



Brussels, **XXX**
[...](2015) **XXX** draft

COMMISSION DELEGATED DIRECTIVE ../.../EU

of **XXX**

amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders of electrical connections to temperature measurement sensors in certain devices

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Subject: Commission Delegated Directive amending, for the purposes of adapting to technical progress, Annex IV of the Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing lead.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2)¹ restricts the use of certain hazardous substances in electrical and electronic equipment. RoHS 2 (recast) entered into force on 21 July 2011.

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

Article 5 of RoHS contains the provisions for the adaptation to scientific and technical progress (inclusion and deletion of exemptions) of Annexes III and IV. Pursuant to Article 5(1)a, exemptions shall be included in Annexes III and IV, 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.

Article 5 establishes a procedure for the adaptation of the Annexes to scientific and technical progress. 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 RoHS 2 Article 20.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

As a consequence of the provisions in Article 5(3) and Annex V for granting, renewing or revoking an exemption, which allows stakeholders to apply for an exemption from the substance restriction, the Commission has received about 50 requests for new exemptions since the publication of RoHS 2 and about 100 requests to renew existing exemptions.

The Commission received an application on the 23 May 2014 in relation to the use of lead in solders used to make electrical connections to temperature measurement sensors designed to be used periodically at temperature below -150°C. In Annex IV to RoHS 2, the exemption 26 covers the use of lead in solders for certain EEE applications that are used durably at a temperature below -20°C under normal operating and storage conditions. Exemption 26 in RoHS Annex IV therefore does not cover the use of lead in sensors in devices that are operated only temporarily below -20°C.

With a view to evaluate the application for exemption, the Commission commissioned a study and carried out the requisite technical and scientific assessment including an official 8-week

¹ OJ L 174, 1.7.2011, p. 88.

online public stakeholder consultation² for the application³. One document was submitted during the stakeholder consultation by the Japanese Business Council in Europe suggesting a possible relation with exemption 7a in RoHS Annex III to the requested exemption; this was considered not applicable since exemption 7a in RoHS Annex III allows the use of lead in high melting point solders with a lead content of at least 85%, while the application concerned requests an use of solders with only 37% of lead.

The final report for the application assessment was written by consultants Oeko Institute, approved by DG Environment and published⁴; stakeholders and Member States were notified. The project page is accessible via the DG Environment webpage⁵.

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A proposed modification of the RoHS 2 Annex IV with all necessary background information was sent out on 9 September 2015 and experts were invited to comment on the proposal by 8 October 2015. The expert group unanimously supported the proposal to the amendment of the exemption 26 in Annex IV with the inclusion therein of solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below –150°C until 30 June 2021. All necessary steps pursuant to Article 5(3) to (7) have been performed. Council and Parliament were notified of all activities.

According to the final report, the following technical information was collected (for further information see footnote 4):

- Lead is present in cryogenic sensors, which are used in a wide variety of applications in EEE. These sensors measure very low temperatures; while in some applications the sensor remains at very low temperatures for many years, in other applications, temperature will rise and fall so that sensors are at low temperature for many shorter periods. Lead is used for electrical connections to cryogenic sensors to prevent the formation of thick intermetallic phases, whiskers, and tin pest.
- Lead-free solders cannot be used in cryogenic applications, as they are prone to tin pest, which seriously affects the reliability of the appliances. It has been proven that, in typically-operated cryogenic sensors, no alternative connection technologies other than soldering are both reliable and available.
- Though other soldering or connection technologies exist, they cannot reliably substitute lead solders in the external contacts of temperature sensors that are used periodically at temperatures below –150°C.
- Technically and scientifically, the justification of the exemption request is very similar to the rationale underpinning exemption 26 of Annex IV to RoHS 2 whose key technical constraint is the tin pest phenomenon occurring at low temperatures.

With respect to the amendment of the exemption 26 in Annex IV with the inclusion therein of *"solders of electrical connections to temperature measurement sensors in devices which are*

² http://ec.europa.eu/environment/consultations/rohs12_en.htm; consultation period from 31.10.2014 to 09.01.2015

³ The list of consulted stakeholders is regularly updated and maintained by the consultants in cooperation with the Commission, and includes electronics related industry organisations, manufacturers and suppliers, recyclers, consumer associations, NGOs, academia, Member States' representatives, etc.

⁴ Direct link to evaluation and recommendation: https://circabc.europa.eu/sd/a/dc3ec089-8ce1-4592-93d7-12e7fbbefc44/20150624_RoHS_Ex_Pack6_Final_Report.pdf, http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20150624_RoHS_Ex_Pack6_Final_Report.pdf.

⁵ http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs1_en.htm.

designed to be used periodically at temperatures below -150°C ", the evaluation results show that at least one of the relevant criteria specified in Article 5(1)(a) is fulfilled and the inclusion of the specific application in the exemptions listed in Annex IV is thus justified. The technical reasons are similar to those justifying the exemption 26 of Annex IV expiring on 30 June 2021. Thus, the same expiry date for this requested exemption should be granted, so that in future potential renewal applications shall be assessed at once. This period is unlikely to have adverse impacts on innovation as no alternative are available today or are likely to come to market in the same period. 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 (RoHS 2), to be listed in Annex IV, for the use of lead in specific applications.

The proposed instrument is a delegated directive, which implements Directive 2011/65/EU, and in particular Article 5(1)(a) thereof.

The objective of the proposed act is to ensure legal certainty and sustainable market conditions for electronic manufacturers, by allowing specific applications of otherwise banned substances in line with the provisions 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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(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 equipment⁶, 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 is used for electrical connections in cryogenic sensors for medical devices and monitoring and control instruments to prevent the formation of thick intermetallic phases, whiskers, and tin pest. Those sensors are used in some applications to measure very low temperatures for short periods.
- (3) Lead-free solders cannot be used in cryogenic applications, as they are prone to tin pest, which seriously affects the reliability of the appliances. It has been proven that, in typically operated cryogenic sensors, no alternative connection technologies other than soldering are both reliable and available.
- (4) Lead solders in the external contacts of temperature sensors that are used periodically at temperatures below –150°C should therefore be exempted until 30 June 2021, as the exemption in point 26 of Annex IV to Directive 2011/65/EU. In view of the innovation cycles for medical devices and monitoring and control instruments, 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 IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

⁶ OJ L 174, 1.7.2011, p. 88.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*OP, please insert, as concrete date, the last day of the 9th month after entry into force of this directive*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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
[\[...\]](#)