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 as an alloying element in steel, aluminium and copper

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 exemptions for lead as an alloying element in steel, aluminium and copper.

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 the 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 ('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 pursuant to 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, ELI: http://data.europa.eu/eli/dir/2011/65/oj.

[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, 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).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission receives requests from business to grant or renew exemptions pursuant to Article 5(3) of the RoHS Directive.[3]

Annex III to the Directive lists three main points for lead as an alloying element in steel, point 6(a), aluminium, point 6(b) and copper, point 6(c), which were initially covered by one point. Based on the results of the latest reviews, those points were expanded to adapt the entries to the technical and scientific progress and to create additional specific sub-entries.

Lead as alloying element in steel

The exemption in point 6(a)-I was included in Annex III to the RoHS Directive by Commission Delegated Directive (EU) 2018/739[4]. Categories 1 to 7 and 10 that were due for revision have been transferred to that new point. The expiry date of the exemption in point 6(a)-I is 21 July 2021. Exemption in point 6(a)-I concerns the use of lead as an alloying element in steel **for machining purposes** and in **galvanised steel**. Compared with the previous exemption in point 6(a), which also remained valid for certain EEE categories, the lower threshold concentration of lead in galvanised steel was lowered to 0.2% lead by weight.

Specifically, the expiry date of point 6(a) is 21 July 2023 for category 8 in-vitro diagnostic (IVD) medical devices, 21 July 2024 for category 9 industrial monitoring and control instruments (IMCI) as well as category 11 'other EEE not covered by any of the other categories' (other EEE).

On 17 January 2020 and 20 January 2020, within the timeframe for renewal set in Article 5(5) of the RoHS Directive, the Commission received two applications to renew the exemption in points 6(a) and 6(a)-I. On 20 January 2023, the Commission received two applications to renew the exemption in point 6(a) concerning category 9 IMCI and 11 other EEE.

Pursuant to Article 5(5), second subparagraph, of Directive 2011/65/EU the existing exemptions remain valid until a decision on the renewal application is taken by the Commission.

Lead as alloying element in aluminium

The exemption in points 6(b)-I and 6(b)-II were included in Annex III to the RoHS Directive by Commission Delegated Directive (EU) 2018/740[5]. The previous exemption in point 6(b) concerns the use of lead as an alloying element in aluminium containing up to 0.4% lead by weight and, similar to the exemption in point 6(a), is still relevant for specific EEE categories. However, most EEE categories have been transferred to the successor sub-exemptions in points 6(b)-I and 6(b)-II. Those two exemptions specify the scope of the previous exemption in point 6(b) in two applications: the exemption in point 6(b)-I covers **leaded aluminium, provided it stems from lead-bearing aluminium scrap recycling**, and the exemption in point 6(b)-II covers **leaded aluminium for machining purposes**.

---

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

4 Commission Delegated Directive (EU) 2018/739 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 as an alloying element in steel (OJ L 123, 18.5.2018, p. 103, ELI: http://data.europa.eu/eli/dir_del/2018/739/oj).

5 Commission Delegated Directive (EU) 2018/740 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 as an alloying element in aluminium (OJ L 123, 18.5.2018, p. 106, ELI: http://data.europa.eu/eli/dir_del/2018/740/oj).

The expiry date of point 6(b) is 21 July 2021 for categories 8 and 9, other than in vitro diagnostic medical devices and industrial monitoring and control instruments. Those latter sub-groups have an expiry date of 21 July 2023 for category 8 in-vitro diagnostic (IVD) medical devices and of 21 July 2024 for category 9 industrial monitoring and control instruments (IMCI). Category 11 'other EEE not covered by any of the other categories' (other EEE) also expires on 21 July 2024.

The expiry date of the exemption in point 6(b)-I is 21 July 2021 and that of point 6(b)-II is 18 May 2021, applicable for categories 1 to 7 and 10.

