



Brussels, **XXX**
[...] (2019) **XXX** draft

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

of XXX

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of cadmium in certain radiation tolerant video camera tubes

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical progress, Annex IV 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 cadmium.

RoHS 2 restricts the use of certain hazardous substances in electrical and electronic equipment, as provided for in its Article 4. It entered into force on 21 July 2011.

The currently restricted substances as listed in Annex II to RoHS 2 are the following: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). 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 provides for the adaptation to scientific and technical progress (inclusion, renewal, amendments and revoking of exemptions) of Annexes III and IV. Pursuant to Article 5(1)(a), exemptions are to be included in Annexes III and IV only if such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006² 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

Since the publication of RoHS 2, the Commission has received numerous³ requests from economic operators, according to the provisions in Article 5(3) and Annex V, for both granting new and renewing existing exemptions.

The Commission received a request for a new exemption for use of cadmium in video cameras designed for use in environments exposed to ionising radiation with a dose rate in excess of 100 Gy/hour and a total dose in excess of 100 kGy with a centre resolution greater than 450 TV Lines in December 2015 (request no. A-2016).

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 OJ L 396, 30.12.2006, p. 1.

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

open-ended stakeholder consultation⁴ on the application. One contribution was made to the stakeholder consultation.

The final report containing the assessment of the application was published⁵; stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS 2 during an expert meeting on 22 September 2017. The experts agreed with the draft presented, with a large group of experts remaining silent. All necessary steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.⁶ The Council and the European Parliament were notified of all activities.

The final report highlighted in particular the following technical information and assessment:

- Radiation tolerant video cameras are used for inspection and general surveillance activities in nuclear power plants as well as in nuclear fuel waste processing plants. To withstand high radiation levels specific to these facilities while reaching a sufficient level of optical performance, specialised camera tubes with a layer containing 58.7% of cadmium by weight are necessary.
- Currently, there are no cadmium-free alternatives available on the market which would provide the necessary combination of optical performance and sufficient radiation resistance.

The applications concerned by the exemption request fall in category 9⁷; the exemption request therefore relates to Annex IV of Directive 2011/65/EU. The evaluation results show the specific exemption would 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. Furthermore, at least one of the relevant criteria specified in Article 5(1)(a) is met by the exemption request: Since for the applications concerned, no reliable alternatives are available today or are likely to come on the market soon, granting the exemption with the maximum validity period of seven years is justified. As reliable substitutes are not yet available, no negative socioeconomic impacts of substitution are to be anticipated for this period. The granted validity period is also not expected to have adverse impacts on innovation.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Directive grants an exemption from the restrictions in Article 4(1), to be listed in Annex IV of Directive 2011/65/EU, for the use of cadmium in specific applications.

The instrument is a Delegated Directive, as provided for by Directive 2011/65/EU, and in particular meeting the relevant requirements of Article 5(1)(a) thereof.

⁴ [Consultation period](#): from 28 October until 22 December 2016.

⁵ <https://publications.europa.eu/en/publication-detail/-/publication/e8c8a008-3e99-11e7-a08e-01aa75ed71a1>

⁶ A list of the required administrative steps is available on the [Commission website](#). Current stage of the procedure can be viewed for each draft delegated act in the Interinstitutional Registry of Delegated Acts at <https://webgate.ec.europa.eu/regdel/#/home>.

⁷ The categories listed in Annex I of Directive 2011/65/EU are namely: 1. Large household appliances; 2. Small household appliances; 3. IT and telecommunications equipment; 4. Consumer equipment; 5. Lighting equipment; 6. Electrical and electronic tools; 7. Toys, leisure and sports equipment; 8. Medical devices; 9. Monitoring and control instruments including industrial monitoring and control instruments; 10. Automatic dispensers; 11. Other EEE not covered by any of the categories above.

The objective of the Delegated Directive is to contribute to the protection of human health and the environment and approximate the provisions for the functioning of the internal market in the field 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 equipment⁸, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) 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 which are specific to medical devices and monitoring and control instruments and are listed in Annex IV 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) Cadmium is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) On 3 December 2015, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex IV to that Directive, for the use of cadmium in certain radiation tolerant video camera tubes ("the requested exemption").
- (5) The evaluation of the request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (6) Cadmium in video camera tubes is necessary to achieve satisfactory radiation tolerance and optical performance of video cameras operating in environments with high radiation exposure, such as nuclear power plants and nuclear waste reprocessing facilities.
- (7) Currently, there are no cadmium-free alternatives available on the market which would provide the necessary combination of optical performance and sufficient radiation resistance.
- (8) Due to the lack of alternatives, a substitution or elimination of cadmium is scientifically and technically impracticable for certain video camera tubes. The exemption is consistent with Regulation (EC) No 1907/2006 of the European

⁸ OJ L 174, 1.7.2011, p. 88.

Parliament and of the Council⁹ and thus does not weaken the environmental and health protection afforded by it.

- (9) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 9.
- (10) The requested exemption should be granted for a duration of 7 years starting from [\[the date of the publication of this Directive in the Official Journal\]](#), in accordance with the first subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (11) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

1. Member States shall adopt and publish, by [\[the last day of the 5th month after the date of entry into force of this Directive\]](#) 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 [\[the last day of the 5th month after the date of entry into force of this Directive + 1 day\]](#).

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.

⁹ 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).

Done at Brussels,

For the Commission
The President
[\[...\]](#)



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ANNEX

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to

Commission Delegated Directive

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ANNEX

In Annex IV to Directive 2011/65/EU, the following entry 44 is added:

"44. Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy

Applies to category 9. Expires on [\[the last day of the 84th month after the publication of this Directive in the Official Journal\]](#)."