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amending Directive 2011/65/EU of the European Parliament and of the Council as regards exemptions for lead and cadmium in certain electrical and electronic equipment

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

The Commission Delegated Directive amends Annexes III and IV 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 exemption for lead and cadmium in certain electrical and electronic equipment. The purpose is to adapt them to technical and scientific progress.

Article 4 of the RoHS Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE). 10 substances are currently restricted and listed in Annex II to the RoHS 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 list the materials and components of EEE for specific applications exempted from the substance restrictions in Article 4(1). 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 only to be included in Annexes III and IV 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:

- the elimination or substitution via design changes or using materials and components that 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;
- 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 socioeconomic impact of substitution. Decisions on the duration of exemptions must take into account as well as any potential impact on innovation. Lifecycle thinking on the overall impact of the exemption must apply too, where relevant.

EEE that is subject to the RoHS Directive is classified in accordance with the categorisation set out in Annex I.

Article 5(1) allows the European 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.

[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, (OJ L 396, 30.12.2006, p. 1).

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) [3]. Annexes III and IV list several exemptions for lead in soda lime glass, in white glass, in ion coloured optical filter glass types, in infrared interference filters, in fluorescent powder, in certain solders, in alloys used for soldering, in crystal glass, in glass frit, in cermet-based trimmer potentiometer elements, for cadmium in striking optical filter glass types, in glazes and in helium-cadmium lasers of Raman spectrometers, for lead and cadmium in oxygen sensors, and lead in alloys as an superconducting material.

The expiry dates of the exemptions set out in points 5(b), 13(a), 13(b), 18(b), 24, 29, 32 and 34 in **Annex III** are:

21 July 2023 for category 8 subcategory 'in vitro diagnostic medical devices' (IVMD) of Annex I;

21 July 2024 for category 9 subcategory 'industrial monitoring and control instruments' (IMCI) and category 11 'other EEE' of Annex I; and

21 July 2021 for all other categories (including the other general categories 8 and 9 of Annex I).

The expiry date for the exemptions set out in points 13(b)-(I), 13(b)-(II) and 13(b)-(III) of Annex III is 21 July 2021 for categories 1 to 7 and 10 of Annex I. The expiry date for the exemption set out in point 18(b)-(I) of Annex III is 21 July 2021 for categories 5 and 8 of Annex I.

The expiry dates for the exemptions in points 1(b), 4, 9 and 11 in **Annex IV** are:
21 July 2023 for category 8 subcategory IVMD of Annex I;

21 July 2024 for category 9 subcategory IMCI of Annex I; and

21 July 2021 for the other general categories 8 and 9 of Annex I.

The expiry date for the exemption in point 12 of Annex IV is 30 June 2021. The expiry date for the exemption set out in point 34 of Annex IV is 22 July 2021 for EEE categories 8 and 9.

The Commission received requests from businesses to renew the exemptions in points 5(b), 13(a), 13(b), 13(b)-(I), 13(b)-(II), 13(b)-(III), 18(b), 18(b)-(I), 24, 29, 32 and 34 of Annex III and points 1(b), 4, 9, 11, 12 and 34 of Annex IV. These technical applications were submitted within the timeframe for renewal set in Article 5(5), first subparagraph. On 11 May 2022, the Commission received a technical application for a new exemption concerning cadmium in Hersch cells for oxygen sensors that are used in IMCI when sensitivity below 100 ppm oxygen is required. Renewal of the preceding exemption under point 43 in Annex IV with an identical wording was not applied for before the deadline passed.

The Commission launched several studies, which were concluded in June 2020 (Pack 19) [4], February 2022 (Pack 24) [5], March 2022 (Pack 21) [6], December 2022 (Pack 23) [7] and May

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

[4] Final Report (Pack 19) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/252f2c11-c577-11ea-b3a4-01aa75ed71a1/language-en.

[5] Final Report (Pack 24) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/0c46722c-9523-11ec-b4e4-01aa75ed71a1/language-en.

[6] Final Report (Pack 21) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/65558f0a-b61f-11ec-b6f4-01aa75ed71a1/language-en.

[7] Final Report (Pack 23) of the study is available at https://op.europa.eu/en/publication-detail/-/publication/0c46722c-9523-11ec-b4e4-01aa75ed71a1/language-en.

2024 (Pack 27) [8], to carry out the required technical and scientific assessment. This included an eight- to ten-week public stakeholder consultation. The Commission has taken account of all the comments that it received. Information on the consultations is provided on the project websites [9].

Pursuant to Article 5(5), second subparagraph, the existing exemptions remain valid until the Commission takes a decision on a renewal application.

(1) Lead in soda lime glass used in glass tube of fluorescent lamps

The exemption in point 5(b) of Annex III, regarding **lead in soda lime glass used in glass tube of fluorescent lamps**, was assessed in February 2022. The exemption was initially introduced as part of the exemption in point 5 listed in the first RoHS Directive (Directive 2002/95/EC[10]). Following a review in 2008, the original exemption was divided and the current exemption in point 5(b) was included. On 16 January 2020, the Commission received a technical application to renew this exemption.

Technical conclusion

The technical and scientific assessment report that was concluded in February 2022 (Pack 24) highlighted the following points.

(a) Lead is not intentionally added to soda lime glass used in the glass tube of fluorescent lamps. The addition is the result of using secondary glass in the manufacture of new lamps.

(b) Secondary glass fractions can contain very small amounts of lead impurities (less than 0.1%). Most lamps do not exceed this threshold.

(c) Substitutes are therefore considered as being available, either in the form of primary glass or in the form of secondary glass with small amounts of lead impunities. The reliability of these substitutes is not questioned.

(d) The use of secondary raw material has a positive environmental effect because it supports resource efficiency (thereby contributing to circularity); conserves energy due to a lower melting temperature; and saves capacity needed for disposal of contaminated glass. The use outweighs the negative effects of new contamination and delays in shifting to toxic free material cycles.

(e) The low lead concentration should not be taken over to the next lighting technology. The exemption for lead in LED retrofit tubes, for which the application was made, should not be granted because lead could be dispersed into other material cycles – which would not be line with the Chemical Strategy for Sustainability [11].

