EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical and scientific progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment ('the RoHS Directive')[1] as regards an exemption for specific applications containing lead.

Article 4 of the RoHS Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE). Currently, 10 substances are restricted and listed in Annex II to the Directive: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

Annexes III and IV to the RoHS Directive list the materials and components of EEE for specific applications exempted from the substance restrictions in Article 4(1) of the Directive. Article 5 provides for Annexes III and IV to be adapted to scientific and technical progress (on granting, renewing and revoking of exemptions). Under Article 5(1)(a), exemptions are to be included in Annexes III and IV only if this does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)[2] and if any of the following conditions is fulfilled:

– the elimination or substitution of the substance via design changes or use of materials and components that do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;

– the reliability of substitutes is not ensured;

– the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

Decisions on exemptions, and their duration, must take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of exemptions must take into account any potential impact on innovation. Life-cycle thinking on the overall impacts of the exemption must apply, where relevant.

Article 5(1) of the RoHS Directive provides for the Commission to include materials and components of EEE for specific applications in the lists in Annexes III and IV by means of individual delegated acts pursuant to Article 20. Article 5(3) and Annex V establish the procedure for submitting exemption applications.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission receives numerous requests from economic operators to grant or renew exemptions under Article 5(3) and Annex V to the RoHS Directive[3].

Exemption 27 was included in Annex IV to the RoHS Directive by Commission Delegated Directive 2014/7/EU[4]. The expiry date set for this exemption was 30 June 2020. The

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

[2] 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

[3] The list is available at: http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm.

[4] OJ L 4, 9.1.2014, p. 57–58.

exemption concerns the use of lead in specific components, which are used in magnetic fields produced by certain medical devices. On 12 December 2018, within the timeframe for renewal laid down in Article 5(5) of the RoHS Directive, the Commission received one application to renew the scope and duration of this exemption. The exemption consisted of two areas of application, (a) and (b). The applicant did not request the continuation of part (b) of Exemption 27 in Annex IV, which refers to specific magnets applied for particle therapy.

In August 2019, the Commission launched a study[5] to carry out the required technical and scientific assessment. The study, including an eight-week public consultation, finished in July 2020. Information about the consultation was provided on the project website[6], although no responses were received to the consultation.

The Commission consulted the Member State expert group for delegated acts under the RoHS Directive on 23 February 2021. It carried out all the required procedural steps relating to exemptions from the restrictions on substances under Articles 5(3) to 5(7)[7] and the Council and the European Parliament were notified of all activities in this context.

The technical and scientific assessment report highlighted the following:

- Lead is used in solders, termination coatings, and connections of electrical wires, shields and enclosed connectors to provide non-magnetic components, which are necessary in magnetic resonance imaging (MRI) devices for diagnostic purposes.
- In newly designed MRI devices and components, the substitution and elimination of lead is scientifically and technically practicable.
- Old designed MRI devices are limited in their compatibility with new lead-free MRI components. In some MRI devices, the new design of lead-free components cannot be used. Other older MRI devices will have to undergo an elaborate redesign process, which shifts manufacturers' limited capacity from developing new lead-free medical devices with superior diagnostic capability to replacing lead in existing products.
- To address sufficiently the demand on MRI equipment for old designed MRI devices, which cannot be redesigned or replaced before the exemption period expires, the use of old MRI equipment containing lead is still necessary.
- The transition to lead-free MRI equipment has progressed at different speeds for MRI devices with integrated coils and those with non-integrated MRI coils.
- Newly designed lead-free non-integrated MRI coils are available in a sufficient variety for health facilities. Due to the complexity of MRI devices with integrated coils and the approval procedure required for these, the transition to non-lead MRI devices requires more time.
- Not granting the exemption may result into premature waste of MRI devices due to a lack of compatible components or redesign options. A supply gap in MRI equipment may also occur, which may result in poorer healthcare for patients.

5 Final Report of the (Pack 18) study is available at https://op.europa.eu/en/publication-detail/-/publication/f44f2383-dd0a-11ea-adf7-01aa75ed71a1/language-en/format-PDF/source-146144383

6 Consultation period: 3 December 2019 until 27 January 2020 https://rohs.exemptions.oeko.info/.

7 A list of the required administrative steps is available on the Commission website. The current stage of the procedure can be viewed for each draft delegated act in the Inter-institutional Registry of Delegated Acts at https://webgate.ec.europa.eu/regdel/#/home.

Newly designed MRI non-integrated coils do not need an exemption and MRI equipment including integrated coils will not need an exemption from 30 June 2024, thus these applications will be excluded in the new wording of the exemption. The distinction will be made by the Declaration of Conformity for this model, which is necessary for a product before being placed on the market in line with Article 7(c) and Article 13 of the RoHS Directive.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The evaluation results show that the exemption to be granted would not weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU.

The Commission's assessment, based on the support study and consultations, concluded that the exemption application meets at least one of the criteria laid down in Article 5(1)(a), that justifies renewing the exemption: 'the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof'.

The delegated directive renews in part Exemption 27 listed in Annex IV to Directive 2011/65/EU 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 for magnetic resonance imaging (MRI) devices. The old formulation in part (a) and (b) of the exemption 27 remains unchanged and remains listed for clarity for stakeholders. A new formulation is introduced in part (c) and (d) which is limited to the actual necessary applications.

The date by which this exemption will expire is set in line with Article 5(2), first subparagraph. As concluded by the evaluation, the state of development of substitutes justifies renewing the exemption for non-integrated MRI coils and for MRI devices including integrated coils, whereby the latter can be substituted earlier. The validity period of the exemption is not expected to have adverse impacts on innovation.

The legal instrument is a delegated directive, as provided for in the Directive 2011/65/EU and meeting the relevant requirements of its Article 5(1)(a).

The objective of the delegated directive is to help protect human health and the environment, and harmonise provisions for the functioning of the single market in the field of EEE, by allowing the use of otherwise banned substances for specific applications, in line with the RoHS Directive and the procedure established therein for adapting Annexes III and IV to the Directive to scientific and technical progress.

The delegated directive has no implications for the EU budget.

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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.

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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).

(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.

(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 [OP please insert the date: the last day of the 5th month after the date of entry into force of this Directive] at the latest, the

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

[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).

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 [OP please insert the date: the last day of the 5th month after the date of entry into force of this Directive + 1 day].

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,

For the Commission
The President
Ursula VON DER LEYEN