On 2 December 2019 and 17 January 2020, within the timeframe for renewal set in Article 5(5) of the RoHS Directive, the Commission received two applications to renew the scope and duration of these exemptions. On 20 January 2023, the Commission received two applications to renew the exemption in point 6(b) concerning categories 9 IMCI and 11 other EEE.

Lead as alloying element in copper

The exemption in point 6(c) of Annex III concerns **lead in copper alloys** and was renewed by Delegated Directive (EU) 2018/741[6]. The exemption has not been changed since the first RoHS Directive 2002/95/EC[7].

The exemption covers all EEE categories. The expiry date of the exemption in point 6(c) is 21 July 2021 for categories 1 to 7, 8 and 9, other than in vitro diagnostic medical devices and industrial monitoring and control instruments, and 10. The expiry date of the exemption in point 6(c) is 21 July 2023 for category 8 in-vitro diagnostic (IVD) medical devices and 21 July 2024 for category 9 industrial monitoring and control instruments (IMCI) as well as category 11 'other EEE not covered by any of the other categories' (other EEE).

On 15 January 2020 and 16 January 2020, within the timeframe for renewal set in Article 5(5) of the RoHS Directive, the Commission received two applications to renew the exemption in point 6(c).

Technical assessment

In October 2020, the Commission launched a study[8], which was concluded in February 2022, to carry out the required technical and scientific assessment, including a ten week public stakeholder consultation. All comments were taken into account. Information on the consultation was provided on the project website.[9]

10 specific contributions were submitted for the exemption in point 6(a) and numerous general contributions during the public consultation.

7 specific contributions were submitted for the exemption in point 6(b)-I, 12 specific contributions for the exemption in point 6(b)-II and numerous general contributions during the public consultation.

---

6 COMMISSION DELEGATED DIRECTIVE (EU) 2018/741 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 as an alloying element in copper (OJ L 123, 18.5.2018, p. 109, ELI: http://data.europa.eu/eli/dir_del/2018/741/oj).

7 Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 37, 13.2.2003, p. 19, ELI: http://data.europa.eu/eli/dir/2002/95/oj).

8 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

9 Consultation period: 23 December 2020 to 03 March 2021; https://rohs.exemptions.oeko.info/.

12 specific contributions were submitted for the exemption in point 6(c) and numerous general contributions during the publication.

To evaluate specific information on the new category from the applications received in 2023, in August 2023 the Commission launched a study[10], which was concluded in April 2024. The technical assessment contained an eight-week public stakeholder consultation, and all comments were taken into account. Information on the consultation was provided on the project website[11].

8 contributions were received for the exemption in point 6(a).

- 13 contributions were received for the exemption in point 6(b) .

Lead as alloying element in steel – technical conclusions

The technical and scientific assessment reports highlighted the following:

(a) lead is used as an alloying element in **steel for machining purposes** to increase the machining performance, stability and smooth surface of the material;

(b) in some cases, the substitution of lead is technically possible. However, this could not be further specified during the technical assessments and overall, barely any progress made on substituting lead in steel for machining purposes since the review in 2015. Revoking the exemption for machining purposes has negative impacts that outweigh the benefits of substituting lead, in particular if a short-term expiry date applies;

(c) to give further time to provide substantial evidence on the technical status of the substitution and to avoid negative impacts on the market, it is appropriate to grant a short term exemption;

(d) lead may be present in **batch hot-dip galvanised steel**. Liquid zinc is used in the galvanisation process to produce a protective zinc coating on steel products. Lead can be present as an impurity in the used zinc coming from secondary zinc or from lead residual concentration of earlier batches. In other cases, intentionally added lead ensure high quality of the coating, in particular for applications with small details. As some lead migrates to steel, the steel produced contains a small amount of lead;

(e) the current threshold concentration of lead (0.2% lead by weight) applicable to batch hot dip galvanised steel components is still appropriate and applicable;

(f) the use of secondary zinc is environmentally beneficial compared to using primary zinc. Revoking the exemption for batch hot dip galvanised steel has negative impacts that outweigh the benefits of substituting lead.It is therefore appropriate to grant the exemption;

(g) in both cases, the steel covered by the exemptions is used in a diverse range of final applications. No sound technical arguments were provided to justify changing the scope or validity period for different EEE categories.

