

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 (recast) (Text with EEA relevance)

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

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Having regard to the opinion of the Committee of Regions<sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(3)</sup>,

Whereas:

- (1) A number of substantial changes are to be made to 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<sup>(4)</sup>. In the interest of clarity, that Directive should be recast.
- (2) The disparities between the laws or administrative measures adopted by the Member States regarding the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) could create barriers to trade and distort competition in the Union and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to lay down rules in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE.
- (3) Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in its scope equipment which falls within certain categories and to study the need to adapt the list of restricted substances on the basis of scientific progress, taking into account the precautionary principle, as endorsed by Council Resolution of 4 December 2000.

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- (4) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste<sup>(5)</sup> gives first priority to prevention in waste legislation. Prevention is defined, inter alia, as measures that reduce the content of harmful substances in materials and products.
- (5) Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium<sup>(6)</sup> invited the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable alternatives do not exist.
- (6) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants<sup>(7)</sup> recalls that the objective of protecting the environment and human health from persistent organic pollutants cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, and can therefore be better achieved at Union level. Pursuant to that Regulation, releases of persistent organic pollutants, such as dioxins and furans, which are unintentional by-products of industrial processes, should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible.
- (7) The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste EEE as set out in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)<sup>(8)</sup> are necessary to reduce the waste management problems associated with the heavy metals and flame retardants concerned. In spite of those measures, however, significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union. Even if waste EEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions.
- (8) Taking into account technical and economic feasibility, including for small and medium sized enterprises (SMEs), the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials. Restricting the use of those hazardous substances is likely to enhance the possibilities and economic profitability of recycling of waste EEE and decrease the negative impact on the health of workers in recycling plants.
- (9) The substances covered by this Directive are scientifically well researched and evaluated and have been subject to different measures both at Union and at national level.
- (10) The measures provided for in this Directive should take into account existing international guidelines and recommendations and should be based on an assessment of

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available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information. The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to 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<sup>(9)</sup>. In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments, in accordance with the new criteria set out in this Directive as part of the first review.

- (11) This Directive supplements the general Union waste management legislation, such as Directive 2008/98/EC and Regulation (EC) No 1907/2006.
- (12) A number of definitions should be included in this Directive in order to specify its scope. In addition, the definition of ‘electrical and electronic equipment’ should be complemented by a definition of ‘dependent’, to cover the multipurpose character of certain products, where the intended functions of EEE are to be determined on the basis of objective characteristics, such as the design of the product and its marketing.
- (13) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products<sup>(10)</sup> enables specific ecodesign requirements to be set for energy-related products which may also be covered by this Directive. Directive 2009/125/EC and the implementing measures adopted pursuant to it are without prejudice to Union waste management legislation.
- (14) This Directive should apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators<sup>(11)</sup> and Regulation (EC) No 850/2004.
- (15) The technical development of EEE without heavy metals, PBDE and PBB should be taken into account.
- (16) As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. To this end, the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies

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with, and reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation (EC) No 1907/2006 while ensuring the mutually independent operation of this Directive and that Regulation. Consultation with the relevant stakeholders should be carried out and specific account should be taken of the potential impact on SMEs.

- (17) The development of renewable forms of energy is one of the Union's key objectives, and the contribution made by renewable energy sources to environmental and climate objectives is crucial. Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources<sup>(12)</sup> recalls that there should be coherence between those objectives and other Union environmental legislation. Consequently, this Directive should not prevent the development of renewable energy technologies that have no negative impact on health and the environment and that are sustainable and economically viable.
- (18) Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured. The decision on exemptions and on the duration of possible exemptions should take into account the availability of substitutes and the socioeconomic impact of substitution. Life-cycle thinking on the overall impacts of exemptions should apply, where relevant. Substitution of the hazardous substances in EEE should also be carried out in such a way as to be compatible with the health and safety of users of EEE. The placing on the market of medical devices requires a conformity assessment procedure, according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>(13)</sup> and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices<sup>(14)</sup>, which could require the involvement of a notified body designated by competent authorities of Member States. If such a notified body certifies that the safety of the potential substitute for the intended use in medical devices or in vitro diagnostic medical devices is not demonstrated, the use of that potential substitute will be deemed to have clear negative socioeconomic, health and consumer safety impacts. It should be possible, from the date of entry into force of this Directive, to apply for exemptions for equipment, even before the actual inclusion of that equipment in the scope of this Directive.
- (19) Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.
- (20) As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available.
- (21) Procedures for assessing the conformity of EEE subject to this Directive should be consistent with relevant Union legislation, in particular Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework

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- for the marketing of products<sup>(15)</sup>. Harmonising conformity assessment procedures should give manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Union.
- (22) The conformity marking applicable for products at Union level, CE marking, should also apply to EEE that is subject to this Directive.
- (23) The market surveillance mechanisms laid down by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products<sup>(16)</sup> provide the safeguard mechanisms to check compliance with this Directive.
- (24) In order to ensure uniform conditions for the implementation of this Directive, particularly with regard to the guidelines and format of applications for exemptions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>(17)</sup>.
- (25) For the purposes of achieving the objectives of this Directive the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation of Annexes III and IV to technical and scientific progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (26) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (27) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex VII, Part B.
- (28) When reviewing this Directive, a thorough analysis of its coherence with Regulation (EC) No 1907/2006 should be carried out by the Commission.
- (29) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making<sup>(18)</sup>, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and their transposition measures, and to make those tables public.
- (30) Since the objective of this Directive, namely to establish restrictions on the use of hazardous substances in EEE, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the problem and its implications in respect of other Union legislation on recovery and disposal of waste and areas of common interest, such as human health protection, be better achieved at Union level, the Union may

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adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

### *Article 1*

#### **Subject matter**

This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

### *Article 2*

#### **Scope**

1 This Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I.

<sup>F1</sup>2 .....

3 This Directive shall apply without prejudice to the requirements of Union legislation on safety and health, and on chemicals, in particular Regulation (EC) No 1907/2006, as well as the requirements of specific Union waste management legislation.

4 This Directive does not apply to:

- a equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
- b equipment designed to be sent into space;
- c equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- d large-scale stationary industrial tools;
- e large-scale fixed installations;
- f means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- g non-road mobile machinery made available exclusively for professional use;
- h active implantable medical devices;
- i photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- j equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis<sup>F2</sup>;

<sup>F3</sup>k pipe organs.]

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### Textual Amendments

- F1** Deleted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
- F2** Substituted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
- F3** Inserted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).

### Article 3

#### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) ‘electrical and electronic equipment’ or ‘EEE’ means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
- (2) for the purposes of point 1, ‘dependent ’ means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function;
- (3) ‘large-scale stationary industrial tools’ means a large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility;
- (4) ‘large-scale fixed installation’ means a large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals;
- (5) ‘cables’ means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other;
- (6) ‘manufacturer’ means any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured and markets it under his name or trademark;
- (7) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (8) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EEE available on the market;
- (9) ‘importer’ means any natural or legal person established within the Union, who places an EEE from a third country on the Union market;

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- (10) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (11) 'making available on the market' means any supply of an EEE for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (12) 'placing on the market' means making available an EEE on the Union market for the first time;
- (13) 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services<sup>(19)</sup> on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC;
- (14) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process or service;
- (15) 'CE marking' means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (16) 'conformity assessment' means the process demonstrating whether the requirements of this Directive relating to an EEE, are met;
- (17) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that EEE complies with the requirements set out in this Directive and does not endanger health, safety or other issues of public interest protection;
- (18) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (19) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (20) 'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjoined or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes;
- (21) 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE;
- (22) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;
- (23) 'active implantable medical device' means any active implantable medical device within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices<sup>(20)</sup>;
- (24) 'industrial monitoring and control instruments' means monitoring and control instruments designed for exclusively industrial or professional use;



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- (25) ‘availability of a substitute’ means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II;
- (26) ‘reliability of a substitute’ means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time;
- (27) ‘spare part’ means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;
- (28) [<sup>F2</sup>‘non-road mobile machinery made available exclusively for professional use’ means machinery, with an on-board power source or with a traction drive powered by an external power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and which is made available exclusively for professional use.]

#### **Textual Amendments**

- F2** Substituted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).

#### *Article 4*

#### **Prevention**

1 Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.

2 For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated. The Commission shall adopt, by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, detailed rules for complying with these maximum concentration values taking into account, inter alia, surface coatings.

[<sup>F23</sup> Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016, to industrial monitoring and control instruments which are placed on the market from 22 July 2017, and to all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market from 22 July 2019.]

4 Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

- a EEE placed on the market before 1 July 2006;
- b medical devices placed on the market before 22 July 2014;
- c in vitro diagnostic medical devices placed on the market before 22 July 2016;
- d monitoring and control instruments placed on the market before 22 July 2014;
- e industrial monitoring and control instruments placed on the market before 22 July 2017;

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- [<sup>F3</sup>ea all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019;]
- f EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.
- [<sup>F25</sup> Provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of spare parts is notified to the consumer, paragraph 1 shall not apply to reused spare parts:
- a recovered from EEE placed on the market before 1 July 2006 and used in EEE placed on the market before 1 July 2016;
  - b recovered from medical devices or monitoring and control instruments placed on the market before 22 July 2014 and used in EEE placed on the market before 22 July 2024;
  - c recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and used in EEE placed on the market before 22 July 2026;
  - d recovered from industrial monitoring and control instruments placed on the market before 22 July 2017 and used in EEE placed on the market before 22 July 2027;
  - e recovered from all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019, and used in EEE placed on the market before 22 July 2029.]
- 6 Paragraph 1 shall not apply to the applications listed in Annexes III and IV.

