



Technical Seminar

EU – Technical Regulations

in the

sector Machinery

Belgrade, 17.-18. 09. 2008

complementary slides by Harald Riekeles



Introduction of Harald Riekeles

formerly

- Managing Director Standardization of VDMA - German Machinery and Plant Manufacturers Association, Frankfurt and of German Standards Committee for Mechanical Engineering (NAM) in DIN
- Rapporteur of CEN Sector Machinery Safety



Principles of ACAAs

Agreements for Conformity Assessment and Acceptance of Industrial Products

Specific Type of MRA “to establish genuine strategic partnerships with the countries adjoining the enlarged Europe”

Use of the **Community system** of standardization and conformity assessment **in selected harmonized sectors** by third countries to facilitate trade and market access in both directions

Model for countries currently **not** candidates for EU:

- **Approximation of third countries’ legislation with that of EU**
- Adoption of appropriate implementing structures, particularly in the field of standardization



Principles of PECAs

Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products

specific types of MRAs with EU candidate countries;
major instrument of the pre-accession strategy in the field of free movement of goods;
create an enlarged Internal Market for products in certain industrial sectors prior to accession.

Under the terms of the **Europe Agreements**, candidate countries for EU membership should approximate their legislation to that of the EU. In the field of industrial standards and conformity assessment, the Europe Agreements aim to achieve the candidate countries' full conformity with Community technical regulations and European standardization and conformity assessment procedures.



EU Legislation

Secondary legal documents:

- Regulations
 - general application
 - directly applicable in the Member States
- **Directives**
 - **addressed to and binding the Member States**
 - freedom for the form of implementation
- Decisions
 - binding entirely upon those to whom they are addressed
- Recommendations
- Opinions
 - have both no binding force



New Approach - Principles -

Technical Rules defined in

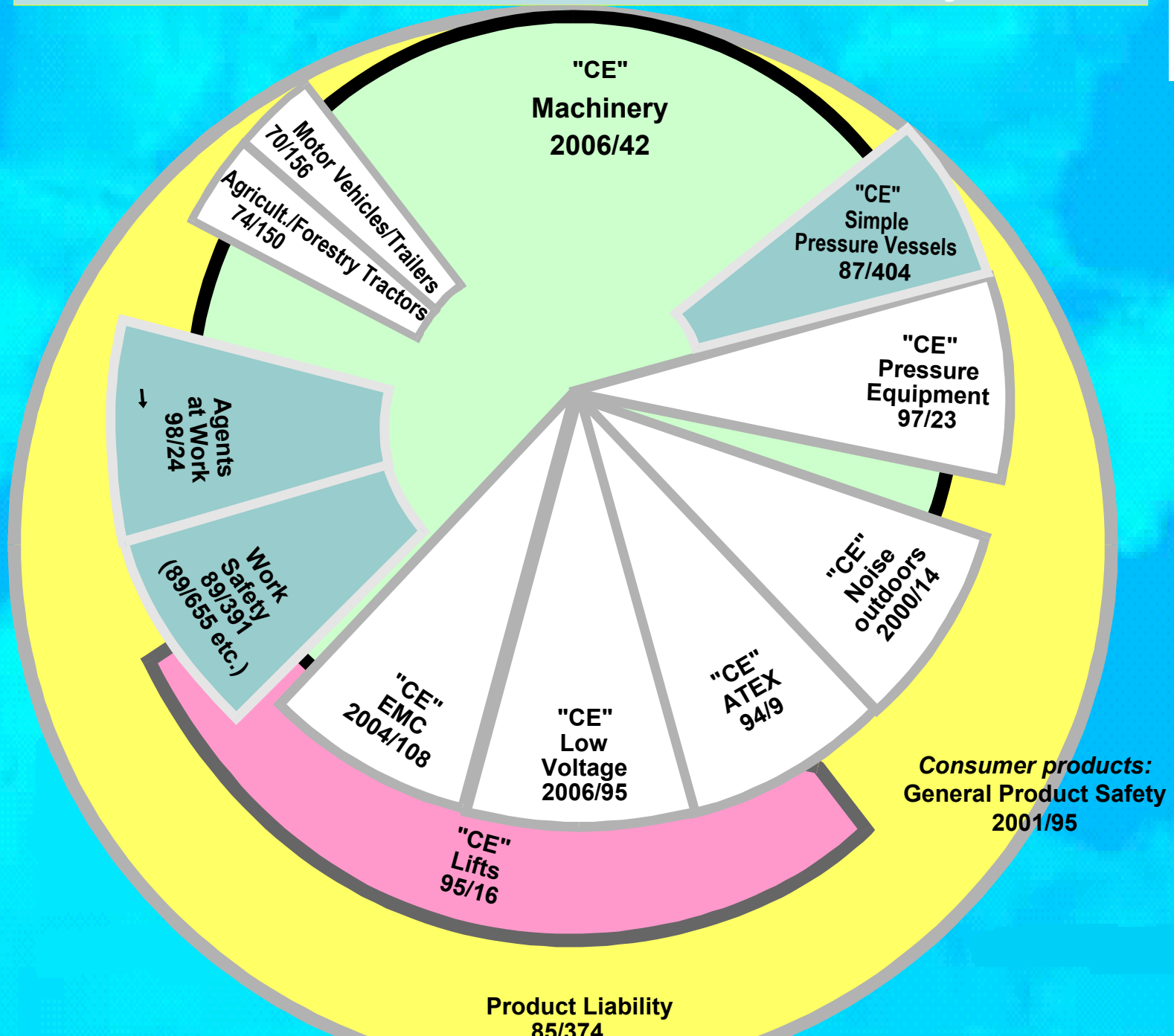
- **Compulsory EC Directives**
with general Essential (Safety) Requirements
 - **Voluntary Harmonized European Standards**
specifying the Essential Requirement(s)
-
- Mandated **Harmonized Standards** referenced in the Official Journal of the European Union - OJEU -
grant a formal **Presumption of Conformity**



