



HSbooster.eu
TRAINING ACADEMY

Beginner 1

Course 5

STANDARDISATION
TRAINING ACADEMY

Topic:

**LEGAL ASPECTS OF
STANDARDISATION –
RELATIONSHIP OF
STANDARDS AND LAW
IN THE EU**

22
November

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Funded by
the European Union

Module Objectives

After completing this module, you should be able to:

1. recognize and discuss the key legal issues of standardisation;
2. explain the differences between law and a technical standard;
3. communicate to non-legal audience what voluntary standards means; and
4. understand the legal status of technical standards.



About The Author

Irene Kamara

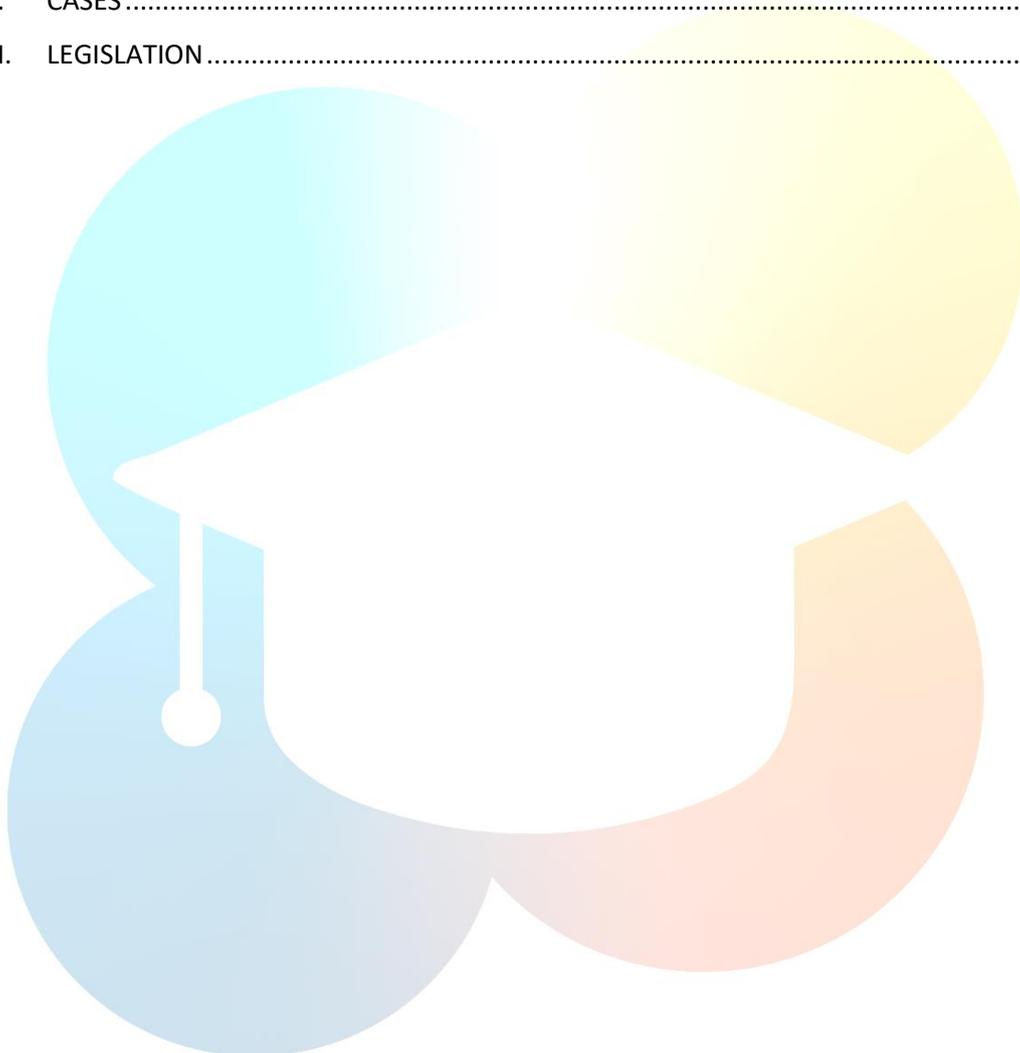
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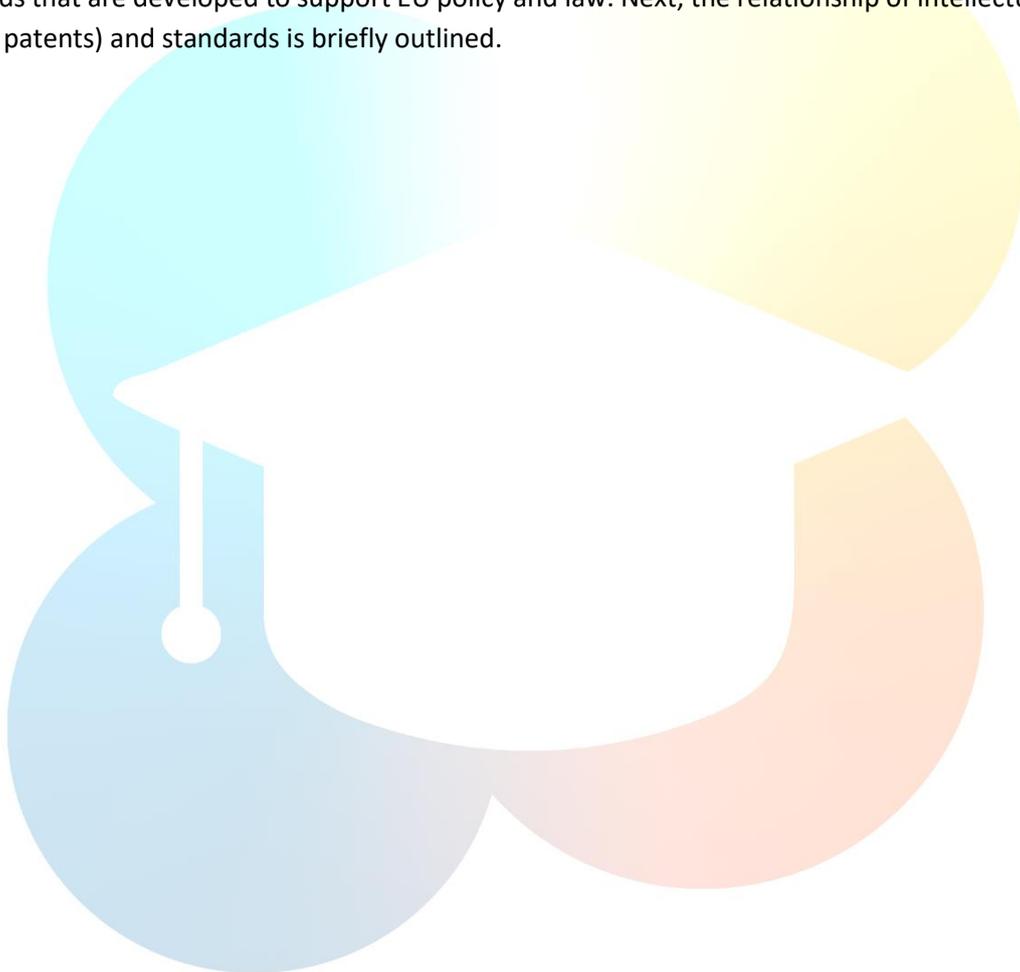
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1 INTRODUCTION

