# The Incorporation of Global Standards into the EU as a 'Regulatory Union'

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## 1. Introduction

Standards[2] set by bodies outside of the institutional architecture of the European Union (EU) enter the EU legal system and may influence EU decision-making procedures through various pathways. These include legislative references and delegation of powers to standardisation bodies, as well as the use of principles developed in the Court of Justice of the European Union (CJEU) case law. The great diversity of types of standards, their origin, the procedure by which they have been established, and their – often hidden – 'entry points' into EU law, raises multiple legality issues. As this chapter will show, this process also calls for some critical reflection on issues of legitimacy, not least due to the powerful role that standards play in regulating EU policies.

## 2. Functions and effects of standards in EU law

In the EU, standards adopted by non-EU actors in the form of international and intergovernmental bodies or private and semi-private actors (referred to in this book generally as 'global standards') are, despite their diverse origins and sources, often used to regulate many EU policy fields, especially the EU's internal market. The origin of standards in the internal market was based on deconstructing regulatory barriers along national lines. With this, the need arose for a subsequent re-establishment of common regulatory standards with a focus on 'neutral', science-based standards. Today, the diversity of sources of standards applied within the EU results in a complex and challenging legal situation. Standards often straddle the line between law and expert scientific knowledge in that they are used to ensure that regulation complies with high levels of scientific understanding and good practices. In this way, the use of standards may contribute to the compatibility of EU policies with its goals of enhancing high-level regulation within the EU, meeting citizens' expectations of good regulatory practice,

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[2] Annex 1.2. of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) [1994] contains a good working definition of a standard as a '[d]ocument approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelinglabeling requirements as they apply to a product, process or production method.'

and complying with regulatory standards that can be agreed upon internationally. The latter is an approach to also enhance external trade.[3]

However, standardisation and integrating standards into the EU legal system is also a political issue. Politically speaking, standards often have a risk-regulating element to them. Questions may arise about who assesses the acceptable risk criteria in society and according to which norms. Another political aspect is the standardisation policy. Over time, the EU has been able to exert considerable external influence through the process of developing, using, and exporting standards. The high degree of integration of the EU into the world economy and the strong interest of the EU to promote its own regulatory standards globally is part of the EU's drive towards a rule-based international legal order. The EU and the Member States do seek to recreate the European approach to joint rule-making by standards on the international level through standard-setting as a means of soft law-based harmonization of trading conditions and approximation of rules globally. At the same time, the active participation of the EU, its Member States, and organizations from the EU in international standard-setting processes allows the promotion of EU standards on the international stage. This extensive participation gives European companies already complying with standards accepted in the EU certain advantages in regulatory compliance.[4] Yet, in the admixture of interests and policy objectives integrated in the process, the question of whose interests are taken into account in creating standards and their application remains more pertinent than ever.

Thus, understanding standardisation's legal and political relevance raises questions about who sets the agenda. Which goals are being pursued by the creation of new standards and their incorporation into or application within EU law? What is a standard's legal value and effect, and what criteria influence this regulatory choice? This question is not merely administrative or technical but is acutely political – if such a distinction is ever possible in a system where the executive branch of powers should act under the political oversight of parliaments. Further questions pertain to the procedures of standard-setting. As several of the contributions in this book show, standards are not always the result of decision-making procedures following principles of good administration, transparency, and possibilities of broad participation. These questions simply indicate the specific challenges standards pose within the EU's constitutional framework.

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[3] Christian Joerges, 'Sound science in the European and global market: Karl Polanyi in Geneva', in Michelle Everson and Ellen Vos (eds.), *Uncertain Risks Regulated* (Routledge Cavendish, 2009), 416, 416.

[4] See e.g., the discussion of Maurizia de Bellis, 'Reinforcing EU financial bodies' participation in global networks: addressing legitimacy gaps?', in Herwig C.H. Hofmann, Ellen Vos, Merijn Chamon (eds.), *The External Dimension of EU Agencies and Bodies* (Edward Elgar, 2019), 126.

These different factors and the great diversity of standards, procedures of adoption and the various substantive conditions complicate the understanding of their legal effects in EU law. This is not made easier by the fact that standards, like in most national constitutional frameworks, are not part of the types of acts outlined in the typology of acts in the Treaties. A further layer of complication is generated by the fact that global standards get to enter the EU legal system through a host of co-regulatory and incentive-based approaches, as will be further discussed in this chapter.

### 3. An overview: The multiple sources of standards

Standards applicable within the EU legal system are those set by national and European standard-setting bodies, as well as a great diversity of 'externally' produced standards.[5] A first indicative look at the sources of standards and procedures of standard-setting reveals a great diversity on the spectrum of standards not directly produced by EU institutions. Those arising from intergovernmental arrangements and cooperation (e.g., the Eurogroup Working Party discussed below) are linked to EU and Member State institutions and bodies. There are also those arising from international organizations (such as the World Health Organization (WHO), the International Labour Organization (ILO), and others). Another type arises from private or semi-private standardisation bodies on the international (e.g., International Organization for Standardisation (ISO)), the European (e.g., European Committee for Standardisation (CEN), European Committee for Electro-technical Standardisation (CENELEC), European Telecommunications Standards Institute (ETSI)) or the national levels (e.g., *Deutsches Institut für Normung* (DIN)). Standards may arise from informal cooperation (e.g., the Basel Committee on Banking Supervision) or private research associations publishing their findings.

World Trade Organization (WTO) law establishes certain minimum requirements for establishing, withdrawing, or amendment of standards relating to goods. Especially the WTO's agreements on product-related rules under the Agreement on Technical Barriers to Trade (TBT) as well as, more specifically, in the area of food and feed-related matters under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) contain such provisions.[6] Under these Agreements, WTO members are bound to use international standards as a basis for their technical regulations, provided that such regulations are necessary and no

[5] Mariolina Eliantonio and Caroline Cauffman, 'The Legitimacy of Standardisation as a Regulatory Technique in the EU', in Mariolina Eliantonio and Caroline Cauffman (eds.), *The Legitimacy of Standardisation as a Regulatory Technique in the EU* (Edward Elgar, 2020), 1, 5.

[6] See e.g., Articles 3, 5(8) and 12 of The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (1995).

more trade-restrictive than necessary to fulfil a legitimate objective.[7] International standardisation bodies are numerous and cover a wide spectrum of matters. For example, the International Organization for Standardisation[8] and the International Electrotechnical Commission (IEC)[9] both have broad mandates for establishing product and safety standards.

Other bodies are more sector-specific, such as the so-called 'Basel Committee on Banking Supervision' (a venue for cooperation between the heads of several central banks and banking supervisory authorities of developed nations, including the EU).[10] In the EU, in the field of banking regulation, standards established by the Basel Committee on Banking Supervision play a prominent role. The same holds true for accounting standards set by the 'International Accounting Standards Board' (IASB, the board of a not-for-profit corporation acting as a privately funded standard setter with a membership reported to include business, academic and regulatory authorities), which are highly influential and are used in various contexts in EU law.[11] The 2008 banking crisis laid bare the degree to which the standards developed by the Basel Committee, the IASB International Financial Reporting Standards, and the International Accounting Standards had entered into the regulatory environment of the EU. According to some accounts, their application went unchecked to a degree about their biases in regulation.[12] Many other examples have been collected by scholars in 'Global Administrative Law' matters[13] and are emerging from comparative studies.[14]

EU bodies' regulatory action often relies on recognising and applying external standards. Examples of this exist in nearly all fields of risk regulation. Where, for example, the European Medicines Agency considers suggesting the admission of a new medical product to the internal

