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Risk Assessment

Section 17.10

The EU Machinery Directive

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European legislation

The legislation in the European Union (EU) builds on:

- Regulations
- Directives
- European (EN) Standards

The EU open market requires

- Free movement of:
  - Goods
  - Persons
  - Services
  - Capital

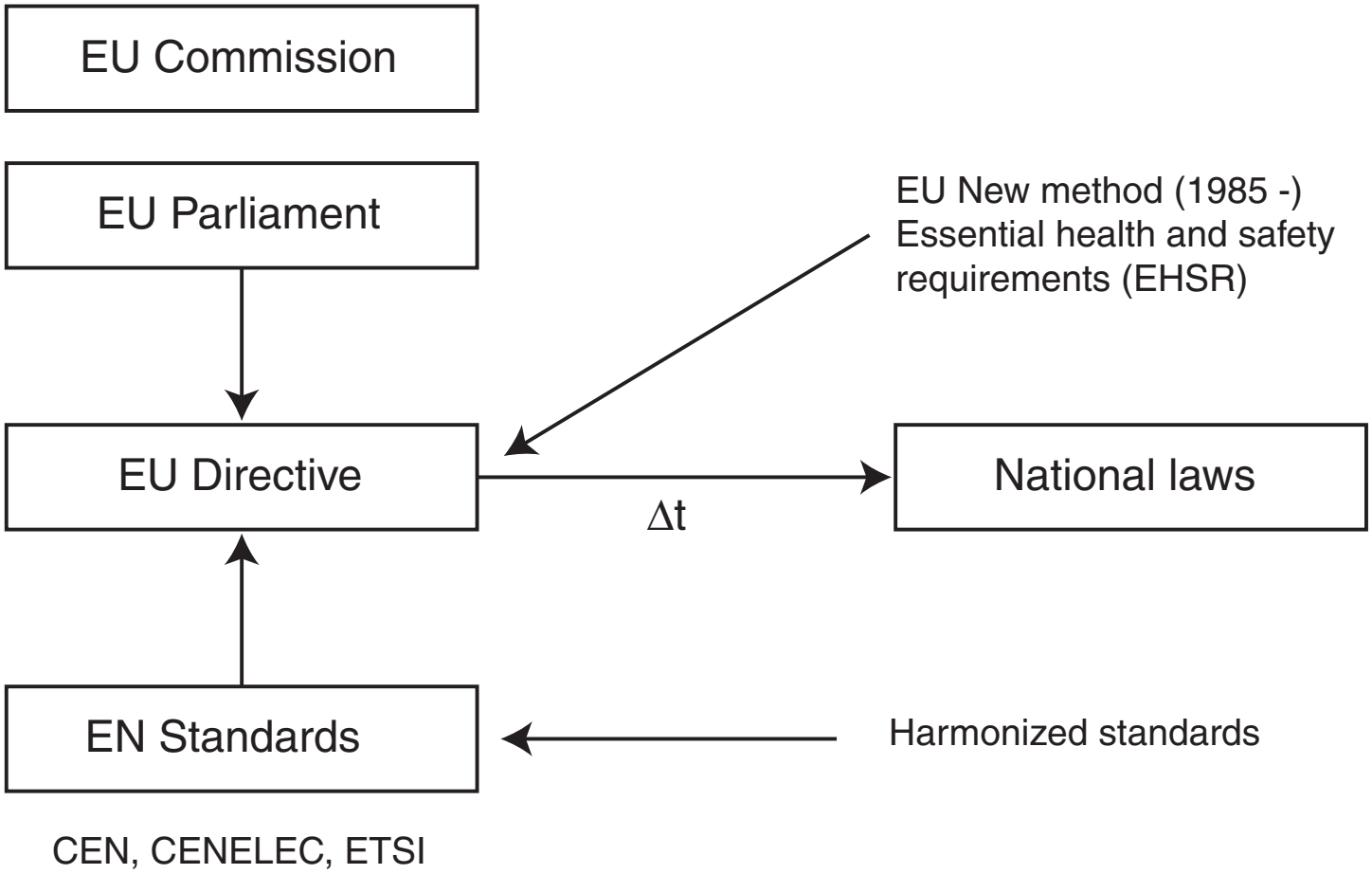
- To obtain free movement of goods, we have to remove business barriers like:
  - Physical barriers (controls at national borders)
  - Technical barriers (national safety requirements)
  - Fiscal (financial) barriers (taxes)