Lead as alloying element in aluminium – technical conclusions

The technical and scientific assessment reports highlighted the following:

[10] 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

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

(a) lead may be unintentionally present in recycled aluminium scrap. This is the case for casting alloys, which are melted in a furnace and cast into a mould;

(b) substituting the lead in aluminium alloys, where the lead stems from aluminium scrap, has neither major environmental advantages nor would it be proportionally achievable at a large industrial scale. That means replacing or diluting secondary aluminium with primary aluminium in cast alloys would not be possible for all areas of applications, in part due to the higher energy consumption needed;

(c) the lead content of aluminium scrap is expected to decrease over time. Additional time is needed to ensure the reliability of lower lead aluminium alloys in industry;

(d) in order to clarify the scope of the exemption, the wording should be specified to **aluminium casting alloys from the recycling of lead-bearing aluminium scrap**;

(e) the maximum threshold value for lead in aluminium casting alloys should be reduced to 0.3% by weight due to technical progress[12] and declining lead concentration in aluminium scrap;

(f) lead is also used as an alloying element in **aluminium for machining purposes** to improve machinability by acting as a lubricant;

(g) reliable substitutes for lead in aluminium for machining purposes exist on the market for most EEE categories. Many applications have replaced lead in aluminium for machining purposes. The transition to lead-free aluminium was already evident in the last review of the exemption carried out in 2016[13];

(h) during the last evaluation process, there was one application, for which a reliable substitution was still not available: gas valves for gas control and regulation in gas household appliances.

(i) substitute material for this application in for gas valves is expected to be finalised at the end of 2024. After a transitional period of 18 months for the existing exemption in point 6(b)-II, a new exemption for lead in such specific applications will no longer be needed;

(j) for categories 9 industrial monitoring and control instruments, and category 11 other EEE, data suggests that the use of lead-free aluminium alloys for machining and the use of aluminium alloys with lead content reduced from 0.4% to 0.3% require redesign and, at least in some cases, requalification of the EEE This requires more time than the time needed for other EEE categories.

Lead as alloying element in copper – technical conclusions

The technical and scientific assessment reports highlighted the following:

(a) copper alloys containing lead have special properties in terms of conductivity, relaxation, corrosion or lubricity. The use of leaded copper alloys can thereforebe based on electrical and/or mechanical functions in EEE;

(b) for electrical components, leaded copper alloys are mostly used as conductors in all kinds of connections in numerous applications. For components using leaded copper alloys

[12] The content of lead in casting aluminium alloys was reduced in standard EN1706 AC 46500 in 2020 to a maximum of 0.29 % of lead content.

[13] Final report (Pack 9) – June 2016 – Oeko-Institut - Study to assess renewal requests for 29 RoHS 2 Annex III exemptions: https://op.europa.eu/en/publication-detail/-/publication/a3fdcc8c-4273-11e6-af30-01aa75ed71a1 .

based on mechanical properties, lead-free copper-zinc alloys exist but these alternatives require adaptations in the machining process, which require more time;

(c) although components with simple geometries could be substituted over the coming next years, there are restrictions on substitution that limit its applicability to certain applications.and a clear demarcation of applications could not be found;

(d) despite individual substitutions, it was concluded that the time was not right to narrow the scope or reduce the maximum concentration value for lead in copper alloys and doing so could have significant impacts;

(e) the lead-containing copper is used in a diverse range of final applications and no sound arguments were provided to justify different scopes or validity periods depending on the EEE category. One expiry date should be set for all EEE categories;

(f) although it is recommended to renew the exemption, application-specific evidence should be provided and, if appropriate, the scope of the exemption should be narrowed in the next review, due to progress in the work to substitute lead in copper alloys.