[7] WTO members may abstain from using international standards when such standards would be ineffective or inappropriate for the fulfilment of the legitimate local policy objectives pursued.
[8] See www.iso.org.
[9] See www.iec.ch.
[10] See www.bis.org/bcbs/index.htm.
[11] Regulation (EC) No. 1606/2002 of the European Parliament and the Council on the application of international accounting standards [2002] OJ L 243/1, authorises the European Commission in Article 3 to decide in a comitology procedure on the applicability of international accounting standards as defined in Article 2. On this basis the European Commission has adopted European Commission Regulation (EC) No. 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) No. 1606/2002 of the European Parliament and of the Council [2008] OJ L 320/1, as amended, which incorporates international accounting standards, by way of direct reference. See also Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy', (2007) 32 *European Law Review*, 443, 455.
[12] See Maurizia De Bellis in this book. See further: Bart de Meester, 'Multilvel Banking Regulation: An Assessment of the Role of the EC in the Light of Coherence and Democratic Legitimacy', in Andreas Follesdal, Rames A. Wessel and Jan Wouters (eds.), *Multilevel Regulation and the EU* (Marinus Nijhoff Publishers, 2008), 101. Cross-reference to Maurizia's chapter to be added.
[13] See e.g., Sabino Cassese *et al.*, *Global Administrative Law: the Casebook* (IRPA-IILJ, 2012), Available at http://ssrn.com/abstract=2140384.
[14] See especially, Sabino Cassese, 'A Global Due Process of Law?', in Gordon Anthony, Jean-Bernard Auby, John Morison and Tom Zwart (eds.), *Values in Global Administrative Law* (Hart Publishing, 2011), 17.

market, the review of this product will also rely on international scientifically proven best practices. In pharmaceuticals, to give another example, standardisation activities of the 'International Council on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use' (ICH), a joint regulatory and industry cooperation established in 1990 by the EU, the US, and Japan with the support of the World Health Organisation, are readily incorporated into EU law.[15]

Private rule-making can be employed to implement Union legislation. This is common practice in the field of social policy.[16] and in the environmental field,[17] as well as in data protection.[18] Codes of conduct play an increasingly important role in commercial practices[19] and professional activities,[20] as well as in corporate governance.[21] Privately set standards are also becoming part of EU institutions' decision-making procedures, where data collections or data processing are undertaken with the help of software provided by private actors. For this reason, the EU has established an agency for EU large-scale systems, eu-LISA, to ensure EU standards are applied in some of the most critical areas of EU data infrastructure.[22]

European and international standardisation organisations cooperate closely and, for this purpose, have concluded cooperation agreements, such as the Vienna Agreement between ISO

[15] See Bärbel Dorbeck-Jung, 'Challenges to the Legitimacy of International Regulation: The Case of Pharmaceuticals Standardisation', in Andreas Follesdal, Rames A. Wessel and Jan Wouters (eds.), *Multilevel Regulation and the EU* (Marinus Nijhoff Publishers, 2008), 51, with reference to the ICH Guidance on Good Clinical Practice being incorporated into the EU Clinical Trials Directive (2001/20/EC) and subsequent regulatory practice. More recently: Sabrina Röttger-Wirtz, *The Interplay of Global Standards and EU Pharmaceutical Regulation: The International Council for Harmonisation* (Hart Publishing, 2021).

[16] See Article 153(3) TFEU (amending Article 137(3) EC by the reference to Article 155 TFEU), which allows Member States to entrust to management and labour the implementation of social policy directives.

[17] See Article 24(3) of Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) [2012] OJ L 197/38, which provides that Member States may transpose certain provisions of the directive 'by means of agreements between the competent authorities and the economic sectors concerned'.

[18] See for example in Article 46 of the GDPR (Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation [2016] OJ L 119/1), which envisages the drawing up of codes of conduct and binding corporate agreements.

[19] Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy', (2007) 32 *European Law Review*, 443, 458-460 and 461-462.

[20] Ibid, 462-463.

[21] Søren Friis Hansen, 'Codes of Conduct', in Birgitte Egelund Olsen and Karsten Engsig Sørensen (eds.), *Regulation in the EU*, (Thomson, 2006), Chapter 8.

[22] Regulation (EU) No. 2018/1726 of the European Parliament and of the Council of 14 November 2018 on the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA), and amending Regulation (EC) No. 1987/2006 and Council Decision 2007/533/JHA and repealing Regulation (EU) No. 1077/2011 [2018] OJ L 295/99. (Hereinafter, the 'eu-LISA Regulation'). With respect to the SIS specifically, eu-LISA's tasks are listed under Chapter III of the SIS-recast, involving responsibilities of operational management (Article 15); security (Article 16); confidentiality (Article 17).

and the European Committee for Standardisation,[23] and the Dresden Agreement between the IEC and the European Committee for Electrotechnical Standardisation.[24] In the cooperation agreements, the European standardisation bodies agree *inter alia* to respond to and take into account comments by non-European members in their own standardisation work,[25] which may take on the appearance of outsourcing of international standardisation to European organizations. On the other hand, the strong presence of European and EU Member State standardisation bodies in international standard-setting organizations also contributes to the fact that many international standards, especially those set by the IEC, are, in fact, themselves based on European standards. The international strength of European standardisation organizations arises from their unique position in regulating the EU's internal market and EU policies.

Beyond the specific standardisation bodies, a host of bodies created under public international law, including intergovernmental agreements between EU Member States and, in some cases, non-EU Member States, can create standards. For example, in the field of economic and monetary law, standards also arise from intergovernmental bodies set up by EU Member States to substitute certain regulations or fill regulatory gaps that have arisen in EU law.[26] One is the Eurogroup, an informal gathering of national finance ministers (recognised in Article 137 TFEU and Protocol No 14) which creates standards for national economic policies in the context of support measures through its 'Eurogroup Working Group'.[27] The use of such standards for the adoption of Memoranda of Understanding (MoUs) in the context of financing

[23] See https://www.cencenelec.eu.

[24] See the IEC-CENELEC Agreement on Common planning of new work and parallel voting [1996] CLC(PERM)003.

[25] Herwig C. H. Hofmann, Gerard C. Rowe and Alexander H. Türk (eds.), *Administrative Law and Policy of the European Union* (Oxford University Press, 2011), 598.

[26] E.g. Case C-370/12, *Thomas Pringle v Government of Ireland and Others*, ECLI:EU:C:2012:756; with much literature having discussed the legality of the structure. See e.g., Matthias Ruffert, 'The European Debt Crisis and European Union Law' (2011) 48(6) *Common Market Law Review*, 1777, 1785; Richard Palmstorfer, 'To bail out or not to bail out? The current framework of financial assistance for euro area Member States measured against the requirements of EU primary law' (2012) 37(6) *European Law Review*, 771; Jean-Victor Louis, 'The no-bailout clause and rescue packages' (2010) 47(4) *Common Market Law Review*, 971, 977; Jörn Pipkorn, 'Legal arrangements in the Treaty of Maastricht for the effectiveness of the economic and monetary union' (1994) 31(2) *Common Market Law Review*, 263, 275; Harald Hofmeister 'To Bail Out Or Not to Bail Out?—Legal Aspects of the Greek Crisis' (2011) 13 *Cambridge Yearbook of European Legal Studies,* 113.

[27] The General Court in T-327/13, *Konstantinos Mallis and Elli Konstantinou Malli v European Commission and European Central Bank (ECB),* ECLI:EU:T:2014:909, para. 53, found explicitly that the decision-making by the Euro Group does not empower it to adopt legally binding measures. In principle, a statement made by the 'Euro Group cannot, therefore, be regarded as a measure intended to produce legal effects with respect to third parties (see, to that effect and by analogy, Case C-301/03, *Italy* v *Commission of the European Communities* ECLI:EU:C:2005:727, para. 28, the order of 3 November 2008 in Case T-196/08 *Srinivasan* v *Ombudsman* ECLI:EU:T:2008:470, not published in the ECR, paras. 11 and 12, and order of 3 December 2008 in Case T-210/07 *RSA Security Ireland* v *Commission of the European Communities* ECLI:EU:T:2008:548, not published in the ECR, paras. 53 to 55).'

operations conducted in the context of European support operations does not call into question their nature as non-binding standards and are thus not subject to an action for annulment before the CJEU.[28]

## 4. The entry point for standards into EU law

Standards are incorporated into EU law through various means. Some of the most important examples of explicit or implicit incorporation of standards in EU law include incorporation by references in EU legislation (4.1), the use of standards to review the consistency of EU institutional decision-making by the CJEU (4.2), and standards as criteria for liability for non-contractual damages under Article 340(2) Treaty on the Functioning of the European Union (TFEU) (4.3). Standards have many other effects on EU law, such as serving as models or inspiration for drafting acts. However, this chapter will focus on the more 'binding' approaches, which are also reflected in the case law of the CJEU.

