Chapter 2
EU Legislation

2.1 EU Legislation

2.1.1 Introduction

A few words about EU legislation is appropriate in order to establish a certain framework for the subjects dealt with in this guideline, which sets focus on fulfilling Machinery Directive requirements—especially the proper carrying through of risk assessments.

The basic or primary EU legislation—only to be shortly mentioned here—is composed of the Treaties on the European Union, introduced by the Treaty of Rome in 1957 and revised through the years by several Treaties—last time in 2007 by the Treaty of Lisbon. The Treaties define e.g. the decision-making process for more specific EU legislation and the possibilities for the adoption of such secondary legislation.

Secondary legislation (i.e. Directives and Regulations) must have legal base in Articles of the applicable Treaty.

Regulations are EU legislation which is directly applicable and binding in all EU Member States without the need for any national implementing legislation. This direct applicability of the EU legislation ensures a more transparent and uniform legislation in EU. For example, the general EU legislation on chemicals is based on the REACH Regulation 1907/2006, and the classification and labeling of chemicals on the CLP Regulation 1272/2008.

Directives are EU legislation which binds the Member States as to—what could be called—the objectives to be achieved within a certain time-limit while leaving the national authorities the choice of form and means to be used. Directives have to be implemented in national legislation in accordance with the procedures of the individual Member States.

T. Jespen, *Risk Assessments and Safe Machinery*,
Springer Series in Reliability Engineering,
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Amongst the directives you encounter directives as the Product directives with the objective of establishing the same requirements (**Total harmonisation**) for a group of products, and directives as the Workplace directives which put forward minimum requirement (**Minimum harmonization**) concerning health and safety at work.

Decisions which are binding for those to whom they are addressed, are also part of the secondary EU legislation. They do not require national implementation.

As supporting non-binding instruments you find **Recommendations** and **Opinions** and also judgments of the European Court of Justice triggered by the European Commission, national courts or individuals.

2.1.2 Product Directives

(Based on Art. 114 of the present Treaty)

Product directives aim at ensuring the **free movement of goods** (a cornerstone of the single market) by preventing technical barriers to trade. The directives are based on complete **technical harmonisation**, i.e. by laying down the Essential Health and Safety Requirements (**EHSR**) that the regulated products placed on the market (and/or put into service) must meet.

The essential requirements deal primarily with the protection of health and safety of the users. Sometimes they cover other fundamental aspects as for example the protection of property or the environment. Only products complying with the essential requirements may be placed on the market and/or put into service.

The essential requirements are elaborated to ensure a high level of protection and the Member States cannot deviate from these requirements, whether to attain a higher or lower protection level, **but** Member States may regulated the use (e.g. restrict the use) of a product as long as the supplementary regulation does not imply a technical modification of the product.

More definite technical specifications of products meeting the essential requirements of the directives are laid down in **harmonised standards**. Products manufactured according to harmonised standards benefit from a presumption of conformity with the corresponding essential requirements, but the application of harmonised standards (as well as other standards) remains voluntary, and manufacturers may always choose other ways of meeting the EHSR requirements and documenting compliance.

Some common elements of Product directives are:

- **Scope** that defines the range of products covered by the directive or the nature of the hazards the directive is intended to avert. Note that several directives may apply to the same product.
- **Essential requirements** that are enumerated in annex(s) to the directive.

- **Conformity assessment procedures** subdivided into modules based on manufacturer (first party) assessment or third party (Notified Body) certification, and related to the design phase, the production phase or both.
- **CE marking** which symbolises compliance with all provisions of the applicable directives providing for its affixing.
- **Technical documentation** (file) which the manufacturer is obliged to draw up, containing the necessary information to demonstrate the conformity of the product to the applicable requirements.
- **Declaration of conformity** (a part of the conformity assessment procedure) which for example must accompany machinery, identifying the directives according to which it is issued and containing information on the manufacturer, Notified Body (if relevant), etc. The Machinery Directive also operates with a **Declaration of incorporation**.

Product directive examples:

- Machinery Directive 2006/42 (MD)
- Low-voltages Directive 2014/35 (LVD)
- Electromagnetic Compatibility Directive 2014/30 (EMC)
- Explosive Atmosphere Equipment Directive 2014/34 (ATEX)
- Pressure Equipment Directive 2014/68 (PED)
- Simple Pressure Vessels Directive 2014/29 (SPVD)
- Lifts Directive 2014/33 (LD)
- Construction Product Regulation 305/2011
- Personal Protective Equipment Directive 89/686 (PPED)
- Hot Water Boilers Directive 92/42

Examples of directive based on the same principles as the above-mentioned Product directives but without CE-marking provisions are:

- Packaging Directive 94/62
- Noise emission Directive 2000/14

2.1.3 Workplace Directives

(Based on Art. 153 of the present Treaty)

Workplace or working environment directives (sometimes also called User directives or health and safety directives) primarily lay down minimum obligations on employers (for the protection of workers' health and safety) and for a minor part on employees. All aspects of health and safety at work are regulated in more or less details by the EU package of workplace directives.

As the directives lay down **minimum requirements**, the Member States may preserve legislation that is more preventive/protective (being on a higher safety and health level) or adopt such regulation when deemed appropriate. As a result EU

workplace legislation is only harmonised regarding the minimum level of protection, and the exact national legislation may differ to some extent from Member State to Member State.

Although the legal obligations are placed on the employer (the formal user), several provisions of workplace directives implies co-operation/assistance or input from relevant suppliers in order to be tackled in a feasible and efficient manner. Therefore a manufacturer/supplier must keep in touch with relevant workplace legislation when he wants to meet/fulfil general customer expectations.