REACH

A similar level of protection should be afforded where the scope of the RoHS Directive is excluded from the restrictions set up by the REACH Regulation.

Pursuant to point 7 of the restriction in point 63 in Annex XVII of the REACH Regulation, lead is restricted in articles and their accessible parts with the aim of minimising children's exposure to lead from articles supplied to the general public. Lead in those articles or accessible parts are restricted to 0.05 % by weight if the components could be placed in the mouth of children. The limit does not apply where the rate of lead release is below a certain level. The size of accessible parts is smaller than 5 cm in one dimension.

According to point 8 of point 63 in Annex XVII of the REACH Regulation, the scope of the RoHS Directive is excluded from this specific restriction requirement. However, according to Article 5(1), point (a), first subparagraph, of the RoHS Directive, the inclusion of materials and components of EEE for specific applications requires that such inclusion does not weaken the environmental and health protection afforded by the REACH Regulation.

EEE devices or parts thereof can significantly exceed the threshold value set out in point 7 of point 63 due to exemptions grant and planned in points 6(a), 6(b) and 6(c) of Annex III to the RoHS Directive. Due to the various types of applications, it cannot be excluded that components may be placed in mouth by children, during normal or reasonably foreseeable conditions of use. I is therefore appropriate and in accordance with Article 5(1), point (a), of the RoHS Directive and with the precautionary principle to add the following footnote to the exemption wording in points 6(a), 6(b) and 6(c) of Annex III to the RoHS Directive:

> *The exemption shall not cover EEE for supply to the general public where the EEE or accessible part thereof may, during normal or foreseeable conditions of use, be placed in the mouth by children. However, the exemption shall apply where it can be both demonstrated that:*
>
> *— the rate of lead release from such an EEE or any accessible part, whether coated or uncoated, does not exceed 0,05 µg/cm2 per hour (equivalent to 0,05 µg/g/h), and,*
>
> *— for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the EEE.*

For the purpose of this footnote, it is considered that an EEE or accessible part of an EEE may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

The footnote constitutes a limitation of the scope but does only apply where the conditions are met, and article or accessible parts of an article are supplied to the general public. Thus, it is understood that the limitation will have a marginal impact, in particular for EEE applied in a professional context.

Consultations

The Commission consulted the Member States' expert group for delegated acts under the RoHS Directive on 11 October 2021 and on 18 September 2024. It carried out all the requisite procedural steps relating to exemptions from the substances restriction pursuant to Article 5(3) to (7).[14] The Council and the European Parliament were notified of all activities in that context.

A main criticism voiced by Member State' experts was the insufficient information provided by the applicants in the technical assessments . Applicants should clearly demonstrate that the criteria under Article 5(1), point (a), are met and should 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. Other contributions from several industry representatives in favour of maintaining the status quo of exemptions, were also considered.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Provided that a footnote is added to the respective exemption entries, the evaluation results show that the exemption, would not weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU.

Lead as alloying element in steel

Both technical applications (lead used for machining purposes or lead as residue in galvanised steel) currently covered by exemptions set out in points 6(a) and 6(a)-I, are split in two sub-exemptions to address technical progress, to give legal certainty to stakeholders and facilitate the next evaluation process. The delegated directive therefore grants two exemptions for lead in steel, in points 6(a)-I and 6(a)-II.

The first exemption in point 6(a)-I, replacing the previous point, covers lead as an alloying element in steel for machining purposes. The second exemption in new point 6(a)-II covers lead as an alloying element in batch hot dip galvanised steel. In both cases, the first intent of the criterion laid out in Article 5(1), point (a), is fulfilled, elimination or substitution is scientifically or technically impracticable for most applications fall under the exemptions.