### 4.1. Incorporation by reference

The most common way in which international standards may enter the EU legal system is through reference to such a measure in a Union legal act. This approach is well developed in various EU policy fields, which provide for this mechanism of incorporation of *initially* non-binding standards by reference into EU legislation, thus giving them a binding nature.[29] There are examples of such references in legislative and non-legislative acts across various fields.[30] Additionally, the specific role of public international law within the EU legal system may result in references to global standards.

#### 4.1.1. Dynamic references in EU legislation

[28] T-327/13, *Konstantinos Mallis and Elli Konstantinou Malli v European Commission and European Central Bank (ECB),* ECLI:EU:T:2014:909, paras. 41-44.

[29] See for an overview e.g., Andreas Follesdal, Rames A. Wessel and Jan Wouters (eds.), *Multilevel Regulation and the EU* (Marinus Nijhoff Publishers, 2008).

[30] See e.g. for food standards Recital 15 and Articles 21, 22 of Regulation (EC) No. 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene [2005] OJ L 35/1 referring to the Codex Alimentarius of the WHO and the Food and Agriculture Organization (FAO). For labour standards e.g. Article 31 of Regulation (EC) No. 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation [2006] OJ L 378/41, making reference to ILO labour standards for public procurement contracts. For data protection standards see e.g., references to Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data ETS No. 108 of 1981, ratified by all EU Member States, in Article 27 of Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA [2016] OJ L 135/53.

Legislative references often contain 'dynamic' links to standards that continue evolving outside the EU legal order. These standards may also evolve because of the case law of courts or dispute settlement mechanisms, such as the European Court of Human Rights (ECtHR) in the case of the European Convention of Human Rights (ECHR) (included in the reference under Article 52(3) Charter of Fundamental Rights (CFR)) or due to clarifications brought to international agreements by quasi-judicial dispute settlement structures such as the WTO's Dispute Settlement Body (DSB).

The development of global standards might also be undertaken in the context of further clarifications and specifications in the working bodies of international organisations. For example, Article 15 of the Aarhus Convention on review of compliance, requires the Meeting of the Parties to establish 'optional arrangements of a non-confrontational, non-judicial and consultative nature for reviewing compliance with the provisions of the Convention'.[31] These documents are taken into account in a variety of cases in which EU law makes reference to outside standards set in international agreements.[32]

The CJEU addressed one example of such a technique in the *OIV* case.[33] Germany had requested the annulment of the Council decision establishing the EU's position about certain resolutions to be adopted in the framework of the International Organisation of Vine and Wine (OIV), an organisation to which the EU is not party. Article 2(1)(c) of the agreement establishing the OIV describes the purpose of contributing 'to international harmonisation of existing practices and standards and, as necessary, to the preparation of new international standards'. The CJEU found that OIV recommendations on matters such as new oenological practices are to be considered as 'acts having legal effects' for the purposes of Article 219 TFEU since EU legislation incorporated those recommendations into EU law by dynamic link. In *OIV,* the General Court made special reference to EU legislation,[34] which explicitly

[31] Accordingly, the Aarhus Convention's signatories adopted at the Meeting of the Parties 'decision I/7 on review of compliance'. The compliance committee may inter alia examine compliance issues on its own initiative and make recommendations; prepare reports on compliance with or implementation of the provisions of the Convention at the request of the Meeting of the Parties. Thereby, the compliance committee establishes standards for the implementation of the Aarhus Convention's specific provisions such as the 'Aarhus Convention Implementation Guide'.

[32] See e.g., references made in EU food law to standards established by the International Organisation of Vine and Wine (OIV) in Article 80(3)(a), 80(5) read with Article 91(c), and 90 (1) and (2) of Regulation (EU) No. 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No. 922/72, (EEC) No. 234/79, (EC) No. 1037/2001 and (EC) No. 1234/2007 [2013] OJ L 347/671.

[33] Case C-399/12, *Federal Republic of Germany v Council of the European Union*, (International Organisation of Vine and Wine, OIV), ECLI:EU:C:2014:2258.

[34] Article 80(5) read with Article 91(c), and 90 (1) and (2) of Regulation (EU) No. 1308/2013 above n. 34 and the first subparagraph of Article 9(1) of European Commission Delegated Regulation (EU) No. 2019/934 of 12 March 2019 supplementing Regulation (EU) No. 1308/2013 of the European Parliament and of the Council as regards

compares OIV recommendations to rules of EU law regarding the methods of analysis for determining the composition of products of the wine sector, the special requirements applicable, in terms of oenological practices, to imports of wine originating from third countries, and the purity and identification specifications of substances used in such practices.[35]

### 4.1.2. Recognition of standards in the EU by way of links to public international law

The recognition of standards incorporated through references contained in legislative and non-legislative acts,[36] was established early on in cases such as *Nakajima* and confirmed in well-known case law such as *Intertanko* and *OIV*. In *Nakajima*, the CJEU had ruled that, despite the lack of direct effect of WTO law within the Union legal framework, where an EU legal act is 'adopted to comply with the international obligations of the Community'[37] This leads to a justiciable obligation on the part of Union bodies to ensure compliance with the provisions of public international law.[38] The CJEU thus oversees the application of WTO criteria within its assessment of the legality of Union actions under EU law,[39] although the WTO's international law character does not change, and its hierarchical position remains secondary to Treaty provisions. However, even where EU law does not grant direct effect to an international agreement, or where the Union itself is not a party to the agreement but its Member States are, the agreement may have an effect in EU law.[40]

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wine-growing areas where the alcoholic strength may be increased, authorised oenological practices and restrictions applicable to the production and conservation of grapevine products, the minimum percentage of alcohol for by-products and their disposal, and publication of OIV files [2019] OJ L149/1.

[35] Case C-399/12, *Federal Republic of Germany v Council of the European Union*, above n. 35, paras. 57-64.

[36] See e.g., C-104/16 P *Council of the European Union v Front Polisario*, ECLI:EU:C:2016:973, paras. 88-93 referring to the UN Charter and UN General Assembly resolutions concerning the Western Sahara; C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others,* ECLI:EU:C:2003:431, para. 79 referring to the Codex Alimentarius.

[37] Case C-69/89, *Nakajima All Precision Co. Ltd v Council of the European Communities,* ECLI:EU:C:1991:186, para. 31.

[38] Case C-104/81, *Hauptzollamt Mainz v C.A. Kupferberg & Cie KG a.A.*, ECLI:EU:C:1982:362, para. 11, and in Case C-266/81, *Società Italiana per l'Oleodotto Transalpino (SIOT) v Ministero delle finanze, Ministero della marina mercantile, Circoscrizione doganale di Trieste and Ente autonomo del porto di Trieste*, ECLI:EU:C:1983:77, para. 28.

[39] Case C-70/87, *Fédération de l'industrie de l'huilerie de la CEE (Fediol) v Commission of the European Communities (Fediol III),* ECLI:EU:C:1989:254; Case C-69/89, *Nakajima All Precision Co. Ltd v Council of the European Communities*, ECLI:EU:C:1991:186.

[40] C-308/06, *International Association of Independent Tanker Owners (Intertanko) and Others v Secretary of State for Transport*, ECLI:EU:C:2008:312, paras. 47-52. In *Intertanko* the CJEU held that, where the EU is not party to an international agreement, in that case the Marpol Convention (on the prevention of pollution from ships), 'the mere fact that Directive 2005/35 has the objective of incorporating certain rules set out in that Convention into Community law is likewise not sufficient for it to be incumbent upon the Court to review the directive's legality in the light of the Convention'. However, the CJEU found that this is necessary 'in view of the customary principle of good faith, which forms part of general international law' and of the principle of sincere cooperation to which the Member States are subject (Article 4(3) Treaty on European Union (TEU)), the European Commission had to 'take account' that some Member States implementing the EU legislation made direct reference to the Marpol Convention in interpreting EU legislation.