New Approach - Directives -

- **Contain general requirements** for defining the **technical characteristics of products**
- **Encompass a large number of similar products** which present the same type of hazards and can therefore be defined by similar requirements
- **Do not define technical details, but state "Essential Requirements - ERs" valid in the whole EU**
- **Provide conformity assessment - / certification procedures**
- In the legal sense only on the basis of the Essential Requirements alone a product will be assessed for its ability to be put on the market
- For a certain product **several Directives may apply** >>>

EU Directives related to Machinery





General EU Directives



No “CE” marking

94/62/EC on Packaging and Packaging Waste

Identification system, composition and the reusable and recoverable (including recyclable) nature of packaging.

2001/95/EC on General Product Safety

for Consumer products and migration products!

For products covered by New Approach Directives additional manufacturer obligations for market surveillance, i.e. recall of products.

85/374/EEC on Product Liability

to prevent placing on the market and putting into service of defective products, which can cause damage to health of persons.



Directives

RoHS 2002/95/EC

and WEEE 2002/96/EC

amended by 2003/108/EC

RoHS = Restriction of use of certain hazardous substances in electrical and electronic equipment

No CE marking

WEEE = Waste electrical and electronic equipment

No CE marking - is an environment directive (art.175)



Recovery of WEEE

Producers / Importers of mainly household and consumer equipment:

Are responsible for **ensuring return of WEEE** to distributors on a “one to-one basis” set-up and operate individual and/or collective take-back systems

Or third parties (on their behalf) set up systems for the **treatment**, permitted and verified by competent authorities, meet certain **recovery** rates **recording** mass etc.

Shall provide **information** to private users how and where to dispose, the potential effects on environment and health, users role

Shall mark the product with the “crossed out wheel bin” symbol and as “new equipment” and identify the producer

Shall provide within one year after putting on the market information to recyclers on reuse and treatment