Standards are technical specifications that provide rules for products, services, processes, etc. How a toy should be manufactured to be safe, the height of a chair be to feel comfortable, the process of protecting a computer system from cyber-attacks and many others. Similarly, legislation also provides rules to be followed on a very broad range of topics, and sometimes overlapping topics. Standards and the law often have a complementary relationship: without standards a law on product safety is too vague; without the law, standards in specific areas do not have the same outreach and success. Sometimes, the relationship between standards and the law is mere co-existence: standards may provide rules on a topic that is of no interest to the legislator e.g. hydraulic turbines, and vice versa. However, the hierarchy between the two is always clear: the rules provided for by a law supersede any conflicting rules provided for in a technical standard.

This module aims at providing an overview of the key issues as regards technical standards and the law and offering insights on the use of standards in support of legislation. The contribution is structured as follows: Section two provides the legal definition of a standard and its elements. Section three offers an oversight of the main differences between technical standards and laws (otherwise: legal regulations). Section 4 focuses on standards that are developed to support EU policy and law. Next, the relationship of intellectual property rights (e.g. patents) and standards is briefly outlined.



2 LEGAL DEFINITIONS OF A TECHNICAL STANDARD

The EU Standardisation Regulation defines in its Article 2(1) a standard as

“a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

-  *‘international standard’ means a standard adopted by an international standardisation body;*
-  *‘European standard’ means a standard adopted by a European standardisation organisation;*
-  *‘harmonised standard’ means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;*
-  *‘national standard’ means a standard adopted by a national standardisation body”*

Definition element	Meaning
Technical specification	See below (art. 4(1) Standardisation Regulation)
Adopted by a recognised standardisation body	Only those technical specifications that are adopted by ‘recognised standardisation bodies’ are considered as <i>standards</i> . The others are simply technical specifications.
For repeated or continuous application	Standards are adopted with a view of long-term use, possibly benefitting a large number of addressees.
Compliance is not compulsory	It is not a legal obligation to comply with technical standards. ¹
“Which is one of the following [...]”	<p>This means that only the following types of technical specifications are considered as technical standards for the EU law:</p> <ul style="list-style-type: none">  International standards, adopted by international standardisation bodies (see below under 2)  European standards, adopted by the European Standardisation Organisations  National standards, adopted by the national standardisation bodies of the EU Member States  Harmonised standards, are European standards, adopted on the basis of requests by the European Commission (‘standardisation requests’) for the application of specific legislation (‘harmonisation legislation’)

Further, a technical specification is defined as:

¹ See discussion on *de facto* binding standards in Schepel, H. (2015) and van Leeuwen, B. (2013).

“a document that prescribes technical requirements to be fulfilled by a product, process, service or system”

The Standardisation Regulation prescribes very specific scopes for technical specifications. Those are exhaustively provided in its Article 4(1) and include the following:

-  the characteristics required of a product including levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;
-  production methods and processes used in respect of agricultural products as defined in Article 38(1) TFEU, products intended for human and animal consumption, and medicinal products, as well as production methods and processes relating to other products, where these have an effect on their characteristics;
-  the characteristics required of a service including levels of quality, performance, interoperability, environmental protection, health or safety, and including the requirements applicable to the provider as regards the information to be made available to the recipient, as specified in Article 22(1) to (3) of Directive 2006/123/EC;
-  the methods and the criteria for assessing the performance of construction products, as defined in point 1 of Article 2 of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction product in relation to their essential characteristics.

3 DIFFERENCES BETWEEN STANDARD-MAKING AND LAW-MAKING

A technical standard is developed by standard setting organisations, which are usually private non-for-profit organisations. It is also possible that ‘standards’, or rather technical specifications, are developed by informal consortia.² In practice, one might encounter the terms *de jure* for those standards adopted by standardization organisations, and *de facto* standards for those that are adopted by other consortia, fora, or entities.³ Who develops technical standards actually matters for their legal significance. The EU legislation recognises technical standards that are adopted by a number of standard-setting organisations,⁴ (‘recognised standardization bodies’) prescribed in the EU Standardisation Regulation.⁵ Those are specifically the following:

² See Module on ICT consortia.

³ See the Glossary: <https://hsbooster.eu/standards-glossary>

⁴ In some cases, ICT technical specifications that are not developed by the above standardization organisations, might be used in public procurement in the European Union (Articles 13 and 14 Standardisation Regulation). This is if certain conditions are met, such as that they are developed by a non-for-profit organization in a process that is open, transparent, and the decision making process was collaborative and consensus based.

⁵ Regulation 1025/2012 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R1025>, which was updated with the following Regulation in 2022: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2480>

- The European Standardisation Organisations, that is European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC), and European Telecommunications Standards Institute (ETSI).
- The international standardization organisations, that is ISO, IEC, and ITU, and
- The national standardization bodies of the EU Member States.⁶

Legislation on the other hand is usually proposed by the executive organs (e.g. government) adopted by democratically elected representatives. Law-making follows a different process than standardization. While technical standards are mainly developed on the basis of rules and procedures established by the standardization organisations, which are private organisations, laws are largely adopted on the basis of rules and procedures that are adopted with democratic public law-making processes.

In the European Union, for example, the main law-making process is the ordinary legislative procedure.⁷ The process involves the European Commission submitting a legislative proposal to two legislative bodies, namely the European Parliament and the Council of the European Union, and those after deliberations and democratic dialogues, reach a decision on whether to adopt or propose amendments to the proposal at the so-called first reading or even to reject at the second reading. The procedural guarantees are provided in the Treaties of the European Union, which are the primary law, foundations of the EU.

Standard-making is not of course free of good governance guarantees, especially when it comes to standards that are developed in support of European Union law. However, those do not amount up to the democratic legitimacy guarantees imposed in a law-making process. This has several consequences: for example, while a law might take quite some years to be adopted, standards may be adopted faster than the law. In addition, standards are in principle revised every 5 years, whereas legislation is revised when there is a need for a revision.