As a result, although standards arising from international organisations cannot as such be used to assess the legality of an EU legal act unless explicitly incorporated into EU law by legislation,[41] they can be used for interpretation of obligations under EU law. For example in *Lesoochranárske zoskupenie,*[42] a case concerning Article 9(3) of the Aarhus Convention, the CJEU held that it has the power to interpret norms of international agreements or statements, guidelines or standards emanating from such international agreements.[43] This is essential to ensure that norms of international agreements that affect the legal system of the EU are interpreted uniformly.

Where EU law can be interpreted in compliance with standards set by international bodies, at least in tax law cases, the CJEU has shown a tendency to take them into account. For example, where a legislative proposal 'draws upon' a Commission and the Organisation for Economic Co-operation and Development (OECD) Model Tax Convention and the OECD's commentaries relating to it, the CJEU has held that it is sufficient for this legislative proposal to pursue 'the same objective' as the OECD 1996 Model Tax Convention (even where this objective is only phrased in comprehensive terms, such as 'avoiding international double taxation')[44] for the Court to be able to interpret the concept 'of 'beneficial owner', which appears in the bilateral conventions based on that model […] [as] relevant when interpreting' an EU directive.[45] The CJEU dismissed the argument that interpreting autonomous EU law in the light of the OECD Model Tax Convention and the commentaries relating to it 'would lack any democratic legitimacy whatsoever'.[46] In its view, the interpretation of EU law under the OECD documents can be upheld in light of the directive's text and the 'legislative history reflecting the democratic process of the European Union'.[47] In this context, the incorporation

[41] See e.g., Joined Cases C-401/12 P to C-403/12 P, *Council of the Euopean Union, European Parliament and European Commission v Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht*, ECLI:EU:C:2015:4, paras. 52-55; and with respect to WTO law Joined cases C-120/06 P and C-121/06 P*, Fabbrica italiana accumulatori motocarri Montecchio SpA (FIAMM) and Others v Council of the European Union and Commission of the European Communities*, ECLI:EU:C:2008:476, para. 108 and the case law cited.
[42] C-240/09, *Lesoochranárske zoskupenie VLK v Ministerstvo životného prostredia Slovenskej republiky*, ECLI:EU:C:2011:125, paras. 40-43.
[43] Regarding the recommendations of a Joint Committee of an international agreement, see Case C-188/91, *Deutsche Shell AG v Hauptzollamt Hamburg-Harburg*, ECLI:EU:C:1993:24, para. 19 and summary grounds number 1 stating that the CJEU 'has jurisdiction to give a preliminary ruling in the interpretation of the arrangements of the Joint Committee established by the Convention on a Common Transit Procedure concluded on 20 May 1987 by the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Kingdom of Norway, the Kingdom of Sweden, the Swiss Confederation and the EEC'.
[44] Joined Cases C-115/16, C-118/16, C-119/16 and C-299/16, *N Luxembourg 1 and Others v Skatteministeriet,* ECLI:EU:C:2019:134, para. 90.
[45] Ibid.
[46] Ibid, 91.
[47] Ibid, 91.

of OECD standards takes place by interpreting EU law in light of the standards the law draws upon.

### 4.1.3. Incorporation of standards by the European Standardisation Organisations and the 'New Approach'

The main model under which standards become relevant within the internal market is predominantly through the so-called 'New Approach'. This model was first developed in the 1980s and has remained applicable with amendments until today. Based on the 'New Approach', the Union has limited itself to adopting only the 'essential requirements' of health and safety regulation as opposed to detailed technical prescriptions with which products must comply to benefit from free movement within the EU. Instead of adopting detailed Union legislation, European Standardisation Organisations (ESOs), i.e., CEN, CENELEC and ETSI, are charged with establishing specific standards based on such requirements,[48] generally based on a mandate from the Commission. The 'New Approach' Directives have been codified in a common framework for the marketing of products by Decision 768/2008[49] with which all Union harmonisation legislation ought to comply.[50] The Decision makes it clear that the incorporation of its provisions cannot be required by law, but constitutes a clear political commitment by the European Parliament and the Council to abide by its provisions in future legislation.[51]

European Standardisation Organisations are not isolated from international standard-setting. They incorporate international standards and international best practices and take these into account in developing European standards.[52] At the same time, the participation of CEN, CENELEC and ETSI as well as of its member bodies in international standardisation allows the exercise of EU influence internationally.[53] Contributing to international standard-setting

[48] See Article 3(2) of Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [2008] OJ L 218/82.
[49] Ibid.
[50] The reference provisions can be found in Annex I of Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [2008] OJ L 218/82.
[51] See Recital (7 of Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [2008] OJ L 218/82.
[52] See, for instance, CEN Annual Report [2020], 16; CENELEC, Annual Report [2020], 17. Both documents are available at https://www.cencenelec.eu. See also Mariolina Eliantonio and Annalisa Volpato, *Legal opinion on the European system of harmonised standards*, 2021, 35, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4055292 .
[53] See e.g., various contributions in Marta Cantero Gamito and Hans-W. Micklitz (eds.), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar, 2020).

and re-introducing international standards in the form of European standards allows for both influence and compliance. Factors such as Brexit, where the cooperation with close trading partners has changed from an EU to public international law framework, has actually enhanced the necessity for that approach.

Until today, the New Approach directives apply to a wide range of products and safety hazards.[54] Under the New Approach, products can be placed on the market or put into service where they comply with the 'essential requirements', usually set out in an annex to the directives.[55] Essential requirements cover public interest concerns[56] and may deal with certain product hazards, focus on the product as such and its performance, or set out the main protection objective.[57] Generally, 'essential requirements define the results to be attained or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so.'[58] This reduces the need for legislative adaptation to ongoing technical progress but also leaves considerable discretion in the hands of the ESOs in the adoption of standards meeting the essential requirements. The function of essential requirements is, therefore, to allow the assessment of conformity with those requirements without harmonised standards if a reference to the standards is published in the Official Journal and transposed into national standards.[59]

Importantly, the EU's approach is that compliance with these harmonised standards is voluntary. Manufacturers and service providers are free to develop their technical solutions. Nonetheless, harmonised standards constitute *de facto* binding rules since the economic incentive to comply with the standards that ensure product marketability is very powerful. The CJEU has consistently emphasised that the obligation of the Member States to respect the presumption of conformity of products produced in accordance with harmonised standards can be rebutted only through the initiation of the safeguard procedure by the competent national

[54] Where a product is not covered by specific Community legislation, including 'New Approach' directives, or where not all hazards are covered by such legislation, it falls within the scope of Directive 2001/95/EC of the European Parliament and of the Council on general product safety [2002] OJ L 11/4.
[55] See Article 1 of Decision 768/2008/EC above n. 53.
[56] Ibid, Article 3(1).
[57] See European Commission: the Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, 4.1.
[58] European Commission: the Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, 4.1. See also Article 3(1) of Decision 768/2008/EC above n. 53. However, Article 3(1)(2) of the Decision makes it clear that Community harmonisation legislation may set out detailed specifications, where recourse to essential requirements is not possible or appropriate; see also Articles 3 and 4 of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety above n. 56.
[59] See e.g., Article 7(2) and (3) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) [2006] OJ L 157/24.

authority.[60] The facts underlying cases such as *Fra.bo* provide illustrations of this.[61] Developing alternative approaches is generally time and cost-intensive and thus might prove unattractive. By creating incentives for compliance with standards, standardisation activity plays an important role in realising an internal market for goods and services and may even be regarded as operating as an essential complement of, or even as a substitute for, Union legislation on the health and safety of products.[62]

An alternative 'entry point' for standards other than incorporation in harmonised standards which, in turn, profit from the presumption of conformity under the New Approach, is through references made to standards by means of contracts setting the applicable law between the parties. A good example for this scenario and its treatment by the CJEU arises from the facts underlying *James Elliot*.[63] This case resulted from the question of the legal nature and value of standards set by European standardisation organisations.

