

PREKAM

SAFE Solutions

- All Machine/Plants shall follow the legislation (directives), MD, ATEX, PED, EMC & LVD.

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PRESENTATION AGENDA

- Start 13:00 ● **Short presentation, PREKAM**
- **The new Global Approach**
- **MD 2006/42/EC (AFS 2008:3)**
- **Harmonized standards/ Why?**
- **LVD 2014/35/EU (ELSÄK 2016:1)**
- **EMC 2014/30/EU (ELSÄK 2016:4)**
- **PED 2014/68/EU (AFS 2016:1)**
- **ATEX 2014/34/EU (AFS 2016:4)**
- End 16:00 ● **Directive 85/374/EEC product**
- End**



ABOUT US

- 2 Offices in Sweden, Stockholm and Malmö
- Delivered over 1200 Projects since 1997
- International projects
- Worked with machine safety issues for over 30 years

PREKAM has a wide network of subcontractors with expertise in the field, reducing vulnerability and enabling us to quality assure.



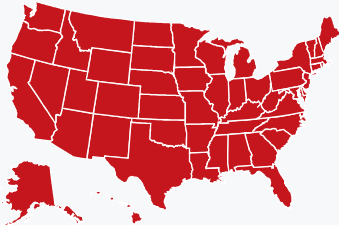
RESPONSIBILITY - SAFETY - QUALITY

PROJECTS INTERNATIONAL

CHINA



USA



SWEDEN

FINLAND

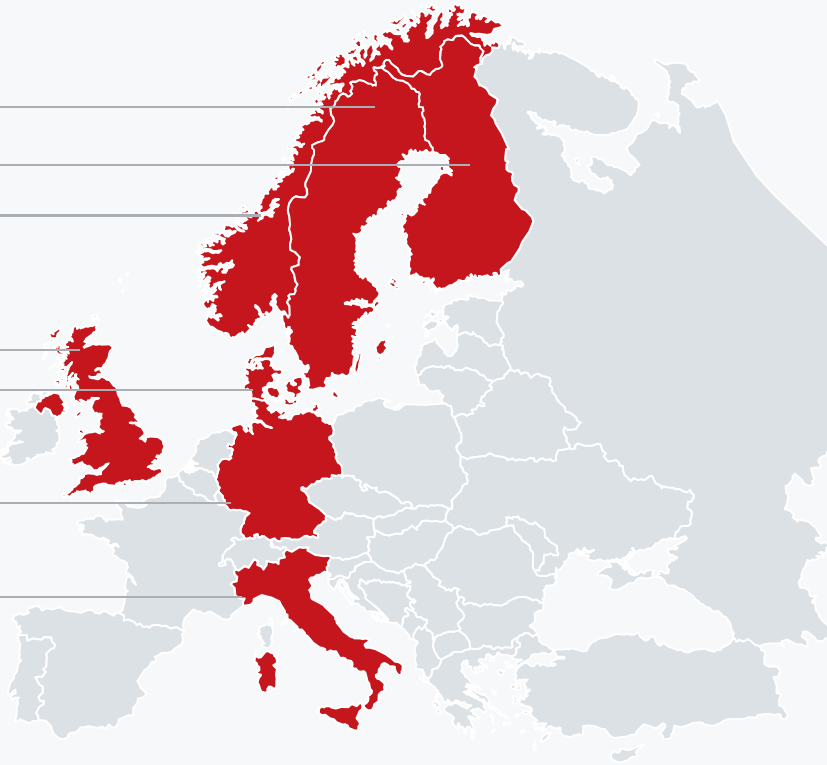
NORWAY

SCOTTLAND

DENMARK

GERMANY

ITALY



OUR CLIENTS



Lantmännen



AstraZeneca

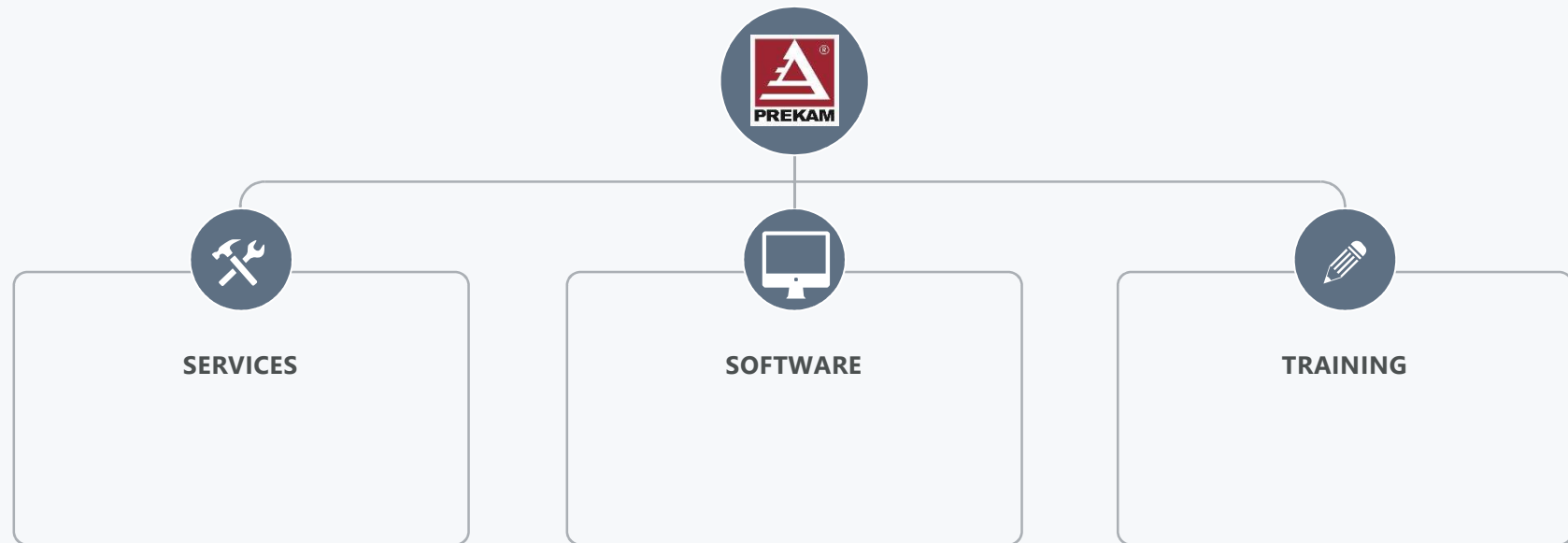




WHAT MAKES PREKAM UNIQUE ?

What makes PREKAM unique is that we have the opportunity to take total responsibility for the entire project, all gathered within the same business.

- **New perspective:** With over 30 years of experience in the field of machine safety and with different industries, we can come in with new and fresh ideas to the project
- **Total solutions:** *Services - Software - Training - We create a comprehensive solution for our clients, helping from start to finish*





THE NEW GLOBAL APPROACH



EU – THE NEW **AND GLOBAL APPROACH**

- European Economic Community was established in 1957
- Three common agreements:
 - The Coal and Steel Treaty 1951
 - The Euratom Treaty 1957
 - The Treaty of Rome 1957
- EU-European Union
 - Treaty in Maastricht in December 1991
 - Head of government and States within the EC
 - Denmark and Great Britain
- Purpose:
 - Focus on the elimination of barriers and on the free movement of goods in the single market



1. The directives were taken under the **new approach** in order to facilitate the free movement of goods and products in the European Union by removing barriers to trade in the **European market**.
2. The accuracy of these guidelines is that they set the basic requirements or **Essential Health and Safety Requirements** (EHSR) that apply to all manufacturers who wish to put their products on the European market.
3. If a product meets the **essential health and safety requirements**, then the product can be placed on the market.
4. One way of demonstrating compliance with the **Essential Health and Safety Requirements** (EHSR) can be done through compliance with **harmonized European standards** or any other solution that allows to demonstrate a similar level of safety.

EU – THE NEW AND GLOBAL APPROACH

Historically, EU legislation for goods has progressed through four main phases:

- the traditional approach or ‘Old Approach’ with detailed texts containing all the necessary technical and administrative requirements,
- the ‘New Approach’ developed in 1985, which restricted the content of legislation to ‘essential requirements’ leaving the technical details to European harmonized standards. This in turn led to the development of European standardization policy to support this legislation,
- the development of the conformity assessment instruments made necessary by the implementation of the various Union harmonization acts, both New Approach and Old Approach,
- the ‘New Legislative Framework’ adopted in July 2008, which built on the New Approach and completed the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from outside the Union.



EU – THE NEW AND GLOBAL APPROACH

The new method:

- The directives are mandatory.
- Standards are voluntary.
- Restricted to a general and superior demand for health, safety, and environment and some other general demands.
- A product manufactured according to a harmonized standard is presupposed to fulfil the directive – However:
- A product that isn't performed according to standards can be accepted if you can show that the demands on the directive in an other way is fulfilled.



EU – THE NEW AND GLOBAL APPROACH

BLUE GUIDE-

https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_sv



WHY?

