Herwig C.H. Hofmann*

Global Standards in the 'European regulatory Union'

Presentation on 18 June 2021

This chapter addresses the role within EU law of standards set by bodies outside of the institutional architecture of the EU.[1] It addresses the interactions and the integration into

* Professor of European and Transnational Public Law, Head of the Department of Law, Robert Schuman Initiative, University of Luxembourg.

[1] Annex 1.2. of the WTO Agreement on Technical Barriers to Trade (TBT) of April 15, 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

decision making procedures in the scope of EU law of standards. Within the EU the use of such standards is closely linked with the project of creating an internal market requiring not only deconstructing of regulatory barriers, i.e. de-regulation, but also considerable re-regulation in order to ensure a joint regulatory standards. Standards, their source and their use as well as their legality are a complex issue in EU law. They stem from multiple sources and are included in the EU legal system in diverse ways requiring also specifically adapted means of judicial review of decision making with standards. The objective of using standards is to ensure highest levels of understanding in terms of scientific findings and good practices. Including standards enables markets to function, to ensure high level regulation thereof in view of citizens' regulatory expectations. Also the use of standards can contribute to compatibility of EU policies with goals of enhancing external trade.[2] In the context of a great diversity of standards also arising from EU and non-EU sources, this paper studies their integration into the EU legal system through the case law of the CJEU. It looks at answers given by the CJEU to challenges regarding their nature and legitimacy, especially in view of the regulatory choices promoted by specific standards. The paper also reviews whether criteria and conditions of delegation of powers in EU law have been used to assess the use of external standards in decision making.

I. The various functions of standards in the EU law

By its very nature of being an autonomous but atypical and permanently developing legal system, sources of EU law including standards adopted by non-EU actors such as international bodies, intergovernmental bodies or private and semi-private actors. The EU not only integrates into its system standards coming from outside its legal system, amongst its strengths has been to use its experience of deconstructing barriers to internal trade also to promote European standards internationally.[3] The great diversity of standards applied and the different nature of their integration into EU decision making procedures however

production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

[2] 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, Abingdon: 2009), 416-425, at p. 416.

[3] Anu Bradford, *The Brussels Effect* (Oxford University Press, Oxford: 2020) 67-98.

complicates the understanding of their effect in EU law. The potential integration of standards into the canon of sources of law within the EU raises many questions regarding their possibility to normatively shape real-life situations, having direct or indirect effects in the EU legal system as well as the conditions – procedural and substantive – for such recognition in EU law. Questions remain especially due to the fact that standards escape the canon of legal acts outlined in the TFEU, especially its Article 288. The plethora of organisations and procedural conditions within which the diverse types of standards arise, makes for a complex environment for understanding the legitimacy of such law.

The issue is not only a legal one. Politically speaking, questions arise as to who assesses the criteria of acceptable risk in society and according to which norms. Another political aspect is the aspect of external influence of the EU by 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 is part of the EU's drive towards a rule-based international legal order. The European approach to joint rule-making by standards is often re-created on the international level through standard setting as a means of soft-law based harmonsiation of trading conditions and approximation of rules globally. Such integration by participation of EU bodies into global standard setting networks ensures not only compatibility of approaches but also, to a certain degree helps settling disputes between EU Member States by reference to 'neutral' international standards, despite difficulties with various compositions and settings.[4] Yet, the question of who's interests are taken into account in creation of standards remains more pertinent than ever.

Setting standardisation goals and choosing which ones to allow for application in the EU and the means to achieve them is thus highly political - not only in the general sense that any administrative action that can go wrong, can become an issue for political oversight over administrative action and political responsibility for action. Yet, standards are not always the result of well-established regulatory procedures, they can also arise from expertise forming best practices or semi-private standardisation bodies. This has an effect also on barriers between public and private regulatory activity and with it the criteria for

[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, *The External Dimension of EU Agencies and Bodies* (Elgar Publishing, Chelthenham: 2019) 126-144.

legitimacy of normative pronouncements by way of standards and thus a specific challenge to the integration of standards within the EU's constitutional framework and the reality of accompanying standard integration into the EU legal system by a host of co-regulatory and incentive-based approaches.

II. Multiple sources of standards

Standards applicable within the EU legal system are not only set by national and European standard setting bodies, the EU's regulatory regime also relies on a great diversity of 'externally' produced standards.[5] On the spectrum of standards not directly produced by EU institutions are those arising from intergovernmental arrangements and cooperation (e.g. the Eurogroup Working Party discussed below) but also those arising from international organisations (such as the WHO, the ILO or others) as well as arising from private or semi-private standardisation bodies on the international (e.g. ISO), the European (e.g. CEN, CENELEC, ETSI) or the national levels (e.g. DIN). Standards may further arise from informal cooperation (e.g. the Basel Committee) or private research associations publishing their findings.