(f) If another renewal is requested, the technical application will need to provide information on how much lead is contained in secondary glass and whether the exemption for fluorescent lamps is still relevant.=

(2) Lead in white glass used for optical applications

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8 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.

9 Project websites including information on the consultation are available under https://rohs.exemptions.oeko.info/index.php?id=127 and https://rohs.biois.eu/.

10 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

11 COM(2020) 667 final.

The exemption in point 13(a) of Annex III regards **lead in white glass used for optical applications**. On 28 November 2019 and on 20 January 2023, the Commission received technical applications to renew the exemption in point 13(a) of Annex III with the current scope for categories 8 and 9.

Technical conclusion

The technical and scientific assessment reports concluded in December 2022 and May 2024 (Packs 23 and 27) highlighted the following points.

(a) Lead is added to types of optical glass that are used in a variety of electrical equipment to achieve a medium to high refractive index, a specific Abbe number, a certain colour aberration, transmission of light with a high proportion of blue/indigo/violet light, low stress birefringence and particular partial dispersion properties.

(b) The amount of lead indicated by the applicant (275 tonnes lead per year) is the same as presented in the previous review in 2017.

(c) There is a lack of precision regarding the non-technical term 'white glass'. The words '(excluding applications falling under 13(b) series of this Annex)' need to be added in order to clarify the scope and to distinguish from the exemption in point 13(b).

(d) The examples provided in the technical applications showed that the exemption is only needed for categories 3, 4, 6, 8, 9 and 11.

(e) In some cases, reliable substitutes do exist for glass used for optical applications and are used where technically feasible. However, lead-containing glass is still needed if lead-free alternatives do not provide the necessary performance. It was not feasible to identify reliable substitute areas with a clear demarcation to needed exemption areas.

(3) Lead and cadmium in optical filter glasses and glasses used for reflectance standards

Since 2018, Annex III has listed **four exemption points for lead and cadmium in optical filter glasses and glasses used for reflectance standards**. These were initially covered by one exemption. The subsequent split was motivated by the need to distinguish between lead and cadmium. On 28 November 2019, the Commission received a technical application to renew the exemptions in points 13(b), 13(b)-(I), 13(b)-(II) and 13(b)-(III) of Annex III. The requested categories for the exemption in point 13(b) of Annex III were categories 8, 9 and 11. For the other exemptions, the requested categories were categories 1 to 7 and 10. On 20 January 2023, the Commission received another technical application to renew the exemption in point 13(b)-(III) of Annex III for category 9.

Technical conclusion

The technical and scientific assessment reports concluded in December 2022 and May 2024 (Packs 23 and 27) highlighted the following points.

(a) In order to reflect scientific and technical progress, it is possible to **merge the exemption into point 13(b) under the exemptions in points in the 13(b)-(I)-(III) series** of Annex III, if some changes are made.

(b) A new exemption must be introduced into point 13(b)-(V) so that infrared interference filters remain within the scope because infrared interference filters would otherwise no longer be within the scope.

(c) If another renewal is requested, separate documents (or at least separate chapters for each exemption in the exemption 13(b) series) have to be provided.

(d) Regarding lead in ion coloured optical filter glass types (13(b)-(I)), the sharp cut-off between blocked and transmitted wavelength range that is required in some applications (in order to ensure that the addition of the ions yields the desired filtering properties) can only be achieved if lead is added to the base glass.

(e) The same wording should be kept for this exemption because removing the term 'ion coloured' could widen the scope.

(f) The information provided by the applicant regarding technical details and potential substitution mostly concerned the individual commercial ion coloured filter glass type denoted VG9. Any future renewal application should contain information on other ion coloured glass types.

(g) Regarding **cadmium in striking optical filter glass types** (13(b)-(II)), the one edge on striking optical filters is particularly sharp or steep. This can only be achieved by adding cadmium to the base glass of filter glass in order to enable the striking process.

(h) Potential alternatives (such as thin film coatings on transparent substrates and transparent plastics with organic pigments) do not produce the same results. The technical properties cannot be achieved without the addition of cadmium.

(i) The same wording should be kept because removing the term 'striking' could widen the scope.

(j) Regarding **cadmium and lead in glazes used for reflectance standards** (the exemption set out in point 13(b)-(III)), lead is not required in reflectance standards and can therefore be removed from the scope. The following exemption in point 13(b)-(IV) concerns only cadmium in glazes used for reflectance standards.

(k) Cadmium is needed to produce red and orange glazes. Only the addition of cadmium-based pigments enables steep slopes in the wavelength required to ensure accuracy of relevant optical equipment. Alternatives do not provide the same stable conditions over the long periods needed for the calibration.

(l) It is not feasible to further narrow the wording to reflect the fact that only the reflectance standards for the colours red and orange require the exemption for cadmium. This is because these colours cannot be described with sufficient technical precision.

(m) The examples provided by the applicant show that the exemption is only required for categories 8 and 9 (including their respective subcategories).

(n) Regarding **lead compound coatings in infrared interference filters** (the exemption set out in 13(b)-(V)), these compounds are used as coating material for the filters because they have one of the highest refractive indexes of coating materials and also provide good blocking properties and steep wavelength cut-off.

(o) These properties cannot currently be met using alternative methods.

(p) The examples provided show that the exemption is only needed for category 9's subcategory for industrial monitoring and control instruments.

(4) Lead as an activator in fluorescent powder

Annex III currently lists two exemptions in points 18(b) and 18(b)-(I) **for lead as an activator in fluorescent powder**. Annex IV currently lists one exemption in point 34 for lead as an activator in fluorescent powder for specific lamps.

The exemption in point 18(b) in Annex III was renewed in 2018. This exemption concerns the use of lead as an activator in fluorescent powder of discharge lamps when **used as sun tanning lamps** containing phosphors such as BSP. In 2015, the exemption in point 18(b)-(I) concerning lead as an activator in fluorescent powder of discharge lamps when **used in medical phototherapy equipment** was included in Annex III. In 2012, the exemption in point 34 concerning lead as an activator in fluorescent powder of discharge lamps when **used in extracorporeal photopheresis lamps** was included in Annex IV.