#### Textual Amendments

- F2** Substituted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
- F3** Inserted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).

### Article 5

#### Adaptation of the Annexes to scientific and technical progress

- 1 For the purposes of adapting Annexes III and IV to scientific and technical progress, and in order to achieve the objectives set out in Article 1, the Commission shall adopt by means of individual delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, the following measures:
- a inclusion of materials and components of EEE for specific applications in the lists 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,
    - 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.

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Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant;

- b deletion of materials and components of EEE from the lists in Annexes III and IV where the conditions set out in point (a) are no longer fulfilled.

2 Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to 5 years and, for categories 8 and 9 of Annex I, a validity period of up to 7 years. The validity periods are to be decided on a case-by-case basis and may be renewed.

[<sup>F2</sup>For the exemptions listed in Annex III as at 21 July 2011, unless a shorter period is specified, the maximum validity period, which may be renewed, shall be:

- a for categories 1 to 7 and category 10 of Annex I, 5 years from 21 July 2011;
- b for categories 8 and 9 of Annex I, 7 years from the relevant dates laid down in Article 4(3); and
- c for category 11 of Annex I, 5 years from 22 July 2019.]

For the exemptions listed in Annex IV as at 21 July 2011, the maximum validity period, which may be renewed, shall be 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified.

3 An application for granting, renewing or revoking an exemption shall be made to the Commission in accordance with Annex V.

4 The Commission shall:

- a acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;
- b inform the Member States of the application without delay and make the application and any supplementary information supplied by the applicant available to them;
- [<sup>F3</sup>ba within 1 month of receipt of an application, provide to the applicant, the Member States and the European Parliament a timeline for the adoption of its decision on the application;]
- c make a summary of the application available to the public;
- d evaluate the application and its justification.

5 An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.

[<sup>F1</sup>The Commission shall decide on an application for renewal of an exemption no later than 6 months before the expiry date of the existing exemption unless specific circumstances justify other deadlines.] The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.

6 In the event that the application for renewal of an exemption is rejected or that an exemption is revoked, the exemption shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision.

7 Before Annexes are amended, the Commission shall, inter alia, consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available.

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8 The Commission shall adopt a harmonised format for applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

#### **Textual Amendments**

- F1** Deleted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
- F2** Substituted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
- F3** Inserted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).

### *Article 6*

#### **Review and amendment of list of restricted substances in Annex II**

1 With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.

The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation.

In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:

- a could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
- b could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
- c could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;
- d could be replaced by substitutes or alternative technologies which have less negative impacts.

During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.

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2 The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:

- a precise and clear wording of the proposed restriction;
- b references and scientific evidence for the restriction;
- c information on the use of the substance or the group of similar substances in EEE;
- d information on detrimental effects and exposure in particular during waste EEE management operations;
- e information on possible substitutes and other alternatives, their availability and reliability;
- f justification for considering a Union-wide restriction as the most appropriate measure;
- g socioeconomic assessment.

3 The measures referred to in this Article shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22.

#### *Article 7*

### **Obligations of manufacturers**

Member States shall ensure that:

- (a) when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;
- (b) manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC or have it carried out;
- (c) where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;
- (d) manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market;
- (e) manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;
- (f) manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof;
- (g) manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;

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- (h) manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;
- (i) manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (j) manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

#### *Article 8*

#### **Obligations of authorised representatives**

Member States shall ensure that:

- (a) manufacturers have the possibility to appoint an authorised representative by written mandate. The obligations laid down in point (a) of Article 7 and the drawing up of technical documentation shall not form part of the authorised representative's mandate;
- (b) an authorised representative performs the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years following the placing on the market of the EEE,
  - further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive,
  - cooperate with the competent national authorities, at their request, on any action taken to ensure compliance with this Directive of EEE covered by their mandate.

#### *Article 9*

#### **Obligations of importers**

Member States shall ensure that:

- (a) importers place only EEE that complies with this Directive on the Union market;

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- (b) importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, [<sup>X1</sup>and that the manufacturer has complied with the requirements set out in points (g) and (h) of Article 7;]
- (c) where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;
- (d) importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;
- (e) importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- (f) importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (g) importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;
- (h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

#### **Editorial Information**

- X1** Substituted by [Corrigendum 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 \(Official Journal of the European Union L 174 of 1 July 2011\)](#).

