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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 25 October 2023 |
| To: | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union |
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| Subject: | COMMISSION DELEGATED DIRECTIVE (EU) .../... of 25.10.2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered rigid polyvinyl chloride |

Delegations will find attached document C(2023) 7088 final.

Encl.: C(2023) 7088 final



EUROPEAN
COMMISSION

Brussels, 25.10.2023
C(2023) 7088 final

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

of 25.10.2023

amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered rigid polyvinyl chloride

(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 specific applications containing cadmium and lead.

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 Regulation')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.

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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).

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 Directive³.

The Commission received a request for a new exemption for use of cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered polyvinyl chloride (PVC) on 14 December 2015 (request no. B-2016). The exemption concerns electrical and electronic equipment listed in category 11 of Annex I⁴.

With a view to evaluating the application for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including an eight-week public stakeholder consultation⁵ on the application. Eighteen contributions were made to the stakeholder consultation. The final report containing the assessment of the application was published⁶ and stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS during the expert meetings on 22 September 2017 and on 21 October 2019⁷. One expert explicitly supported the granting of the exemption, two Member State experts expressed their opposition, stressing mainly the need for alignment with the REACH as well as to apply the same requirements to virgin and recycled material. In addition, one of the comments asked for removal of the symbol with “PVC” from the wording. This comment was accepted and the draft Delegated Directive subsequently amended accordingly. The remainder of experts remained silent. In accordance with the Better Regulation Guidelines, the draft Delegated Directive was published on the Better Regulation Portal for a four-week public feedback period. Two comments were received, both supporting the draft proposal while requesting an exemption validity period of fifteen years.

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

- Cadmium and lead are used in PVC frame material for windows and door sets for the purpose of polymer stabilisation of the PVC profiles.
- Most of the applications for window and door sets are not electrical. Only a small amount compared to all windows and doors requires a time-limited exemption as they are EEE according to Article 3(1) of the RoHS Directive.

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

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. Category 11 enters in scope of Directive 2011/65/EU on 22 July 2019, as per Article 4(3) to that Directive.

⁵ [Consultation period](#): from 28 October until 22 December 2016.

⁶ [Study to assess 2 RoHS new exemption requests - #1 for cadmium in video cameras designed for use in environments exposed to ionising radiation, #2 for lead and cadmium in PVC profiles of electric windows and doors : final report](#)

⁷ E02810 - Expert Group for RoHS 2 adaptation and enforcement - <https://ec.europa.eu/transparency/expert-groups-register/screen/home?lang=en>

- While lead- and cadmium-free technologies used in virgin PVC are available on the market, use of recovered PVC⁸ requires lower amounts of energy and natural resources (such as water, petroleum and natural salt) than would be otherwise needed for use of virgin PVC. The use of recovered PVC is thus associated with socio-economic benefits in particular with regard to decarbonisation, circular economy and raw material availability.
- 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. use of virgin PVC not containing lead and cadmium associated with high use of raw material and primary energy) are likely to outweigh the total environmental, health and consumer safety benefits thereof (avoidance of lead and cadmium in EEE to be placed on the market).

In accordance with Article 5(1)(a) of Directive 2011/65/EU, the specific exemption should not weaken the environmental and health protection afforded by the REACH Regulation.

Cadmium is restricted by entry 23 of Annex XVII to the REACH Regulation. By way of derogation, the restriction does not apply to articles containing recovered PVC if their concentration of cadmium does not exceed 0,1% by weight of the plastic material in articles, including doors and windows. No changes on this entry are planned in the near future.

Lead is restricted by entry 63 of Annex XVII to the REACH Regulation. A revision of this restriction entry on lead in PVC started in 2016. In order not to weaken the protection level afforded by the REACH Regulation, the decision under the RoHS Directive had to be aligned with the REACH Regulation restriction proposal. In 2019, the Commission proposed a draft Commission Regulation restricting the use of any concentration of lead and its compounds in PVC articles in a concentration equal to or greater than 0,1% by weight of the PVC material. A resolution objecting to the draft regulation was adopted by the European Parliament plenary on 12 February 2020⁹.

The adoption of the draft delegated act under the RoHS Directive was therefore suspended until a new restriction proposal, taking into account the resolution of the Parliament, is prepared. The Commission amended some of the provisions of the draft regulation to reflect the arguments brought forward by the Parliament and take into account relevant new data. A new draft regulation was prepared and finally adopted on 3 May 2023¹⁰.

Taking into account this Commission Regulation (EU) 2023/923, the proposed exemption wording under RoHS required adaptation in order to fulfil the first requirement under Article 5(1)(a). By adapting the wording and including limiting requirements (e.g., reducing maximum concentration of lead in recovered PVC) of the exemption, the proposed exemption, subject to this delegated directive, does not weaken the environmental and health protection afforded by the REACH Regulation.