WTO law establishes certain minimum requirements for the establishment, withdrawal, or amendment of standards relating to goods have to comply with requirements under international economic law. Especially the World Trade Organisation's (WTO) agreements on product-related rules under the TBT (Agreement on Technical Barriers to Trade) as well as, more specifically, in the area of food and feed related matters under the SPS (Agreement on the Application of Sanitary and Phytosanitary Measures) contain such provisions. 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 more trade-restrictive than necessary to fulfil a legitimate objective.[6] International standardisation bodies are numerous and cover a wide spectrum of matters.

[5] Mariolina Eliantonio, Caroline Cauffman, The Legitimacy of Standarsiation as a Regulatory Technique in the EU, in: Mariolina Eliantonio, Caroline Cauffman (eds.) The Legitimacy of Standarsiation as a Regulatory Technique in the EU (Elgar, Cheltenham: 2020), 1-19, at p. 5.

[6] 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.

For example, the International Standardisation Organisation (ISO)[7] and the International Electrotechnical Commission (IEC)[8] both have broad mandates for establishing product and safety standards. Other bodies are more sector-specific such as for example the Basel Committee on Banking Supervision.[9]

EU bodies rely in their regulatory action on external standards. Examples for 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, the review of this will take place according to EU legislation and according to the practice of the agency on international scientifically proven best practice. In pharmaceuticals, for example, standardisation activities of the 'International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceutical 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.[10] In the field of banking regulation, standards established by the so called 'Basel Committee on Banking Supervision' a venue for cooperation of the heads of several central banks and banking supervisory authorities of developed nations and the EU, as well as the 'International Accounting Standards Board' (IASB), the board of the a not-for profit corporation acting as a privately funded standard setter with a membership reported to include business, academic and regulatory authorities are highly influential. Accounting standards are used in various contexts in EU law.[11] The Banking crises following the years

[7] www.iso.org (last access 29 December 2015).
[8] www.iec.ch (last access 29 December 2015).
[9] www.bis.org/bcbs/index.htm (last access 29 December 2015).
[10] See Bärbel Dorbeck-Jung, 'Challenges to the Legitimacy of International Regulation: The Case of Pharmaceuticals Standardisation', in: Andreas Follesdal, Rames A. Wessel, Jan Wouters (eds.), *Multilevel Regulation and the EU*, Marinus Nijhoff Publishers (Leiden, Boston 2008), at pp. 51-71 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.
[11] Regulation (EC) 1606/2002 of the European Parliament and the Council of 19 July 2002 on the application of international accounting standards, OJ 2002 L 243/1, authorises the 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 Commission has adopted Commission Regulation (EC) 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) 1606/2002 of the European Parliament and the Council, OJ 2008 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', 32 *European Law Review* (2007), 443-466, at p. 455.

after 2008 has laid bare the degree to which Basel regulations and the IASB developed International Financial Reporting Standards as well as the International Accounting Standards have entered into the regulatory environment of the EU, to some accounts rather unchecked for the biases in regulation they provide for.[12] Many other examples have been collected by scholars looking into 'Global Administrative Law' matters,[13] and some common standards are emerging from comparative studies.[14]

Private rule-making can also be employed for implementing Union legislation, as in the field of social policy[15] or in the environmental field,[16] as well as in data protection.[17] Codes of conduct play an increasingly important role in commercial practices,[18] and professional activities,[19] as well as in corporate governance.[20] Privately set standards are also becoming part of EU institution's decision making procedure where data collections or data processing is undertaken with the help of software provided for by private actors. For this reason, the EU has established an agency for EU large scale data basis, eu-LISA, in order to ensure EU standards being applied in some of the most critical areas of EU data infrastructure.[21]

---

[12] 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, Jan Wouters (eds.), *Multilevel Regulation and the EU*, Marinus Nijhoff Publishers (Leiden, Boston 2008), 101-143.

[13] See e.g. Sabino Cassese et al., *Global Administrative Law: the Casebook*, 3rd ed., IRPA-IILJ (Rome 2012), Available at SSRN: http://ssrn.com/abstract=2140384.

[14] See especially, Sabino Cassese, A Global Due Process of Law?, in: Gordon Anthony, Jean-Bernard Auby, John Morison, Tom Zwart, *Values in Global Administrative Law*, Hart Publishing (Oxford 2011), 17-60.

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

[16] See Article 17(3) of Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), OJ 2003 L 37/24, which provides that Member States may transpooratise certain provisions of the directive 'by means of agreements between the competent authorities and the economic sectors concerned'.

[17] See for example in Article 46 of the GDPR, which envisages the drawing up of codes of conduct and binding corporate agreements.

[18] Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy', 32 *European Law Review* (2007), 443-466, at pp. 458-460 and 461-462.

[19] Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy', 32 *European Law Review* (2007), 443-466, at pp. 462-463.