The new method

- Directives give basic requirements to safety, health, and the environment (SHE) (- and do not contain technical specifications)
- Technical specifications are given in harmonized standards
- It is up to the user whether or not she wants to comply with the standards
- Products that are made according to harmonized standards are assumed to comply with the directive's "Essential health and safety requirements" (EHSR)

The "new approach" was created to overcome the difficulties of the "old approach", which lead to highly technical and complex directives.

New method directives



Two main types of directives

- Business barrier directives (100A)
  (e.g., the Machinery Directive). These directives are also called “maximum directives”

- Minimum directives (118A)
  (e.g., the Environmental Impact Assessment (EIA) Directive, and the Seveso II Directive)

Benefits of product directives

- Before, manufacturers had to comply with multiple conflicting national compliance systems
- A product that complies with the requirements can be sold in all member countries in EU/EEA
- The required activities may result in safer products and/or enhanced manufacturing processes

Standards organizations

The EU standards are developed by:

- CEN (Comité Européen de Normalisation)
- CENELEC (Comité Européen de Normalisation Electrotechnique)
- ETSI (European Telecommunication Standards Institute)

A total of approximately 750 standards “support” the Machinery Directive.

The Machinery Directive

- The first Machinery Directive, 89/392/EEC, was approved in 1989
- The current version is 98/37/EEC - approved in 1998
- A new version, 2006/42/EC was approved in 2006 - and will enter into force in 2008

The revised directive 2006/42/EC does not introduce any radical changes compared with 98/37/EC but aims to consolidate the achievements of the Machinery Directive in terms of free circulation and safety of machinery while improving its application.

Objectives of the Directive

The objectives of the Machinery Directive are:

- To ensure free circulation of machinery on the internal market
- To ensure a high level of protection of users and other exposed persons against risk
- To ensure safety by design

Stakeholders

The main parties that should be interested in the EU Machinery Directive are:

- Manufacturers of machinery
- Their representatives in the European Union
- Importers
- Trade companies
- The responsible for placing the product on the EU market

Placing on the market

A product is placed on the EU market when it is made available for the first time. This is considered to take place when a product is transferred from the stage of manufacture with the intention of distribution or use on the EU market.

What is machinery?

☞ Machinery: An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

– An assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion.

For more details, see the Machinery Directive Article 2.

Interchangeable equipment

☞ Interchangeable equipment: A device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

Safety components

☞ Safety component: A component, provided that it is not interchangeable equipment, which the manufacturer or his authorized representative established in EU places on the market to fulfill a safety function when in use and the failure or malfunction of which endangers the safety or health of exposed persons.

Safety components are listed in Annex V of the directive. An example of a safety component is an emergency stop device.

Are these machines?

- An office chair?
- A wheelchair?
- An outboard motor?
- A food processing plant?
- A power station?
- An oil refinery?

What is a machine?

The following “machines” are exempted from the scope of the Machinery Directive:

- Manually powered machinery (except for lifting)
- Machinery for medical use, used in direct contact with patients
- Special equipment for use in fairgrounds and/or amusement parks
- Steam boilers, tanks and pressure vessels
- Machinery used for nuclear purposes
- Firearms
- Seagoing vessels
- Agricultural and forestry tractors
- and so on

A complete list of excluded machinery is found in Article 1, para. 3 of the Directive.

Requirements

The manufacturer or his representative, resident in the EU is responsible for the following:

- To carry out a hazard assessment to analyze all of the risks related to the machinery and if required apply measures to reduce these
- To ensure that the machinery conforms to the relevant essential health and safety requirements
- To draw up an EU declaration of conformity/incorporation and affix a CE mark
- To draw up a technical file

Machines for own use

The Machinery Directive also applies for companies producing machines for own use.

