EUROPEAN
COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in glass or ceramic components

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 and scientific progress, Annex III 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 ceramics and glass.

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

Annexes III and IV to the RoHS Directive list the materials and components of EEE for specific applications exempted from the substance restrictions in Article 4(1) of the Directive. Article 5 allows Annexes III and IV to be adapted to scientific and technical progress (on granting, renewing and revoking exemptions). Under Article 5(1)(a), exemptions are to be included in Annexes III and IV only if that does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 ('the REACH Regulation')[2] and if any of the three following conditions are met:

- if the elimination or substitution via design changes or materials and components that do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- if the reliability of substitutes is not ensured;
- if 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 impact of the exemption must apply, where relevant.

EEE subject to the RoHS Directive is classified in accordance with the categorisation set out in Annex I to that Directive.

Article 5(1) of the RoHS Directive allows the Commission to 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 lay down the procedure for submitting exemption applications.

[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 requests from economic operators to grant or renew exemptions pursuant to Article 5(3) of the RoHS Directive[3].

Annex III to the RoHS Directive lists in point 7(c)-I an exemption for components containing lead in a glass or ceramic (other than dielectric ceramic in capacitors), e.g. piezoelectronic devices, or in a glass or ceramic matrix compound. The exemption in point 7(c)-I was renewed most recently by Commission Delegated Directive (EU) 2018/736[4].

Annex III to the RoHS Directive lists in point 7(c)-II a closely linked exemption for lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher. The exemption in point 7(c)-II was renewed most recently by Commission Delegated Directive (EU) 2019/169[5].

The exemptions in points 7(c)-I and 7(c)-II were to expire on 21 July 2021 for categories 1-7 and 10 as well as for categories 8 and 9 other than *in vitro* diagnostic (IVD) medical devices and industrial monitoring and control instruments (IMCI). The exemptions were to expire on 21 July 2023 for category 8 *in vitro* diagnostic medical devices and on 21 July 2024 for category 9 industrial monitoring and control instruments and category 11 'other EEE not covered by any of the other categories' ('other EEE').

Between 19 December 2019 and 22 January 2020, the Commission received six renewal requests for the exemption in point 7(c)-I. In addition, the Commission received a similar request for category 8 *in vitro* diagnostic medical devices on 20 January 2022 and a similar request for category 9 industrial monitoring and control instruments as well as category 11 'other EEE' on 20 January 2023. On 19 December 2019, the Commission received one renewal request for the exemption in point 7(c)-II. All applications were received within the timeframe for renewal laid down in Article 5(5) of the RoHS Directive.

According to Article 5(5), second subparagraph, of the RoHS Directive, existing exemptions are to remain valid until a decision on the renewal application is taken by the Commission.

Technical assessment

In October 2020, the Commission launched a study[6], concluded in February 2022, to carry out the required technical and scientific assessment, including a 10-week public stakeholder consultation. All comments were taken into account. Information concerning the consultation was provided on the project website[7].

Six individual contributions for the exemption in point 7(c)-I were submitted during the public consultation. For the exemption in point 7(c)-II, three individual contributions were received. Industry representatives mainly supported a renewal of both exemptions.

In August 2023, the Commission launched a study[8], concluded in April 2024, to evaluate new category-specific information from the applications received in 2022 and 2023. The technical

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

4 OJ L 123, 18.5.2018, p. 94.

5 OJ L 33, 5.2.2019, p. 5.

6 The final report (Pack 22) of the study is available at: https://op.europa.eu/en/publication-detail/-/publication/c774eb67-7cc6-11ec-8c40-01aa75ed71a1/language-en.

7 Consultation period: 30 March 2021 to 8 June 2021; https://rohs.exemptions.oeko.info/.

8 The final report (Pack 27) of the study is available at: https://op.europa.eu/en/publication-detail/-/publication/708d9a2a-26e1-11ef-a195-01aa75ed71a1/language-en/format-PDF/source-327348441.

assessment contained an 8-week public stakeholder consultation and all comments were taken into account. Information on the consultation was provided on the project website[9].