Workplace directive examples are:

- Directive 89/391 on the introduction of measures to encourage improvements in the safety and health of workers at work (the **Framework directive** which constitutes the legal basis for several more specific daughter-directives)
- Directive 89/655 on the use of work equipment (Workplace directive complementary to the Machinery directive 2006/42)
- Directive 89/656 on the use of personal protective equipment (Workplace directive complementary to the Personal Protective Equipment directive 89/686)
- Directive 1999/92 on the risks from explosive atmospheres (Workplace directive complementary to the ATEX Equipment directive 2014/34)

The Workplace directive 92/58 on safety signs contain basic technical principles which manufacturers of machinery must comply with—see Sect. 4.3.

In general, when the delivery not only includes equipment/machinery but extends to units where workplaces are included, the supplier must ensure compliance with relevant national workplace legislation or obtain the customers approval of the suggested design.

Special attention should be given to national implementations of Workplace directive 92/57 on temporary or mobile construction sites, often done in the framework of more comprehensive legislation named **Construction Design and Management** (CDM) legislation which includes responsibilities regarding the design, construction, use and maintenance of structures.

2.1.4 Other Directives

EU Environment legislation (based on Art. 192 of the present Treaty) is generally putting down minimum requirements to plants (plant owner/employer obligations), but more or less directly they are also of importance for suppliers of plant departments and their equipment.

EU legislation on hazardous chemical substances and mixtures is primarily directed towards producers and importer of chemicals, stipulating indispensable harmonized rules as for example on registration, classification, marking and information (Safety Data Sheets—SDS) which are also of high importance for the users and manufacturers of equipment that use, handle or produce such substances.

2.2 Standards

2.2.1 Standards

A standard may be defined as a set of specifications (or guidelines) for some or all aspects of a product (for example a piece of equipment or a service) or an activity (for example a quality system or an environment management system) which fulfil agreed criteria/expectations and possesses broad acceptance (but compliance is not legally required).

Only documents that are developed and agreed according to international adopted rules, as the ISO and EN standards should be named "standards" (in English, in German: Normen and in French: Normes, having brought about the European designation of standards as EN: Euro Norms).

Although standards in principle are voluntary documents, the designation may in some cases in some countries be equivalent to legislation, or national legislation may refer to a standard and by doing so, making the standard equal to legislation or at least making it an indicator of the level (e.g. of protection or safety) laid down by the legislation.

Some **documents with less formal background** are presented in Sect. 2.2.4 below. Other "un-formal" documents may be seen carrying titles as "Code", "Guideline" or "Code of good practice", although "code" may also mean legislation in some countries.

A major task for standardisation is to facilitate trade especially between countries and make it fair, but also to provide governments with a technical base for health, safety and environment legislation and conformity assessments.

Standards are issued at 3 levels:

International level, e.g. by:

- **ISO** (In French: OIN) International Organization for Standardization (ISO standards)
- **IEC** International Electrotechnical Commission (IEC standards)

Regional level, e.g. by:

- **CEN** European Committee for Standardisation (EN standards)
- **CENELEC** European Committee for Electrotechnical Standardisation (EN standards)
- **ETSI** European Telecommunication Standards Institute (EN standards)
- **EASC** Euro-Asian Council for Standardisation, Metrology and Certification—chartered by CIS (Commonwealth of Independent States, i.e. for Soviet Republics COST standards)

National level, e.g. by:

- **DIN** Deutche Institut für Normung
- **ANSI** American National Standards Institute
- **BSI** British Standards Institution (BS standards)

- **AFNOR** Association Française de Normalisation (NF standards)
- **JISC** Japanese Industrial Standards Committee (JIS standards)
- **GOST R** Russian federal Agency on Technical Regulation and Metrology

ISO has about 157 national standards bodies as members (one per country), including above-mentioned national institutions (GOST R as a correspondent member).

Standards may be classified in numerous ways, e.g. as basic, terminological, test and measurement, product, process, service, system, interface and data standards (based on purpose).

Linked to standardisation, one also meets the following concepts:

- **Certification**: A procedure by which a third party (e.g. a Notified Body) gives written assurance that a product, process or service is in conformity with certain standards
- **Certification Body** or **Notified Body**: An organisation/institution performing certification
- **Accreditation**: The evaluation and formal recognition of a certification program (to be executed by a certification body) by an authoritative body

2.2.2 Harmonised Standards

A **harmonised standard** is a standard that supports one or more EU Product directives, has been produced by CEN or CENELEC under a mandate from the European Commission, and with reference published in the Official Journal (OJ) of EC (EU).

Following the publication of the reference in the OJ and the publication of the EN standard as a national standard by at least one CEN member, a user of the standard is permitted to claim "presumption of conformity" to designated essential health and safety requirements (EHSR) covered by the standard. Therefore, a harmonised standard could be regarding as something between a normal standard and legislation.

Harmonised standards as well as other EN standards cannot be procured through CEN or CENELEC, but only through the national standardisation bodies.

Concerning harmonised standards you can say that the Product directives state the basic legal objectives (the essential requirements) and the harmonised standards identify the technical means to meet these legal objectives.

The most up-to-date list of harmonised standards is available from the list published by the European Commission on their homepage.

In order to respond to the global market there is an increasing trend for standards to be produced at the international level (by ISO or IEC). The standards will still appear in the CEN/CENELEC programme as a potential harmonised standard, and

will be processed in parallel as a CEN/CENELEC standard. The final harmonised standard will then appear e.g. as an EN ISO standard.

Harmonised standards developed in support of the **Machinery directive** are divided into three categories in order to deal with the very diverse nature of the topic covered by "machinery":

2.2.2.1 Type A Standards

Type A standards are basic safety standards dealing with basic concepts, methodology and general principles for design and construction which apply to all machinery.

There is one very important standard in this category:

- EN ISO 12100: Safety of machinery—General principles for design—Risk assessment and risk reduction

Comment: Many elements of this standard may be characterised as inspiration sources for or broad guidance on fulfilling basic concepts of the Machinery directive (especially for the drawing up of B and C standards).