The *James Elliot* case concerned a private law dispute about the quality of materials provided in the context of a building project (i.e., whether the building materials complied with a CEN standard incorporated into EU law by Article 4(2) of Directive 89/106).[64] Under the EU's approach to product safety, a product's compliance with the technical requirements defined by such a standard allows the presumption that the product satisfies the essential safety and quality requirements and such product is then authorised to circulate, to be placed on the market and to be used freely within the EU. The result is that Member States may not impose additional requirements on such products for their effective use on the market and use within the territory,[65] and while '…evidence of compliance of a construction product with the essential requirements contained in Directive 89/106 may be provided by means other than

[60] See Case 815/79, *Criminal proceedings against Gaetano Cremonini and Maria Luisa Vrankovich*, ECLI:EU:C:1980:273, para. 10; Case C-112/97, *Commission of the European Communities v Italian Republic*, ECLI:EU:C:1999:168, para. 39; Case C-100/00, *Commission of the European Communities v Italian Republic*, ECLI:EU:C:2001:211, paras. 3 and 7; Case C-6/05, *Medipac-Kazantzidis AE v Venizeleio-Pananeio (PE.S.Y. KRITIS)*, ECLI:EU:C:2007:337, paras. 42 and 49. The presumption of conformity also applies in tendering procedures which are subject to Community public procurement rules, see Case C-6/05, *Medipac-Kazantzidis AE v Venizeleio-Pananeio (PE.S.Y. KRITIS)*, ECLI:EU:C:2007:337, para. 50; Case C-489/06, *Commission of the European Communities v Hellenic Republic*, ECLI:EU:C:2009:165, para. 43.

[61] C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas- und Wasserfaches eV (DVGW)*, ECLI:EU:C:2012:453, paras. 30, 31.

[62] See Michelle P. Egan, *Constructing a European Market* (Oxford University Press, 2001); Harm Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* (Hart Publishing, 2005).

[63] Case C-613/14, *James Elliott Construction Limited v Irish Asphalt Limited*, ECLI:EU:C:2016:821.

[64] Ibid.

[65] Ibid, para. 41 with reference to C-100/13, *European Commission v Federal Republic of Germany*, ECLI:EU:C:2014:2293, paras. 55, 56 and 63.

proof of compliance with harmonised standards, that cannot call into question the existence of the legal effects of a harmonised standard.'[66]

However, at the time of the James Elliot case, these legal effects of standards were subject to prior publication of a reference to the standards by the Commission in the 'C' series of the Official Journal (OJ). As a consequence, according to the CJEU, an act by a Union body, the Commission in this case, consisting of publishing a reference to a standard in the OJ had to be considered as an essential procedural requirement for the binding effect of a standard created by a private body such as CEN.[67] The procedures leading up to the creation of standards and their publication are equally detailed in EU law.

In the aftermath of the *James Elliott* ruling, the Commission has changed the practice of publishing references to standards in the OJ's L-series as Commission's Implementing Decisions, which would indicate the Commission advocating an understanding of a more binding nature of harmonised standards after the Court had held that 'it may be inferred from the case-law of the Court that a harmonised standard, drawn up by an organisation governed by private law, may be considered to be part of the EU legal order when that standard was conceived, managed and monitored by the Commission and when it produces binding legal effects following publication of its references in the *Official Journal of the European Union*'.[68]

Despite harmonised standards becoming generally applicable by means of references to them in the OJ, arguments have been forwarded, denying accessibility to these standards due to the protection of intellectual property rights.[69] This position stands in contradiction with the fundamental requirement – under a system based on the rule of law – that legal norms be made accessible to citizens obliged to comply with them. In *Stichting Rookpreventie,*[70] the CJEU accepted that 'the principle of legal certainty requires that the reference to such standards be clear and precise and predictable in its effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law.'[71] In *Public Resource,* it more fully turned towards a position required by a system under the rule of law. There, it held

[66] Case C-613/14, *James Elliot Construction v Irish Asphalt*, above n. 65, para. 42.
[67] Ibid, paras. 43-45.
[68] C-185/17, *Mitnitsa Varna v "SAKSA" OOD*, ECLI:EU:C:2018:108, para. 39 with reference to Case C-613/14, *James Elliot Construction v Irish Asphalt*, above n. 65, paras. 40, 43-44.
[69] See the discussions reflected in Advocate General Saugmandsgaard Øe, Opinion C-160/20 of 15 July 2021 [2021] ECLI:EU:C:2021:618, although establishing the importance of access in paras. 25, 26 and 69-71 finding that paywalls for access may be justified (paras. 89-91); Accepted also in: T-185/19, *Public.Resource.Org, Inc. and Right to Know CLG v European Commission*, ECLI:EU:T:2021:445, para. 72.
[70] C-160/20, *Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport*, ECLI:EU:C:2022:101, paras. 40-52.
[71] Ibid, para. 45; C-482/17, *Czech Republic v European Parliament and Council of the European Union*, ECLI:EU:C:2019:1035, para. 148 with further references.

that an overriding public interest existed "arising from the principles of the rule of law, transparency, openness and good governance" where "standards form part of EU law owing to their legal effects."[72]

The CJEU has also held that standards established in this way and published can be enforced by the Commission through infringement actions provided for in Article 258 TFEU.[73] The CJEU has considered that a Member State may not impose 'additional requirements', for example, on construction products themselves, which are covered by several harmonised standards for effective market access.

Harmonised standards have, in the past, not in themselves been understood as reviewable acts of the Union and thus subject to an action for annulment under Article 263 TFEU.[74] Therefore, the challenge of a standard as an act of an EU institution or body remains controversial.[75] However, an important avenue for the judicial review of harmonised standards is the preliminary reference procedure under Art 267 TFEU.[76] Review of such standards can be undertaken in the context of compliance with the obligations arising from the Standardisation Regulation.[77] That Regulation sets out basic principles for the adoption of standardisation procedures by the ESOs requiring, for example, the establishment and publication of work programmes (Articles 3 and 8), rules on participation of stakeholders and national bodies (Articles 5 and 7), transparency and accessibility (Articles 4 and 6), as well as the process of formal standardisation requests (Article 10). Although private organisations, the ESOs are financed by public funds and exercise when acting in the context of formal

[72] C-588/21 P, *Public.Resource.Org and Right to Know v Commission and Others*, ECLI:EU:C:2024:201, para 89. Overriding the General Court, the CJEU clarified that an overriding public interest in access to documents held by EU institutions (in view of Article 4(2) with respect to the intellectual property defense in Article 4(2) of regulation 1049/2001. The Court recalls the relevance of the matter by referring to the constitutional nature of the question (in para 83) that "the principle of transparency is inextricably linked to the principle of openness, which is enshrined in the second paragraph of Article 1 and Article 10(3) TEU, in Article 15(1) and Article 298(1) TFEU and in Article 42 of the Charter."

[73] C-100/13, *European Commission v Federal Republic of Germany*, above n. 67.

[74] See e.g. T-264/03, *Jürgen Schmoldt and Others v Commission of the European Communities*, ECLI:EU:T:2004:157, paras. 108-125.

[75] See e.g. Carlo Tovo, 'Judicial Review of Harmonsied Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55(4) *Common Market Law Review*, 1187; Mariolina Eliantonio, 'Judicial Control of the EU Harmonised Standards: Entering a Black Hole?' (2017) 44(4) *Legal Issues of Economic Integration*, 395, 399.

[76] Case C-613/14, *James Elliot Construction v Irish Asphalt*, above n. 65, paras. 34-36, 41.

[77] 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 (the Standardisation Regulation) [2012] OJ L 316/12; a consolidated version with changes was published in 2015: http://data.europa.eu/eli/reg/2012/1025/2015-10-07.

standardisation requests and public functions. Their action should arguably also be held to comply with general principles of EU administrative law, such as the principles of good administration and the duty of care.[78] An additional review can be carried out incidentally as to whether the standards comply with the mandate – i.e., the health and safety requirements contained in the underlying legislation – even though such a review must necessarily respect the technical discretion of the ESOs as main decision-making bodies.

