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"EU New Legal Framework “

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Elements of EU legislation

European Treaty

Treaty on the Functioning of the European Union (TFEU) 1957, Treaty of Lisbon 2009

- Defining the aims, principles and fields of European integration.
- Highest position in EU law and supersedes all other EU legislation as well as the MSs national legislation.

Regulation

- **Direct legal force:** MSs are obliged to enforce the aspects solved by the Regulation, **without necessity to implement it into national law.**

Directive

- **Is not directly effective**. To become effective, MSs must **implement the directives into their national legislation**. Different MSs may choose different ways of implementation into their law.

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Elements of EU legislation

Decision

- Is an **executive tool** solving a concrete specific problem. It is obligatory only for subjects to which it is addressed.

Recommendations, Opinions, Resolutions

- Are not enforceable, they are giving recommendation to common approach

Free Movement of Goods

Goal

- Remove technical barriers to internal EU trade, deriving from national technical regulations, standards and conformity assessment procedures

- **Treaty of Rome Art. 28-29/EC**: take appropriate measures to ensure Internal market
- **Treaty of Rome: Art. 30/EC**: avoid unjustified measures restricting the circulation of goods

Instruments

- Mutual Recognition
- Technical Harmonization

- **1983: Directive 98/34/EC** on information procedure for technical standards and regulations.
- **Council Resolution of 7 May 1985 on "New Approach"**
- **Council Resolution of 21 Dec 1989 on "Global Approach"** Council Decision 93/465/EEC on the "modules" for conformity assessment

Timeline of the EU legislation for goods

Restricted the content of legislation to 'essential requirements' leaving the technical details to European harmonised standards.

- Built on the New Approach
- Completed the overall legislative framework for effective conformity assessment, accreditation and market surveillance including the control of products from outside the Union

Traditional approach or 'Old Approach'

'New Approach' (1985)

Global Approach- Conformity assessment instruments (1989)

'New Legislative Framework' (2008)

Detailed texts containing all the necessary technical and administrative requirements

Procedures required to demonstrate that a product, before it is placed into the market, conforms to these essential requirements of the directive that apply to it.

Old Approach

The "Old Approach" Directives contained a high degree of technical detail.

- Applied to products by which the nature of risk required extensive product-by product or even component-by component legislation and was carried out by means of detailed directives.
- The detailed technical requirements are defined in the legislations.
- Compliance with the prescribed requirements is confirmed by the state authority
- A product recognised and approved in one EC country should also be imported and sold in other EC countries without the need for any additional approval
- Separate directive for each product
- Creation of certification and authorisation structures
- Mandatory pre-market control

Old Approach- Drawbacks

Achieving this type of harmonization was slow for two reasons:

- The process of harmonization became highly technical, with attention being given to very detailed product categories including components.
- The adoption of Old Approach Directives required unanimity in the Council, which meant that the issuing of directives was a slow process.

The limitations of this approach as a broad tool for tackling technical barriers to trade became clearly apparent in the 1970s and early 1980s, when new national regulations were **proliferating at a much faster pace than the European Commission could finalize these "Old Approach" Directives. These national specifications often proved to be trade barriers.**

New Approach

New Approach

A legislative technique developed in 1985 by the EU in order to:

- accelerate the development of a single market in Europe
- harmonize the technical regulations and standards of the EC member states in order to assure the free movement of goods among these countries while guaranteeing a high level of safety for consumers.

New Approach was a real success and absolutely necessary for the development of a single market in Europe.

New Approach principles (1)

Harmonisation is limited to essential requirements.

Only products fulfilling the essential requirements may be placed on the market and put into service.

Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.

Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.

Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

New Approach principles (2)

Technical details on how to meet the minimum health and safety requirements are left to the following three groups:

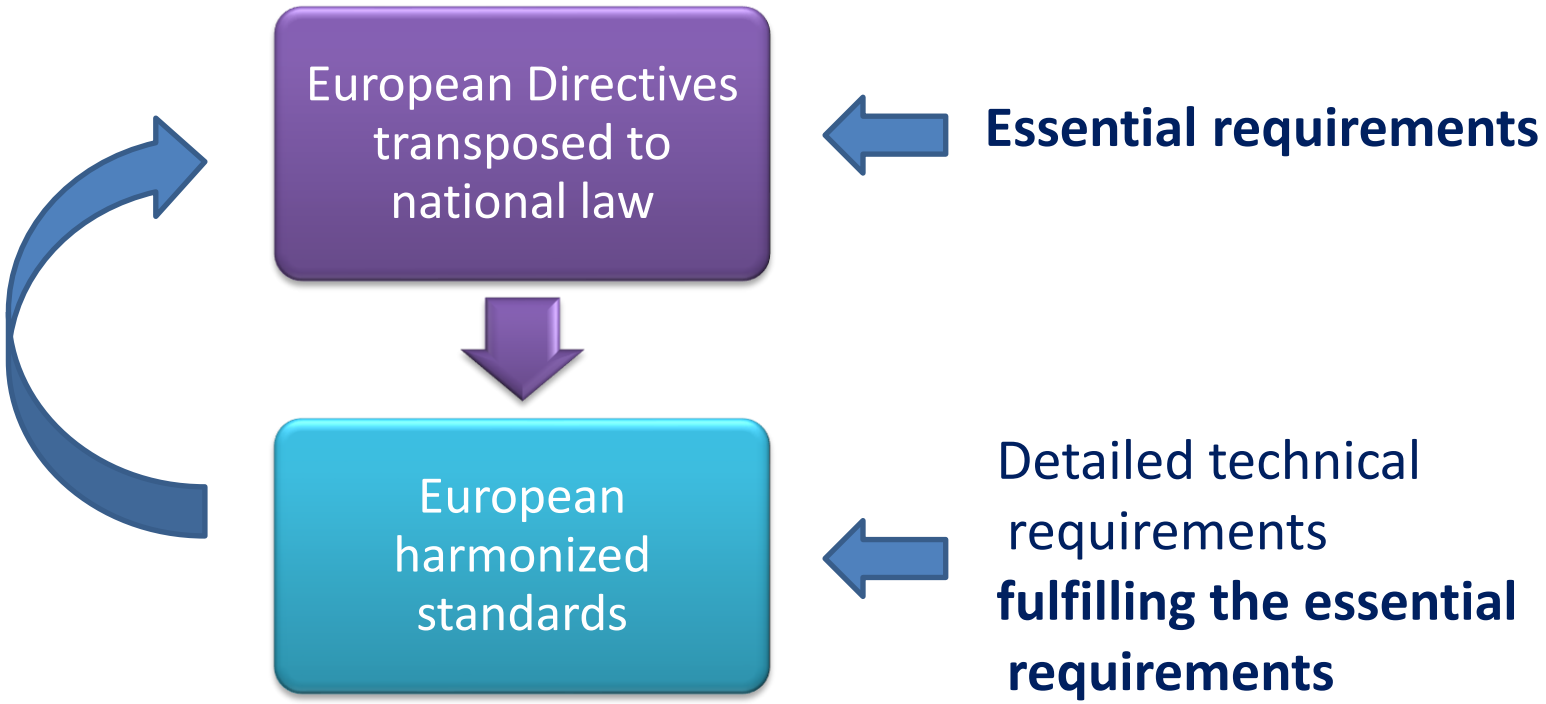
1) Manufacturers who self-certify products by meeting the requirements of the applicable directives, in some cases by using appropriate European standards

2) The three regional European standards organizations (CEN, CENELEC and ETSI), which now develop Europe-wide standards covering product sectors falling under the New Approach Directives

3) Government-appointed product certification bodies (notified bodies), which provide testing and product approvals.