September 2017

Evaluation of Directive 2006/42/EC on Machinery

Final Report

- **Relevance** – the extent to which the Directive’s objectives correspond to market and user needs
- **Effectiveness** – the extent to which the two objectives were achieved (and factors preventing this)
- **Coherence** – the extent to which the Directive is coherent with other legislation (i.e. whether it sets requirements that contradict other legislation), including other product Directives
- **Efficiency** – the extent to which the two objectives of the Directive were achieved at a reasonable cost (including compliance costs for manufacturers).
- **EU added value** – the extent to which the European Directive adds value compared to what could have been achieved at Member State level



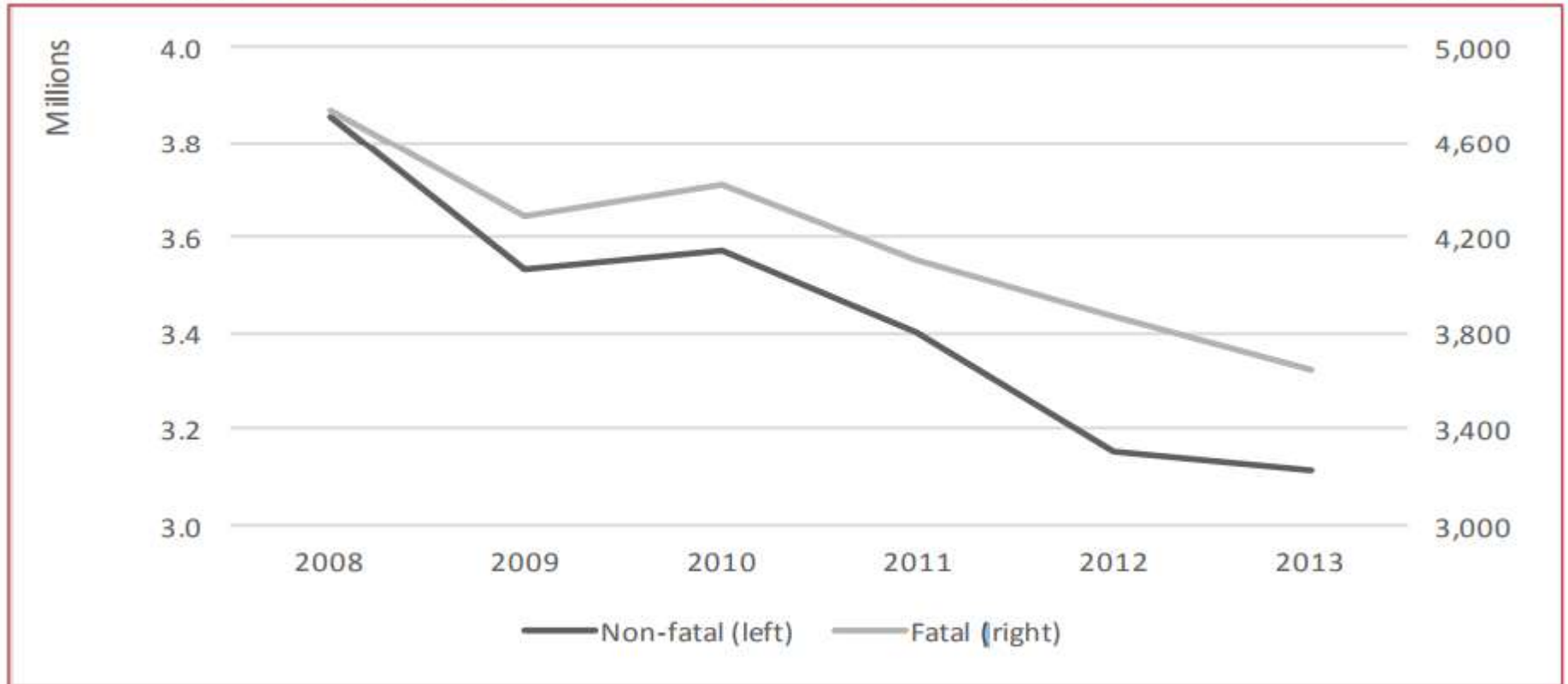
MACHINERY DIRECTIVE

The purpose of this Directive is to

- Ensuring the health for users and making a safer environment
- Ensure free movement of machinery without lowering existing justified levels of protection in the Member States.
- To reduce the social cost of the large number of accidents caused directly by the use of machinery.



Figure 8 Fatal accidents and non-fatal accidents with more than 3 days of absence from work, 2008-13, EU27



Source: ESAW



Table 14 Fatal accidents, by economic activity of employer (NACE). EU27

Fatal	2008	2009	2010	2011	2012	2013	2008-2013 change
Manufacturing	837	704	710	684	651	609	-27%
Construction	1,258	1,156	1,049	958	869	787	-37%
Agriculture, forestry & fishing	591	484	583	552	527	467	-21%
Total (3 sectors)	2,686	2,344	2,342	2,194	2,047	1,863	-31%

Source: ESAW.

Table 15 Accidents resulting in more than 3 days of absence from work, by economic activity of employer (NACE). EU27

Non-fatal (>3 days absence)	2008	2009	2010	2011	2012	2013	2008-2013 change
Manufacturing	939,818	760,427	770,658	723,826	673,639	652,606	-31%
Construction	626,313	548,657	504,532	479,869	418,414	378,246	-40%
Agriculture, forestry & fishing	127,649	168,869	163,496	164,892	150,918	154,884	21%
Total (3 sectors)	1,693,780	1,477,953	1,438,686	1,368,587	1,242,971	1,185,736	-30%

Source: ESAW.



Table 20 Estimated cost of accidents at work in the UK (per injury)

Type	Non-financial human cost	Financial cost	Total cost
Fatal injuries	€ 1,423,457	€ 520,494	€ 1,944,444
Non-fatal injuries: 7+ days absence	€ 21,728	€ 12,469	€ 34,198
Non-fatal injuries: <7 days absence	€ 407	€ 679	€ 1,086

Source: Costs to Britain of workplace fatalities and self-reported injuries and ill health, 2013/14 (HSE, 2014).
Figures converted by Technopolis based on exchange rate of £1: €1.23



For the Manufacturing, Construction and Agriculture sectors combined (those of highest relevance to machinery), the number of fatal accidents decreased by **767 (-29%)**

The number of non-fatal accidents dropped by **472,718 (-28%)** between 2008 and 2013 (figures adjusted for changes in employment in these sectors during the period).

Combining this information with UK Health and Safety Executive estimates of the financial and non-financial costs incurred allowed the study to monetise the value (savings) from the reduction in relevant accidents during the period.

This results in total cost savings from a reduction in accidents in machinery-related sectors during the period was **€401m per year** or **€2.0b for the full five-year period**



MACHINERY DIRECTIVE

The purpose of this Directive is to

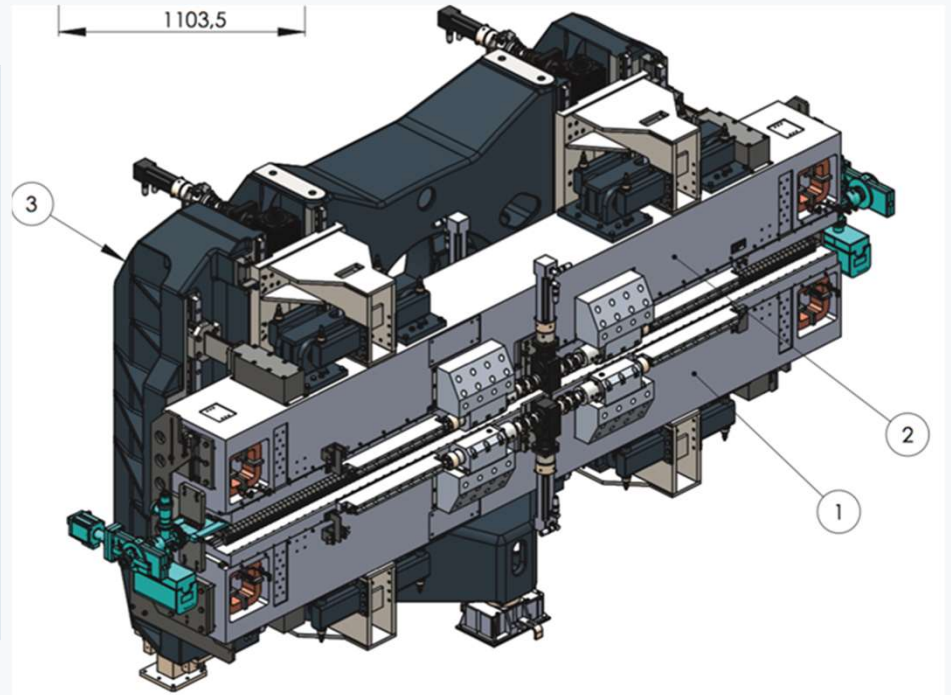
- Ensuring the health and making a safer environment
- Ensure free movement of machinery without lowering existing justified levels of protection in the Member States.
- To reduce the social cost of the large number of accidents caused directly by the use of machinery.





MD

2016/42/EC





MACHINERY DIRECTIVE AND CE MARKING

MD, CE marking and your legal obligations

- What are EU Directives?
 - Machinery directive?
 - What is CE marking?
 - Who is responsible for CE marking?
- Legal framework

Applying Directives

- How to identify which Directives apply?

EMC,LVD ?

- Routes to conformity

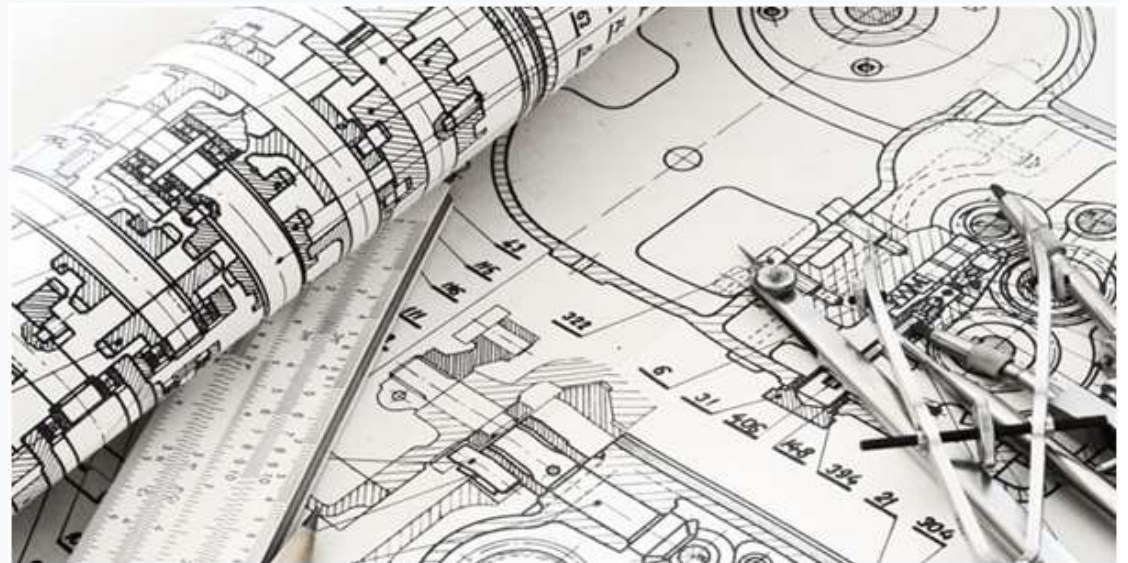
Essential requirements and Harmonized standards.



