Subject: Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 – Consultation of stakeholders

Background:

Regulation (EU) No 1025/2012 (“the Standardisation Regulation”) has, since its entry into force, provided the main legal framework for the European standardisation system, including the division of responsibilities and obligations of the key actors involved. However, further clarification of certain provisions of the Standardisation Regulation appears necessary, notably in light of the recent case law of the Court of Justice of the European Union (“the Court”).

Therefore, on 22 November 2018, the Commission published a Communication on “Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market” defining specific actions to be undertaken by the Commission to further support the implementation of the Standardisation Regulation.

One of the actions announced in this Communication is the elaboration of “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.”

Furthermore, the Communication announced that this guidance document (“the Guidance”) would be elaborated “in consultation with stakeholders”. The purpose of this note is to request feedback from the main stakeholders on the points to be addressed in the Guidance. Any comments with regard to the Guidance should be provided to the functional mailbox of the Standardisation Unit of DG GROW (GROW-B3@ec.europa.eu) by 27 September 2019.

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2 Case C-613/14, James Elliott Construction Limited v Irish Asphalt Limited, Judgment of 27 October 2016; Case T-474/15, Global Garden Products Italy SpA (GGP Italy) v European Commission, Judgement of 26 January 2017; Case C-630/16, Anstar Oy vs Turvallisuus- ja kemikaalivirasto (Tukes), Judgment of 14 December 2017.

3 COM (2018)764 final
1. **Objective of the Guidance**

The main objective of the Guidance is to clarify the division of roles and responsibilities of relevant actors in the development process of harmonised standards, and by that to:

- increase legal clarity and certainty
- improve transparency
- increase predictability and efficiency

of the development process of harmonised standards.

2. **Scope of the Guidance**

The Guidance will cover the whole process of the development of harmonised standards. It will follow the chronological order of the main stages of the development process, starting from planning, drafting and adoption of a standardisation request by the Commission through the drafting and adoption of requested harmonised standards by the European standardisation organisations up to the publication of references of harmonised standards in the OJEU by the Commission.

The Guidance will address the relevant provisions (in particular Articles 10 and 11) of the Standardisation Regulation with regard to standardisation requests and formal objections, and will also be relevant for analogous or related provisions in other legal acts of the EU such as Articles 17 and 18 of Regulation (EU) No 305/2011 on construction products and Article 4 of Directive (EC) No 2001/95 on general product safety.

3. **Structure of the Guidance**

3.1 **Standardisation request**

The Commission intends to address in particular the following points:

- the responsibility of the Commission as regards the preparation and the adoption of standardisation requests;
- the [need for a clear] definition of the scope of standardisation requests;
- the [need for a clear] definition of the temporal validity of standardisation requests;
- the indication in the requested documents of the correspondence between the technical specifications and the legislative requirements they aim to cover;
- the elaboration and the nature of the work programme prepared by an ESO in response to a standardisation request;
- the procedure to amend standardisation requests.

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3.2 Assessment of the standard, publication of its reference in the OJ and formal objections

The Commission intends to address in particular the following points:

- the submission of the standard and the necessary documents to the Commission;
- the responsibility of the Commission and of the ESOs in the assessment of the standard;
- the role of the “Harmonised Standards Consultants” in the assessment;
- the responsibility of the Commission as regards the publication of the reference of the standard in the OJ;
- the case in which the Commission considers that the standard does not satisfy the requirements it aims to cover;
- the relationship between the procedure leading to the publication of the reference of the standard and a formal objection.

4. Relation to the existing guidance documents:

The Guidance does not aim to replace the existing guidance documents with regard to the implementation of the Standardisation Regulation, rather to complement these guidance documents.

5. Implementation of the Guidance:

The successful implementation of the Guidance will require cooperation of the Commission with the relevant actors, in particular the European standardisation organisations.

Questions with regard to the Guidance:

1. Do the foreseen elements of the Guidance cover the relevant aspects of the process of harmonised standards development, which require clarification in order to improve its transparency and increase its predictability and efficiency?

2. Are there any particular aspects from the recent relevant case law that you would like to see addressed in particular in this Guidance?

3. Do you have any other comments?

(e-signed)
Radek MALY

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