The categories 8 and 9, currently covered by the exemption set out in point 6(a), will be covered by the two new sub-entries in points 6(a)-I and 6(a)-II. No changes are made to the scope for the exemption concerning lead in steel. Since no actual scope restriction is linked to the shift and consequently, no significant implications are expected, the previous exemption set out in 6(a) will expire within 12 months.

[14] 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.

In view of the advanced time from the conducted technical assessment, the new sub-exemptions should have a shorter validity period than the maximum possible validity period orientated on the technical recommendations. In addition, due to open scope questions and incomplete data from the industry, a short deadline is justified to give applicants the chance to substantiate their claims. As applicants have the burden of proof to show that one of the criteria of Article 5(1), point (a), is met, they should submit complete data at the next assessment, otherwise the Commission must consider not renewing the exemption due to a lack of missing data.

According to the technical assessment, the new sub-exemption in point 6(a)-I should expire earlier than sub-exemption in point 6(a)-II. However, a longer expiry date due to the advanced time does not justify a longer expiry date for the sub-exemption in point 6(a)-II. In light of the technical evaluation, it is appropriate to set one expiry date for all categories in Annex I to Directive 2011/65/EU.

Lead as alloying element in aluminium

The current point 6(b)-I covering aluminium stemming from lead-bearing aluminium scrap recycling is transferred to the new point 6(b)-III. The new point specifies the scope and sets the maximum lead concentration at 0.3% by weight. The criterion laid down in Article 5(1), point (a), second intent, is fulfilled, the reliability of substitutes is not ensured.

The application covering lead in aluminium for machining purposes no longer meets the relevant criteria set in Article 5(1), point (a), for categories 1 to7 and 10. Since the industry might require additional time to adjust to this change, a maximum transitional period according to Article 5(6) of the RoHS Directive should apply.

The previous exemption in point 6(b) evolves in its sub-entries. Relevant applications meeting the criteria of the RoHS Directive are transferred in the succeeding sub-entries and thus, it is appropriate that the previous point 6(b) should expire within 12 months. Categories 8, 9 and 11, currently covered by the exemption in point 6(b), will be covered by points 6(b)-I and 6(b)-III. For category 9 industrial monitoring and control instruments and category 11, the exemption in point 6(b)-I will remain valid. It is appropriate that other EEE categories, be covered by the new point 6(b)-III.

In view of the advanced time from the conducted technical assessment, the new sub-exemptions should have a shorter validity period than the maximum possible validity period orientated on the technical recommendations. In addition, due to open scope questions and incomplete data from the industry, a short deadline is justified to give applicants the chance to substantiate their claims. As applicants have the burden of proof to show that one of the criteria of Article 5(1), point (a), is met, they should submit complete data at the next assessment, otherwise the Commission must consider not renewing the exemption due to a lack of missing data.

Since no technical data were provided to justify the introduction of different expiry dates for different EEE categories, it is appropriate to set one expiry date for all categories set out in Annex I to the RoHS Directive.

Lead as alloying element in copper

The applications covered by the current scope of the exemption set out in point 6(c) of Annex III meet at least one criterion laid down in Article 5(1), point (a), of the RoHS Directive, namely that the reliability of substitutes is not ensured.

No technical information was provided showing that there are technical differencesbetween EEE categories regarding the substitution of lead in copper alloys. In light of the technical

evaluation, it is appropriate to set one expiry date for all categories set out in Annex I to the RoHS Directive.

In view of the advanced time from the conducted technical assessment, the new sub-exemptions should have a shorter validity period than the maximum possible validity period orientated on the technical recommendations. In addition, due to open scope questions and incomplete data from the industry, a short deadline is justified to give applicants the chance to substantiate their claims. As applicants have the burden of proof to show that one of the criteria of Article 5(1), point (a), is met, they should submit complete data at the next assessment, otherwise the Commission must consider not renewing the exemption due to a lack of missing data.