Standardization

Standardization Bodies

Role of Standards

Mandated Harmonized Standards



European Standards Bodies



**CEN (Comité Européen de Normalisation /
European Committee for standardization)**

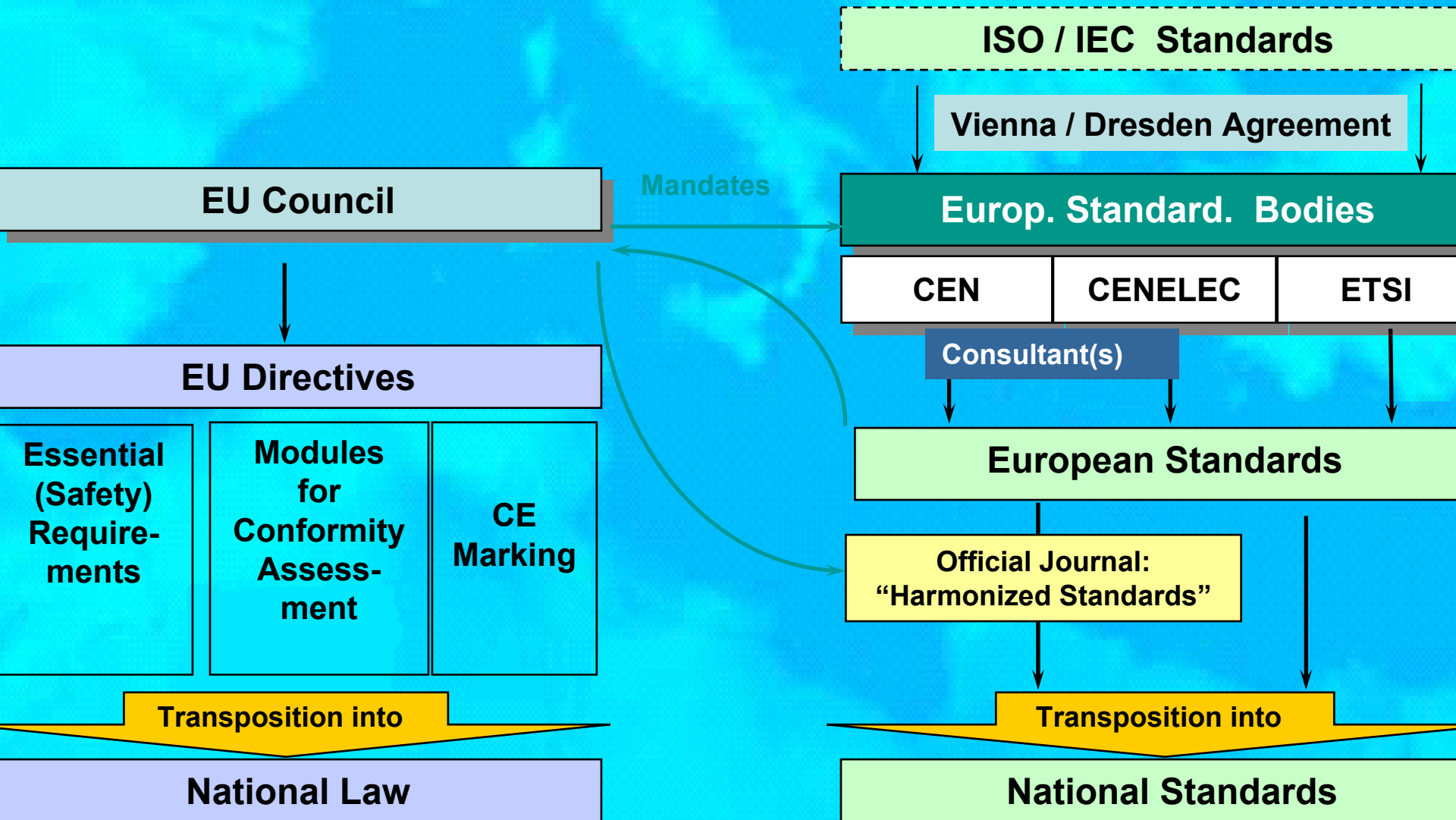


**CENELEC (Comité Européen de Normalisation
Electrotechnique /
European Committee for Electrotechnical
standardization)**



**ETSI (European Telecommunications Standards
Institute)**

Role of European and International Standards in the “New Approach”





New Approach Standards

Harmonized Standards

- define the technical details for fulfilling the Essential Requirements of Directive(s)
- mandated by the Commission
- drafted by a European or International Standards Organization
- approved by a European Standards Organization (CEN, CENELEC or ETSI)
- conveyed to the Commission for publication in the Official Journal under the Directive(s) in question
- transposed by all Member States as national standard

Presumption of conformity

- products made according to harmonized Standards are presumed to fulfill the Essential Requirements dealt with >>>



New Approach Directives - Presumption of Conformity -

Presumption of Conformity:

products made according to Harmonized Standards are presumed to fulfil the Essential Requirements, BUT...

only presumption of conformity within the Scope of the standard and ESRs dealt with

the standard may refer to other directives that can be applicable to the product

information on presumption of conformity to be found in Annex Z of the Harmonized Standard

presumption of conformity can also be reached without applying standards





Information in Mandated harmonized Standards on Presumption of Conformity

ANNEX Z (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive

Once this standard is cited in the OJEU under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard ((*except clause(s)*)) confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements ((*except Essential Requirement(s).....*)) of that Directive

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard



Role of Harmonized Standards for Market Surveillance

- harmonized standards constitute the basis for rational market surveillance.
- harmonized standards provide means of compliance with legal requirements.
- Provisions of harmonized standards are not compulsory, but give criteria for the assessment of other means (e.g. level of safety).
- Provisions in product standards take precedence over those of basic and group standards.