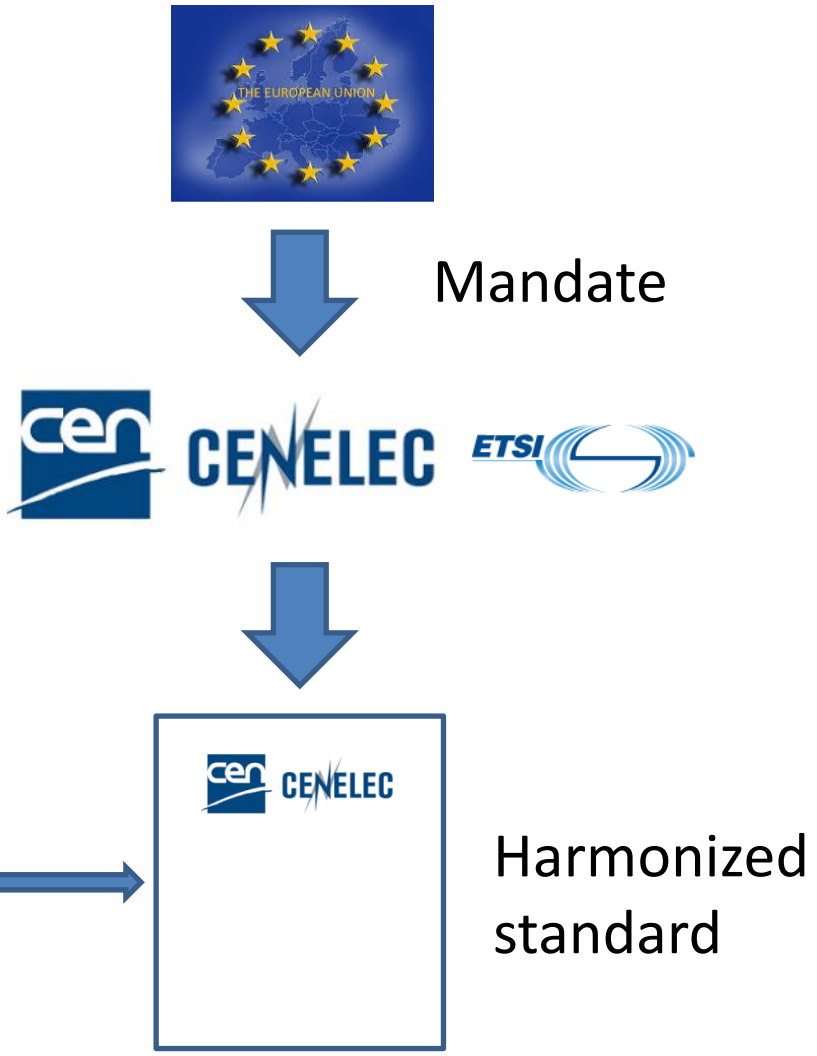
New Approach principles (3)

- Clear division of requirements:



New Approach principles (4)

- Presumption of conformity to the directives



New Approach principles (5)

European harmonized standards

OIML

European Cooperation in Legal Metrology
WELMEC

Manufacturer

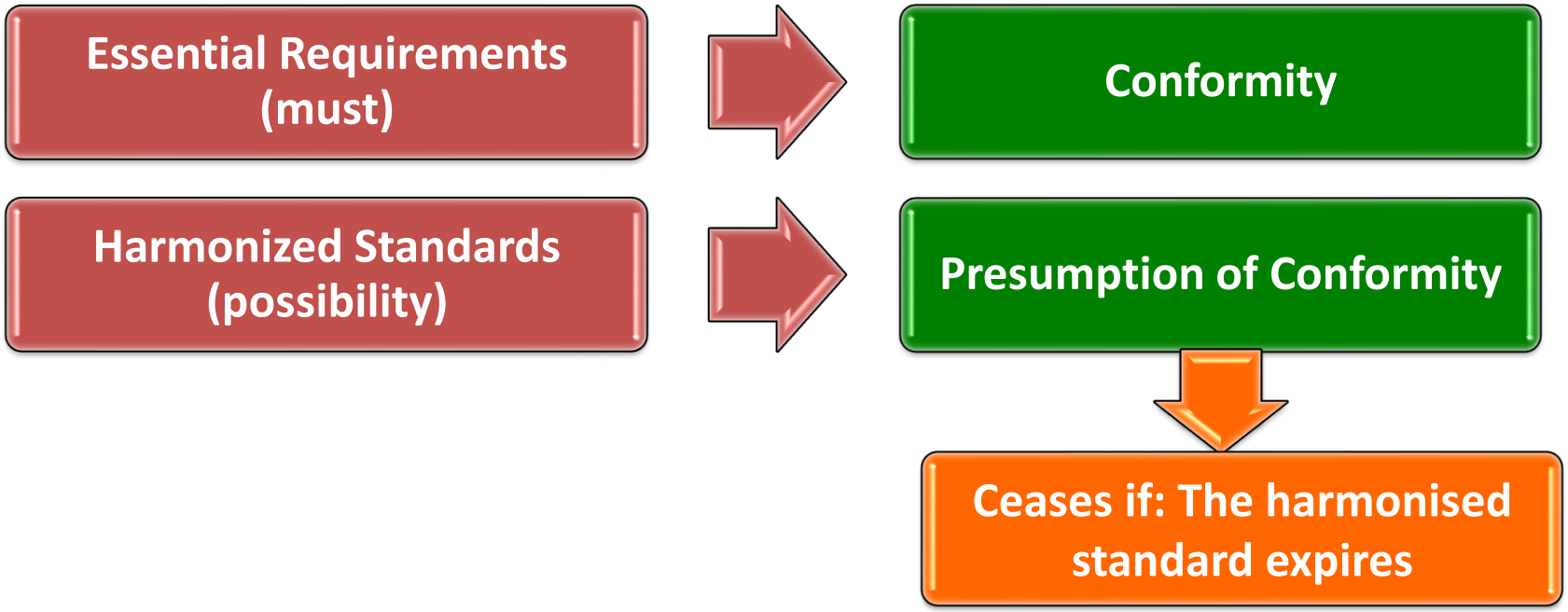
Contract

Notified body

Conformity assessment:

- **Type examination**
- **Conformity to type**
- **Quality assurance of production process**

Presumption of Conformity



- The conformity of a product may be demonstrated not only by harmonised standards but also by other technical specifications.
- Other technical specifications however do not benefit from the presumption of conformity.