Delegated Act

Due to the technical proximity and the presence of lead in alloys used for EEE, one decision should be taken for all three exemptions. The legal instrument is a delegated directive, as provided for in the RoHS Directive, meeting the requirements set in Article 5(1), point (a).

The objective of the delegated directive is to contribute to the protection of human health and the environment, and to harmonise provisions for the functioning of the internal market in the field of EEE. To this end, it allows the use of otherwise banned substances for specific applications, in accordance with the RoHS Directive and the procedure established therein to adapt Annexes III and IV to scientific and technical progress.

The expiry dates of the exemptions is set in accordance with Article 5(2), first subparagraph, of RoHS Directive. The expiry dates should take into account the minimum period of 18 months before the expiry date, in which a renewal requests needs to be submitted in accordance with Article 5(5), first subparagraph, of the RoHS Directive, to give the industry enough time to prepare renewal requests.

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

The Delegated Directive has no implications for the Union budget.

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 as an alloying element in steel, aluminium and copper

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) and (b), 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) 2018/739[2] granted an exemption for the use of lead as an alloying element in steel for machining purposes containing up to 0,35% lead by weight and in batch hot dip galvanised steel components containing up to 0,2% lead by weight, as set out in point 6(a)-I of Annex III to Directive 2011/65/EU. That exemption covers categories 1 to 7 and category 10 of electrical and electronic equipment, listed in Annex I to Directive 2011/65/EU. The application of the exemption set out in point 6(a) of Annex III to that Directive was limited to electrical and electronic equipment categories 8, 9 and 11.

(5) Commission Delegated Directive (EU) 2018/740[3] granted exemptions for the use of lead as an alloying element in aluminium containing up to 0,4% lead by weight either for machining purposes or for recycling of lead-bearing aluminium scrap. The exemptions are set out in points 6(b)-I and 6(b)-II of Annex III to Directive

---

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

2 Commission Delegated Directive (EU) 2018/739 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 as an alloying element in steel (OJ L 123, 18.5.2018, p. 103, ELI: http://data.europa.eu/eli/dir_del/2018/739/oj).

3 Commission Delegated Directive (EU) 2018/740 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 as an alloying element in aluminium (OJ L 123, 18.5.2018, p. 106, ELI: http://data.europa.eu/eli/dir_del/2018/740/oj).

2011/65/EU. Those exemptions cover categories 1 to 7 and category 10 of electrical and electronic equipment, listed in Annex I to Directive 2011/65/EU. The application of the exemption set out in point 6(b) of Annex III to that Directive was limited to electrical and electronic equipment categories 8, 9 and 11.

(6) Commission Delegated Directive (EU) 2018/741[4] granted an exemption for the use of copper alloy containing up to 4 % lead by weight for all categories, as set out in point 6(c) of Annex III to Directive 2011/65/EU.

(7) On 17 January 2020 and 20 January 2020, the Commission received two applications for renewing the exemptions set out in points 6(a) and 6(a)-I of Annex III to Directive 2011/65/EU in light of scientific and technical progress, in particular with regard to its scope. On 2 December 2019 and 17 January 2020, the Commission received two applications for renewing the exemption set out in points 6(b), 6(b)-I and 6(b)-II of Annex III to Directive 2011/65/EU and on 15 January 2020 and 16 January 2020, the Commission received two applications for renewing the exemption set out in point 6(c) of Annex III to Directive 2011/65/EU.

(8) For the exemptions set out in points 6(a), 6(b) and 6(c) of Annex III to Directive 2011/65/EU, the electrical and electronic equipment category 8 'in vitro diagnostic medical devices', referred to in Annex I to Directive 2011/65/EU, were to expire on 21 July 2023 and the 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 to expire on 21 July 2024. On 20 January 2023, two renewal applications were received for each exemption set out in points 6(a) and 6(b) of Annex III to Directive 2011/65/EU and specifically regarding those three categories. In accordance with Article 5(5), second subparagraph, of Directive 2011/65/EU, their submission extended the validity of the existing exemptions until a decision on the renewal applications is taken.