### *Article 10*

#### **Obligations of distributors**

Member States shall ensure that:

- (a) when making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be

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easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points (g) and (h) of Article 7 and in point (d) of Article 9;

- (b) where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, that distributor does not make the EEE available on the market until it has been brought into conformity, and that that distributor informs the manufacturer or the importer as well as the market surveillance authorities to that effect;
- (c) distributors who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with this Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (d) distributors, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.

#### *Article 11*

#### **Cases in which obligations of manufacturers apply to importers and distributors**

Member States shall ensure that an importer or distributor is considered a manufacturer for the purposes of this Directive and that he is subject to the obligations of the manufacturer under Article 7, where he places EEE on the market under his name or trademark or modifies EEE already placed on the market in such a way that compliance with the applicable requirements may be affected.

#### *Article 12*

#### **Identification of economic operators**

Member States shall ensure that economic operators, on request, identify the following to the market surveillance authorities, for 10 years following the placing on the market of the EEE:

- (a) any economic operator who has supplied them with an EEE;
- (b) any economic operator to whom they have supplied an EEE.

#### *Article 13*

#### **EU declaration of conformity**

1 The EU declaration of conformity shall state that it has been demonstrated that the requirements specified in Article 4 have been met.



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2 The EU declaration of conformity shall have the model structure and shall contain the elements specified in Annex VI and shall be updated. It shall be translated into the language or languages required by the Member State on the market of which the product is placed or made available.

Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up.

3 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EEE with this Directive.

#### *Article 14*

### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### *Article 15*

### **Rules and conditions for affixing the CE marking**

1 The CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate. Where that is not possible or not warranted on account of the nature of the EEE, it shall be affixed to the packaging and to the accompanying documents.

2 The CE marking shall be affixed before the EEE is placed on the market.

3 Member States shall build upon existing mechanisms to ensure the correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the CE marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

#### *Article 16*

### **Presumption of conformity**

1 In the absence of evidence to the contrary, Member States shall presume EEE bearing the CE marking to comply with this Directive.

2 Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the requirements of this Directive.

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### Article 17

#### **Formal objection to a harmonised standard**

1 Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 4, the Commission or the Member State concerned shall bring the matter before the Committee set up pursuant to Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, after consulting the relevant European standardisation bodies, deliver its opinion without delay.

2 In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3 The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

### Article 18

#### **Market surveillance and controls of EEE entering the Union market**

Member States shall carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008.

### Article 19

#### **Committee procedure**

1 The Commission shall be assisted by the committee set up pursuant to Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

### Article 20

#### **Exercise of the delegation**

1 The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.

2 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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3 The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.

#### *Article 21*

### **Revocation of the delegation**

1 The delegation of power referred to in Article 4(2), Article 5(1) and Article 6 may be revoked at any time by the European Parliament or by the Council.

2 The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3 The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

#### *Article 22*

### **Objections to delegated acts**

1 The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by 2 months.

2 If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3 If the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

#### *Article 23*

### **Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 2 January 2013 and shall notify it without delay of any subsequent amendment affecting them.

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## Article 24

### Review

1 No later than 22 July 2014 the Commission shall examine the need to amend the scope of this Directive in respect of the EEE referred to in Article 2, and shall present a report thereon to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE.

2 No later than 22 July 2021 the Commission shall carry out a general review of this Directive, and shall present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal.

## Article 25

### Transposition

1 Member States shall adopt and publish, by 2 January 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. 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 26

### Repeal

Directive 2002/95/EC as amended by the acts listed in Annex VII, Part A is repealed with effect from 3 January 2013 without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directive set out in Annex VII, Part B.

References to the repealed acts shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VIII.

## Article 27

### Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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*Article 28*

**Addressees**

This Directive is addressed to the Member States.

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## ANNEX I

**Categories of EEE covered by this Directive**

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.

## ANNEX II

**Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials**

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)

## ANNEX III

**APPLICATIONS EXEMPTED FROM THE RESTRICTION IN ARTICLE 4(1)**

<b>Exemption</b>		<b>Scope and dates of applicability</b>
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
a	OJ L 326, 29.12.1969, p. 36.	
b	[ <sup>F4</sup> Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]	