On 20 January 2020, the Commission received a technical application to renew points 18(b) and 18(b)-(I) of Annex III and point 34 of Annex IV for categories 5, 8 and 9 of Annex I. The technical application requested that these exemptions be combined. On 13 January 2023, the Commission received another technical application to renew the exemption in point 18(b) of Annex III for category 11.

Technical conclusion

The technical and scientific assessment reports concluded in February 2022 and May 2024 (Packs 24 and 27) highlighted the following points.

(a) Lead is required to activate barium silicate phosphor so that it can fluoresce in the designated wavelength.

(b) This required property cannot be achieved using substitutes like cerium doped phosphate (YPO4). Replacing this with LED technology is currently not suitable. Lead reduction is not possible because a certain amount of lead is needed in order to activate the phosphor's emissions.

(c) The exemptions differ regarding their application areas, their end-of-life treatment and their target groups. It is therefore not practical to merge all three exemptions, but it is feasible to distinguish between, on the one hand, discharge lamps used as sun tanning lamps and, on the other hand, lamps used in medical phototherapy equipment. These applications have given to their markets different substitution roadmaps.

(d) **Indoor sun tanning discharge lamps** (point 18(b)) produce UVA and UVB in predetermined dosages with the intention of creating artificial sunlight.

(e) Over 90% of such indoor tanning lamps produced and used throughout the EU contain lead as an activator.

(f) Using lead in tanning equipment places 190 kg of lead on the EU market every year. Substitution will therefore have a greater and faster impact and pay off more quickly.

(g) UV discharge lamps are used for **(medical) skin treatment** (covered by the exemption set out in point 18(b)-(II)). They have specific spectral distribution and exposure schedules (depending on the application and patient needs).

(h) Treatment with **extracorporeal photopheresis equipment** (covered by the exemption set out in point 18(b)-(II)) involves exposing leukocytes that have been temporarily removed from the patient's blood to light. This requires a unique light spectrum.

(i) Using lead in medical phototherapy equipment and extracorporeal photopheresis lamps places only 2.5 kg of lead on the EU market every year.

(j) A technical application for another renewal would need to clearly detail the progress made in substituting lead between one exemption evaluation and another.

(5) Lead in solders for ceramic multilayer capacitors

The exemption in point 24 of Annex III regarding **lead in solders for soldering to machined through hole discoidal and planar array ceramic multilayer capacitors** was introduced in 2005/2006 with the current wording. The wording and scope were not changed following the reviews in 2009 and 2016. On 10 January 2020, the Commission received a technical application to renew the exemption in point 24 of Annex III for all the categories in Annex I.

Technical conclusion

The technical and scientific assessment report concluded in February 2022 (Pack 24) highlighted the following points.

(a) Lead is required for soldering to machined through hole discoidal and/or planar array ceramic multilayer capacitors because of its good wetting action, ductility and melting point.

(b) Alternatives such as selective soldering, spring clips, sintering and palladium-silver terminations are not technically viable or are not suitable for all applications.

(c) The current scope covers the two cases of high melting point and low melting point (HMP and LMP) solders without differentiating between them. HMP solders have a much higher lead content than LMP solders.

(d) LMP solders do not exceed 50% lead by weight and are either bonded by selective soldering or are mechanically mounted. HMP solders contain 85% or more lead by weight and are only used when reflow is required at a lower temperature (step soldering) or the component is used at a high temperature.

(e) The two cases have to be differentiated in order to ensure that HMP solders are only used where necessary. The exemption should therefore specifically address LMP solders and HMP solders separately.

(f) There is an overlap with exemption 7(a) in Annex III to Directive 2011/65/EU, but the exemptions should be kept separate going forward.

(g) Any future technical application for renewal should provide more detailed information on the research and the use of spring clips as well as more data on specification of application fields and technologies. The goal would be to split the exemptions for HMP and LMP solders.

(6) Lead in crystal glass

The exemption in point 29 of Annex III regarding **lead bound in crystal glass** was evaluated in 2009 and 2015/2016. On 20 December 2019, the Commission received a technical application to renew this exemption for categories 3, 4, 5 and 11 in Annex I.

Technical conclusion

The technical and scientific assessment report that was concluded in February 2022 (Pack 24) highlighted the following points.

(a) Lead is used as a raw material to produce lead that is bound in crystal glass due to its high refractive index, high dispersion and transmission of light and sharp colour transitions.

(b) Crystal glass is a component of lighting and decoration applications. One of the functions of leaded crystal glass is its specific appearance, which cannot be obtained with non-leaded glass.

(c) High-quality (lead-free) substitutes are forthcoming for certain applications. However, alternatives in the form of a one-to-one substitute or a lead-free glass formulation do not yet have the same technical properties and are not suitable for all applications.

(d) Lead is not released from the vitreous matrix and, due to its high value, only occasionally ends up in WEEE management. Potential emissions of lead from use and the end-of-life phase are negligible.

(e) Lead has an impact on the viscosity of the glass and its thermal properties, so it increases the working time and thus saves energy.

(f) The exemption has a socioeconomic impact because the production of hand-crafted lead crystal glass is considered a cultural heritage in some EU regions.

(g) Any future technical application for a renewal should contain detailed information on the exact whereabouts and disposal of the 46 tonnes of lead that enters the EU market every year under this exemption. In particular, the quantity flows of lead-containing crystal glass in residual waste and in the glass recycling of container glass must be examined.

(7) Lead in gas lasers

The exemptions in point 32 of Annex III and points 4 and 9 of Annex IV all concern **gas lasers**.

The current exemption in point 32 of Annex III regarding **lead used as a sealing material for argon and/or krypton laser tubes** was introduced in 2006. It was evaluated twice in 2010/2011 and 2016 and renewed without change. On 20 January 2020, the Commission received a technical application to renew the exemption in point 32 of Annex III for categories 6, 8 and 9 of Annex I.

