DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2022/1631

of 12 May 2022

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([1]), and in particular Article 5(1), point (a), thereof,

Whereas:

(1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications, which are specific to medical devices and monitoring and control instruments, and are listed in Annex IV to that Directive.

(2) The categories of electrical and electronic equipment (EEE) to which Directive 2011/65/EU applies are listed in Annex I to that Directive.

(3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.

(4) On 25 March 2019, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex IV to that Directive, for the use of lead in bismuth strontium calcium copper oxide superconductor for use in cables and wires and lead in related electrical connections to other EEE components ('the requested exemption'). Lead-doped BSCCO can be used to create superconducting magnetic circuits for medical devices and monitoring and control instruments.

(5) The evaluation of the requested exemption included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

(6) Lead-containing solders are used to connect the superconducting wires and cables to other EEE components. There is currently no lead-free alternative available on the market that would provide a sufficient level of reliability for applications, where properties such as ductility and low electrical resistivity at low temperatures are required.

(7) The evaluation of the requested exemption, which included a technical and scientific assessment study ([2]), concluded that the addition of lead to BSCCO provides technical and functional advantages that cannot be achieved without the use of lead. Those technical and functional advantages consist in higher resolution images for medical diagnosis or for research and innovation, and allow a more stable operation mode of the relevant applications. The addition of lead to BSCCO makes it possible to produce more efficient and reliable equipment, which is beneficial for health care and innovation.

([1]) OJ L 174, 1.7.2011, p. 88.

([2]) Study to assess seven exemption requests relating to Annex III and IV to Directive 2011/65/EU.

(8) It is currently not possible to substitute or otherwise eliminate lead in the superconducting material and the related solders with the same technical performance, nor is it expected to be so in the foreseeable future. The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]) and does not weaken the environmental and health protection afforded by it.

(9) It is, therefore, appropriate to grant the requested exemption.

(10) The technical advantages of the lead-doped BSCCO-material have the potential to promote improvements and innovation in medical diagnostics and in research. The duration of the exemption is unlikely to have adverse impacts on innovation. Therefore, it is appropriate to grant the exemption for an extensive validity period, in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.

(11) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 28 February 2023 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those provisions to the Commission.

They shall apply those provisions from 1 March 2023.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law, which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 12 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

ANNEX

In Annex IV to Directive 2011/65/EU, the following entry is added:

'48.	Lead in bismuth strontium calcium copper oxide (BSCCO) superconductor cables and wires and lead in electrical connections to these wires Expires on 30 June 2027.'