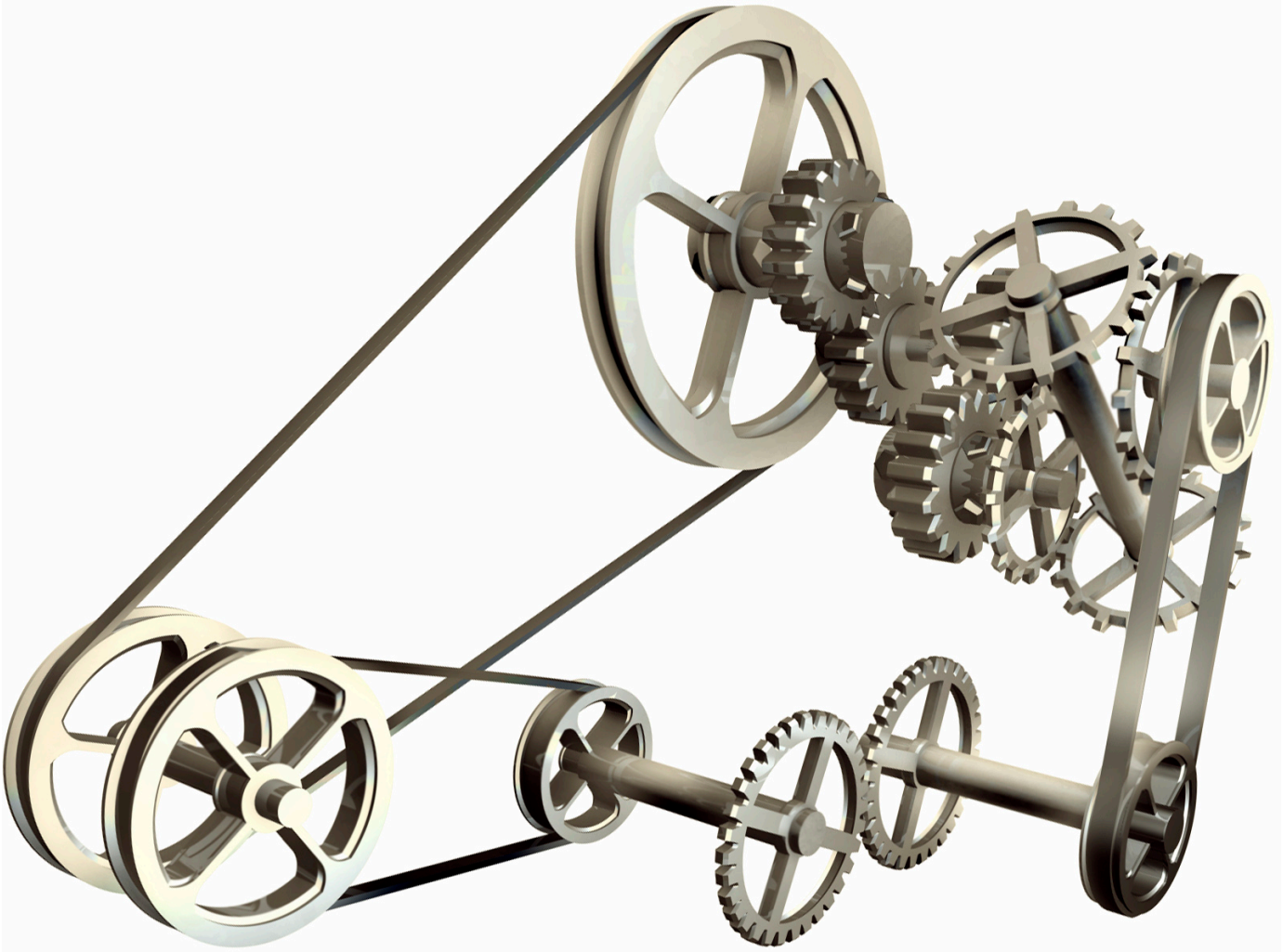
Overview of the Machinery Directive (2006/42/EC)



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Brief history & context of the Directive

In 1985, a series of 'New Approach Principles' were introduced into the European Community (EC) that would enable the free movement of goods across the region. They laid out a set of market parameters for the EC such as Essential Health and Safety Requirements for workers in the Community and minimum product requirements for goods going on sale in the region. From these principles, a number of specific Directives were developed to govern particular types of products and operating characteristics, including:

- Low Voltage Directive
- EMC Directive
- Machinery Directive
- ATEX (Explosive Atmospheres)
- Pressure Equipment Directive
- Gas Appliances Directive

Within the Directives specific minimum performance criteria is given and products that meet these can be said to have a 'presumption of conformity'. This can be validated through product assessment against harmonised Standards, either by an in house laboratory or by a third-party assessment organisation – such as an accredited certification body.

Products that meet the essential requirements of the Directives that govern them can be placed on the market but a declaration of conformity must be made, a technical file for the product must available in the EU and the product must carry the mandated CE Marking as required by the Directives.