MACHINERY DIRECTIVE AND CE MARKING

Technical documentation required to demonstrate compliance

- Declaration of conformity
- Technical File Contents
- Technical File Compilation





WHAT ARE EU-DIRECTIVES

- “New Approach” Directives (Community Law) set out the **Essential Requirements**, written in **general term**, which must be met before products may be sold in the European Community
- European **Harmonized Standards** provide the detailed technical information to meet the Essential Requirements. (they complement each other)
- Directives also explain how manufacturers can **demonstrate conformity** with the Essential Requirements
- Products which meet the Essential Requirements must display CE marking
- CE marking means that the product can be sold anywhere in the EU
- 20+ are CE marking Directives



DIRECTIVE AND METHOD OF ANALYSIS

COMMON RULES





MACHINERY DIRECTIVE

- **The Machinery Directive 2006/42/EC**
- **The Low Voltage Directive 2006/95/EC**
- **The EMC Directive 2004/108/EC**
- **The Pressure Equipment Directive 2014/68/EU**





DIRECTIVE AND METHOD OF ANALYSIS

TWO KINDS OF DIRECTIVES

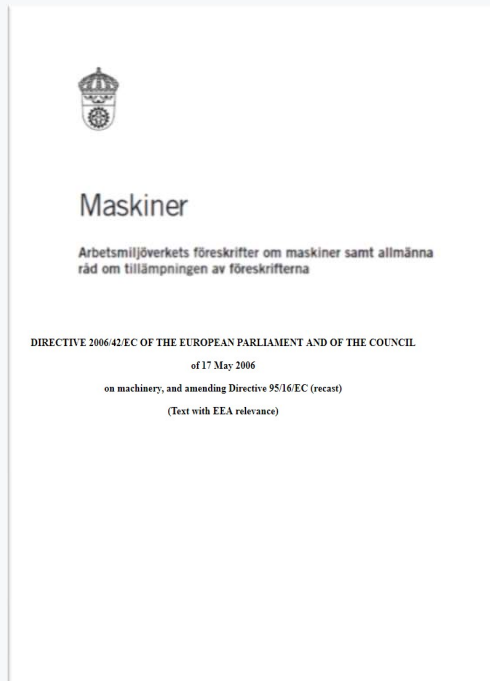
- Product directives which specify the requirements of a product's safety on a certain level – LIKE THE MD
- Users directive (customers) refers to regulation of the conditions of the workplace, to safeguard certain minimum level of health, safety and environment



DIRECTIVE AND METHOD OF ANALYSIS

New and old machines

THE MANUFACTURER - NEW



THE USER Directive 2009/104/EC - OLD



ANNEX I - ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

ANNEX I

Essential health and safety requirements relating to the design and construction of machinery

GENERAL PRINCIPLES

- 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).
 - The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.
 - The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.
 - This Annex is organised in several parts. The first one has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.
- ESSENTIAL HEALTH AND SAFETY REQUIREMENTS
 - 1.1. GENERAL REMARKS



Health



Safety



MACHINERY DIRECTIVE

- BENEFITS
- IMPLICATIONS
- REQUIREMENTS





MACHINERY DIRECTIVE

BENEFITS – ONE market

750 million people in the EU – Big market: ONE directive!





MACHINERY DIRECTIVE

▪ IMPLICATIONS

- Criminal offence
- Banned product
- Bad reputation
- Insurance





MACHINERY DIRECTIVE

- **REQUIREMENTS**
 - Documentation to prove compliance





THE MACHINERY DIRECTIVE – HOW DO WE COMPLY?

1. Demonstrate compliance with Essential Health and Safety requirements (Annex I)
2. Carry out the appropriate conformity assessment procedure (Tec File)
3. Draw up and issue the Declaration of Conformity
4. Apply the CE mark



MACHINERY DIRECTIVE 2006/42/EC

This Directive applies to the following products:

- (A) machinery;
- (B) interchangeable equipment;
- (C) Safety components;
- (D) Lifting accessories;
- (E) Chains, ropes and webbings;
- (F) removable mechanical transmission devices;
- (G) Partly completed machinery;





MACHINERY DIRECTIVE

- **Complex assembly by interlinking a series of machines**
- **Change to the function or performance of the machine/assembly**
- **Repair without change of function**



MACHINERY DIRECTIVE

Complex assembly by interlinking a series of machines

- If you are creating a complex assembly by interlinking a series of existing machines - you are in Effect creating something new!
- Therefore who ever is carrying out the work must ensure that he whole assembly complies with the Directive. Regardless of the age of the machine!

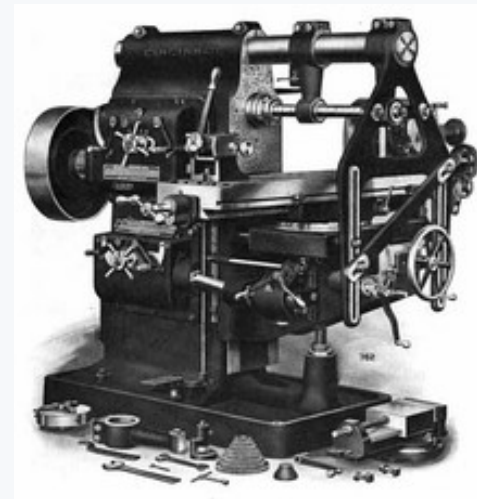




MACHINERY DIRECTIVE

Change to the function or performance of the machine/assembly

- **If you are altering the function or performance of a machine or complex assembly you are again creating something NEW and must ensure that the Directive is complied with = NEW CE MARKING**





MACHINERY DIRECTIVE

Repair without change of function

Changing a machine in a complex assembly or component in a single machine.

- IF the function or performance are NOT altered this is classes as a repair and no action is required.





RESPONSIBILITIES – RISK ASSESSMENT AND INTENDED USE

LEGAL RESPONSIBILITIES

- The manufacturer or his Authorised Representative must carry out a Risk Assessment on the machinery in order to determine the health and Safety Requirements which apply to the machinery have been met.
- The manufacturer or his Authorised Representative must determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof.



RESPONSIBILITIES - MANUFACTURER

Manufacturer - Means any natural or legal person who designs and/or manufactures machinery or partly completed machinery.

- You are the manufacturer if the product is marketed under your brand name, if you have the product made on your behalf, or if you make the product yourself.
- Responsible for compliance with all legislation
- Cannot discharge responsibility
-e.g.: to authorized representative distributor or retailer





RESPONSIBILITIES - MANUFACTURER

Manufacturer

1. Carry out conformity assessment
2. Establish technical documentation
3. Draw up Declaration of Conformity
4. Provide instructions and safety information
5. Satisfy traceability requirements:
 - Keep documentation for at least 10 years
 - Ensure equipment bears type, batch or serial no, etc...
 - Product name, company name or trade mark and address
6. Affix CE marking



QUALITY AND TRACEABILITY

According to Annex VIIA & VIIB in Machinery Directive 2006/42/EC

- **The directives demands traceability**
- **Make it available within a period of Commensurate with its complexity.**
- **Available at least 10 years in case of control from the competent national authorities – After that “end of life”**
- **The directives demands quality**
- **Internal and external document control**



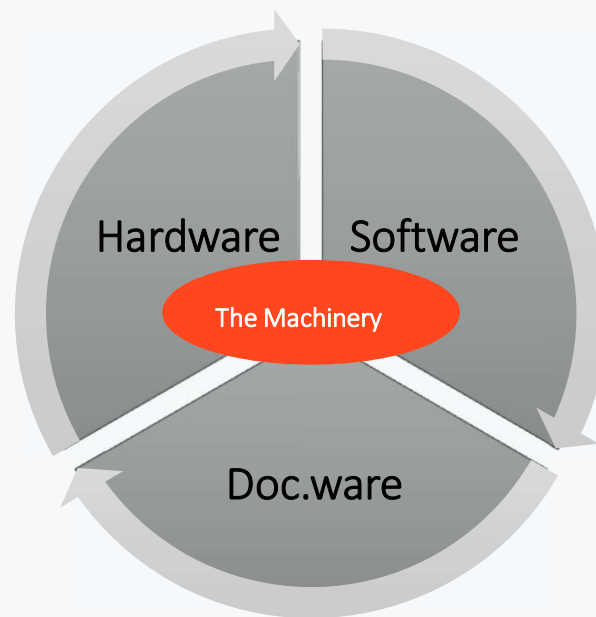
QUALITY AND TRACEABILITY

- If manufacturer within EU
 - Marked with manufacturers address
 - Applies even if actual production occurs outside the EU
- If manufacturer outside the EU
 - Marked with manufacturers address
 - Also marked with the importers address
- Own brand products
 - Marked with importer/distributor address only





