordance with Annex 8 (2)(c) in the previous Machinery Directive, as the previous procedure was withdrawn in 2006/42/EC.

Regulations for putting machinery into service or placing it on the market
Before the manufacturer or his representative may put machinery into service or release it to market, the following conditions must be met:

- The machinery must comply with the applicable sections of the essential Health and Safety requirements as set out in Annex 1.
- The technical documentation as set out in Annex 7, chapter A, must be accessible.
- Provide all necessary information, for example, the machinery's operating instructions.
- Conduct a suitable procedure for the assessment of conformity in accordance with Articles 10-13.
- Issue an EC Declaration of Conformity in accordance with Annex 2, part 1, chapter A. Ensure that the Declaration is supplied together with the machinery.
- Affix the CE marking in accordance with Annex 3.

Risk analysis
The most widely-accepted means of designing machinery or machine guards today is by using a risk analysis as a basis. An early risk analysis makes for safer, more easily-operated machine. A risk analysis can be conducted using a variety of different methods. The ISO 14121-1:2007 standard provides the necessary guidelines in order to conduct a risk analysis. Within a few years this standard, previously known as EN 1050, will be incorporated into ISO 12001. ISO 14121 describes procedures for the identification of risk sources and the estimation and evaluation of risks.

Risk analyses are normally divided into different steps:
- *Status report:* describes the machinery's current status and states its viability.
- *Identification of risks:* identifies risks based on the Machinery Directive's Health and Safety requirements.
- *Risk assessment:* assessment and evaluation of the risks. The result serves as guidance for measures to be taken.
- *Risk reduction:* describes the prescribed action, when taken and the person responsible.
- *Methodology:* describes the method used and how the analysis is to be interpreted.

A 'step' model is often used in risk reduction. The 'step' model looks like this:
- In the first instance a risk is removed by means of design.
- In the second instance a risk is removed by means of protection.
- In the third instance you can warn or inform about the risk.

All steps in the model have to be considered when taking measures regarding the risk. If the risk analysis is conducted at an early stage in the design process,it makes it easier to get to the model's first step.

Working with standards
A standard can be likened to a specification for designing a machine so that it meets the Machinery Directive's requirements. The Machinery Directive is a legal instrument and the rules and regulations therein must be observed. The standards, on the other hand, are recommendations for the design of machinery in a particular manner. If used properly, the standards are useful for aiding the design of safe and accessible machinery. A standard:

- Is a recommendation for the design of a product in a certain manner.
- Provides examples of solutions for a recurrent problem.
- Is developed by representatives from manufacturers, users and authorities.

Standardisation shall lead to simplification, safety, profitability and improved communications. The standards have been produced by technical committees and working groups. Work is in progress to change existing standards from EN to ISO. The majority have already been changed and all will eventually become ISO standards.

Harmonised standards
A harmonised standard means that all Member States have approved the contents of the standard in question. Once the standard has been approved it is published in the "Official Journal of the European Communities", and is then designated as an EN standard. Once a standard fulfills the requirements of a directive it becomes 'presumed'. An example of such a standard is EN 60204-1 (Safety of Machinery - Electrical Equipment). If the standard's recommendations are fulfilled, the requirements in the Low Voltage Directive (LVD) are automatically met.

Different types of standard
There are several different levels of standards. They are type A, B and C standards. The type A standard has a comprehensive content and a type C standard is more specific.

The type A standard
is a European Standard covering basic requirements for all categories of machinery. It interprets the requirements of the Machinery Directive. EN ISO 12100-1 is one such example.

The type B standard
is a European Standard for safety. This has been adopted as a national standard. The type B standard concerns a safety aspect or type of safety-related appliance. The standard is used for a broad range of machine categories.

There are two types of B standard:
1. B1 standard: specific safety aspects:
2. B2 standard: safety-related devices.

Type C standards
are safety-related European Standards for specific types of machinery. They contain detailed safety requirements for unique risk sources. An example of a type C standard is EN 619 (Continuous handling equipment and systems).

Standards related to machine safety

Using the applicable harmonised standards in the development of machinery, protection and safety applications is a good aid to, and efficient means of ensuring that the end product fulfills the Machinery Directive's requirements.