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

[21] Regulation (EU) 2018/1726 of the European Parliament and of the Council of 14 November 2018 on the European Agency for the operational management of large-scale IT systems in the [AFSJ], and amending Regulation (EC) No 1987/2006 and Council Decision 2007/533/JHA and repealing Regulation (EU) No 1077/2011, OJ 2018 L 295/99–137. [Hereafter, the 'eu-LISA Regulation']. With respect to the

European and international standardisation organisations cooperate closely and, for this purpose, have concluded cooperation agreements such as the Vienna Agreement between ISO and the European Committee for Standardization (CEN),[22] and the Dresden Agreement between the IEC and the European Committee for Electrical Standardization (CENELEC).[23] 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. This almost takes on the appearance of an outsourcing of international standardisation to European organisations. In the inverse, the strong presence of European and EU Member State standardsiation bodies in international standard setting organisations 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 organisations arises from their unique position in regulating the EU's internal market, still one of the largest markets in the world.

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 regulation or fill regulatory gaps which have arisen in EU law.[24] 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'. The General Court in *Mallis*[25] reviewed the use of such standards for the adoption

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).

[22] See http://www.cencenelec.eu/intcoop/Pages/default.aspx.

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

[24] E.g. Case C-370/12 *Pringle* of 27 November 2012 ECLI:EU:C:2012:756.; with much literature having discussed the legality of the structure. See e.g. See for instance, Mathias Ruffert, 'The European Debt Crisis and European Union Law' (2011) 48 C.M.L. Rev. 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 *E.L. Rev.,* 771-784; Jean-Victor Louis, 'The no-bailout clause and rescue packages' (2010) 47 *C.M.L.Rev.* 971, 977; Jörn Pipkorn, 'Legal arrangements in the Treaty of Maastricht for the effectiveness of the economic and monetary union' (1994) 31 *C.M.L.Rev.* 275; Harald Hofmeister 'To Bail Out Or Not to Bail Out?—Legal Aspects of the Greek Crisis', (2010-2011) 13 *Cambridge Yearbook of European Legal Studies,* 113 – 134.

[25] T-327/13 *Mallis* of 21. April 2016 EU:T:2014:909, paras. 41-44, 53.

of MoUs in the context of financing operations conducted in the context of European support operations.

III. The entry point for standards into EU law

Standards are incorporated into EU law by various means. In the following the examples of forms of explicit or implicit incorporation recognised by the CJEU's case law will be discussed: References in EU legislation (1), the use of standards for review of consistency of EU institutional decision-making (2), and, standards as criteria for liability for non-contractual damages under Article 340(2) TFEU (3).

1. Integration by legislative reference

The most common way in which international standards may become sources of EU administrative law is through reference to such a measure in a Union legal act.

The CJEU interprets Union law in consistency with public international law. It however keeps a keen eye to ensuring the autonomy of EU law and its essential features such as the protection of EU fundamental rights.[26]

This approach was well developed in various EU policy fields, which provide for this mechanism of incorporation of *initially* non-binding standards, by reference or explicit incorporation into EU legislation and thus give them binding nature.[27] The latter bears upon legislative and non-legislative acts across various fields.[28]

---

[26] See especially, Joined Cases C-402 & 415/05 P *Kadi and Al Barakaat International Foundation v Council and Commission* [2008] ECR I-6351. Apart from this, incorporation of international instruments into EU law may take place through references in primary law. A model-approach of binding incorporation is the reference to minimum standards of fundamental right protection in Article 52(3) CFR arising from the ECHR and the ECtHR's case law interpreting the Convention.

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

[28] See e.g. for food standards Recital 15 and Articles 21, 22 of Regulation (EC) no 183/2005 of the EP and of the Council of 12 January 2005 laying down requirements for feed hygene, OJ 2005 L 35/1 referring to the WHO's and the FAO's Codex Alimentarius. For labour standards e.g. Article 31 of Regulation (EC) No 1995/2006 of the EP and the Council of 18 December 2006 establishing a financing instrument for development cooperation, OJ 2006 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 EP and of the Counciol of 11 May 2016 on the EU Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Cocunil Decisions 2009/317/JHA, 2009/934/JHA, 2009/936/JHA and 2009/968/JHA, OJ 2016 L134/53.

a) Dynamic links

Such references often contain 'dynamic' links to legal standards which continue to evolve outside the EU legal order. These standards may evolve because of case law of courts or dispute settlement mechanisms like the ECtHR in the case of the ECHR (included in the reference under Article 52(3) CFR) or the due to clarifications brought to international agreements by quasi-judicial dispute settlement structures such as the WTO's DSB.

The development of standards might also be undertaken in the context of further clarifications and specifications in international organisation's working bodies. 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."[29] These guidance documents are taken into account in a variety of cases, where EU law makes reference to outside standards set in international agreements.[30]

One example for such approach was addressed by the CJEU in the OIV case.[31] Germany had requested the annulment of the Council decision establishing the EU's position with regard to 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 to contribute "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 by dynamic link those recommendations into EU law. The General Court

[29] 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'.

[30] See e.g. references made in EU food law to standards established by the International Organisation of Vine and Wine (OIV) in Article 120f(a), 120g and 158 a(1) and (2) of Council Regulation 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation, OJ 2007 L 299/1 as amended by Regulation 1234/2010 of the EP and of the Council of 15 December 2010 , OJ 2010 L 346/11.