The Machinery





MACHINERY DIRECTIVE

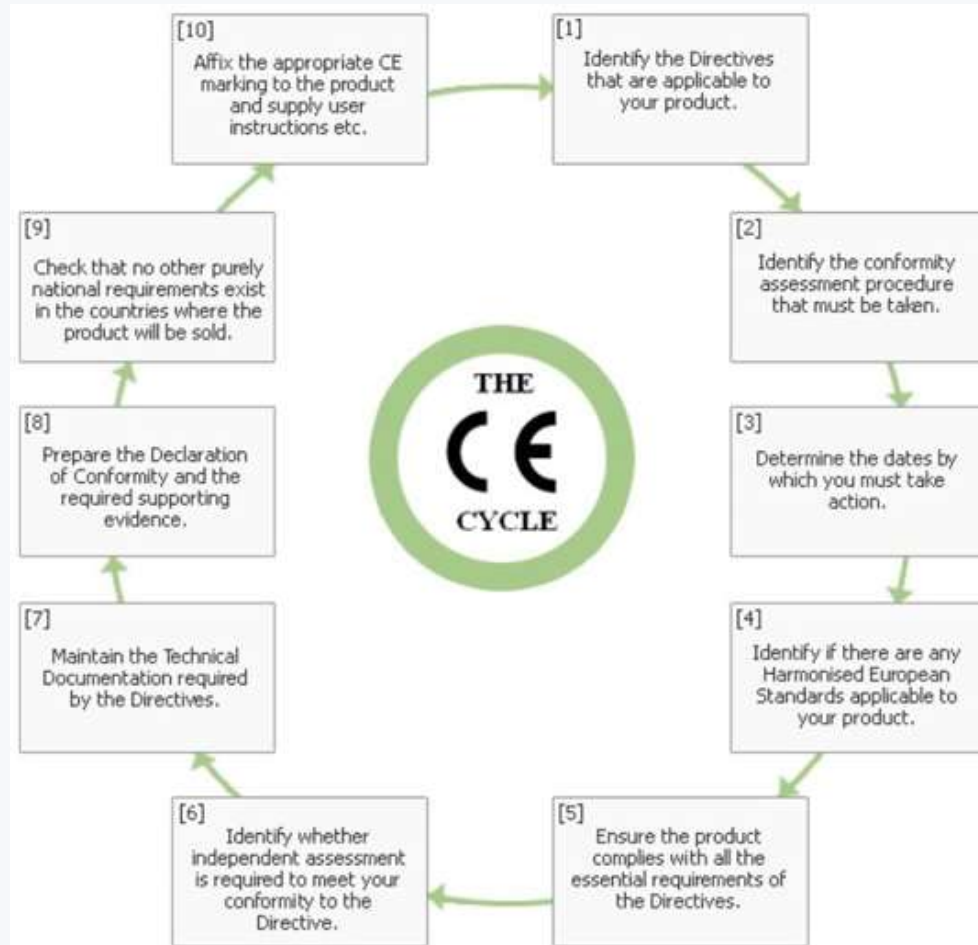
Machine, account all phases of its life

- | | |
|--------------------------|-------------------------|
| 1. Assembly | 8. Commissioning |
| 2. Test-Operation | 9. Operation |
| 3. Packing | 10. Adjustment |
| 4. Transport | 11. Maintenance |
| 5. Storage | 12. Service |
| 6. Unpacking | 13. Dismantling |
| 7. Installation | 14. Disposal |



WHAT IS CE MARKING

- Designed to enable free trade around European Union (EU) member states
- Places responsibility with the manufacturer or importer of goods, whoever places the equipment on the market
- Relates to EU Directives (European Law)
- Primarily self certification
- Not evidence compliance in itself
- CE marking is NOT a quality mark!





MACHINERY DIRECTIVE

INSTRUCTIONS/MANUALS

- **Instructions and manuals must be and are, a part of the machine and shall be treated as a machine in all other aspects.**
- **Assembly -and disassembly instructions**
- **Packing instructions**
- **Operators instructions**
- **Maintenance instructions**
(In order to be able to use the machine correctly and safely)



MACHINERY DIRECTIVE

CE CONFORMITY MARKING

- warning and signals signs are a integrated part of the machine

The purpose with warnings and signals are to reduce and minimize damages





DECLARATION OF CONFORMITY

1. A formal statement that the product complies with
 - Applicable Directives
 - Applicable Standards

2. Signed by responsible person within the organization
e.g. Company director

3. It is not evidence of compliance in itself



DECLARATION OF CONFORMITY – RELEVANCE

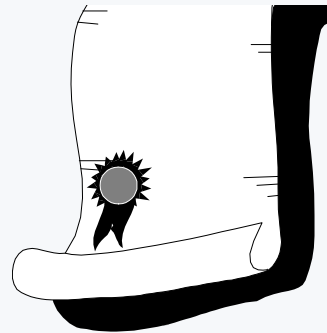
- Legal claim that the product comply with all applicable directives
- Manufacturer attests conformity with all relevant Directives and takes sole legal responsibility
- Signatory accepts liability for compliance with the Directives
- Signatory may be subject to prosecution or imprisonment
- In some instances Directives may require a Notified Body to issue a Certificate of Conformity in order to verify compliance of the product or consistency of production.



TECHNICAL FILES

TECHNICAL CONSTRUCTION FILE ACCORDING TO ANNEX VII

- Before the Declaration of Conformity Annex IIA is performed
- The following document must be available: The Technical Files





TECHNICAL FILES

TECHNICAL CONSTRUCTION FILE ACCORDING TO ANNEX VII

Your documented evidence to show that products properly comply with the requirements of the Directives which apply



TECHNICAL FILES

Technical documentation must include:

- **A overall drawing of the machine**
- **Electrical drawings**
- **Hydraulic schedule**
- **Pneumatic schedule**
- **Method description (Risk Assessment)**
- **Calculations connected to safety**
- **Drawings with emphasis on safety**
- **Copy of the Instructions manual etc.**



TECHNICAL FILES

Technical documentation must include:

- **Descriptions and explanations** – Necessary for the understanding of drawings and schemes and the operation of the equipment.
- **List of the standards applied** – In full part, and description of solutions adopted to satisfy requirements where standards have not been applied
- **List of components**
 - Complete listing of all components, materials and parts used
 - Approval information on critical components and materials