⁸ 'Recovered PVC' refer to mixtures produced from PVC waste.

⁹ European Parliament resolution of 12 February 2020 on the 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 (OJ C 294, 23.7.2021, p. 2).

¹⁰ Commission Regulation (EU) 2023/923 of 3 May 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC (OJ L 123, 8.5.2023, p. 1–6).

The exemption is requested for a maximum validity period, which is five years according to Article 5(2). The Commission Regulation (EU) 2023/923 allows profiles for windows and doors containing recovered rigid PVC with lead concentration lower than 1,5% by weight, until 28 May 2033. By 28 May 2028, the Commission shall review entry 63, point 18, of Annex XVII to Regulation (EC) No 1907/2006 in light of new scientific information and, if appropriate, modify it accordingly. In line with the REACH decision and in view of lacking technologies, which can completely eliminate legacy substances, the expiry date of the exemption under the RoHS Directive should be set with 28 May 2028.

The Commission consulted the Member States expert group for delegated acts under RoHS during the expert meeting on 5 June 2023. The link to the REACH restriction entry was emphasised and the Members were informed about the expiry date. The new draft Delegated Directive was published on the Better Regulation Portal for a four-week public feedback period. Ten comments were received, mainly from manufacturers and suppliers of PVC windows and doors, but also from individual stakeholders who pointed to the general significance. However, no changes to the draft legal text were necessary.

All necessary steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.¹¹ The Council and the European Parliament were notified of all activities.

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 III of Directive 2011/65/EU, for the use of cadmium and 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 total negative environmental impacts caused by substitution are likely to outweigh the total environmental benefits.

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 the RoHS Directive 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.

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¹¹ A list of the required administrative steps is available on the [Commission website](https://commission.europa.eu/interinstitutional-registry). 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>.

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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 equipment¹ 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 applications listed in Annexes III and 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) Cadmium and lead are restricted substances listed in Annex II to Directive 2011/65/EU. Lead is restricted with a maximum concentration value of 0,1% and cadmium with a maximum concentration value of 0,01% by weight in homogenous materials.
- (4) On 14 December 2015, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for granting an exemption for cadmium and lead in electrical and electronic windows and doors containing recovered polyvinyl chloride (PVC) ("the requested exemption").
- (5) A technical and scientific assessment study² was carried out to evaluate the requested exemption. The evaluation included stakeholder consultations as required by Article 5(7) of Directive 2011/65/EU.

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¹ OJ L 174, 1.7.2011, p. 88.

² [Study to assess 2 RoHS new exemption requests - #1 for cadmium in video cameras designed for use in environments exposed to ionising radiation, #2 for lead and cadmium in PVC profiles of electric windows and doors : final report](#)

- (6) Cadmium and lead are used in recovered PVC frame material for window and door sets for the purpose of polymer stabilisation of the PVC profiles.
- (7) The electrical and electronic equipment described in the requested exemption falls under category 11 of Annex I to Directive 2011/65/EU.
- (8) While lead- and cadmium-free virgin PVC is available on the market, the use of recovered PVC requires lower amounts of energy and natural resources (such as water, petroleum and natural salt) than the amounts that would be otherwise needed for the use of virgin PVC. Therefore, the total negative environmental, health and consumer safety impacts caused by substitution would likely outweigh the total environmental, health and consumer safety benefits thereof. Thus, the requested exemption meets at least one of the relevant conditions specified in Article 5(1), point (a), of Directive 2011/65/EU.
- (9) The exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council³. The scope of the exemption is limited to the current cadmium and lead restriction entries under that Regulation. In particular, the scope of the exemption has been aligned with the derogation for lead in recovered PVC set out in Commission Regulation (EU) 2023/923⁴.
- (10) It is, therefore, appropriate to grant the exemption by including the applications covered by that exemption in Annex III to Directive 2011/65/EU with respect to electrical and electronic equipment of category 11 of Annex I to Directive 2011/65/EU.
- (12) The expiry date of the exemption should be limited to 28 May 2028, by which time the restriction entry 63, points 18, of Annex XVII to Regulation (EC) No 1907/2006 shall be reviewed. The expiry date is in accordance with the first subparagraph of Article 5(2) of Directive 2011/65/EU.
- (13) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

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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).

⁴ Commission Regulation (EU) 2023/923 of 3 May 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC (OJ L 123, 8.5.2023, p. 1).

Article 2

1. Member States shall adopt and publish, by [OP: please insert 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 to the Commission the text of those provisions.

They shall apply those provisions from [OP: please insert 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, 25.10.2023

For the Commission
The President
Ursula VON DER LEYEN