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### **SUBJECT**

**CEN-CLC Position Paper on the use of technical specifications in NLF-legislation**

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### **BACKGROUND**

The CEN-CENELEC Legal Platform (LP) is mandated by the CEN and CENELEC Administrative Boards to provide advice to the Governing Bodies on specific legal matters of relevance for the CEN and CENELEC communities where coordinated actions are needed.

In Annex 1, for information to the CEN and CENELEC BTs, is the Position Paper on the use of technical specifications in New Legal Framework (NLF) legislation, as drafted by the LP.

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2021-08-16 – JC

# LP Position Paper on the use of technical specifications in NLF-legislation

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## I.

The CEN-CENELEC Legal Platform (“LP”) realizes that some harmonization legislation based on the New Legal Framework confers implementing powers on the Commission to establish technical specifications (sometimes called “common specifications”), for example:

- Directive 2016/2102 on the accessibility of the websites and mobile applications of public sector bodies
- Regulation 2017/745 on medical devices
- Regulation 2017/746 on in vitro diagnostic medical devices
- Directive 2019/882 on the accessibility requirements for products and services
- Regulation 2019/1009 on fertilizing products

Furthermore, this approach is suggested in recent proposals for harmonization legislation, for example:

- Proposal for a Regulation on batteries and waste batteries
- Proposal for a Regulation on artificial intelligence
- Proposal for a Regulation on machinery products

Technical specifications have in common that they should serve as a fall back solution for the European Commission when harmonized standards do not exist, e.g. the standardization process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of a harmonized standard. Products and services which are in conformity with the technical specifications shall be presumed to be in conformity with the essential requirements of the harmonization legislation.

## II.

The LP is of the opinion that harmonization legislation conferring implementing powers on the European Commission to establish technical specifications is not in compliance with the New Legal Framework. Specifically, it would violate Article 3 of Decision 768/2008/EC. This article does not foresee the adoption of implementing acts establishing technical specifications.

Instead, according to Article 3(1), legislation shall restrict itself to setting out the essential requirements determining the level of the protection of public interests, and, according to Article 3(2), where the legislation sets out essential requirements, it shall provide for recourse to harmonized standards. Only where recourse to essential requirements is not possible or not appropriate, in view of the objective of ensuring the adequate protection of consumers, public health and the environment or other aspects of public interest protection, detailed specifications may be set out in the legislation concerned, Article 3(1) second subparagraph.

Technical specifications in the form of implementing acts would violate Article 3(1) second subparagraph in two ways. First, technical specifications are not “set out in the legislation concerned”. Instead, they are adopted separately by following a different

procedure, namely following the examination procedure according to Art. 5 of Regulation 182/2011. Second, even if technical specifications would be “set out in the legislation concerned”, their adoption needs to be justified by the requirement that “recourse to essential requirements is not possible or not appropriate”. This justification is missing. In any case, it is not sufficient to state that the Commission needs a fall back solution when harmonized standards do not exist, e.g. the standardization process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of a harmonized standard. Article 3(1) second subparagraph calls for an ex-ante assessment in view of the public interests which the legislation aims to protect. In view of the protection of those interests, Article 3 of Decision 768/2008/EC provides for only two options between which the legislator has to choose: (1) either it is sufficient – which it normally is – to set out the essential requirements and provide for recourse to harmonized standards or (2) detailed specifications have to be set out in the legislation concerned. One of those options has to be chosen. Article 3 of Decision 768/2008/EC does not provide for the possibility to implement them both. However, that would be the case in conferring implementing powers on the Commission as a fall back solution when harmonized standards do not exist.

### III.

However, if the legislator chooses to confer implementing powers on the Commission to establish technical specifications, it must be clear that this can be only a fall back solution when harmonized standards do not exist. Unfortunately, this is not the case regarding the harmonization legislation existing or recently proposed. Therefore, the LP suggests the following model article to be used in the future for similar cases:

*The Commission may adopt implementing acts establishing technical specifications for the essential [...] requirements where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require after consulting the relevant stakeholders and where the following conditions have been fulfilled:*

*(a) the Commission has concluded, that contrary to Article 10(6) of Regulation (EU) No 1025/2012 a harmonised standard does not satisfy the requirements which it aims to cover and which are set out in the corresponding Union harmonisation and has therefore not published a reference of such harmonised standard in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;*

*(b) the Commission has requested one or more European standardization organisations to draft a harmonised standard for the essential health and safety requirements and there are undue delays in the standardisation procedure;*

*(c) the request has, without reason, not been accepted by the European standardization organisations concerned.*

*A [...] product which is in conformity with the technical specifications or parts thereof shall be presumed to be in conformity with the essential [...] requirements covered by those technical specifications or parts thereof as long as those requirements are not covered by harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.*

## **The Legal Platform (LP)**

The Legal Platform (LP) is mandated by the CEN and CENELEC Administrative Boards to provide advice to the Governing Bodies on specific legal matters of relevance for the CEN and CENELEC communities where coordinated actions are needed. It may provide advice, either upon request or by its own initiative. The Platform also serves to animate and encourage the exchange of information and practices among legal advisors from national, European and international standardization bodies in view to provide advice on specific legal issues. The Platform is composed of legal experts appointed by the CEN and CENELEC NSBs-NCs, and open to ETSI, ISO, IEC legal advisors for all those issues of common interest, and when to share information and best practices with these organizations is needed.