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

makes special reference to Articles 120g and 158a(1) and (2) of Regulation No 1234/2007 and the first subparagraph of Article 9(1) of Regulation No 606/2009 which explicitly compare OIV recommendations to rules of EU law as regards 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.[32]

b) The role of the Nakajima principle

The recognition of standards incorporated for references undertaken in legislative and non-legislative acts,[33] is known as the 'Nakajima principle'. In *Nakajima*, the CJEU had ruled that, despite the lack of direct effect of WTO law within the Union legal framework, EU legislation could reference WTO law as a standard for the legality of Commission action. Where an EU legal act is "adopted in order to comply with the international obligations of the Community"[34] this leads to a justiciable obligation upon Union bodies "to ensure compliance with" the provisions of public international law.[35] The CJEU thus oversees the application of WTO criteria within its assessment of the legality of Union actions under EU law,[36] although the WTO's international law character does not change, and its hierarchical position remains secondary to EU law. This was confirmed by the CJEU in *Intertanko*. 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.[37] Where tools for the interpretation thereof exist

---

[32] Case C-399/12, Germany v Council (International Organisation of Vine and Wine, OIV) ECLI:EU:C:2014:2258, paras 57-64.

[33] See e.g. C-104/16 P *Council 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 Agricultura Italia* ECLI:EU:C:2003:43, para 79 referring to the Codex Alimentarius.

[34] Case C-69/89 *Nakajima v Council* [1991] ECR I-2069, para 31.

[35] Case 104/81 *Hauptzollamt Mainz v Kupferberg* [1982] ECR 3641, para 11, and in Case 266/81 *SIOT v Ministre delle Finanze and Others* [1983] ECR 731, para 28.

[36] Case 70/87 *Fediol v Commission (Fediol III)* [1989] ECR 1781; Case C-69/89 *Nakajima v Council* [1991] ECR I-2069.

[37] C-308/06 *Intertanko* 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

on the international level, this will, by extension, then also be true for those statements and standards developed. This has been expanded policy areas, as the OIV wine and vine case cited above illustrates.[38]

It is now repeatedly confirmed by the CJEU that although standards arising from international organisations cannot be used to assess the legality of an EU legal act,[39] they can be used for purposes of interpretation of obligations under EU law. For example in *Lesoochranárske zoskupenie,*[40] 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.[41] This is essential to ensure that norms of international agreements which have an effect within the legal system of the EU are interpreted in a uniform manner.

In the inverse, 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" an OECD model tax convention and the OECD's commentaries relating thereto, the CJEU has held it sufficient for a legislative proposal pursue "the same objective" as the OECD 1996 Model Tax Convention even where this is only in very broad terms such as "namely avoiding international double taxation"[42] in order to interpret the concept "of 'beneficial owner', which appears in the bilateral conventions based on that model … therefore, relevant when

subject (Article 4(3) TEU), the Commission had to 'take account' that some Member States implementing the EU legislation made direct reference to the Marpol Convention in interpreting EU legislation.

[38] See e.g. C-399/12 *Germany v Council* ECLI:EU:C:2014:2258 on the standards set by the International Organisation of Vine and Wine.

[39] See e.g. Joined Cases C-401/12 P to C-403/12 P (Grand Chamber) *Council, EP and 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 *FIAMM and Others* v *Council and Commission* EU:C:2008:476, para 108 and the case-law cited.

[40] C-240/09 *Lesoochranárske zoskupenie*, paras 40-43.

[41] 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 #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."

[42] Joined Cases C-115/16, C-118/16, C-119/16 and C-299/16 *N Luxembourg and Others* ECLI:EU:C:2019:134, para 90.

interpreting" an EU directive.[43] Outright the CJEU dismissed the argument explicitly made in the cases that interpreting autonomous EU law in the light of the OECD Model Tax Convention and of the commentaries relating thereto "would lack any democratic legitimacy whatsoever" where 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."[44]

c) The European Standardisation Organisations and the 'New Approach'

Standards become relevant within the internal market predominantly by the so called 'New Approach' directives of the 1980ies. Therein, the Union has limited itself to adopting only the 'essential requirements' of health and safety regulation as opposed to detailed technical proscriptions with which products must comply in order to benefit from free movement within the EU. Instead of adopting detailed Union legislation, European Standardisation Organisations (ESOs), CEN, CENELEC and ETSI, are charged with establishing specific standards based on such requirements. The task of developing harmonised standards falls to the ESOs,[45] generally, on the basis of 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[46] with which all Union harmonisation legislation ought to comply.[47] 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.[48] European Standardisation Organisations incorporate international standards and international best practices and take these into account. Some even explicitly refer to them. In fact, the participation of CEN, CENELEC and ETSI as well as of its member bodies in international standardisation is beneficial for such international exchange. Factors such as BREXIT, where the