The standards below are the most common standards within the Machine Safety category:

Standard	Type	Description	Content*
ISO/TR 18569:2004		Safety of machinery - Guidelines for the understanding and use of safety of machinery standards	How to apply to relevant Type A and Type B safety of machinery standards.
ISO 12100-1	**A**	Safety of machinery – Basic Concepts - General principles for design.	Basic terminology and methodology
ISO 12100-2	**A**	Safety of machinery – Basic Concepts - General principles for design.	Technical principles
EN 614-1:2006	**A**	Safety of machinery - Ergonomic Design Principles - Terminology and General Principles	Design of the machinery and ergonomic design of the workspace.
EN 614-2:2006 +A1:2008	**A**	Safety of machinery - Ergonomic design principles - Interactions between the design of machinery and work tasks	Design of the machinery and ergonomic design of the workspace.
ISO 14121-1:2007	**A**	Safety of machinery - Principles of risk assessment	Described procedures for identifying hazards, estimating and evaluating risk.
ISO 13857:2008	**B**	Safety of machinery - Safety distances to prevent hazard zones being reached by upper or lower limbs	Describes distances to Hazard zone for legs, arms and fingers.
EN 1005-4:2005 +A1:2008	**B**	Safety of machinery - Human physical performance - Evaluation of working postures and movements in relation to machinery	It provides guidance for the design of machinery or its component parts.
EN 60204-1	**B**	Safety of machinery - electrical equipment of machines - General requirments	Safety of persons and property etc. relating to electrical equipment of machines.
ISO 13855	**B**	Safety of machinery - Positioning of protective equipment with respect to the approach speeds of parts of the human body	What distance to a hazard zone to have with light curtains, laser scannners etc.
ISO 11161	**B1**	Safety of machinery - Integrated manufacturing systems - Basic requirements	Includes information about gap between floor and Safe guard(8.5.2) etc.
EN954-1 (ISO 13849-1)	**B1**	Safety of machinery - Safety related parts of control systems - General principles for design	Includes guidance for the selection of categories (risk estimation) etc.
EN 953	**B2**	Safety of machinery – General requirements for the design and construction of fixed and movable guards	This is the manual how to design Safe guarding. (fixed or movable)
EN 1088+A2:2008	**B2**	Safety of machinery - Interlocking devices associated with guards - Principles for design and selection	Describes how interlocks (switches) should be designed.
ISO 10218-1	**C**	Robots for industrial environments - Safety requirements - Robot	Describes basic hazards associated with robots and requirements to eliminate/reduce the risks.
ISO 10218-2	**C**	Robots for industrial environments - Safety requirements - Robot systems and integration	This covers how to integrate all equipment into a robot system.
EN 62061	**C**	Safety of machinery – Functional safety of safety related electrical, electronic and programmable electronic control systems	It contains requirements for machinery, which cannot be carried by hand during the work.
EN 619	**C**	Continuous handling equipment and systems – Safety and EMC requirements for equipment for mechanical handling of unit loads	Provides Safety instructions for usage of Material handling equipment.

**Text not taken from the standards.*

The importance of safety devices

It could crassly be said that the content of the Machinery Directive is that a machine must be safe to use. Some regard the requirement for CE marking as tiresome, expensive and demanding. There are other benefits apart from fulfilling the Directive's requirements. For example the working environment becomes safer, machine operation becomes more reliable and production becomes more efficient.

Guidelines for the selection of safety devices

The manufacture of safety devices for a machine requires consideration. Generally there are no problems in removing all risks through protection. The problem is to protect against the risk whilst at the same time maintaining the machine's ease of usage and accessibility. Four concepts ought to be taken into consideration when selecting safety devices:

- Accessibility - Safety - Cost - The Machinery Directive requirements

The following standards offer good guidance for the manufacture of safety devices:
- ISO 11161, Machine Safety - Integrated manufacturing systems. Basic requirements.
- ISO 13855, Machine Safety - Positioning of safety devices taking into consideration the speeds at which body parts approach the danger area.
- EN ISO 13857:2008, Machine Safety - Safety Distance to prevent arms and legs entering a danger area.
- EN 953, General requirements for design and manufacture of fixed and opening guards.
- EN 1088+A2:2008, Interlocking devices for combination with guards - Principles for design and selection.

Access control

The Machinery Directive states that it shall not be possible to reach moving and dangerous parts before the machine is in a safe condition. In exceptional cases the machine may be in operation, but at a reduced speed and controlled by a "hold-to-run" type of device.

It is therefore extremely important that the safety devices are positioned at the correct distance from the machine. Otherwise the machine will not have time to achieve a safe condition (standing still), before anyone enters the danger area. This is apparent, for example, in the case of interlocking moveable safety devices. The safety system will certainly stop the machine when the door is opened, however, will all of the machine's moving parts stop immediately?

Definitions

Compared to previous directives the list of definitions is clearer and more expansive. The definition of Safety Component is clearer. Annex 5 of the Directive also contains an indicative list of safety components.