Technical conclusion

The technical and scientific assessment report concluded in February 2022 (Pack 24) highlighted the following points.

(a) Lead oxide is used in a solder glass frit as a vacuum seal in the manufacture of argon or krypton laser tube. This glass frit connects the glass of a mirror to the laser metal tube.

(b) The two main properties of using lead oxide are that, firstly, the melting temperature of the solder glass/glass frit is lowered and thus does not thermally damage the fragile components that are being joined; and, secondly, for stress-free sealing, the material has a coefficient of thermal expansion that closely matches that of the components.

(c) Alternatives (e.g. bismuth-based glass frits, bismuth-free glass frits, the use of malleable metals as sealing mechanism, solid state lasers and other laser technologies) do not yet meet these requirements.

(d) Argon and krypton lasers are only used when their unique properties are required. Their market volume of lead is therefore very low and declining.

(e) The current formulation should be amended without limiting the scope because the gases can either be used separately or in a mixed gas laser.

(f) The addition of the words ‘as sealing material’ clarifies the function of lead and helps to differentiate this exemption from others.

(g) If another renewal is requested, information on the status of development of mechanical seal alternatives and other laser technologies would have to be provided.

The current exemptions in points 4 and 9 of Annex IV regarding **lead in glass frit of X-ray tubes and gas lasers** and **cadmium in helium-cadmium lasers** were introduced in 2011, when Annex IV was published and enacted. The exemptions have not been reviewed yet. On 20 January 2023 and 19 January 2023, the Commission received technical applications to renew these exemptions for category 9 (subcategory industrial monitoring and control instruments) of Annex I.

Technical conclusion

The technical and scientific assessment report concluded in May 2024 (Pack 27) highlighted the following points.

(a) Lead in glass frit binders in gas lasers enables high wavelength stability, long coherence length and long lifetime of components.

(b) The **exemption in point 4 of Annex IV** is only required for helium-neon gas lasers that are used in heterodyne interferometry calibration and positioning applications. The scope can therefore be narrowed.

(c) The **exemption in point 9 of Annex IV** is only needed for helium-cadmium lasers of Raman spectrometers for stress measurement in semiconductors. This is because helium-cadmium lasers have a specific property that enables wavelengths of 325 nm to be used in Raman spectroscopy measurements.

(d) Diode-pumped solid-state (DPSS) lasers are a lead-free alternative. However, they do not have the same properties as regards wavelength accuracy and spectral stability.

(e) The justification for the exemption in point 32 of Annex III is relevant for this exemption, so the validity periods should be aligned with that exemption point.

If another renewal is requested for the exemption in point 4, the development of a mechanical seal as an alternative should be assessed and a merger with the exemption in point 32 of Annex III should be considered. Regarding the exemption set out in point 9 of Annex IV to Directive 2011/65/EU, DPSS laser manufacturers should take part in the evaluation and state whether they consider their technology to be an appropriate means of eliminating the need for this exemption.

(8) Lead in cermet-based trimmer potentiometer elements

The current exemption in point 34 of Annex III regarding **lead in cermet-based trimmer potentiometer elements** was introduced in 2006 to complement current exemption 7(c)-(I) to Annex III to Directive 2011/65/EU. It was renewed twice in 2007 and 2017 without changing the scope. On 15 January 2020 and 9 October 2020, the Commission received a technical application to renew the exemption point 34 of Annex III for all categories in Annex I.

Technical conclusion

The technical and scientific assessment report concluded in February 2022 (Pack 24) highlighted the following points.

(a) Lead is required to fabricate a resistive layer (the cermet). This has electrical, thermal and mechanical characteristics that are required in order to create a functional element in trimmer potentiometers.

(b) The cermet layer is produced by partially coating a ceramic body with glass paste, which contains 40-50% lead oxide by weight.

(c) No alternatives meet the critical performance requirements (e.g. high mechanical abrasion resistance and constant electrical contact resistance). However, the requirements are only necessary for exceptional applications rather than for most EEE.

(d) The exemption in point 7(c)-(I) of Annex III to Directive 2011/65/EU excludes cermet materials. The exemption in point 34 of Annex III only applies to trimmer potentiometers (except panel potentiometers that are not meant to be operated by end-users of EEE).

(e) If another renewal is requested, information on the technical details on the different applications and on the quantity would have to be provided.

(9) Lead and cadmium in oxygen sensors

The exemption in point 1(b) of Annex IV allows the use of lead anodes in electrochemical oxygen sensors. The exemption in point 43 of Annex IV is closely linked and allows cadmium in Hersch cells for oxygen sensors to be used in IMCI (where sensitivity below 100 ppm is required).

Technical conclusion

(a) Several different oxygen sensor technologies are covered under the exemption requests: capillary, Hersch cell and permeable membrane oxygen sensors measuring oxygen in gases. Lead-containing oxygen sensors offer superior performance and can be used within broad operating conditions.

(b) For capillary oxygen sensors, there is a trend towards lead-free amperometric sensors, but there will be no substitution of lead in the coming years.

(c) Hersch cells have extremely low detection limits thanks to cadmium anodes. Lead and cadmium can still not be substituted, but the development of lead substitution has advanced further.

(d) Lead-free permeable membrane oxygen sensors have been available on the market for several years, but not all applications can successfully remove lead. A shorter validity period has nevertheless been recommended in order to avoid hampering innovation and the transition to lead-free technology.

(e) Besides these three identified technologies, lead is used in sensors that measure levels of oxygen in inhaled/exhaled air and dissolved oxygen in low concentration areas for medical purposes. Substitution and elimination of lead are not yet practicable, scientifically and technically, for either of these applications, which were already identified in the first technical study. However, the development of lead-free technology is progressing and a shorter validity period has been recommended as the maximum period.

It can be concluded that lead in electrochemical oxygen sensors cannot be substituted or eliminated, even if the developments are at different stages. In order to sufficiently recognise this development for specific technologies, the exemption point should be split into subexemptions so as to focus discussions on relevant points in the next review.