[43] Joined Cases C-115/16, C-118/16, C-119/16 and C-299/16 *N Luxembourg and Others* ECLI:EU:C:2019:134, para 90.
[44] Joined Cases C-115/16, C-118/16, C-119/16 and C-299/16 *N Luxembourg and Others* ECLI:EU:C:2019:134, para 91.
[45] See Article 3(2) of Decision 768/2008/EC, OJ 2008 L 218/82.
[46] Decision 768/2008/EC, OJ 2008 L 218/82.
[47] The reference provisions can be found in Annex I of Decision 768/2008/EC, OJ 2008 L 218/82.
[48] See Recital 7 of Decision 768/2008/EC, OJ 2008 L 218/82.

cooperation with close trading partners has changed from EU law 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.[49] 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.[50] Essential requirements cover public interest concerns[51] and may deal with certain product hazards, focus on the product as such and its performance, or set out the main protection objective.[52] 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."[53] This reduces the need for legislative adaptation to ongoing technical progress, but also leaves a 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 in the absence of harmonised standards if published in the Official Journal and transposed into national standards.[54]

Importantly, the EU's approach is that compliance with these harmonised standards is voluntary. 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 authority.[55] Manufacturers and service providers are

[49] Where 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 of 3 December 2001 on general product safety, OJ 2002 L 11/4.

[50] See Article 1 of Decision 768/2008/EC, OJ 2008 L 218/82.

[51] See Article 3(1) of Decision 768/2008/EC, OJ 2008 L 218/82.

[52] See European Commission: the Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, 4.1.

[53] 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)(1) of Decision 768/2008/EC, OJ 2008 L 218/82. 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.

[54] See e.g. Article 5(2) of Directive 98/37/EC of the European Parliament and the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ 1998 L 207/1.

[55] See Case 815/79 *Cremoni and Vrankovich* EU:C:1980:273 [1980] ECR 3583, para 10; Case C-112/97 *Commission v Italy* EU:C:1999:168 [1999] ECR I-1821, para 39; Case C-100/00 *Commission v Italy* EU:C:2001:211 [2001] ECR I-2785, paras 3 and 7; Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557,

free to develop their own technical solutions. Nonetheless, harmonised standards constitute *de facto* binding rules since the economic incentive to comply with the standards which ensure marketability of products is very strong. Developing alternative approaches generally time and cost-intensive and thus might prove un-attractive. By creating incentives for compliance with standards, standardisation activity plays an important role in the realisation of an internal market for goods and services and may even be regarded to operate as an essential complement of, or even as a substitute for, Union legislation on health and safety of products.[56]

Under this approach to market-based incentives, one specifically interesting 'entry point' for standards is thus the reference made to standards by means of private contract. A good example for this treatment by the CJEU arises from studying the facts underlying *James Elliot*.[57] This was a case resulting from the question of the legal nature and value of standards set by European standardisation organisations. The presumption of conformity and therefore benefit from free movement of goods and services was assumed, if the standards were published in the OJ and transposed into national law.

The case *James Elliot* concerned a private law dispute about the quality of materials provided in the context of a building project. Did the building materials comply with a CEN standard incorporated into EU law by Art. 4(2) of Directive 89/106.[58] 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 that 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

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* EU:C:2007:337 [2007] ECR I-4557, para 50; Case C-489/06 *Commission v Greece* EU:C:2009:165 [2009] ECR I-1797, para 43.

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

[57] Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821.

[58] FULL CITATION

additional requirements on such products for their effective use on the market and use within the territory,[59] and

> "… evidence of compliance of a construction product with the essential requirements contained in Directive 89/106 may be provided by means other than proof of compliance with harmonised standards, that cannot call into question the existence of the legal effects of a harmonised standard."[60]

However, these so defined legal effects of standards, were at the time of the *James Elliot* case "subject to prior publication by the Commission of its references in the 'C' series of the *Official Journal of the European Union*." The effect of this finding is that an act by a Union body, here the Commission, consisting of publishing the standard in the OJ is an essential procedural requirement for the binding effect of the standard created by a private body such as CEN.[61] The procedures leading up to the creation of standards and their publication are equally detailed in EU law. In the interim, the Commission has changed the practice to publishing standards in the OJ's L-series, which would indicate an understanding of a more binding nature. This change might be seen in the context of case law of the CJEU as to the reviewability of standards. While AG Campos Sánchez-Bordona in *James Elliot* had not accepted the interpretation of standards as acts of the Union and thus declared them outside the reach of an action for annulment under Article 263 TFEU,[62] the Commission, by publication in the L-series, is signalling a different approach.[63]

Since, the CJEU has confirmed that

---

[59] Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821 para 41 with reference to C-100/13 *Commission* v *Germany* EU:C:2014:2293 paras 55, 56 and 63.

[60] Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821 para 42.

[61] Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821 paras 43-45.

[62] Opinion of AG Campos Sánchez-Bordona in Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:63 para 40.

[63] Adrian Volpato, Mariolina Eliantonio, The Contradictory Approach of the CEJU to the Judicial Review of Standards, in: Mariolina Eliantonio, Caroline Cauffman (eds.) The Legitimacy of Standarsiation as a Regulatory Technique in the EU (Elgar, Cheltenham: 2020), 91-109, at p. 101.