For the **exemption in point 7(c)-I**, a distinction can be made between applications where lead is part of a **glass material** and applications where it is part of a **ceramic material**. The amount of lead placed on the market under the exemption in point 7(c)-I was estimated at around 650 tonnes per year.

For lead in **glass materials and components**, lead is used in **low melting point glass solders**, in **glass frits, chip resistors and encapsulations** of semiconductor components, as well as in **electronic glasses**. The first two applications are rather based on mechanical and physical properties like reducing the melting temperature of glass, improving wettability between materials or increasing the chemical resistance of the bond. This last type of application is additionally based on specific electronic properties enabling current flows within the glasses.

For lead in ceramic materials, lead is used for **piezoelectric materials** and **positive temperature coefficient thermistors**. In positive temperature coefficient thermistors, lead enables the thermal characteristics and resistive value stability of the ceramic material, which make it possible for the material to remain stable under changing temperatures. Lead in piezoelectric materials is important among others to convert mechanical energy from vibrations into an output electrical charge and vice versa.

Available substitutes are understood not to provide comparable performance, not enabling application or resulting in bonds and seals of lower reliability. Thus, the technical assessment concluded that the exemption is justified as available substitutes either: (i) are not suitable and cannot be fabricated into lead-free components that could be used in the same applications; or (ii) provide an inferior reliability leading to malfunctions that would not be acceptable in the respective EEE.

However, a more specific and focused assessment is difficult since there is a broad range of applications. The exemption in point 7(c)-I can be split into applications for glass and applications for ceramic materials. Furthermore, limiting the scope of exemptions to specific sets of applications would enable a more detailed assessment in the future. Based on the review carried out in 2015-2016[10] and its previous efforts to split the exemption in point 7(c)-I into sub-groups, the following applications for glass materials were identified:

(1) for protection and electrical insulation in glass beads of high-voltage diodes on the basis of a zinc-borate glass body;

(2) for hermetic sealing between ceramic packages and glass or ceramic lids;

(3) for bonding purposes in a limited process parameter window;

(4) for use as a resistive material such as ink, excluding trimmer potentiometers; and

(5) for use in chemically modified glass surfaces for microchannel plates (MCPs), single channel electron multipliers (CEMs) and resistive glass products (RGPs).

(6) For ceramic materials, the following applications were identified:

(7) for use in piezoelectric lead zirconium titanate (PZT) ceramics;

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9 Consultation period: 16 October 2023 to 11 December 2023; https://rohs.biois.eu/.

10 The final report (Pack 9) of the study is available at: https://op.europa.eu/en/publication-detail/-/publication/a3fdcc8c-4273-11e6-af30-01aa75ed71a1.

(8) for providing ceramics with a positive temperature coefficient (PTC).

As there has been sufficient time to adapt to and help develop these sub-groups, the segmentation into sub-groups is not considered a disproportionate administrative burden for the industry. In addition, the scope of the applications was appropriately designed to cover the existing scope of exemption in point 7(c)-I. The sub-entries should remain under the entries 7(c)-V and 7(c)-VI. To allow the industry to refine the applications identified, a short-term renewal is recommended for the previous point 7(c)-I.

For the exemption in point 7(c)-II, high-voltage capacitors (i.e. with a rated voltage of 125 V AC or 250 V DC or more) are mainly applied in power supply devices and protection devices. Such discrete ceramic high-voltage capacitors are incorporated into a wide range of EEE to store and release electric charges, which is necessary for the products to function as needed. Lead influences the electromagnetic properties of the solid-state dielectric (ceramic material), in particular capacitance and dielectric losses of capacitors. The ceramics contain lead in concentrations of 0.1-60% by weight of the homogeneous material.

Substituting lead in ceramic dielectrics for high-voltage capacitors is scientifically possible in some cases, but not yet practicable from an industrialised technical point of view. In addition, lead-free capacitors heat up when high voltage is applied and can become unstable, so that reliability is not a given. Given the current state of the market, a short-term phase-out of lead in the full range of this application is impossible, as specific materials and probably also design adjustments would need to be tested before lead-free alternatives could be applied.

