

Legal issues when developing compliance frameworks

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Structure of the presentation

- **Introductory notes**
- Exchanging regulatory information in the European Union
- Free movement of good (construction products)
- Setting requirements for construction works

UBAtc not for profit organisation

What is UBAtc?

UBAtc

- Belgian Technical Approval Body
- Designated in 2013 for the issuing of European Technical Assessments in the framework of Regulation (EU) N° 305/2011 by the Belgian authorities
- Assumed responsibility for the issuing Technical Approvals serving the needs of Belgian stakeholders in 2009 (previously Federal Public Services Economy)
- Partner in the development of compliance frameworks with (Belgian) certification bodies

UEAtc

What is UEAtc?



- De facto organisation of Technical Approval Bodies
- Objectives:
 - Promoting mutual recognition of conformity assessment results, aiming at avoiding useless repetition of activities (tests, inspections, ...)
 - Exchanging (technical) experiences
 - Supporting innovation

Some terms

What is compliance?

- the term **compliance** is used to distinguish the action of doing what is required (e.g. an organization “complies” by making something conform or by fulfilling a regulatory requirement).
- ... **compliance** means conforming to a rule, such as a specification, policy, standard or law.
- **conformity assessment** is concerned with “fulfilment of specified requirements”

Policies based on technical compliance framework

Walking a tight rope

- Imposing obligations or providing incentives without technical compliance requirements may lead to bad quality works
- Obligations or incentives based on technical compliance requirements need to be finely tuned, ensuring respect of the **legal framework**

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Information to prevent new barriers to trade

- **Aim:** preventing creation of new technical barriers to trade
- **How:** Member states are required at a draft stage to inform the European Commission, and other member states, about their technical regulations
- **Applicable legislations:**
 - **Directive 98/34/EC** (1998) laying down a procedure for the provision of information in the field of technical standards and regulations
 - Exchanging information on anything but standards
 - **Regulation (EU) N° 1025/2012** (2012) on European standardisation
 - amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC
 - Exchanging information on standards

Structure of the presentation

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- **Free movement of goods** (construction products)
- Setting requirements for construction works



Treaty on the functioning of the EU

Free movement of goods in the internal market

- Facilitating buying and selling products in 28 Member States with a total population of more than 500 million
- Wide choice of products at best available price
- Around 75 % of intra-EU trade is in goods
- Free trade agreements might expand scope of provisions



Treaty on the functioning of the EU

Articles of the Treaty 34, 35, 36



Article 34 (intra-EU imports)

- Prohibits 'quantitative restrictions and all measures having equivalent effect' between Member States;

Article 35 (exports from one Member State to another)

- Prohibits 'quantitative restrictions and all measures having equivalent effect';

Article 36

- Provides for derogations to the internal market freedoms of Articles 34 and 35 TFEU that are justified on certain specific grounds

Treaty on the functioning of the EU

Applicability of Articles 34, 35 and 36



- Treaty articles 34, 35 and 36 do not apply in case a given product is fully harmonised by more specific EU legislation:
 - Machinery directive (2006/42/EC) (Machines)
 - Low Voltage directive (2006/95/EC) (Electrical equipment)
 - Electromagnetic Compatibility directive (2004/108/EC) (electrical and electronic appliances, systems and installations)
 - Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) (2011/65/EU)
 - Ecodesign directive (2009/125/EC)
 - Construction products regulation (Construction products)

Treaty on the functioning of the EU

EU directives

- “New approach directives”
 - Directives comprise generally phrased requirements
 - Manufacturers may demonstrate compliance directly or use harmonised standards to this effect
 - Manufacturers issue a declaration of conformity and CE mark their products
 - For the machinery directive, the “putting into service” is also covered



The image shows a sample Declaration of Conformity form. At the top, it says "Declaration of Conformity". Below that, there are fields for "Product" and "Model", with "CE047" entered in the Model field. There is also a field for "Year of placing CE marking" with "2011" entered. The form contains several paragraphs of text, including a declaration that the manufacturer is responsible for the product's compliance with the applicable requirements of the CE marking. At the bottom, there are fields for the manufacturer's name and address, and a signature line.