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1(a)	For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2,5 mg shall be used per burner after 31 December 2012
1(b)	For general lighting purposes $\geq 30$ W and < 50 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011
1(c)	For general lighting purposes $\geq 50$ W and < 150 W: 5 mg	
1(d)	For general lighting purposes $\geq 150$ W: 15 mg	
1(e)	For general lighting purposes with circular or square structural shape and tube diameter $\leq 17$ mm	No limitation of use until 31 December 2011; 7 mg may be used per burner after 31 December 2011
1(f)	For special purposes: 5 mg	
[ <sup>F5</sup> 1(g)]	For general lighting purposes < 30 W with a lifetime equal or above 20 000 h: 3,5 mg	Expires on 31 December 2017]
2(a)	Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):	
2(a)(1)	Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e.g. T2): 5 mg	Expires on 31 December 2011; 4 mg may be used per lamp after 31 December 2011
2(a)(2)	Tri-band phosphor with normal lifetime and a tube diameter $\geq 9$ mm and $\leq 17$ mm (e.g. T5): 5 mg	Expires on 31 December 2011; 3 mg may be used per lamp after 31 December 2011
2(a)(3)	Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and $\leq 28$ mm (e.g. T8): 5 mg	Expires on 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011
2(a)(4)	Tri-band phosphor with normal lifetime and a tube	Expires on 31 December 2012; 3,5 mg may be used

**a** OJ L 326, 29.12.1969, p. 36.

**b** [<sup>F4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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	diameter > 28 mm (e.g. T12): 5 mg	per lamp after 31 December 2012
2(a)(5)	Tri-band phosphor with long lifetime ( $\geq 25\,000$ h): 8 mg	Expires on 31 December 2011; 5 mg may be used per lamp after 31 December 2011
2(b)	Mercury in other fluorescent lamps not exceeding (per lamp):	
2(b)(1)	Linear halophosphate lamps with tube > 28 mm (e.g. T10 and T12): 10 mg	Expires on 13 April 2012
2(b)(2)	Non-linear halophosphate lamps (all diameters): 15 mg	Expires on 13 April 2016
2(b)(3)	Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
2(b)(4)	Lamps for other general lighting and special purposes (e.g. induction lamps)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
3	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp):	
3(a)	Short length ( $\leq 500$ mm)	No limitation of use until 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011
3(b)	Medium length ( $> 500$ mm and $\leq 1\,500$ mm)	No limitation of use until 31 December 2011; 5 mg may be used per lamp after 31 December 2011
3(c)	Long length ( $> 1\,500$ mm)	No limitation of use until 31 December 2011; 13 mg may be used per lamp after 31 December 2011
4(a)	Mercury in other low pressure discharge lamps (per lamp)	No limitation of use until 31 December 2011; 15 mg may

**a** OJ L 326, 29.12.1969, p. 36.

**b** [<sup>4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]



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		be used per lamp after 31 December 2011
4(b)	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$ :	
4(b)-I	$P \leq 155 \text{ W}$	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(b)-II	$155 \text{ W} < P \leq 405 \text{ W}$	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(b)-III	$P > 405 \text{ W}$	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(c)	Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner):	
4(c)-I	$P \leq 155 \text{ W}$	No limitation of use until 31 December 2011; 25 mg may be used per burner after 31 December 2011
4(c)-II	$155 \text{ W} < P \leq 405 \text{ W}$	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(c)-III	$P > 405 \text{ W}$	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(d)	Mercury in High Pressure Mercury (vapour) lamps (HPMV)	Expires on 13 April 2015
4(e)	Mercury in metal halide lamps (MH)	

**a** OJ L 326, 29.12.1969, p. 36.

**b** [F<sup>4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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4(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	
[ <sup>F6</sup> 4(g)]	Mercury in hand crafted luminous discharge tubes used for signs, decorative or architectural and specialist lighting and light-artwork, where the mercury content shall be limited as follows: (a) 20 mg per electrode pair + 0,3 mg per tube length in cm, but not more than 80 mg, for outdoor applications and indoor applications exposed to temperatures below 20 °C; (b) 15 mg per electrode pair + 0,24 mg per tube length in cm, but not more than 80 mg, for all other indoor applications.	Expires on 31 December 2018]
5(a)	Lead in glass of cathode ray tubes	
5(b)	Lead in glass of fluorescent tubes not exceeding 0,2 % by weight	
6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	
6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	
6(c)	Copper alloy containing up to 4 % lead by weight	
7(a)	Lead in high melting temperature type solders (i.e.	

