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Legal Opinion

On the European System of Harmonised Standards

Commissioned by the German Federal Ministry for Economic Affairs and Energy ("BMWi")

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A.
Executive Summary

1. The judgment of the ECJ in the case *James Elliott* (C-613/14), in which the Court comes to the conclusion that harmonised standards form "part of Union law", relates solely to the specific context of the Court's jurisdiction in preliminary rulings under Article 267 TFEU. It is evident that the Court did not intend to thereby subject harmonised standards to the same conditions of validity and the same legal consequences that apply to all other EU law, and thus ultimately call into question the New Approach. The latter is based precisely on the fact that, beyond legislative processes, the essential requirements of harmonisation legislation are specified by harmonised standards of the private standardisation organisations, the application of which is voluntary (see C.I.).

2. Before publishing a reference of a harmonised standard in the Official Journal according to Article 10(5) and (6) of the Standardisation Regulation 1025/2012, the European Commission can and must examine whether the harmonised standard corresponds with the request made for it and whether it satisfies the requirements of the corresponding harmonisation legislation that it aims to cover. However, the examination is generally limited to a comparison of the contents of the standard with the underlying requirements of the standardisation request and of the corresponding harmonisation legislation, which must primarily refer to formal aspects and the completeness and logical consistency of the standard. In particular, the Commission must not use the assessment of the harmonised standard as an opportunity to duplicate the standardisation process or even to replace the contents agreed by the standardisation organisations with its own technical rules. In addition, the Standardisation Regulation does not provide for a comprehensive examination of the requirements relating to transparency and inclusiveness of the standardisation process prior to the decision to publish the reference of a harmonised standard in the Official Journal. If the Commission were to attempt to specify a corresponding depth of assessment in a revised version of its working documents, this would not be in line with the requirements of the Standardisation Regulation (see C.II.).

3. The European Union is not liable for damage resulting from errors in a harmonised standard itself. However, it may be held liable for decisions the Commission takes under the Standardisation Regulation that relate to standardisation requests, publication of references of harmonised standards in the Official Journal, or formal objections. The EU's responsibility for liability thus only goes as far as the Commission's assessment obligation goes. The Commission's tendency to significantly expand its scope of

assessment is therefore not likely to reduce its liability risk, but on the contrary may potentially lead to an increase in its liability. As a result, liability will nevertheless regularly be ruled out because the additional requirements of causality or a sufficiently qualified infringement will usually not be fulfilled (see C.III.).

4. Unless the Standardisation Regulation, that lists the three European standardisation organisations CEN, CENELEC and ETSI exhaustively, is amended, the Commission may not request any other standard setters to draw up harmonised standards (see C.IV.1.b)).

5. The EU Committee on Standards referred to in Article 22 of the Standardisation Regulation, which is composed of representatives of the Member States, assists the European Commission with its standardisation activities. It is involved in various decision-making processes of the Commission, especially in the adoption of standardisation requests. If the Committee delivers an unfavourable opinion by qualified majority on a draft standardisation request, the Commission cannot adopt it. If the Committee does not deliver a formal opinion, for example because the necessary qualified majority is not reached, the Commission is likewise prevented from adopting the request where it relates to the protection of the health or safety of humans, animals or plants, as will generally be the case. The same applies if the Committee members reject the request by a (mere) simple majority. The right of the Committee on Standards to be involved cannot be curtailed unilaterally by the Commission (see C.IV.1.).

6. The Member States may seek redress before the European Courts against individual procedural steps taken by the Commission under the Standardisation Regulation. Both the Commission's decision to publish the reference of a harmonised standard in the Official Journal, and the final rejection of such publication can be challenged by action for annulment. In addition, Member States may also bring an action for failure to act in cases where the Commission does not proceed to publish the reference of a harmonised standard in the Official Journal, even though the standard meets the legal requirements (see C.IV.2.).

7. The Commission can use guidelines, guidance notes and other working documents, to explain how it interprets the applicable law and how it intends to use the scope of discretion it has been granted. Such guidelines are usually not binding but may create a self-binding obligation on the part of the Commission. They cannot generally be challenged by way of an action for annulment (see C.V.).

B.
Current legal situation and request for an expert opinion

I. Current legal and political situation

Within the framework of the New Approach (see 1.), the European standardisation organisations develop harmonised standards at the request of the Commission following a prescribed procedure (see 2.). Due to the judgment of the European Court of Justice (ECJ) in the *James Elliot* case in October 2016, which classifies harmonised standards as "part of Union law", the Commission has most recently felt compelled to substantially modify the standardisation procedure, which makes efficient standardisation more difficult (see 3.). The German Federal Ministry for Economic Affairs and Energy (BMWi) has therefore commissioned us with providing an expert legal opinion on certain questions regarding the consequences of the ECJ judgment and on the new procedural rules of the Commission introduced on the occasion of the judgment (see B.II.).

1. Principles of the New Approach

At EU level, the harmonisation of product regulations follows the so-called New Approach, which was approved by the Council on 7 May 1985 in its "Resolution on a New Approach to technical harmonisation and standards"[1], which was updated in 2008 by the so-called New Legislative Framework.[2] The main feature of the New Approach is to limit the harmonisation of product safety laws to the essential requirements to which products put on the market in the EU must conform in order to enjoy free movement on the internal market of the European Union.[3] The task of giving these essential requirements a more concrete form is subsequently entrusted to the three European standardisation organisations – CEN, CENELEC and ETSI.[4] They are responsible for

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1 OJ 1985, no. C 136, p. 1.

2 Decision no. 768/2008/EC of the European Parliament and of the Council of 09 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC of the Council, OJ 2008, no. L 218, p. 82 et seqq.

3 Cf. from the comprehensive literature on the principles of the *New Approach* merely the so-called Blue Guide (Commission Notice, The 'Blue Guide' on the implementation of EU products rules 2016, OJ 2016, no. C 272, p. 1 (7 et seq.), *Anselmann*, Die Bezugnahme auf harmonisierte technische Regeln im Rahmen der Rechtsangleichung, in: Müller-Graff (editor), Technische Regeln im Binnenmarkt, 1991, p. 101 et seqq., and *Schucht*, 30 Jahre New Approach im europäischen Produktsicherheitsrecht – prägendes Steuerungsmodell oder leere Hülle?, EuZW 2017, 46.

4 See Annex I to Regulation (EU) no. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, OJ 2012, no. l 316, last amended by Directive (EU) 2015/1535 of 9 September 2015, OJ 2015, no. L 241, p. 1 et seqq.

drawing up technical specifications in the form of so-called harmonised standards[5] on the request of the European Commission (so-called mandate) to further specify the requirements of harmonisation legislation.

The application of such harmonised standards is voluntary; thus, manufacturers are free to furnish proof of compliance with the essential requirements by other means. If, however, manufacturers manufacture their products in conformity with harmonised standards it is presumed that the product in question conforms to the essential safety requirements of the harmonisation legislation (so-called presumption of conformity).

This concept replaced the attempt – that was increasingly found to be unsuitable – to achieve product-related harmonisation in the form of detailed legal requirements (the so-called concept of detailed harmonisation)[6] with sectoral directives (and ultimately regulations, too) that can be "supported" and given a more concrete form by using harmonised standards[7]. However, since the application of these standards is voluntary, the essential requirements of the harmonisation legislation must be sufficiently comprehensive, self-standing and comprehensible to be applied directly by economic operators, even without specific harmonised European standards.[8]

2. Basic principles of the harmonised standards development process

At EU level, the harmonised standards development process is primarily laid down in Regulation (EU) No 1025/2012[9] (hereinafter: Standardisation Regulation), which is the fundamental legal framework of the European standardisation system.[10] Other provisions and/or forms of implementation of the legal requirements can be found in the

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5 Cf. the definition in Article 2(1)(1)(c) of Regulation (EU) no. 1025/2012 (above fn. 4), to which the harmonisation legislation adopted since the adoption of this Regulation makes reference. Previous harmonisation legislation adopted under the New Approach contains comparable definitions.

6 *Schepel*, The New Approach to the New Approach: The Juridification of Harmonised Standards in EU Law, MJ 20 (2013), 521, 523, aptly states: "*fantastically complicated and detailed directives on matters of sometimes questionable importance which, moreover, took so long to be adopted that they were often outdated long before they entered into force*".

7 *Schucht,* 30 Jahre New Approach im europäischen Produktsicherheitsrecht – prägendes Steuerungsmodell oder leere Hülle?, EuZW 2017, 46.

8 European Commission, Better Regulation Toolbox, Tool #18: The Choice of Policy Instruments, abrufbar unter https://ec.europa.eu/info/files/better-regulation-toolbox-18_en, section 3.2: Technical standards, p. 114 et seq.

9 Regulation (EU) no. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, OJ 2012, no. L 316, p. 12 et seqq.; last amended by Directive (EU) 2015/1535 of 09 September 2015, OJ 2015, no. L 241, p. 1 et seqq.

10 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee — Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market COM(2018) 764 final of 22 November 2018, p. 2.

rules of procedure of the European standardisation organisations[11] and in various Commission working documents, in particular the Vademecum on European Standardisation[12] – a Commission working document in three parts – and in the Blue Guide[13], a Commission guide to the implementation of product legislation.

Where harmonisation legislation of the EU provides that harmonised standards are the means for specifying the essential requirements to which products must conform, the Commission may make a request to a European standardisation organisation under Article 10(1) and (2) of the Standardisation Regulation to draw up a harmonised standard.[14] Such standards are adopted in the form of an implementing decision as defined under Article 291 TFEU, that is adopted in an examination procedure according to Article 5 of Regulation (EU) No 182/2011[15] (hereinafter: Comitology Regulation) after consultation with the European standardisation organisations, stakeholders and experts in the sector concerned (for more details see C.IV.1.b)).[16] The request, the (current) form of which is specified in Part II of the Vademecum, must specify the requirements as to the content of the requested standard and a deadline for its adoption.

If the European standardisation organisation accepts the request within the one-month deadline laid down in Article 10(3) of the Standardisation Regulation, it shall agree on the work programme for the execution of the request in consultation with the Commission. Changes of the work programme must be notified to the Commission. On this basis, the responsible technical committee of the standardisation organisation will then develop a draft of a harmonised standard, taking into consideration the requirements relating to the transparency of the activities and of draft standards that are laid down

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11 Cf. merely CEN/CENELEC-Internal Rules, Part 2: Common rules for standardisation work, May 2018.

12 Commission Staff Working Document, Guidelines for European Standardisation supporting legislative and political measures of the Union, Part I – Role of the Commissions‘ standardisation requests to the European standardisation organisations; Part II – Preparation and adoption of the Commission’s standardisation requests to the European standardisation organisations; Part III – Guidelines for the execution of standardisation requests, SWD(2015) 205 final of 27 October 2015.

13 Commission Notice, The ‘Blue Guide’ on the implementation of EU product rules 2016 („Blue Guide“), OJ 2016, no. C 272, p. 1.

14 For more information on the function and preparation of standardisation requests, European Commission Vademecum – Part 2 (above fn. 12).

15 Regulation (EU) no. 182/2011 of the European Council and of the European Parliament of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, OJ 2011, no. L 55, p. 13.

16 Harmonisation legislation adopted before the entry into force of the Standardisation Regulation itself regularly contains rules on procedure and refers to Article 6 of the meanwhile replaced Directive 98/34/EC of the European Parliament and of the Council of 22.06.1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, OJ 1998, no. L 104, p. 37, last amended by Directive 98/48/EC of 20 July 1998, OJ 1998, no. L 217, p. 18.

in Articles 3 to 6 of the Standardisation Regulation, and to the participation of stakeholders. According to Article 10(5), first sentence, of the Standardisation Regulation, the European standardisation organisations will then inform the Commission about the activities undertaken to develop the harmonised standards.

If, following a public enquiry and the consideration of any opinions delivered in the final formal vote, the European standardisation organisation accepts the draft with the required majority of votes, the standardisation organisation will ratify the harmonised standard in the three official languages German, English, and French, and transmit its basic data (in particular the reference number and the title in all official languages[17]) to the Commission.

In accordance with the provisions of the CEN/CENELEC Internal Regulations and with individual harmonisation legislation, harmonised standards – as do other European standards – must be "transposed" by the national standardisation organisations.[18] This is taken care of by the national standardisation organisations who make the standard available in identical form as a national standard in one of the three official languages or in translated form in one of the other languages of the CEN/CENELEC Member States. Any conflicting national standards must be withdrawn within a certain period of time ("co-existence period").

The conditions for the presumption of conformity, which applies in favour of the manufacturer when the requirements of the harmonised standards are satisfied, are not established until the last stage of the procedure: in the case of products that are manufactured in conformity to the harmonised standards, conformity with the essential requirements of the legislation covered by the standards is presumed if the "reference" of the harmonised standard is published in the Official Journal of the European Union.[19] Publication of the reference by the Commission in the Official Journal is thus a constitutive element of the presumption of conformity.[20]

In any case, since the introduction of the Standardisation Regulation, such publishing by the Commission does not (or has ceased to) automatically ensue after the transmission of the reference by the European standardisation organisation. Instead, in accordance with Article 10(5), sentence 2, (6) of the Standardisation Regulation 1025/2012

17 Blue Guide (cf. fn. 13), p. 44.

18 Cf. CEN/CENELEC-Internal Rules, Part 2 (fn. 11), no 11.2.1.1; Blue Guide (cf. fn. 13), p. 45.

19 Cf. in general Blue Guide (cf. fn. 13), p. 47 et seq.

20 Cf. *Schepel*, The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets, 2005, p. 235.

– resp. corresponding provisions in the harmonisation legislation[21] – and prior to publication, the Commission together with the European standardisation organisations examine whether the harmonised standard corresponds with the request adopted for it and whether it satisfies the requirements of the corresponding harmonisation legislation that it aims to cover. If this is the case, the Commission will publish the reference of the harmonised standard immediately in the Official Journal of the EU. If, by contrast, the Commission comes to the conclusion that the standards developed by the European standardisation organisations do not satisfy the requirements of the standardisation request and the harmonisation legislation it aims to cover, the Commission may refuse to publish it or set certain limitations that are published together with the reference in the Official Journal. The Standardisation Regulation does not specify the scope and depth of the Commission's assessment and – especially more recently – it has been the subject of controversy between the Commission, the standardisation organisations, and the Member States (see C.II.).

The Commission's publication decision under Article 10(5), sentence 2, and (6) of the Standardisation Regulation 1025/2012 has no impact on the (continued) effectiveness of the standard *per se*.[22] Through its decision on the publication – with limitations where necessary – of the reference in the Official Journal, the Commission is merely able to control whether and to which degree products that conform to the requirements of the applicable harmonised standard can be afforded the presumption of conformity. Consequently, European (harmonised) standards[23] can exist without the legal effect of the presumption of conformity (cf. Article 2(1)(c) of the Standardisation Regulation 1025/2012).

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21 Cf., e.g., Article 17(5)(2) of Regulation (EU) no. 305/2011 of the European Parliament and of the Council of 09 March 2011 laying down harmonised conditions for the marketing of the construction products, OJ 2011, no. L 88, p. 5; last amended by the Delegated Regulation (EU) no. 574/2014 of the Commission of 21 February 2014, OJ 2014, no. L 159, p. 41 (hereinafter: Construction Product Regulation)

22 Blue Guide (cf. fn. 13), p. 48.

23 The terminology is not entirely uniform here. According to the definition in Article 2(1)(c) of the Regulation, the characteristic feature of a European "harmonised" standard – as distinct from a simple "European" standard within the meaning of Article 2(1)(b) – is that the standard has been adopted by a European standardisation body "on the basis of a request made by the Commission for the application of Union harmonisation legislation". By contrast, a presumption of conformity is not a condition of the definition of a harmonised standard. From a legal point of view, therefore, standards which have been drawn up under a request from the Commission but whose references have not been published in the Official Journal must also be regarded as "harmonised" standards. In practice, however, such standards are commonly referred to as "European" standards without a presumption of conformity.

3. ECJ judgment in the *James Elliott* case (C-613/14) and the reaction of the Commission

In its judgment of 27 October 2016 in the *James Elliott* case, the ECJ decided for the first time that it has jurisdiction to interpret harmonised standards in preliminary rulings proceedings under Article 267 TFEU. The arguments it presented in favour of its jurisdiction was that the harmonised standard in the main proceedings was by its nature a measure for implementing or applying an act of EU law and therefore formed "part of EU law" (see below C.I.1.).[24]

The consequences of this decision – and the judgments of both the ECJ[25] and the General Court[26] (GC) that are based on it – have henceforward been the subject of controversy both in jurisprudence[27] and in the standardisation practice. In a "Non-Paper" early 2017, the European standardisation organisations CEN and CENELEC highlighted the specific context of the preliminary ruling and pointed out that the ECJ had confirmed both the non-binding nature of harmonised standards and the classification of standardisation organisations as organisations of private law. By contrast, the European Commission felt compelled by the judgment to make various changes to, and "clarify" the standardisation procedure. The most obvious of these changes is that very recently the Commission has ceased publishing its decisions on the publication of the references of harmonised standards in the form of a notice in the C series (*Communication)* of the Official Journal but instead in the form of an implementing decision in the L series (*Legislation*). Furthermore, since mid-2018, the Commission has been using the assistance of so-called HAS Consultants (*Harmonised Standards Consultants*) to perform its duties in the standardisation procedure and who have replaced the previous system of so-called NA Consultants (*New Approach Consultants*).[28] In addition, the Commission has changed the form of its standardisation requests, which are given to the European standardisation organisations in the form of implementing decisions and which were previously adopted on the basis of the model in point 4 and Annex II

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24 ECJ, judgment of 27 October 2016, James Elliott Construction, C-613/14, EU:C:2016:821.

25 ECJ, judgment of 14 December 2017, Anstar Oy, C-630/16, EU:C:2017:971.

26 General Court, judgment of 26 January 2017, Global Gardens Products Italy SpA (GGP Italy) / European Commission, T-474/15, EU:T:2017:36.

27 Cf. merely *Colombo/Eliantonio*, Harmonised technical standards as part of EU law: Juridification with a number of unresolved legitimacy concerns?, MJ 24 (2017), 323; *Klindt/Wende*, comment on ECJ, Rs. C-613/14 – James Elliott, NJW 2017, 66; *Nusser*, comment on ECJ, Rs. C-613/14 – James Elliott, NJW 2017, 315; *Tovo*, Judicial Review of Harmonised Standards, CMLRev 55 (2018), 1187; *Volpato*, The harmonised standards before the ECJ: James Elliott Construction, CMLRev 54 (2017), 591.

28 For the earlier system CEN/CENELEC see Guide 15 – Tasks and responsibilities of the New Approach Consultants, April 2009.

of Part II of the Vademecum[29], in several respects. Not only do these requests now identify the harmonised standards to be adopted in much more detail than before, but, for the very first time, they also provide for an expiry date for the validity of the decision in the relevant provision concerning the validity of the standardisation request.

In addition, the Commission published a Communication on harmonised standards in November 2018 in which it reports on the initiatives introduced in the previous years to promote the implementation of the Standardisation Regulation "in the light of the relevant case-law of the Court of Justice of the European Union" also.[30] In the Communication, it states in particular with regard to the *James-Elliott* judgment that it had to "pay particular attention to the content of the harmonised standards" because the Court had

> "reiterated the Commission's responsibility in the process of initiating, managing and monitoring of harmonised standards. The Commission has thus the obligation to follow the development process of harmonised standards thoroughly and to assess whether they comply with the requirements set out in harmonised Union legislation and/or standardisation requests in order to ensure that harmonised standards fully comply with the applicable legislation. This does not only include the technical aspects of standards but also other elements of the European Standardisation Regulation, such as whether their development process has been inclusive. It is the Commission's intention to fulfil these obligations in a manner which is as swift and efficient as possible."[31]

In addition, in the Communication the Commission announced that as one of three measures to improve the functioning of the European standardisation system, it would

> "elaborate over the next months in consultation with stakeholders, a guidance document on practical aspects of implementing the Standardisation Regulation, paying particular attention to the division of roles and responsibilities in the development process of harmonised standards as well as to efficiency and speed."[32]

The guidance document was designed to complement the existing documents – namely the Blue Guide and the Vademecum – and in particular to clarify the substantive and

29 European Commission, Vademecum – Part II (see fn. 12), p. 22 et seqq.

30 Commission Communication of 22 November 2018 (see fn. 10), p. 1.

31 Ibid., p. 3.

32 Ibid., p. 6.

procedural aspects of the new format of the standardisation request and the role of the Commission and the expert consultants (HAS-Consultants) it engaged.

Following this announcement, the Commission conducted a stakeholder consultation between July and the end of September 2019 on the content of its planned Guidance Note and its relationship to the existing guidance documents.[33] The consultation did not provide a fully consistent picture. However, it shows that most stakeholders are critical of both the new system of HAS Consultants and of the new formats for standardisation requests and publication decisions in the Official Journal, which are often regarded as overly cumbersome and an incorrect implementation of the Court's decisions. Another major concern of the comments received was the practice of the publishing of harmonised standards in the Official Journal that was perceived as too restrictive and slow and as one of the consequences of excessive assessments conducted by the Commission. For instance, according to an overview compiled by CEN/CENELEC of January 2020, the references of a whole row of harmonised standards was not published in the Official Journal, despite the fact that they had already been assessed positively by the *HAS Consultants*. The comments also proposed that, instead of a new guidance document, the existing documents should be revised in order to avoid the coexistence of diverging guidance documents.[34] The preparation of the new document, i.e. the prospective revision of the existing guidance documents is still ongoing.

II. Commissioned legal opinion

In view of the above, the German Federal Ministry for Economic Affairs and Energy has commissioned us to examine and provide an expert legal opinion on the compatibility of the new procedural rules with the EU Standardisation Regulation and the other documents and handouts relevant for standardisation, in particular the Blue Guide and the Vademecum.

The expert legal opinion shall focus on the following questions:

1. What is the legal nature of harmonised standards in the light of recent EU case-law? In particular, must a distinction be made between harmonised standards in general and those based on the Construction Products Directive or standards that

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33 See Document of the Commission of 11 July 2019, Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 – Consultation of stakeholders, Ref. Ares(2019)4465012.

34 See Document of the Commission of 06 January 2020, Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 – Results of the consultation of stakeholders, accessible at https://ec.europa.eu/docsroom/documents/38922, p. 3.

are subject to a comparable regulatory apparatus? Does recent EU case-law or the new course of procedure of the Commission in the development of standards expose the Commission to liability risks?

2. Does the most recent EU case-law require the Commission to introduce control mechanisms? In view of the so-called New Approach and the requirements of the EU Standardisation Regulation, which of them must be considered mandatory and sufficient? Does the Commission have the right to review standards and, if so, what is the scope of the review right? In this context, to which extent is the Commission permitted to use alternative means of developing standards other than standardisation or to commission other rule setters?

3. Which role will the Member States and the EU Committee on Standards play in future in the development and implementation of new standardisation procedures? For instance, can an abstention by the EU Committee on Standards on a standardisation request of the Commission be ignored and the standardisation mandate nevertheless be given to the standardisation organisations?

4. Which options of legal redress are there against new work procedures of the Commission?

5. To which degree can procedural papers and rules developed by the Commission and created with or without the participation of the Member States, e.g. the so-called "Vademecum" or the "Guidance Note", have a binding effect?

C.
Legal Assessment

I. The legal nature of harmonised standards

In the *James Elliott* judgment (C-613/14), the ECJ stated inter alia that a harmonised standard accepted on behalf of the Commission based on the then applicable Construction Production Directive, the reference of which was published in the Official Journal, formed "part of Union law". On closer examination, this statement relates to the specific context of the Court's powers of interpretation in the preliminary ruling procedure according to Article 267 TFEU (see 1.). It does not follow from this that harmonised standards must be subjected to the same conditions of validity and the same legal consequences as other EU law (see 2.).

1. Statements in and context of the *James Elliott* judgment

a) Reasoning of the ECJ

The ECJ judgment in the *James Elliott* case was given on the Irish Supreme Court's request for a preliminary ruling. It was based on a private law dispute between the construction company James Elliott Construction Limited and its supplier Irish Asphalt Limited concerning the breach of contractual obligations by a delivery of allegedly defective construction products. Under the contract, Irish Asphalt was obliged to supply certain construction materials of merchantable quality. According to the national court, the merchantable quality is specified by an Irish standard[35] which transposes the harmonised European standard EN 13242:2002[36]. The standard was adopted in 2002 in accordance with a mandate from the Commission on the basis of the former Construction Products Directive 89/106/EEC.

The Irish Supreme Court referred a number of questions to the ECJ for a preliminary ruling on the interpretation and legal significance of the harmonised standard or the Irish standard transposing it. It also asked the Court to clarify the more immediate question – which is primarily relevant in the present context – whether it had jurisdiction to give a preliminary ruling on the interpretation of a harmonised standard (or of the national standard transposing it). According to Article 267 sub-paragraph (1)(b) TFEU, such competence on the part of the ECJ is (only) established for "acts of the institutions, bodies, offices and agencies of the Union.

Having left this question open in its *Latchways* judgment in 2010[37], the Court of Justice held in the *James Elliott* case that it had jurisdiction for preliminary rulings on harmonised standards the references of which were published in the Official Journal. Whilst Advocate General *Campos Sanchez-Bordona* had previously reached the same conclusion in his Opinion[38], the reasoning of the ECJ differs significantly from that of the Advocate General.[39] In his Opinion the Advocate General took the view that harmonised standards, such as the one at issue in the main proceedings, constituted an act of

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35 I.p. EN 13242:2002 of the National Standard Authority of Ireland.

36 "Aggregates for unbound and hydraulically bound mixtures for civil engineering and road construction" of 23 September 2002, written on the basis of a mandate by the Commission dated 6 July 1998 (M 125 – Mandate to CEN/CENELEC concerning harmonised standards for aggregates for certain uses) by the Technical Committee CEN/TC 154 "Aggregates".

37 ECJ, judgment of 21 October 2010, C-185/08, Latchways und Eurosafe Solutions, EU:C:2010:619; recital 32 et seqq.

38 Opinion of the Advocate General *Campos Sánchez-Bordona* of 28 January 2016, James Elliott, C-613/14, EU:C:2016:63.

39 Ebenso *Colombo/Eliantonio*, Harmonised technical standards as part of EU law: Juridification with a number of unresolved legitimacy concerns?, MJ 24 (2017), 323, 326 et seqq.

an institution, body, office or agency within the meaning of Article 267 TFEU. He argued in particular that at all stages of the procedure, the Commission exercised significant control over CEN's drafting procedure for harmonised technical standards. He thus held that this was a case of 'controlled' legislative delegation for the benefit of a private standardisation body.[40] Even if it remained unclear in his conclusions whether the Advocate General attributed the standard to the Commission and thus concluded that an act of an EU body existed or whether he considered the CEN an "other agency of the Union", he held that the ECJ had jurisdiction in any case directly on the grounds of the wording of Article 267 TFEU.

The ECJ's chain of reasoning has different origins. In order to establish its jurisdiction, it refers to prior case-law, according to which the ECJ has jurisdiction beyond the wording of Article 267 TFEU for the interpretation of – binding and non-binding – acts that, while indeed adopted by bodies which *cannot* be described as "institutions, bodies, offices or agencies of the Union" within the meaning of the provision, were nevertheless by their nature measures implementing or applying an act of EU law.[41]

Previous cases where the cited case-law applied exclusively concerned acts of institutions that were established under a treaty concluded between the Union and third countries and that were entrusted with its implementation.[42] In its *James Elliott* judgment the ECJ now, for the first time, transferred this line of reasoning to the acts of a legal person governed by private law, such as CEN or CENELEC, which is organised as an international not-for-profit organisation under Belgian law and whose members are composed of the Member States' and EFTA's national standardisation organisations[43].

The ECJ essentially justifies such a transfer of reasoning with three considerations: [44] Firstly, Article 7(3) of the [former] Construction Products Directive 89/106/EEC, pro-

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40 Ibid., recital 38.

41 Recital 34 of the *James Elliott* judgment (cf. fn. 24) with references to ECJ, C-192/89 – Sevince, EU:C:1990:322, recital 10 and C-188/91 – Deutsche Shell, EU:C:1993:24, recital 17.

42 The *Sevince* case concerned the interpretation of decisions of the Association Council established by the Association Agreement between the former EEC and Turkey; the Deutsche Shell case concerned non-binding recommendations of the Joint Committee concerning the management and implementation of the Agreement between the former EEC and Austria, Finland, Iceland, Norway, Sweden and Switzerland.

43 Rightly critical of this transfer *Tovo*, Judicial Review of Harmonised Standards, CMLRev 55 (2018), 1187, 1193, who rightly points out that measures of bodies set up by an international agreement concluded between the Union and third countries and entrusted with its implementation automatically become part of the Union law, whereas harmonised standards require an 'incorporation act' in the form of a publication of the reference by the Commission.

44 Recital 37 et seqq. of the *James Elliott* judgment (cf. fn. 24).

vided that the Commission publish the references of the harmonised standards produced by the European standardisation organisations in the `C´ series of the European Union's Official Journal [currently: L series, see above B.I.3.].

Secondly, the ECJ invoked the legal effects of the harmonised standards: according to Article 4(2) of the Construction Products Directive 89/106/EEC in conjunction with the eleventh recital, the publication of the references of the harmonised standard had the effect of conferring on products which are covered by that directive, and which satisfy the technical requirements defined in the harmonised standards relating to those products, the benefit of a presumption of conformity with the basic requirements of that directive. The presumption of conformity enabled the product in question to circulate, to be placed on the market, and to be used freely within the territory of all Member States, with the result that, as the ECJ had previously decided in infringement proceedings against Germany[45], Member States may not impose additional conditions on such products in order for them to be effectively used on the market and used within the territory.

It is also the presumption of conformity on which the ECJ based its findings cited in the introduction, namely that a harmonised standard, such as that at issue in the main proceedings, "forms part of EU law" ("*fait partie du droit de l'Union*" (French); „*ist […] Teil des Unionsrechts*" (German); "*forma parte del Derecho de la Unión*" (Spanish)). Although evidence of compliance of a construction product with the essential requirements contained in Directive 89/106 could be provided by means other than proof of compliance with harmonised standards, this could not call into question the existence of the legal effects of a harmonised standard.

The Court's third argument was that while the development of such a harmonised standard was entrusted to an organisation governed by private law, it was nevertheless a necessary implementation measure which was strictly governed by the essential requirements defined by that directive, and was initiated, managed and monitored by the Commission. Moreover, the Commission, by means of infringement proceedings provided for in Article 258 TFEU, ensured that harmonised standards are fully effective.

b) Applicability to other harmonised standards

This line of argument also shows that the classification by the ECJ as forming part of Union law is not limited to harmonised standards that were adopted on the basis of the former Construction Products Directive 89/106/EEC.

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45 ECJ, judgment of 16 October 2014, C-100/13, Commission/Germany, EU:C:2014:2293, recital 55 et seq., 63.

The Directive contained a number of particularities compared to other harmonisation legislation that was introduced as part of the New Approach. These particularities are due to the fact that in the construction sector the focus is not on the requirements concerned with the safety of the (construction) products but with the protection of lives and health during the use of buildings and the protection of the environment and the climate against the impact of buildings.[46] In view thereof, the basic safety requirements contained in the Construction Products Directive referred not to the construction products as such but to the buildings manufactured using said products.[47]

Due to this specific harmonisation approach, on which the current Construction Products Regulation 305/2011 is based as well[48], the essential requirements a construction product must satisfy were not laid down in the Construction Products Directive itself but were reserved wholly to the subsequent level – and thus predominantly to harmonised standards[49]. In these standards, the technical requirements were determined for each product individually with regard to the basic requirements for buildings and the different uses of each product. Consequently, under the Construction Products Directive or the national rules transposing it, a manufacturer was only able to put its construction product intended for use in buildings on the market with a CE mark if the product was covered by a harmonised standard (or if on the manufacturer's request a European Technical Assessment had been issued for the product). Therefore, the implementation of the Directive ultimately depended on the existence of harmonised standards.[50] This does not apply in the same way in other areas of product safety law. On the contrary, the basic safety requirements – that have to be defined with sufficient precision[51] – for products that are placed on the internal market are already contained in the harmonisation legislation. Consequently, they are effective regardless of the adoption of harmonised standards.

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46 *Abend*, Neues Unionsrecht für die Vermarktung von Bauprodukten, EuZW 2013, 611 (612); *Jarass*, Probleme des Europäischen Bauproduktenrechts, NZBau 2008, 145.

47 The new Construction Product Regulation makes this difference clear in terms of wording by no longer using the terminology "essential requirements" but "basic requirements", cf. Article 2(4) of the Construction Product Regulation 305/2011 (fn. 21).

48 However with the difference that the Construction Product Regulation 305/2011 does not lay down the rules for the substantive conformity of the construction products but merely for the identification of the service performed.

49 *Abend*, Neues Unionsrecht für die Vermarktung von Bauprodukten, EuZW 2013, 611 (612 et seq.); *Jarass*, Probleme des Europäischen Bauproduktenrechts, NZBau 2008, 145 (147).

50 *Schepel*, The Constitution of Private Governance – Private Standards in the Regulation of Integrating Markets, 2005, p. 228; Opinion of the Advocate General *Trstenjak* of 29 March 2007, Carp, C-80/06, EU:C:2007:200, recital 34.

51 Council Resolution of 07 May 1985 on a new approach to technical harmonisation and standards, outline of the main principles and elements which should form the core of directives, B. III. 1., OJ 1985, no. C 136, p. 1 (4); Decision no. 768/2008/EG (cf. fn. 2), recital 11.

As shown above, the ECJ does not invoke the particularities of construction product law to justify its jurisdiction. It rather reverts to the argument of the publication of the reference in the Official Journal, the presumption of conformity following from a product's compliance with the requirements of the harmonised standard, and the fact that the standard is developed on the initiative and under the influence of the Commission. All three circumstances apply equally to all other harmonised standards. The essential statements made in the judgment therefore also apply to other harmonised standards that are adopted on the basis of harmonisation legislation according to the concept of the New Approach and the references of which are published in the Official Journal.

In contrast, the judgment cannot be transferred to those standards or parts thereof the reference of which the Commission has denied to publish in the Official Journal.[52] These standards can therefore not be considered "part of Union law" and are not within ECJ's jurisdiction to give a preliminary ruling.

c) Context of the classification of harmonised standards as forming "part of Union law"

As to the classification and scope of the ECJ's above statements one must however take into account the specific context of the judgment: the Court comes to the conclusion that harmonised standards form "part of Union law" in the specific context of an examination of its jurisdiction to give a preliminary ruling under Article 267 TFEU.[53] Accordingly, the ECJ's understanding of "institutions, bodies, offices or agencies of the Union", on which its judgment is based and which goes beyond the wording of the cited Article and also includes the acts of private-law bodies outside the EU institutions, can only be understood if one considers the telos and the central significance of the cited Article: The primary function of the preliminary rulings procedure stipulated in Article 267 TFEU is to ensure uniform interpretation of all rules that form part of the EU's legal order within the EU and to thus preserve the unity and the observance of Union law.[54]

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52 ECJ, judgment of 21 October 2010, C-185/08, Latchways und Eurosafe Solutions, EU:C:2010:619, recitals 30 et seqq.

53 Likewise *Volpato*, The harmonised standards before the ECJ: James Elliott Construction, CMLRev 54 (2017), 591 (601), who (still) denies the admissibility of an action for annulment under Article 263 TFEU against harmonised standards against this background.

54 *Karpenstein*, in: Grabitz/Hilf/Nettesheim (Hrsg.), Das Recht der Europäischen Union, as of: 69. EL 2020, Article 267 AEUV, recital 2. Cf. on the significance of the preliminary ruling procedure also ECJ, judgment of 18 October 1990, Dzodzi, C-297/88 and 197/89, EU:C:1990:360, recital 33, and ECJ, judgment of 13.01.2001, PreussenElektra, C-379/98, EU:C:2001:160, recital 38; judgment of 19 February 2002, Arduino, C-35/99, EU:C:2002:97, recital 24.

The Court can fulfil its duty of ensuring that the law is observed (Article 19(1)(1) TEU) only with regard to "Union law" that delineates the outer limit of the Court's powers of interpretation. The most recent case-law appears to draw this limit on the basis of the question whether a Union institution or body has participated in the adoption of a measure. As this is the case with harmonised standards the development of which is "initiated and monitored by the Commission",[55] the ECJ thus assumes that it has jurisdiction for the interpretation of standards for preliminary rulings according to Article 267 TFEU. In a more recent decision, on the other hand, the Court refused to interpret the rules of procedure of the Council of National Insurers' Bureaux of the Member States – a set of rules agreed between private insurers' bureaux and referred to in an act of Union law – on the basis of its competence under Article 267 TFEU:

> "The Court noted that those acts were drawn up and concluded by bodies governed by private law without any institution or body of the European Union having participated in their conclusion".[56]

Indeed, the participation of an institution or body of the Union in the adoption of a measure – in particular if connected with (limited) legal effects, as in the case of harmonised standards – may give rise to a need for a uniform interpretation throughout the Union, which can only be guaranteed if the ECJ has jurisdiction in the context of the preliminary ruling and therefore presupposes a classification as "Union law" for the purposes of Article 19(1), first sentence, TEU, Article 267 TFEU. However, the mere participation of an EU institution does not justify drawing general conclusions for other areas from this classification in the context of Article 267 TFEU. This is also demonstrated by the approach of the ECJ itself, which – unlike the Advocate General – does not classify the harmonised standards as acts of an EU institution, body, office or agency. The court expressly confirmed this yet again in a subsequent decision related to a standard concerning a test method for diesel fuels on the basis of Directive 98/70/EG:[57]

> "Standard EN 590:2013 was adopted not by an EU body, but by the CEN, an organisation governed by private law."[58]

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55 Recital 43 of the *James Elliott* judgment (cf. fn. 24).

56 ECJ, judgment of 15 June 2017, Lietuvos Respublikos transporto priemonių draudikų biuras, C-587/15, EU:C:2017:463, recital 37; cf. by contrast Opinion of the Advocate General *Bobek* in the case C-587/15 – Lietuvos Respublikos transporto priemonių draudikų biuras, EU:C:2017:234, recital 84.

57 Directive 98/70/EG of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ 1998, L 350, p. 58).

58 ECJ, judgment of 22 February 2018, SAKSA, C-185/17, EU:C:2018:108, recital 38.

Accordingly, the ECJ too ruled that the publication of a reference in the Official Journal by the Commission, but not the standard itself, constituted an act of an EU institution.[59]

Incidentally, the European Parliament appears to share this view when it explicitly emphasised in a resolution of 4 July 2017 on "European Standards for the 21st Century" that

> "standards cannot be seen as EU law, since legislation and policies regarding the level of consumer, health, safety, environment and data protection and the level of social inclusion are determined by the legislator".[60]

2. Harmonised standards cannot be equated with other Union law

The fact that the ECJ rightly regards harmonised standards as part of Union law only in the specific context of Article 267 TFEU is supported by the fact that a more far-reaching classification of harmonised standards as "genuine" Union law with all the associated characteristics would not only conflict with the New Approach (see a)), but would also entail considerable legal difficulties (see b)).

a) Inconsistency with the nature of the New Approach

That harmonised standards outside the context of Article 267 TFEU cannot be qualified as a full "part of Union law" already follows from the very nature of the New Approach.

As illustrated above (see above B.I.1.), harmonisation according to the New Approach is characterised by the fact that the Union legislator confines itself to defining the main safety requirements, the further specification of which is left to the (non-binding) technical specifications of the European standardisation organisations.[61] The content of harmonised standards is therefore decidedly not to be included in EU legislation, but must be developed by private law organisations outside the institutional framework of

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59 General Court, judgment of 26 February 2017, GGP Italy / Commission, T-474/15, EU:T:2017:36, recital 60.

60 European Parliament, resolution of 04 July 2017 on "European standards for the 21st century" (2016/2274(INI)), A8-0213/2017.

61 Cf. also, e.g., *Anselmann*, Die Bezugnahme auf harmonisierte technische Regeln im Rahmen der Rechtsangleichung, in: Müller-Graff (Hrsg.), Technische Regeln im Binnenmarkt, 1991, p. 101 (105), who refers to a deregulation and a shift of regulation to the voluntary field.

the Union. Since the transition to the New Approach, this concept has been the basis for numerous EU harmonisation acts.

This fundamental political decision was again expressly confirmed when the Standardisation Regulation was adopted in the year 2012. In the impact assessment the European Commission carried out beforehand it considered creating a European standardisation agency as an alternative model – i.e. a specialised agency of the EU – that should adopt implementation legislation containing technical specifications. Ultimately, however, this option was rejected in favour of the current model. The stated reasons lay in the difficulty of ensuring sufficient technical expertise and considerable anticipated costs.[62]

On this basis, qualifying harmonised standards as "genuine" Union law would be diametrically opposed to the New Approach. By way of interpretation contra legem, harmonised standards would be turned into something the Union legislator did not want them to be. De facto, this would be tantamount to an abandonment of the New Approach and a reintroduction of the assumedly obsolete "old concept" of detailed legal acts by the back door.

b) Legal problems of classification as "genuine" Union law

Moreover, classifying harmonised standards as EU legislation would entail considerable legal inconsistencies and difficulties. Not just to avoid those, it is necessary, in accordance with the approach of the ECJ, to confine the statement of the *James Elliott* ruling to the specific context of Article 267 TFEU.

Firstly, if one regarded harmonised standards as EU legislation, they would have to satisfy all the conditions that would result from such classification. This would mean, for example, that harmonised standards would have to be translated into all official languages of the EU (Article 342 TFEU in conjunction with Article 4 of the Council Regulation No 1 of 15 April 1958 determining the languages to be used by the European Economic Community). Moreover, according to Article 296(2) TFEU all EU legislation must be provided with a statement of reasons. The statement of reasons must show clearly and unequivocally the reasoning of the author of the measure so as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review.[63] Neither the Standardisation Regulation nor

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62 Commission Staff Working Paper, Impact assessment accompanying document to the Proposal for a Regulation on European Standardisation, SEC(2011) 671 final of 01.06.2011, p. 24 ("Policy Option 1.B: create a European Agency for Standards that would manage the standard-setting process. The agency would merge and replace the existing ESOs."), p. 30 et seqq.

63 See, e.g., ECJ, judgment of 16 June 2015, Gauweiler, C-62/14, EU:C:2015:400, recital 70.

the harmonisation legislation concerned provide that harmonised standards need to contain such statements of reasons. Accordingly, standards do not contain such statement of reasons in practice.

Secondly, classifying harmonised standards as "genuine" Union law would necessarily mean that all requirements and characteristics of Union law – such as its general primacy over all conflicting national laws – would apply to them. Again, it is clear that the Union legislator did not intend this. It would also conflict with the *James Elliott* judgment itself. In it, the ECJ precisely does not assume a general precedence of harmonised standards over the laws of the Member States because the provisions of the national laws on contracts for the sale of goods can impose requirements relating to the usability of products that diverge from said standards.[64]

Accordingly, the German Federal Administrative Court found in a judgment of September 2018 that, in its *James Elliott* decision, the ECJ

> "does not attach any direct effect, or even the rank of a legislative act with external effect, to harmonised standards adopted by a private European standardisation body, which would be included in a secondary Community law mechanism for the presumption of fitness for use of a product. The Court found that the standard only had binding effect insofar as its fulfilment was the basis for presuming that the relevant technical requirements were satisfied – which could also be proven by other means – and was therefore not permitted to deny the Member States market access on the grounds that the requirements were not satisfied. By contrast it expressly denied that the judge's assessment under (civil) law of the fitness of the product for its intended use was bound by the harmonised standard (cf. margin no. 3, 52 et seqq., 73)."[65]

Since the ECJ precisely did not attribute the harmonised standards to the Commission as a body of the EU, as illustrated above, their classification as acts of EU law would additionally require that the European standardisation organisations were granted legislative powers. Such delegation of powers, however, did not take place – which coincides with the ECJ's point of view. This is already reflected by the fact that the relations between the Commission and the European standardisation organisations are

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64 Cf. recital 54 et seqq.. of the *James Elliott* judgment (cf. fn. 24).

65 BVerwG, judgment of 19 September 2018 – 8 C 6/17, BVerwGE 163, 93, juris recital 27 (translation from German original).

governed by contracts and by jointly developed "General Guidelines for Cooperation".[66] The equivalence of the stakeholders is also shown by the fact that it is left to the European Standards Organisations to refuse standardisation requests from the European Commission, which is what actually happens in practice.[67] Even if such delegation had taken place, it is doubtful whether the restrictions imposed by the ECJ on the delegation of legislative powers to private entities could be observed.[68]

In addition, this would entail numerous other problems, for instance the publication of the standards themselves – not merely their references – in the Official Journal (cf. Article 297 (2)(2) TFEU) and the potential direct commitment of European and national standardisation organisations to fundamental rights (cf. Article 51 Charter of Fundamental Rights). The Union legislature clearly did not give any thought to any of this. This is further evidence that the Court was not proceeding on the assumption that the European standardisation organisations had the power to adopt EU legal acts.

Thirdly, constitutional problems would arise. According to the case-law of the German Federal Constitutional Court on the EU Banking Union, the transfer of legislative and enforcement powers to institutions not provided for in the EU treaties would face "not inconsiderable concerns".[69] Within the framework of Article 114(1) TFEU – the legal basis for the Standardisation Regulation and numerous harmonisation legislation – such a transfer would have to remain "limited to narrowly defined exceptions". Moreover, specific precautions are required to ensure that the measures of the body in question are democratically legitimised. If basic acts of the EU did not meet these requirements, the German Federal Constitutional Court would regard them as *ultra vires* and as a violation of the German constitutional identity and declare them inapplicable in Germany. Also to avoid such problems, harmonised standards should not be classified as act of Union law.

3. Interim result

Ultimately, one can conclude both from the context of the judgment and from systematic legal considerations that the ECJ, with its statement that harmonised standards

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66 General guidelines for cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association of 28 March 2003, OJ 2003, no. C 91, p. 7.

67 Most recently on 16 June 2020, when a standardisation request relating to medical devices (in support of Regulation (EU) 2017/745) and in-vitro diagnostics (in support of Regulation (EU) 2017/746) was rejected.

68 See ECJ, judgment of 22.01.2014, United Kingdom / Parliament and Council, C-270/12, EU:C:2014:418, recital 41-43; judgment of 13.06.1958, Meroni / High Authority, C-9/56, EU:C:1958:7.

69 See BVerfG, judgment of 30 July 2019 – 2 BvR 1685/14 et al., BVerfGE 151, 202, in particular recitals 240, 246 and 267 et seq.

formed part of Union law, merely wanted to establish its jurisdiction for preliminary rulings within the framework of Article 267 TFEU. The intention of the Court was evidently not to subject harmonised standards to the same conditions of effectiveness and legal consequences as other EU law and thus ultimately question the New Approach.

II. Powers and obligations of assessment of the Commission

According to Article 10(5), sentence 2, and (6) of the Standardisation Regulation, prior to publication of the reference of a harmonised standard in the Official Journal of the EU, the Commission shall assess whether the standard meets the requirements of the standardisation request. Although the Regulation does not contain any explicit provisions in this respect, the better reasons speak in favour of confining the Commission's powers of assessment essentially to formal aspects of compliance of the harmonised standard with the underlying standardisation request and harmonisation legislation. Thus, the Commission may not undermine the opinion-forming process of the European standardisation organisations by replacing the assessments of their technical committees with its own assessment (see 1.). Against this background, the comprehensive assessment powers the Commission appears to believe it has, judging from its more recent course of procedure, are likely to be partially incompatible with the requirements of the Standardisation Regulation (see 2.).

1. Scope and depth of the Commission's assessment under Article 10(5) and (6) of the Standardisation Regulation

For a long time, the publication of references of harmonised standards in the Official Journal was not preceded by a systematic and legally established ex ante control of the standard by the Commission.[70] For instance, a guidance document of the European Commission on the method of referencing standards in European legislation from the year 2002 reads:

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[70] Cf. e.g. Report from the Commission to the Council and the European Parliament, Efficiency and Accountability in European Standardisation under the New Approach, COM(1998)0291 final, No 6: „The New Approach also introduced institutional changes. Responsibility for presenting European standards as "harmonised" standards under the New Approach has been given to the European standardisation organisations. At the same time, public authorities have committed themselves to not insisting on approving the technical content of such standards; no positive decision is required by which authorities approve the standards, even if previously such technical aspects were subject of regulation." Cf. also *Schepel*, The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets, 2005, p. 235: "The Commission does not engage in any technical verification of the standards and publishes their references 'blindly'".

> "[T]he New Approach leaves the technical work complementing and specifying legislation to bodies without legislative authority. […] [A]n ex-ante control of the technical work by the legislator does not take place. The European legislator has faith in the accountability of the European Standards system. […]".[71]

This approach of limiting control to a mere ex-post control by means of formal objections changed when the Standardisation Regulation entered into force, which lead to a legalisation of the procedure and strengthened the Commission's role in the standardisation process. Article 10(5) and (6) of the Standardisation Regulation requires the Commission to carry out an assessment before publishing the reference of the standard in the Official Journal of the EU. The relevant provisions state:

> "(5) The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the documents referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.
>
> (6) Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the *Official Journal of the European Union* or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation."

Accordingly, before publishing the reference of a harmonised standard in the Official Journal, the Commission, together with the European standardisation organisations, must first assess whether the standard drawn up by the standardisation organisations complies with the standardisation request on which it is based (Article 10(5), sentence 2, of the Standardisation Regulation). Secondly, since paragraph (6) provides for publication of the reference in the Official Journal only if the standard "satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation", the sixth paragraph also appears to implicitly stipulate an

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[71] European Commission, Methods of referencing standards in legislation with an emphasis on European legislation, 2002, p. 9.

assessment obligation – this time solely on the part of the Commission without the participation of the standardisation organisations.[72]

The relationship between the two paragraphs and the assessments they provide for is not entirely clear. At first glance, the assessment to be carried out according to para. (5), sentence 2, falls short of that implicitly required by para. (6): whilst para. (5), sentence 2, provides that only the conformity of the standard with the standardisation request must be assessed, para. (6) requires conformity not only with request but also with the requirements of the respective harmonisation act.

On closer examination, however, the object of assessment referred to in both paragraphs will frequently be the same. By definition, harmonised standards serve to implement EU harmonisation legislation on the basis of a request made by the Commission (see Article 2(1)(c) of the Standardisation Regulation). A request for the development of such standards must clearly refer to the legal requirements it is intended to cover. The model for standardisation requests developed in Part II of the Vademecum accordingly provides that the "requirements to be met by the content of the requested European standards" shall be established in an annex.[73] There must be "a clear reference to the essential or other legal requirements that are the starting point for the requested deliverables". Thus, the standardisation request indispensably describes the content for the essential requirements of the relevant harmonisation legislation. Consequently, compatibility with the underlying requirements of the standardisation legislation, to be assessed according to para. 5, sentence 2, generally also implies compatibility with the underlying requirements of the harmonisation legislation.

However, according to the Vademecum there are differences between Article 10(5), sentence 5, and (6) of the Standardisation Regulation in terms of the time of the assessment: According to the Vademecum, the conformity assessment under Article 5 to be conducted in cooperation with the European standardisation organisations shall preferably be carried out before the standardisation organisation formally accepts a document.[74] By contrast, according to the workings of paragraph (6) the assessment shall take place before the decision on the publication of the reference of the standard in the Official Journal is taken, i.e. after the harmonised standard is ratified.

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72 German version: „Wenn eine harmonisierte Norm den Anforderungen genügt, die sie abdecken soll und die in dem entsprechenden Harmonisierungsrechtsvorschriften der Union festgelegt sind, [...]". French version: « Lorsqu'une norme harmonisée répond aux exigences qu'elle vise à couvrir et qui sont définies dans la législation correspondante d'harmonisation de l'Union [...] ».

73 European Commission, Vademecum – Part II (s. fn. 12), p. 25.

74 European Commission, Vademecum – Part I (see fn. 12), p. 30.

It can therefore be assumed that the *scope* of the assessments provided for in paragraphs (5), sentence 2, and (6) is basically the same. However, this leaves the question of the *depth* of the assessment to be conducted by the Commission. Since this cannot be derived directly from the Standardisation Regulation itself, it must be determined by way of interpretation, taking into account the Commission's working documents and the more recent case-law of the ECJ since the *James Elliott* judgment:

a) Interpretation of the wording

To begin with, the wording of Article 10 of the Standardisation Regulation is open to interpretation with regard to the depth of the Commission's assessment and allows for two different interpretations: On the one hand, it is conceivable that the Commission's assessment is limited to a purely formal comparison of the provisions of the harmonised standard with the requirements of the standardisation request in the sense of "ticking them off". The Commission would merely have to decide whether or to which extent the standard in question covers the requirements of the standardisation request and the harmonisation legislation. In this case, neither the substantive correctness of the standard, in particular its technical adequacy, nor the compliance with the procedural requirements of transparency and participation of the standardisation process would have to be assessed.

On the other hand, it is conceivable that the wording could be interpreted in the sense that under Article 10(5), sentence 2, and (6), the Commission would have to assess comprehensively whether a standard "satisfies" the requirements of the standardisation request and the harmonisation legislation in term of substantive law and the requirements of the Standardisation Regulation in formal terms. In particular, it could also be necessary to assess whether the provisions contained in it correspond to the state of the art.

b) Systematic interpretation

Likewise, a systematic interpretation taking into consideration the parallel clause of Article 11 of the Standardisation Regulation does not lead to an entirely clear result but suggests a certain restriction of the depth of the Commission’s assessment.

This provision makes it possible to raise formal objections against harmonised standards which do not fully comply with the relevant requirements of the harmonisation legislation. It reads as follows:

"Article 11 – Formal objections to harmonised standards

> (1) When a Member State or the European Parliament considers that a harmonised standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation, it shall inform the Commission thereof with a detailed explanation and the Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or after other forms of consultation of sectoral experts, decide,
> a) to publish, not to publish or to publish with restriction the references to the harmonised standard concerned in the Official Journal of the European Union;
> b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the Official Journal of the European Union."

Formal objections according to Article 11(1) of the Standardisation Regulation can relate not just to the incompleteness of a standard. A Member State or the European Parliament may comprehensively claim that a harmonised standard does not "entirely satisfy the requirements", which would include the claim of the incorrectness of its content.

This understanding of the formal objection procedure could initially suggest that the Commission's assessment obligation preceding publication of the references under Article 10(6) of the Standardisation Regulation would have to be interpreted in a comparably comprehensive sense. The wording of Articles 10(6) and 11(1) of the Standardisation Regulation is very similar: in both cases the crucial criterion is whether a harmonised standard "satisfies" the requirements of the harmonisation legislation in question.[75] In addition, the purpose of the Commission's ex-ante assessment is to correct any shortcomings in standards at an early stage, so as to avoid the need for raising formal objections ex-post. This follows from recital 25 of the Standardisation Regulation:

> "Due to the importance of standardisation as a tool to support Union legislation and policies and in order to avoid *ex-post* objections to and modifications of harmonised standards, it is important that public authorities participate in standardisation at all stages of the development of those standards where they may be involved and

[75] In the German version, the wording in both provisions is not the same, but very similar („*den Anforderungen genügt*"/„*den Anforderungen […] entspricht*").

especially in the areas covered by Union harmonisation legislation for products."

However, the procedural provisions of the Standardisation Regulation preclude such a parallel interpretation of the two provisions as complementary comprehensive powers of assessment: According to Article 10(1) and (2) of the Standardisation Regulation, the Commission adopts standardisation requests in the form of implementing decisions in the assessment procedure provided for in Article 22(3) of the Standardisation Regulation and Article 5 of the Comitology Regulation. In this procedure, the Commission is assisted by a committee of representatives of the Member States, whose opinion is in principle binding on the Commission (for more details see below C.IV.1.b)). The procedure for a formal objection under Article 11(1) of the Standardisation Regulation is similar. This procedure also ends with an implementing decision of the Commission, which is adopted under Article 11(5) and Article 22(2) or (3) of the Standardisation Regulation with the participation of the Committee of Representatives of the Member States.

By contrast, Article 10(6) of the Standardisation Regulation does *not* provide that the reference of a harmonised standard is published by way of a formal decision. *Nor* does it provide that the Commission is assisted by a committee of representatives of the Member States when examining a standard and subsequently publishing the reference. Instead, it states rather succinctly that the Commission shall publish the reference of a standard that satisfies the requirements in the Official Journal "without delay".

This remarkable circumstance suggests that the Union legislator wanted to restrict the Commission to a largely formal role at this stage. The intention was to set the course for the conformity of the harmonised standard with the requirements of the harmonisation legislation as early as the adoption of the standardisation request – for this reason, it is also provided that representatives of the Member States shall participate in the examination procedure.[76] The substantial preparation of the relevant standards, by contrast, is, on principle, to be the responsibility of the European standardisation organisations in a staged procedure. This, however, is inconsistent with the assumption that the Commission can use the assessment of harmonised standards prior to publication of their references in the Official Journal as a possibility to practically duplicate the standardisation activities of the technical committee or even to replace the content agreed by the standardisation organisations with its own technical rules.

[76] On the significance of the standardisation request also cf. ECJ judgment of 14 December 2017, Anstar, C-630/16, EU:C:2017:971, recital 35 et seq.

In its assessment preceding publication of the reference in the Official Journal, the Commission must therefore carry out a comparison of the standard with the standardisation request, which may well be detailed, but must primarily relate to formal aspects, completeness and consistency of the standard. A fundamental full review of the content of the standard shall not take place. It is (only) for this reason, that the Standardisation Regulation leaves this procedural step to the Commission alone, without the participation of the committee of representatives of the Member States.

If, on the other hand, there is concrete evidence – in particular following a formal objection – of a possible deficiency in the harmonised standard, this justifies an in-depth review of the content of the standard. However, such in-depth review can and should then only be carried out with the participation of the committee of representatives of the Member States.

If the Commission were always to be granted comprehensive substantive examination competence prior to the publication of references, as well as outside the procedure for formal objections, there would be no conceivable reason for the Union legislator to not subject this particular examination, of all things, to a comitology procedure under the Comitology Regulation.

c) Teleological interpretation

Another crucial argument against a comprehensive substantive assessment obligation on the part of the Commission is the history and purpose of the Standardisation Regulation.

As described above (see B.I.2. above), the Standardisation Regulation defines the procedures and responsibilities of the New Approach. Recital 5 of the Standardisation Regulation, for instance, accordingly states as follows:

> "European standards play a very important role within the internal market, for instance through the use of harmonised standards in the presumption of conformity of products to be made available on the market with the essential requirements relating to those products laid down in the relevant Union harmonisation legislation. Those requirements should be precisely defined in order to avoid misinterpretation on the part of the European standardisation organisations."

The statement of reasons of the Commission's proposal for the Regulation already provided similar explanations:

> "European standardisation is a process of voluntary, transparent and open cooperation, where industry,

> SMEs, public authorities and other civil society stakeholders work together. For the European industry, standards contain the collective technical expertise of the stakeholders involved and as such represent the consolidation of best practices in one particular."[77]

A comprehensive examination of the content of harmonised standards, including their technical aspects, by the Commission would be diametrically opposed to the nature and purpose of the New Approach. The responsibility for the content of standards would no longer lie with the European standardisation organisations, to whom this task was assigned on the grounds of legislative self-restraint, but ultimately with the Commission. Standards would therefore no longer be private sets of rules drawn up by the standardisation organisations, but quasi atypical implementing acts of the Commission. The basic principle of the New Approach, the objective of which is to give legislative requirements a concrete form by way of voluntarily applicable, non-binding technical specifications, would thus be thwarted.[78] Moreover, such a comprehensive examination of the content of harmonised standards would be likely to overburden the Commission both technically and in terms of human resources.[79]

This could not be countered by using external service providers (so-called HAS Consultants). It is true that the Commission is in principle entitled to seek assistance from service providers. However, the responsibility for the fulfilment of its tasks lies with the Commission itself and cannot be transferred to private entities.[80] Therefore, if one regarded a comprehensive assessment of harmonised standards as necessary, this would in principle have to be carried out by the Commission itself. External service providers could assist it, but not replace it. This is all the more so as the Union legislator has created a sophisticated system in the form of the Standardisation Regulation, that draws on the private expertise of standardisation organisations and their experts to support product regulation in the public interest. In this context, Article 10(5), sentence 2, of the Standardisation Regulation explicitly provides that the Commission "together with the European standardisation organisations shall assess" whether a standard complies with the initial request. It would therefore be incompatible with the Standardisation Regulation to replace the technical assessment of the standardisation organisations appointed for this purpose by the Union legislator with the assessment

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77 European Commission, Proposal for a Regulation of the European Parliament and of the Council on European standardisation, COM(2011) 315 final, p. 2.

78 Also *Karpenstein*, Gefährdet der EuGH den New Approach?, EuZW 2017, 321 et seq.

79 Similarly and earlier *Schepel*, Maastricht Journal of European and Comparative Law 20 (2013), 521, 533; similarly CEN/CENELEC, Position on the consequences of the judgment of the European Court of Justice on James Elliott Construction Limited v Irish Asphalt Limited, 17 May 2017, p. 6.

80 Cf. also on the limits of delegating powers to private entities: ECJ, judgment of 22.01.2014, United Kingdom / Parliament and Council, C-270/12, EU:C:2014:418, recital 41-43.

of private service providers whose role is not laid down in either the Standardisation Regulation or in harmonisation legislation. The Commission's increasing recourse to *HAS Consultants* is thus also an argument in favour of limiting their assessment to a primarily formal comparison of the harmonised standard with the request underlying it.

d) Commission working documents

In any case, until recently even the Commission itself seems to have taken the view that the assessment of harmonised standards to be carried out by the Commission does not cover their content. As already described above, the Commission even regarded such an assessment as largely or entirely dispensable for a long time before the Standardisation Regulation entered into force (see above under C.II.1). Guidelines from the year 2005 on the publication of the references of harmonised standards in the Official Journal provided that standards the reference of which were to be published had to be reviewed as to whether they were covered by the relevant directive and subject to the initial request. However, this too was limited to a purely formal comparison, which follows from the fact that the directive stated:

> "As a general rule, the Commission should not review the technical adequacy of the content of a standard. The ESO are responsible for the content and are expected to deliver correct data. Their procedures should ensure that the translated titles, as presented, refer to the correct identification number of the standard."[81]

The Commission has maintained this approach on principle – with a greater emphasis on its own testing scheme – even after the Standardisation Regulation entered into force. In the Blue Guide of 2016, which was developed as a follow-up to the Standardisation Regulation and is based on it[82], the Commission emphasises that the technical content of harmonised standards is the sole responsibility of the standardisation organisations and is not reviewed by public bodies:

> "The technical contents of such harmonised standards are under the *entire responsibility of the European standardisation organisations*. Once public authorities have agreed on a request, the search for technical solutions should in principle be left to the interested parties.

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81 European Commission, Guidelines for the publication of references of standards in the Official Journal of the European Union, 06 April 2005, D(2005) C2/MJE/IG – D (2005) 7049, p. 3.

82 Cf. European Commission, Blue Guide (fn. 13), p. 1, 8.

> In certain areas, such as the environment and health and safety, the participation of public authorities on a technical level is important in the standardisation process. However*, Union harmonisation legislation for products do not foresee a procedure under which public authorities would systematically verify or approve either at Union or national level the contents of harmonised standards*, which have been adopted by European standardisation organisations."[83]

The Commission also stresses that its examination of harmonised standards prior to the publication of the references does not relate to their technical content:

> "During this verification there is *no need for a review of the technical content* as the Commission does not, in general, accept the technical content or takes responsibility for it."[84]

A similar approach is taken in the Commission's Vademecum on European Standardisation. It provides that the assessment conducted by the Commission covers two aspects: On the one hand, it must be assessed "to what extent" a standard covers the legal requirements. On the other hand, the examination must determine whether the standard "addressed sufficiently" the requirements it covers. On the other hand, the Commission may not influence how the standardisation organisations "select specifications in the requested deliverables, as this is fully their responsibility"[85]. Thus, according to the Vademecum, too, examination by the Commission does not comprise the technical content of a standard.

Proceeding from these working documents, in November 2016 – and thus shortly after the *James Elliott* judgment of the ECJ – the Commission developed a kind of checklist for an internal assessment procedure to be carried out prior to the publication of the reference of a harmonised standard in the Official Journal of the Union.[86] The procedure comprises a total of three assessment steps, which in turn are divided into nine assessment questions: The first step is an assessment of the procedural modalities of the Standardisation Regulation, namely Articles 3, 5 and 6; the second step is a (purely) quantitative verification of the legal requirements aimed to be covered by the request for standardisation, usually a simple comparison with Annex Z (for CEN) or ZZ (for

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83 European Commission, Blue Guide (Fn. 13), p. 1, 41; own emphasis.

84 European Commission, Blue Guide (Fn. 13), p. 1, 45; own emphasis.

85 European Commission, Vademecum – Part I (fn. 12), p. 30 et seq.

86 European Commission, Verification of conditions for the publication of references of harmonised standards in the Official Journal, 16 November 2016, Ares(2016)6548298.

CENELEC) to be added by the standardisation organisations, which summarises in table form the information on the legal requirements to be covered by a harmonised standard.[87]

Less clear in terms of its scope is the – particularly relevant – third assessment step, which comprises a qualitative assessment of whether a standard "sufficiently satisfies the relevant legal requirements". The assessments provided for in this context are by all means detailed and partly their requirements are difficult to grasp. Some assessment points appear to be of a more methodological legal nature. For example, the aim is to examine whether a standard is inconsistent in itself, does not in fact (fully) cover a particular requirement, or gives the user a choice that is not provided for in the relevant harmonisation legislation. Other questions, on the other hand, might indicate that the Commission also intended to claim, for itself or the consultants supporting it, a (selective) substantive-technical power of assessment from the end of 2016: one of the verification questions requires, in any case, in the event of a revision of a standard already published in the Official Journal, an assessment of whether the level of safety, interoperability, repeatability, reproducibility, etc. has deteriorated and disregards developments in the state of the art or the actual legal obligation. However, the assessment was only to be carried out relatively, i.e. in comparison with the previously published standard; here too, an original technical assessment was not provided for.

The Commission hence does not appear to have finally abandoned its approach of leaving the substantive technical assessment to the standardisation organisations or the relevant technical committees until its Communication of 2018, in which it explains (see B.I.3. above) that following the *Elliott* judgment of the European Court of Justice it must "pay particular attention to the content of harmonised standards". This included not only "the technical aspects of standards, but also other elements of the European Standardisation Regulation, such as whether their development process" had been inclusive.[88]

87 Cf. Vademecum – Part III (fn. 12), p. 9.

88 European Commission, Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 22 November 2018, COM(2018) 764 final, p. 3.

e) Case-law of the ECJ: Irrelevance of the *James Elliott* judgment for the question of the depth of the assessment

The Commission invoked the *James Elliott* judgment of the ECJ as the reason for its altered position. On closer examination, however, the judgment does not define any requirements with regard to the Commission's power and duty of assessment.

The Court states in its grounds for the judgment that a harmonised standard is an implementing measure "strictly governed by the essential requirements defined by that directive, initiated, managed and monitored by the Commission".[89] However, the judgment does not define the meaning and scope of "managed" and "monitored". The grounds of the judgment provide no answers whatsoever to the question relevant here of the scope and depth of the assessment to be carried out by the Commission. The same is the case of the Advocate General's Opinion.[90]

Moreover, the above-cited text passage of the judgment clearly does not make any normative statement on the role of the Commission. It does not indicate that European standardisation may or must be "managed and monitored" by the European Commission in any particular way. In particular, it appears that the ECJ does not wish to make its jurisdiction for the interpretation of harmonised standards in the context of preliminary ruling procedures dependent on any particular threshold of influence of the Commission. Rather, it is clear from the context of the grounds of the judgment that the relevant passage merely describes the factual role that the Commission played in the preparation of harmonised standards under the former Construction Products Directive. The fact that the Commission plays a certain role in this respect is one of several arguments used in the grounds of the judgment to justify the Court's power of interpretation of harmonised European standards. This is evidently not linked to a request to the Commission to extend its assessment of harmonised standards.

It cannot be derived from the statement of the Court, namely that harmonised European standards are "part of Union law", either that such standards need to be subjected to a comprehensive examination by the Commission. As already explained (see above under C.I.1.c)), the ECJ's statement must be seen in the specific context of Article 267 TFEU. Outside this specific context, no further consequences can be deduced from the judgment, for example with regard to the necessary depth of the assessment to be carried out by the Commission. This is clearly confirmed by the fact that "part of Union

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89 See ECJ, judgment of 27 October 2016, James Elliott Construction, C‑613/14, EU:C:2016:821, recital 43.

90 Cf. Advocate General Campos Sanchez-Bordona, Opinion of 28 January 2016, James Elliott Construction, C-613/14, EU:C:2016:63.

law" in this sense also includes decisions of bodies of international law which the EU is involved in.[91] The *James Elliott* judgment refers to this explicitly.[92] However, such decisions are undoubtedly not subject to review by the Commission.

Subsequent rulings of the European courts on standardisation issues do not address the question of the depth of assessment either.[93] The extent to which the Commission is authorised and obliged to assess harmonised standards had to and still must therefore be determined (exclusively) by interpreting the Standardisation Regulation. The *James Elliott* judgment and the subsequent case-law have not changed this situation.

An interpretation of the Standardisation Regulation which could allow for the depth of assessment that the Commission (evidently) claims for itself could, if at all, result from a completely different context arising from a more recent line of case-law. The Treaty on the European Stability Mechanism (ESM), an instrument of international law outside the order of Union law, assigns certain tasks to the Commission when it grants financial support to Member States, within the framework of borrowed agencies. In this context, the ECJ has pointed out that Article 17(1) TEU assigns to the Commission the task of promoting the general interests of the Union and overseeing the application of Union law. It concluded that, even when acting outside the order of Union law, the Commission retains its role as the "guardian of the Treaties" and may not take part in measures whose consistency with Union law it doubts.[94]

As shown above, this line of case-law originates from a completely different context; there is no direct link with European standardisation and, as far as can be seen, no such link has been established in the ECJ's case-law. However, in view of the recent tendency to generally codify[95] standardisation as a whole, it cannot be entirely ruled out that the Court might also apply the topos "guardian of the Treaties" to the Standardisation Regulation. It is therefore conceivable that, based on a corresponding line of reasoning, the Commission could be granted a more comprehensive right and obligation of assessment regarding the question whether a harmonised standard meets the

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91 See ECJ, judgment of 20 September 1990, Sevince, C-192/89, EU:C:1990:322, recital 10; judgment of 21.01.1993, Deutsche Shell, C-188/91, EU:C:1993:24, recital 17.

92 See ECJ, judgment of 27 October 2016, James Elliott Construction, C‑613/14, EU:C:2016:821, recital 34.

93 Cf. ECJ, judgment of 22 February 2018, SAKSA, C-185/17, EU:C:2018:108, recital 39; General Court, judgment of 26 February 2017, GGP Italy / Commission, T-474/15, EU:T:2017:36, recital 60 et seqq.

94 See ECJ, judgment of 20 September 2016, Ledra Advertising / Commission and ECB, C-8/15 P, EU:C:2016:701, recital 59; judgment of 27 November 2012, Pringle, C-370/12, EU:C:2012:756, recital 163 et seq.

95 Cf. e.g. ECJ, judgment of 12 July 2012, Fra.bo, C-171/11, EU:C:2012:453, recital 32; judgment of 27 October 2016, James Elliott Construction, C‑613/14, EU:C:2016:821, recital 40; on the tendency to codify also see *Schepel*, Maastricht Journal of European and Comparative Law 20 (2013), 521; *Volpato*, Common Market Law Review 54 (2017), 591, 597.

underlying requirements of harmonisation legislation. However, even such examination rights would relate solely to the compatibility of the harmonised standard with Union law – in this case in particular with the respective underlying harmonisation legislation and the Standardisation Regulation – and could not justify a comprehensive technical examination of the standard. Moreover, even if the case-law were to be transferred to the Standardisation Regulation, the rule would continue to apply that the Commission must not, in any event, structurally undermine the opinion-forming process within the European standardisation organisations – and thus ultimately the New Approach – by using the assessment of harmonised standards prior to its decision to publish the reference as an opportunity to replace the decisions of the European standardisation organisations with its own decisions within the context of harmonised standards.

f) Interim result

According to the systematics and telos of Article 10(5) and (6) of the Standardisation Regulation, the Commission does not have jurisdiction to conduct a comprehensive and detailed technical assessment of the harmonised standards prepared by the standardisation organisations. In particular, it would be contrary to the nature and purpose of the New Approach if the Commission, with the help of HAS Consultants, was ultimately able to duplicate the standardisation process and substitute its assessment for that of the standardisation committees. According to its working documents, until very recently the Commission shared this perception. The *James Elliott* judgment of the ECJ and the subsequent case-law on which it now relies to extend its assessment competences does not contain any specifications regarding the necessary depth of assessment and is therefore not suitable to justify a change in its assessment practices.

2. Compatibility of the powers of assessment claimed by the Commission with the Standardisation Regulation

If the Commission's comments in its Communication of 2018 as illustrated above (see above under C.II.1.d)) must indeed be interpreted as meaning that the Commission now claims an unlimited right of assessment, this would not be compatible with the requirements of the Standardisation Regulation outlined above. This would particularly apply in the case of assessments of the content of standards, including a review of the technical content, i.e. specifically an assessment of whether the content laid down by the European standardisation organisation reflects the state of the art (see a)). But there are also legal concerns as to whether an examination of the requirements of

the Standardisation Regulation relating to transparency and inclusiveness of the standardisation procedure is permitted (see b)).

a) Unlawful duplication or replacement of standardisation activities by the Commission

Based on the interpretation above of the requirements of Article 10(5), sentence 2, and (6) of the Standardisation Regulation for the Commission's conformity assessment, there is much to suggest that the Commission's claim to (inter alia) thoroughly monitor and assess "the technical aspects of standards" would not be consistent with the requirements of the Standardisation Regulation, at least in this unlimited form. Such a far-reaching depth of assessment could therefore not be stipulated in a legally effective manner even in a recast of the Vademecum or the Blue Guide or the adoption of a new guidance document (for more details on legal protection see below under C.IV.2.).

A detailed substantive-technical assessment by the Commission would – as explained – run counter to the nature of the New Approach and would in fact amount to a return to detailed harmonisation, because the Commission would ultimately end up reviewing once again all the work done in the Technical Committees and possibly even replacing it with its own assessments. This would also pose the risk of already paralysing the process of harmonised standardisation in the short term, because the Commission would in all likelihood lack both the expertise and the human resources for such an examination. The resulting delays in the publication even of positively assessed standards have already occurred, as data from CEN/CENELEC shows. For example, the references of harmonised standards for the Radio Equipment Directive 2014/53/EU[96] were not published in the Official Journal in time before the expiry date of the prior standards.

A different assessment on the lawfulness of such comprehensive substantive and technical examinations by the Commission could probably not be derived from the above-mentioned case-law on the Commission's role as guardian of the Treaties either (see above under C.II.1.e)). Firstly, this case-law originate from a completely different context. Secondly, as explained, even if the case-law were to be transferred to the Standardisation Regulation, it would still apply that the Commission would be limited in its examination to legal questions of the compatibility of the standard with the harmonisation legislation and the Standardisation regulation, and would not be permitted to

[96] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the availability of radio equipment on the market and repealing Directive 1999/5/EC, OJ 2014, no. L 153, p. 63, last amended by Regulation (EU) 2018/1139 of the European Parliament and of the Council of 04 July 2018, OJ 2018, no. L 212, 1.

structurally undermine the opinion-forming process within the European standards organizations and thus ultimately the New Approach by replacing the decisions of the competent standards committees with its own decisions. Any other understanding would be incompatible with the basic decision of the European legislator expressed in the Standardisation Regulation.

b) Unlawfulness of an examination of the procedural requirements of Article 3 et seqq. of the Standardisation Regulation

In addition, according to its 2018 Communication, the Commission (as of late) considers itself obliged to "closely monitor the standardisation process." It is required to "thoroughly follow the development process of harmonised standards". One of the crucial aspects it states is "whether the process of developing harmonised standards is based on consensus and is transparent and inclusive".[97] Here, again, it seems questionable whether this is consistent with the requirements of the Standardisation Regulation.

The wording of the Standardisation Regulation does not provide an explicit basis for such a procedural test. Articles 4 through 6 of the Standardisation Regulation contain provisions relating to the transparency of standards, the participation of stakeholders and the access of SMEs. However, the addressees of these obligations are the national and European standardisation organisations, which are also obliged under cartel law to take these requirements into account. Accordingly, under the Commission's so-called Horizontal Guidelines it is presumed that standards only fall outside the scope of the ban on cartels according to Article 101(1) TFEU in the absence of a restriction on competition if there is an unrestricted possibility to participate in the standardisation process, if the procedure for adopting the standard in question is transparent, there is no obligation to comply with the standard and third parties are granted access on fair, reasonable and non-discriminatory terms.[98]

The European standardisation organisations take into account the requirements of stakeholder participation and transparency, inter alia, by organising, together with the national standardisation organisations, a public consultation[99] on the draft standard prior to its adoption. In the course of this consultation, all interested parties may submit comments through the national standardisation organisations, which are then examined by the relevant technical committee (see also Article 4(3) of the Regulation). This

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97 European Commission, Harmonised standards: Enhancing transparency and legal certainty for a fully functioning internal market, Communication to the European Parliament, the Council and the European Economic and Social Committee, 22 November 2018, COM(2018) 764 final, p. 3.

98 Ibid., recital 280.

99 Blue Guide (cf. fn. 13), p. 44.

is probably one of the reasons why the Standardisation Regulation does not provide for the Commission to examine to which extent the procedure for adopting the harmonised standard was transparent and inclusive before publishing a reference. A procedural equivalent to Article 10(5), sentence 2, and (6) of the Standardisation Regulation has wisely been omitted.

In this respect, the Regulation takes a different approach: pursuant to Article 17(4)(b) of the Standardisation Regulation, general inclusiveness is in principle a condition for granting Union subsidies to the standardisation organisations. According to this provision, grants will only be paid, except in sufficiently substantiated cases, if SMEs, consumer organisations and environmental and social stakeholders can participate adequately in European standardisation activities. This suggests that the Union legislator does not want the publication of the reference of an individual standard to depend on how inclusive the procedure for its adoption was. Rather, the procedural requirements of the Standardisation Regulation should be enforced via the granting of subsidies.

The Commission cannot circumvent this fundamental decision of the Union legislation by including procedural requirements in its standardisation requests in order to be able to assess compliance with them under Article 10(5), sentence 2, of the Standardisation Regulation. Such an approach would probably not be compatible with Article 10(1), sentence 3, of the Standardisation Regulation. According to this provision, the Commission shall determine in its standardisation request the requirements as to the content to be met by the requested document and a deadline for its adoption. Conversely, this suggests that a standardisation request may not contain any requirements relating to the standardisation procedure.

A contrary view on this issue, based on the cited case-law on the Commission's role as the role as 'guardian of the Treaties', does not seem entirely untenable. Here too, however, it must be borne in mind that the case-law originates from a completely different context. In addition, with regard to procedural issues of the standardisation process, the Commission already fulfils its role as 'guardian of the Treaties' as required by the ECJ in other ways, namely in the granting of subsidies and, where appropriate, in the context of cartel law. Even if the case-law could be transferred to the New Approach, the Commission would therefore not be entitled to comprehensively review the standardisation process in individual cases prior to its decision to publish the reference of a harmonised standard in the Official Journal.

3. Interim result

Article 10(5), sentence 2, and (6) of the Standardisation Regulation must be interpreted as meaning that the Commission may (and must) assess the conformity of a harmonised standard with the request on which it is based and the harmonisation legislation before publishing the reference of the standard in the Official Journal. But since it is precisely the nature of the New Approach that the technical specification of the essential requirements is left to the European standardisation organisations, the assessment is, however, limited to a largely formal comparison of the contents of the standard with the underlying requirements of the request. In particular, it is not the responsibility of the Commission to examine whether the contents of the standard correctly reflect the state of the art, since this assessment must be carried out within the standardisation organisations. In addition, the Standardisation Regulation does not provide for a comprehensive examination of the requirements relating to transparency and inclusiveness of the standardisation process prior to the decision to publish the reference of a harmonised standard in the Official Journal.

If the Commission were to attempt to lay down such a depth of assessment in a recast of its working documents, this would conflict with the requirements of the Standardisation Regulation.

III. Liability of the Union in connection with harmonised standards

The extent to which the EU is liable for damage caused in connection with harmonised standards has not been clarified in court. In principle, liability for the harmonised standard itself is unlikely; however liability for the Commission's own conduct, i.e. its decisions on standardisation requests, the publication of references of harmonised standards, or on formal objections, is conceivable (see 1.). In practice, however, such liability is unlikely to be significant, as the other conditions of a qualified breach and causality will regularly not be fulfilled (see 2. through 4.).

1. Attribution

a) Criteria

According to Article 340(2) TFEU, the Union shall make good any damage caused by its institutions or by its servants in the performance of their duties, in accordance with the general principles common to the laws of the Member States. The term 'institution'

within the meaning of Article 340(2) TFEU must be understood broadly. It covers not only the institutions in the strict sense, as defined in Article 13 TEU. Rather, the Union is in principle liable for the conduct of any institution established by or under the Treaties and empowered to act in the name and on behalf of the EU.[100] The Union's liability for the European Investment Bank[101] and the European Ombudsman[102], for example, has been affirmed. However, it was rejected for political groups in the European Parliament.[103] The behaviour of third parties, such as Member States, third countries or private individuals, does not generally lead to liability on the part of the EU.

However, the situation may be different where such bodies act on the instructions of a Union institution or as a result of a loan from the EU.[104] Not only binding, legal measures constitute potential grounds for liability but real acts and, where appropriate, omissions on the part of an institution, too.[105] According to recent case-law, even actions of the Commission and the ECB within the framework of the European Stability Mechanism (ESM), i.e. on the basis of an international treaty outside the Union order of law, may give rise to liability on the part of the Union.[106]

b) No direct liability for harmonised standards

According to the above principles, the EU is not directly liable for harmonised standards.

The European standardisation organisations are not bodies within the meaning of Article 340(2) TFEU. They are bodies governed by private law which, although referred to in Union legislation, do not have the power to act in the name and on behalf of the

100 Cf. ECJ, judgment of 01 December 1992, SGEEM / EIB, C-370/89, EU:C:1992:482, recital 15; in more depth *Jacob/Kottmann*, in: Grabitz/Hilf/Nettesheim, Das Recht der EU, 69. EL 2020, Art. 340 AEUV recital 69 et seqq.

101 See ECJ, judgment of 01 December 1992, SGEEM / EIB, C-370/89, EU:C:1992:482, recital 12 et seqq.

102 See ECJ, judgment of 23 March 2004, European Ombudsman / Lamberts, C-234/02, EU:C:2004:174, recital 52.

103 See ECJ, judgment of 22 March 1990, Le Pen / Puhl, C-201/89, EU:C:1990:133, recital 8 et seqq.

104 Cf. ECJ, judgment of 26 February 1986, Krohn / Commission, C-175/84, EU:C:1986:85, recital 23; judgment of 19 September 1985, Murri frères / Commission, C-33/82, EU:C:1985:354, recital 34 et seq.; judgment of 12.06.1962, Worms / High Authority, C-18/60, EU:C:1962:26, p. 417; in more depth *Berg*, in: Schwarze, EU-Kommentar, 4th ed. 2019, Article 340 TFEU recital 34.

105 Cf. ECJ, judgment of 07 November 1985, Adams / Commission, C-145/83, EU:C:1985:448, recital 44.

106 ECJ, judgment of 20 September 2016, Ledra Advertising / Commission and ECB, C-8/15 P, EU:C:2016:701, recital 55 et seqq.

EU. Nor do these organisations act on the instructions of the Commission when drafting standards. Under Article 10(3) of the Regulation, they are free to not accept standardisation requests, which, as has been pointed out, does indeed occur in practice.[107]

Furthermore, harmonised standards are not acts of a body within the meaning of Article 340(2) TFEU. In particular, they cannot be attributed to the Commission[108]. In its *James Elliott* judgment, the ECJ stated that the development of harmonised standards is indeed "managed and monitored by the Commission" and deduced its power of interpretation from this. At the same time, however, it stressed that such standards do not qualify as acts of a Union institution:

> "Second, it must be recalled that, according to case-law, the Court has jurisdiction to interpret acts which, while indeed adopted by bodies which *cannot* be described as 'institutions, bodies, offices or agencies of the Union', are by their nature measures implementing or applying an act of EU law."[109]

In particular, the Court – unlike the Advocate General – avoided classifying standardisation as a case of delegated legislation.[110] In a later judgment, the ECJ also emphasised that the standard in dispute there "was adopted not by an EU body, but by the CEN, an organisation governed by private law".[111]

c) Liability for the conduct of the Commission

By contrast, the Commission's conduct in connection with harmonised standards can on principle give rise to EU liability.

aa) Standardisation request

As stated above, the first sentence of Article 10(1) of the Standardisation Regulation provides that the Commission may, within the limitation of the competences laid down in the Treaties, request one or several European standardisation organisations to draft up a European standard or a European standardisation deliverable within a set deadline. In accordance with the third sentence of Article 10(1) of that Regulation, the

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107 See above fn. 67.

108 Likewise *Colombo/Eliantonio*, Maastricht Journal of European and Comparative Law 24 (2017), 323, 328; *Volpato*, Common Market Law Review 54 (2017), 591, 601; dissenting opinion: *Tovo*, Common Market Law Review 55 (2018), 1187, 1195 et seqq.

109 ECJ, judgment of 27 October 2016, James Elliott Construction, C-613/14, EU:C:2016:821, recital 34; own emphasis.

110 Cf. Opinion of Advocate General *Campos Sanchez-Bordona* of 28 January 2016, James Elliott Construction, C-613/14, EU:C:2016:63, recital 55.

111 ECJ, judgment of 22 February 2018, SAKSA, C-185/17, EU:C:2018:108, recital 38.

Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption. As follows from Article 10(2) of the Standardisation Regulation, such standardisation requests are issued in the form of an (implementing) decision in the comitology procedure according to Article 22(3) of the Regulation.

Such a decision undoubtedly constitutes an act of an institution which, under Article 340(3) TFEU, may, in principle, render the Union liable. In practice, however, causality is likely to be lacking in this respect. For according to Article 10(3) of the Standardisation Regulation, the European standardisation organisations are free on principle to reject a standardisation request (see above C.I.2.b)).

bb) Assessment and publication of references

According to Article 10(5), second sentence, of the Standardisation Regulation, the Commission together with the European standardisation organisations shall assess the compliance of the documents with the initial request. According to Article 10(6) of the Regulation, the Commission shall publish a reference of a harmonised standard in the Official Journal "without delay" if it "satisfies the requirements which it aims to cover and which are set out in the corresponding Union legislation".

Accordingly, the conduct of the Commission in this context may in principle also give rise to liability on the part of the EU under Article 340(2) TFEU. More recently, the Commission appears to be proceeding on the assumption that it is required to adopt a separate implementing decision on the publication of a reference. This interpretation is not the most obvious one considering the systematics of Article 10 of the Standardisation Regulation. While the Union legislator firmly prescribes that standardisation requests within the meaning of Article 10(1) of the Regulation must be adopted in the form of a decision, there is no corresponding provision for the publication of a reference. For the present question of liability, however, this question may be left unanswered, since Article 340(2) TFEU is applicable not only to binding acts of law but also to notifications, real acts, or omissions.

It is therefore also clear that an expansion of the Commission's activities potentially increases liability risks. The more the Commission influences the standardisation process or the content of a standard beyond the wording of the Regulation, the more likely it is to be held responsible for any damage.

cc) Decision on formal objections

Under Article 11(1) of the Standardisation Regulation, where a Member State or the European Parliament considers that a harmonised standard does not entirely satisfy the requirements in question, it must inform the Commission accordingly. The Commission shall then decide whether or not to publish the references concerned or to publish them with restrictions or to maintain them, maintain them with restrictions, or withdraw them from the Official Journal.

If the Commission makes a mistake in this respect, this too may in principle give rise to liability of the Union under Article 340(2) TFEU. In this respect, reference can be made to the statements above.

2. Breach of rule of law for the protection of the individual

a) Criteria

According to established case-law, liability under Article 340(2) TEUF requires that a breach of a "rule of law for the protection of the individual has occurred".[112] Therefore, it must be determined whether (i) the provision in question is also intended to protect individual interests and (ii) whether the claimant belongs to the circle of protected persons. Protection of the individual in this sense is provided, for example, by EU fundamental rights and freedoms.[113] This can also be the case with secondary legislation. For example, the Commission's powers of examination under the Merger Regulation protect the individual in relation to the companies concerned.[114] By contrast, the principles of the division of competences between the EU and the Member States[115] and the Commission's power to initiate infringement proceedings[116], for example, do not have protective character. Similarly, the tasks of the supervisory authorities for deposit-guarantee schemes under Directive 94/19 did not protect individuals in relation to depositors in the respective credit institutions.[117] The fact that a provision is intended solely to protect the public interest does not, however, rule out the possibility

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112 See ECJ, judgment of 04 July 2000, Bergaderm / Commission, C‑352/98 P, EU:C:2000:361, recital 41 et seq.; judgment of 09 September 2008, FIAMM / Rat und Commission, C‑120/06 P, EU:C:2008:476, recital 172 et seq.

113 In detail *Jacob/Kottmann*, in: Grabitz/Hilf/Nettesheim, Das Recht der EU, 69. EL 2020, Art. 340 AEUV recital 78 et seqq.

114 See General Court, judgment of 09 September 2008, MyTravel Group / Commission, T-212/03, EU:T:2008:315, recital 44 et seqq.

115 ECJ, judgment of 13 March 1992, Vreugdenhil / Commission, C-282/90, EU:C:1992:124, recital 20.

116 ECJ, decision of 23 May 1990, Asia Motors France, C-72/90, EU:C:1990:230, recital 13.

117 ECJ, judgment of 12 October 2004, Paul, C-222/02, EU:C:2004:606, recital 30.

that its infringement may at the same time conflict with other provisions which themselves protect individuals.[118]

b) Commission's assessment obligations

Regardless of their material scope, the assessment obligations of the Commission under Article 10(5) and (6) of the Standardisation Regulation could qualify as such a rule of law for the protection of the individual.

Assessment obligations are primarily in the public interest. Their purpose is to ensure that harmonised standards comply with the relevant standardisation request. In this respect, Article 10(1), second sentence, of the Standardisation Regulation provides that standards must take account of the public interest.

Furthermore, recital 5 of the Regulation stresses that standards are "of vital importance for the internal market".

However, this does not rule out that the Commission's assessment obligations may also protect the individual interests of enterprises and/or consumers affected by standards. For example, recital 11 of the Regulation states that for the content of standards "the needs of the economic operators and stakeholders directly or indirectly affected by such standards prevail". Similarly, Recital 22 of the Regulation recognises that standards can have "a broad impact", inter alia, on "the safety and well-being of citizens". Against this background, there are strong arguments in favour of an assessment obligation on the part of the Commission that serves these interests.

However, the EU's responsibility for liability only goes as far as the Commission's assessment obligation goes. As already explained, the better reasons speak in favour of limiting the Commission's power and obligation to assessing harmonised standards in terms of formal aspects such as completeness and consistency, and not comprehensively in terms of the adequacy of their content (see above under C.II.). On this basis, only the publication of the reference of an incomplete standard or one containing logical inconsistencies would be relevant for liability. On the other hand, the EU would not have to take responsibility for the publication of the reference of a standard which later proves to be technically deficient. Against this background, the recent tendency of the Commission to interpret its assessment obligations widely bears a certain risk with regard to liability rules.

[118] ECJ, judgment of 19 April 2012, Artegodan / Commission, C-221/10 P, EU:C:2012:216, recital 81.

3. Sufficiently serious breach of law

According to established case-law, not every unlawful conduct of an institution gives rise to liability under Article 320(2) TFEU. Rather, what is required is a "sufficiently serious" breach of the law.[119] Contrary to German public liability law, no fault is required on principle. However, the criteria developed by the ECJ often lead to similar results.[120] Thus, a breach is 'sufficiently serious' if a Union institution has 'manifestly and gravely' disregarded the limits on its discretion.[121] This depends, inter alia, on the clarity and precision of the rule breached, the measure of discretion left to the acting body and whether the damage caused was intentional or involuntary.[122] In general, the Union Courts have a rather restrictive approach to liability under Article 340(2) TFEU. This is similar to the approach of German courts to official liability under § 839 BGB in conjunction with Article 34 GG.

Consequently, one would assume that the liability risks associated with harmonised standards are limited. According to settled case-law, the Commission enjoys a "wide margin of discretion" when assessing technically and scientifically complex issues. Judicial review is limited to the question whether there has been a "manifest error of appraisal".[123] The ECJ has granted such a wide discretion to the Commission in particular when deciding on formal objections to harmonised standards in the field of construction products.[124] The judgment of the ECJ is not convincing for other reasons. However, it is comprehensible that the Commission would enjoy a wide margin of discretion when assessing harmonised standards.[125]

Against this background, it will often not be possible for the applicant to prove a sufficiently serious breach of the Commission's assessment obligations, irrespective of

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119 Established case-law since ECJ, judgment of 02 December 1971, Zuckerfabrik Schöppenstedt / Rat, C-5/71, EU:C:1971:116, recital 11.

120 In more depth *Jacob/Kottmann*, in: Grabitz/Hilf/Nettesheim, Das Recht der EU, 69. EL 2020, Art. 340 AEUV recital 87 et seqq.; *Lenaerts/Maselis/Gutman*, EU Procedural Law, 2014, p. 522 et seqq.

121 ECJ, judgment of 04 July 2000, Bergaderm / Commission, C-352/98, EU:C:2000:361, recital 43.

122 Cf. ECJ, judgment of 05 March 1996, Brasserie du pêcheur, C-46/93, EU:C:1996:79, recital 56.

123 See ECJ, judgment of 21 November 1991, TU Munich, C-269/90, EU:C:1991:438, recital 13; judgment of 08 July 2010, Afton Chemical, C-343/09, EU:C:2010:419, recital 28; General Court, judgment of 11 September 2002, Pfizer Animal Health, T-13/99, EU:T:2002:209, recital 166 et seqq.

124 See General Court, judgment of 09 July 2019, Germany / Commission, T-53/18, EU:T:2019:490, recital 57 et seq.

125 An appeal by the Federal Republic of Germany is pending against the judgment, alleging, inter alia, that the General Court granted the Commission de facto a completely unrestricted discretion, thereby infringing Regulation (EU) No 305/2011. However, the appeal does not challenge the very principle that the Union institutions have a certain margin in assessing technically complex issues.

the scope of its assessment obligations. Liability should therefore be limited to severe and rare cases.

4. Causality

Finally, according to settled case-law, liability under Article 340(2) TFEU presupposes that there is a causal link between the disputed breach and the alleged damage. This is missing if the damage is ultimately due the injured party's own conduct or the intervention of a third party.[126]

This requirement is another reason why claims for damages against the EU in connection with standards are likely to fail regularly. According to the product harmonisation legislation, the economic operators addressed, who usually are the manufacturer or his authorised representative, must themselves ensure that the product complies with the essential requirements before placing it on the market.[127] They cannot escape this responsibility by applying harmonised standards. Even when applying harmonised standards, a manufacturer bears the sole responsibility for assessing all risks associated with his product.[128] Harmonised standards and the associated presumption of conformity are instruments of market access. Their sole purpose is to ensure the free movement of the products concerned, but they do not define the liability of their users.[129]

5. Interim result

As a result, EU liability for damages connected with deficient harmonised standards can generally be ruled out, if only because the condition of causality or a sufficiently qualified infringement, which are required for liability, is not fulfilled. In principle, however, it is conceivable that the EU could be held liable for decisions taken by the Commission under the Standardisation Regulation concerning standardisation requests, publications of references of harmonised standards or formal objections – but not for the harmonised standard itself. The EU's responsibility for liability thus only goes as far as the Commission's assessment obligation goes. Against this background, the Commission's tendency to significantly extend its assessment is counterproductive

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126 See ECJ, judgment of 09 September 2008, FIAMM / Council and Commission, C-120/06 P, EU:C:2008:476, recital 106; judgment of 18 March 2010, Trubowest / Commission, C-419/08, EU:C:2010:147, recital 61; judgment of 07 July 1987, Étoile commerciale / Commission, C-89/86, EU:C:1987:337, recital 18 et seqq.

127 See, e.g., Article 5(1)(a) of the Machine Directive.

EU standards committee 128 Blue Guide (fn. 13), p. 42.

129 See ECJ, judgment of 27 October 2016, James Elliott Construction, C‑613/14, EU:C:2016:821, recital 50 et seqq.

in terms of liability, as this potentially also entails an extension of the EU's liability risks.

IV. Role of the Member States and the EU Committee on Standards in the standardisation process and means of redress

Through their national representatives on the EU Committee on Standards pursuant to Article 22 of the Standardisation Regulation, the Member States have an important role to play in key procedural steps within the standardisation process (see 1.). They can also take action against individual procedural steps of the Commission which they consider to be unlawful, both by means of an action for annulment and an action for failure to act (see 2.).

1. Participation of the EU Committee on Standards in the standardisation process

Article 22(1) of the Standardisation Regulation provides that the Commission shall be assisted in its activities under the Regulation by a committee. The committee is a committee within the meaning of the Comitology Regulation,[130] composed of representatives of the Member States (see Article 3(2) Comitology Regulation). It is chaired by a representative of the Commission, who does not have the right to vote (Article 3(2) Comitology Regulation).

The Standardisation Regulation provides at various points for the participation of the committee in decisions to be taken by the Commission, although the influence of the committee varies according to the participation procedure prescribed. In particular, participation is provided for in the adoption of the annual work programme for European standardisation under Article 8(4) of the Standardisation Regulation (see a)), in making standardisation requests to one or more standardisation organisations under Article 10(2) of the Standardisation Regulation (see b)) and in the decision on the publication of the reference of a harmonised standard in the Official Journal following formal objections pursuant to Article 11(1) of the Standardisation Regulation (see c)).

a) Adoption of the work programme for European standardisation

According to Article 8 of the Standardisation Regulation, the Commission adopts an annual work programme for European standardisation. The programme specifies, inter

130 See above fn. 15.

alia, the standards with which it intends to mandate the European standardisation organisations in accordance with Article 10 of the Regulation. The work programme is adopted after full consultation of the relevant stakeholders, the European standardisation organisations and the Member States represented in the Committee on Standards (Article 8(1) and (4) of the Regulation). The Committee's influence in this procedure is therefore rather limited to a right of consultation.

b) Adoption of standardisation requests

The Committee – and thus the representatives of the Member States who sit on it – has greater influence over the adoption of standardisation requests (so-called mandates).

As already explained on several occasions, the Commission may mandate one or more European standardisation organisation to draw up a European standard within a given period (Article 10(1) of the Standardisation Regulation; cf. also, for example, Article 17(1) of the Construction Products Regulation). Subject to an amendment to Annex I of the Standardisation Regulation, which lists the – currently three – European standardisation organisations exhaustively, this shows clearly that it is not permitted to mandate other organisations with the task of setting technical standards. The procedures laid down by the Standardisation Regulation are mandatory and are not at the discretion of the Commission. The Union legislator has deliberately chosen to place European standardisation in the hands of the European standardisation organisations, whose activities are regulated, inter alia, by the Standardisation Regulation. Moreover, under the relevant harmonisation instruments, standards drawn up by a European standardisation body alone can regularly give rise to a presumption of conformity which is important for the free movement of goods. Any standards set by alternative bodies would not have such an effect.[131]

According to Articles 10(2) and 22(3) of the Standardisation Regulation in conjunction with Article 5 of the Comitology Regulation, a standardisation request is adopted as an implementing decision of the Commission in the so-called assessment procedure. This procedure essentially takes place as follows:

– The Chair, a representative of the Commission, submits the draft standardisation request to the Committee. If the Committee delivers a positive opinion, the Commission adopts the request (Articles 3(3) and 5(2) of the Comitology Regulation). According to Article 5(1) of the Comitology Regulation, the opinion is delivered by qualified majority, in line with the decision-making process in the

131 See, e.g., Article 2 lit. l) and Article 7(2) of the Machine Directive 2006/42/EC.

Council. This means that a majority of at least 55% of the members of the Committee, which is composed of at least 15 members, is required, provided the Member States represented by them represent at least 65% of the population of the Union.[132]

– If, on the other hand, the Committee delivers an unfavourable opinion, again by the abovementioned qualified majority, the Commission shall not adopt the request.[133]

– If the Committee does not deliver a formal opinion within the meaning of the Standardisation Regulation at all (for example, because no qualified majority can be obtained for either adoption or rejection of the draft), the following applies:

  - In principle, Article 5(3) of the Comitology Regulation allows the Commission to adopt the standardisation request in such a case.

  - However, if no opinion is given as provided for in Article 5(4)(2)(a) of the Comitology Regulation, the Commission may *not* adopt the standardisation request if it concerns the "protection of the health or safety of humans, animals or plants". This should regularly be the case for standardisation requests based on product safety directives. According to Article 10(1), sentence 3, of the Standardisation Regulation, a standardisation request specifies the requirements for the content of the standard concerned. As recital (22) of the Regulation acknowledges, such content may have "a broad impact" on, inter alia, "the safety and well-being of citizens". Consequently, the Commission *cannot* make requests for safety and health standards if the Committee on Standards abstains.

  - Furthermore, according to lit. c) of Article 5(4), second subparagraph, of the Comitology Regulation, the Commission may not adopt a standardisation request even if the members of the Committee reject it by a simple majority, i.e. by a majority of the component members.[134] Thus, a simple majority in

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132 See Article 5(1) of the Comitology Regulation in conjunction with Article 16(4) TEU.

133 The derogation provided for in Article 7 of the Comitology Regulation, where there is a risk of significant disruption of agricultural markets or a risk for the Union's financial interests, does not seem to be relevant in the case of standardisation.

134 The fact that a simple majority of the members of the Committee is required is not clearly expressed in the German language version, which speaks only of "simple majority". However, other language versions like the English version are unambiguous in this respect (see also French: "*une majorité simple des membres qui composent le comité*"; Spanish: "*una mayoría simple de los miembros que componen el comité*").

the Committee on Standards is sufficient to prevent a standardisation request.

This procedure, which is laid down in the Standardisation and Comitology Regulations, cannot be changed unilaterally by the Commission. In particular, the Commission cannot issue a non-binding communication to limit the influence of the Committee provided for by law. Against this background, the wording under point 1. of the Communication of 22 November 2018, stating that the Commission "shall develop the standardisation requests in an inclusive and transparent procedure together with the Member States"[135], must be understood as a reference to the assessment procedure under Articles 10(2) and 22(3) of the Standardisation Regulation in conjunction with Article 5 of the Comitology Regulation.