(10) Lead in alloys as a superconductor in certain devices

The exemption in point 11 in Annex IV covers lead in alloys as a superconductor and thermal conductor in magnetic resonance imaging (MRI) devices. In 2013, a new exemption in point 12 of Annex IV was introduced for lead and cadmium in metallic bonds that create superconducting magnetic circuits in MRI devices; superconducting quantum interference devices (SQUID); and nuclear magnetic resonance (NMR) or Fourier transform mass spectrometer (FTMS) detectors. The Commission has not received any specific renewal requests concerning FTMS devices.

Technical conclusion

(a) MRI devices are used for the generation of three-dimensional images. SQUID detectors are used to measure extremely weak magnetic fields (e.g. those in devices that measure brain activity). NMR spectroscopy instruments are used for chemical analysis. MRI and SQUID detectors are mainly used in hospitals and research institutions. NMR detectors are particularly used in product research.

(b) Lead alloys are used in metallic bonds that create superconducting magnetic circuits for these devices. Reliable and sufficient robust metallic bonds without lead and with appropriate superconductor properties are not yet available. Substituting lead in MRI, SQUID and NMR devices is not practicable, technically or scientifically.

(c) The current exemption in point 12 also covers cadmium. An exemption for the use of cadmium in metallic bonds in MRI, NMR and SQUID devices is no longer required because cadmium-free substitutes are available.

(d) The exemption in point 26 in Annex IV covers lead in thermal conductors. This makes its additional inclusion in the exemption in point 11 redundant.

(e) The exemptions in points 11 and 12 in Annex IV allow the use of lead in alloys as a superconductor in MRI devices. Cadmium is no longer relevant for exemption 12. MRI and NMR equipment have technically identical needs related to superconductive bonds. It is therefore appropriate to cover these devices under a exemption point that is separate from the exemption point covering SQUID detectors.

(f) Not granting an exemption may negatively impact the health sector, as well as research and development activities.

The Commission consulted the Member States' expert group for delegated acts under the RoHS Directive on 23 February 2021 and 30 April 2025. It carried out all the requisite procedural steps relating to exemptions from the substances restriction pursuant to Article 5(3) to 5(7) [12]. The Council and the European Parliament were notified of all activities in that context.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

None of the exemptions covered by this delegated act weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU.

[12] 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.

The first purpose of the criteria laid out in Article 5(1)(a) of Directive 2011/65/EU has been fulfilled. The Delegated Directive therefore renews the exemptions set out in points 13(a), 13(b)-(I), 13(b)-(II), 13(b)-IV, 13(b)-(V), 18(b), 18(b)-(II), 24(a), 29, 32 and 34 in Annex III and points 1(b), 4(a), 9(a), 11(a) and 12(a) in Annex IV. The same criteria have been fulfilled as regards the new exemption application for the use of cadmium in Hersch cells for oxygen sensors. Elimination or substitution of the applications is scientifically or technically impracticable.

The Delegated Directive grants the exemption in point 5(b) of Annex III because the third purpose of the criteria laid out in Article 5(1)(a) has been fulfilled. The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh its total environmental, health and consumer safety benefits.

In detail

The current wording of the **exemption in point 5(b) of Annex III** is complemented with the wording '(not intentionally added)' in order to give legal certainty. The exemption only covers category 5 of Annex I, because this is the only category that was applied for and for which the application covered by this exemption is needed. Expanding the scope to include new lighting equipment entails a risk of contaminating other glass waste streams and delaying the phasing-out of lead in such applications. Consequently, the request to extend the scope to various types of lighting equipment (especially LED lamps) does not meet the criteria laid out in Article 5(1)(a) and the previous exemption has been renewed with a slightly changed wording.

The current wording of the **exemption in point 13(a) i Annex III** has been complemented with the wording '(excluding applications falling under 13(b) series of this Annex)' in order to differentiate glasses covered by the exemption in point 13(a) from glasses covered by the exemption in point 13(b) in Annex III. The exemption has been granted for categories 3, 4, 6, 7, 8, 9 and 11 in Annex I. The other categories, for which the applicant could not provide sufficient evidence, have not been renewed.

Categories 8, 9 and 11 are currently covered by the **exemption in point 13(b) in Annex III** and will be covered by the **exemptions currently set out in points 13(b)-(I), 13(b)-(II), 13(b)-(III) and 13(b)-(IV) in Annex III**. The scope of these exemptions is more specific and therefore narrower. In addition, the **new exemption set out in point 13(b)-(V) in Annex III** has been granted in order to keep the scope the same as under exemption 13(b) in Annex III. Article 5(6) states that an exemption that has been revoked needs an expiry date between 12 and 18 months. The scope has been transferred to the 13(b) series of Annex III and no significant implications are therefore expected, so the old exemption in point 13(b) in Annex III will expire after 12 months.

Categories 8, 9 and 11 of Annex I has been added to the **scopes of exemptions points 13(b)-(I) and 13(b)-(II) in Annex III**, so these exemptions now cover all categories.

The **exemption in point 13(b)-(IV) in Annex III** replaces the **old exemption in point 13(b)-(III)**. The elimination of lead in glazes used for reflectance standards is scientifically and technically practicable. Lead can therefore be removed from the scope. The elimination of lead reflects only the technical development, so the previous exemption in point 13(b)-(III) in Annex III expires within 12 months. The exemption in point 13(b)-(IV) in Annex III is only granted for categories 8 and 9 in Annex I (transferred from exemption 13(b)). It is not required for other categories.

The **new exemption in point 13(b)-(V) in Annex III** has been granted because the scope of this exemption is currently covered under the exemption in point 13(b) in Annex III, which

will expire. It is only required for category 9 (subcategory industrial monitoring and control instruments) in Annex I.

Lead that falls under the **exemption in point 18(b) in Annex III** is still needed for discharge lamps that are used as sun-tanning lamps. The exemption currently set out in point 18(b)-(I) in Annex III has been combined with the exemption currently set out in point 34 in Annex IV in the **new exemption point 18(b)-(II) in Annex III**. The exemption in point 34 in Annex IV has been deleted.