Some of the Directives, e.g. ATEX and Gas also require that CE Marking for certain product types is supported by mandatory certification from a qualified body. On these Products the CE Marking is accompanied by the Notified Body Number below the CE symbol. Compliance with these regulations is then enforced by surveillance activities carried out by member states.

More information on the New Approach Directives can be found at:
http://www.newapproach.org/Directives/Default.asp

Overview: The Machinery Directive (2006/42/EC)

The Directive has been put in place because:

"The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance" (Paragraph 2).

The Directive will ensure safe design, installation and use of machines in the EU. Compliance with the Directive is mandatory for machines being put into service or on the market in the EU. Article 2 of the Directive specifies the types of products that the Directive applies to:

- 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,
- an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
- assemblies of machinery referred to in the first, second and third indents or partly completed machinery
- an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

Exclusions

- Fairground/amusement park equipment
- Machinery for nuclear purposes
- Agricultural and forestry tractors
- Motor vehicles and their trailers covered by Directive 70/156/EEC
- 2 or 3 wheeled motor vehicles covered by Directive 2002/24/EC
- Motor vehicles intended for competition
- Means of transport by air, water or rail (but not equipment mounted on them)
- Seagoing vessels and mobile offshore units
- Machinery designed for military or police purposes
- Mine Winding Gear
- Machinery intended to move performers during artistic performances
- Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery

- Weapons, including firearms
- Machinery specifically designed and constructed for research purposes for temporary use in laboratories
- Electrical and electronic products falling under Directive 73/23/EEC of 19 February 1973 (including household appliances, ordinary office machinery, low voltage switchgear and control gear)**
- High Voltage Switchgear and control gear
- High Voltage Transformers

Partly completed machinery

Directive 2006/42 EC also contains requirements for partially completed machinery in Article 13

> "Procedure for partly completed machinery
>
> 1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:
>
>   (a) the relevant technical documentation described in Annex VII, part B is prepared;
>   (b) assembly instructions described in Annex VI are prepared;
>   (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.
>
> 2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery."

ANNEX VI also makes a requirement for assembly instructions for partly completed machinery

> "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, so as not to compromise safety and health.
>
> The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.
>
> Risk assessment documentation should be included in the technical file
>
> Declaration of incorporation and assembly instructions for partly completed machinery incorporated into machinery are now required."

Radiation & hazardous substances

The Directive contains sections governing the risk to operators from both ionizing and non-ionizing radiation and hazardous substances. They read:

> "1.5.10 Radiation
>
> Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.
>
> Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.
>
> Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.
>
> 1.5.13 Emissions of Hazardous materials and substances
>
> Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.
>
> Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.
>
> Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect."

Surveillance and enforcement

The combined clauses of Articles 4, 14 and 19, ensure strong surveillance and enforcement of the Directive for machines and incomplete machines and facilitate the sharing of information between member states – to make the process of surveillance and compliance enforcement more rigorous across the EU.

Article 4 leads with:

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.

2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.

3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment"

The sharing of information between member states and their willingness to ensure safe and compliant equipment is in the region should not underestimated by machine manufacturers. Surveillance and enforcement in the EU is becoming more sophisticated as time progresses.

'Under conditions that can reasonably be foreseen'

'Foreseeable' other use (or misuse) of Machinery must also be taken into consideration when assessing the product for compliance with the Directive. This concept appears several times during the text of the Directive – most notably in Annex 1 in clause 1.1.2. c)

> c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably 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.

Perhaps this can best be addressed by manufacturers and facility staff via a risk assessment, where 'foreseen' alternative uses for a machine can be highlighted and mitigated as necessary. Similarly, manufacturers must also take into account that some types of equipment will be operated by non-professional operators and so designers and builders will need to be aware of that when they create the equipment – this should encourage inherently safer and more intuitive design.

Safe 'transportation' not just handling

Annex 1.1.5 of the Directive makes specific reference to how 'transportation' of the machinery, not just 'handling' should be taken into consideration. This explicitly extends the protection of the Directive to those involved in the freight and logistical transfer of equipment as well as those who might handle it on site.

Requirements on ergonomics, operating positions and seating

The Directive is not only concerned with the safety of the machinery, it also expressly requires that ergonomic factors and stresses faced by operators must be taken into consideration in the design of the machine.

"1.1.6. Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

- allowing for the variability of the operator's physical dimensions, strength and stamina,
- providing enough space for movements of the parts of the operator's body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. Operating positions

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery. The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided."

Instruction documentation

The requirements for instructional documentation are significant in the Directive:

"1.7.4 All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service. The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand."

Interestingly, the concept of 'under conditions that can be reasonably foreseen' appears again in the instructions annex, with 1.74.1 requiring the manufacturer should take any foreseeable misuse into consideration when drafting their instructions, despite the fact that it is still misuse and could be hazardous.

