The Blue Guide

GROW D3

Orsolya Deli-Vidács

The historical perspective of harmonisation

Five phases of the evolution:

- Old Approach: very detailed legislations
- New Approach (1985): ‘essential requirements’, while the details are in harmonised standards
- Development of the conformity assessment instruments
- The New Legislative Framework (2008): built on the New Approach, complemented it and brought coherence (conformity assessment, accreditation, market surveillance)
- The adoption of the new Market Surveillance Regulation and the new Mutual Recognition Regulation (2019).

The New Legislative Framework (NLF)

Objectives:

- Reinforcing the New Approach
- Simple, clear and coherent legislation
- More effective market surveillance and accreditation of conformity assessment bodies
- EU framework for their accreditation
- Enhanced credibility of the CE marking

The New Legislative Framework

REGULATION (EC) No 765/2008 + Regulation (EU) 2019/1020

- Accreditation
- Market surveillance
  - internal
  - imported products
- CE marking general principles
- Financing elements

DECISION No 768/2008/EC

- Definitions / obligations
- Essential requirements + Harmonised standards
- Conformity assessment procedures
- Notification (criteria / process / accreditation)
- Safeguard mechanisms (& market surveillance)
- CE marking

Basis for future legislation

Union product legislation/acts aligned to the NLF

EU Legislation	Description
Directives	
Toy Safety Directive	Directive 2009/48/EU
Transportable Pressure Equipment Directive	Directive 2010/35/EU
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive	Directive 2011/65/EU
Pyrotechnic Articles Directive	Directive 2013/29/EU
Recreational Craft and Personal Watercraft Directive	Directive 2013/53/EU
Civil Explosives Directive	Directive 2014/28/EU
Simple Pressure Vessels Directive	Directive 2014/29/EU
Electromagnetic Compatibility Directive	Directive 2014/30/EU
Non-automatic Weighing Instruments Directive	Directive 2014/31/EU
Measuring Instruments	Directive 2014/32/EU
Lifts Directive	Directive 2014/33/EU
ATEX Directive	Directive 2014/34/EU
Radio Equipment Directive	Directive 2014/53/EU
Low Voltage Directive	Directive 2014/35/EU
Pressure Equipment Directive	Directive 2014/68/EU
Marine Equipment Directive	Directive 2014/90/EU
Regulations	
Construction Products Regulation**	Regulation (EU) No 305/2011
Cableway Installations Regulation	Regulation (EU) 2016/424
Medical Devices Regulation	Regulation (EU) 2017/745
Personal Protective Equipment Regulation	Regulation (EU) 2016/425
In vitro Diagnostic Medical Devices Regulation	Regulation (EU) 2017/746
Gas Appliances Regulation	Regulation (EU) 2016/426
EU Fertilising Products Regulation	Regulation (EU) 2019/1009
Delegated acts	
Commission Delegated Regulation on unmanned aircraft systems and on third-country operators of unmanned aircraft systems	Commission Delegated Regulation (EU) 2019/945

Blue Guide

- A hands-on document explaining EU product legislation;
- The 1st edition was published in 1994 with a blue cover;
- Subsequent editions: 2000, 2014 and 2016

Update 2022:

- Market Surveillance Regulation 2019/1020;
- Complementary information on certain issues (substantial modifications);
- Withdrawal of the UK from the EU

Product coverage

Union harmonisation legislation applies to non-food, non-agri industrial products:

- to products placed on the Union market and to any subsequent operation until it reaches the end-user;

- to all forms of selling (catalogue, online, distance sale when offer to the Union market and includes an ordering and shipping system);

- to newly manufactured products but also to used and second-hand products imported from a third country when they enter the Union market for the first time;

- to finished products;

- to a product which has been subject to ‘substantial modifications’.

Making available and placing a product on the EU market

A product is **made available on the market** when:

→ it is **supplied for distribution, consumption or use on the Union market in the course of a commercial activity**, whether in return for payment or free of charge

- The concept of making available refers to each individual product.

A product is **placed on the market** when:

→ it is **made available for the first time on the Union market**.

- According to Union harmonisation legislation, each individual product can only be placed once on the Union market.
- Why is the date of the placing on the market is important?

Making available and placing a product on the EU market

Distance sale: an offer targeted at end users in the Union:

- **Blue Guide 2016:** A product intended to be placed on the Union market has to comply with Union harmonisation legislation when the catalogue or website targets its offer to the Union market and includes an ordering and shipping system
- **Blue Guide 2022:** Market Surveillance Regulation introduced a legal presumption: Products offered for sale online or through other means of distance sales are deemed to be made available on the market if the offer is targeted at end users in the Union

Does an offer target EU-end users?

Case-by-case analysis

→ Availability of the website in the Member States is not sufficient

→ Delivery in the EU; accepting payment by EU consumers/end users; uses EU languages

Legal consequence: checks by the market surveillance authorities and the economic operator offering the product has to cooperate with the authorities

New Legislative Framework – Key features (1)

1) **Essential requirements** – level of protection of public interests: health, safety, protection of consumers or environment.

2) **Harmonised standards** detailing technical solutions to meet the essential requirements

- Voluntary – manufacturers can use other methods
- Presumption of conformity with the essential requirements they cover

New Legislative Framework – Key features (2)

3) **Division of responsibilities** along the distribution chain.

Manufacturers, authorised representative, importer, distributor, *fulfillment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation*

4) **Conformity assessment procedures** (the so-called “modules")

Choice of procedure : Risk-based approach

No third-party involvement- preferred for low to medium risk products;

Third-party conformity assessment.

5) **Uniform rules for the designation and supervision of notified bodies** – only notified conformity assessment bodies can perform the conformity assessment tasks.

New Legislative Framework – Key features (3)

6) **Accreditation** – preferred method to demonstrate the competence of the notified body

7) **Market surveillanc**e

- The authorities' obligation to check products covered by Union harmonisation legislation made available on the Union market
- May range from control of formal requirements to in-depth laboratory examinations

8) **CE marking**

- A declaration by the manufacturer that the product conforms to all the essential requirements of the relevant legislation
- Only the manufacturer can affix it on the product
- Visible, indelible

Thank you

Internal market, Industry, Entrepreneurship and SMEs

European Commission