The **exemption in point 18(b) in Annex III** has been granted for the requested and relevant categories 5, 8, 9 and 11 in Annex I. The exemption in point 18(b)-(II) in Annex III has been granted for the requested categories 5, 8 and 9 in Annex I.

The **exemption in point 24(a) in Annex III** replaces the current exemption in point 24 in Annex III. The exemption in point 24 in Annex III covers the two cases of high-melting-point and low-melting-point solders. The new exemption in point 24(a) in Annex III differentiates between those solders. The scope is therefore more specific and narrower. Time is needed to assess the scope restriction and carry out surveys to determine the applications requesting HMP solders. The revoked exemption in point 24 in Annex III will therefore expire within the maximum period of 18 months. The exemption in point 24(a) in Annex III has been granted for all categories of Annex I.

The **exemption in point 29 in Annex III** covers categories 3, 4, 5 and 11 in Annex I because are relevant for the applications under this exemption.

The **exemption in point 32 in Annex III** is required for categories 6, 8, 9 and 11 in Annex I.

The **exemption in point 4(a) in Annex IV** replaces the current exemption in point 4 in Annex IV.

The **exemption in point 9(a) of Annex IV** replaces the current exemption in point 9 in Annex IV. The scope restriction only reflects the technical development, so the previous exemptions set out in points 4 and 9 in Annex IV will (in accordance with Article 5(6)) expire after 12 months. The new exemptions in points 4(a) and 9(a) in Annex IV are only required for category 9 subcategory industrial monitoring and control instruments in Annex I.

The **exemption in point 34 in Annex III** covers all the categories in Annex I because their renewal has been requested and is needed for the applications covered by this exemption.

The **exemption in point 1(b) in Annex IV** covers lead in oxygen sensors and cadmium in oxygen sensors (these were previously covered by the exemption in point 43 in Annex IV). Subexemptions under points 1(b)-I to 1(b)-VI have been granted under the exemption in point 1(b) to address specific technologies and applications. This enables a more targeted review in the future. Most of the specific subexemptions will expire after 36 months. This validity period takes into consideration the ongoing transition to lead-free applications as well as the requested expiry dates. The maximum validity period has therefore not been granted. The aligned validity periods in the subentries will enable a joint review, which is advantageous for all parties using similar technology. No substitution is foreseeable in the near future for the new exemption concerning cadmium in Hersch cells for oxygen sensors. The maximum validity period has been granted, pursuant to Article 5(2), first subparagraph.

- The scope of exemption point 1(b) has been transferred to the subexemption points 1(b)-I to 1(b)-VI. The old exemption in point 1(b) will therefore expire after a short transition period, pursuant to Article 5(6) of the RoHS Directive.

The **exemptions in points 11a and 12a in Annex IV** replace the previous exemptions in points 11 and 12 in Annex IV. The scope of both exemptions has been amended. The

exemption in point 11a covers the similar technologies of MRI and NMR devices. The exemption in point 12a only covers the use of lead in SQUID detectors (instead of covering all technologies – as was previously the case). The exemptions in points 11 and 12 in Annex IV have been revoked (with a short transitional period to allow sufficient time for administrative changes in accordance with Article 5(6) of the RoHS Directive). The advanced timing of the finalisation of the technical assessments and the indications of the development of suitable substitutes make it appropriate to grant the exemptions until the end of 2030. The validity period that has been granted is not expected to adversely impact innovation.

Expiry Dates

The expiry dates of these exemptions have been set in accordance with Article 5(2), first subparagraph.

In the cases of the exemptions in points 5(b), 32 and 34 in Annex III and points 4(a) and 9(a) in Annex IV, a future evaluation might conclude – in view of the time that has elapsed since the conducted technical assessments and due to the existence of promising substitutes – that the criteria of Article 5(1)(a) are no longer met. There is a lack of information on the criteria. The burden of proof is on the applicants to show that one of the criteria has been fulfilled. The Commission must otherwise decide not to review the exemption due to insufficient data. As for the exemption in point 5(b), information on the actual amount of used lead has to be provided. Information on the development of substitutes and the different applications should be provided for the other exemptions. A short validity period is therefore appropriate in order to give stakeholders an opportunity to substantiate their claims.

In the cases of exemptions 13(a), 13(b), 13(b)-(I), 13(b)-(II), 13(b)-(IV), 13(b)-(V) and 29 in Annex III, the technical assessment was mostly concluded at a significantly earlier stage. Taking into consideration the requested expiry dates, the technical recommendations as well as the ongoing transition to lead-free and cadmium-free applications in the sector, a shorter period than the maximum validity period should be given.

The exemptions in points 18(b), 18(b)-(II) and 24(a) in Annex III and the exemptions in points 1(b)-I to -IV and -VI in Annex IV have been granted for medium-term validity periods because no substitution is foreseeable in the near future. For exemptions 1(b)-V, 11(a) and 12(a) in Annex IV, long-term validity periods have been granted in view of the maximum validity periods of seven years.

For the exemptions regarding similar technology, aligned validity periods enable a joint review, which is advantageous for all parties involved. No sufficient evidence has been provided to grant validity periods for certain EEE categories that differ from those for all the other categories.

Delegated act

One single decision has been adopted for all these exemptions due to the technical proximity and the presence of lead and cadmium used for various types of EEE. The legal instrument is a delegated directive (as provided for in the RoHS Directive) and meets the requirements set out in Article 5(1)(a) and (b) of that directive.

The two objectives of the Delegated Directive are to contribute to the protection of human health and the environment; and to harmonise the provisions for the functioning of the internal market in the field of EEE. It therefore allows the use of substances that are otherwise banned for specific applications. This is 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 have been set in accordance with Article 5(2), first subparagraph, of the RoHS Directive. The expiry dates take into account the minimum period (starting 18 months before the expiry date) during which a renewal requests must be submitted in accordance with Article 5(5), first subparagraph, of the RoHS Directive. This gives the industry enough time to prepare and submit renewal requests. The expiry dates are not expected to adversely impact innovation.