The process of authorising ESOs to develop harmonised standards and the procedure followed to produce them are well-organised and transparent in comparison to some standard-setting processes applied in international organisations. Gaps remain from a potential lack of oversight over participation and representativeness. Procedurally, the influence of national standardisation institutes has grown in tandem with the evolution of European standards since only the national bodies have a vote and the right to negotiate in the preparation and adoption of European standards. Stakeholders such as manufacturers, applicants, consumers, certification bodies, scientists, authorities, and environmental associations have no voting rights in the European standardisation process.[79] Their avenue for participation is through national standardisation organisations in so-called 'mirror committees'.[80]

These gaps in oversight might have to be addressed in line with delegation principles in EU law, especially those developed concerning delegation to private parties in the seminal *Meroni* case.[81] ESOs standardisation appears aligned with criteria summarised in *Meroni*.[82] Applying, by analogy, the limitations to the delegation of powers to private parties established in that case suggests that entrusting functions to ESOs is possible only if the powers received are the result of an express delegation and are of a clearly defined executive nature. Moreover,

[78] See e.g., Mariolina Eliantonio, 'Private Actors, Public Authorities and the Relevance of Public Law in the Process of European Standardisation' (2018) 24(3) *European Public Law*, 473, 480; Herwig C. H. Hofmann, 'The Duty of Care in EU Public Law – A Principle Between Discretion and Proportionality' (2020) 13(2) *Review of European Administrative Law*, 87.

[79] They do however have an observer role as laid down in Article 5 of the Standardisation Regulation, above n. 78.

[80] Josef Falke, 'Standardisation by professional organisations', in Gerd Winter (ed.), *Sources and Categories of European Union Law,* (Nomos, 1996), 656. Under Article 5(1) of the Standardisation Regulation, above n. 78: European standardisation organisations shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities. They shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations receiving Union financing in accordance with this Regulation at the policy development level and at the following stages of the development of European standards or European standardisation deliverables.

[81] Cases C-9 and C-10/56, *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community*, ECLI:EU:C:1958:7.

[82] Ibid.

the exercise of such powers must be subject to strict supervision and the same obligations that the delegating authority would have had to observe had it adopted the measures itself.

Criteria of legality, however, require adaptation to different levels of standards. For example, even in the world of ESO standards, there are various levels of formality and recognition. Recital 31 of the Standardisation Regulation establishes a distinction between those standards established by the ESOs in the 'ordinary' EU standardisation procedure under the regulation and other technical specifications, which 'do not hold an equivalent status to European standards' where these 'are not developed in accordance with the founding principles.' This refers to the further distinction between ESO activity in the context of a formal Commission standardisation mandate and other activities of ESOs establishing technical specifications that are also useful as standards but beyond the conferral of public powers on the ESOs in a strict sense.

All in all, therefore, one of the central differences between the reference to global standards in EU legislation, on the one hand, and the European standardisation approach(es) is essentially one of the procedures and safeguards in the production of standards. The relatively privileged position of European standardisation over global standards can mainly be defended by the possibility of control of EU legislation over the criteria of legitimacy and ensuring representativity and inclusion of knowledge in decision-making.[83] That said, however, there is not a great deal of difference between the approach to referring to global standards rather than European standards in EU legislation and the judicial review of acts based on such legislation and its interpretation, as the following part of this chapter will show.

### 4.2 The integration of standards by decision-making practices of EU institutions and bodies and the role of the duty of care

Standards expressing good practice or summarising certain expertise play a role in the judicial review of EU decision-making by the CJEU. One of the fundamental roles of standards is that they can 'crystallise' best practice and current knowledge on a topic. Amongst the most important approaches is the obligation to take the standards into account in the EU legal order, especially under the obligations arising from the 'duty of care'[84] – a central principle in the review of discretionary decision-making.

[83] See e.g., the discussion in this book on limited participation in global standard-setting activities.
[84] Herwig C. H. Hofmann, 'The Duty of Care in EU Public Law – A Principle Between Discretion and Proportionality' (2020) 13(2) *Review of European Administrative Law*, 87.

Under the now famous *TU München* formula, the CJEU must review whether an administration has examined and scrutinised, carefully and impartially,[85] all the relevant aspects of a case 'in order to make a finding in full knowledge of all the facts relevant at the time of adoption'.[86] This requires not only quantitively that all relevant information be taken into account prior to decision-making, but also qualitatively that an administration take recourse to expertise where such is not existent in-house.[87] The obligation to seek expertise was further spelt out in *TU München*, and has been reconfirmed in subsequent case law.[88]

Under this case law, even in the absence of a statutory requirement, the duty of care obliges a decision-maker to consult external scientific expertise where sufficient knowledge is not available in-house, and where such knowledge proves necessary for the collection of all necessary information.[89] In risk regulation matters, the CJEU quite broadly states that, under the duty of care, 'the Commission is, as a rule, obliged to take account, in its decisions in the field of the environment, of all new scientific and technical data'.[90] This implies that the institutions 'ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research',[91] a consistency obligation the General Court explicitly links to compliance with the rule of law.[92] Complying with these obligations may, especially, require taking into account standards set by international expert bodies or by private bodies in the field.

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[85] Case C-269/90, *Technische Universität München v Hauptzollamt München-Mitte*, ECLI:EU:C:1991:438 and Case C-16/90, *Detlef Nölle, trading as "Eugen Nölle" v Hauptzollamt Bremen-Freihafen*, ECLI:EU:C:1991:402, para. 29.

[86] Case C-367/95 P, *Commission of the European Communities v Chambre syndicale nationale des entreprises de transport de fonds et valeurs (Sytraval) and Brink's France SARL,* ECLI:EU:C:1998:154, paras. 60, 62.

[87] For instance, in the seminal *Netherlands v High Authority* case (C-6/54, Kingdom of the Netherlands v High Authority of the European Coal and Steel Community, ECLI:EU:C:1955:5), the CJEU had addressed the need to conduct studies, *inter alia* about pricing in certain markets prior to taking a decision as to maximum prices in the steel industry.

[88] See e.g., Joined Cases C-439/05 P and C-454/05 P, *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, ECLI:EU:C:2007:510, para. 32.

[89] Case C-269/90, *Technische Universität München v Hauptzollamt München-Mitte*, ECLI:EU:C:1991:438; Case C-212/91, *Angelopharm GmbH v Freie Hansestadt Hamburg*, ECLI:EU:C:1994:21 and Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, paras. 56 and 57.

[90] Case C-405/07 P, *Kingdom of the Netherlands v Commission of the European Communities*, ECLI:EU:C:2008:613, paras. 56 and 61.

[91] Case T-326/99, *Nancy Fern Olivieri v Commission of the European Communities and European Agency for the Evaluation of Medicinal Products*, ECLI:EU:T:2003:351, para. 68; Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para. 158 and Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, para. 171. This approach is in compliance with Article 114 TFEU (Art 95(3) EC), which obliges the European Commission, in the case of legislative proposals in these matters, to take into 'account in particular any new development based on scientific facts'.

[92] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para. 172 and Case T-70/99, *Alpharma Inc. v Council of the European Union*, ECLI:EU:T:2002:210, para. 183.