2.2.2.2 Type B Standards

Type B standards are generic safety standards dealing with a variety of topics that are common for the design of most machines, and subdivided into:

- B1 standards on particular safety aspects, e.g. safety distances, surface temperatures, noise and fire prevention and protection
- B2 standards on safety devices, e.g. two-hand control devices, interlocking devices, pressure-sensitive devices, guards, prevention of unexpected start-up

2.2.2.3 Type C Standards

Type C standards are machine safety standards dealing with detailed safety requirements for a specific machine or group of machines, and providing a presumption of conformity for the essential requirements covered in the standard.

Using a C standard, when available, therefore facilitates the obligatory risk assessment and the documentation of compliance with relevant essential health and safety requirements.

Examples of C standards are:

- EN 617: Storage of bulk material
- EN 618: Handling of bulk materials except fixed belt conveyors
- EN 619: Mechanical handling of unit loads
- EN 620: Fixed conveyors for bulk materials

2.2.3 Eurocodes and Similar Building Codes

The Eurocodes are a set of European standards (EN) for the design of buildings and other civil engineering works and construction products, drawn up by CEN.

The elaboration of the codes started in 1974 on the basis of an initiative by universities and the profession supported by the European Commission. In 1989 the work was transfer by a mandate from the Commission to CEN in order to develop the codes as EN standards.

The Eurocodes cover in a comprehensive manner all principal construction materials (concrete, steel, timber, masonry and aluminium), all major fields of structural engineering (basis of structural design, loading, fire, geotechnics, earthquake, etc.) and a wide range of types of structures and products (buildings, bridges, towers and masts, silos, etc.).

The Eurocodes suite is made up by 10 European standards for structural design:

- EN 1990—Eurocode: Basis of structural design
- EN 1991—Eurocode 1: Actions on structures
- EN 1992—Eurocode 2: Design of concrete structures
- EN 1993—Eurocode 3: Design of steel structures
- En 1994—Eurocode 4: Design of composite steel and concrete structures
- EN 1995—Eurocode 5: Design of timber structures
- EN 1996—Eurocode 6: Design of masonry structures
- EN 1997—Eurocode 7: Geotechnical design
- EN 1998—Eurocode 8: Design of structures for earthquake resistance
- EN 1999—Eurocode 9: Design of aluminium structures

Member States are required to adopt the Eurocodes for structural products and construction work and recognize that the use of these codes raises a presumption of conformity with the essential requirements of Regulation 305/2011 on Construction products.

The Eurocodes (apart from EN 1990) constitute a coherent EU-wide framework of common calculation methods with facilities to adopt their functioning to national settings and priorities through a set of Nationally Determined Parameters (NDPs).

Like that the Eurocodes differ from normal EN product standards, and the Member States must define the NDPs to be observed on their territory taking into account justified differences in climate, geographic conditions (e.g. seismic risks), level of safety or traditions (In EU it has to be recognized that e.g. the level of safety in a country remains its prerogative).

It is expected that the Eurocodes will meet broad acceptance outside EU especially because they are:

- A complete set of design standards
- The most up-to-date codes of practice
- Flexible, offering the possibility for each country to choose their set of national parameters (NDPs)

Generally speaking, the world is covered by different building codes developed by government agencies or quasi-governmental standards organisations (Some of them are more linked to local authorities). When enacted by the appropriate authority, these building codes become the law of a particular jurisdiction.

Russia has an extensive network of regulatory documents which include a series of national building codes (SNiP), standards (GOST R), territorial building codes (TSN) and guiding regulations (RDS).

A well-know building code was the **Uniform Building Code** (UBC) used primarily in the western United States. The UBC was replaced in 2000 by the new **International Building Code** (IBC) published by the International Code Council (ICC). IBC has been adopted throughout most of the United States.

The other large US provider of similar codes, **NFPA** (National Fire Protection Association) continues to develop its own codes/the Comprehensive Consensus Codes or C3) including the NFPA 5000 building code. Unlike the IBC, the NFPA 5000 conforms to ANSI-established policies and procedures for the development of voluntary standards.

2.2.4 Semi-standards

Besides the formal standards which have to be elaborated and approved according to specific rules and procedures, CEN also produces the following kinds of documents, characterised by the possibility for been elaborated and approved much faster than ordinary standards:

2.2.4.1 Technical Specifications (TS)

Technical specifications are documents developed and approved by a CEN Technical Committee (CEN/TS), sometimes regarded as a pre-standard which contains technical requirements for innovative technology.

A “TS” must not conflict with an EN standard. A “TS” may be adopted as a national standard.

2.2.4.2 Technical Reports (TR)

A Technical report (TR) is a document providing information on the technical content of standardisation work. A “TR” is approved by the Technical Board or by a Technical Committee by simple majority.

2.2.4.3 Guides

A Guide is a document published by CEN (or CENELEC) giving orientation, advice or recommendations relating to European standardisation.

Guides are approved by a corporate body by simple majority vote.

2.2.4.4 CEN Workshop Agreements (CWAs)

A CWA is a standardisation document developed in a CEN workshop (which is open to direct participation of anyone with an interest in the development of the agreement—including persons outside Europe).

National standards bodies are of course not obliged to adopt a CWA as a national standard.

2.2.4.5 Draft European Standards (PrEN)

In order to be complete, it should also be mentioned that a prEN is an EN standard under development, drafted by a Technical Committee and submitted to CEN members for a public enquiry. It is not an EN standard. It is circulated for review and comments and subject to change without notice.

When (and if) the draft (amended or not) becomes an EN standard, CEN members must implement it as a national standard without any alteration.

2.2.5 Supplementary Comments

"Standards" is a core issue regarding international trade in products and services. Standards facilitate the communication/understanding between supplier and costumer, and in doing so contribute to fulfilling customer expectations, not only concerning simple technical specifications but in relation to the overall quality and safety aspects of the products/services, including legal and environmental considerations.