> "It is true 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*".[64]

The CJEU has also held that standards so established and published, can be enforced by the Commission through actions for failure to fulfil obligations provided for in Article 258 TFEU.[65] The CJEU has considered that a Member State may not impose "additional requirements" for example on construction products themselves covered by several harmonised standards for effective market access. Therefore, standards have in the past not in themselves been understood as reviewable acts of the Union subject to an action for annulment under Article 263 TFEU.[66] The challenge of a standard as an act thus remains a controversial proposition.[67] Member States and other EU institutions can, however, have the Commission decision to publish the standard in the OJ reviewed. In that case, the Courts do generally not engage in substantive review but may review procedural irregularities in the ESO elaboration procedure.[68]

Irrespective of this, the main avenue for the judicial review by standards as arising from the European Standarisation Organisations (ESOs), is, as established by the CJEU in *James Elliot* form part of EU law may be subject to a preliminary reference procedure under Art 267 TFEU.[69] Review of such Standards will be undertaken in the context of obligations under the standardisation regulation.[70] That regulation sets out basic principles for the

[64] C-185/17 *Mitnitsa Varna* ECLI:EU:C:2018:108, para 39 with reference to Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821 paras 40, 43-44.

[65] C-100/13 *Commission* v *Germany* EU:C:2014:2293.

[66] See e.g. T-264/03 *Schmoldt and Others v Commission* [2004] ECR II-1515, paras 108-125.

[67] See e.g. Carlo Tovo, Judicial Review of Harmonsied Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law, 55 Common Market Law Review (2018), 1187-1216; Mariolina Eliantonio, Judicial Control of the EU Harmonised Standards: Entering a Black Hole? 44 Legal Issues of Eoncomic Integration (2017) 399-404.

[68] See e.g. T-264/03 *Schmoldt and Others v Commission* [2004] ECR II-1515, paras 108-125.

[69] Case C-613/14 *James Elliot Construction v Irish Asphalt* ECLI:EU:C:2016:821, paras 34-36, 41.

[70] 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,

adoption of standardisation procedures by the ESOs requiring for example the establishment and publication of work programmes (Articles 3, 8), rules on participation of stakeholders and national bodies (Articles 5, 7), transparency and accessibility (Articles 4, 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 standardisation requests, public functions. Their action should arguably thus also be held to comply with general principles of EU administrative law such as the principles of good administration and the duty of care. Therefore, the standardisation regulation needs to be interpreted in the context of compliance with these principles.

Thus, the process of authorising ESOs and the procedure applied are comparatively well organised and transparent by comparison to some standard setting in international organsiations. Lacunae remain from a potential lack of oversight over participation and representativeness. Procedurally, the influence of national standardization institutes has grown in tandem with the re-valuation 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, appliers, consumers, certification bodies, science, authorities, and environmental associations are, not directly involved in European standardizati[11] Their avenue for participation is through national standardization organizations in so-called 'mirror committees'.[71]

On the other hand, ESO standardisation appears aligned with criteria summarised in the *Meroni* principles.[72] Applying, by analogy, the standards of the EU's limitations of delegation of powers to private parties established by the *Meroni* doctrine suggested 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, the exercise of

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 2012 L 316/12; a consolidated version with changes was published in 2015: http://data.europa.eu/eli/reg/2012/1025/2015-10-07.

[71] Josef Falke, 'Standardization by professional organisations', in Gerd Winter (ed.), *Sources and Categories of European Union Law,* Nomos (Baden-Baden 1996), at p. 656.

[72] Cases 9 and 10/56 *Meroni v High Authority* [1957/58] ECR 133.

such powers must be subject to strict review and the same obligations which the delegating authority would have had to observe, had it adopted the measures itself.

However, even in the world of ESO standards, there are different levels of formality and recognition. Recital 31 of the standardisation regulation (1025/2012) clarifies for EU law 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, like some "ICT technical specifications 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 also useful as standards but beyond the conferral of public powers on the ESOs strictly speaking.

2. Integration of standards by decision-making practice of EU institutions and bodies and the duty of care

Standards expressing good practice or summarising certain expertise may have to be taken into account in the EU legal order under the obligations arising from the duty of care and the compliance and consistency of decision making will be reviewed by the CJEU.

a) Obligations to take into account expertise

Taking recourse to standards and best practices in EU decision making also arises from the general principle of the 'duty of care'.[73] Under the now famous *TU München* formula, the CJEU must review whether an administration has examined and scrutinized, carefully and impartially,[74] all relevant aspects of a case "in order to make a finding in full knowledge of all the facts relevant at the time of adoption".[75] This requires not only quantitively, that all relevant information be taken into account prior to decision making but also qualitatively,

[73] Herwig CH Hofmann, 'The Duty of Care in EU Public Law - A Principle Between Discretion and Proportionality' (2020) 13 Review of European Administrative Law 87-112.
[74] Case C-269/90 *Technische Universität München v Hauptzollamt München-Mitte* [1991] EU:C:1991:438 and Case C-16/90 *Nölle v Hauptzollamt Bremen-Freihafen (Nölle I)* [1991] EU:C:1991:402, para 29.
[75] Case C-367/95 P *Sytraval* [1998] EU:C:1998:154, para 60, 62.

that an administration take recourse to expertise where such is not existent in-house.[76] The obligation to seek expertise was further spelt out in *TU München*, and has been reconfirmed in subsequent case law.[77] 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 proves necessary for the collection of all necessary information.[78] 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".[79] 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",[80] an obligation the General Court explicitly links to compliance with the rule of law.[81] Complying with these obligations may, especially, require taking into account standards set by international expert bodies or by private bodies in the field.

b) Reference to external expertise

The duty of care approach and the review of consistency of interpretation of decisions in the context of EU law 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.