Procedures for partly completed machinery

This new section describes what the manufacturer or his representative has to do before a partially completed machine can be released onto the market.

Legal amendment concerning Directive 95/16/EC

This is a correction concerning the Directive for Lifting Devices. The clearer definitions for lifting devices make it easier to determine which directive is to be applied.

Essential Health and Safety requirements

The new Health and Safety requirements contain nine definitions. The previous Directive had only three.

1.1.2(a) Principles for safety integration

This section concerns machinery lifespan. The previous Directive only covered assembly and decommissioning, whilst the new Directive also covers transport, assembly, disassembly, measures for making it unusable and scrapping.

1.1.6 Ergonomics

This point stipulates that discomfort, fatigue, physical and mental effects that the operator can be exposed to under the intended working conditions are to be reduced to a minimum.

1.1.7 Workstations

This new section covers safety-related requirements for operators.

1.1.8 Seats

This new section covers safety-related requirements for operators.

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1.2.1 Control system safety and reliability
This point has been developed and made clearer.

1.2.2 Control devices
The previous Directive stated a requirement for the operator to be able to see the machine from the primary operating position. The new Directive stipulates that the operator must be able to ensure that no-one is in the danger zone from every control position. This implies other requirements for the control systems of machines with two or more control positions. As an example the control system must be designed so that the use of one control position excludes the use of the others.

1.2.3 Starting
This point has been developed and made clearer.

1.2.4.2 Stop during operation
This point requires the Stop condition to be monitored and maintained when, for operational reasons, a Stop device is required not to interrupt the power supply to the drive function.

1.3.9 Risk of uncontrolled movements
This new section concerns movements that can arise following part of the machinery being stopped.

1.4 Required characteristics of guards and protective devices
See changes under the sub-headers below.

1.4.1 General requirements
This point stipulates that guards shall if possible protect against the ejection or falling of materials or objects, and against emissions generated by the machine.

1.4.2.1 Fixed guards
This point states that the fixing systems must remain attached to the guards or to the machinery when the guards are removed. There are different types of fixing solutions available. The machine manufacturer ought to select an appropriate fixing system in order to optimise the cost of procurement and installation.

The new Directive also states that the guards as far as possible must remain attached to the machinery when open.

1.4.2.2 Interlocking moveable guards
This section replaces 1.4.2.2 (Moveable guards) in the previous Directive. Moveable guards were previously divided into types A and B. The new Directive refers instead to interlocking moveable guards and moveable guards that are used together with an interlocking device and a guard locking device.

The following additional requirements have been added:
”Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, moveable guards must be equipped with a guard locking device in addition to an interlocking device that prevents the start of hazardous machinery functions until the guard is closed and locked, and keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.”

EN 1088 or ISO 14119 provide good guidelines for interlocking moveable safety devices.
EN 1088 is, however, currently being re-written.

1.5.1 Electricity supply
The point states that where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be eliminated. In other words the machinery must meet the requirements of the Low Voltage Directive (LVD).

1.5.7 Explosions
This point has been slimmed down. It does, however, refer to the specific Community Directive:

”Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.”

1.5.8 Noise and 1.5.9 Vibration
The extent of noise emission and vibration levels may be assessed with reference to comparative data for similar machinery.

1.5.15 Risk of slipping, tripping or falling
The section now clearly states that it is advisable to fit the machinery with handholds fixed relative to those parts in which people may conceivably move around.

1.5.16 Lightning strike
This section states that any machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.

1.7 Information
This section more clearly describes how information and warnings are to be presented on the machinery.

1.7.4.1 General principles for the drafting of instructions
This new section covers the requirements from point 1.7.4 in the previous Directive. In addition the information about the concepts of ”Original instructions” and ”Translation of the original instructions” is now clearer.

1.7.4.2 Contents of the instructions
This section covers the material previously under point 1.7.4 in the previous Directive. The material is clearer and more expansive. The requirements are described point by point in the new Directive.

1.7.4.3 Sales support material
This new section encompasses the requirements from point 1.7.4 in the previous Directive. In addition the section states that:
- Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects.

- Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

2.1 Foodstuffs machinery and machinery for cosmetics or pharmaceutical and hygiene products.
The section deals with machinery intended for use with foodstuffs or with cosmetics or pharmaceutical and hygiene products. The previous Directive only covered foodstuffs.

2.2.2 Portable fixing and other impact machinery
This section covers portable machinery for fixing and other portable impact machinery. The previous Directive did not address this type of machine.

3. Additional essential health and safety requirements to prevent the particular risk sources that arise due to machinery mobility
The section has been largely re-written for the purposes of clarification. It also contains a number of additions, such as references concerning control systems.