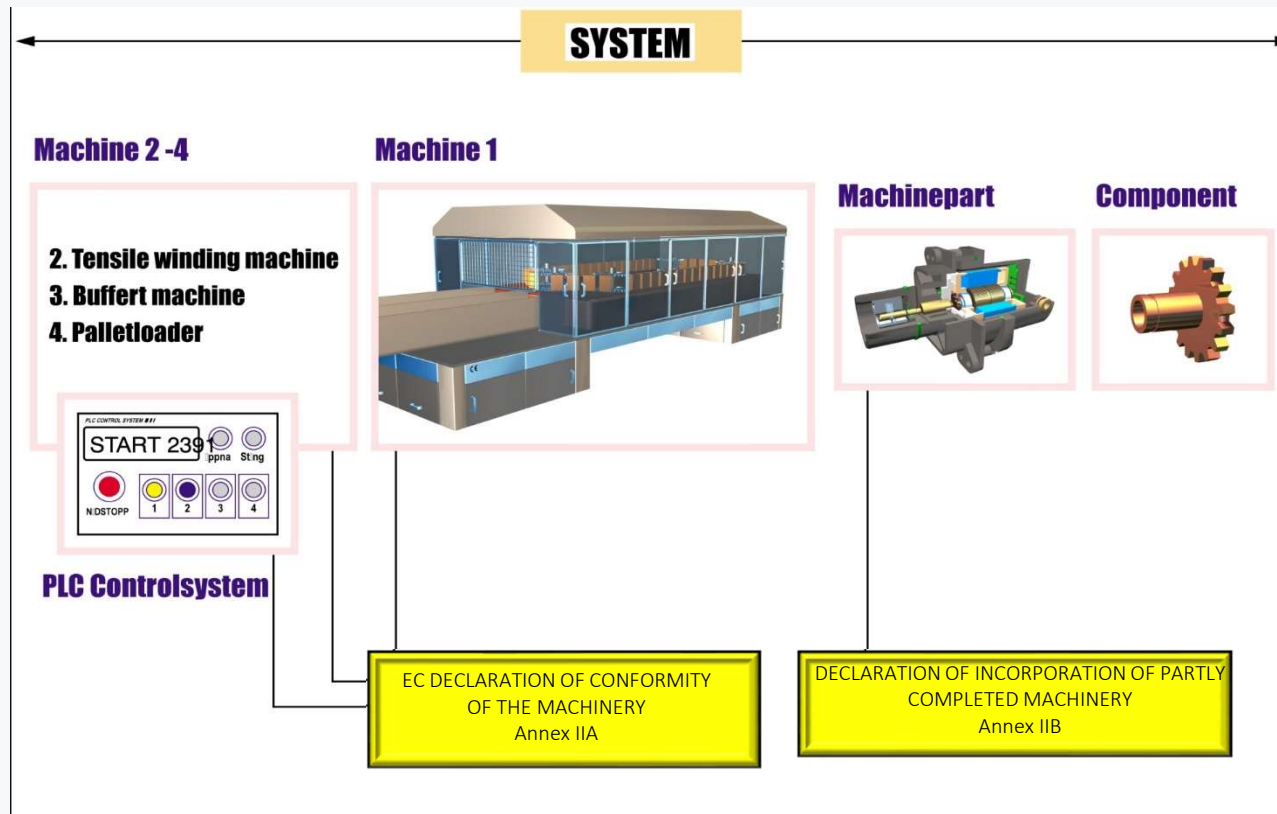


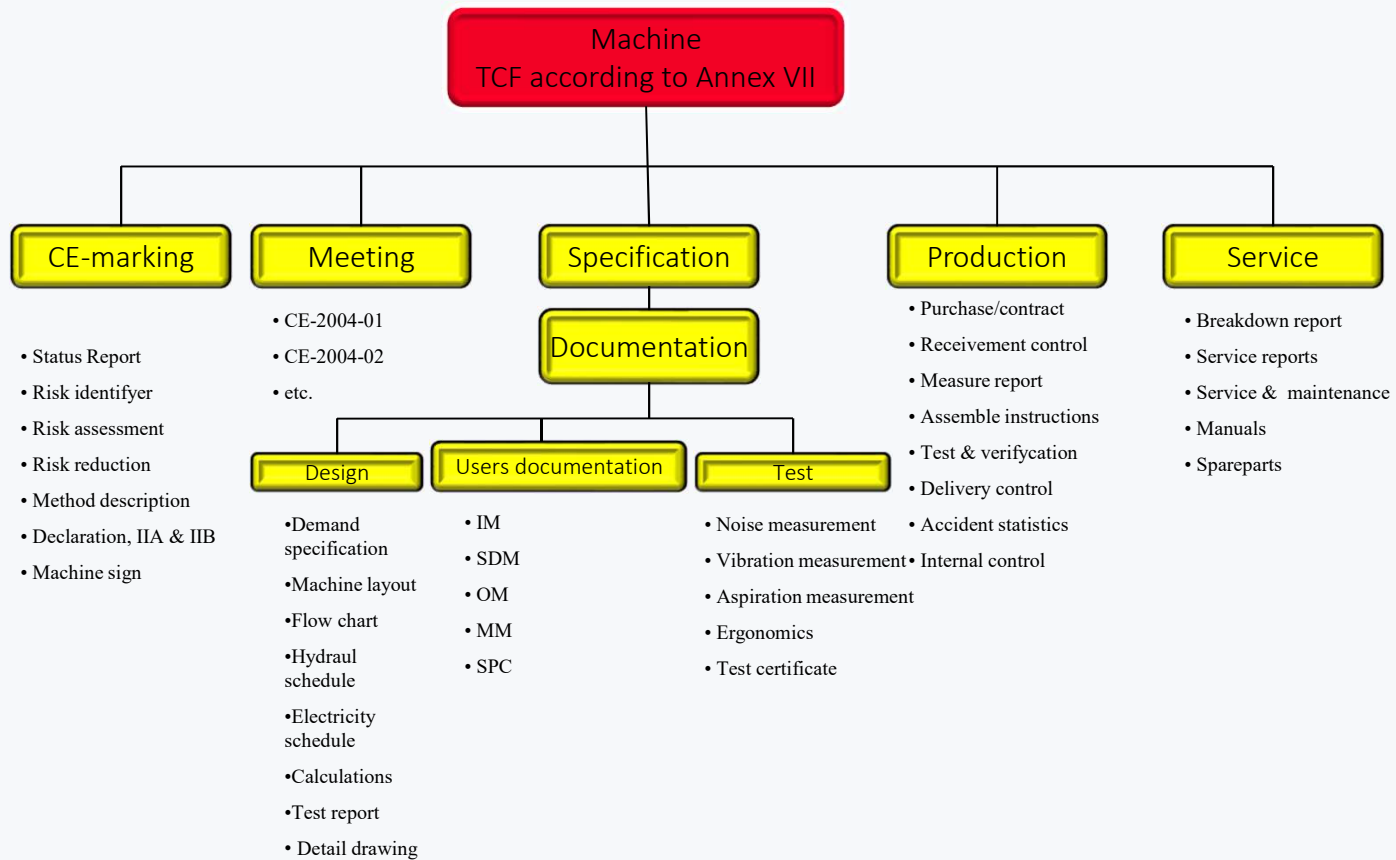
TECHNICAL FILES

Technical documentation must include:

- **Must contain all required information**
- **Can be traditional paper file**
- **Information may be stored electronically**
 - Hyperlinks can be used to link documents
 - Needs to be backed up
- **Easy to produce documentation on short notice (CE-Certifier)**
- **Be Easy to maintain and keep up to date (cant just do it and forget it)**

Directive and method of analysis Machinery means







DIRECTIVE **AND METHOD OF ANALYSIS**

WHEN CAN YOU DO THE RISK ASSESSMENT?

- **The product development phase**
- **Prototype phase**
- **First production batch**
- **Serial production**
- **On to the market**



DIRECTIVE **AND METHOD OF ANALYSIS**

SAFETY ANALYSIS

Experts in group of analysis:

- **Project leaders**
- **Designers**
- **Technical information specialists**
- **Operators**
- **Service and maintenance personnel etc.**



DIRECTIVE AND METHOD OF ANALYSIS

SAFETY ANALYSIS

- Minimize the risk for damage
- Optimize safety
- Accessibility

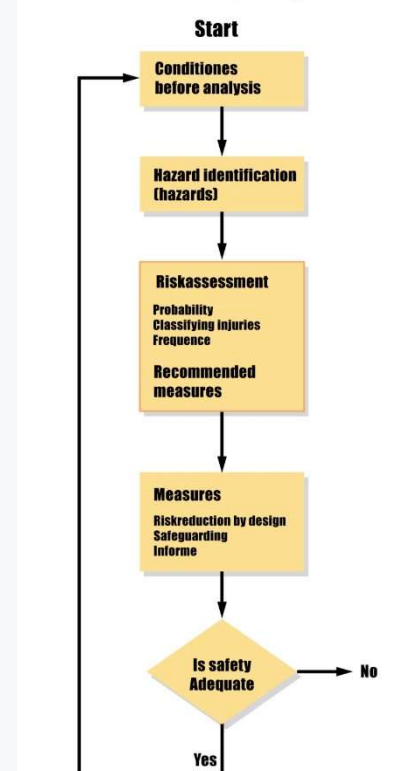




DIRECTIVE AND METHOD OF ANALYSIS

SAFETY ANALYSIS

Method for analysing hazards





DIRECTIVE **AND METHOD OF ANALYSIS**

RISK ASSESSMENT

The following methods are general and are used for product improvement as well as safety improvement:

- **Requirements review**
- **Failure mode and effects analysis (FMEA)**
- **Fault tree analysis (FTA)**



DIRECTIVE **AND METHOD OF ANALYSIS**

FMEA

Purpose

- **Failure Mode and Effects Analysis is used to identify and improve weaknesses in a design which can lead to safety risks, operation failures or increased maintenance. One version of the method includes an evaluation of risk (criticality) at the heart of the fault (FMECA).**



DIRECTIVE **AND METHOD OF ANALYSIS**

SAFETY ANALYSIS

Safety assessment generally address measures for improved safety, through:

- **Documentation of existing safety operations**
- **Design changes**
- **Material and components**
- **Safety related devices**
- **Instructions**
- **Protective equipment**
- **Other health, safety and environmental considerations**



MACHINERY DIRECTIVE

MACHINERY SIGN (MARKING)

All machinery must be marked and indelibly with the following:

- **Name and address of the manufacturer,**
- **EC-mark**
- **Designation of series or type,**
- **Serial number, if any**
- **Year of manufacture**



MACHINERY DIRECTIVE



PREKAM

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SE-238 41 Oxie
Sweden

Tel +46 70 593 89 98
Internet www.prekam.se
Email larry.falk@prekam.se



Year of manufacture

2016

Type

Tegelstaplare

Number

1995-001

Weight (Kg)

1280

Id skylt.ai



MACHINERY DIRECTIVE

Market surveillance

Enforcement authority can:

- Challenge product on the market

Pull samples from the market for examination

Request manufacturer, importer or retailer to provide technical documentation

Enlist assistance of 3rd party laboratories to test or check products

- Respond to public complaint
- Notify other member states
- Instigate legal proceedings:
 - Banning of product sale
 - Ordering product recall
 - Fines
 - Imprisonment





MACHINERY DIRECTIVE

When?

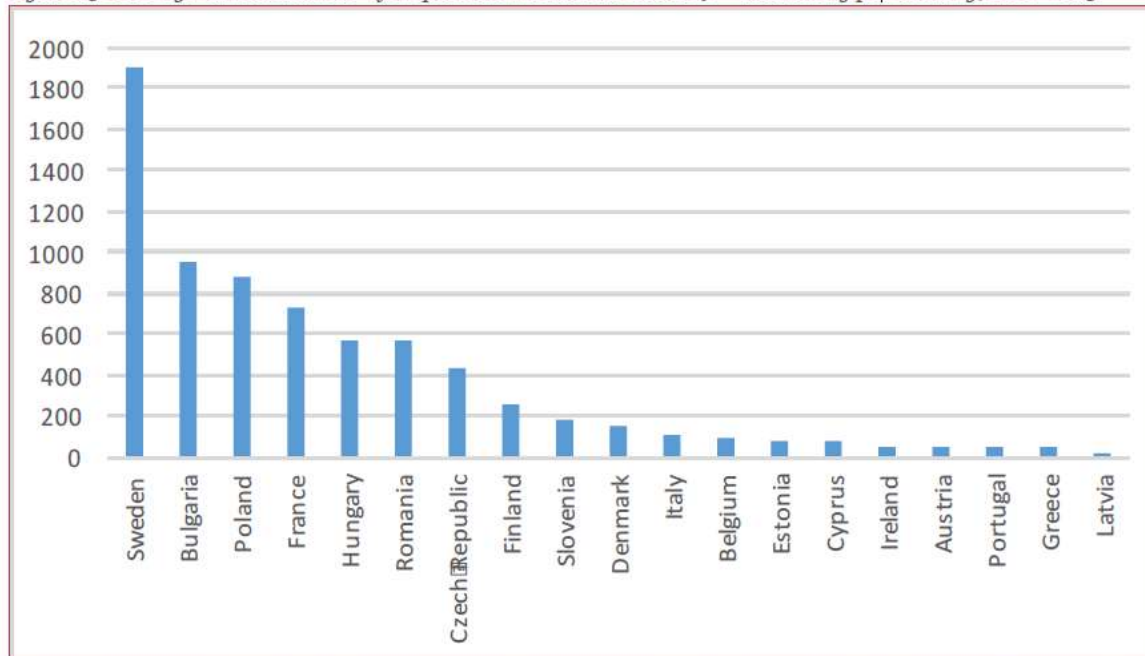
- Failure to provide a Technical File
- Failure to provide operating instructions
- Failure to provide a Declaration of conformity
- Incorrect application of the CE mark
- None application of the CE mark



Number of inspections undertaken

According to the MSA Report, the number of inspections per year varies significantly between different Member States (Figure 15) –as well as from year to year. Sweden indicated by far the largest number of inspections, with an average of 1,900 inspections per year, including a total of 5,003 inspections in 2012. Bulgaria, Poland, France, Hungary, and Romania carried out an average of between 500 and 1,000 inspections per year, and the Czech Republic, Finland, Slovenia, Denmark, and Italy between 100 and 500.