(9) In order to evaluate the applications received, a technical and scientific assessment study was carried out and finalised in 2022[5]. A further study focussing on the categories for which a renewal was requested at a later stage was carried out and finalised in 2024[6]. The evaluations included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(10) The evaluation of the requested exemption renewal concluded that, regarding the exemption set out in point 6(a)-I of Annex III to Directive 2011/65/EU, lead is still necessary in steel to achieve certain machining properties. A substitution or elimination in batch hot dip galvanised steel is currently not technically feasible nor economically viable. However, both technical applications can be split between points 6(a)-I and 6(a)-II of Annex III to Directive 2011/65/EU, to allow a more dedicated examination in the next review.

---

4 Commission Delegated Directive (EU) 2018/741 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 as an alloying element in copper (OJ L 123, 18.5.2018, p. 109, ELI: http://data.europa.eu/eli/dir_del/2018/741/oj).

5 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 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.

(11) In order to provide sufficient time to substitute lead in steel and to avoid negative impacts, which outweigh the benefits of a substitution, it is appropriate to grant a short-term validity period for those applications, in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU. As regards points 6(a), 6(a)-I and 6(a)-II of Annex III to Directive 2011/65/EU, it is appropriate to set one expiry date for all categories listed in Annex I of that Directive.

(12) The exemption set out in point 6(a) of Annex III to Directive 2011/65/EU should expire 12 months after the date of the decision on the renewal application, in accordance with Article 5(6) of that Directive.

(13) As regards the exemption set out in point 6(b)-I of Annex III to Directive 2011/65/EU concerning lead in aluminium stemming from lead-bearing aluminium scrap recycling, it was found that the lead concentration can further be reduced to 0,3% by weight in aluminium. That should be set out in a new point, specifying that such aluminium is a casted alloy.

(14) The use of intentionally added lead in aluminium for machining purposes is no more needed for electrical and electronic equipment. Reliable substitutes for lead in aluminium exist on the market. The last application area relying on such an exemption is expected to be replaced by alternatives by 2025. In accordance with Article 5(6) of Directive 2011/65/EU, the maximum transition period of 18 months should be set to allow individual market participants in the industry to adapt.

(15) It was found that the use of aluminium alloys containing lead with lead concentration below 0,4% by weight requires redesign and requalification of electrical and electronic equipment falling under category 9 'industrial monitoring and control instruments' and open-scope category 11 'other electrical and electronic equipment', which requires more time for compliance when compared to other categories referred to in Annex I to Directive 2011/65/EU. Therefore, longer validity periods should be considered for those two categories.

(16) As regards point 6(c) of Annex III to Directive 2011/65/EU concerning copper alloys containing up to 4% lead by weight, it was not possible during the scientific and technical assessment to identify and define application areas that no longer require the exemption, despite many indications that lead could be successfully substituted in certain applications. Since substitutes are not sufficiently reliable, an extension of the exemption should be granted. In view of the technical evaluation, it is appropriate to set one expiry date for all categories listed in Annex I to Directive 2011/65/EU.

(17) The inclusion of materials and components of electrical and electronic equipment should not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[7]. Pursuant to point 7 of the restriction set out in point 63 of Annex XVII to Regulation (EC) No 1907/2006, lead is restricted in articles and their accessible parts with the aim of minimising children's lead exposure from articles supplied to the general public. Lead in those articles or accessible parts is restricted to not more than 0,05% by weight if

[7] 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).

those components may be placed in the mouth of children. To ensure compliance with the protection level established by Regulation (EC) No 1907/2006, the approved exemption entries should be marked with a footnote, which further restricts the applications in accordance with point 7 of the restriction set out in point 63 of Annex XVII to Regulation (EC) No 1907/2006.

(18) 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.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen