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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 16 May 2023 |
| To: | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union |
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| Subject: | COMMISSION DELEGATED DIRECTIVE (EU) .../… of 16.5.2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices |

Delegations will find attached document C(2023) 3138 final.

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EUROPEAN
COMMISSION

Brussels, 16.5.2023
C(2023) 3138 final

**COMMISSION DELEGATED DIRECTIVE (EU) .../…**

**of 16.5.2023**

**amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices**

(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 ('the RoHS Directive')[1] as regards an exemption for lead in polyvinyl chloride (PVC) used as base material in sensors used in in-vitro diagnostic medical devices.

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

Annexes III and IV to the Directive list the materials and components of electrical and electronic equipment for specific applications exempted from the substance restrictions in Article 4(1). 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) provides for the Commission to include materials and components of electrical and electronic equipment 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].

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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.

On 1 December 2021, the Commission received an application for a new entry to be added to Annex IV. The requested exemption concerns lead as a thermal stabilizer 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 creatinine and blood urea nitrogen (BUN) in whole blood.

In March 2022, the Commission launched an evaluation to carry out the required technical and scientific assessment. The study, which included a six-week public stakeholder consultation, was published in September 2022[4]. Information about the consultation was provided on the project website[5] and no stakeholder contribution was received.

On 26 October 2022, the Commission consulted the Member States expert group for delegated acts under the RoHS Directive; one comment was received. It carried out all the required procedural steps relating to exemptions from the restrictions on substances under Articles 5(3) to 5(7)[6]. In this context, the European Parliament and the Council were notified of all activities.

The draft delegated directive was made available for public feedback for a period of four weeks, from 16 January 2023 to 13 February 2023. No contribution was received and no changes to the draft act were required.

**Technical evaluation**

Lead is a toxic substance which affects the development of the nervous system, produces chronic kidney disease and has adverse effects on blood pressure.

Lead is used as thermal stabiliser in PVC as base material for sensor cards. Those cards are part of disposable cartridges used in diagnostic medical analyser that can provide accurate measurement of specific analytes (e.g., sodium, chloride, glucose, pH value etc.) on a single whole blood sample. Those medical analysers are used to obtain blood results in a short time near the point of care (e.g., in emergency departments). The previous exemption 41 in Annex IV of the RoHS Directive covered such applications.

The substitution of lead in such applications is progressing and other manufacturers of similar devices have already substituted lead in their sensors. However, for sensor cards analysing the parameter creatinine and blood urea nitrogen (BUN), the development is not sufficiently progressed to replace such sensor cards. Lead-free sensor cards are in development by the applicant but are not yet market ready as their lead substitution is not reliable enough or their accuracy is too low.

It is expected that the development and validation of substitutes for lead in sensor cards relevant for the two parameters creatinine and BUN can be finalised by the end of 2023. Rejecting the exemption request can be expected to have a considerable impact on health

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4 Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer 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 creatinine and blood urea nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26) https://op.europa.eu/en/publication-detail/-/publication/49205318-3249-11ed-975d-01aa75ed71a1/language-en

5 Consultation period: 07 April 2022 to 19 May 2022 (https://rohs.exemptions.oeko.info/exemption-consultations/2022-consultation-1 ).

6 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.

service providers using equipment already on the market, as such devices can become non-functional as long as lead containing PVC sensor cards cannot be replaced.

It is expected that under a potential exemption for this period until end of 2023 less than 14.2 kg of lead is placed on the market.

## 3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Directive grants an exemption from the substance restrictions in Annex II to Directive 2011/65/EU, to be listed in Annex IV, for lead in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices.

In-vitro diagnostic medical devices can be assigned to the EEE category 8 “medical devices” according to Annex I.

At least one of the relevant criteria specified in Article 5(1)(a) is met by the exemption request: the reliability of substitutes for the specific application subject to the exemption request is not ensured. Also, the total negative environmental, health and consumer safety impacts and the socioeconomic impacts of not granting an exemption are being taken into account, in light of Article 5(1)(a), third indent and the second subparagraph of Article 5(1)(a). Granting an exemption would prevent negative impacts on health facilities as specific parameters could be continued to be analysed with sufficient accuracy and medical devices already on the market could continue to be used.

Lead and its compounds are also restricted by REACH entry 63 of Annex XVII. This entry is currently under review and should include in future a restriction of lead for articles produced from polymers or copolymers of PVC. A possible restriction for lead in PVC will come into force later than 2023. The requested exemption under RoHS is only necessary until lead is replaced in the specific sensor cards, which is foreseen for the end of 2023. With an expiry date not later than end of 2023, 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.

In summary, the unavailability of a reliable substitution for the concrete application combined with negative environmental, health and consumer safety impacts of not granting the exemption, justifies granting the exemption for a limited duration when substitution of lead is envisaged.

The expiry date of the exemption would hence be set with 31 December 2023, in line with Article 5(2), first subparagraph, RoHS Directive.

It is proposed to add a new entry 41a for the relevant application in Annex IV. Since the in-vitro diagnostic medical devices described in the exemption request fall under category 8 “medical devices” of Annex I, the scope of the exemption should be limited to those.

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

The objective of the delegated directive is to protect human health and the environment, and to harmonise provisions for the functioning of the single market in the field of electrical and electronic equipment, 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.

**COMMISSION DELEGATED DIRECTIVE (EU) .../…**

**of 16.5.2023**

**amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical 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) 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 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) On 1 December 2021, the Commission received an application 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 lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices (‘the requested exemption’).

(5) The in-vitro diagnostic medical devices described in the requested exemption fall under category 8 ‘medical devices’ of Annex I to Directive 2011/65/EU.

(6) A technical and scientific assessment study[2] was carried out to evaluate the requested exemption. 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.

(7) The evaluation of the requested exemption concluded that the substitution of lead in specific sensors is not completed yet. The availability of substitutes for such specific

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

[2] Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer 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 creatinine and blood urea nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26)

devices is not ensured as current lead substitutions are not reliable for all parameters (for example, creatinine and blood urea nitrogen) or have a low accuracy for such parameters. In addition, the evaluation concluded that rejecting the requested exemption would negatively affect the health service.

(8) The requested exemption thus meets at least one of the relevant conditions specified in Article 5(1), point (a), of Directive 2011/65/EU as the reliability of substitutes for the specific application subject to the exemption request is not ensured. Also, the overall negative environmental, health and consumer safety impacts and the socioeconomic impacts of not granting an exemption are being taken into account.

(9) The requested 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 that Regulation.

(10) It is, therefore, appropriate to grant the requested exemption by including the relevant application in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 8.

(11) In light of the expected availability of substitution of lead in the application subject to the exemption and of possible future restrictions on lead in polyvinyl chloride in Regulation (EC) No 1907/2006, it is necessary to grant the exemption for a limited validity period until 31 December 2023. That validity period is set in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.

(12) 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 fifth 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 the text of those provisions to the Commission.

   They shall apply those provisions from [*OP please insert the date: the last day of the fifth 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.

[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), 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/E EC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

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, 16.5.2023

*For the Commission*
*The President*
*Ursula VON DER LEYEN*