Figure 15 Average annual number of inspections relevant to Sector 9 – Machinery per country, 2010-2013



Source: Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery)

Table 46 Average annual number of inspections (2010-13) relevant to Sector 9 – Machinery, as a proportion of production value, imports and exports, by country

Machinery	Number of Inspections...	...Per 100 enterprises (2013)	...Per €1bn of production value (2013)	...Per €1bn of import value (2013)	...Per €1bn of export value (2013)
Sweden	1,904	60	91	61	56
Bulgaria	951	109	785	200	263
Poland	884	19	101	22	22
France	727	15	19	7	9
Hungary	570	23	81	20	17
Romania	559	44	206	35	41
Czech Republic	434	8	38	11	9
Finland	248	17	18	20	20
Slovenia	178	24	130	38	29
Denmark	152	9	9	10	8
Italy	103	0	1	2	1
Belgium	93	7	9	2	3
Estonia	76	51	239	19	21
Cyprus	71	120	1661	133	349
Ireland	52	19	27	5	5
Austria	52	4	3	2	1
Portugal	52	3	23	6	7
Greece	42	2	47	8	21
Latvia	22	13	116	8	11
EU (19 countries)	7,168	13	27	16	14

Sources: Inspections (Report on the Member States – Sector 9 Machinery), Number of enterprises and Production values (Eurostat [sbs_na_ind_r2]), Import / export values (COMEXT EU trade data).



GOOD EXAMPLES

HSE Goals 2017

- 4 Safety meetings/manager
- 8 HSE hours/Employee
- Accidents <1

HSE-Day

MESTO

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INTERNATIONAL AB



HSE Alert – LTI 4

Pinched hand with fingernail torn off

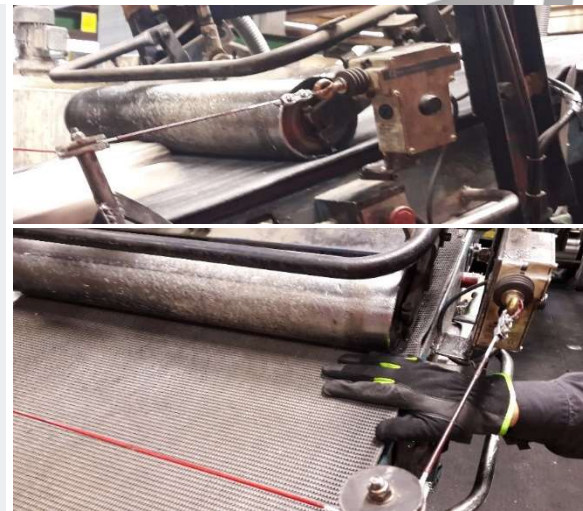
Incident description

An operator got stuck between press-roll and conveyer belt, when handling rubber. He managed to get his hand out but a fingernail was torn away and his little finger got a thin crack.

He got medical treatment at the emergency care. He is on sick leave for two weeks.

Causes

- Rotated parts not fully guarded
- The operator shouldn't have had his hand in that position



Key Learning

- Think before doing!
- Rotated parts must be guarded

Location: Ersmark, Sweden

Date: 12.10.2017

HSE Alert – RW

Puncture hand finger with pneumatic stapler

Event description:

Employee was doing the checklist (pneumatic stapler) connected to the air line, and he pushed the trigger on same time that he pushed safety lock. In this moment the staples puncture his finger.

Immediate actions:

- Reoriented all employees to follow the (JSA) job safety analysis rules. The job safety analysis for this task requires to perform the check list out air line connected to the stapler.

Causes (investigation process ongoing):

- Wrong working method: the employee doesn't follow the rules (JSA);
- Non-compliance with the working procedure;

Key Learnings:

- Allways follow (JSA) Job Safety Analysis rules.



Location: DC Sorocaba Equipament

Date: Set 28, 2017



PRODUCT LIABILITY
DIRECTIVE
85/374/EEC-



COUNCIL DIRECTIVE 85/374/EEC

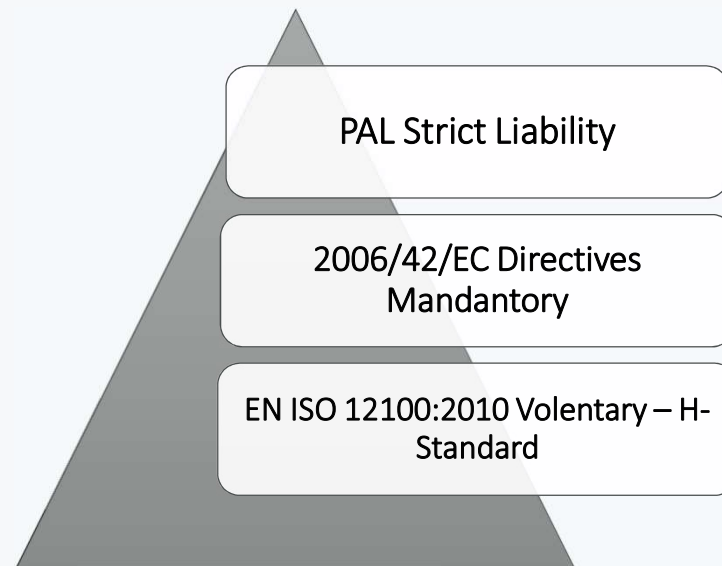
- Liability for defective product





MACHINERY DIRECTIVE

Hierarchy





Great Britain

"The Consumer Protection Act"

Deutschland

"Produkthaftungsgesetz"

Italia

**"Decreto del Presidente della
Repubblica no 224"**

Council Directive 85/374/EEC

France

"Code Civil"

Danmark

"Lov om produktansvar"



COUNCIL DIRECTIVE 85/374/EEC

- **Strict liability**
 - **Lack of safety (defect product)**
 - **Machine/machine line/facilities**
 - **Personal injuries (main purpose)**
 - **Damage to property (minor purpose)**
- **NB ! Made and only available within branch of business**



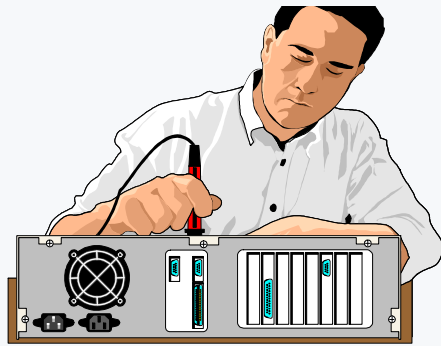
COUNCIL DIRECTIVE 85/374/EEC

Article 1:

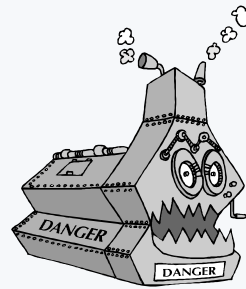
- **The producer is liable for damage caused by a defect in his product**



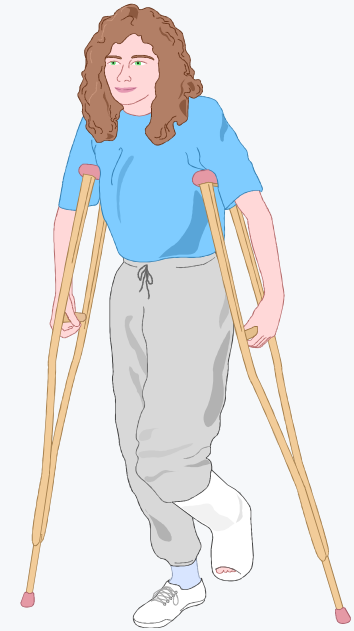
COUNCIL DIRECTIVE 85/374/EEC



The producer



The product



The injured



COUNCIL DIRECTIVE 85/374/EEC

ARTICLE 14

- Nuclear injury or damage arising from nuclear accidents:
 - is not applicable in this law,
 - covered by international conventions

- The law does not apply to damage covered by the Act (2010: 950) on liability and compensation for nuclear accidents. Act (2010: 975)



COUNCIL DIRECTIVE 85/374/EEC

DEFECTS

- **Fault in the design**
- **Production fault**
- **Fault in the instructions, operators, services and packing manuals etc.**





COUNCIL DIRECTIVE 85/374/EEC

PRODUCER/MANUFACTURER MEANS:

Manufacture of :

- Component/element
- a assembled/compound machine
- Any person putting his name, trade mark or other distinguishing feature one the product
- Imports into the community fore sale or use
- The producer of the product cannot be identified, **each supplier** shall be treated as its producer

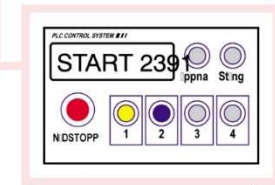
No compensation obligation:

- Agent
- A person that works with goods to be forwarded

SYSTEM

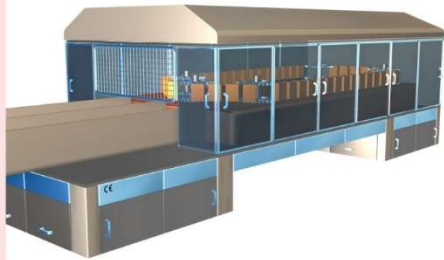
Machine 2-4

- 2. Tensile winding machine
- 3. Buffert machine
- 4. Palletloader

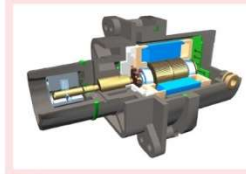


PLC Controlsystem

Machine 1



Machinepart



Component





COUNCIL DIRECTIVE 85/374/EEC

Manufacture



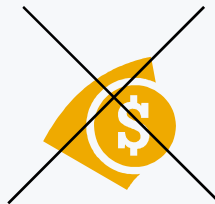
Strict responsible irrespective of carelessness

Reparation will be paid

Prove that the damage suffer has been careless and the carelessness has contributed to the damage

Be excused from paying reparation
1) Not in circulation in the Community
2) No lack of safety (defect product)
3) Forced regulations
4) Development miscalculation

Prove limitation



The injured person

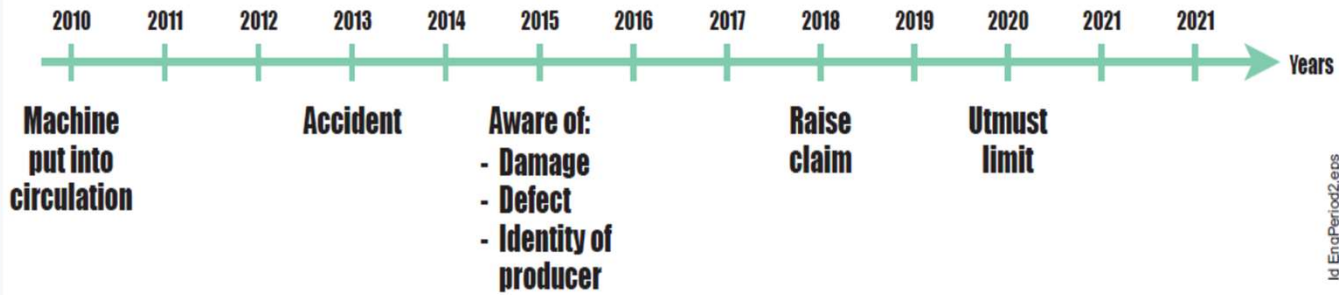


Prove

- 1) Personal or property damage
- 2) Lack of safety (defect product)
- 3) That defect product has caused the damage

Adjustment due to cause

PERIOD OF LIMITATION





STANDARDS



STANDARDS





STANDARDS

- ISO-International Organization for Standardization
- CEN-European Committee for Standardization
- National standard bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom





STANDARDS

Standardization shall lead to

- **Simplification**
- **Safety**
- **Profitability**
- **Easier communication**



HARMONIZED STANDARDS

- The general requirements are stipulated in the product directives, usually named "The New Approach".
- The standards contain detailed specifications of technical details.
- The standards are requests.
- Don't take to mean the directives if there is a harmonized standard – C standard

Official Journal
of the European Union





HARMONIZED STANDARDS

The categorizing of CEN and CENELEC

- **Type A standards are basic safety standards covering basic concepts, design principles and general aspects that can be applied to all machinery.**

EN-ISO 12100:2010 is one of these standards. These are adopted as national standards and refer to the underlying type B standards.



