EUROPEAN
COMMISSION

Brussels, XXX
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**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 high melting temperature solders**

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*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 high melting temperature solders.

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 where any of the 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.

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.

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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 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 under point 7(a) an exemption for **lead in high melting temperature type solders** (i.e. lead-based alloys containing 85 % by weight or more lead). The exemption in point 7(a) was renewed most recently by Commission Delegated Directive (EU) 2018/742[4]. The wording of that exemption has not been changed since its introduction in 2003.

The exemption in point 7(a) was to expire on 21 July 2021 for categories 1 to 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 exemption was 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').

On 15 and 16 January 2020, the Commission received renewal requests for exemption in point 7(a) concerning categories 1-10. In addition, on 9 October 2020, the Commission received a similar request for category 11. All applications were received within the timeframe for renewal laid down in Article 5(5) of the RoHS Directive.

For category 9 industrial monitoring and control instruments and category 11 other EEE, the Commission received two renewal applications on 20 January 2023, 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 should remain valid until a decision on the renewal application is taken by the Commission.

**Technical assessment**

In October 2020, the Commission launched a study[5], 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[6].

Seven individual contributions for the exemption in point 7(a) were submitted during the public consultation. Industry representatives mainly supported a renewal of the exemption in point 7(a), whereas public authorities criticised the undefined scope and a lack of justification when implementing that exemption.

The main points derived from the technical and scientific assessment are as follows.

(a) Lead-containing high melting temperature type solders are used in different components for different EEE categories. They can be used in EEE as a die attach material, as internal electrical interconnections, as sealing material, in lamps or in audio transducers.

(b) These types of solders use between 85% and 95.5% lead by weight. The high concentration of lead contributes to important material properties, like having high melting points (>260 °C) and good thermal and electrical conductivity, ductility,

[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. 112.

[5] 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.

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

corrosion-resistivity, appropriate oxidation nature, and wettability. These properties are especially relevant in harsh environments, e.g. applications exposed to vibration or high temperatures. These material properties also facilitate an easier and faster manufacturing of EEE components and thus a better cost efficiency in manufacturing EEE.

(c) The exemption in point 7(a) of Annex III for lead in high melting temperature solders covers between 150 and 9 400 tonnes of lead per year and is therefore probably one of the exemptions that uses the most lead under the RoHS Directive.

(d) The exemption in point 7(a) is often used as justification for high lead values in solders for various products although there is no technically discernible necessity. The scope does not define the area of application and neither does it address the functional purpose of lead based on its properties.

(e) There are lead-free solders for higher temperatures that could be used in certain applications. One area where progress was made in designing lead-free solutions were high and low frequency audio transducers. However, for other sectors, the engagement to develop substitutes for lead-containing high melting temperature type solders is limited.

(f) The technical assessment concludes that lead-free solutions will not be available for all applications in the next 3 years. The different applications of and required conditions for the materials are too various to justify a discontinuation of the exemption based on individual solutions at this time.

(g) However, similar to the approach proposed in the most recent technical assessment, in 2016, splitting the exemption point into more specific sub-entries would make it easier to provide tailored evidence and to assess the availability and reliability of alternatives in the future. The segmentation of exemption 7(a) into areas of application supported by technical conditions is the most appropriate categorisation. This approach would help to focus the next technical assessment on these areas of application.

(h) The technical study investigated potential demarcations between technical application areas to enable such a categorisation. Practical sub-categories were developed based on the current technical state of the art and considering the input of key stakeholders from the sector. The intention is to cover all applications currently in the scope of the exemption in point 7(a) to avoid any unacceptable distortion in the sector.

The following application areas were identified:

(a) internal interconnections in EEE;

(b) integral connections of die attach in EEE components;

(c) integral connections for components other than die to be mounted on sub-assemblies (first level solder joints);

(d) second level solder joints for the attachment of components to printed circuit board or lead frames;

(e) hermetic sealing materials;

(f) lead-containing high melting temperature type solders in certain lamps;

(g) audio transducers.

As there has been sufficient time to adapt to and help develop these sub-categories, the segmentation into sub-categories is not considered a disproportionate administrative burden for the industry. In addition, the scope of the application areas was appropriately designed to cover the existing scope of exemption in point 7(a). However, it is understood that industry

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should have the possibility to apply for new sub-categories. Therefore, a short-term renewal is recommended for the previous point 7(a).

In order to assess the category-specific renewal applications for category 9 industrial monitoring and control instruments and category 11 other EEE, a technical and scientific assessment study was carried out and finalised in 2024[7]. The evaluations included stakeholder consultations in accordance with Article 5(7) of the RoHS Directive.

Lead in high melting temperature type solders covered by exemption in point 7(a) is used in a diverse range of final applications and no sound technical arguments were provided to justify different scopes or validity periods depending on the EEE category. That was confirmed by the second technical assessment study, which focused on category-specific information.

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. Lead-containing high melting temperature type solders are applied in internal electrical components, not accessible under normal circumstances to consumers. Thus, renewing the exemption in point 7(a) 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)[8]. 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.

For most applications covered by the exemption in point 7(a), substitutes either are not available 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.

