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 the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical progress, Annex IV of 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] (RoHS) as regards an exemption for specific applications containing mercury.

RoHS restricts the use of certain hazardous substances in electrical and electronic equipment, as provided for in its Article 4. It entered into force on 21 July 2011.

The currently restricted substances as listed in Annex II to RoHS are the following: 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 RoHS list the materials and components of electrical and electronic equipment (EEE) for specific applications exempted from the substance restriction of RoHS Article 4(1).

Article 5 provides for the adaptation to scientific and technical progress (inclusion, renewal, amendments and revoking of exemptions) of Annexes III and IV. Pursuant to Article 5(1)(a), exemptions are to be included in Annexes III and IV only if such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)[2] and where any of the following conditions is fulfilled: their elimination or substitution via design changes or materials and components which 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; or 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.

Decisions on exemptions, and their duration, are furthermore to take into account the availability of substitutes and the socioeconomic impact of substitution; and decisions on the duration of exemptions shall take into account any potential impact on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.

Furthermore, Article 5(1) provides that the European Commission (the Commission) shall include materials and components of EEE for specific applications in the lists in Annexes III and IV by means of individual delegated acts in accordance with Article 20. Article 5(3) and Annex V establish the procedure for submitting applications for granting, renewing, or revoking an exemption.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Since the publication of the RoHS Directive, the Commission has received numerous[3] requests from economic operators, according to the provisions in Article 5(3) and Annex V, for both granting new and renewing existing exemptions.

The current Annex IV exemption 42 permits the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

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1 OJ L 174, 1.7.2011, p. 88.

2 OJ L 396, 30.12.2006, p. 1.

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

The Commission received one application for renewal of this exemption in October 2017. While exemption 42 had 30 June 2019 as expiration date, in line with the requirements of the RoHS Directive (Article 5(5), second subparagraph), it continues to apply until a decision on the renewal application is taken by the Commission.

With a view to evaluating the application for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including a seven-week online open-ended stakeholder consultation[4] on the application. No contributions were made to the stakeholder consultation.

The final report containing the assessment of the application was published[5]; stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS during an expert meeting on 21 October 2019. The experts agreed with the draft presented, with a large group of experts remaining silent. All necessary steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.[6] The Council and the European Parliament were notified of all activities.

The final report highlighted in particular the following technical information and assessment:

- Intravascular ultrasound (IVUS) imaging is a technique that emits sound energy from a transducer at the tip of a small catheter that is guided into the coronary arteries of the heart. Sound waves reflected from vascular tissues are received by the transducer and sent to the system console, where a high resolution, cross sectional image is displayed in real time. The IVUS technique provides in vivo visualization of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of the coronary artery wall. Mercury is used in based slip rings which provide the electrical conduction path between the rotating transducer and stationary electronic equipment. The use of mercury enables inter alia higher frequency operation which allows obtaining higher resolution imaging beneficial for patients.
- Currently, the substitution of mercury in applications concerned is technically impracticable.

The evaluation results show that the specific exemption would not weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU. Furthermore, at least one of the relevant criteria specified in Article 5(1)(a) is met by the exemption request: Since for the applications concerned, no reliable alternatives are available today or are likely to come on the market soon, granting the exemption with the validity period until 30 June 2026 is justified. As reliable substitutes are not yet available, no negative socioeconomic impacts of substitution are to be anticipated for this period. The granted validity period is also not expected to have adverse impacts on innovation.

4 Consultation period: from 31 October 2018 until 19 December 2018.

5 https://op.europa.eu/en/publication-detail/-/publication/7e6bf135-f0b9-11e9-a32c-01aa75ed71a1/language-en/format-PDF/source-120742148

6 A list of the required administrative steps is available on the Commission website. 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.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Directive grants an extension of the validity period of an exemption listed in Annex IV of Directive 2011/65/EU, for the use of mercury in specific applications.

The instrument is a Delegated Directive, as provided for by Directive 2011/65/EU, and in particular meeting the relevant requirements of Article 5(1)(a) thereof.

The objective of the Delegated Directive is to contribute to the protection of human health and the environment and approximate the provisions for the functioning of the internal market in the field of electrical and electronic equipment, by allowing the use of otherwise banned substances for specific applications, in line with the provisions and under the conditions of RoHS and the therein established procedure for the adaptation of the Annexes III and IV to scientific and technical progress.

In accordance with the principle of proportionality, the measure does not go beyond what is necessary to achieve its objective.

The proposal has no implications for the EU budget.

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

(4) By Delegated Directive (EU) 2015/574[2], the Commission granted an exemption for the use of mercury in intravascular ultrasound imaging systems ("the exemption"), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 30 June 2019, in accordance with the third subparagraph of Article 5(2) of that Directive.

(5) The Commission received an application for renewal of the exemption ("the renewal request") on 6 October 2017 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 these consultations were made publicly available on a dedicated website.

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1 OJ L 174, 1.7.2011, p. 88.

2 Commission Delegated Directive (EU) 2015/574 of 30 January 2015 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 mercury in intravascular ultrasound imaging systems (OJ L 94, 10.4.2015, p. 6).

(7) Mercury is used in electric rotating connectors of intravascular ultrasound imaging systems which provide the electrical conduction path between the rotating transducer and stationary electronic equipment. The use of mercury enables inter alia higher frequency operation which allows obtaining higher resolution imaging beneficial for patients.

(8) Due to the lack of alternatives, a substitution or elimination of mercury in the applications concerned is currently scientifically and technically impracticable. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3] and thus does not weaken the environmental and health protection afforded by it.

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

(10) The exemption should be renewed for the maximum duration of 7 years until 30 June 2026, in accordance with Article 4(3) and the third subparagraph of Article 5(2) 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.

(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 [the last day of the 12th 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 forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from [the last day of the 12th 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.

[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, 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 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