Standards for Machinery Safety

Harald Riekeles



CEN - Machinery Safety

Hierarchy of standards

Typ A-Standards

Basic safety standards

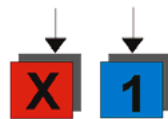
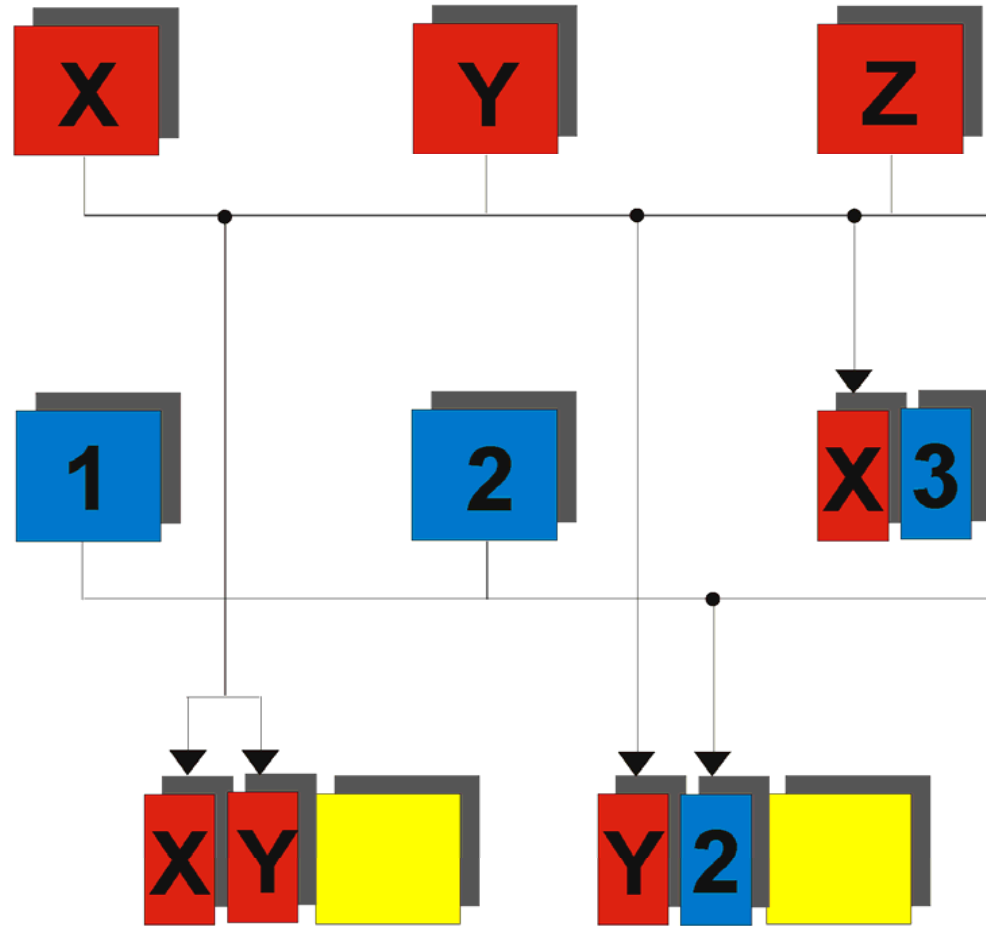


Typ B-Standards

Group safety standards

Typ C-Standards

Machine safety standards



Reference to type A- and B-standards

machine specific as "added values"