The Delegated Directive has no implications for the EU's budget.

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

amending Directive 2011/65/EU of the European Parliament and of the Council as regards exemptions for lead and cadmium in certain electrical and electronic equipment

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[13], and in particular Article 5(1), points (a) and (b), thereof,

Whereas:

(1) Article 4(1) of Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment (EEE) placed on the market does not contain the hazardous substances listed in Annex II to that Directive. The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive

(2) Lead and cadmium are restricted substances listed in Annex II to Directive 2011/65/EU. The maximum tolerated concentration values are 0,1 % lead and 0,01 % cadmium by weight in homogenous materials. The restrictions do not apply to certain [exempted] applications listed in Annexes III and IV to Directive 2011/65/EU.

(3) The exemptions set out in points 5(b), 13(a), 13(b), 13(b)-(I). 13(b)-(II),13 (b)-(III), 18(b),18(b)-(I), 24, 29, 32 and 34 of Annex III to Directive 2011/65/EU, and in points 1(b), 4, 9, 11, 12 and 34 of Annex IV to that Directive cover all use of lead and/or cadmium EEE.

(4) The exemptions set out in points 5(b), 13(a), 13(b), 18(b), 24, 29, 32 and 34 of Annex III to Directive 2011/65/EU were to expire on 21 July 2023 in respect of in vitro diagnostic medical devices (subcategory of category 8), on 21 July 2024 in respect of industrial monitoring and control instruments (subcategory of category 9) and of category 11, and on 21 July 2021 in respect of all other categories and subcategories of EEE.

(5) The other exemptions set out in Annex III to Directive 2011/65/EU are limited to certain categories of EEE. The exemptions set out in points 13(b)-(I), 13(b)-(II) and 13(b)-(III) of that Annex concerning categories 1 to 7 and 10, the exemption set out in point 18(b)-(I) of that Annex concerning categories 5 and 8 were to expire on 21 July 2021.

(6) The exemptions set out in points 1(b), 4 and 9 of Annex IV to Directive 2011/65/EU were to expire on 21 July 2023 in respect of in vitro diagnostic medical devices (subcategory of category 8), on 21 July 2024 in respect of industrial monitoring and control instruments (subcategory of category 9) and on 21 July 2021 in respect of all

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

other subcategories of categories 8 and 9. The exemptions set out in points 11, 12 and 34 of that Annex were to expire on 22 July 2021 in respect of categories 8 and 9.

(7) The Commission received technical applications pursuant to Article 5(3) of Directive 2011/65/EU to renew the exemptions referred to above. In accordance with paragraph 5, second subparagraph of that Article, their submission extended the validity of the existing exemptions until decisions on the renewal applications are taken.

(8) In May 2022, the Commission has received a new exemption technical application concerning cadmium in Hersch cells for oxygen sensors. That application is technically similar to the renewal applications for the exemption set out in point 1(b) of Annex IV to Directive 2011/65/EU, which was formerly covered by the exemption set out in point 43 of that Annex.

(9) In order to evaluate the technical applications received, technical and scientific assessment studies were carried out and finalised in July 2020 (Pack 19), in February 2022 (Pack 24), in April 2022 (Pack 21), December 2022 (Pack 23) and May 2024 (Pack 27)[14]. The evaluations included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(10) Regarding the exemption set out in point 5(b) of Annex III to Directive 2011/65/EU, the use of lead is still necessary as the total benefits outweigh the total environmental, health and consumer impacts caused by substitution. Lead in soda lime glass is a result of the use of secondary glass. That use has outweighing benefits, such as the support of resource efficiency, the contribution to circularity and the conservation of energy. Therefore, the criterion set out in Article 5(1), point (a), third indent of Directive 2011/65/EU is met and the exemption set out in point 5(b) of Annex III to that Directive should be granted.

(11) Regarding the exemptions set out in points 13(a), 13(b)-(I), 13(b)-(II) 18(b), 18(b)-(II), 24(a), 29, 32 and 34 as well as the exemptions to be set out in points 13(b)-(IV), 13(b)-(V) of Annex III to Directive 2011/65/EU and in points 4(a) and 9(a) of Annex IV to that Directive, lead or cadmium, or both, are still necessary for the individual applications covered by those exemptions. Elimination or substitution is currently not scientifically nor technically feasible. Therefore, the criterion set out in Article 5(1), point (a), first indent of Directive 2011/65/EU is met for those exemptions.

(12) Regarding the exemption set out in point 13(a) of Annex III to Directive 2011/65/EU, lead-free alternatives do not achieve the necessary properties, in particular a medium high refractive index, a certain color aberration, low stress birefringence and a certain partial dispersion. Therefore, as for the justified technical applications under point 13(a) of Annex III to that Directive, an exemption should be granted. For legal certainty and clarity, the scope of point 13 (a) should be modified so that it better delineates the exemptions set out in point 13(a) in relation to those set out in points 13(b) of Annex III to Directive 2011/65/EU and its sub-entries.

(13) Regarding the exemption set out in point 13(b) of Annex III to Directive 2011/65/EU, the justified applications for categories 8, 9 and 11 should be included under more specific sub-entries of that point. To keep the scope of point 13(b), a new sub-entry 13(b)-(V) should be introduced in Annex III to Directive 2011/65/EU. As lead is

[14] The final reports for [?] all completed assessment studies are available under https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/rohs-directive-implementation_en

scientifically no longer required in glazes used for reflectance standards, such use should be removed from the scope of the exemption set out in point 13(b)-(III) of that Annex. As the scope of the exemption set out in point 13(b) of Annex III to Directive 2011/65/EU has a broad and generic scope and as the removal of the exemption set out in point 13(b)-(III) of that Annex reflects the technical development, those exemptions should, in accordance with Article 5(6) of Directive 2011/65/EU, expire 12 months after the entry into force of this Directive.

