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COMMISSION DELEGATED DIRECTIVE (EU) .../…

of 4.5.2023

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 mercury in melt pressure transducers for capillary rheometers under certain conditions

(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 mercury in melt pressure transducers for capillary rheometers under certain conditions.

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 26 April 2021, the Commission received an application for a new entry in Annex IV. The requested exemption concerns the use of mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar.

In October 2021, the Commission launched an evaluation to carry out the required technical and scientific assessment. The study, which included a ten-week public stakeholder consultation, finished in August 2022[4]. Information about the consultation was provided on the project website[5] and two stakeholder contributions were received.

On 26 October 2022, the Commission consulted the Member States expert group for delegated acts under the RoHS Directive. One comment was received. The Commission 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.

Technical evaluation

Mercury is used as a filling in the pressure transducer of capillary rheometer to transmit the pressure of the probe to a sensor outside the high temperature and pressure area.

Capillary rheometers can analyse viscosity e.g., of melted polymers to predict its behaviour e.g., for an extrusion process. The used pressure transducer consists of electrical components and thus, it is an electrical measurement device in the scope of the RoHS Directive. The capillary rheometers in question are no large-scale technologies that are covered by Article 2(4)(d) of the Directive.

In lower pressure areas mercury can be substituted. A substitution for the requested given range of operation over 300°C and over 1000 bar is scientifically and technically impracticable at the time being.

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 mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar.

Capillary rheometer can be assigned to the EEE category 9 “monitoring and control instruments” according to Annex I.

The evaluation shows 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.

At least one of the relevant criteria specified in Article 5(1)(a) is met. The elimination or substitution of mercury in melt pressure transducers for capillary rheometers under certain

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4 Study to assess requests for two (-2-) exemptions, for mercury in pressure transducer and DEHP in a PVC base material, in Annex IV of Directive 2011/65/EU (Pack 25) https://op.europa.eu/en/publication-detail/-/publication/3bc5a902-1f69-11ed-8fa0-01aa75ed71a1/language-en/format-PDF/source-265633428

5 Consultation period: 30 November 2021 until 8 February 2022 (https://rohs.exemptions.oeko.info/exemption-consultations/2021-consultation-2).

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.

conditions is scientifically and technically impracticable. Therefore, the exemption is to be granted and an expiry date is to be set.

The exemption was requested for seven years in accordance with Article 5(2) of the RoHS Directive.

At the fourth meeting of the Conference of the Parties to the Minamata Convention on Mercury, the European Union proposed phase out dates for certain mercury-added products[7], and based on this proposal, the Conference of the Parties decided to amend Part I of Annex A to the Convention[8]. Accordingly, electrical and electronic measuring devices like melt pressure transducers, melt pressure transmitters and melt pressure sensors have to be phased out (i.e., including the restriction of placing on the market) until end of 2025, except those installed in large-scale equipment or those used for high-precision measurement, where no suitable mercury-free alternative is available. Although, there is no official definition for high-precision measurement, the use of mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar is considered not to fall under the exception cases, neither of large-scale nor for high-precision measurement.

The restrictions under the Minamata Convention on Mercury will be transposed in Regulation (EU) 2017/852[9]. Thus, the validation period of a possible exemption must be limited, and an expiry date of 31 December 2025 is proposed. The date by which this exemption will expire is set in line with Article 5(2), first subparagraph, RoHS Directive.

It is proposed to add a new entry 49 for the relevant application in Annex IV. Since the capillary rheometers described in the exemption request fall under category 9 “monitoring and control instruments” 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.

7 UNEP/MC/COP.4/26/Add.1 2021
8 UNEP/MC/COP.4/28/Add.1 2022
9 OJ L 137, 24.5.2017, p. 1–21.

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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), 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 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) On 26 April 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 mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar ('the requested exemption').

(5) The used pressure transducer, incorporated in capillary rheometers, consists of electrical components and is an electrical measurement device in the scope of the Directive 2011/65/EU. The capillary rheometers described in the requested exemption fall under category 9 'monitoring and control instruments' of Annex I to Directive 2011/65/EU.

(6) The evaluation of the exemption application, which included a technical and scientific assessment study[2], concluded that substitution of mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1000 bar are currently scientifically and technically impracticable. The evaluation included stakeholder consultations as required by Article 5(7) of Directive 2011/65/EU.

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

[2] Study to assess requests for two (-2-) exemptions, for mercury in pressure transducer and DEHP in a PVC base material, in Annex IV of Directive 2011/65/EU (Pack 25)

(7) One of the relevant conditions specified in Article 5(1), point (a), of Directive 2011/65/EU is met, namely that the elimination and substitution is scientifically or technically impracticable.

(8) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 9.

(9) In order to comply with future restrictions on mercury-added products under Regulation (EU) 2017/852, it is necessary to limit the validity period of the exemption to 31 December 2025. The period is set in accordance with Article 5(2), first subparagraph of Directive 2011/65/EU.

(10) 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 sixth 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 sixth 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, 4.5.2023

For the Commission
The President
Ursula VON DER LEYEN