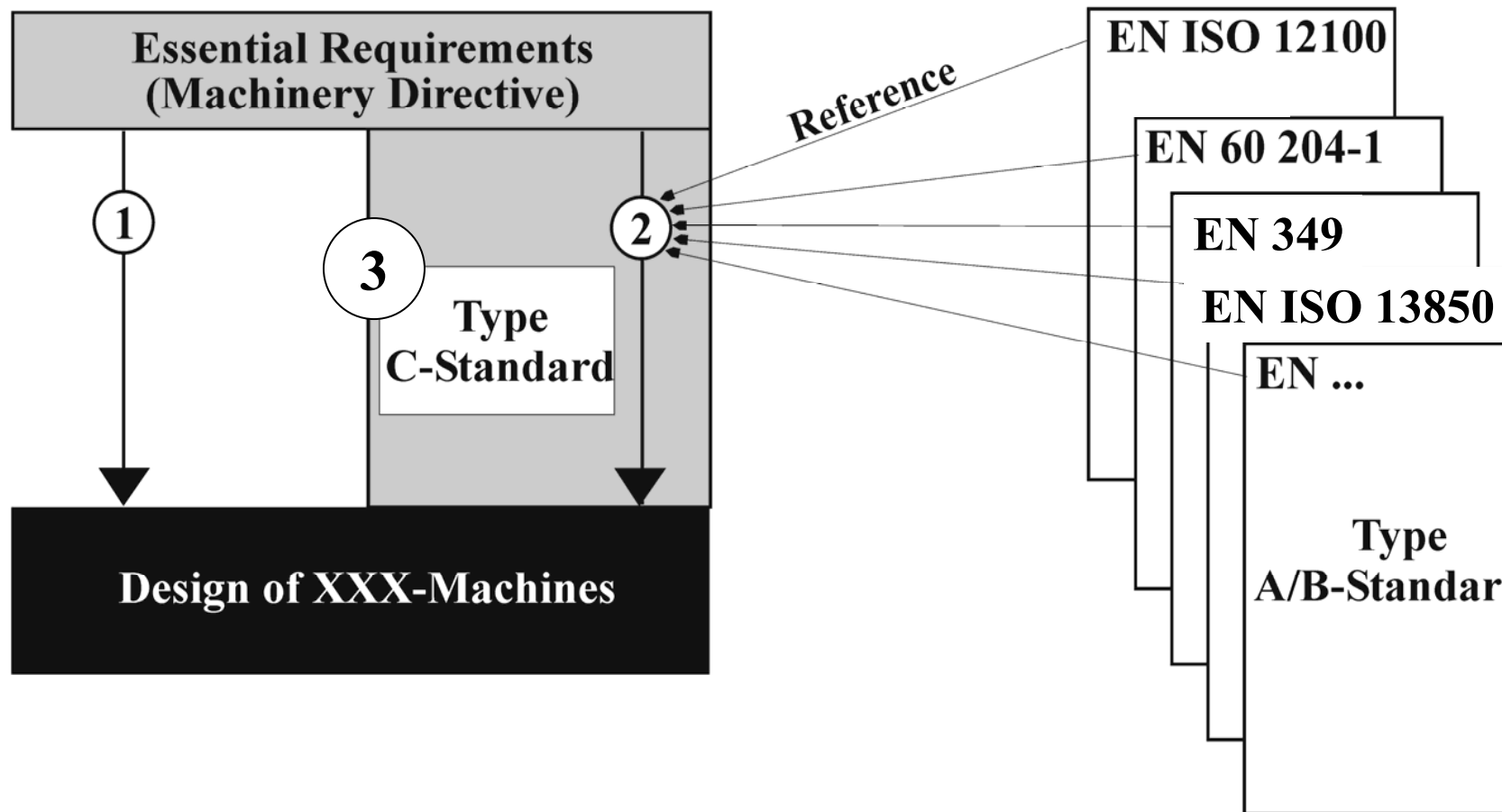
ENs for Machinery

Machinery in conformity with **harmonized ENs** (approved by **CEN** or **CENELEC**) is **presumed to fulfill the ESRs** dealt with in these standards.

Application of standards is voluntary!

- **Type A:** the basic safety standards applicable to all machinery,
- **Type B:** standards on safety aspects e.g. noise, distances, or safety devices such as guards and electro-optical protective devices,
- **Type C:** standards for specific types of machinery providing **Presumption of Conformity**

Fulfilling Essential Requirements by applying harmonized Standards





Technical Committees

Machinery Safety

Type A- / B-Standards

- CEN/TC 114 - Safety (general)
- CEN/TC 122 - Ergonomics
- CEN/TC 169 - Lighting
- CEN/TC 211 - Acoustics
- CEN/TC 231 - Vibrations
- CEN/TC 305 - Explos. Atmosph.
- CLC/TC 44x - Electrot. Aspects
-
- total > 130 Standards-Projects

Type C-Standards

- CEN/TC 10 - Lifts
- to
- CEN/TC 322 - Rolling Mills
- CLC/TC 61, 61F Electr. Too
- Electr. Household Equip
-
- total > 40 TCs
- with 650 Standards-Project