HARMONIZED STANDARDS

CEN and CENELEC'S categorization

Type B standards are generic safety standards covering safety aspects or one type of safeguard that can be used across a wide range of machinery. However, there are two types of B standards, Type B1 standards for particular safety aspects and Type B2 standards for safeguards.

1. B1 standards; particular safety aspects, such as safe distance Uper and lower limbs, for example BS - EN ISO 13857, sections of human bodies crushed BS - EN 349 + A1
2. B2 standards; safety related devices such as two-hand operated devices EN 574, Emergency stop BS – EN ISO 13850



HARMONIZED STANDARDS

CEN and CENELEC'S categorization

- **Type C standards are machine safety standards dealing with details safety requirements for a particular machine or group of machines. Example:**
- **SS-EN 619:2010 - Transports and transportation system**
- **SS-EN 1570-1 - Lifting table**
- **SS-EN 415-4 - Safety of packaging machines - Palletizers and depalletizers**

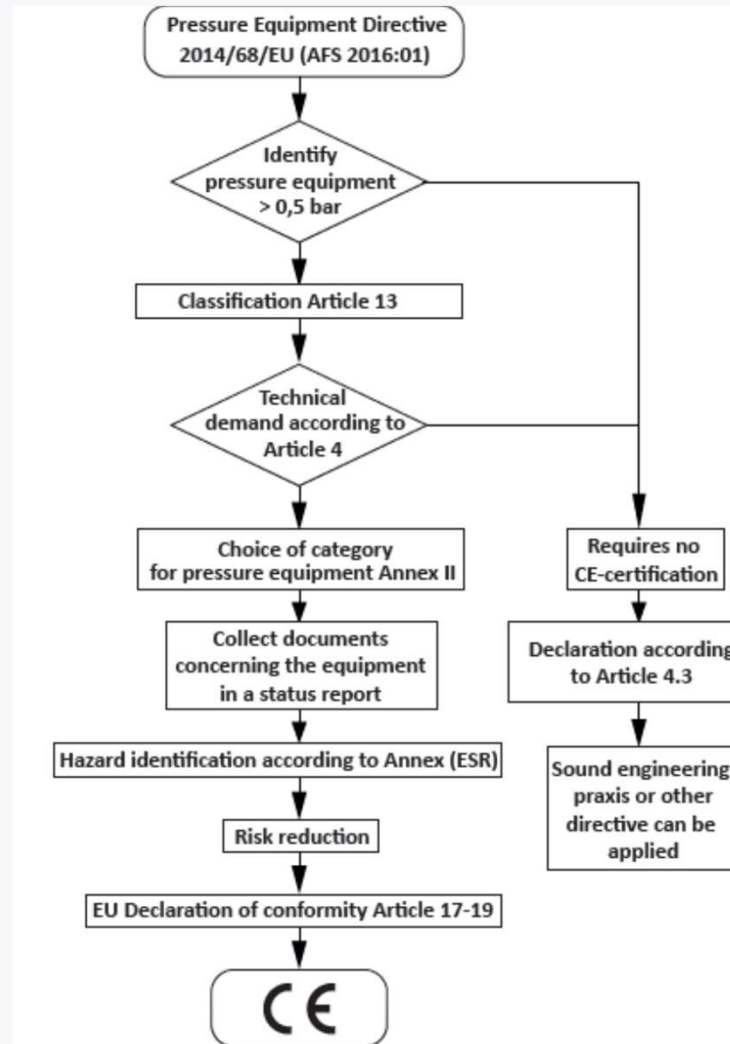


PED

2014/68/EU



The Process



Pressure Equipment Directive

2014/68/EU

- **Generally the pressure equipment must be fitted with a CE mark.**
- **Generally, the pressure equipment must be approved by a notified body (third party)**
- **The marking shall be accompanied by the identification number of the notified body engaged.**

Pressure Equipment Directive

2014/68/EU

The new Directive 2014/68/EU (AFS 2016:01) will fully enter into force on 20 July 2016

Pressure Equipment Directive classification fluids – article 13

For the purposes of such classification fluids shall be divided into the following two groups:

Fluidgroup 1 & 2

- **Fluidgroup 1 that are classified as hazardous:**

- - flammable gases, category 1 and 2;
- - oxidising gases, category 1;
- - flammable liquids, category 1 and 2;
- - oxidising liquids, category 1, 2 and 3;
- - oxidising solids, category 1, 2 and 3;
- - organic peroxides types A to F;
- - acute oral toxicity, category 1 and 2;



Pressure Equipment Directive classification fluids

**group 2 consisting of substances and mixtures not referred to
in Fluid group 1**



Pressure Equipment Directive

2014/68/EU

Technical requirements

- ***Article 4 (6§)***
- **1. The following pressure equipment shall satisfy the essential safety requirements set out in **Annex I**:**
- **(a) vessels, except those referred to in point (b), for:**
- **(i) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:**

Module	Conformity Assessment	Description
A	Internal production control.	This module describes the procedure by which manufacturer ensures and declares that pressure equipment satisfies the requirements of the Directive which apply to it.
A1	Internal production control with monitoring of final assessment.	As above but in addition includes monitoring of final assessment by notified body.
B	EC type - examination.	Describes the part of the procedure where a notified body ascertains and attests that a representative example of the production meets the provisions of the Directive which apply to it.
B1	EC design - examination.	Describes the part of the procedure where a notified body ascertains and attests that the design of an item meets the provisions of the Directive which apply to it.
C1	Monitoring of final assessment.	Describes procedures where the manufacturer, or authorised representative ensures and declares that the pressure equipment is in conformity with the type as described in the EC type examination certificate and satisfies the requirements of the Directive which apply to it.
D	Quality assurance for production, final inspection and testing.	Describes procedures where the manufacturer ensures and declares that the pressure equipment conforms with the type described in the EC type examination certificate or the EC design certificate and satisfies the requirements of the Directive which apply to it.
D1	Quality assurance for production, final inspection and testing.	This module describes the procedure by which manufacturer ensures and declares that pressure equipment satisfies the requirements of the Directive which apply to it.
E	Quality assurance for final inspection and testing.	Describes procedures where the manufacturer ensures and declares that the equipment is in conformity with the type described in the EC type examination certificate and satisfies the requirements of the Directive which apply to it.
E1	Quality assurance for final inspection and testing.	Describes the procedure where the manufacturer ensures and declares that the equipment satisfies the requirements of the Directive that apply to it.
F	Product verification.	Describes the procedure where the manufacturer or authorised representative ensures and declares the pressure equipment is in conformity with the type as described in the EC type examination certificate or the EC design certificate and satisfies the requirements of the Directive.
G	Unit verification.	Describes the procedure where the manufacture ensures and declares the pressure equipment which has been issued with a certificate of conformity for tests carried out satisfies the requirements of the Directive.
H	Full quality assurance	Describes the procedure where the manufacture ensures and declares the pressure equipment satisfies the requirements of the Directive.
H1	Full quality assurance with design examination and monitoring of final assessment.	As above.

Pressure Equipment Directive

2014/68/EU

Technical requirements

Article 4 (6§)

Depending on the pressure equipment and the functionality, it is based on: pressure, volume, media and / or temp.

Selects charts and obtains the category the pressure equipment falls under.