Treaty on the functioning of the EU

Construction Products Regulation – CPR

- Regulation (EU) N° 305/2011
(Construction Products Regulation – CPR)
 - Basis for declaration of (product) performance (not conformity!) and CE marking
 - Obligation for manufacturers to declare performance for essential requirements through this mechanism only
 - Relevant for construction products covered by harmonised standards and European Technical Assessments

Harmonized technical specifications

Brief explanation

- Harmonized European standard
 - Standard developed in the framework of an EC mandate to CEN
 - Annex ZA of the standard identifies the essential characteristics relevant for CE marking and the conformity assessment system
 - Manufacturers are obliged to CE mark if products covered by harmonized standard
- European Technical Assessment (ETA)
 - Case-by-case assessment for products deviating from harmonized standards
 - Manufacturers may apply for an ETA (no obligation)

The harmonised area

CPR - Article 19

EU member states may specify national requirements for construction products

- For which no harmonised standard exist AND
- Which performances may not or may not fully be assessed on the basis of an existing harmonised standard.

The existence of a harmonised standard (and the corresponding Declaration of performance and CE marking), is insufficient to conclude that EU member states have lost their regulatory prerogatives completely for the concerned construction products.



CE marking

Implications for regulators



■ CE marking

- Informs (authorities) regarding **construction product performances** for the essential characteristics
- is not a quality mark and does not guarantee that CE marked products may be used in each EU member state.

■ EU member states

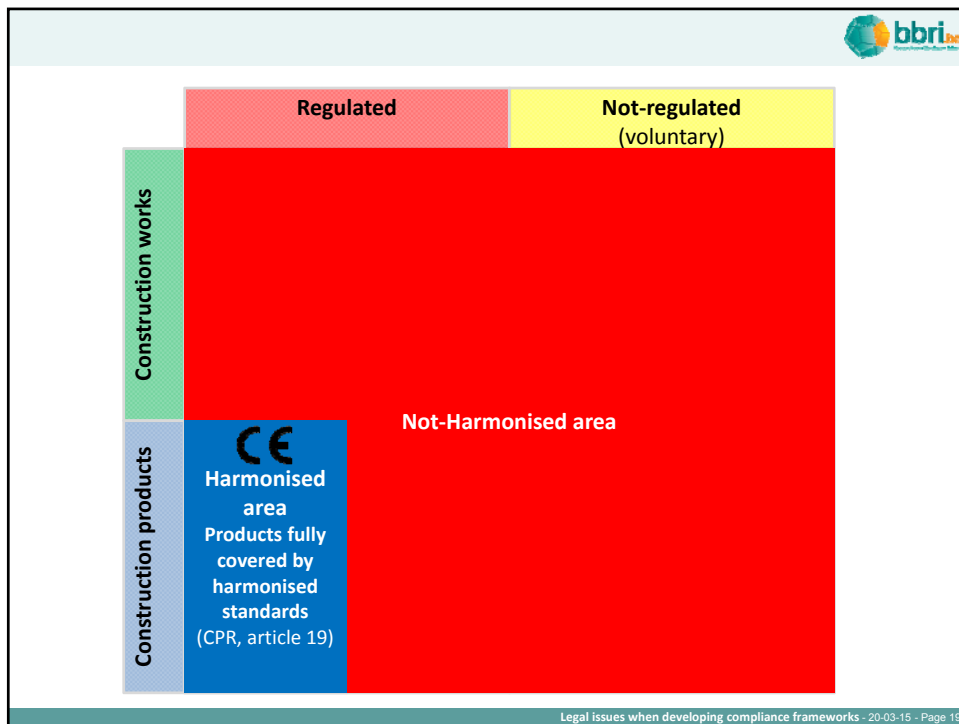
- Maintain their regulatory prerogatives to regulate at the level of the works.
- May use their regulatory prerogatives for construction products for which the essential requirements have not or have not (yet) been incorporated in a harmonised standard or for which the evaluation method(s) is/are inappropriate.

CE marking

EU Member States



- May foresee national provisions in the not-harmonised area, e.g. by referring to national regulatory or voluntary systems.
- Need to foresee in such cases an equivalence clause, permitting products that have already demonstrated compliance with the regulatory requirement through conformity with equivalent systems (e.g. attestation systems in other countries).