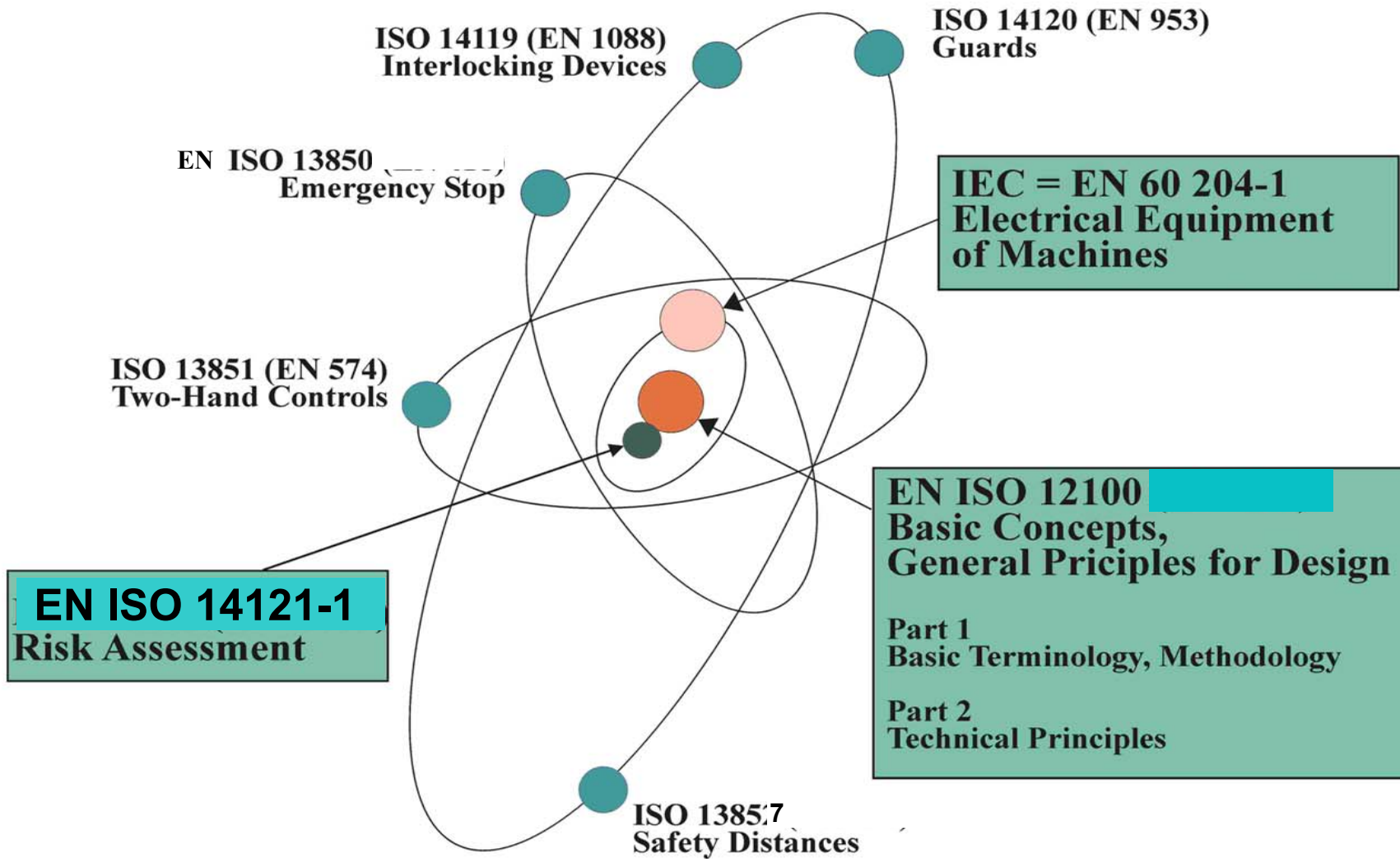
New Approach Standardisation in the Internal Market

Directives & Standards

Directive reference	Subject of directive	Info about directive	Standards activities
90/396/EEC	Appliances burning gaseous fuels	▶	▶
90/269/EEC	Cableway installations designed to carry persons	▶	▶
89/106/EEC	Construction products	▶	▶
89/336/EEC	Electromagnetic compatibility	▶	▶
94/9/EC	Equipment and protective systems in potentially explosive atmospheres	▶	▶
93/15/EEC	Explosives for civil uses	▶	▶
95/16/EC	Lifts	▶	▶
73/23/EEC	Low voltage equipment	▶	▶
98/37/EC	Machinery safety	▶	▶
90/385/EEC	Medical devices: Active implantable	▶	▶
93/42/EEC	Medical devices: General	▶	▶
98/79/EC	Medical devices: In vitro diagnostic	▶	▶
92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)		▶
90/384/EEC	Non-automatic weighing instruments		▶
94/62/EC	Packaging and packaging waste		▶
89/686/EEC	Personal protective equipment	▶	▶
97/23/EC	Pressure equipment	▶	▶
99/5/EC	Radio and telecommunications terminal equipment	▶	▶
94/25/EC	Recreational craft	▶	▶
87/404/EEC	Simple pressure vessels	▶	▶

Basic- and Group-Standards

The “Core” EN ISO 12100 - Parts 1 / 2 , and its Satellites



Guide to horizontal standards for Safety of Machinery (1)

Basic standards (Type A)

Basic concepts, principles for design	EN ISO 12100-1	Methodology, terminology
	EN ISO 12100-2	Technical principles
Hazard analysis, risk assessment	EN ISO 14121-1	Principles, list of hazards
Explosive atmospheres	EN 1127-1	Explosion prevention; methodology