[76] For instance, in the seminal *Netherlands v High Authority* case, 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.

[77] See e.g. Case C-439/05 P and C-454/05 P *Land Oberösterreich and Austria* v *Commission* [2007] EU:C:2007:510, para 32.

[78] Case C-269/90 *Technische Universität München v Hauptzollamt München-Mitte* [1991] EU:C:2009:438; Case C-212/91 *Angelopharm* [1994] EU:C:1994:21 and Case C-405/07 P *Netherlands* v *Commission* [2008] EU:C:2008:613, paras 56 and 67.

[79] Case C-405/07 P *Netherlands* v *Commission* [2008] EU:C:2008:613, paras 56 and 61.

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

[81] Case T-13/99 *Pfizer Animal Health v Council* [2002] EU:T:2002:209, para 172 and Case T-70/99 *Alpharma v Council* [2002] EU:T:2002:210, para 183.

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.[82] 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".[83] 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"[84] 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 from this, the General Court uses the OECD guidelines as criteria of consistency of the Commission's decision towards Ireland concerning Apple's tax arrangements. This analysis is undertaken in the context of the duty of care by EU institutions in decision making according to which an administration not only needs 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.[85]

The General Court then notes that "even though the Commission was entitled to observe that it cannot be formally bound by the principles developed within the OECD" when the Commission relies "in its primary line of reasoning" and "refers directly to the Authorised OECD Approach when substantiating its considerations",[86] it is "certainly of practical significance when interpreting questions relating to that profit allocation."[87]

---

[82] Cases T-778/16 and T-892/16 *Ireland v Commission (Apple State Aid)* ECLI:EU:T:2020:338. At the time of writing this case is under appeal as C-465/20 P.

[83] 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 Commission (Apple State Aid)* ECLI:EU:T:2020:338, para 237.

[84] Cases T-778/16 and T-892/16 *Ireland v Commission (Apple State Aid)* ECLI:EU:T:2020:338

[85] 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 Review of European Administrative Law 87.

[86] Cases T-778/16 and T-892/16 *Ireland v Commission (Apple State Aid)* ECLI:EU:T:2020:338, para 236.

[87] Cases T-778/16 and T-892/16 *Ireland v Commission (Apple State Aid)* ECLI:EU:T:2020:338, para 237.

In this context Advocate General Kokott stated 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."[88]

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. [89] This same approach also governs other General Court's tax state aid cases.[90] There the General Court reviews the consistency and logic of the Commission's decision with the help of the OECD tax guidelines.[91]

As a result, the direct or indirect referencing of standards such as OECD tax guidelines by the Commission can be used to analyse the consistency of acts and their inner logic. Where EU law or MS law is in line with them, the considerations expressed therein may be useful as illustration of legislative intent or good practice in their interpretation. The Commission, when basing its reasoning on these guidelines must be consistent. It must be possible to draw the conclusions from the application of guidelines when the latter are used as an

[88] Opinion of AG Kokott C-437/19 *Luxembourg v L* ECLI:EU:C:2021:450, para 67 with references her Opinions in : C-115/16 *N Luxembourg 1* para 50 et seq.; C-116/16 *T Danmark* EU:C:2018:144, para 81 et seq.; C-117/16 *Y Danmark* EU:C:2018:145, para 81 et seq.; C-118/16 *X Danmark* EU:C:2018:146, para 50 et seq.; C-119/16 *C Danmark I* EU:C:2018:147, para 50 et seq.; C-299/16 *Z Danmark* EU:C:2018:148, para 50 et seq.

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

[90] See e.g. Cases T-816/17 et T-318/18 Grand-Duché de Luxembourg v Commission ECLI:EU:T:2021:252.

[91] Cases T-816/17 et T-318/18 Grand-Duché de Luxembourg v Commission ECLI:EU:T:2021:252, para 202 : « De plus, il y a lieu de souligner que selon le point 1.22 des lignes directrices de l'OCDE, il peut être « intéressant et utile, lorsque l'on identifie et l'on compare les fonctions exercées, de prendre en compte les actifs qui sont ou seront mis en œuvre » et qu'« il convient à cet égard d'envisager le type d'actifs utilisés (usines, équipements, éléments incorporels, etc.) et les caractéristiques de ces actifs (âge, valeur marchande, localisation, existence de droits de propriété industrielle, etc.) ». En d'autres termes, il est préconisé de prendre en compte le fait qu'une société mette à disposition des actifs dans le cadre de la transaction contrôlée pour l'examen des fonctions exercées. Il en découle donc que, contrairement à ce qu'affirme la Commission, la mise à disposition d'actifs incorporels devait être prise en compte pour examiner les fonctions exercées ou assumées par une partie à une transaction intragroupe, sans qu'une distinction entre des fonctions « actives » et « passives » soit pertinente. »

argument. The latter is in line with considerations under the duty of care – full and impartial assessment of all relevant facts – in the context of review of discretionary powers.