Advantages of the New Approach (1)

1. The responsibility for the safety of a product was given back to the manufacturer.

2. The essential health and safety requirements for a product are laid down in Directives.

3. Detailed technical solutions how to fulfil these requirements are given in harmonised European standards.

Advantages of the New Approach (2)

4. The manufacturer is free to apply the harmonized European standards. (Flexibility in design and development, presumption of conformity)

5. Conformity assessment procedures (involvement of notified bodies) are dependent on the risk associated with the use of a product.

6. State control is reduced to the absolute minimum, which is necessary to protect health and safety of the citizens (market surveillance).

Global Approach

Was adopted in 1993 (1989) in support of the New Approach.

- Introduced a modular approach, which subdivided conformity assessment into a number of operations (modules).
- Lays down general guidelines and detailed procedures for conformity assessment that are to be used in order to comply with the essential requirements of the New Approach directives.
- Harmonises the rules for the affixing and use of the CE marking.

Conformity assessment procedures

- Regulation setting:
  - ✓ Essential requirements
  - ✓ Conformity assessment procedures
- Conformity assessment
  - ✓ By the manufacturer or importer
  - ✓ With a notified body when requested
  - ✓ Facilitated through the use of harmonized standards (presumption of conformity)

Declaration of conformity

CE marking

The CE marking process

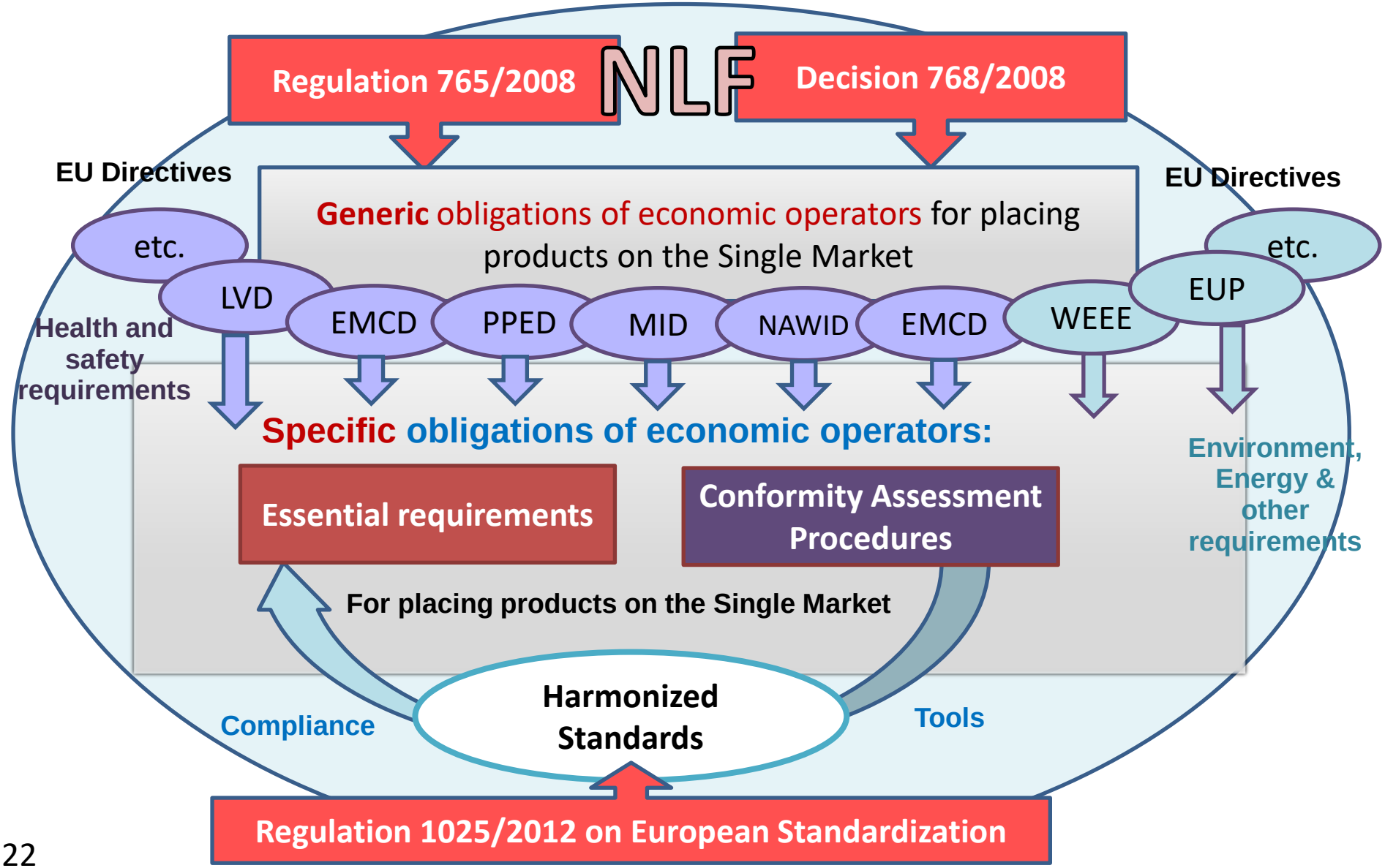
1. Identify the applicable Directive(s)
2. Identify the applicable requirements of the Directive(s)
3. Identify the appropriate route to conformity
4. Assessment of the product's conformity
5. Compile the technical documentation
6. Make a Declaration and affix CE mark

New Legal Framework- Why to introduce it?

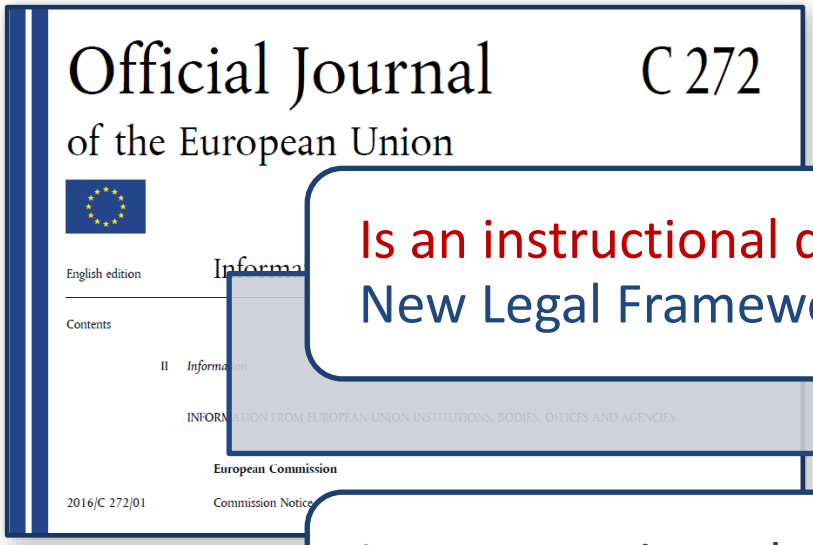
- Experience showed Directives did not function in the same way in all Member States
- Different levels of controls in Member States
  - Unequal treatment, distortion of competition
  - Many non conforming products bearing CE marking- Lack of trust in marking
  - Different ways of controlling Notified Bodies- no transparency
  - Differing definitions, unclear obligations for importers, distributors

Objectives of the New Legal Framework

New Approach



NLF- Blue Guide


Official Journal C 272
of the European Union
English edition
Contents
II
European Commission
2016/C 272/01

Is an instructional document outlining the effect of the New Legal Framework (NLF) on product regulations

Its purpose is to describe how the product legislation fit together.