**a** OJ L 326, 29.12.1969, p. 36.

**b** [<sup>F4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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	lead-based alloys containing 85 % by weight or more lead)	
7(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications	
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	
7(c)-III	Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
[ <sup>F7</sup> 7(c)-IV	Lead in PZT based dielectric ceramic materials for capacitors which are part of integrated circuits or discrete semiconductors	Expires on 21 July 2016]
8(a)	Cadmium and its compounds in one shot pellet type thermal cut-offs	Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012
8(b)	Cadmium and its compounds in electrical contacts	
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up	

a OJ L 326, 29.12.1969, p. 36.

b [<sup>F4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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	to 0,75 % by weight in the cooling solution	
9(b)	Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	
11(a)	Lead used in C-press compliant pin connector systems	May be used in spare parts for EEE placed on the market before 24 September 2010
11(b)	Lead used in other than C-press compliant pin connector systems	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
12	Lead as a coating material for the thermal conduction module C-ring	May be used in spare parts for EEE placed on the market before 24 September 2010
13(a)	Lead in white glasses used for optical applications	
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	
14	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80 % and less than 85 % by weight	Expired on 1 January 2011 and after that date may be used in spare parts for EEE placed on the market before 1 January 2011
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	
16	Lead in linear incandescent lamps with silicate coated tubes	Expires on 1 September 2013
17	Lead halide as radiant agent in high intensity discharge (HID) lamps used for	

**a** OJ L 326, 29.12.1969, p. 36.

**b** [F<sup>4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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	professional reprography applications	
18(a)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ((Sr,Ba) <sub>2</sub> MgSi <sub>2</sub> O <sub>7</sub> :Pb)	Expired on 1 January 2011
18(b)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi <sub>2</sub> O <sub>5</sub> :Pb)	
19	Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL)	Expires on 1 June 2011
20	Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCDs)	Expires on 1 June 2011
21	Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	
23	Lead in finishes of fine pitch components other than connectors with a pitch of 0,65 mm and less	May be used in spare parts for EEE placed on the market before 24 September 2010
24	Lead in solders for the soldering to machined through hole discoidal	

**a** OJ L 326, 29.12.1969, p. 36.

**b** [F<sup>4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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	and planar array ceramic multilayer capacitors	
25	Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring	
26	Lead oxide in the glass envelope of black light blue lamps	Expires on 1 June 2011
27	Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers	Expired on 24 September 2010
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC <sup>a</sup>	
30	Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more	
31	Lead in soldering materials in mercury free flat fluorescent lamps (which, e.g. are used for liquid crystal displays, design or industrial lighting)	
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes	
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	

<sup>a</sup> OJ L 326, 29.12.1969, p. 36.

<sup>b</sup> [<sup>F4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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34	Lead in cermet-based trimmer potentiometer elements	
36	Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display	Expired on 1 July 2010
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39	Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm <sup>2</sup> of light-emitting area) for use in solid state illumination or display systems	Expires on 1 July 2014
[ <sup>F8</sup> 40	Cadmium in photoresistors for analogue optocouplers applied in professional audio equipment	Expires on 31 December 2013]
[ <sup>F4</sup> 41	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council <sup>b</sup> )	Expires on 31 December 2018]

**a** OJ L 326, 29.12.1969, p. 36.

**b** [<sup>F4</sup>Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).]

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### Textual Amendments

- F4** Inserted by Commission Delegated Directive 2014/72/EU of 13 March 2014 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 solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems (Text with EEA relevance).
- F5** Inserted by Commission Delegated Directive 2014/14/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for 3,5 mg mercury per lamp in single capped compact fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20000 h (Text with EEA relevance).
- F6** Inserted by Commission Delegated Directive 2014/76/EU of 13 March 2014 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 Mercury in hand crafted luminous discharge tubes (HLDTs) used for signs, decorative or architectural and specialist lighting and light-artwork (Text with EEA relevance).
- F7** Inserted by Commission Delegated Directive 2012/50/EU of 10 October 2012 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 applications containing lead (Text with EEA relevance).
- F8** Inserted by Commission Delegated Directive 2012/51/EU of 10 October 2012 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 applications containing cadmium (Text with EEA relevance).

## ANNEX IV

### **Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments**

Equipment utilising or detecting ionising radiation

1. Lead, cadmium and mercury in detectors for ionising radiation.
2. Lead bearings in X-ray tubes.
3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
4. Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.
5. Lead in shielding for ionising radiation.
6. Lead in X-ray test objects.
7. Lead stearate X-ray diffraction crystals.
8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers. Sensors, detectors and electrodes
  - 1a. Lead and cadmium in ion selective electrodes including glass of pH electrodes.
  - 1b. Lead anodes in electrochemical oxygen sensors.



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- 1c. Lead, cadmium and mercury in infra-red light detectors.
- 1d. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.
- Others
- 9. Cadmium in helium-cadmium lasers.
- 10. Lead and cadmium in atomic absorption spectroscopy lamps.
- 11. Lead in alloys as a superconductor and thermal conductor in MRI.
- [<sup>F9</sup>12. Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021.]