User instructions should include:

"1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

(a) the business name and full address of the manufacturer and of his authorised representative;

(b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);

(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;

(d) a general description of the machinery;

(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;

(f) a description of the workstation(s) likely to be occupied by operators;

(g) a description of the intended use of the machinery;

(h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;

(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;

(j) instructions relating to installation and assembly for reducing noise or vibration;

(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

(n) the essential characteristics of tools which may be fitted to the machinery;

(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;

(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;

(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;

(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

(u) the following information on airborne noise emissions:

- the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,

- the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),
- the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A). These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

Symbols and pictograms

With the increasing migration of workers between member states, local language instructions may not necessarily be understood by machine operators, so the Directive makes provision for non-textual communication on the machinery so risks and warnings can be easily understood by all.

Conformity assessment requirements

Annexe IV of the Machinery Directive defines categories of machinery to which the Conformity Assessment routes outlined in Article 12 refer, creating 3 categories of equipment, Non-Annexe IV Machinery, Annexe IV Machinery and Safety Components and Incomplete Machinery.

The requirements for Non-Annexe IV Machinery are:

- Self declaration
- Technical File
- That manufacturer takes all necessary measures to ensure that the manufacturing process ensures compliance with the Technical File and the Directive

The requirements for Annexe IV Machinery using Harmonised Standards are:

- Machine manufactured in accordance with Harmonised Standards AND, these standards meet the EHSR's
- While the onus is on the manufacturers to ensure 'state of the art' they must choose one of the following approaches:
  - Internal checks as Annexe VIII
  - EC Type Examination by Notified Body and Internal checks as Annexe VIII
  - Full Quality Assurance by Notified Body to Annexe X
  - Onus on manufacturer to ensure 'State of the Art'

The requirements for Annexe IV Machinery using Non-Harmonised Standards are:

- Machine manufactured in accordance with Non-Harmonised Standards or Harmonised standards only partially applied, or if Harmonised standards do not exist or these standards meet do not address all the EHSR's
- While the onus is on the manufacturers to ensure 'state of the art' they must choose one of the following approaches:
    - EC Type Examination by Notified Body and Internal checks as Annexe VIII
    - Full Quality Assurance by Notified Body to Annexe X

NB: Full Quality Assurance to Annexe X by Notified Body is a robust solution

Paragraph 20 of the Directive states:

> "Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable."

Paragraph 23 additionally states:

> "The manufacturers or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures"

Therefore for conformity assessment, the first thing a manufacturer should do is a risk assessment on the proposed product. Annex 1 helpfully states what this should include:

> "1. The manufacturer of machinery or his authorised 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.
>
> By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:
>
> - determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,
> - identify the hazards that can be generated by the machinery and the associated hazardous situations,
> - estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
> - evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,
> - eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b)."

Then a manufacturer should review all the Directives that are applicable to their products – not just the Machinery Directive. If they need guidance on which Directives these are, their test and certification partner will be happy to identify them. These are likely to include the Atex Directive, EMC Directive, the Energy Using Products Directive, the Pressure Equipment Directive and the Gas Appliances Directive.

Once the correct Directives have been identified the machine should be applied to the appropriate test processes – as outlined in specific harmonised Standards.

Once the product has been tested to confirm compliance, then a test report and a Technical File (including the risk assessment, test reports etc) and a manufacturers 'Declaration of Conformity' for the machine needs to be generated.

Then CE Marking can be applied to the machine and it can be shipped with the declaration and the instructions for assembly and use.

Requirements: The Technical File

The technical file is a mandatory requirement and should include:

- Equipment's general description
- Drawings/Service manual
- Information on standards applied
- Test reports / Photos
- Rationale for compliance including reference to Harmonized or other Technical Standards
- Copy of Declaration of Conformity
- Changes control procedure
- ISO 9001 – Approval Related Procedures
- Any other safety related documents/procedures

Requirements: The EC Declaration of Conformity

The declaration of conformity must identify:

- Manufacturer
- Responsible person (by name and job title)
- Exact product type/name
- Year of affixation of CE Marking

- List of applicable standards
- Place and Date

It is the written declaration by the manufacturer or his authorised representative that *the equipment to which CE Marking has been affixed, complies with the Machinery Directive.* The person who signs the Declaration of Conformity is personally responsible for the conformity of the product. Making a false Declaration can lead to prosecution, fines and in extreme cases imprisonment.

A flow chart illustrating the Conformity Assessment Routes can be found in Appendix 1 at the end of this document.

Conclusion

The Machinery Directive 2006/42/EC is as much about improving the design of a Machine, as it is about manufacturing it, building it correctly and using it safely. Fortunately to demonstrate compliance with the Directive, help is available from your partner test and certification body, who will be happy to go through the requirements, processes and options with you. To review a copy of Machinery Directive (2006/42/EC) for yourself, visit the Europa Website at: http://ec.europa.eu/enterprise/mechan_equipment/machinery/revdir.htm

For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDLAB, email icenter@intertek.com, or visit our website at www.intertek-etlsemko.com.

Appendix 1:
Conformity Assessment Routes