(14) Regarding the exemptions set out in the sub-entries of point 13(b) of Annex III to Directive 2011/65/EU, neither do lead-free substitutions achieve the necessary properties, nor is elimination technically feasible. Regarding the exemption set out in point 13(b)-(I) of that Annex, the desired filtering properties can only be achieved when lead is added. Regarding the exemption set out in point 13(b)-(II) of that Annex, cadmium is needed to enable the striking process. Regarding the exemption to be set out in point 13(b)-(IV) of that Annex, the addition of cadmium ensures the necessary stable conditions. Finally, regarding the exemption to be set out in point 13(b)-(V) of that Annex, lead compounds combine a high refractive index, good blocking properties and a steep wavelength cut-off. Therefore, as for the justified technical applications under points 13(b)-(I),13(b)-(II), 13(b)-(IV) and 13(b)-(V) of Annex III, those exemptions should be granted.

(15) As both concern lead in medical phototherapy equipment, the exemptions set out in points 18(b)-(I) of Annex III to Directive 2011/65/EU and in point 34 of Annex IV to that Directive should b combined in a new point 18(b)-(II). Regarding the exemptions set out in points 18(b) and 18(b)-(II) of Annex III to Directive 2011/65/EU, the required property of lead as an activator cannot be substituted. Therefore, those exemptions should be granted as for their justified applications.

(16) The scope of the exemption set out in point 24 of Annex III to Directive 2011/65/EU covers high and low melting point solders. In order to carry out an effective evaluation of the technologies and their applications in the future, those solders have to be addressed separately. Therefore, a new point 24(a) should be introduced to this effect. Since the scope of point 24 is broad and time is needed to assess practical uses, in accordance with Article 5(6) of Directive 2011/65/EU, the exemption set out in point 24 of Annex III to that Directive should expire 18 months after entry into force of this Directive. In order to keep a good wetting action, ductility and melting point, lead used in hole discoidal and/or planar array ceramic multilayer capacitors is still required and cannot be substituted. Therefore, the exemption set out in point 24(a) of Annex III to Directive 2011/65/EU should be granted.

(17) Regarding the exemption set out in point 29 of Annex III to Directive 2011/65/EU, the appearance of leaded crystal cannot be achieved with non-leaded glass, since no one-to-one substitute has the same technical properties. In addition, being considered a cultural heritage in European regions, substitution would have a negative socio-economic impact. Therefore, the exemption set out in point 29 of Annex III to Directive 2011/65/EU should be granted as for its justified applications.

(18) Regarding the exemption set out in point 32 of Annex III to Directive 2011/65/EU, the requirements of being thermally resistant and having a stress-free sealing, which are fulfilled where lead oxide is used, are not met by any alternatives. Therefore, that exemption should be granted as for its justified applications.

(19) Regarding the exemption set out in point 34 of Annex III to Directive 2011/65/EU, no substitutes meet the critical performance requirements, in particular high mechanical

abrasion and constant electrical contact resistance. Therefore, reflecting the justified technical applications, that exemption should be granted.

(20) Regarding the exemption set out in point 1(b) of Annex IV to Directive 2011/65/EU, there are developments ongoing to replace lead-based technologies, which are at different substitution stages. Overall, the lead-free alternatives cannot serve all applications or under all conditions. The substitution and elimination of lead in oxygen sensors for medical devices, sensors with very low detection level, capillary oxygen sensors, permeable membrane oxygen sensors and oxygen sensors based on Hersch cells is still scientifically and technically impracticable. The different substitution stages should be taken into account through tailored exemptions set out in a number of sub-entries and a shorter validity period than the maximum allowed period. Newer models complying with the requirements should be excluded. Therefore, a time-limited exemption should be granted.

(21) Regarding the exemptions set out in points 4 and 9 of Annex IV to Directive 2011/65/EU, the scope of those exemptions should be adjusted to their technical applications needed. As this reflects the scientific and technical development, those exemptions should, in accordance with Article 5(6) of that Directive, expire 12 months after the entry into force of this Directive. For the remaining technical applications, alternatives do not provide the same wavelength accuracy and spectral stability. Therefore, two new sub-entries 4(a) and 9(a) should be introduced in Annex IV to Directive 2011/65/EU and the corresponding exemptions granted as for their justified technical applications.

(22) Regarding the exemptions set out in points 11 and 12 of Annex IV to Directive 2011/65/EU, the elimination or substitution of lead in metallic bonds creating superconducting electric circuits in magnetic resonance imaging (MRI) devices, superconducting quantum interference devices (SQUID) and nuclear magnetic resonance (NMR) devices is scientifically and technically impracticable. Cadmium is no longer needed in the applications under point 12. Moreover, due to technical similarities, MRI and NMR devices should be covered under a new sub-entry 11(a), whereas SQUID devices should be addressed under a new sub-entry 12(a). The current exemptions set out in points 11 and 12 should be discontinued.

(23) The validity periods of the exemptions should be set in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU. Due to the long period of time that has elapsed since the technical conclusions and given that there are indications of new developments, in particular possible substitution, it is appropriate to grant a medium-term validity period for the exemptions set out in points 5(b), 32 and 34 of Annex III to Directive 2011/65/EU and points 4(a) and 9(a) of Annex IV to that Directive. As regards the exemptions set out in points 13(a), 13(b), 13(b)-(I), 13(b)-(II), 13(b)-(IV), 13(b)-(V) and 29 of Annex III to Directive 2011/65/EU, considering the long period of time that has elapsed since the technical conclusions and the ongoing transition to replace lead and cadmium-based technologies, granting medium-term validity periods is appropriate also for those exemptions. Finally, since for the exemptions set out in points 18(b), 18(b)-(II) and 24(a) of Annex III and in points 1(b)-I-VI, 11(a) and 12(a) of Annex IV to Directive 2011/65/EU, no alternatives are foreseeable soon, medium to long-term validity periods are appropriate. Regarding the validity periods, no information was provided to justify different expiry dates for certain EEE categories.

(24) The renewal of the exemptions is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[15] and does not weaken the environmental and health protection afforded by it.

(25) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes III and IV to Directive 2011/65/EU are 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

This Directive shall enter into force on the [twentieth] day following that of its publication in the *Official Journal of the European Union*.

Article

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

[15] 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).