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#### Textual Amendments

**F9** Substituted by [Commission Delegated Directive 2014/9/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR \(Nuclear Magnetic Resonance\) or FTMS \(Fourier Transform Mass Spectrometer\) detectors \(Text with EEA relevance\).](#)

- 13. Lead in counterweights.
- 14. Lead in single crystal piezoelectric materials for ultrasonic transducers.
- 15. Lead in solders for bonding to ultrasonic transducers.
- 16. Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay.
- 17. Lead in solders in portable emergency defibrillators.
- 18. Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm.
- 19. Lead in Liquid crystal on silicon (LCoS) displays.
- 20. Cadmium in X-ray measurement filters.
- [<sup>F10</sup>21. Cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020.]

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#### Textual Amendments

**F10** Inserted by [Commission Delegated Directive 2014/2/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020 \(Text with EEA relevance\).](#)

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- [<sup>F11</sup>22. Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment. Expires on 30 June 2021.]

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**Textual Amendments**

- F11** Inserted by Commission Delegated Directive 2014/3/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead acetate marker for use in stereotactic head frames for use with CT (Computed Tomography) and MRI and in positioning systems for gamma beam and particle therapy equipment (Text with EEA relevance).

- [<sup>F12</sup>23. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.]

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**Textual Amendments**

- F12** Inserted by Commission Delegated Directive 2014/1/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation (Text with EEA relevance).

- [<sup>F13</sup>24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.]

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**Textual Amendments**

- F13** Inserted by Commission Delegated Directive 2014/4/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers (Text with EEA relevance).

- [<sup>F14</sup>25. Lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below – 20 °C under normal operating and storage conditions. Expires on 30 June 2021.]

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**Textual Amendments**

- F14** Inserted by Commission Delegated Directive 2014/6/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below – 20 °C under normal operating and storage conditions (Text with EEA relevance).

- [<sup>F15</sup>26. Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:

- (a) solders on printed circuit boards;
- (b) termination coatings of electrical and electronic components and coatings of printed circuit boards;

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- (c) solders for connecting wires and cables;
- (d) solders connecting transducers and sensors.

Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

These exemptions expire on 30 June 2021.]

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#### Textual Amendments

**F15** Substituted by [Commission Delegated Directive \(EU\) 2016/1028 of 19 April 2016 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 \(Text with EEA relevance\).](#)

- [<sup>F16</sup>27. Lead in
- solders,
  - termination coatings of electrical and electronic components and printed circuit boards,
  - connections of electrical wires, shields and enclosed connectors,

which are used in

- (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or
- (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy.

Expires on 30 June 2020.]

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#### Textual Amendments

**F16** Inserted by [Commission Delegated Directive 2014/7/EU of 18 October 2013 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, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used \(a\) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or \(b\) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy \(Text with EEA relevance\).](#)

- [<sup>F17</sup>28. Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards. Expires on 31 December 2017.]

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#### Textual Amendments

**F17** Inserted by [Commission Delegated Directive 2014/8/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of](#)

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the Council as regards an exemption for lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards (Text with EEA relevance).

- [<sup>F18</sup>29. Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments. Expires on 30 June 2021.]

#### Textual Amendments

**F18** Inserted by Commission Delegated Directive 2014/10/EU of 18 October 2013 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 alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments (Text with EEA relevance).

- [<sup>F19</sup>30. Hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020.]

#### Textual Amendments

**F19** Inserted by Commission Delegated Directive 2014/11/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020 (Text with EEA relevance).

- [<sup>F20</sup>31. ....]

#### Textual Amendments

**F20** Deleted by Commission Delegated Directive (EU) 2016/585 of 12 February 2016 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, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes (Text with EEA relevance).

- [<sup>F21</sup>31a. Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

Expires on:

- (a) 21 July 2021 for the use in medical devices other than *in vitro* diagnostic medical devices;
- (b) 21 July 2023 for the use in *in vitro* diagnostic medical devices;

- (c) 21 July 2024 for the use in electron microscopes and their accessories.]

**Textual Amendments**

**F21** Inserted by Commission Delegated Directive (EU) 2016/585 of 12 February 2016 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, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes (Text with EEA relevance).

- [<sup>F22</sup>32. Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment. Expires on 31 December 2019.]

**Textual Amendments**

**F22** Inserted by Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment (Text with EEA relevance).

- [<sup>F23</sup>33. Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb.]

**Textual Amendments**

**F23** Inserted by Commission Delegated Directive 2014/13/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators (Text with EEA relevance).

- [<sup>F24</sup>34. Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi<sub>2</sub>O<sub>5</sub>:Pb) phosphors. Expires on 22 July 2021.]

**Textual Amendments**

**F24** Inserted by Commission Delegated Directive 2014/16/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi<sub>2</sub>O<sub>5</sub>:Pb) phosphors (Text with EEA relevance).

- [<sup>F25</sup>35. Mercury in cold cathode fluorescent lamps for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017

Expires on 21 July 2024.]