Another consequence and issue to be considered is that while laws are binding, meaning that entities or individuals to whom they are addressed (e.g. manufacturers) have to comply with those. Non-compliance with a legal obligation has legal consequences that can be of administrative nature (e.g. a fine to be paid to an authority), civil law nature (e.g. damages to be paid to those persons that suffered from the non-compliance or prohibition of a certain activity in the future) or criminal/punitive nature (e.g. imprisonment). On the other hand, complying with a standard is voluntary. Several authors argue that harmonized standards, developed at the request of the European Commission in support of EU policy or law, have some quasi-binding effect.⁸ This is a debated issue and a scholarly discussion beyond the scope of this training module.

In case of conflicting rules, it is important to note that technical standards do not override legislation. In other words, the law supersedes technical standards.

⁶ <https://www.standardsplusinnovation.eu/get-started>

⁷ <https://www.consilium.europa.eu/en/council-eu/decision-making/ordinary-legislative-procedure/>

⁸ Degallaix (2018).

4 STANDARDS IN SUPPORT OF THE LAW

4.1 Better Regulation

Standards are often developed to support policy or legislation. Better Regulation is an initiative of the European Commission aiming at improving law making at EU level. In this framework, the European Commission improved its approach to design and evaluate EU policies and law, with key aspects being transparency and efficiency among others. In this context, standardization is part of the toolbox for Better Regulation. The Commission has actually characterized standardization as a softer approach than the law, and co-regulation.

*“Co-regulation is a mechanism whereby the Union Legislator entrusts the attainment of specific policy objectives set out in legislation or other policy documents to parties which are recognised in the field (such as economic operators, social partners, non-governmental organisations, standardisation bodies or associations)”.*⁹

According to the European Commission, standardization supports the Single Market and the competitiveness of the European industry in the global markets. The Better Regulation agenda is currently being updated.¹⁰

4.2 Harmonised standards in support of EU law and policy

While standards are developed independent of any local or regional legal framework in mind, they may also be developed by standardization organisations intentionally to support some specific policy goals or legislation. One such special category of standards is the European harmonized standards, which as mentioned earlier are developed to support harmonization law or policy. There are several reasons for this provided by the example of New Approach legislation and harmonized standards. In brief,¹¹ the so-called New Approach, established in a Council Resolution in 1987, was an approach adopted to prevent legislation in some technical field being overly prescriptive and quickly outdated due to the evolution of technologies and the state of the art, faster than the lawmaking process would require.

In essence, the New Approach is based on the four following principles:¹²

⁹ https://commission.europa.eu/system/files/2022-06/br_toolbox-nov_2021_en_0.pdf

¹⁰ https://commission.europa.eu/system/files/2021-04/better_regulation_joining_forces_to_make_better_laws_en_0.pdf

¹¹ See also here: <https://boss.cen.eu/reference-material/guidancedoc/pages/newapproach/>

¹² Council Resolution of 7 May 1985, Annex II.

- Harmonisation of laws is limited to the essential requirements (e.g. safety or other requirements in the general interest) with which products placed in the market must conform.
- For the production and placing in the market of those products that will conform to the essential requirements, technical specifications are needed, which will be drawn up by competent standardization organisations.
- Those technical specifications are not mandatory, thus remaining voluntary standards.
- National authorities are obliged to recognize “that products manufactured in conformity with harmonized standards [...] are presumed to conform to the ‘essential requirements’ established” by the relevant Directive.

The latter, also known as “presumption of conformity,” is one of the strongest benefits of harmonized standards. This is that a product that is found to conform to a harmonized standard is presumed to comply with the essential requirement established in the harmonization law and addressed by that harmonized standard. The Council Resolution also stresses that a producer should have the choice to not follow those harmonized standards. But in that case, the producer has to “prove that his products conform to the essential requirements of the Directive.”

This practice has been largely adopted in many areas of law and policy making in the European Union.¹³ Recent legislation (or proposed acts) in the areas of cybersecurity,¹⁴ regulation of Artificial Intelligence systems,¹⁵ and others has been following the same legislative technique.¹⁶

Harmonised standards are developed on the basis of standardization requests, that are drafted by the European Commission. The standardization requests, which are Commission Implementing Decisions, request the European Standardisation Organisations (ESOs) to draft a European standard or European standardisation deliverable within a set deadline. The ESOs may accept or reject the request. In case they accept, they develop the harmonized standards, in line with the procedural guarantees provided in the Standardisation Regulation.¹⁷ After the requested standards (or standardization deliverables) are developed, the Harmonised Standards (HAS) consultants are assessing whether the developed standards correspond to the standardization request and provide an opinion to the Commission. If the harmonized standards are aligned with the standardization request, then those harmonized standards are published in the Official Journal of the European Union (OJ). The Court of Justice of the EU (CJEU) has ruled in the landmark *James*

¹³ See for example Toy Safety Directive; Construction products regulation; Civil explosives; Radio equipment directive; Marine Equipment Directive; Medical Devices Regulation and others: https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

¹⁴ <https://digital-strategy.ec.europa.eu/en/library/cyber-resilience-act>

¹⁵ Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts COM/2021/206 final.