For a manufacturer, it is recommended that **references to standards** shall not include the publication date. Several standards are often amended leading to the publication of a new edition, which could necessitate a lot of adjustments in the manufacturer's documentation (Technical file, etc.). The edition of the standards listed in any documentation should always be seen as the edition that is valid at the time of publication of the document.

When an EN standard is also an ISO standard, it shall be referred to as an EN ISO standard, e.g. "EN ISO 12100 Safety of machinery—general principles for design—Risk assessment and risk reduction".

In some cases an EN standard is equivalent to an ISO standard, e.g. EN 1037 on "Unexpected start-up" is equivalent to ISO 14118. In such cases it is recommended to mention the equivalent standard in brackets.

Note that copying a standard requires the permission of the publisher (i.e. the relevant national standardisation body).

Adherence to relevant **harmonised standards** is generally recommended as an important element of the company policy regarding safe products. Minor derogations from such standards may exceptionally be the case due to well-founded reasons, and be clearly explained in the technical documentation (underlining the fact that the derogation does not entails any lowering of the prescribed level of safety).

It is worth noting that the ILO code of practice "Safety and health in the use of machinery", published in 2013, recommends that employers should only buy machinery which comply with national laws and regulation and relevant **international standards**.

2.3 EU Legislation and Responsibilities

2.3.1 Product Directives (and Regulations)

Note: This part deals with Product directives which—as the Machinery directive 2006/42—fall under the "old" legislative Framework. The many (updated versions of older Product directives) directives adopted in 2014 and entering into force in April 2016 under the "New Legislative Framework" are dealt with in the following Sect. 2.4.

2.3.1.1 Manufacturer

The manufacturer is the natural or legal person who is responsible for design and/or manufacturer of a product with a view to **placing it on the EU market** under his own name or trademark. Anyone who substantially modifies a product with a view to placing it on the EU market, takes on the manufacturer responsibility.

Who has in reality designed and manufactured the product is not decisive. In some cases an importer or a user (employer) has to take on the manufacturer responsibility, see subsequent Sect. 2.3.1.3 and 2.3.4.

The directives do not require the manufacturer to be established in EU.

A product may be put into service without prior placing on the EU market. When the applicable directive(s) also covers **putting into service**, the person who puts the product into service must then assume the responsibilities of the manufacturer. Import from outside EU for own use is equivalent to the import situation dealt with in subsequent Sect. 2.3.1.3.

The manufacturer has sole and ultimate responsibility for the conformity (including conformity assessment procedure) of the product to the applicable directives.

2.3.1.2 Authorised Representative

A manufacturer—established in EU or not—may appoint an authorised representative established in EU to act on his behalf in carrying out certain tasks required in the applicable directives (Note: This is not an obligation).

Commercial representatives such as authorised distributors do not have to take on roles of an authorised representative in the meaning of the Product directives.

The delegation of tasks to the authorised representative must be explicit and should be in writing.

The tasks that may be delegated to the authorised representative according to the directives are of an administrative nature, but an authorised representative can, at the same time, act as a subcontractor. He can also at the same time act as an importer (or the person responsible for placing the product on the EU market).

Note: The Machinery directive 2006/42 requires that a person, who must be established in EU, is authorised (designated) to compile the technical file—whose identity must appear on the Declaration of Conformity.

2.3.1.3 Importer (or Person Responsible for Placing It on the Market)

An importer—who must be established in EU—is any natural or legal person who places a product from outside EU on the EU market.

The importer must be able to provide relevant authorities with a copy of the Declaration of Conformity and to make the technical documentation (file) available (where the manufacturer is not established in EU and has no authorised representative).

An importer should require formal assurance in writing from the manufacturer that he will be capable of fulfilling the above-mentioned duties.

In some situations the importer is required to assume manufacturer responsibilities, i.e. ensuring compliance with essential requirements and that the appropriate conformity assessment procedure has been applied. This is clearly the case when a person on his own behalf imports and puts on the market machinery, marked by him and accompanied by a Declaration of Conformity signed by him.

In any case the importer should be very careful in selecting the supplier because he may very well be held jointly responsible with the manufacturer in a non-EU country or any representative he may have. Since legal proceedings against a manufacturer not established in EU may be associated with some difficulty, a direct importer may have to face the consequences of non-conformity or an accident.

2.3.1.4 Distributor

A distributor is considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the EU market.

Provisions regarding distributors are in general not included in the "old" Product directives.

A distributor shall in any case act with due care in order not to place clearly non-compliant products on the EU market, and he shall also be capable of demonstrating this to the relevant authorities.

2.3.1.5 Assembler and Installer

Some products can only be used after an assembly, an installation or other manipulations have been carried out.

Where the directive(s) in question covers putting into service as the Machinery directive, and where an assembly, an installation or other manipulations have an impact on maintaining the compliance of the product, the person responsible for such manipulation must ensure that they do not cause a non-compliance with the essential requirements.

2.3.2 Product Liability Directive 85/374

This directive covers any product, including raw materials and components:

- manufactured or imported into EU, which
- lacks safety, and
- causes damage to individuals or private property

The liability (the responsibility to pay for damages) is placed on the producer who is either a:

- Manufacturer of a finished product, or
- Manufacturer of a component part of a finished product, or
- Producer of any raw material, or
- Person presenting himself as the producer

Importers placing products on the EU market from third countries are considered to be producers according to this directive.

The injured person, buyer or user of the defective product must claim his rights to obtain compensation. He must prove that:

- He has suffered damage
- The product was defective, and
- That the product caused the damage

Adherence to any standard does not exempt the producer from liability.
Note: More about this directive in Sect. 2.5 on "Producer liability".

2.3.3 General Product Safety Directive 2001/95

Although the directive is not relevant in the framework of this guideline, it is briefly mentioned here for the sake of completeness.