Generic/group safety standards (Type B1) for safety aspects

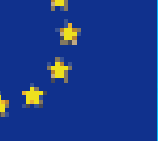
Dangerous materials	EN 626-1	Reduction of risks to health
	EN 626-2	Verification procedures
	EN 1093-1	Air pollution, test methods
Electromagnetic Compatibility	EN 61000-6-1	Electromagnetic immunity - residential, light industry
	EN 61000-6-2	Electromagnetic immunity - industrial environment
	EN 61000-6-3	Electromagnetic emission - residential, light industry
	EN 61000-6-4	Electromagnetic emission - industrial environment
Ergonomic design	EN 614-1	Principles for design
	EN 547-3	Anthropometric data
	EN 1005-1	Human physical performance; terminology
	EN 1005-2	Manual handling of objects
	EN 1005-3	Force limits machinery operation
	EN 13861	Guide for application of ergonomic standards
Fire	EN ISO 14738	Design of workstations for machinery
	EN 13478	Fire prevention and protection

Guide to horizontal standards for Safety of Machinery (2)


Generic/group safety standards (Type B1) for safety aspects

(continued)

Hygiene	EN 1672-2	Food processing machines (Type C-standard)
	EN ISO 14159	Requirements for machinery
Laser	EN ISO 11553-1	Laser processing machines
	EN 60825-1	Laser products
Noise	EN ISO 3740	Guidelines for determination of sound power level
	EN ISO 3744	Determination of sound power levels using sound pressure – engineering method
	EN ISO 4871	Declaration, verification
	EN ISO 11200	Guidelines for determination of sound pressure level
	EN ISO 11688-1	Low noise machinery – planning
	EN ISO 11688-2	Physics of low-noise design
	EN ISO 11689	Comparison of emission
Radiation	EN 12198-1	Assessment and reduction of risk
	EN 12198-2	Radiation emission measurement
	EN 12198-3	Reduction of radiation by attenuation or screening
Safety distance	EN ISO 13857	Upper and lower limbs
	EN 349	Avoiding of crushing of parts of the human body
	EN 999	Approach speed
Temperatures	EN ISO 13732-1	Hot surfaces
	EN ISO 13732-3	Cold Surfaces
Vibrations	EN 1299	Vibration isolation

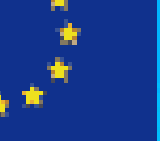


Guide to horizontal standards for Safety of Machinery (3)



Generic/group standards for systems and safeguards (Type B2)

Access to machines	EN 547-1	Whole body access
	EN 547-2	Access openings
	EN 547-3	Anthropometric data
	EN ISO 14122-1	Choice of means of access between two levels
	EN ISO 14122-2	Working platforms and walkways
	EN ISO 14122-3	Stairways, stepladders and guard-rails
	EN ISO 14122-4	Fixed ladders
Control systems and devices	EN ISO 13850	Emergency stop
	EN 574	Two-hand control devices
	EN ISO 13849-1	Safety related parts of control systems, design
	EN ISO 13849-2	- " -, Validation
	EN 1037	Unexpected start-up
	EN 1760-1	Pressure sensitive mats and floors
	EN 1760-2	Pressure sensitive edges and bars
	EN 1760-3	Pressure sensitive bumpers, plates, wires
	EN 62061	Electrical/electronic programable control systems
Electrical equipment	EN 60204-1	General requirements



Safety of Machinery (4)



Generic/group standards for systems and safeguards (Type B2)

(continued)

Explosion protection	EN 12874	Flame arresters
	EN 13237	Terms for equipment & protective systems
	EN 13463-1	Basic requirements for non-electrical equipment
	EN 13463-2	Protection by flow restricting enclosure
	EN 13463-3	Protection by flameproof enclosure
	EN 13463-5	Protection by constructional safety
	EN 13463-6	Protection by control of ignition source
Fluid power equipment	EN 13463-8	Protection by liquid immersion
	EN 982	Hydraulics
Guards	EN 983	Pneumatics
	EN 953	Design of fixed and movable guards
	EN 1088	Interlocking devices
Lighting	EN 61496-1	Electro-sensitive protective equipment
	EN 1837	Integral lighting of machines
Signals and actuators	EN ISO 7731	Auditory danger signals
	EN 842	Visual danger signals
	EN 894-1	Interaction with displays and control actuators
	EN 894-2	Design of displays
	EN 894-3	Design of control actuators
	EN 981	Auditory/visual systems
	EN 61310-1	Visual, auditory and tactile signals
EN 61310-2	- " -, Marking	
EN 61310-3	- " -, Actuators; location, operation	



Risk assessment

Assess risks by using standards: **EN ISO 14121 - 1**,
EN ISO 12100 part 1 and 2, or type B and C standards.

