



Brussels, **XXX**
[...](2016) **XXX** draft

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

of **XXX**

amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in white glasses used for optical applications

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical progress, Annex III of 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 (recast)¹ (RoHS 2) as regards an exemption for specific applications containing lead.

RoHS 2 restricts the use of certain hazardous substances in electrical and electronic equipment. RoHS 2 entered into force on 21 July 2011.

The restricted substances are listed in Annex II to RoHS 2; while the restriction of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers is being enforced to date, the restriction of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP) shall be applied from 22 July 2019. Annexes III and IV to RoHS 2 list the materials and components of electrical and electronic equipment (EEE) for specific applications exempted from the substance restriction of RoHS 2 Article 4(1).

Article 5 makes provision for the adaptation to scientific and technical progress (inclusion, renewal, amendments and deletion of exemptions) of Annexes III and IV. Pursuant to Article 5(1)(a), for exemptions to be included in Annexes III and IV, it has to be provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled: their 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; the reliability of substitutes is not ensured; or the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Furthermore, Article 5(1) provides that the European Commission (the Commission) shall 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 establish the procedure for submitting applications for granting, renewing, or revoking an exemption.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

As a consequence of the provisions in Article 5(3) and Annex V which allows stakeholders to apply for an exemption from the substance restrictions, since the publication of RoHS 2 the Commission has received numerous² requests for both granting new and renewing existing exemptions.

On 11 November 2014 the Commission received an application for renewing exemption 13(a) of Annex III in relation to the use of lead in white glasses used for optical applications.

With a view to evaluating the application for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including an eight-week online

¹ OJ L 174, 1.7.2011, p. 88.

² The list is available at: http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm

open-ended³ stakeholder consultation⁴ on the application. No contributions were received during the stakeholder consultation.

The final report containing the assessment of the application was published⁵; stakeholders were notified. The project page is accessible via the Europa webpage⁶.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS 2. An amendment proposal of RoHS 2 Annex III was sent out on 17 March 2016 with all necessary background information, and experts were invited to comment on the proposal at the meeting of 19 April 2016. The expert group unanimously supported the proposal to exempt lead in white glasses used for optical applications for five years from the original expiration date of the exemption 13(a). All necessary steps pursuant to Article 5(3) to (7) have been performed. Council and Parliament were notified of relevant activities.

The final report highlighted in particular the following technical information (see report in footnote 5):

- Lead-based glasses are used because they have unique combinations of properties and characteristics, such as light transmission performance, optical dispersion, thermal conductivity, birefringence and others.
- Lead-free optical glasses of alternative designs exist in the form of lead-free glass, plastic lenses and alternative equipment design. Nonetheless, those alternatives cannot provide for several properties and their combinations comparable to lead-based glasses.
- Where finding substitutes was relatively straightforward, this has already occurred and substitutes are being used. Alternatives for the remaining applications are still not available. Thus substitution for the full application range is not possible in general.

The evaluation results for categories 1 to 7 and 10 show that at least one of the relevant criteria specified in Article 5(1)(a) is met by the exemption request relating to entry 13(a) in Annex III when formulated as "Lead in white glasses used for optical applications", and the renewal is thus justified. Since, for the applications concerned, no sufficiently reliable alternatives are available today or are likely to come to the market soon, and considering the typical innovation pace of the sector, the five-year validity period of the exemption is not expected to have adverse impacts on innovation. For categories other than categories 1 to 7 and 10, the existing exemption remains as per the validity periods set out in Article 5(2). The specific exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH) in accordance with Article 5 of Directive 2011/65/EU.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The proposed act grants an exemption from the substance restrictions of Directive 2011/65/EU for the use of lead in specific applications.

The proposed instrument is a delegated directive, as provided for by Directive 2011/65/EU, and in particular Article 5(1)(a) thereof.

³ The list of consulted stakeholders is regularly updated and maintained; it includes industry organisations, manufacturers and suppliers, recyclers, consumer associations, NGOs, academia, Member States' representatives, and others.

⁴ [Consultation period](#): from 24.04.2015 to 19.06.2015

⁵ [Evaluation report](#)

⁶ http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm

The objective of the proposed act is to ensure legal certainty and sustainable market conditions for manufacturers of electrical and electronic equipment, by allowing the use of otherwise banned substances for specific applications, in line with the provisions and under the conditions of RoHS 2 and the therein established procedure for the adaptation of the Annexes III and IV to scientific and technical progress.

In accordance with the principle of proportionality, the measure does not go beyond what is necessary to achieve its objective.

The proposal has no implications for the EU budget.

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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 equipment⁷, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of lead in electrical and electronic equipment placed on the market.
- (2) Lead-based glasses are used because they have unique combinations of properties and characteristics, such as light transmission performance, optical dispersion, thermal conductivity, birefringence and others.
- (3) Lead-free optical glasses of alternative designs exist in the form of lead-free glass, plastic lenses and alternative equipment design. Nonetheless, those alternatives that cannot provide for several properties and their combinations comparable to lead-based glasses.
- (4) Where finding substitutes was relatively straightforward, this has already occurred and substitutes are being used. Alternatives for the remaining applications are still not available. Thus substitution for the full application range is not possible in general. Lead in white glasses used for optical applications should therefore be exempted until 21 July 2021 for categories 1 to 7 and 10. In view of the innovation cycles for this type of optical applications, the duration of this exemption is unlikely to have adverse impacts on innovation.
- (5) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

⁷ OJ L [...], [...], p. [...].

Article 2

1. Member States shall adopt and publish, by [OP, please insert, as concrete date, 12 months after the date of entry into force of this directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from [OP, please insert, as concrete date, 12 months after the date of entry into force of this directive].

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
[...]



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ANNEX 1

ANNEX

to

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In Annex III, point 13(a) is replaced by the following:

13(a)	Lead in white glasses used for optical applications	Applies to all categories; expires on: <ul style="list-style-type: none">• 21 July 2023 for category 8 in vitro diagnostic medical devices;• 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;• 21 July 2021 for all other categories and subcategories
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