The directive lay down safety requirements etc. on products placed on the market where its provisions are not covered by specific provisions with the same objective in other directives (or other EU legislation governing the safety of the product concerned).

A product is defined as any product—including provision of service—which is intended for **consumers** or likely to be used by consumers even if not intended for them, and is supplied or made available in the course of a commercial activity and whether new, used or reconditioned.

2.3.4 Workplace Directives

First of all, workplace directives lay down minimum requirements on the employer (for protecting the health and safety of the workforce) which for example influences the choice, use and maintenance of equipment covered by the Product directives.

As an example, the employer is obliged to perform workplace risk assessments (e.g. to draw up an explosion protection document before commencement of work where ATEX regulations are relevant) assisted by the required information (markings, instructions etc.) received from the equipment suppliers which again are based on their equipment risk assessments as required in the relevant Product directives.

Product directives are only directly relevant (applicable) when an employer takes on manufacturer responsibility related to putting equipment into service, see previous Sect. 2.3.1.1.

Depending on the delivery and contract, national workplace legislation may be relevant for the supplier e.g. when he takes on the role as adviser or designer according to the present Construction, design and management (CDM) legislation.

2.4 New Legislative Framework (NLF)

2.4.1 Introduction

The New Legislative Framework (NLF) was launched in July 2008 by the adoption of Regulation 765/2008 and Decision 768/2008 on a common framework for the marketing of products.

Decision 768/2008, which does not have any immediate legal effect, may be characterized as a toolbox for future legislation regarding products and the internal market.

The toolbox will be put into action in April 2016 regarding a revision of ten Product directives:

- Low Voltage Directive (LVD), now with no. 2014/35
- Electromagnetic Compatibility Directive (EMC), now with no. 2014/30
- ATEX Directive, now with no. 2014/34
- Lifts Directive, now with no. 2014/33
- Pressure Equipment Directive (PD), now with no. 2014/68
- Simple pressure Vessels Directive (SPVD), now with no. 2014/29
- Measuring Instruments Directive, now with no. 2014/32
- Non-automatic Weighing Instruments Directive, now with no. 2014/31
- Civil Explosives Directive, now with no. 2014/28
- Pyrotechnic Articles Directive, now with no. 2013/29

Other directives under the NLF frame have been adopted and more will probably follow in the future, but the Machinery directive 2006/42 has not been mentioned as a candidate for revision and alignment under NLF. So, concerning the structure of this directive, please refer to Sect. 2.3.

2.4.2 Background

NLF aims at solving the following problems and shortcomings of the Product harmonisation directives:

- Different levels of import control and market surveillance in Member States
- Different ways of controlling Notified Bodies (of which some have shown an unsatisfactory performance)
- Many non-compliant products on the EU market
- Unclear definitions
- Unclear obligations for importers and retails
- CE-marking uncertainties

To remedy these shortcomings the Regulation and the Decision initiates actions regarding the following topics:

- Accreditation of Notified Bodies and the regulation of Notified Bodies
- Strengthened enforcement of the legislation (e.g. concerning market surveillance and import control, including a better traceability of products in the supply chain)
- Common definitions (e.g. of manufacturer, importer, placing on the market)
- Common obligations (e.g. of manufacturers, importers, distributors)
- Common legislative elements (e.g. Declaration of Conformity model structure, 16 conformity assessment procedure models)
- CE-marking only as and when required by the legislation in order to voice conformity and conformity responsibility

2.4.3 Important New Aspects

Based on the Decision 768/2008 legislative toolkit and the alignment package of draft directive revisions, the following new aspects warrant special attention:

- Specification of an importer's obligations
- Specification of a distributor's obligations
- Strengthening of product traceability, e.g. by requiring importer identification on the product, where applicable
- Manufacturer/importer obligation to supply relevant parts of the technical dossier in a language easily understood by the competent national authority in question (when having received a reasoned request)

Comment: This obligation is judged to apply only regarding the Member State markets in which the product is placed or made available, in line with the Declaration of conformity translation obligations.

- EU Declaration of conformity in compliance with the model structure set out in Decision 768/2008
- A product must only have one EU Declaration of conformity (covering all relevant legislative compliance specification) which must be available (in the technical dossier) translated into the language(s) required on the market(s) where the product is placed or made available. The declaration is not required to accompany every single product

Note: The requirements of the Machinery directive 2006/42 regarding the obligatory existence of an authorised representative in EU when the manufacturer is placed outside EU, and the obligation to identify documents by "original" or "translated", is not a part of NLF.

Note: The basic technical content of the abovementioned directives has not been changed substantially. Therefore the directives do not affect the standards in use.

2.4.4 Obligations of Economic Operators

Some important general obligations of the economic operators (manufacturers, importers, distributors and authorised representatives) according to NLF are presented below:

2.4.4.1 Manufacturer Key Obligations

Subject	Obligation
Technical requirements	Ensure that the product complies with the relevant technical requirements (EHSR) set out in the directives
Technical documentation	Draw up the technical documentation (dossier or file) demonstrating directive compliance—which according to a reasoned request from a national authority must be provided in a language which can be easily understood by that authority
Information	Draw up the necessary instruction and safety information to accompany the product—in a language which can easily be understood by users
Conformity assessment	Carry out—or have it carried out—the appropriate conformity assessment procedure
Compliance guarantee	Draw up only one EU Declaration of conformity stating conformity with all relevant legislation—which must be specified—and affix the CE-marking on the product
Product marking	Besides the CE-marking, the product must as a minimum identify the manufacturer and bear some marking allowing its identification (e.g. serial number)

2.4.4.2 Importer Key Obligations

Subject	Obligation
Basic	Only compliant products must be placed on the market
Supervising the manufacturer	Ensure (*Comment*: Be able to demonstrate) that • Appropriate conformity assessment has been carried out • The manufacturer has drawn up the technical documentation • The product bears required markings • The product being accompanied by the required documents
Product marking	Marking of the product with importer identification
Information	Ensure that the product is accompanied by instructions and safety information in the required language(s)
Technical documentation	Based on a reasoned request from a national authority provide the authority all the necessary information/documentation in a language which can be easily understood by the authority

2.4.4.3 Distributor Key Obligations

As a general obligation a distributor shall act with due care in relation to applicable requirements when making a product available on the market.