The duty of care approach and this assessment of the consistency of decisions with international standards is also applicable where EU institutions, such as the Commission, make reference in their decisions to international standards or when an EU body reviews Member State decision-making taking into account international standards for the limitations of fundamental freedoms. A good example for that approach is the discussion of the use of OECD model tax in fields of fiscal state aid as exemplified by the Irish *Apple* case.[93] There, the Commission had made reference in its decision qualifying a certain Irish approach to calculating the tax burden of Apple to Article 7(2) and Article 9 of the 'OECD Model Tax Convention' as well as 'the guidance provided by the OECD on profit allocation or transfer pricing'.[94] The General Court explicitly clarifies that such guidance is 'non-binding', but that it 'nonetheless constituted useful guidance on how to ensure that transfer pricing and profit allocation arrangements produce outcomes in line with market conditions'[95] in Irish tax law as well as for the Commission when reviewing the Irish provisions in the light of compliance with EU State aid rules. Following on from this, the General Court used the OECD guidelines as criteria of consistency, within its assessment of the compliance with the duty of care, in the review of the Commission's decision towards Ireland concerning Apple's tax arrangements. This analysis is undertaken in the context of the duty of care in decision-making according to which an administration (thus also the EU institutions) needs not only to fully and impartially assess all relevant elements of a file prior to decision-making, but must also demonstrate that the conclusions drawn are actually capable of being supported by the factual analysis.[96]

The General Court then noted that 'even though the Commission was entitled to observe that it cannot be formally bound by the principles developed within the OECD', when it relies 'in its primary line of reasoning' and 'refers directly to the Authorised OECD Approach when substantiating its considerations',[97] these references are 'certainly of practical significance

[93] Cases T-778/16 and T-892/16, *Ireland v European Commission (Apple State Aid)*, ECLI:EU:T:2020:338. At the time of writing this case is under appeal as C-465/20 P.
[94] OECD, Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, adopted by the Committee on Fiscal Affairs of the OECD on 27 June 1995 and revised on 22 July 2010 ('the OECD Transfer Pricing Guidelines'). The General Court notes that in that regard, it should be noted that the Authorised OECD Approach is an approach that is based on work carried out by groups of experts and which reflects international consensus regarding profit allocation to permanent establishments. Cases T-778/16 and T-892/16 *Ireland v European Commission (Apple State Aid)* ECLI:EU:T:2020:338, para. 237.
[95] Cases T-778/16 and T-892/16, *Apple State Aid*, above n. 95.
[96] Further discussion of the principle, see e.g., Herwig CH Hofmann, 'The Duty of Care in EU Public Law – A Principle Between Discretion and Proportionality' (2020) 13(2) *Review of European Administrative Law*, 87.
[97] Cases T-778/16 and T-892/16 *Apple State Aid*, above n. 95, para. 236.

when interpreting questions relating to that profit allocation.'[98] Clarification of the approach can be found in Advocate General Kokott's statement that standards such as the

> 'OECD Model Tax Conventions are not legally binding, multilateral conventions under international law; they are simply the unilateral acts of an international organisation in the form of recommendations to its member countries. A fortiori, therefore, the commentaries on the OECD Model Tax Convention are not legally binding on the Court.'[99]

It follows that mere non-compliance by a Member State with the OECD guidelines cannot *per se* be seen as a violation of standard procedures which would lead to the classification of a tax policy granting an individual advantage as a State aid.[100] This same approach also governs other General Court's tax state aid cases.[101] There the General Court reviews the consistency and logic of the Commission's decision with the help of the OECD tax guidelines.[102]

As a result, the referencing of standards such as OECD tax guidelines by the Commission can be used to analyse the consistency of EU acts and their inner logic. Where EU law or Member States' law is in line with them, the considerations expressed therein may be useful as illustrations of legislative intent or good practice in their interpretation. It must be possible to draw conclusions from the application of guidelines when the latter are used as an argument. The latter is in line with the requirements mandated by the duty of care – in particular the need for a full and impartial assessment of all relevant facts – in the context of a review of discretionary powers. In short, the Irish *Apple* case illustrates the possibility that standards are

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[98] Ibid, para. 237.

[99] Advocate General Kokott, Opinion C-437/19 of 3 June 2021 [2021] ECLI:EU:C:2021:450, para. 67 with references to her Opinions in : C-115/16, *N Luxembourg 1 and Others v Skatteministeriet*, ECLI:EU:C:2018:143, para. 50 et seq.; C-116/16, *Skatteministeriet v T Danmark*, ECLI:EU:C:2018:144, para. 81 et seq.; C-117/16, *Skatteministeriet v Y Danmark Aps*, ECLI:EUU:C:2018:145, para 81 et seq.; C-118/16, *X Danmark A/S v Skatteministeriet*, ECLI:EU:C:2018:146, para. 50 et seq.; C-119/16, *C Danmark I v Skatteministeriet*, ECLI:EU:C:2018:147, para. 50 et seq.; C-299/16, *Z Danmark v Skatteministeriet*, ECLI:EUU:C:2018:148, para. 50 et seq.

[100] Cases T-778/16 and T-892/16, *Ireland v European Commission (Apple State Aid)*, ECLI:EU:T:2020:338, para. 319.

[101] See e.g., Cases T-816/17 and T-318/18, *Grand-Duché de Luxembourg v European Commission*, ECLI:EU:T:2021:252.

[102] Ibid, para. 202 : 'In addition, it should be noted that, according to paragraph 1.22 of the OECD Guidelines, it may be 'relevant and useful in identifying and comparing the functions performed to consider the assets that are employed or to be employed' and that 'this analysis should consider the type of assets used, such as plant and equipment, the use of valuable intangibles, etc., and the nature of the assets used, such as the age, market value, location, property right protections available, etc.'. In other words, it is recommended that account be taken of the fact that a company makes assets available in the context of the controlled transaction for the purpose of examining the functions carried out. It therefore follows that, contrary to the Commission's assertions, the making available of intangible assets had to be taken into account for the purpose of examining the functions performed or assumed by a party to an intra-group transaction, without any distinction between 'active' and 'passive' functions being relevant'.

not binding on the EU nor incorporated into the EU legal system, but still need to be taken into account in the assessment of the legality of EU and Member State actions.

### 4.3 Liability of the Union

Liability of Union bodies for the use or abuse of international standards incorporated into EU law appears still a rather open question. Few cases have been litigated, but it does not seem impossible for liability cases to be used to establish the relevance of standards as a yardstick for the actions of EU institutions or Member State bodies. One area where international standards have been used to ground the Union's liability is the field of the intergovernmental arrangements for financial assistance of Member States following the 2008 financial crises. However, possibly due to the specificities of the matter, the CJEU has been very cautious.

For example, in the Grand Chamber judgement in *Chrysostomides*, the CJEU held that, in the respect of standards established for the adoption of MoUs with Member States in the context of disbursement of economic crises support measures, neither the European Stability Mechanism (ESM) nor the Eurogroup are to be considered as EU institutions, bodies, offices or agencies subject to liability under Article 340(2) TFEU in the context of standards it had established for the adoption of MoUs with Member States in relation to the disbursement of economic crises support measures. The MoUs were adopted under guidelines of the ESM and the Eurogroup, but concluded between EU institutions and the Member States.[103] In other words, despite the guidelines of intergovernmental organisations having an indirect effect on the conduct of EU bodies, the EU bodies are not liable for consequences resulting from the application thereof. Whether this is a specific case arising from the very complex institutional and organisational arrangements in the area of the Economic and Monetary Union (EMU) and the various financial arrangements linked to this, remains to be seen with the developing case law of the CJEU.

## 5. Concluding remarks: the legitimacy of the integration of global standards into the EU as 'regulatory Union'

Standards facilitate the achievement of an internal market through regulation by bodies with both expertise in and familiarity with specific matters. Beyond cases of references being made

[103] Joined Cases C-597/18 P, C-598/18 P, C-603/18 P and C-604/18 P, *Council of the European Union v Dr. K. Chrysostomides & Co. LLC and Others,* ECLI:EU:C:2020:1028, para. 131, with reference to Joined Cases C-8/15 P to C-10/15 P, *Ledra Advertising Ltd and Others v European Commission and European Central Bank (ECB),* ECLI:EU:C:2016:701, para. 53.

to standards of a diverse nature in EU legislation and of global standards being incorporated into European harmonised standards under the New Approach, EU bodies are obliged to take into account best practice and scientific knowledge as expressed in standards of varying nature under the general principle of the duty of care. Standards can also be used in private contractual relations under EU law, and their violation can be the basis of claims of non-contractual liability by the Union or Member States.

