Commission Implementing Decision (EU) 2019/1729 of 15 October 2019 on the harmonised standard for conformity assessment drafted in support of Regulations (EC) No 765/2008 and (EC) No 1221/2009 of the European Parliament and of the Council, Directive 2006/42/EC of the European Parliament and of the Council and Union acts incorporating the reference provisions of Decision No 768/2008/EC of the European Parliament and of the Council (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1729

of 15 October 2019

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council[(1)], and in particular Article 10(6) thereof,

Whereas:

(1) Regulation (EC) No 765/2008 of the European Parliament and of the Council[(2)] and Decision No 768/2008/EC of the European Parliament and of the Council[(3)] brought together, in what is called the New Legislative Framework, all the elements required for a comprehensive regulatory framework to operate effectively for the safety and compliance of industrial products and for the proper functioning of the single market. One of the main objectives of the New Legislative Framework is to ensure a robust and reliable conformity assessment for products in the Union. Regulation (EC) No 765/2008 established the legal basis for accreditation and market surveillance. Decision No 768/2008/EC consolidated the technical instruments for Union harmonisation legislation and, in particular, the criteria for designation of conformity assessment bodies as well as the conformity assessment procedures and the rules for their use. Decision No 768/2008/EC requires Union legislation harmonising the conditions for the marketing of products to incorporate, as far as possible, the reference provisions set out in Annex I to that Decision.

(2) In accordance with Article 11(1) of Regulation (EC) No 765/2008, national accreditation bodies that demonstrate conformity with the criteria laid down in the

relevant harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, by having successfully undergone peer evaluation under Article 10 of Regulation (EC) No 765/2008 are to be presumed to fulfil the requirements laid down in Article 8 of that Regulation.

(3) In point 10 of Article 2 of Regulation (EC) No 765/2008 accreditation is defined as an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

(4) Union legislation incorporating the reference provisions included in Annex I to Decision No 768/2008/EC provides, in certain cases, for the intervention of third party conformity assessment bodies in the relevant conformity assessment procedures. Furthermore, all such legislation, by incorporating Articles R17 and R18 of Annex I to Decision No 768/2008/EC, sets out the requirements that conformity assessment bodies must meet and stipulates that where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it is to be presumed to comply with the requirements set out in that Union act, insofar as the applicable harmonised standards cover those requirements.

(5) There is also Union legislation which does not incorporate Article R17 of Annex I to Decision No 768/2008/EC. However, it requires the intervention of third party conformity assessment body and provides for accreditation of those bodies in accordance with Regulation (EC) No 765/2008 to demonstrate the competence of such bodies. For example, Regulation (EC) No 1221/2009 of the European Parliament and of the Council[(4)] in its Article 2(20) defines the 'environmental verifier' as a conformity assessment body as defined in Regulation (EC) No 765/2008 or any association or group of such bodies, which has obtained accreditation in accordance with that Regulation.

(6) By letter M/417 of 4 December 2007 the Commission made a request to the European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (Cenelec) and European Telecommunications Standards Institute (ETSI) for the completion of the work on harmonised standards in support of the New Legislative Framework (revision of the New Approach) as well as sectoral certification schemes, in particular, European standards covering accreditation, conformity assessment or quality assurance were considered necessary for the implementation of the New Legislative Framework. That mandate covers both existing and future standards. In that context, the Commission tasked those organisations to identify all international standards that were relevant to the New Legal Framework and/or certain sectoral certification schemes and to adopt them at European level as European standards. Therefore, European standards in support of the Regulation (EC) No 765/2008, Union acts incorporating the reference provisions of Annex I to Decision No 768/2008/EC and Regulation (EC) No 1221/2009 fall within the scope of the mandate.

(7) On the basis of the request M/417 of 4 December 2007, CEN and Cenelec therefore completed the work on the harmonised standard EN ISO 19011:2018 — Guidelines for auditing management systems, by adopting international standard ISO 19011:2018 as an equivalent European standard EN ISO 19011:2018.

(8) The Commission together with CEN and Cenelec has assessed whether EN ISO 19011:2018 drafted by CEN complies with the request M/417 of 4 December 2007.

(9) EN ISO 19011:2018 satisfies the requirements which it aims to cover and which are set out in Regulations (EC) No 765/2008, (EC) No 1221/2009 and the Union Acts incorporating the reference provisions set out in Annex I to Decision No 768/2008/EC. More specifically, it satisfies the requirements for conformity assessment bodies included in Article R17 of Annex I to Decision No 768/2008/EC for the purposes of performing audits in the context of conformity assessment procedures as set out in that Decision. It is therefore appropriate to publish the references of that standard in the *Official Journal of the European Union.*

(10) EN ISO 19011:2018 is a revised version of EN ISO 19011:2011, the reference of which is published in the *Official Journal of the European Union*[(5)] and thus supersedes it. It is therefore necessary to withdraw the reference to harmonised standard EN ISO 19011:2011 from the *Official Journal of the European Union*. In order to give economic operators and third party conformity assessment bodies the necessary time to adapt their management systems and auditing methods, respectively, to the revised harmonised standard, it is necessary to defer the withdrawal of the reference to EN ISO 19011:2011.

(11) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The reference of the harmonised standard EN ISO 19011:2018 — Guidelines for auditing management systems (ISO 19011:2018), drafted in support of the Union acts listed in the Annex to this Decision is hereby published in the *Official Journal of the European Union*.

Article 2

The reference of the harmonised standard EN ISO 19011:2011 — Guidelines for auditing management systems (ISO 19011:2011), is hereby withdrawn from the *Official Journal of the European Union*, with effect from 1 January 2021.

Article 3

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/1729. (See end of Document for details)

Done at Brussels, 15 October 2019.

For the Commission

The President

Jean-Claude JUNCKER