Subject	Obligation
Verification	Verify (*Comment*: Be able to demonstrate appropriate check) that: • The product bears required CE-marking and other markings • The product being accompanied by the required documents and by instructions and safety information in the required language(s)
Technical documentation	Based on a reasoned request from a national authority provide the authority all the necessary information and documentation (*Comment*: Which is foreseen to be provided by the manufacturer or importer in the appropriate language)

2.4.4.4 Authorised Representative Key Obligations

The obligations of an authorized representative are to be specified in a mandate drawn up by the manufacturer.

Manufacturer obligations regarding technical requirements and documentation (see Sect. 2.4.4.1 above) shall not form part of the mandate.

The following obligations must form part of the mandate:

- Keeping the EU Declaration of conformity and the technical documentation at the disposal of national authorities
- Based on a reasoned request from a national authority, provide the authority with all the necessary information and documentation to demonstrate compliance
- Cooperate with national authorities, at their request, on any actions to eliminate risk posed by the product

2.4.5 Some General Conclusions

According to NLF, the alignment package and the Machinery directive, the following conclusions may be put forward:

- Being an EU manufacturer of a product, you always have to comply with relevant Product directives when placing your product on the EU market. Compliance is also required for own use (putting into service) in some cases as for machinery, ATEX equipment and equipment covered by the Electromagnetic compatibility

directive or the Simple pressure vessels directive. A distributor entering the product supply chain must comply with distributor obligations.

- Being an EU importer of a non-EU product, which you put on the market makes you an importer with importer obligations provided that you can fulfill these obligations (e.g. that the non-EU manufacturer takes on EU manufacturer obligations), **otherwise** you must take on the manufacturer obligations yourself, i.e. you are not considered as an importer but as the manufacturer.
- In general, a non-EU manufacturer may (as an EU manufacturer) place his product directly on the EU market when his product is in compliance with applicable directives. Concerning machinery, the non-EU manufacturer must, based on a written mandate, appoint an authorized representative established in EU (who is to be identified on the Declaration of conformity).
- If you enter the supply chain concerning such non-EU manufactured products as the first person in the EU supply chain, the assessment is that you will be regarded as an importer required to fulfill importer obligations.
- Own use (putting into service) of non-EU products requires you to fulfill applicable directive obligations where the directives are not only valid concerning "placing on the market" but also regarding "putting into service". Fulfilling such obligations is facilitated by an EU Declaration of conformity from the non-EU manufacturer, but you—as an industrial user—are assessed to have some kind of an independent obligation for ensuring compliance, which probably would be in line with some of the importer obligations.
- Where non-EU products (coming directly from outside EU) are incorporated in an EU manufactured product, which is going to be placed on the EU market, the final EU manufactured product must of course comply completely with any applicable directive. Fulfilling these requirements regarding the non-EU component parts is assessed to be of a similar kind as to the above-mentioned case with own use of non-EU products.
- Finally, it is to be emphasized that **CE-marking** requires compliance with all applicable EU legislation providing for CE-marking. The marking must not be affixed to any other product and shall be affixed only by the manufacturer or his authorized representative (CE-marking legislation is only legally enforceable in EU, but the assessment is that the EU Commission will do its best to avoid any misuse of the CE-marking outside EU).

2.5 Producer Liability

2.5.1 Introduction

This section tries to throw some light on the aspects of liability where a product—exemplified by machinery—is not in conformity with relevant EU Product directives or when the product has caused personal injury.

Contractual liability and liability of property damage are outside the scope of this chapter—although these aspects may imply bigger economic risks.

The focus is on EU legislation which to a large extent is similar to the liability principles found in other countries. However, the amount at stake may differ considerably from state to state.

2.5.2 Liability According to Product Directives

As mentioned in Sect. 2.3, the manufacturer is the natural or legal person responsible for the compliance with Product directives with a view to the product being placed on the market under his own name or trademark or for own use.

Member State competent authorities shall ensure (based on appropriate measures) that machinery is placed on the market and/or put into service only if it satisfies the relevant provisions of the Machinery directive and does not endanger health and safety of persons, and where appropriate, domestic animals and property.

Art. 23 of the Machinery directive obliges Member States to lay down the rules on penalties applicable to infringements of the implemented national provisions adopted pursuant to the directive.

The penalties provided for must be effective, proportionate and dissuasive (in order for manufacturers to refrain from placing on the market or using machinery which is not in conformity with the directive).

It is up to the competent authorities to prove non-compliance, which does not have to be linked to any specific injury or damage caused by the product.

The competent authority focuses only on the compliance with directive provisions, and does not interfere directly in product liability and compensation questions regarding personal injuries or property damage caused by the product. But any actual damage may influence the size of the penalty.

Generally it is not possible to contract insurance covering above-mentioned penalties.

2.5.3 Product Liability Directive 85/374

The Product Liability Directive (see also Sect. 2.3) aims at harmonising the civil liability systems and ensuring a high level of consumer protection and compensation against/connected with damage cause by defective products.

The directive covers consumer products and products used at work. Products are defined as all movables even if incorporated into another movable or into an immovable.

The directive establishes the principle of objective liability (or liability without fault) of the producer in case of damage by a defective product.

The damage covered is damage caused by death or by personal injury and damage to property (other than the product in question) with some limitations as for example: It has to be property intended for private use and mainly used accordingly.

Therefore, regarding non-consumer products, the liability covered by the directive, concerns products (equipment) which is used at work and has caused personal injury or death.

