COMMISSION DELEGATED DIRECTIVE (EU) 2022/1632

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 certain magnetic resonance imaging devices

(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 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) By Delegated Directive 2014/7/EU ([2]), the Commission granted an exemption for the use of lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors that are used in certain medical magnetic resonance imaging (MRI) equipment ('the exemption'), by including those applications in Annex IV to Directive 2011/65/EU. The exemption was to expire on 30 June 2020.

(5) On 12 December 2018, the Commission received an application for renewal of the exemption ('the renewal request') that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.

(6) The evaluation of the renewal request 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.

(7) The evaluation of the renewal request, which included a technical and scientific assessment study ([3]), concluded that old design MRI devices depend on lead-containing MRI components and are highly limited in their compatibility with new lead-free MRI components. That evaluation further concluded that lead-free models of non-integrated MRI coils are already available. However, as concerns MRI devices with integrated coils, the technical development and the approval procedure to develop lead-free solutions require additional time.

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

([2]) Commission Delegated Directive 2014/7/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used (a) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy (OJ L 4, 9.1.2014, p. 57).

([3]) Study to assess seven exemption requests relating to Annex III and IV to Directive 2011/65/EU (Pack 18).

(8) The use of lead in newly designed non-integrated MRI coils and in upcoming lead-free MRI devices with integrated coils should be excluded from the exemption with specific dates.

(9) Not granting the renewal request could result in premature wastage of MRI devices due to a lack of compatible components or redesigning options. This could result in a supply gap of MRI equipment, which could in turn adversely affect health care for patients.

(10) The total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) and thus does not weaken the environmental and health protection afforded by it.

(11) It is, therefore, appropriate to grant the renewal of the exemption.

(12) In order to provide compatible MRI equipment for health services and to allow time for the development of lead-free alternatives, it is appropriate to grant the renewal of the exemption, with a revised scope, for the maximum duration of 7 years until 30 June 2027, in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

(13) 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*.

([4]) 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).

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

ANNEX

In Annex IV to Directive 2011/65/EU, in entry 27, the following points (c) and (d) are added:

	'(c) MRI non-integrated coils, for which the Declaration of Conformity of this model is issued for the first time before 23 September 2022, or (d) MRI devices including integrated coils, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, for which the Declaration of Conformity is issued for the first time before 30 June 2024. Expires on 30 June 2027.'