Para: 8.7: "...The same obligations shall apply to any person assembling machinery or parts thereof or safety components of various origins or constructing machinery or safety components for his own use."

Annexes to the Machinery Directive

1. Essential health and safety requirements (EHSR) relating to the design and construction of machinery and safety components
2. Contents of the declaration of conformity
3. CE-marking
4. “Dangerous” machines and safety components – that need a special procedure and involvement of a notified body
5. List of safety components
6. Assembly instructions
7. Technical file

(The above titles are abbreviated)

Contents of Annex I

Annex I defines the essential health and safety requirements (EHSR) the machines must fulfill. Annex I has the following chapters:

- EHSR (general)
- EHSR for certain categories of machinery
- EHSR to offset the particular hazards due to the mobility of machines
- EHSR to offset the particular hazards due to lifting operations
- EHSR for machinery intended for underground work
- EHSR to offset the particular hazards due to lifting or moving of persons

Example of EHSR in Annex I

1.2.1 Safety and reliability of control systems

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

- They can withstand the intended operating stresses and external influences
- A fault in the hardware or the software of the control system does not lead to hazardous situations
- Errors in the control system logic do not lead to hazardous situations
- Reasonably foreseeable human error during operation does not lead to hazardous situations

Comment: This is an example of an EHSR that needs to be elaborated and specified in a standard.

Example of EHSR in Annex I

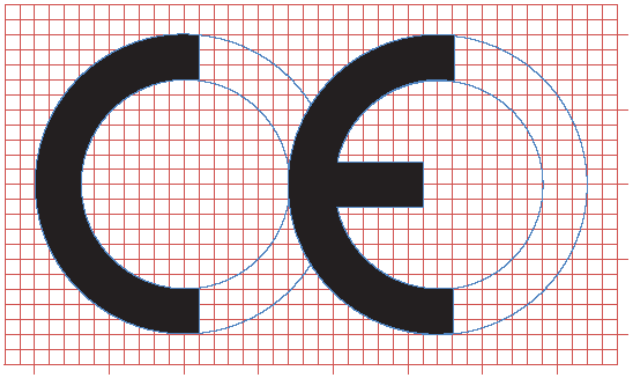
1.7.3 Marking of machinery

All machinery must be marked visibly, legibly, and indelibly with the following minimum particulars:

- The business name and full address of the manufacturer and, where applicable, his authorized representative,
- The CE marking (as specified in Annex III)
- Designation of series or type
- Serial number (if any)
- The year of construction

CE-mark

CE is an abbreviation for Communauté Européenne being the French way of saying European Community.



Foreseeable misuse

Annex I, para. 1.1.2 c): When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorized representative must envisage not only the intended use of the machinery but also any reason- ably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user’s attention to ways—which experience has shown might occur—in which the machinery should not be used

Examples of “dangerous” machines in Annex IV

- Circular saws
- Band saws
- Portable chain-saws
- Presses
- Planing machines for woodworking
- Machines for manufacture of pyrotechnics
- and so on

The above list is abbreviated - see Annex IV for a complete list.

Instructions handbook

The required contents of the instructions handbook is listed in Annex I, para. 1.7.4

- Foreseen use of the machinery
- Workstations likely to be occupied by operators
- Instructions for safe:
  - putting into service
  - use
  - handling
  - assembly, dismantling
  - adjustment
  - maintenance (service and repair)
- Training instructions (if necessary)
- and so on

See Annex I for details

Technical file

- An overall drawing of the machinery together with drawings of the control circuits
- Full detailed drawings, accompanied by any calculation notes, test results, etc. required to check the conformity of the machinery with the essential safety requirements
- A list of:
  - The EHSRs
  - Applicable harmonized standards
  - Other standards used
  - Other technical specifications

  that were used when the machinery was designed
- A description of methods adopted to eliminate hazards presented by the machinery

Technical file

(cont.)