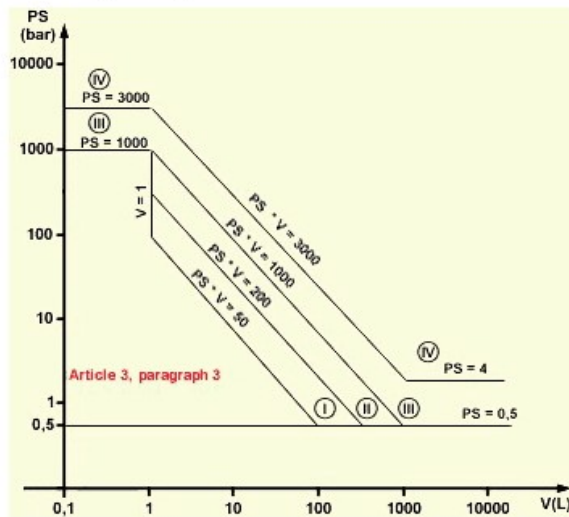
Assessment of the in the following table in Annex II

Pressure Equipment Directive 2014/68/EU

Selecting category and module

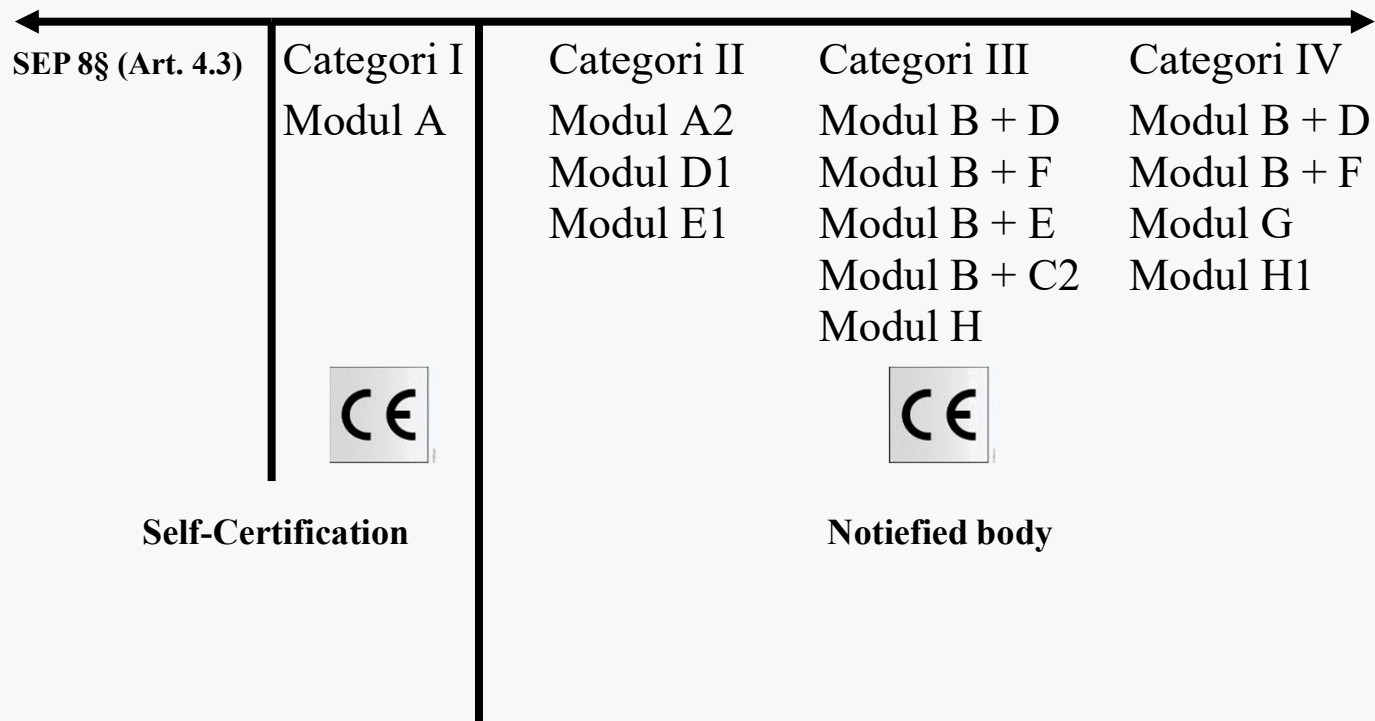
Selection of Category

According to diagram: 2





Pressure Equipment Directive AFS 2016:01 (2014/68/EU)





EMC

2014/68/EU



DIRECTIVE **AND METHOD OF ANALYSIS**

EMC DIRECTIVE

Electromagnetic Combability:

- Applies to all electrical and electronic apparatus which are liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance.

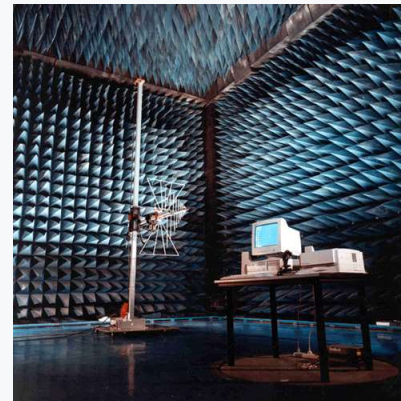


DIRECTIVE AND METHOD OF ANALYSIS

EMC DIRECTIVE

The EMC directive prescribe:

- All electrical and electronic devices together with equipment and devices and installations which contain electrical and/or electronic components
- The devices shall manage electromagnetic disturbance level described in the harmonized standards for emission/immunity





ESSENTIAL REQUIREMENTS - EMC

EMC DIRECTIVE

Equipment shall be designed and manufactured to ensure that:

The electromagnetic disturbance it generates does not exceed a level above which radio and telecommunications equipment or other equipment cannot operate as intended;

It has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.



ATEX

2014/34/EU

ATEX – Directive

ATEX = ATmosphere EXplosible

A potentially explosive atmosphere exists when a mixture of air gases, vapors, mists, or dusts combine in a way that can ignite under certain operating conditions.

Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX) cover a range of products, including those used on fixed offshore platforms, petrochemical plants, mines, and flour mills, amongst others.




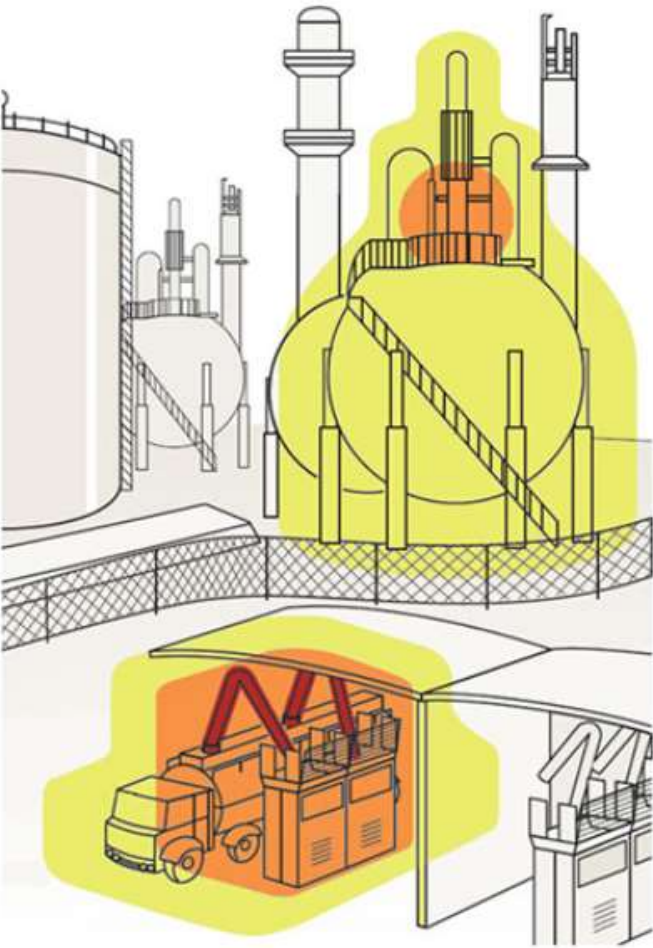


ATEX - Zones

- Zone 0 - A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is present continuously or for long periods or frequently
- Zone 1 - A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is likely to occur in normal operation occasionally.
- Zone 2 - A place in which an explosive atmosphere consisting of a mixture with air of dangerous substances in the form of gas, vapor or mist is not likely to occur in normal operation but, if it does occur, will persist for a short period only.

*Hazard - Dusts

- Zone 20 - A place in which an explosive atmosphere in the form of a cloud of combustible dust in air is present continuously, or for long periods or frequently.
- Zone 21 - A place in which an explosive atmosphere in the form of a cloud of combustible dust in air is likely to occur in normal operation occasionally.
- Zone 22 - A place in which an explosive atmosphere in the form or a cloud of combustible dust in air is not likely to occur in normal operation but, if it does occur, will persist for a short period only.

User Directive	Manufacturer Directive	ATEX Environment
<p>Zoning definition</p> <p>ATEX Gas (or ATEX Dust)</p> <p>Zone 2 (or 22)</p>  <p>Zone 1 (or 21)</p>  <p>Zone 0 (or 20)</p> 	<p>Equipment category</p> <p>ATEX Gas (or ATEX Dust)</p> <p>Category 3G/2G/1G (or 3D/2D/1D)</p> <p>Category 2G/1G (or 2D/1D)</p> <p>Category 1G (or 1D)</p>	<p>ATEX Environment</p> 

ATEX – Directive 2014/34/EU

Equipment for potentially explosive atmospheres AFS 2016: 4

Section 1 These regulations apply to the following products:

1. **Equipment and protective systems** intended for use in potential explosive atmospheres.
2. **Security and regulatory devices** intended for use outside potentially explosive atmospheres but required for, or contributing to equipment and safety systems should work safely taking into account the explosion hazards.
3. **Components** intended to be installed in such equipment and equipment such security systems as referred to in paragraph 1.

ATEX – Directive 2014/34/EU

The regulations do not apply to

1. the design and execution of electrical equipment covered by the Swedish Civil Protection Agency's electrical equipment and electrical safety systems intended for use in potentially explosive atmospheres;

ELSÄK-FS 2006: 4

Electrical Safety Agency's regulations on electrical equipment for potentially explosive atmospheres and general advice on the application of the prescriptions (Celex 394L0009)

User Responsibility:

**About minimum requirements for improvement of safety
and health workers**

which may be endangered by explosive atmospheres



1999/92/EG



Användardirektivet



LVD

2014/35/EU



LVD

LOW VOLTAGE DIRECTIVE

The directive states that all electrical equipment means all equipment intended for use with a rated voltage of 50-1000 V alternating current and 75-1500 V direct current – EN 60204-1 elsäk-stand



LVD

LVD DIRECTIVE

Each National Electrical Safety Board aims to prevent injury to persons and damage to property caused by electricity. They also endeavor to ensure that electrical equipment and installations are designed and carried out so that they do not disturb each other when used together



LVD

Traceability

Products must:

- Be marked with their rated characteristics
- Be clearly marked with the brand name or the trade mark
- Be made in such way as to ensure that it can be safely and properly assembled and connected
- Protect against hazards arising from the electrical equipment to ensure:-
 - That persons of physical injury or other harm which might be caused by direct or indirect contact;
 - That temperatures, arcs or radiation which would cause a danger, are not produced;
- * That the insulation must be suitable for foreseeable conditions



PREKAM

SAFE Solutions

THANK YOU FOR YOUR TIME!

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