¹⁶ The same goes for conformity assessment and the New Legislative Framework. See https://europa.eu/youreurope/business/product-requirements/compliance/conformity-assessment/index_en.htm

¹⁷ Art. 10 Standardisation Regulation.

Elliot case that harmonized standards are part of EU law, in the sense that they apply or implement an act of EU law.¹⁸

It is important to highlight that the standardization process and the standardization deliverables in support of law, needs to be subject to several good governance principles such as for example transparency,¹⁹ stakeholder participation,²⁰ accessibility of SMEs²¹ and the right to object.²²

5 INTELLECTUAL PROPERTY RIGHTS AND STANDARDS

Technical standards are copyright protected. The copyright belongs to the drafting standardization organisations. However, this is not the only intellectual property right matter relating to technical standards. Several technologies are subject to restrictions due to patent rights. Several standards however are relying on patented technologies, especially in the mobile telecommunications domain. Those patents are called “standard-essential patents” (SEP). Standardisation organisations have in place licensing policies and procedures that ensure the use of those patented technologies in standardisation, while also respecting the investment of the patent-holders.²³

¹⁸ While the implications of this case are beyond the scope of this module, see analysis of the case:

<https://europeanlawblog.eu/2017/01/24/a-harmonised-european-technical-standard-provision-of-eu-law-judgment-in-c-61314-james-elliott-construction/>

¹⁹ Art. 4 Standardisation Regulation.

²⁰ Arts. 5 and 7 Standardisation Regulation. See also Annex III Standardisation Regulation.

²¹ Art. 6 Standardisation Regulation

²² Art. 11 Standardisation Regulation.

²³ See for example the 2019 CEN-CENELEC Guide.

SUMMARY

Technical standards are different in many aspects from legislation, but at the same they interact. While standards may develop independently from legislation, they are also used as an instrument of regulation, supporting policies and legislative goals. Good governance guarantees and specific processes provided in the EU Standardisation Regulation apply in case standards are developed with a view to support legislation.



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Additional material

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Blog: Medzmariashvili M. A Harmonised European (technical) Standard-Provision of EU Law! (Judgment in C-613/14 James Elliott Construction), European Law Blog <https://europeanlawblog.eu/2017/01/24/a-harmonised-european-technical-standard-provision-of-eu-law-judgment-in-c-61314-james-elliott-construction/>

Video: IPR, patents & Standards – StandarDays, by CEN and CENELEC <https://www.youtube.com/watch?v=y0z2P9I5bWk>

Video: Harmonized European standards: Drafting standards compliant with EU legislation, by CEN and CENELEC, https://www.youtube.com/watch?v=6MWvPm1j_Bs



Appendix I. CASES

Court of Justice of the European Union (CJEU)

Judgment of 12 May 2010, EMC Development AB, Case T-432/05, EU: T:2010:189

Judgment of 12 July 2012, Case C-171/11, Fra.bo SpA, EU:C:2012:453

Judgment of 16 February 2017, Elisabeth Schmitt, C-219/15, EU:C:2017:128.

Judgment of 27 October 2016, James Elliot, Case C-613/14, EU:C:2016:821.

Judgment of the Court 8 November 2018 Dyson, Case T-544/13 RENV EU: T:2018:761.

Judgment of the General Court of 14 July 2021, Public.Resource.Org et al v European Commission, Case T-185/19, ECLI:EU:T:2021:445

Judgment of 22 February 2022, Stichting Rookpreventie Jeugd and Others, C-160/20, ECLI:EU:C:2022:101

Opinion of Advocate General of 28 January 2016, James Elliot, Case C-613/14, EU:C:2016:63.

Appendix II. LEGISLATION

Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (OJ C, C/136, 04.06.1985, p. 1, CELEX: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985Y0604\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985Y0604(01))).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 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 of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance, *OJ L 316, 14.11.2012, p. 12–33*.

Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 1025/2012 as regards decisions of European standardisation organisations concerning European standards and European standardisation deliverables (Text with EEA relevance) PE/58/2022/REV/1, *OJ L 323, 19.12.2022, p. 1–3*





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