4. Supplementary essential health and safety requirements to
offset hazards due to lifting operations
Point 4.1.1 (Definitions) has been formulated to make the information clearer.

4.1.2.8 Machinery serving fixed landings
This new section contains five sub-headings.

4.1.3 Fitness for purpose
New section.

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6.1.1 Mechanical strength
This section states that: ”If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.”

Much of chapter 6 has been re-written in the interests of clarity. Section 6.4 (Machinery serving fixed landings) has been added.

Annex 2: Assurance

1.

A. EC Declaration of conformity of the machinery
The EC Declaration of conformity of the machinery must show the date and location.

B. Declaration of incorporation of partly completed machinery
This is an entirely new section that was not in the previous Directive.

Note that there is no longer a specific declaration of conformity for safety components.

2. Custody
A new requirement is that the manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery. This is valid for both machinery and partially completed machinery.

Annex 3: CE marking
This annex stipulates that the CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique. For further information refer to the legislation for CE marking (SFS 1992:1534).

Supplement: Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.

Annex 4: Categories of machinery to which one of the procedures referred to in Articles 12 and 13 must be applied
Parts of the contents have been re-worded for improved clarity. Other noteworthy changes are:
- Machinery for the manufacture of pyrotechnical products is no longer on the list.
- Closed combustion engines for mounting on underground machinery are no longer on the list.
- The point ”Logic units ensuring the safety functions of two-handed control units” has been replaced by ”Logic units to ensure safety functions.”
- The point ”Portable cartridge-operated fixing and other impact machinery”, has been added.

Annex 5: Indicative list of safety components referred to in Article 4 (c)
This annex includes some of the points referred to in Annex 4, for example guards for removable mechanical transmission devices, protective devices designed to detect the presence of persons, roll-over protective structures (ROPS) and falling-object protective structures (FOPS). The annex also encompasses different types of safety devices, valves, extraction systems for machinery emissions, monitoring systems, control systems, overspeed limitation devices, noise and vibration dampers and hoisting equipment.

Note that the list is intended as an illustration. Other products can also be considered as being safety components.

Annex 6: Assembly instructions for partly completed machinery
The annex stipulates that the assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery. The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partially completed machinery will be assembled, or to his authorised representative.

Annex 7:

A. Technical manufacturing documentation for machinery
The contents of this new annex previously belonged to Annex 5 (Declaration of conformity). The new Directive states that the technical documentation must contain a general description of the machinery. Even if this information is available in the instructions a copy of the description must be filed with the technical documentation.

The previous Directive only intimated that a copy of the risk analysis was to be included in the technical documentation. The new Machinery Directive now stipulates that this is the case.

The new Machinery Directive also stipulates that a copy of the EC Declaration of conformity of the machinery is to be included in the technical documentation. For partly completed machinery, the technical documentation must contain both the EC Declaration of conformity of the machinery and relevant assembly instructions.

For series manufactured machinery the technical documentation must contain the internal measures taken to ensure that the machinery remains in conformity with the Directive.

B. Relevant technical documentation for partly completed machinery
This section is new and is similar in content to that in part A.

Annex 8: Assessment of conformity with internal checks on the manufacture of machinery
This annex describes the regulations concerning serial manufactured machinery. It states that the manufacturer or his representative must draw up technical documentation for each series concerned. The manufacturer must also take all necessary measures in the manufacturing process to ensure that the manufactured machinery concurs with the technical documentation.

Annex 9: EC type inspection
This new annex is similar to Annex 6 in the previous Directive, however point 9.2 stipulates that the machinery manufacturer must continually ensure that the machinery conforms to the level of technical development.

By way of addition point 9.3 states that the manufacturer must every fifth year request the notified body to review the validity of the EC type inspection certificate.

Annex 10: Full quality assurance
The annex describes the conformity assessment of machinery, referred to in Annex 4, manufactured using a full quality assurance system. It also describes the procedure for the notified body to assess and approve.

Annex 11: Cancellation or withdrawal of issued documents or approvals
This new annex is similar to Annex 7 in the previous Directive. Section 8 states that notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

Section 9 is an addition stipulating that Member States must take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the documentation of its customers are sent to another body or are made available to the Member State which has notified it.

Annex 12: Correlation table
This table lists the relationship between the previous and the new Directives. The table helps to identify material that has been added.

For further information
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Int. head office: Troax AB P.O. Box 89 SE-330 33 Hillerstorp Sweden
Tel +46 (0)370 828 00 Fax +46 (0)370 828 11 info@troax.se www.troax.com

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