- ## Free movement on goods
- ### Some conclusions
- The treaty on the functioning of the EU foresees mutual recognition
 - CE marking facilitates circulation of goods in the EU, preventing barriers to trade; CE marking may address
 - conformity with requirements specified in directives; or
 - Product performance (CPR, Eco-design, ...)
 - Members states may (continue to) foresee national provisions in the not-harmonised area
- bbri logo is located in the top right corner.
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Treaty on the functioning of the EU

Article 101 (restrictions or distortions of competition)

- **Incompatible with the internal market:**
 - All **agreements** between undertakings, decisions by associations of undertakings and concerted practices which
 - may affect trade between Member States and
 - which have as their object or effect the prevention, restriction or distortion of competition within the internal market;
- **Standards, terms of access to a particular quality / compliance mark or for approval by a regulatory body and therefore also compliance frameworks may affect trade ...**



MESSAGE:

Great care is needed when setting up compliance frameworks in relation to the works

Treaty on the functioning of the EU

Preventing restrictions on competition when elaborating compliance frameworks



- restrictive effects on competition by potentially restricting price competition and limiting or controlling production, markets, innovation or technical development.
- where participation in standard-setting is **unrestricted** and the procedure for adopting the standard in question is **transparent**, standardisation agreements which contain **no obligation to comply** with the standard and provide **access to the standard on fair, reasonable and non-discriminatory terms** will normally not restrict competition within the meaning of Article 101

Treaty on the functioning of the EU

Preventing restrictions on competition when elaborating compliance frameworks



MESSAGE:

When specifying requirements, care must be taken that requirements are proportional with the risk, that equivalence is embedded and that mutual recognition is ensured.

MESSAGE:

All parties concerned must be invited to participate, the adoption procedure for specifications must be transparent and specifications are preferably open ended to ensure an inclusive scope and the possibility of alternative solutions

Subsidiarity principle

- Member states are responsible for ensuring that **building and civil engineering works** on their territory are designed and executed so as not to endanger the safety of persons, domestic animals and property nor damage the environment: **National regulations on construction works**
- Regulation (EU) N° 764/2008 (procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State)

Mutual recognition principle

- Rules which may have a direct influence on the requirements of construction products: **Construction products regulation**

MESSAGE:

Member states may impose additional requirements, unless these have a direct influence on construction product requirements (if harmonised)

CE marking and the Public Procurement Directive (2014/24/EU)

- Public procurers (*member state administrations purchasing goods or services from the private sector*)
 - May choose construction products that meet their needs best
 - May foresee requirements that go beyond the essential characteristics foreseen in harmonised technical specifications
- Should – as far as relevant and appropriate – refer to harmonised technical specifications
- As far as relevant, information in the declaration of performance (accompanying the CE marking) needs to be accepted as proof that requirements have been met



MESSAGE:

Public procurers may specify criteria that meet their needs

Services directive (2006/123/EC)

- Aim: promote the growth potential of services markets in Europe by removing legal and administrative barriers to trade in the services sector
- Member States are to remove unjustified and disproportionate burdens and to substantially facilitate:
 - **the establishment of a business**, i.e. cases in which a natural or legal person wants to set up a permanent establishment in a Member State, and
 - **the cross-border provision of services**, i.e. cases in which a business wants to supply services across borders in another Member State, without setting up an establishment there.

MESSAGE:

Care needs to be taken when imposing requirements on workers/companies

...

Services directive

Relevance

- Technical competence requirements (proportionate, not intended to exclude foreign service providers, ...)
- Recognition requirements (transparent, non-discriminatory processes)

Some conclusions

Legal provisions

Whereas imposing technical compliance criteria is possible and may be considered necessary, it is essential

- To prevent new **technical barriers to trade** (authorities should use the notification process)
- To ensure **free movement of goods** by allowing CE marked products to circulate without restrictions and by facilitating mutual recognition
- To develop **proportionate, inclusive** requirements allowing **equivalence**, using **transparent processes** and **involving all concerned parties**

Some conclusions

Technical provisions

Solutions exist

- Specifications for products exist, both at European and national level (European standards, European Technical Assessment and Approvals, confirmation of Technical Approvals with national use, ...)
- Conformity assessment instruments exist which may benefit from mutual recognition (CE marking, voluntary and regulatory compliance marks)

