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COMMISSION DELEGATED DIRECTIVE (EU) 2025/2364

of 8 September 2025

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([1]), and in particular Article 5(1), point (a) 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 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.

([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).

([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).

(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.

(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.

([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.

(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 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 30 June 2026 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 1 July 2026.

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.

([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).

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, 8 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex III to Directive 2011/65/EU, points 6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II and 6(c) are replaced by the following:

‘6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Expires on 11 december 2026
6(a)-I	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight (*)	Expires on 30 June 2027 for all categories.
6(a)-II	Lead as an alloying element in batch hot-dip galvanised steel components containing up to 0,2 % lead by weight (*)	Expires on 30 June 2027 for all categories.
6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	Expires on 11 June 2027
6(b)-I	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling (*)	Expires on 11 december 2026 for categories 1-7, 10. Expires on 30 June 2027 for categories 9 industrial monitoring and control instruments, and 11.
6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight (*)	Expires on 11 June 2027 for categories 1-7, 10. Expires on 30 June 2027 for categories 9 industrial monitoring and control instruments and 11 (*).
6(b)-III	Lead as an alloying element in aluminium casting alloys containing up to 0,3 % lead by weight provided it stems from lead-bearing aluminium scrap recycling (*)	Expires on 30 June 2027 for categories 1-8, 9 other than industrial monitoring and control instruments, and 10.
6(c)	Copper alloy containing up to 4 % lead by weight (*)	Expires on 30 June 2027.

(*) 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 the following can be both demonstrated:

— the rate of lead release from such an EEE or any accessible part, whether coated or uncoated, does not exceed 0,05 µg/cm^2 per hour (equivalent to 0,05 µg/g/h),

— 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.’.