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The European System of Harmonised Standards

– Q&A commissioned by the Federal Ministry for Economic Affairs and Energy* –

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 are subject to a comparable regulatory apparatus?

In its judgment of 27 October 2016 in the *James Elliott* case (C-613/14), the European Court of Justice (ECJ) stated that harmonised standards form "part of Union law". According to the grounds of the judgment, this classification applies not only to harmonised standards that were adopted on the basis of the former Construction Products Directive 89/106/EEC, but to all harmonised standards the references of which have been published in the Official Journal of the European Union. However, it relates solely to the specific context of the Court's jurisdiction in preliminary rulings under Article 267 TFEU. It is evident that the ECJ 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. Accordingly, the ECJ also assumes that harmonised standards are not acts of an institution, body, office or agency of the Union.

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?

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

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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. The *James Elliott* judgment of the ECJ and the subsequent case law of the ECJ and the General Court on which the Commission 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. If the Commission were to attempt to stipulate 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.

3. 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?

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.

4. 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?

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.

5. 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?

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.

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

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.

7. 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?

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.

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