

The Machinery Directive 2006/42/EC



European Commission
Enterprise and Industry



European Commission
Enterprise and Industry

Aims of the Machinery Directive

- To ensure the free movement of machinery on the EU market whether manufactured in the EU or imported
- To ensure a high level of protection of users of machinery (workers and consumers) and other exposed persons
- To ensure safety by design

Scope

the basic definition of machinery

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

Machinery also includes

- Assemblies missing only components for connexion to the energy supply
- Assemblies to be mounted on a means of transport or a building
- Assemblies of machinery that function as an integral whole
- Manually powered lifting machinery

Other products in the scope designated by « machinery »

- (b) Interchangeable equipment
- (c) Safety components
(indicative list in Annex V)
- (d) Lifting accessories
- (e) Chains ropes and webbing for lifting
purposes
- (f) Removeable mechanical
transmission devices (PTO shafts)

Partly completed machinery (PCM)

- Almost machinery – lacking some elements in order to function
- Cannot perform a specific application
- Intended to be incorporated with other machinery, other PCMs or other equipment to form final machinery
- Subject to a specific procedure

Not subject to the Directive as such

- Machinery components other than safety components
- Sub-assemblies that are not PCMs
- The machinery manufacturer must choose components and sub-assemblies that enable the machinery to comply with the Directive

Excluded from the scope

- Fairground equipment
- Machinery for nuclear purposes
- Weapons
- Tractors, road vehicles, ships
- Temporary research machinery
- Machinery for police or military purposes

Exclusions (continued)

- Certain categories of low voltage electrical machinery
 - household appliances for domestic use
 - audio and video equipment
 - information technology equipment
 - ordinary office machinery
 - circuit-breakers and switches
 - electric motors
- High voltage switch and control gear and transformers

When the Directive applies

- The Directive applies to machinery when it is first placed on the EU market
= when it is first made available for distribution or use in the EU
- Applies to new machinery manufactured in the EU and new or used machinery imported from outside the EU

Obligations of machinery manufacturers

- Make a risk assessment
- Apply the relevant essential health and safety requirements
- Constitute a technical file
- Carry out a conformity assessment
- Draw up and sign an EC Declaration of conformity
- Affix the CE marking

Obligations of manufacturers of partly completed machinery

- Draw up and sign a Declaration of incorporation
- State which essential health and safety requirement have been fulfilled
- Constitute the relevant technical documentation
- Provide assembly instructions to the manufacturer of the final machinery

Authorised representative

- The manufacturer may entrust an authorised representative established in the EU with all or part of his obligations
- It is not mandatory to have an authorised representative in the EU
- It is mandatory to nominate a contact person in the EU for the technical file

Annex I - essential health and safety requirements (EHSRs)

1. General principles and requirements for all machinery
2. Foodstuffs, portable hand-held and woodworking machinery
3. Mobility of machinery
4. Lifting operations
5. Underground machinery
6. Machinery for lifting persons

Application of EHSRs

- Based on the risk assessment
- Taking account of the state of the art
- Principles of safety integration

Order of priority:

1. Inherently safe design measures
2. Technical protective measures
3. Warnings, signs and instructions

Harmonised standards

- EHSRs are mandatory when the risk exists
- The EHSRs are supported by the technical specifications of European harmonised standards
- Harmonised standards are voluntary
- Their application confers a presumption of conformity to the EHSRs they cover

A, B and C-type standards

- A-type standards
 - methodology
- B-type standards -
 - common safety solutions
- C-type standards -
 - particular categories of machinery

C-type standards take precedence

Conformity assessment procedures

- Most categories of machinery (not listed in Annex IV) are subject to the procedure for assessment of conformity with internal checks on manufacture
- For these categories there is no need for third-party conformity assessment

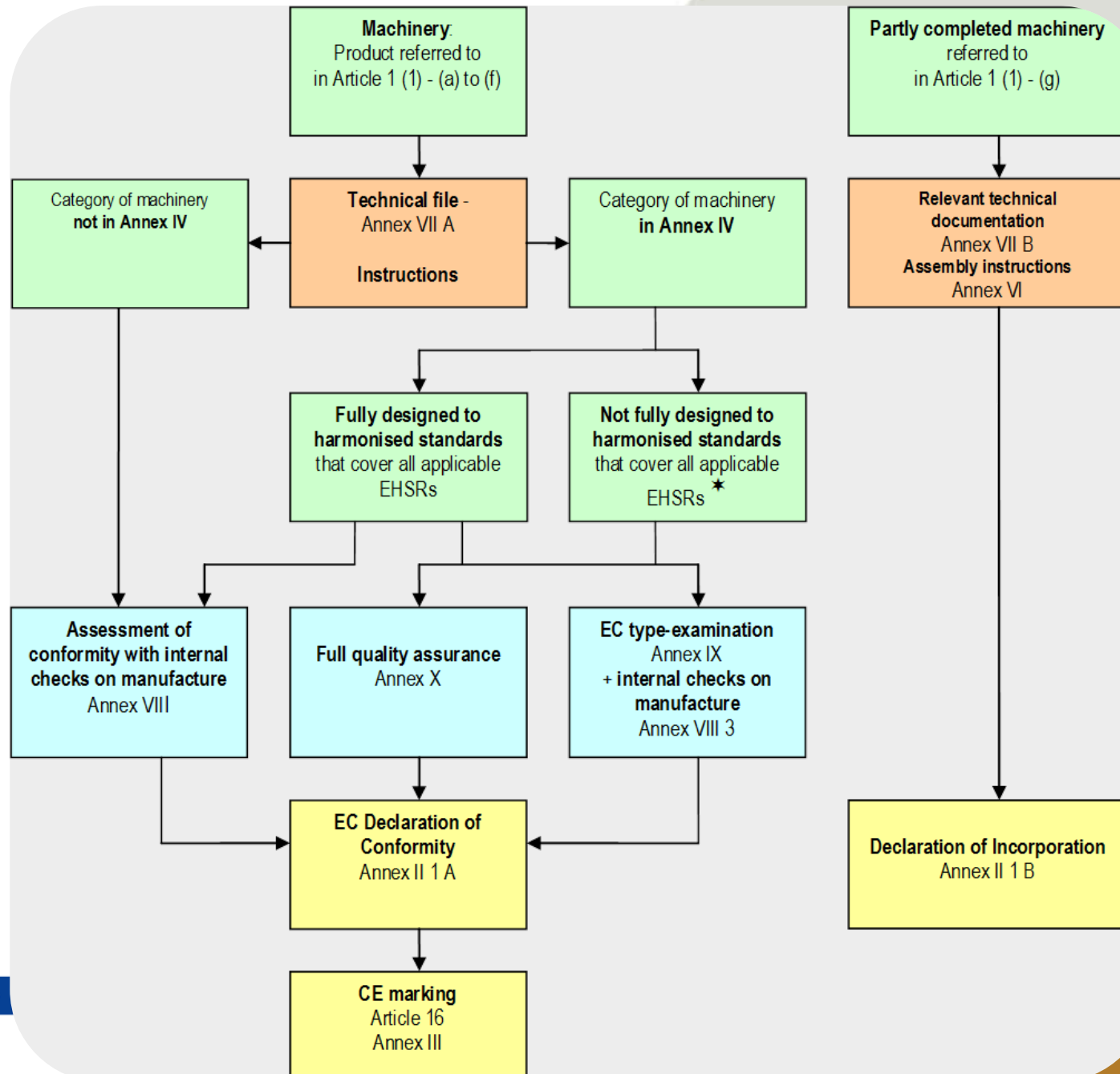
Machinery listed in Annex IV

- If the machinery complies with harmonised standard(s) that cover all the applicable EHSRs
 - internal checks
- If not
 - EC type-examination by a Notified Body or
 - Approval of full quality assurance

Notified Bodies

- Manufacturers can address any Notified Body that is competent for the category of machinery and the procedure concerned
- EC type-examination certificates or approvals of full quality assurance systems are valid throughout the EU

Conformity Assessment procedure for machinery and PCM



Enforcement - market surveillance

- The Member States are responsible for market surveillance
- Basic rules – EC Regulation 765/2008
- Customs can check the conformity of products entering the EU
- Manufacturers may be required to bring their products into conformity
- Unsafe products must be removed from the market

Directive 2006/42/EC

Date of application

- The revised Machinery Directive has been applicable since 29 December 2009
- Machinery placed on the market before 29/12/09 was subject to Directive 98/37/EC

Further information

http://ec.europa.eu/enterprise/sectors/mechanical/machinery/index_en.htm

Thanks for your attention !

ANNEX

Institutions dealing with Machinery Directive

