EUROPEAN
COMMISSION

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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 lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases

(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 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 2) as regards an exemption for specific applications containing lead.

RoHS 2 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 2 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 2 list the materials and components of electrical and electronic equipment (EEE) for specific applications exempted from the substance restriction of RoHS 2 Article 4(1).

Article 5 makes provision 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[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 RoHS 2, 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 41 permits the use of lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices

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

for the analysis of blood and other body fluids and body gases. The Commission received one application for renewal of this exemption in June 2017. While exemption 41 had 31 December 2018 as expiration date for category 8 in vitro diagnostic medical devices, 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.[4]

With a view to evaluating the request for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including a six-week online open-ended stakeholder consultation[5] on the application. One contribution was received during the stakeholder consultation.

The final report containing the assessment of the application was published[6]; stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS 2 during an expert meeting on 29 October 2018. The experts agreed with the proposal presented, with a large majority of absent or silent members. All applicable steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.[7] The Council and the European Parliament were notified of all activities.

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

- Lead in the PVC sensor card of concerned in vitro medical devices (blood analysers) is enhancing sensor performance which is necessary for the optimum performance in terms of analytical reliability claimed in product publications and thus for fulfilment of requirements set by EU legislation on in vitro diagnostic medical devices.
- While lead-free technologies are available on the market for certain analysers of other manufacturers, the applicant requires additional time to test the reliability of substitutes and to achieve compliance. Should the lead-based applications be discontinued without providing additional time to the applicant, a premature generation of 112,000 kg of waste EEE can be expected. Furthermore, as the devices concerned cover 30 % of blood analysers market in the EU, significant costs for health providers are presumed.
- At least one of the relevant criteria specified in Article 5(1)(a) is met by the application subject to the exemption request: the total negative environmental, health and consumer safety impacts by substitution (i.e. premature generation of waste EEE) are likely to outweigh the total environmental, health and consumer safety benefits thereof (avoidance of approx. 157 kg of lead to be placed on the market).

The evaluation results for categories 8 in vitro medical devices show that the specific exemption would at this point not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH), in accordance with Article 5 of Directive 2011/65/EU. Under Regulation (EC) No 1907/2006 (REACH), there is a restriction process

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4 The categories listed in Annex I of Directive 2011/65/EU are namely: 1. Large household appliances; 2. Small household appliances; 3. IT and telecommunications equipment; 4. Consumer equipment; 5. Lighting equipment; 6. Electrical and electronic tools; 7. Toys, leisure and sports equipment; 8. Medical devices; 9. Monitoring and control instruments including industrial monitoring and control instruments; 10. Automatic dispensers; 11. Other EEE not covered by any of the categories above.

5 Consultation period: from 20.10.2017 to 01.12.2017.

6 https://publications.europa.eu/en/publication-detail/-/publication/33a336f0-e0ef-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-85019010 .

7 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.

on lead in PVC ongoing since 2016. The recent publication of a draft restriction proposal under REACH[8] provides sufficient indications with regard to lead in PVC in order to proceed with the decision under RoHS. In any case, in light of the ongoing REACH restriction process, the renewal of the exemption should be granted for a short validity period of 2 years starting from the date of the publication of the Delegated Directive in the Official Journal to ensure alignment with REACH once the restriction process is concluded. The validity period for the exemption being very short, it is also not expected to have adverse impacts on innovation. The exemption renewal granting additional time for achieving compliance will further avoid negative socioeconomic impacts of substitution for certain health providers that would otherwise arise. The granted validity period is also not expected to have adverse impacts on innovation.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Directive grants an exemption from the restrictions in Article 4(1), to be listed in Annex IV of Directive 2011/65/EU, for the use of lead 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 2 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.

[8] Draft Commission Regulation amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead and its compounds is available here: http://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=668&dspLang=en&basdatedeb=10/07/2019&basdatefin=18/07/2019&baspays=&basnotifnum=&basnotifnum2=&bastypepays=ANY&baskeywords=.

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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) Article 4(1) of 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 (EU) 2015/573[2], the Commission granted an exemption for the use of lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases ("the exemption"), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 31 December 2018, 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 25 May 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.

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1 OJ L 174, 1.7.2011, p. 88.

2 Commission Delegated Directive (EU) 2015/573 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 lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices (OJ L 94, 10.4.2015, p. 4).

(7) Lead in the PVC sensor card of concerned in vitro medical devices (blood analysers) enhances sensor performance which is necessary for the optimum performance of the device in terms of analytical reliability claimed in product publications and thus for fulfilment of requirements laid down in Directive 98/79/EC of the European Parliament and of the Council[3].

(8) While lead-free technologies are available on the market for certain analysers of other manufacturers, reliability testing of substitutes for the specific application subject to the current renewal request requires additional time.

(9) Discontinuation of the exemption is expected to avoid a total of 157 kg of lead being placed on the Union market. At the same time, however, it will result in the need to replace the entire diagnostic device, and consequently, is expected to lead to a premature generation of 112 000 kg of waste electrical and electronic equipment. Furthermore, significant socioeconomic impacts on health providers using the devices concerned would be incurred.

(10) The exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council.[4] In light of the restriction process on lead in PVC provided for in Regulation (EC) No 1907/2006, the exemption should be granted for a short validity period of 2 years to ensure full alignment with that Regulation once the relevant restriction process is concluded.

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

(12) The exemption concerns category 8 of electrical and electronic equipment to which Directive 2011/65/EU applies and it should be renewed for the duration of 2 years starting from [the date of the publication of the Delegated Directive in the Official Journal], in accordance with 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.

(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 [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].

[3] OJ L 331, 7.12.1998, p. 1–37.

[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) and establishing a European Chemicals Agency (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 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
[…]