When assessing risks consider:

- possible severity of injury and health hazard,
- probability of an injury or harm to health,
- identify technical and human factors which affect the level of risk,
- take into account the equipment's whole life-span.

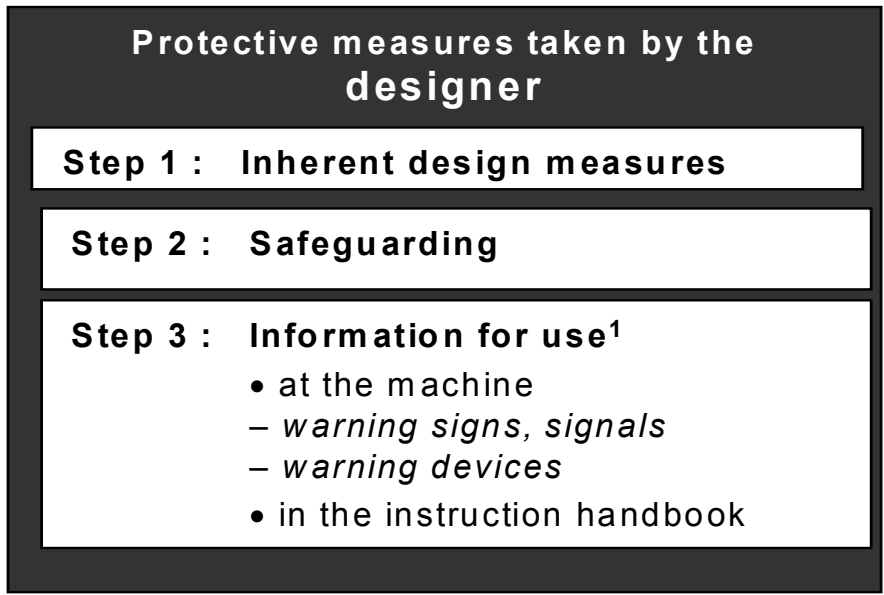
*Eliminate or reduce risks as far as possible by using
Essential Requirements and harmonized Standards*



Risk Reduction

Duties of the manufacturer (*in this order*):

- **eliminate the hazards or reduce the risks by inherent design measures**
- **take the necessary protective measures**
- **inform users of the residual risks that cannot be safeguarded adequately**

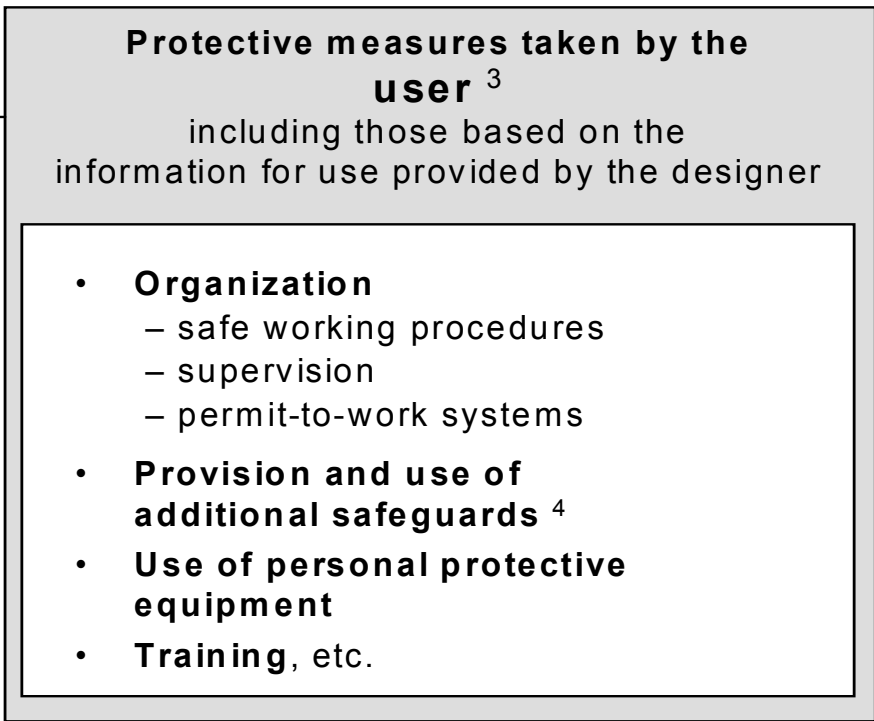


Residual risk after protective measures taken by the designer



User input ²

Designer input



Residual risk remaining after all protective measures have been taken