3. Liability of the Union and standards

Liability of Union bodies for the use or abuse of international standards appears still an open question. Few cases have been litigated as far as can be seen. One area where the approach was attempted was in the field of the intergovernmental arrangements for financial assistance of Member States following the 2008 financial crises. But, 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 neither the ESM nor the Eurogroup are 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 the context of disbursement of economic crises support measures. These MoUs were adopted under guidelines of the ESM and the Eurogroup but concluded between EU institutions and the Member States.[92] With 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 EMU and the various financial arrangements linked to this remains to be seen with the developing case law of the CJEU.

IV. Legitimacy of Standards and their Recognition in EU Law

Standards established in this system facilitate the achievement of an internal market through regulation by bodies with both expertise and familiarity with specific matters. Beyond cases of explicit references being made to standards of a diverse nature in EU legislation, 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

[92] Joined Cases C-597/18 P, C-598/18 P, C-603/18 P and C-604/18 P Council v K. Chrysostomides & Co. 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 and Others* v *Commission and ECB* EU:C:2016:701, para 53.

duty of care. Standards can be used in private contractual relations under EU law and their violation can be the basis of claims of Union or Member States non-contractual liability.

Standards are thus have diverse origin but potentially far reaching effects in determining the outcome of decision-making. Although they might protect against arbitrariness of decision-making and misuse of hard to control discretionary powers, 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.[93]

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 own next to the assessment of risks also political judgments concerning the margins of risk-tolerance and approaches risk management.[94]

In other contexts, this example of standard setting procedures, shows the type of issues that might give reason for concerns. 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 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. How to enforce transparency and participation standards, how to ensure that all relevant actors are present is not evident. 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.[95]

---

[93] The EU is of course not alone with 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 accessed 12 November 2009). 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.

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

[95] Günther Teubner, 'Substantive and Reflexive Elements in Modern Law', 17 *Law & Society Review* (1983), 239-285, at p. 275.

Where EU law makes reference to standards and where standards are taken into account by EU institutions, offices, bodies and agencies under standards of 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, Article 290 TFEU. This requires that a Union legislative act determine the 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.[96] 'Law' in this sense is legal code derived from pre-defined decision-making procedures in conformity with legislative procedures. In EU law, this comes in forms recognized under Article 288 TFEU. Any limitations of fundamental rights which might result from the application of standards must therefore be pre-determined by in what is recognisable as law under Article 52(1) CFR.

With regard to standards, importantly, the notion of 'law' is conceptually linked to its accessibility. 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. Not all standards are publicly accessible, and it is not clear whether all standards applied are existent at the time of decision-making. The Apple Ireland cases offer an ample discussion about this. There, the Commission had been accused of applying OCED tax guidelines retroactively to assess whether Ireland had granted state aid in the form of allowing specific calculations of profit and loss.

Accordingly, in a case of the use of foreign standards for the processing of air-passenger data arising from the EU, the CJEU has requested 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

[96] 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.

> entails the interference must lay down clear and precise rules governing the scope and application of the measure in question and imposing minimum safeguards…"[97]

The CJEU requests that such "pre-established models and criteria (…) should be specific and reliable."[98] That means that the normative legal programming of limitations must be represented in the standards applied. Increasingly this is becoming relevant with respect to computer assisted automated decision making procedures where standards might be contained in computer programming code.

It thus 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. More specifically, standards may be applicable only where the decision-making process within bodies formulating standards has to provide for an adequate representation of the parties concerned and mechanisms in order to ensure a balanced process of bargaining or deliberation.[99] 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, 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."[100] 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 in EU law, undertaken in the context of judicial review of standards or in the context of ESO standard setting under the New Approach.

---

[97] Opinion 1/15 (*EU-Canada PNR Agreement*) of 26 July 2017, EU:C:2017:592, paras 139-141.
[98] Opinion 1/15 (*EU-Canada PNR Agreement*) of 26 July 2017, EU:C:2017:592, para 172.
[99] See Dagmar Schiek, 'Private rule-making and European governance – issue of legitimacy', 32 *European Law Review* (2007), 443-466, at p. 465, who considers this as prerequisites for 'substantive autonomy'.
[100] Case T-135/96 *UEAPME v Council* [1998] ECR II-2335, para. 89.

Such disquiet is not necessarily shared by the Court as the use of OECD guidelines show, but that might be a specific situation. The *Meroni* principles could be read suggest that an entrusting of quasi rule-making functions to standardization bodies 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 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 supervision of standards applied in EU law and the procedural conditions of their creation.