The injured person (or party in case of death) must prove:

- The actual damage,
- The defect in the product, and
- The causal relationship between damage and defect

A key question here is the meaning of a "defect" or a "defective product" which is defined as a product not providing the safety which a person is entitled to expect —taking all circumstances into account, including:

- The presentation of the product (including instructions, warnings, packaging and advertising)
- Whether the product is being put to reasonable use, and
- The time the product was put into circulation (Subsequent circulation of a better product does not automatically render the older models defective)

Note: Hazardous products, as knifes, razors, hammers and food processing machinery are not considered defective products when all the circumstances are taken into consideration.

The objective liability (i.e. liability without negligence, gross negligence or on purpose) is repealed if the producer for example proves:

- That the defect causing the damage came into being after the product was put into circulation by him, or
- That the defect is due to compliance of the product with mandatory regulations issued by the public authorities (**Note**: Compliance with harmonised standards does not free the producer from liability, but may reduce the likelihood of damage), or
- That the state of scientific and technical knowledge at the time when the product was put into circulation, was not such as to enable the defect to be discovered (Member States are permitted to take measures by way of derogation)

The last mentioned liability exemption resembles "**the state of the art**" consideration regarding compliance with the Essential Health and Safety Requirements (EHSR) of the Machinery directive—see also Sects. 3.1 and 3.3. So in case the defect is caused by non-compliance with the EHSR of the directive, the exemption cannot be used by the producer.

It may also be concluded that for products, as machinery put on the market with inborn defects (as defined by the product Liability Directive) the objective liability of producers very much resembles the "normal" liability situation outside contracts. Here the liability is based on negligence, gross negligence or purpose (culpa or

subjective liability) and any Machinery directive non-compliance will be classified as negligence.

A similar conclusion is valid for other products having health and safety aspects regulated by Product directives.

When damage has occurred at work suspected to be caused by a defective product regulated by a Product directive, the competent authorities will normally be asked to evaluate a possible non-compliance with the directive provisions.

In the working environment, such a case may often be somewhat complicated because all the circumstances have to be evaluated included any employer liability.

In many cases it is strongly recommended to take out Product Liability insurance. It may be motivated or justified on economic reasons and/or the fact that no production control system is 100 % reliable.

The Product Liability Directive is a supplement to other national provisions governing contractual or non-contractual liability. The directive does not affect any rights which an injured person may have according to already existing liability rules.

2.5.4 Liability Outside Contract—Subjective/Culpa Liability

In general, the following four conditions have to be fulfilled before liability may be imposed on you:

- A liability basis, where culpa is the common rule (culpa with inverted burden of proof and objective liability are other forms)
- Causal relationship between act and damage
- The damage is a probable consequence (foreseeable) of the damaging act (An aspect which the injured person does not have to prove under the Product Liability Directive)
- A loss or interest (economic loss, injury or death) to be compensated

In some cases you are exempted from liability or the liability is modified e.g. when an injured person had accepted the risk or when the person is also to blame.

Culpa (subjective liability) means that you are to blame and liable because your act (including the production and marketing of products) is categorised as negligence, gross negligence or on purpose. An unforeseen accident is outside the culpa area and without liability.

It is up to the injured person to prove that the "act" falls under the culpa concept, the causal relationship and the damage being a foreseeable consequence.

Without going into details it should be mentioned that the employer in general is liable regarding damage caused by his employees.

2.6 Language Requirements

2.6.1 Introduction

"Language" is of course an important issue—especially concerning safety and health aspects—with so many Member States and languages in EU.

Language requirements laid down in the Product directives are generally related to the official languages of the EU Member States (or the EEA area Member States which also include Iceland, Liechtenstein and Norway, as these countries follow the EU Product directives).

Languages—Official EU and EEA languages

(In brackets the language code according to ISO 639 is indicated)

Austria	German (DE)
Belgium	Flemish (Dutch) + French (FR) + German (DE)
Bulgaria	Bulgarian (BG)
Croatia	Croatian (HR)
Cyprus	Greek (EL) + English (EN)
Czech Republic	Czech (CS)
Denmark	Danish (DA)
Estonia	Estonian (ET)
Finland	Finish (FI) + Swedish (SV)
France	French (FR)
Germany	German (DE)
Greece	Greek (EL)
Hungary	Hungarian (HU)
Ireland	English (EN) + Irish/Gaelic (GA)
Italy	Italian (IT)
Latvia	Latvian (LA)
Lithuania	Lithuanian (LT)
Luxembourg	French (FR) + German (DE)
Malta	Maltese (MT) + English (EN)
Netherlands	Dutch (NL)
Poland	Polish (PL)
Portugal	Portuguese (PT)
Romania	Romanian (RO)
Slovakia	Slovak (SK)
Slovenia	Slovenian (SL)
Spain	Spanish (ES)
Sweden	Swedish (SV)
United Kingdom	English (EN)

(continued)

(continued)

Other EEA countries:	
Iceland	Icelandic (IS)
Liechtenstein	German (DE)
Norway	Norwegian (NO)

Note: Belgium and Finland accept the use of one language only in areas where only that language is spoken. Cyprus, Malta and Ireland accept the sole use of English.

The EU-related countries Switzerland (French, German and Italian) and Turkey (Turkish) have the official languages, here stated in the brackets.

This section contains an overview over the language requirement of documents, specified by the Machinery directive 2006/42 and a few other directives.

In general these documents belong to one of the following classes:

- Conformity declarations
- Instructions (Manuals)
- Technical file documents, including documents, reports and correspondence relating to conformity assessment procedures involving Notified Bodies (Third parties) and certificates (and similar documents) issued by these bodies

Instructions, which are required by the Product directives, means information relevant for the safe use of the product—except regarding the EMC directive, which does not directly regulate safety aspects.

Marking/labelling supplementing the CE-marking may also in some cases take the form of documents.