- Any technical report or certificate obtained from a competent body or laboratory (optional)
- A copy of the instruction for the machinery
- For series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive

The documentation shall be retained and kept available for up to ten years from the time of last manufacture of the machinery.

Declaration of conformity

After performing a critical design review, making changes to the product design that will minimize risks of harm, and compiling the “Technical file,” the manufacturer may affix the CE-mark and prepare a “Declaration of conformity.” The Declaration must identify:

- Who you are
- What product it refers to
- What directives are involved
- What standards are applicable
- Where test results can be found
- Who is responsible in your company

Notified body

- A notified body must be located within the geographical boundaries of EU/EEA
- An approval by a notified body located anywhere in the EU/EEA is valid throughout the EU/EEA

Eight steps

1. Does the Machinery Directive apply?
2. Do other legislations apply?
3. Who is responsible?
4. Hazard analysis
5. Principles of safety requirements
6. Use European standards for details
7. Documentation
8. Declaration of conformity and CE Mark

Standards related to the Machinery Directive

A-Standards

Design principles and methods for all machinery

B_1-Standards

Aspects of safety valid for a wide range of machinery

B_2-Standards

Aspects of safety devices valid for a wide range of machinery

C-Standards

Safety of one category of machinery

The use of standards is not mandatory. Conformity with the EHSRs may also be demonstrated directly.

Examples of standards

A-Standards

EN 292 (Basic machine safety issues)

EN 1050 (Risk analysis)

B_1-Standards

EN 294 (Safety distances to avoid that parts of the human body are endangered)

B_2-Standards

EN 418 (Emergency stop equipment)

C-Standards

EN 1218 (Safety requirements related to wood treatment machinery)

EN, national and ISO standards

When EN standards are issued, they are (normally) published as national standards, for example:

- EN 292-1 $\Rightarrow$ NS-EN 292-1 in Norway, and BS-EN 292-1 in Britain.

Many EN standards are now transformed into international standards, for example:

- EN 292-1 $\Rightarrow$ ISO 12100-1
- EN 1050 $\Rightarrow$ ISO 14121

Strategy for risk reduction

The designer shall take the following actions: (ISO 12100-1)

- Specify the applications and limitations of the machine
- Identify the hazards and evaluate the risk
- If possible, remove the hazards or reduce the risk as far as possible
- Implement barriers and/or safety functions against the residual risks
- Inform and warn the user against residual risks
- Consider other required actions

Strategy for risk reduction

When describing the application(s) of the machine, we have to consider:

- Potential incorrect use resulting from carelessness and foreseeable misuse (e.g., children's use of the machine)
- Reflex actions of operators when failures of the machine occur
- Expect that the simplest way to carry out actions is selected by the users of the machine
- Consider actions by special users like disabled, children, and so on.

Risk assessment

The manufacturer of the machinery or his authorized representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

Machinery under the scope of the machinery directive must comply with the ESRSs of Annex I of the Directive concerning design and construction.

Proposed risk assessment methods

The following methods are proposed in ISO 12100 (EN 1050):

- Preliminary hazard analysis (PHA)
- What-if analysis
- Failure modes and effects analysis (FMEA)
- Fault simulation for control systems
- MOSAR
- Fault tree analysis (FTA)
- Delphi technique

A detailed list of relevant hazards is provided in ISO 12100

Elements of risk

RISK

related to the considered hazard

is a function of

SEVERITY

of the possible harm that can result from the considered hazard

and

PROBABILITY OF OCCURRENCE of that harm

- Frequency and duration of exposure
- Probability of occurrence of hazardous event
- Possibility to avoid or limit the harm

PHA worksheet

For machinery risk analysis

For simple machinery systems it is often sufficient to use a version of preliminary hazard analysis (PHA) for the risk analysis. The last three columns are used to document risk reduction in (i) design, (ii) guards and protective measures, and (iii) information about risk and special requirements like certificates.

System/equipment: Performed by:

Phase: Date:

Ref	Hazard	Event/where	Cause	Consequence	P	C	Design/constr.	Protection	Inform.

For further information about PHA, see the PHA presentation.