It is used to create a cohesive implementation of the regulatory regimes required to effectively populate a manufacturer's technical file

Functioning of the single market

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Accreditation

Notification

Member States

Accreditation Bodies

Assess and monitor the competence of laboratories to assess conformity to a specific regulation

Laboratories

Notified (conformity assessment) Bodies

Contribute to the assessment of product conformity

Member States

Notifying Authorities

[Assess, monitor] and notify laboratories having the competence to assess conformity to a specific regulation

Standardization mandate

EU

Harmonization Legislation

Defines essential requirements

Manufacturer

Conformity Assessment

Manufacturer assesses conformity to the product

Manufacturer

CE Marking

Manufacturer affixes CE marking and issues declaration of conformity

Products

CEN/CENELEC/ETSI

Harmonized Standards

Define accepted solutions (technical requirements)

Presumption of conformity

Member States

Market Surveillance

MS authorities control compliance

Idea: EASA Opinion No 01/2018

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Conformity Assessment (CA)

WHAT is it?

Demonstration that specified requirements relating to the product, process, system, person or body are fulfilled.

WHO can perform it?

Manufacturer by itself (first party) costumer (second party) third party (notified body, competent body…)

WHICH activities covers it?

Calibration, testing, inspection, certification

WHY?

Before placing a product on the market, the manufacturer must subject the product to a CA procedure provided in the applicable directive. Third party CA provided by Notified bodies with the view to affixing the CE marking

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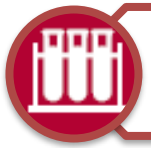
6 steps of Conformity Assessment procedures

Identify Directives applicable to your product-Definition of modules that can be used

Verify Essential Characteristics

Determine if a Notified Body is required



Test the product- Application of technical standards and quality system standards

Preparation of technical documentation-Draft Declaration of Conformance

Affix CE Mark

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The Two Parts of the New and the Global Approaches

PRE-MARKET ASSESSMENT

Products placed on the market must fulfil essential requirements, under the responsibility of the manufacturer, who assures this by affixing the CE marking on the product

POST-MARKET CONTROL

Member States must control that the products on their market are in compliance with the essential requirements. This is done by national authorities using market surveillance

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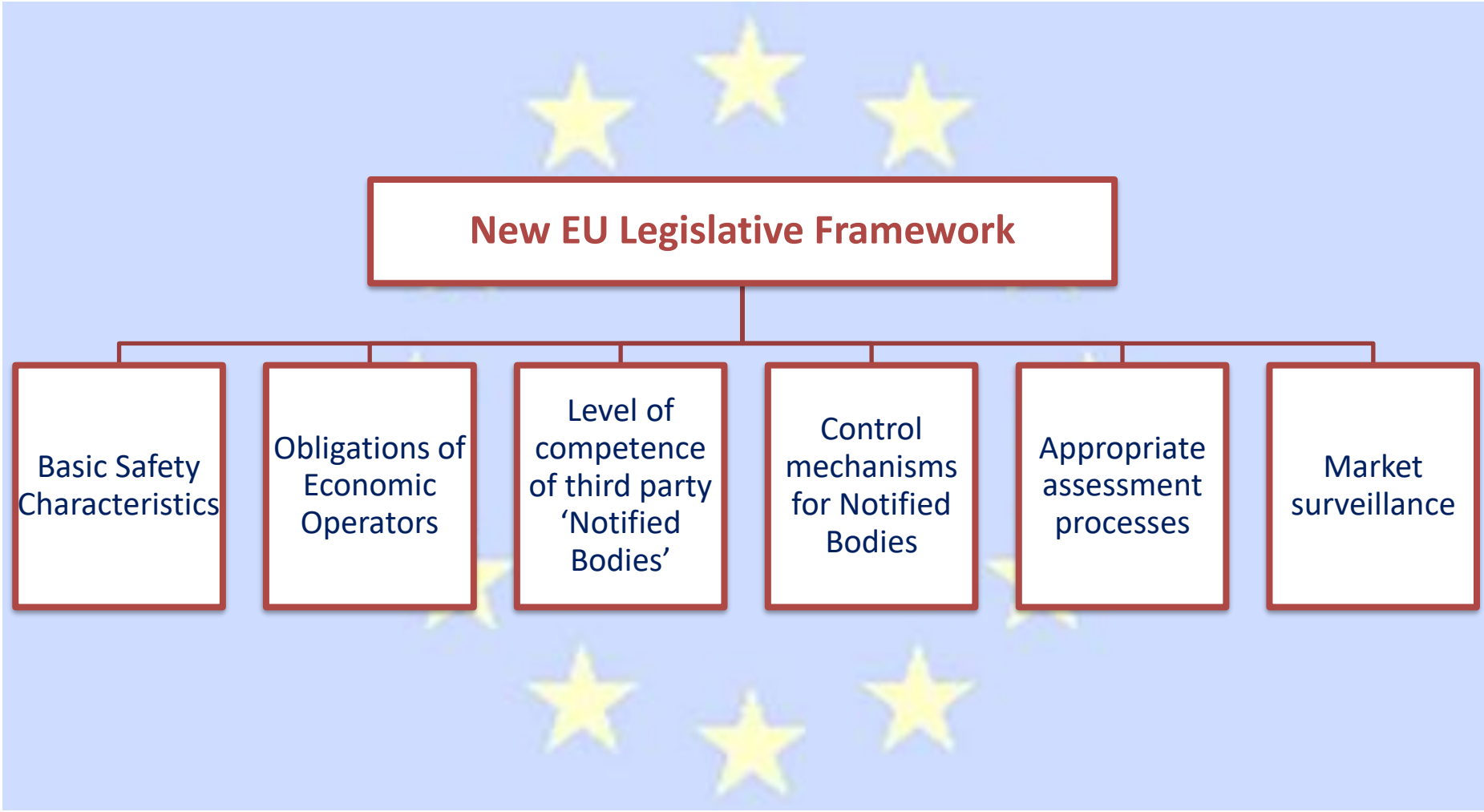
New Legal Framework



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New Legal Framework

- The New Legislative Framework consists of
- Regulation (EC) 765/2008 setting out the requirements for accreditation ~~and the market surveillance of products~~ superseded by Regulation (EC) 1020/2019
- Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation.
- Regulation (EC) ~~764/2008~~ superseded by Regulation (EC) 515/2019 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country
- More information available in the 'Blue Guide' on the implementation of EU product rules 2016 (First version 2000)

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Decision (EC) No 768/2008 on marketing of products

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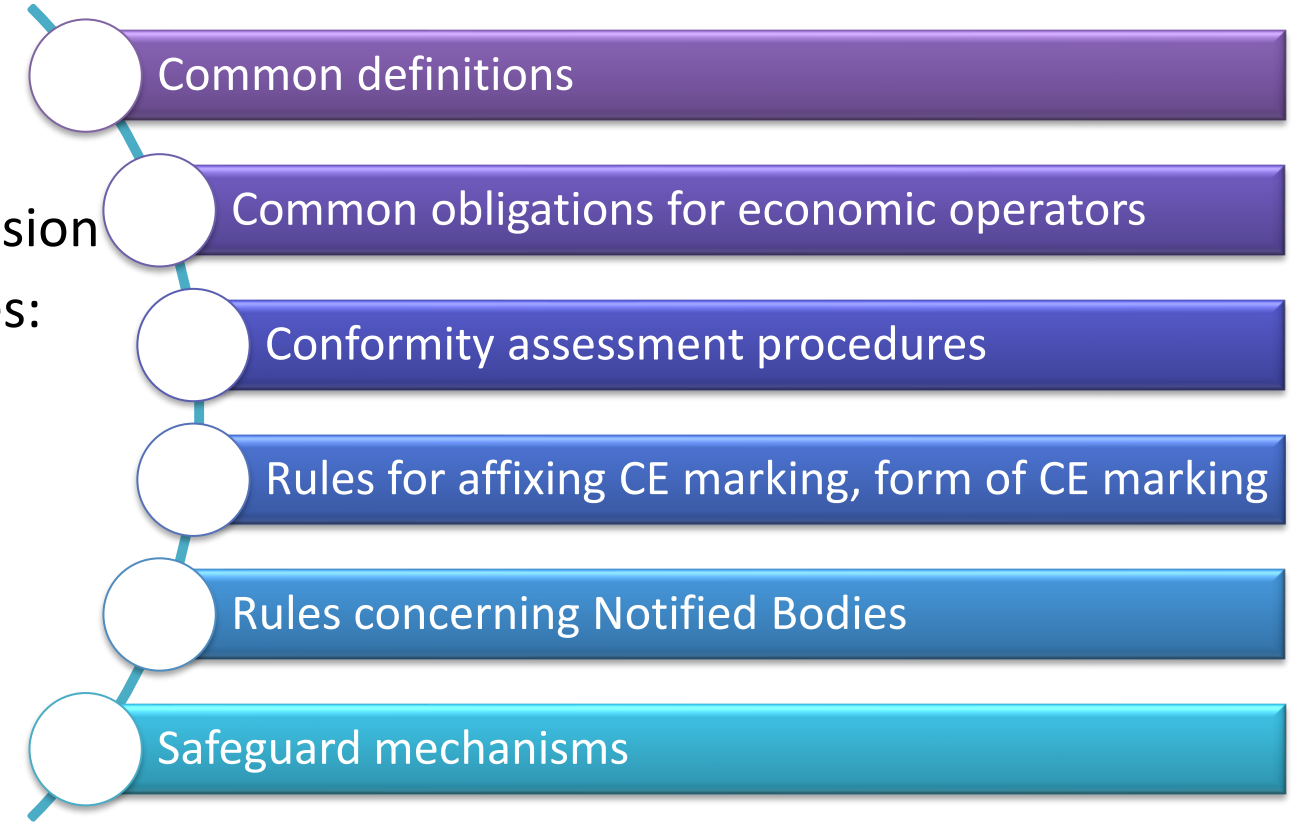
Decision 768/2008/EC (1)

A common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised

The Decision provides:



Decision 768/2008 (2)

- Model for future product legislation.
- Is a kind of template, which shall be used by creators of a new legislation- especially amended New Approach Directives.

Contents

Main Actors- ‘economic operators’

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‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

Common element: they make products available on the market

‘authorised representative’ shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

‘importer’ shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

Only the manufacturer and the importer place products on the market.

‘distributor’ shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

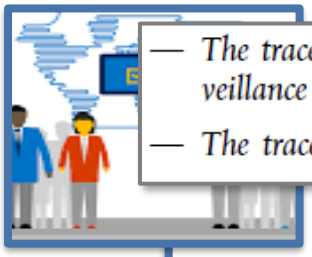
Clarifications!

"Making available on the market" is the overall concept. Any transfer between economic operators of a product is considered as making available.

"Placing on the market" is a specific case of making available, namely it is the first time that the product is introduced on the market. It is important because at that moment the EU legislation applies.

Any subsequent transfer is a "making available".

Main Actors: Manufacturers



— *The traceability requirements allow tracing the history of the product and support market surveillance. It allows market surveillance authorities to find the liable economic operators and obtain evidence of the product compliance.*

— *The traceability requirements include labelling the product and identifying the economic operators in the distribution chain.*

- Is responsible for the CA of the product and is subject to a series of obligations including traceability requirements.
- When placing a product on the Union market, the responsibilities of a manufacturer are the same whether he is established outside the European Union or in a Member State.
- The manufacturer must cooperate with the competent national authorities in charge of market surveillance in case of a product presenting a risk or being non-compliant

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Main Actors: Authorized Representative

- *Irrespectively of whether he is established in the EU or not, the manufacturer may appoint* ***an authorised representative in the Union*** *to act on his behalf in carrying out certain tasks.* (Blue Guide)- A manufacturer established outside the European Union is not obliged to have an authorised representative.
- To be able to act on behalf of the manufacturer, the authorised representative must be established inside the Union
- Commercial representatives of the manufacturer (such as authorised distributors or agents), are not to be confused with the authorised representative in the meaning of Union harmonisation legislation. The delegation of tasks from the manufacturer to the authorised representative must be explicit and set out in writing

Main Actors: Importer

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- *Importer's obligations build on the obligation of the manufacturer.*
- Before placing a product on the market the importer must ensure that the manufacturer has:
  - Carried out the appropriate conformity assessment procedure,
  - Drawn up the technical documentation,
  - Drawn up the EU Declaration of Conformity,
  - Affixed the CE marking,
  - Fulfilled their traceability obligations, and
  - Accompanied the product required instructions and safety information.

Main Actors: Distributor

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- *Distributors are subject to specific obligations and have a key role to play in the context of market surveillance.*
- Must act with due care in relation to the applicable requirements.
- They have to know product and labelling requirements, user instructions or other accompanying documents, and what is a clear indication of the product being non-compliant.
- They have an obligation to demonstrate to the national market surveillance authority that they have acted with due care and ensure that the manufacturer, or his authorised representative, or the person who provided him with the product has taken the measures required by the applicable Union harmonisation legislation as listed in the obligations for distributors.
- ….And many others

Main Actors: End users

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- Contrary to economic operators, end-users are not defined in Union harmonisation legislation and are not subject to obligations

- Many products covered by Union harmonisation legislation are used at work. According to legislation based on Article 153 TFEU, **employers** have obligations as regards the use of work equipment by workers at the workplace.

Presumption of Conformity

- Conformity with a national standard that transposes a harmonised standard confers a presumption of conformity with the essential requirements of the applicable New Approach directive
- References of harmonized standards are published in the Official Journal for the directive in question (For an updated list: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en)
- Member States must publish the reference of the national standard that transposes a harmonised standard (useful to indicate the link with the legislation in question)
- The application of harmonised standards, which give a presumption of conformity, remains voluntary in the field of New Approach directives

Withdrawal of the presumption of conformity

The Commission withdraws the presumption of conformity

- if it has been established that the harmonised standard does not fully meet the essential requirements.

Revision of harmonised standards

The principles concerning the mandate and the adoption of harmonised standards, their availability, and the presumption of conformity to the essential requirements **apply also to the revised version of harmonised standards.**

During the transitional period**, both the old and the revised standards give presumption of conformity**, provided that the conditions for this are met by both standards.

Declaration of Conformity (DoC)

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The manufacturer or the authorised representative established within the Union must draw up and sign an EU DoC as part of the conformity assessment procedure provided for in the Union harmonisation legislation.

The EU DoC must contain all relevant information to identify the Union harmonisation legislation according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other technical specifications.

- A single DoC is required whenever a product is covered by several pieces of Union harmonisation legislation requiring an EU DoC.
- The single DoC can be made up of a dossier containing all relevant individual declarations of conformity.

Actors in Conformity Assessment

The main actors in CA are the legislator, the manufacturer and (if provided for by the legislation) the notified or in-house accredited CA body.

- CA is the responsibility of the manufacturer, whether the legislation provides for the involvement of a notified or in-house accredited CA body, or not.
- The modules used for both the design and the production phase or for each phase may or may not involve a notified body.
- In-house accredited CA bodies must demonstrate the same level of technical competence and impartiality as notified bodies. (must not have any activities other than CA and must be independent from any commercial, design and production entities

Rules and conditions for affixing the CE marking

General principles for CE marking are set out in Regulation 765/2008.

Notified body	Where it is involved in the production control phase according to the applicable Union harmonisation legislation, its identification number must follow the CE marking
Manufacturer or the authorised representative	Affixes the identification number if the legislation requires so, under the responsibility of the notified body.
Additional markings and marks	A product may bear additional markings and marks, provided that they fulfil a different function from that of the CE marking, are not liable to cause confusion with it, and do not reduce its legibility and visibility

Notified bodies

Notified Bodies provide conformity assessment services on the conditions set out in EU legislation when a third party is required.

- 1100+
- Independent third parties
- Notified by Member States, who ensure their competence
- Co-operation
- ….and **competition**

Notified bodies Roles and Responsibilities

Notified bodies **must**:

- have at their disposal the necessary personnel, who have sufficient and relevant knowledge and experience
- ensure confidentiality of the information obtained
- be adequately insured to cover their professional activities
- provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies
- operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner

Notified bodies Roles and Responsibilities

Notified bodies:

- are free to offer their conformity assessment services to any economic operator established either inside or outside the Union (on the territory of other Member States or of third countries).
- May demonstrate their competence through accreditation (preferred way)
- Participate in the relevant standardization activities (or be informed of such)
- They may subcontract specific tasks connected with CA, but shall take full responsibility for the tasks performed by subcontractors and ensure that the subcontractor fulfils the requirements
- Subcontracting must be based on a contract, which makes it possible to ensure the transparency of and have confidence in the notified body's operations.

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Assessment of notified bodies

Member States designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the **assessment and notification of CABs and the monitoring of notified bodies**, including compliance with the provisions of Decision 768/2008/EC.

Member States may decide that the assessment and monitoring referred to above **shall be carried out by a national accreditation body** within the meaning of and in accordance with Regulation (EC) No 765/2008.

Requirements for notifying authority

- **No conflict of interest** with CAB. Not offer or provide any activities that CABs perform or consultancy services on a commercial or competitive basis.
- Safeguard objectivity and impartiality of its activities.
- Decision relating to notification of a CAB is **taken by competent persons different from those who carried out the assessment**
- Safeguard the confidentiality of the information it obtains.
- Have a **sufficient number of competent personnel** at its disposal for the proper performance of its tasks.

Notification

Member States take the **final responsibility** for the competence of their notified bodies with respect to the other Member States and the EU institutions.

- Member States **notify the Commission and the other Member States** of bodies authorised to carry out third-party conformity assessment tasks under community legislation.
- Notifying authorities may notify only CABs which have satisfied the requirements laid down in the Decision 768/2008/EC.
- **Application for notification to be accompanied with an accreditation certificate,** where one exists, issued by a national accreditation body attesting that the CAB fulfils the requirements laid down in Decision 768/2008/EC.

Notification

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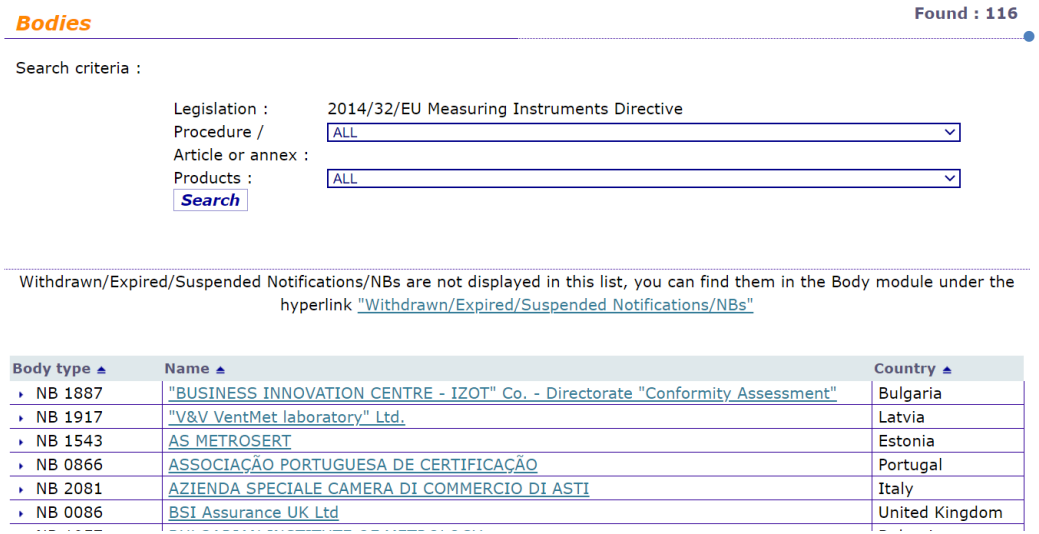
When a Member State does not base its notification on accreditation, *"it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Union harmonisation legislation in question"*.

- a formal application procedure
- assessment against applicable requirements.
- production of an assessment report
- periodic surveillance including on-site visits, in order to verify the continued fulfilment of requirements by the notified body
- demonstration of the national authority's own technical competence to assess conformity assessment bodies
- The assessment itself should consist of: a review of documents and an on-site audit to check technical and procedural aspects
- Reference: Document CERTIF 2010-08 REV1 - Notification without accreditation (Art. 5.2 of Regulation 765/2008)

Notification



Bodies Found : 116

Search criteria :

Legislation : 2014/32/EU Measuring Instruments Directive
Procedure / Article or annex : ALL
Products : ALL
Search

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "Withdrawn/Expired/Suspended Notifications/NBs"

Body type	Name	Country
NB 1887	"BUSINESS INNOVATION CENTRE - IZOT" Co. - Directorate "Conformity Assessment"	Bulgaria
NB 1917	"V&V VentMet laboratory" Ltd.	Latvia
NB 1543	AS METROSERT	Estonia
NB 0866	ASSOCIAÇÃO PORTUGUESA DE CERTIFICAÇÃO	Portugal
NB 2081	AZIENDA SPECIALE CAMERA DI COMMERCIO DI ASTI	Italy
NB 0086	BSI Assurance UK Ltd	United Kingdom

NANDO

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

- If there is no objection, within 2 weeks with accreditation and 2 months without accreditation, from Commission or other Member States, CAB may perform activities of a notified body.
- Notification is electronic (NANDO), providing all details of approved scope

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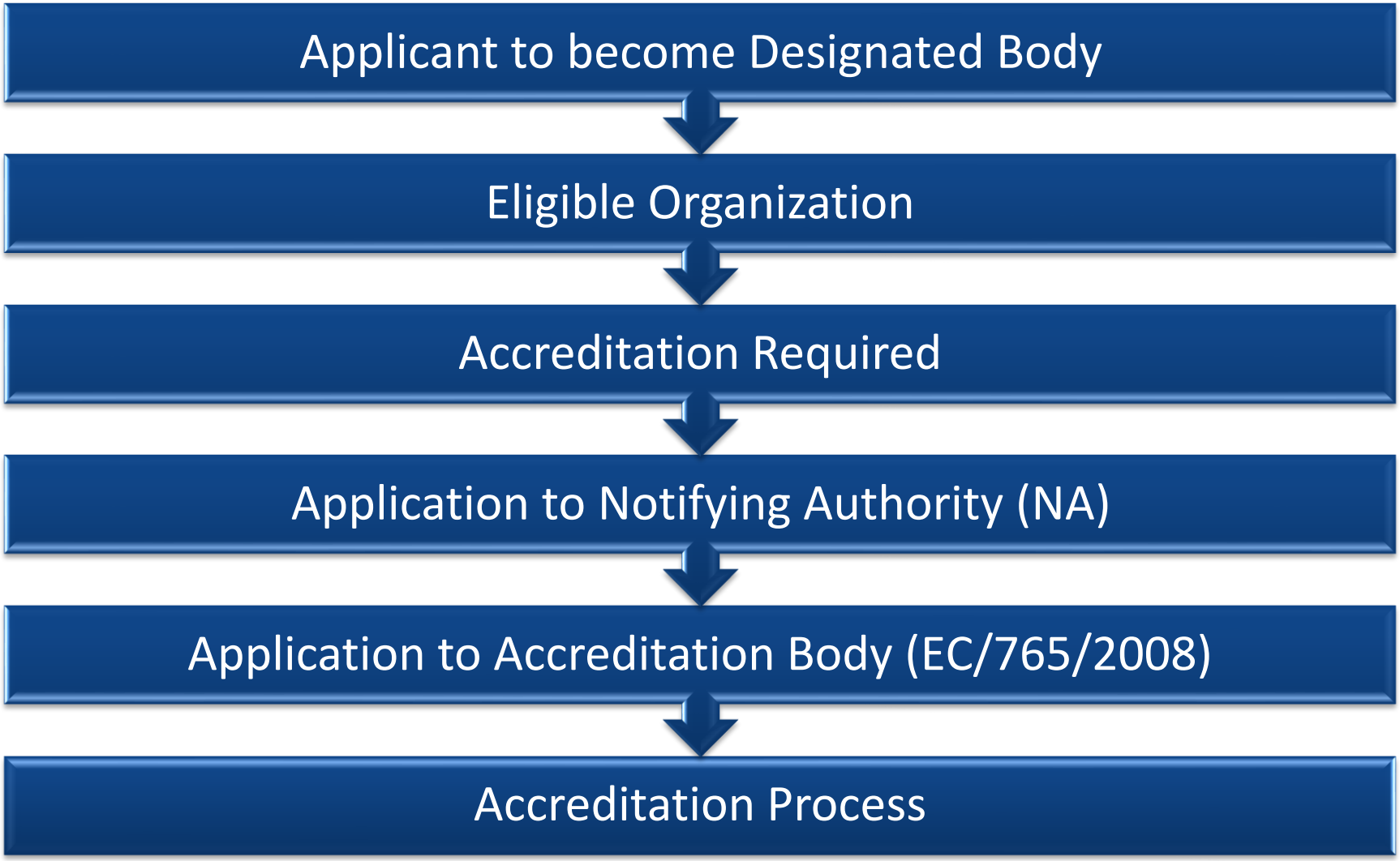
Procedure to become Notified Body



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Procedure to become Notified Body

AB confirms Certification and Scope to the NA

↓

Initial Assessment by the NA

↓

Final Assessment by the NA

↓

Letter of Designation- Notify Commission

↓

Surveillance and Assessment according to the Accreditation Scheme of the AB

Safeguard mechanisms for Member States

It is a mechanism allowing all interested parties to be kept informed about restrictive measures on the market.

The safeguard clause procedure:

- is designed to provide a means to inform all national market surveillance authorities about dangerous products, and, accordingly, to have the necessary restrictions extended to all Member States, so as to ensure an equivalent level of protection throughout the EU.
- it allows the Commission to take a position on the national measures restricting the free movement of products with a view to ensuring the functioning of the internal market.

- Distinct from the RAPEX procedure!

Modules (1)

- **Conformity assessment (CA)**
- CA, through CA procedures, may be carried out by public authorities, manufacturers or notified bodies.
- CA procedures are modules relating to the design phase, production phase or both; eight basic modules and their eight possible variants can be combined
- The manufacturer has the possibility to set up appropriate CA procedure, by choosing from among the modules, taking into account the type of the product and the nature of risks entailed by the product
- Where third party involvement (notified body) is mandatory, the manufacturer has a choice between quality assurance and product certification modules

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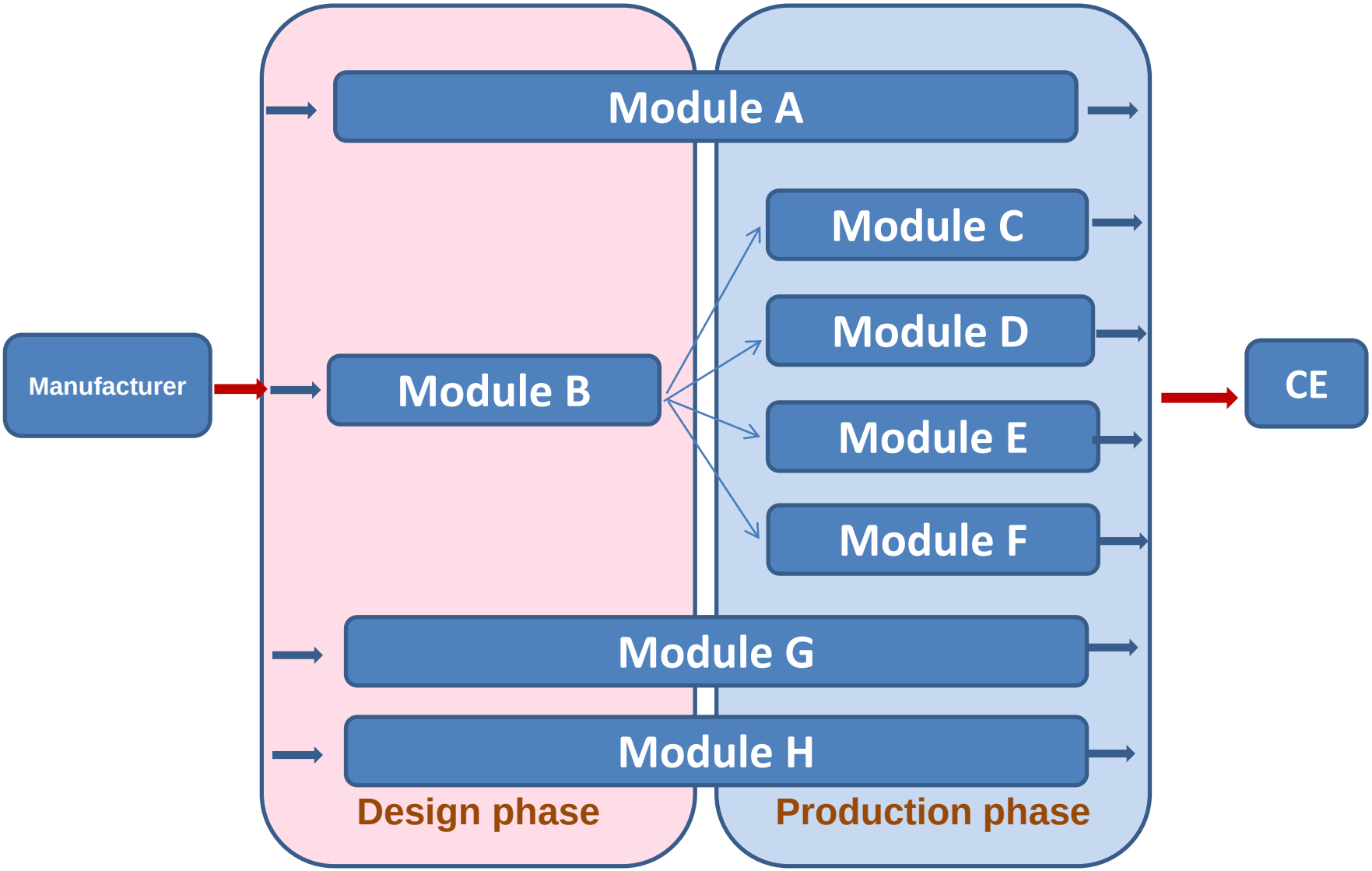
Modules (2)

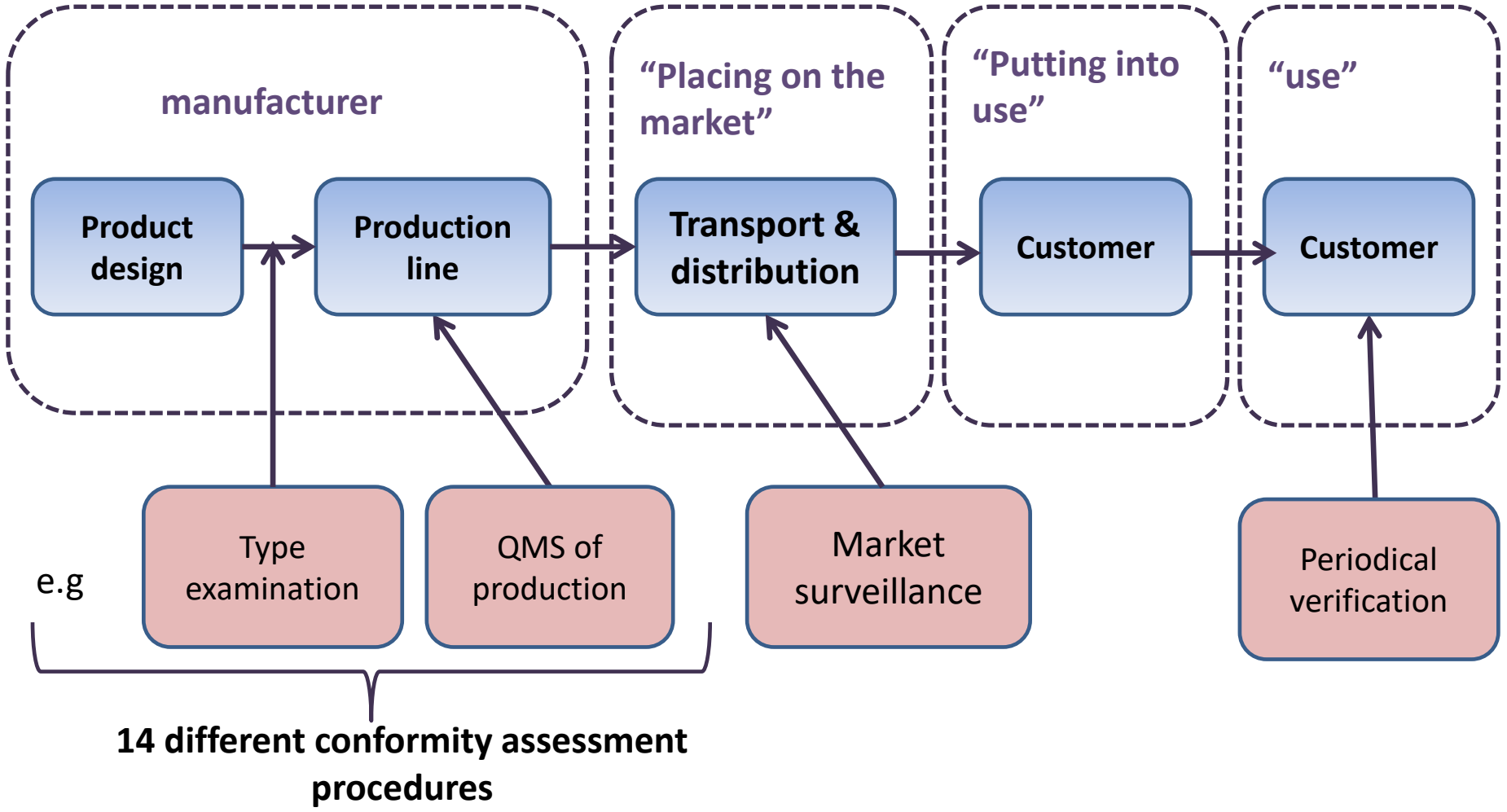


Modules (3

Module		Use	Notified body intervention
A	Internal production control	Design and production phase	**No**
B	EU-type examination	Design phase; to be followed by a module for production phase	Yes
C	Conformity to type based on internal production control	Production phase; follows Module B	**No**
D	Conformity to type based on quality assurance of production process	Production phase; follows Module B	Yes
E	Conformity to type based on product quality assurance	Production phase; follows Module B	Yes
F	Conformity to type based on product verification	Production phase; follows Module B	Yes
G	Conformity based on unit verification	Design and production phase	Yes
H	Conformity based on full quality assurance	Design and production phase	Yes

Module variants: A1, A2, B1, C1, C2, E1, F1 and H1

New Approach- Example Measuring Instruments



Thank you for your attention!

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