The directives do not always specify language requirements and a judgment must be performed, taking into consideration the following rules-of-thumb:

- Documents, required by a Product directive, to accompany the product must at least be written in the official language(s) of the user country (where the product is placed on the market and intended to be put into service)
- Documents required to be filed (Technical file/documentation) by the manufacturer or his representative and, on request, to be submitted to the relevant authorities, must be written in one or more official EU languages (i.e. you have some flexibility here)
- Where a Notified Body is involved in the compliance assessment procedure, the documents submitted by the manufacturer and issued by the Notified Body must be in an official EU language accepted by the Notified Body.

Where observance of specified standards is stated, supplementary requirements on documentation may have to be fulfilled.

2.6.2 Machinery Directive 2006/42

The Machinery directive covers machinery (which per definition also includes equipment such as safety components and lifting accessories) and partly completed machinery.

2.6.2.1 Regarding Machinery

The **Declaration of conformity** and the **Instructions** (for safe use) which shall accompany the machinery, must comply with the following:

The documents must be written in one or more official EU languages and wear the word "Original" indicating the manufacturer's verification of the version(s).

Translations of these documents, which may be done by the manufacturer, his representative or the person bringing the machinery into the language area in question, must wear the words "Translation of the original".

The documents required to accompanying the machinery must be in the official language(s) of the Member State in which it is placed on the market and/or put into service. Where this requirement is covered by a translated document, an original document must be enclosed.

An exception exists for maintenance instructions intended for specialised personnel where an EU language understood by the personnel may be used.

Concerning **lifting equipment** falling under the supplementary requirements in Annex I, part 4 to the Machinery directive, documentation in the form of test reports/certificates may be relevant. Such documentation must be seen as belonging to the Technical file—see below. The certificate required for **chains, ropes and webbing** must be seen as belonging to marking information, which must be in the official language(s) of the user country.

Documents belonging to the **Technical file** must be in one or more official EU languages, except for the Instructions which must follow the above-mentioned provisions.

Machinery (such as logic units to ensure safety functions) referred to in Annex IV of the Machinery directive may require the involvement of a Notified Body in order to comply with the conformity assessment procedure. Language questions are only referred to regarding EC-type-examinations (Annex IX), where relevant papers and certificates must be in an official EU language acceptable to the Notified Body.

Observance of certain **standards** may entail the preparation of supplementary documentation. These documents must be seen as belonging to the Technical file (and be written in one or more official EU languages).

2.6.2.2 Regarding Partly Completed Machinery

Language requirements regarding the **Declaration of incorporation** and the **Technical documentation** are the same as for the equivalent machinery documents.

Assembly instructions must be written in an official EU language acceptable to the manufacturer (or his representative) of the "final" machinery.

2.6.3 Explosive Atmosphere Directive 2014/34 (ATEX)

The ATEX directive covers equipment and protective systems intended for use in potentially explosive atmospheres, some kind of safety devices and components essential to the safe functioning of equipment and protective systems but with no autonomous function.

Equipment, protective systems and safety devices must bear the CE marking and be accompanied (in general) by an **EU Declaration of conformity**, drawn up by the manufacturer. The declaration must be translated into the language(s) required by the Member State in which the product is placed or made available on the market.

Concerning components (not to be CE marked), the manufacturer must draw up an **Attestation of conformity** which shall accompany (in general) the component. In conformity with the European Commission's guide on the implementation of the Product directives regarding documents accompanying the products, it is assumed that the attestation have to be in the official language of the user country.

All equipment and protective systems must be accompanied by **Instructions** and safety information in a language easily understood by end-users, as determined by the Member State concerned.

Art. 13 of the Directive specify with reference to several annexes conformity assessment procedures according to item, equipment-group and equipment category —which in several cases involve a Notified Body. **Documents and correspondence** related to those procedures shall be drawn up in a language determined by the Member State concerned. The collection of these documents constitutes the **Technical documentation (file)** for the product in question.

The involvement of a Notified Body may—according to the conformity assessment procedure—entail issue (by the Notified Body) of documents such as:

- EU type-examination certificate
- Quality assurance notification
- Conformity to type notification
- Certificate of conformity concerning the tests carried out

These documents belong to the above-mention Technical file, not required to accompany the product.

Based on a reasoned request from a competent national authority, the manufacturer shall provide it with all the information and documentation necessary to demonstrate the conformity of the product with the directive, in a language which can be easily understood by that authority. The amount of information could in principle constitute the whole Technical documentation.

2.6.4 Low-Voltage Directive 2014/35 (LVD)

The LVD directive covers electrical equipment designed for use within a voltage range of 50–1000 V (a.c.) or 75–1500 V (d.c.).

Exempted from the scope is for instance electrical equipment for use in an explosive atmosphere—see more details in Annex II to the directive.

The responsibility for the preparation of **CE marking documentation**, and the **EU declaration of conformity** relies solely on the manufacturer.

Through the **Technical documentation,** it should be possible for the manufacturer to demonstrate compliance to the relevant national authority in a language which can be easily understood by that authority.

The **Declaration of conformity** drawn up by the manufacturer shall be translated into the language(s) required by the Member State in which the equipment is placed or made available on the market.

The equipment must be accompanied by **Instructions** and safety information in a language understood by consumers and other end-users, as determined by the Member State concerned.

2.6.5 Electromagnetic Compatibility Directive 2014/30 (EMC)

The EMC directive covers a lot of electrical/electronic equipment (apparatus and fixed installation) aiming to ensure the free movement of such equipment by requiring the equipment to comply with an adequate level of electromagnetic compatibility. The directive does not directly regulate safety aspects of the equipment in respect of people or propriety.

The provisions and language requirements regarding **CE marking**, **EU declaration on conformity**, **Technical documentation** and **Information**, are similar to what has been mentioned above in Sect. 2.6.4 on the LVD directive.

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