Standards thus have diverse origin but potentially far-reaching effects in determining the decision-making outcome. Although they might protect against arbitrariness of decision-making and serve as a criterion for the review of discretionary powers through their role under the duty of care, standards may also raise concerns about the accountability of their creators. Depending on the nature and origin, very different groups and interests have access to them.[104] For example, although European standard-setting by CEN, CENELEC and ETSI requires a mandate from the Commission, standards do not always merely require technical translations of a specific political mandate by the Commission. Their creation may require – next to the assessment of risks – also to undertake political judgments concerning the margins of risk-tolerance and approaches to risk management.[105] This places them squarely in the difficult territory of delegation doctrines within the EU, as evidenced by the above discussion of the relevant EU principles summarised in the *Meroni* ruling. Depending on the reader's point of view this also shows the difficulties of drawing the distinctions suggested by *Meroni* and subsequent case law, attempting to differentiate between technical/administrative matters and political decision-making.

Standard-setting shows the type of issues that might give reason for concerns also in terms of the public/private distinction in rule-making. Where the Union institutions retreat and leave it to private and semi-private bodies to fill a legal void, the procedural legitimacy of such standard-setting procedures becomes an issue of public interest. This might be all the more relevant in the case of standards created not within the EU, under known but imperfect procedures, but in international bodies or organisations as well as ad-hoc regulatory bodies.[106] How to enforce transparency and participation standards or ensure that all relevant actors are

[104] The EU is of course not alone in its tendency to delegate standardisation to private or semi-private bodies. Such practices have long predated the EU/EC on the national level (see for an overview the introduction on the International Standardisation Organisation's website www.iso.org). References to standards set in this way also exist in the realm of international economic law, e.g., in various provisions of the WTO's SPS and TBT agreements.

[105] Harm Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets,* (Hart Publishing, 2005), 256.

[106] See further discussion e.g., Herwig C.H. Hofmann, 'Dealing with Trans-Territorial Executive Rule-Making' (2013) 78(2) *Missouri Law Review*, 423.

present is not evident in these processes. In view of international obligations to take standards into account within the TBT and the SPS agreements, for example, or in view of dynamic references to such international legal obligations in EU legislation, such questions arise all the more forcefully.[107]

Where EU law incorporates standards and where standards are taken into account by EU institutions, offices, bodies and agencies under the duty of care, legal requirements arising from limits to delegation of powers must be complied with. Limits to delegation are set out and must be possibly used by analogy, in Article 290 TFEU. This requires that a Union legislative act determine at a minimum the content, scope and duration of a delegation and address all essential elements of a policy. Where matters concern the exercise of fundamental rights, Article 52(1) CFR requires that any limitation on the exercise of the rights and freedoms to 'be provided for by law' and be defined therein.[108] In other words, 'law' limiting rights must contain 'pre-established models and criteria'.[109] Putting these requirements together, this requires that 'law' under Article 52(1) CFR, arguably, is legal code derived from pre-defined decision-making procedures recognised in EU law, such as those established in conformity with legislative procedures. In EU law, this comes in the forms recognised under Article 288 TFEU. Any limitations of fundamental rights which might result from the application of standards must therefore be pre-determined by what is recognisable as law under Article 52(1) CFR.

The notion of 'law' is conceptually linked to its accessibility.[110] In order for a norm to impose obligations or to be held against an individual, those individuals must be able to discern from freely available and officially published texts which limitations to their rights and freedoms they might be asked to endure. In this sense, it may be highly problematic that not all standards having effect in EU law are publicly accessible.[111]

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[107] Günther Teubner, 'Substantive and Reflexive Elements in Modern Law' (1983) 17(2) *Law & Society Review*, 239, 275.

[108] The notion of a limitation of a fundamental right is broad. It pertains to limitations of the exercise of rights due to public policy concerns but also due to balancing of various rights. It also pertains to rights and freedoms protected as general principles of EU law, to which, under the CJEU's ERT case law, the same criteria of limitation arise as to fundamental rights. In that sense, see Case C-260/89, *Elliniki Radiophonia Tiléorassi AE and Panellinia Omospondia Syllogon Prossopikou v Dimotiki Etairia Pliroforissis and Sotirios Kouvelas and Nicolaos Avdellas and others*, ECLI:EU:C:1991:254, para. 45.

[109] Opinion 1/15 of the Court (*EU-Canada PNR Agreement*) of 26 July 2017, ECLI:EU:C:2017:592, para. 172.

[110] Case C-345/06, *Gottfried Heinrich*, ECLI:EU:C:2009:140, paras. 41-47 and 64-66.

[111] See, however, now the case C-588/21 P, *Public.Resource.Org and Right to Know v Commission and Others*, ECLI:EU:C:2024:201, paras 68-84.

In fact, to a degree more worrying is that some standards applied had not even been written at the time of their application as illustrated by the Irish *Apple* case,[112] where the Commission had been accused of applying OECD tax guidelines retroactively to assess whether Ireland had granted state aid in the form of allowing specific calculations of profit and loss before the OECD itself had formulated the OCED tax guidelines.

Beyond accessibility, another relevant criterion is 'clarity'. For example, in a case on the use of foreign standards, the CJEU held, with respect to Canadian norms contained in border control for the processing of air-passenger data for passengers arriving from the EU, that

> 'the requirement that any limitation on the exercise of fundamental rights must be provided for by law implies that the legal basis which permits the interference with those rights must itself define the scope of the limitation on the exercise of the right concerned.[…] In order to satisfy that requirement, the legislation in question which entails the interference must lay down clear and precise rules governing the scope and application of the measure in question and imposing minimum safeguards…'[113]

The CJEU thus requests that 'pre-established models and criteria (…) should be specific and reliable.'[114] Arguably, it falls to the Union legislator to frame the relationship between the Union interest and the participation of private actors, and to the Commission to supervise this relationship – irrespective of whether the standards applied belong to a foreign country or whether the idea is to apply standards arising from an international organisation within the single market.

Another criteria for the legitimacy of standards could relate to the decision-making process within standard-setting bodies, in terms of providing for an adequate representation of the parties concerned and mechanisms to ensure a balanced process of bargaining or deliberation.[115] An old ruling of the General Court putting effectively to rest the generalisation of agreements in the context of labour law comes to mind here. In *UEAPME*, the General Court had offered an explanation for the legitimacy of the privileged position for standard-setting by social partners in the Union's law-making process. It held that 'the principle of democracy on which the Union is founded requires – in the absence of the participation of the European Parliament in the legislative process – that the participation of the people be otherwise assured,

[112] See Cases T-778/16 and T-892/16, *Apple State Aid)* above n. 95 (case under appeal at the time of writing in Case C-465/20P); see also C-160/20, *Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport*, above n. 72, paras. 45 to 51.
[113] Opinion 1/15 of the Court, above n. 110, paras. 139-141.
[114] Ibid, para. 172.
[115] See Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy' (2007) 32 *European Law Review*, 443, 465, who considers this as prerequisites for 'substantive autonomy'.

in this instance through the parties representative of management and labour who concluded the agreements which is endowed by the Council…with a legislative foundation at Community level.'[116] On this basis, the Court imposed on the Commission and the Council the duty to ascertain that the rule-makers were sufficiently representative. Similar requirements could be imaginable for the review of recognition of standards entering the EU law, undertaken in the context of a judicial review of standards or in the context of the ESO's standard-setting under the New Approach.

The disquiet as to the legitimacy of standards arising from outside EU decision-making structures is not necessarily shared by the Court, as the use of OECD guidelines show. However, that might be a specific situation. The *Meroni* principles could be read as suggesting that entrusting quasi rule-making functions to standardisation bodies of various kinds is possible only if the powers received are the result of an express delegation and are of a clearly defined executive nature. Moreover, the exercise of such powers must be subject to strict review and to the same obligations which the delegating authority would have had to observe had it adopted the measures itself. This is especially so where they are not merely technical norms, but have a political content in shaping risk and resource allocation. Here, the *Meroni* principles are a reminder that the Union institutions cannot abdicate their political responsibility for the supervision of standards applied in the EU legal system and for the procedural conditions of their creation.

[116] Case T-135/96, *Union Européenne de l'artisanat et des petites et moyennes entreprises (UEAPME) v Council of the European Union*, ECLI:EU:T:1998:128, para. 89.