According to the threshold requirement under Article 5(1)(a) of the RoHS Directive, an exemption cannot weaken the environmental and health protection afforded by the REACH Regulation. However, electrical and electronic components containing lead in glass or ceramic (including capacitors) are not accessible under normal circumstances to consumers. Thus, renewing exemptions 7(c)-I and 7(c)-II carries no risk of violating the protection level set by the REACH Regulation.

The Commission consulted the Member State expert group for delegated acts under the RoHS Directive on 11 October 2021 and on 18 September 2024. It carried out all the required procedural steps relating to exemptions from the substance restrictions in accordance with Article 5(3) to (7)[11]. The Council and the European Parliament were notified of all relevant activities.

The main point of criticism from Member State experts concerned the insufficient information provided by applicants as part of the technical assessments. Applicants should clearly demonstrate that the criteria under Article 5(1)(a) of the RoHS Directive are met and substantiate their claims. Otherwise, no exemption should be granted. The Commission has taken this into account by creating sub-entries and short validity periods, where necessary. The Commission also considered other contributions, from several industry representatives, in favour of maintaining the status quo in terms of exemptions.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The evaluation results show 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 the RoHS Directive.

[11] 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 Inter-institutional Registry of Delegated Acts at https://webgate.ec.europa.eu/regdel/#/home.

For both exemptions 7(c)-I and 7(c)-II of Annex III to the RoHS Directive, substitutes either are not available for most applications covered by these entries, or lack in reliability or performance. Thus, the criteria set out in Article 5(1)(a), first and second indent, are fulfilled: the 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, and the reliability of substitutes is not ensured.

For exemption in point 7(c)-I, it is appropriate to create sub-entries for glass and ceramic applications. Thus, two exemptions should be granted: 7(c)-V for lead in glass applications and 7(c)-VI for lead in ceramic applications. In addition, sub-entries should specify what application areas are relevant for these exemptions.

Although the scope of the proposed exemptions in points 7(c)-V and 7(c)-VI should be identical to the previous scope of the exemption in point 7(c)-I, the old exemption in point 7(c)-I should be granted a short-term validity period enabling industry to request missing areas of application.

The exemption in point 7(c)-II should be renewed with the same scope and with the clarification that the entries 7(c)-I and 7(c)-IV are not covered by it.

Given the amount of time that has passed since the technical assessment was carried out (concluded in February 2022), exemptions 7(c)-II, 7(c)-V and 7(c)-VI should have a limited validity period rather than the maximum possible validity period. In order to give applicants the chance to provide missing data, to complete and substantiate claims made in the previous technical assessment, a short deadline is seen as sufficient to provide such data. As the burden of proof that a criterion of Article 5(1)(a) is met lies with the applicant, complete data should be submitted at the next assessment, otherwise a renewal due to missing data must be considered.

In view of the technical evaluation, it is appropriate to set one expiry date for all categories listed in Annex I to the RoHS Directive.

The dates on which these exemptions should expire are set in line with Article 5(2), first subparagraph. The validity period of these exemptions should be long enough for the industry to prepare renewal requests in accordance with Article 5(5), first subparagraph, of the RoHS Directive, which stipulates that applications for renewal of an exemption must be made no later than 18 months before the exemption expires.

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

The delegated directive aims to contribute to the protection human health and the environment, and to harmonise provisions for the functioning of the single market in the field of EEE, by allowing the use of otherwise banned substances for specific applications, in line with the RoHS Directive and the procedure laid down in that Directive for the adaptation to scientific and technical progress of its Annexes III and IV.

The validity periods granted are not expected to have adverse impacts on innovation.

The delegated directive has no implications for the Union budget.

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amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in glass or ceramic components

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 III 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. The maximum tolerated concentration value is 0,1% by weight of lead in homogenous materials.

(4) Commission Delegated Directive (EU) 2018/736[2] granted an exemption for electrical and electronic components containing lead in glass or ceramic or in glass or ceramic matrix compound, as set out in entry 7(c)-I of Annex III to Directive 2011/65/EU. The exemption was to expire on 21 July 2021, 21 July 2023 and 21 July 2024, respectively for each of the relevant electrical and electronic equipment category.

(5) Commission Delegated Directive (EU) 2019/169[3] granted an exemption for lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher, as set out in entry 7(c)-II of Annex III to Directive 2011/65/EU. The exemption was to expire on 21 July 2021, 21 July 2023 and 21 July 2024, respectively for each of the relevant electrical and electronic equipment category.