However, it is appropriate to revise the wording of the current point 7(a) of Annex III and to create sub-categories for the different areas of application of high temperature point solders

[7] 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.

[8] 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.eu=-ropa.eu/regdel/#/home.

under that point. Thus, the delegated act introduces seven sub-entries I to VII under the exemption set out in point 7(a).

Even though the scope of all sub-entries should be identical to the previous scope of the exemption in point 7(a), the previous exemption in point 7(a) should be granted a short-term validity period enabling industry to request missing areas of application.

Given the amount of time that has passed since the technical assessment was carried out (concluded in February 2022), the new sub-exemptions should have a limited validity period rather than the maximum possible validity period, based on the technical recommendations For the purpose of giving applicants the chance to provide missing data and to complete and substantiate claims made in the previous technical assessment, a short deadline is considered sufficient. 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.

Sub-exemptions in points 7(a)-I to 7(a)-VII should have a slightly longer validity than the old exemption in point 7(a) to give industry time to prepare renewal requests with more detailed information concerning these areas of application. 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 those exemptions should expire are set in line with Article 5(2), first subparagraph. The validity period of those 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 of 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 high melting temperature solders**

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) 2018/742[2] granted an exemption for the use of lead in lead in high melting temperature type solders, as set out in point 7(a) of Annex III to Directive 2011/65/EU. The scope of the exemption has not changed since its introduction. For most electrical and electronic equipment categories, the exemption was to expire on 21 July 2021.

(5) In January 2020 and October 2020, three renewal requests were received for the exemption referred to in recital 4 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. In order to evaluate the applications received, a technical and scientific assessment study was carried out and finalised in 2022[3]. The evaluations 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, ELI: http://data.europa.eu/eli/dir/2011/65/oj.

2 Commission Delegated Directive (EU) 2018/742 of 1 March 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 high melting temperature solders (OJ L 123, 18.5.2018, p. 112, ELI: http://data.europa.eu/eli/dir_del/2018/742/oj).

3 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.

(6) The exemption regarding electrical and electronic equipment in category 8 ‘in vitro diagnostic medical devices’, referred to in Annex I to Directive 2011/65/EU was to expire on 21 July 2023 and the exemptions regarding categories 9 ‘industrial monitoring and control instruments’ and 11 ‘other electrical and electronic equipment not covered by any of the categories’, referred to in Annex I to Directive 2011/65/EU, were set to expire date on 1 July 2024. On 20 January 2023, two renewal applications were submitted for category 9 and category 11 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. . In order to evaluate the applications received, a technical and scientific assessment study was carried out and finalised in 2024[4]. The evaluations included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(7) The evaluation of the requested exemption renewal concluded that high melting temperature type solders containing lead are used in various applications of electrical and electronic equipment. Those types of solders contain more than 85% lead by weight and have crucial properties such as high melting point, electrical conductivity, thermal conductivity, ductility, corrosion-resistivity, appropriate oxidation nature, and wettability.

(8) Although individual substitutes and alternatives are partly available, lead-free solutions will not be available, or be only available with insufficient reliability for all relevant applications, in the next three years.

(9) However, the exemption set out in point 7(a) of Annex III to Directive 2011/65/EU is widely used and sometimes without any technical need for it. To minimize the inappropriate use of that exemption and to enable an application-tailored evaluation, it is appropriate to split the exemption in sub-entries. A technical and scientific assessment with several rounds of stakeholder consultations was carried out focusing on developing adequate sub-entries.

(10) The technical and scientific assessment referred to in recital 9 identified seven areas of application covering the scope of the current exemption set out in point 7(a) of Annex III to Directive 2011/65/EU, namely internal interconnections in electrical and electronic equipment (‘EEE’), integral connections of die attach in EEE components, integral connections for components other than die to be mounted to sub-assemblies (first level solder joints), second level solder joints for the attachment of components to printed circuit board or lead frames, hermetic sealing materials, high melting temperature type solders in certain lamps, audio transducers. Those areas of application are further specified by technical conditions.

(11) As there has been sufficient time provided to contribute and to adapt to the development of sub-entries, and since all relevant areas of application covered by the currently applicable exemption set out in point 7(a) of Annex III to Directive 2011/65/EU should continue to be covered by the renewed exemption, the segmentation into sub-entries is not considered as a disproportionate administrative burden for the industry. To prevent any significant market distortion in the relevant sector, a period to identify missing areas of application should be provided. Therefore, a short-term validity period for the phasing out of the exemption set out in point 7(a)

[4] 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.

of Annex III to Directive 2011/65/EU should be granted, in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.

(12) For the sub-entries, a sufficient validity period should be granted considering the conclusions of the technical assessment referred to in recital 9 to allow stakeholders to supplement information on the application areas. The expiry dates 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(a) of Annex III to Directive 2011/65/EU, it is appropriate to set one expiry date for all categories of EEE set out in Annex I to Directive 2011/65/EU.

(14) The renewal of the exemption set out in point 7(a) of Annex III to Directive 2011/65/EU and the introduction of its sub-entries does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5].

(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*.

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[5] 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).

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*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission*
*The President*
*Ursula von der Leyen*

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