However, since it is (solely) the Commission's responsibility to submit a proposal for a standardisation request in the context of the assessment procedure, the Commission is in principle free to deviate from the model structure provided for in Part II of the Vademecum and, for example, to change the wording and content of the articles in relation to the model structure. It is also conceivable that the model structure could be generally adjusted as part of a revision of the Vademecum or a recast in a new Guidance Document without the approval of the Member States or the Committee. It is of course possible for the representatives of the Member States in the Committee to deliver a negative opinion on such draft standardisation requests – even on a case-by-case basis – if, for example, they do not wish to support the inclusion of a limit on the period of validity of standardisation requests. As described above, a simple majority of the component members of the Committee is sufficient to prevent the Commission from adopting the request. However, the Commission's sole right of initiative means that the Committee cannot itself modify the content of the request or adopt only certain articles of the proposal. Indirectly, however, the rejection can undoubtedly put pressure on the Commission to withdraw its proposal or to present it in an amended form if only then it can be sure of the sufficient qualified majority in the Committee.

c) Assessment and publication of references

In the context of the ex-ante assessment of a harmonised standard by the Commission before publication of its reference in the Official Journal, the wording of the Standardisation Regulation does not provide for a procedural role of the Member States, as already illustrate above (see C.II.1.b)). Against this background, there is no reason to

135 European Commission, Communication of 28 November 2018, COM(2018) 764 final, p. 2.

object to the Commission stating in the Communication that it will publish the reference in the Official Journal if the standard is in conformity with the request and Union legislation.[136] It is unclear and not mentioned in the Standardisation Regulation whether the decision on publication must take the form of a (implementing) decision of the Commission. As already explained, this is not evident (see above under C.III.1.c)bb)). However, ultimately this is of no significance for the Member States, since they are not entitled to any participation rights in the decision on publication of the reference, irrespective of the legal form chosen.

By contrast, the Committee does have a right of participation in the decision to publish the reference of a harmonised standard in the Official Journal, if formal objections have been raised against the harmonised standard under Article 11(1) of the Standardisation Regulation. If the Commission decides, in response to an objection raised prior to publication, either to publish the reference of the harmonised standard in the Official Journal or not to publish it or to publish it only with restrictions (Article 11(1)(a) of the Standardisation Regulation), the so-called advisory procedure applies.[137] In this procedure, the Committee delivers its opinion, if necessary by taking a vote. In case of a vote, the opinion must be delivered by a simple majority of the members of the committee. The Commission then decides on publication, taking "the utmost account of the conclusions drawn from the discussions with the committee and of the opinion delivered" (Article 4(2) of the Comitology Regulation). The Commission is therefore not formally bound by the opinion of the Committee and may, if necessary, disregard it.

If, according to Article 11(1)(b) of the Standardisation Regulation, a formal objection to a harmonised standard is raised subsequently, the Commission must decide whether to maintain, restrict or withdraw the reference of the harmonised standard in the Official Journal. This decision is taken in accordance with Articles 11(5) and 22(3) of the Standardisation Regulation in conjunction with Article 5 of the Comitology Regulation – as is the adoption of standardisation requests – in the so-called assessment procedure. With regard to the procedural requirements, reference is made to the comments above under C.IV.1.b).

136 Ibid., p. 3.

137 Article 11(4), Article 22(2) of the Standardisation Regulation in conjunction with Article 4 of the Comitology Regulation.

2. Legal remedies of the Member States against procedural acts of the Commission

The Member States may take action against individual procedural steps of the Commission, either by way of an action for annulment or by way of an action for failure to act (see a)). It is questionable whether standardisation organisations can also bring admissible actions against procedural acts of the Commission before the European Courts (see b)).

a) Types of action

The legal nature of the publication of references under Article 10(6) of the Standardisation Regulation is – as explained above – unclear and controversial. More recently, the Commission assumed that it has to publish the references of harmonised standards by means of a formal decision listed in Part L of the Official Journal. However, this classification is irrelevant for legal protection. According to Article 263(1) TFEU, an action for annulment may be brought, inter alia, against any "act" of the Commission, unless recommendations or opinions are concerned. According to established case-law, this means this that an action for annulment can be brought against all acts which – irrespective of their form – are intended to produce binding legal effects.[138] Accordingly, the General Court has already ruled that the publication of the reference of a harmonised standard qualifies as an act which is open to challenge in the action for annulment.[139]

The same is likely to apply in the opposite case where the Commission refuses to publish a reference. Such a measure also produces binding legal effects by denying a harmonised standard the presumption of conformity and the (limited) status attached to it as forming "part of Union law".[140] An action for annulment can therefore also be brought against the (final) refusal to publish a reference. In this context, it should also be noted that according to Article 296(2) TFEU, the Commission must provide reasons for its acts. This obligation is not limited to formal measures, but includes all measures which produce binding effects.[141] Thus, if the Commission refuses to publish a reference, it must state sufficient reasons for doing so. If it fails to do so, the refusal is

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138 ECJ, judgment of 31 March 1971, Commission / Council (AETR), C-22/70, EU:C:1971:32, recital 38; judgment of 20 September 2016, Mallis und Malli / Commission and ECB, C-105/15 P, EU:C:2016:702, recital 51.

139 General Court, judgment of 26 February 2017, GGP Italy / Commission, T-474/15, EU:T:2017:36, recital 60.

140 Cf. ECJ, judgment of 27 October 2016, James Elliott Construction, C‑613/14, EU:C:2016:821, recital 38 et seqq.

141 See ECJ, judgment of 01 October 2009, Commission / Council, C-370/07, EU:C:2009:590, recital 42.

already unlawful on grounds of breach of essential procedural requirements and must be set aside by the Union Courts.

Legal protection also exists against delays in the publication of references. Pursuant to Article 265(1) TFEU, an action for failure to act may be brought against an institution of the Union for failure to adopt a legally relevant act in breach of its obligations. Under the second paragraph of Article 264 TFEU, the precondition for an action for failure to act is that the institution concerned has first been called upon to act and has not complied with that request within two months. Under Article 10(6) of the Standardisation Regulation, the Commission shall publish "without delay" the reference of a harmonised standard in the Official Journal when it satisfies the relevant requirements. If the Commission fails to act and does not comply with the request for action, the available remedy is an action for failure to act.

b) Legal standing

The Member States have the right to bring both types of action. As so-called privileged applicants, they can bring actions for annulment and actions for failure to act pursuant to Article 263(2), 265(1) TFEU without having to demonstrate that they are legally affected.[142]

Individual market participants, on the other hand, do not have the right to bring an action. Pursuant to Article 263(4), Var. 2 TFEU, any natural or legal person may bring an action for annulment against an act which directly and individually affects him. This requirement is also applied by case-law to actions for failure to act. It provides that natural or legal persons may bring proceedings for failure to act where a Union institution has failed to act in respect of an act which is of direct and individual concern to them. [143] Direct concern shall be presumed where an act has a direct effect on the legal position of the applicant without further acts being required.[144] A person is individually concerned when an act affects him or her by reason of certain attributes which are peculiar to him or her or which by reason of other circumstances set him or her

142 In more detail *Dörr*, in: Grabitz/Hilf/Nettesheim, Das Recht der EU, 69th EL 2020, Art. 263 AEUV recital 52.

143 See General Court, decision of 04 May 2012, UPS Europe / Commission, T-344/10, EU:T:2012:216, recital 34 with further references

144 See, e.g., ECJ, judgment of 13 October 2011, Deutsche Post / Commission, C-463/10 P, EU:C:2011:656, recital 44.

apart from other persons. This is confirmed by case-law, in particular where EU secondary legislation grants a person certain procedural rights.[145] Individual market participants who are all affected in the same way by failure to publish the reference of a harmonised standard in the Official Journal and who are not granted their own procedural rights in the Standardisation Regulation are not affected individually.

The legal standing of standardisation organisations is questionable. In contrast to market participants, standardisation organisations are likely to be *individually* affected by the publication of a reference or its rejection, since the Standardisation Regulation gives them an important procedural position.[146] However, there is much to suggest that the organisations are not *directly* affected. The legal effects of a publication of a reference in the form of a presumption of conformity affect the market participants (even if not individually) and the authorities of the Member States.[147] For the standardisation organisations themselves, however, publication of a reference directly generates neither rights nor obligations. The same applies to the refusal to publish a reference. In particular, the financing of the standardisation organisations under the Standardisation Regulation is linked to the development and revision of standards, but not formally to the publication of their references in the Official Journal. Obligations of the national standardisation organisations – such as the obligation to withdraw conflicting national standards – are also not specifically linked to the publication of the reference in the Official Journal. Against this background, there are many reasons to suggest that standardisation organisations do not have the right to bring actions for annulment or for failure to act due to (omitted) procedural steps by the Commission. However, this has not been clarified by the ECJ, so that a different decision seems possible.

3. Interim result

The EU Committee on Standards, which is composed of representatives of the Member States, supports the European Commission in its activities under the Standardisation Regulation. It is involved in various decision-making processes of the Commission, in particular in the adoption of standardisation requests. If the committee delivers a negative opinion by qualified majority on a draft standardisation request, the Commission cannot adopt it. If the committee does not deliver an opinion, for example because no

145 See, e.g., ECJ, decision of 16 September 2005, Schmoldt / Commission, C-342/04 P, EU:C:2005:562, recital 40; in more detail *Kottmann*, Plaumanns Ende: Ein Vorschlag zu Artikel 263 Abs. 4 AEUV, ZaöRV 2010, 547, 549 et seq.

146 Cf. General Court, decision of 25 May 2004, Schmoldt / Commission, T-264/03, EU:T:2004:157, recital 100 et seq.

147 Cf. General Court, decision of 25 May 2004, Schmoldt / Commission, T-264/03, EU:T:2004:157, recital 91 et seqq.

qualified majority can be obtained for either adoption or rejection, the Commission is likewise prevented from adopting the standardisation request if it concerns the protection of the health or safety of humans, animals or plants, as will regularly be the case. The same applies if the Committee rejects the proposal (only) by a simple majority, i.e. a majority of the component members.

Member States may seek redress before the European Courts against individual procedural steps taken by the Commission under the Standardisation Regulation. An action for annulment may be brought against the Commission's decision to publish the reference of a harmonised standard in the Official Journal or against the final refusal of such publication. In addition, Member States may also bring an action for failure to act when the Commission does not publish a harmonised standard in the Official Journal despite a request for action and even though the standard meets the legal requirements

V. Importance of guidelines, guidance notes and similar working documents

In the field of European standardisation, guidance and similar documents published by the Commission, in particular the Blue Guide[148] and the Vademecum[149], are of considerable practical importance. In principle, the Commission is free to adopt such guidelines or working documents (see 1.). As a rule, they are not legally binding, but they may establish a Commission commitment (see 2.). Due to their legally non-binding nature, they may not, in principle, be challenged in court (see 3.).

1. Development of guidance documents

The adoption of guidelines, communications, guidance notes or similar working documents is in principle permitted, even if the Treaties or secondary legislation do not contain a specific legal basis for it.[150] Said documents must however remain within the limits of the applicable law. Therefore, they may not depart from the relevant provisions of the Treaties or secondary legislation.[151] Secondly, they may not contain legally

148 See fn. 13.

149 See fn. 12.

150 Cf., e.g., ECJ, judgment of 18 July 2013, Schindler Holding / Commission, C-501/11 P, EU:C:2013:511, recital 68; in more detail *Gundel*, Der prozessuale Status der Beihilfenleitlinien der EU-Kommission, EuZW 2016, 606, 607.

151 Cf., e.g., ECJ, judgment of 11 July 2013, Ziegler / Commission, C-439/11, EU:C:2013:513, recital 59.

binding orders which the Commission is not empowered to issue.[152] In other words, the Commission may use guidance notes to explain how it interprets the applicable law and how it intends to use the discretionary powers at its disposal. Further content is not permitted.

2. No binding effect

Guidance notes and similar working documents are generally not binding. This means in particular that they cannot create legal obligations either for Member States or for private parties.[153] The Blue Guide expressly emphasises this.[154] However, the Commission may, to the extent that the applicable law leaves it discretionary powers, commit itself by publishing guidelines. It can then only deviate from the self-imposed obligation in duly justified individual cases. Otherwise, it would violate the principles of equal treatment and the protection of legitimate expectations.[155]

3. Voidability

It follows from the non-binding nature of guidelines that they cannot, in principle, be challenged by an action for annulment under Article 263 TFEU.

According to settled case-law, the action for annulment is open to all measures of the EU institutions intended to produce legal effects. The form or designation is irrelevant.[156] In so far as a guidance document is confined to explaining the legislation in force and its interpretation by the Commission, it does not have any legal effects of its own and is therefore not a valid subject-matter for an action. However, this is not the case, where, contrary to its name, a guidance document is designed to create obligations which go beyond the relevant provisions of primary and secondary law. In this respect, it can be challenged by an action for annulment under Article 263 TFEU. At

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152 Cf. ECJ, judgment of 20 March 1997, France / Commission, C-57/95, EU:C:1997:164, recital 11 et seqq.

153 Cf. ECJ, judgment of 13 December 2012, Expedia, C-226/11, EU:C:2012:795, recital 29; *von Graevenitz*, EuZW 2013, 169, 171 et seq..

154 Blue Guide (fn. 13), p. 1, 5: "This is intended purely as a guidance document — only the text of the Union harmonisation act itself has legal force."

155 ECJ, judgment of 13 December 2012, Expedia, C-226/11, EU:C:2012:795, recital 28.

156 ECJ, judgment of 20 March 1997, France / Commission, C-57/95, EU:C:1997:164, recital 7 with further references.

the same time, the legal limits for guidance documents are often exceeded in such a case. The admissibility and the merits of an action therefore often coincide.[157]

The extent to which a guidance document is designed to create independent obligations must be examined on the basis of an individual assessment of its content. In other words, each statement must be examined separately to see whether it merely reflects the law in force and the way in which the Commission applies it, or whether it goes beyond that.[158] This may involve difficult questions of differentiation. It is therefore not possible to generally assess in an abstract manner to which extent prospective future guidelines to European standardisation – or amendments of the existing ones – could be the subject-matter of an action for annulment.

4. Interim result

Guidelines, guidance notes and other Commission working documents are generally not legally binding and therefore cannot be challenged in an action for annulment.

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[157] Cf. ECJ, judgment of 20 March 1997, France / Commission, C-57/95, EU:C:1997:164, recital 11 et seqq.; in more depth *Thomas*, Die Bindungswirkung von Mitteilungen, Bekanntmachungen und Leitlinien der EG-Commission, EuR 2009, 423, 425.

[158] Cf. General Court, judgment of 20 May 2010, Germany / Commission, T-257/06, EU:T:2010:214, recital 25 et seqq.