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1 OJ L 174, 1.7.2011, p. 88, ELI: http://data.europa.eu/eli/dir/2011/65/oj.

2 Commission Delegated Directive (EU) 2018/736 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for certain electrical and electronic components containing lead in glass or ceramic (OJ L 123, 18.5.2018, p. 94, ELI: http://data.europa.eu/eli/dir_del/2018/736/oj).

3 Commission Delegated Directive (EU) 2019/169 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in certain capacitors (OJ L 33, 5.2.2019, p. 5, ELI: http://data.europa.eu/eli/dir_del/2019/169/oj).

(6) The Commission received in total eight renewal requests for the exemption referred to in recital 4, covering all electrical and electronic equipment categories. For the exemption referred to in recital 5, the Commission received one renewal request. All requests were received within the timeframe for renewal laid down in Article 5(5) of Directive 2011/65/EU. In accordance with Article 5(5), second subparagraph, of Directive 2011/65/EU, the existing exemption remains valid until a decision on the renewal application is taken by the Commission.

(7) In order to evaluate the applications received, a technical and scientific assessment study was carried out and finalised in 2022[4]. A further study focussing on the electrical and electronic equipment categories requested for renewal at a later stage was carried out and finalised in 2024[5]. The evaluations included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(8) The evaluation of the requested exemption renewal concluded that in ceramics, lead provides particular dielectric, piezoelectric, pyroelectric, ferroelectric, semiconductor, magnetic properties over a wide use range in terms of temperatures, voltages or frequencies. In glass, lead provides crucial properties such as lowering the melting and softening points, improving workability, machinability, and chemical stability and others.

(9) Substitutes for lead-containing ceramics and glasses are either not technically practicable for all applications or substitutes are not sufficiently reliable for specific applications. Thus, the requested renewal meets the criteria set out in Article 5(1), point (a), first and second indent, of Directive 2011/65/EU, namely, that the elimination or substitution through the 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 and that the reliability of substitutes is not ensured.

(10) In order to allow a more focussed technical assessment in the future, the current exemption set out in entry 7(c)-I of Annex III to Directive 2011/65/EU should be split in two points, namely 7(c)-V for lead in glass applications and 7(c)-VI for lead in ceramic applications. It is appropriate to specify the technical applications in those entries.

(11) The evaluation referred to in recital 7 concluded that even though it is scientifically possible to substitute lead in ceramic dielectrics for high-voltage capacitors for some applications under the exemption set out in point 7(c)-II of Annex III to Directive 2011/65/EU, it is not technically practicable for most applications. In addition, such lead-free capacitors lack the sufficient reliability in practice. Thus, the requested renewal meets the criteria set out in Article 5(1), point (a), first and second indent, of Directive 2011/65/EU.

(12) The renewed exemptions should be granted with validity periods which take into account the technical conclusions of the evaluation referred to in recital 7. The exemption set out in point 7(c)-I of Annex III to Directive 2011/65/EU should be renewed for a short-term validity period in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU. The expiry dates of the exemption set out in

[4] Final Report (Pack 22) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/c774eb67-7cc6-11ec-8c40-01aa75ed71a1/language-en.

[5] Final Report (Pack 27) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/708d9a2a-26e1-11ef-a195-01aa75ed71a1/language-en/format-PDF/source-327348441.

points 7(c)-II and the exemptions to be set out in points 7(c)-V and 7(c)-VI of Annex III to that Directive should take into account the minimum period of 18 months before the expiry date, in which renewal requests need to be submitted in accordance with Article 5(5), first subparagraph, of Directive 2011/65/EU.

(13) Due to the remaining short-term renewal of the exemption set out in point 7(c)-I of Annex III to Directive 2011/65/EU, it is appropriate to set one expiry date for all categories of electrical and electronic equipment set out in Annex I to Directive 2011/65/EU.

(14) The renewal of the exemptions does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6].

(15) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2011/65/EU is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by [the last day of the 6th 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 6th 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.

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6 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/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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

Done at Brussels,

For the Commission
The President
Ursula von der Leyen