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COMMISSION DELEGATED DIRECTIVE (EU) .../…

of 11.8.2021

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 bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils

(Text with EEA relevance)

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 (recast)[1] (the RoHS Directive) as regards an exemption for specific applications containing bis(2-ethylhexyl) phthalate (DEHP).

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). DEHP, BBP, DBP and DIBP were added to the list by Commission Delegated Directive (EU) 2015/863[2] and will be prohibited in medical devices covered by the RoHS Directive from 22 July 2021.

Annexes III and IV to the RoHS Directive list the materials and components of EEE for specific applications exempted from the substance restrictions in its Article 4(1). Article 5 provides for Annexes III and IV to be adapted to scientific and technical progress (as regards the 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)[3] and any of the following conditions is fulfilled:

– their elimination or substitution via design changes or 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, are to 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.

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1 OJ L 174, 1.7.2011, p. 88.

2 OJ L 137, 4.6.2015, p. 10.

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

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission receives numerous requests[4] from economic operators to grant or renew exemptions under the RoHS Directive (Article 5(3) and Annex V).

On 12 September 2018, the Commission received an application for a new exemption for the use of DEHP in polyvinylchloride (PVC) for coil-cable strain-relief devices in magnetic resonance imaging (MRI) scanners. In November 2018, in order to evaluate the application for this new exemption, the Commission launched a study[5] to carry out the required technical and scientific assessment. The study, which was concluded in 2020, involved an 8-week online stakeholder consultation, during which no contributions were received. Information concerning the consultation was provided on the project website[6].

On 2 October 2019, the Commission received a similar request for a new exemption for the use of DEHP in plastic components in MRI detector coils. Due to the similarity of the two requests and as additional information was required on the availability of substitutes and socio-economic aspects, it launched an in-depth study in November 2019, which concluded in June 2020[7].

In an 8-week public consultation, stakeholders were informed about new steps and information was provided on the project website[8]. No contributions were received during the consultation, but MRI manufacturers other than the applicant were interviewed as part of the information-gathering exercise.

The Commission consulted the Member States' expert group for delegated acts under the RoHS Directive on 23 February 2021. Some experts expressed agreement with the drafts presented, with a large group remaining silent. The Commission has taken all necessary steps relating to exemptions from the substance restriction pursuant to Article 5(3) to (7)[9]. It notified the Council and the European Parliament of all activities in this context.

The technical and scientific assessment reports highlighted that:

- the first request concerned the use of DEHP in PVC cable strain reliefs in MRI detector coils. The second had a wider coverage and concerned the use of DEHP in flexible polymers used in plastic components in MRI detector coils. The evaluation found that a joint exemption would be appropriate;
- for many MRI scanners, there are currently no DEHP-free coils available. However, at least one manufacturer provides DEHP-free MRI components;
- the development of alternatives and substitutes will require more time to ensure appropriate and broad availability;
- given the present lack of sufficient appropriate alternative technologies and substitutes, not granting an exemption would probably result in a supply shortage for health services, which depend on original MRI coils. This may result in health impacts for

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4 http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm

5 For the final report of the study (Pack 17), see: https://op.europa.eu/en/publication-detail/-/publication/df0ab036-8b52-11ea-812f-01aa75ed71a1/language-en/format-PDF/source-146143357

6 Consultation period: 18 March to 17 May 2019; https://rohs.exemptions.oeko.info/

7 For the final report of the study (Pack 20), see: https://op.europa.eu/en/publication-detail/-/publication/185e9d5b-d5fc-11ea-adf7-01aa75ed71a1/language-en/format-PDF/source-146144567

8 Consultation period: 10 January to 20 February 2020; https://rohs.exemptions.oeko.info/

9 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 Interinstitutional Registry of Delegated Acts at https://webgate.ec.europa.eu/regdel/#/home

many patients in the EU linked to the lack of relevant diagnosis and treatment facilities.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

While DEHP in articles is restricted by entry 51 in Annex XVII to the REACH Regulation, EEE within the scope of the RoHS Directive is exempted from this restriction. The evaluation results show that granting the exemption would not weaken the environmental and health protection afforded by REACH, thereby satisfying the condition in Article 5 of the Directive.

Furthermore, the exemption requests meet at least one of the criteria in Article 5(1)(a) of the Directive: the reliability of substitutes is not sufficiently ensured and the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

In view of the manufacturers' ongoing efforts to find a reliable and widely available alternative, the duration of the exemption until 1 January 2024, as requested is unlikely to have adverse impacts on innovation. Therefore, the exemption should be granted for the requested duration.

The proposed act grants an exemption from the substance restrictions in Annex II to the RoHS Directive, to be listed in its Annex IV (on exemptions specific to medical devices and monitoring and control instruments), for the use of DEHP in specific applications.

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

The objective of the delegated directive is to contribute to the protection of human health and the environment, and harmonise the provisions for the functioning of the internal 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 the adaptation to scientific and technical progress of its Annexes III and IV.

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 bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils

(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 the Directive. That restriction does not apply to certain exempted applications listed in Annex IV to the Directive.

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

(3) Bis(2-ethylhexyl) phthalate (DEHP) is a restricted substance listed in Annex II to Directive 2011/65/EU, as amended by Commission Delegated Directive (EU) 2015/863[2]. DEHP is not to be used, from 22 July 2021, in medical devices, including *in vitro* medical devices above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.

(4) On 12 September 2018 and 2 October 2019, the Commission received applications 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 DEHP in plastic components in magnetic resonance imaging (MRI) detector coils ('the requested exemption')

(5) Two technical and scientific assessment studies were carried out to evaluate the exemption applications. The first study[3] covered the first application received. Due to the similarity of the second application to the first, the second study[4] evaluated both applications together. The evaluation of the applications, which took into account the

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

[2] Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (OJ L 137, 4.6.2015, p. 10).

[3] For the final report of the study (Pack 17), see: https://op.europa.eu/en/publication-detail/-/publication/df0ab036-8b52-11ea-812f-01aa75ed71a1/language-en/format-PDF/source-146143357.

[4] For the final report of the study (Pack 20), see: https://op.europa.eu/en/publication-detail/-/publication/185e9d5b-d5fc-11ea-adf7-01aa75ed71a1/language-en/format-PDF/source-146144567.

availability of technically practicable and reliable substitutes and the socioeconomic impact of substitution, concluded that no suitable alternatives to DEHP are sufficiently available on the market and that not granting the exemption is likely to result in total negative environmental, health and consumer safety impacts caused by substitution, which outweigh the benefits thereof. The evaluation included stakeholder consultations as required by Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

(6) The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5] and thus does not weaken the environmental and health protection afforded by it.

(7) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU.

(8) To ensure that compatible plastic components for MRI coil detectors for health services are widely available on the Union market and to allow time for the development of suitable and widely available alternatives, the requested exemption should be granted until 1 January 2024, 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.

(9) Directive 2011/65/EU should therefore be amended accordingly.

(10) In the interest of legal certainty and in order to protect the legitimate expectations of operators supplying the medical devices concerned that the requested exemption applies by the date of entry into force of the prohibition for the use of the restricted substance in question, and in the absence of any legitimate interest in creating a disruption to the supply of those medical devices as a result of the entry into force of that prohibition, this Directive should enter into force as a matter of urgency and should apply with retroactive effect from 21 July 2021,

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 [the last day of the 5th month after the date of entry into force of this Directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall communicate the text of those provisions to the Commission forthwith.

   They shall apply those provisions from 21 July 2021.

[5] 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).

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 that they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 11.8.2021

For the Commission
The President
Ursula VON DER LEYEN