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#### Textual Amendments

**F25** Inserted by [Commission Delegated Directive 2014/75/EU](#) of 13 March 2014 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 mercury in cold cathode fluorescent lamps (CCFLs) for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017 (Text with EEA relevance).

[<sup>F26</sup>36. Lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments.

Expires on 31 December 2020. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.]

#### Textual Amendments

**F26** Inserted by [Commission Delegated Directive 2014/74/EU](#) of 13 March 2014 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 used in other than C-press compliant pin connector systems for industrial monitoring and control instruments (Text with EEA relevance).

[<sup>F27</sup>37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:

- (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;
- (b) measurements of solutions where an accuracy of +/- 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:
  - (i) solutions with an acidity < pH 1;
  - (ii) solutions with an alkalinity > pH 13;
  - (iii) corrosive solutions containing halogen gas;
- (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.

Expires on 31 December 2018.]

#### Textual Amendments

**F27** Inserted by [Commission Delegated Directive 2014/73/EU](#) of 13 March 2014 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 platinized platinum electrodes used for conductivity measurements (Text with EEA relevance).

[<sup>F28</sup>38. Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in X-ray detectors of computed tomography and X-ray systems.

Expires on 31 December 2019. May be used after that date in spare parts for CT and X-ray systems placed on the market before 1 January 2020.]

#### Textual Amendments

**F28** Inserted by [Commission Delegated Directive 2014/71/EU of 13 March 2014 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 solder in one interface of large area stacked die elements](#) (Text with EEA relevance).

[<sup>F29</sup>39. Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:

- (a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;
- (b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:
  - (i) a response time shorter than 25 ns;
  - (ii) a sample detection area larger than 149 mm<sup>2</sup>;
  - (iii) a multiplication factor larger than  $1,3 \times 10^3$ .
- (c) a response time shorter than 5 ns for detecting electrons or ions;
- (d) a sample detection area larger than 314 mm<sup>2</sup> for detecting electrons or ions;
- (e) a multiplication factor larger than  $4,0 \times 10^7$ .

The exemption expires on the following dates:

- (a) 21 July 2021 for medical devices and monitoring and control instruments;
- (b) 21 July 2023 for in-vitro diagnostic medical devices;
- (c) 21 July 2024 for industrial monitoring and control instruments.]

#### Textual Amendments

**F29** Inserted by [Commission Delegated Directive 2014/70/EU of 13 March 2014 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 micro-channel plates \(MCPs\)](#) (Text with EEA relevance).

[<sup>F30</sup>40. Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments.

Expires on 31 December 2020. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.]

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#### Textual Amendments

**F30** Inserted by [Commission Delegated Directive 2014/69/EU](#) of 13 March 2014 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 dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments (Text with EEA relevance).

[<sup>F31</sup>41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on 31 December 2018.]

#### Textual Amendments

**F31** Inserted by [Commission Delegated Directive \(EU\) 2015/573](#) of 30 January 2015 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 polyvinyl chloride sensors in in-vitro diagnostic medical devices (Text with EEA relevance).

[<sup>F32</sup>42. Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

Expires on 30 June 2019.]

#### Textual Amendments

**F32** Inserted by [Commission Delegated Directive \(EU\) 2015/574](#) of 30 January 2015 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 mercury in intravascular ultrasound imaging systems (Text with EEA relevance).

[<sup>F33</sup>43. Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10 ppm is required.

Expires on 15 July 2023.]

#### Textual Amendments

**F33** Inserted by [Commission Delegated Directive \(EU\) 2016/1029](#) of 19 April 2016 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 cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments (Text with EEA relevance).



## ANNEX V

### **Applications for granting, renewing and revoking exemptions as referred to in Article 5**

Applications for exemptions, renewal of exemptions or, *mutatis mutandis*, for revoking an exemption may be submitted by a manufacturer, the authorised representative of a manufacturer, or any economic operator in the supply chain and shall include at least the following:

- (a) the name, address and contact details of the applicant;
- (b) information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested and its particular characteristics;
- (c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in Article 5;
- (d) an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;
- (e) information on the possible preparation for reuse or recycling of materials from waste EEE, and on the provisions relating to the appropriate treatment of waste according to Annex II to Directive 2002/96/EC;
- (f) other relevant information;
- (g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;
- (h) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- (i) when applying for an exemption, proposal for a precise and clear wording for the exemption;
- (j) a summary of the application.

## ANNEX VI

### **EU DECLARATION OF CONFORMITY**

1. No ... (unique identification of the EEE):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
4. Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with 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<sup>(21)</sup>:

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6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:

7. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

## ANNEX VII

### PART A

#### REPEALED DIRECTIVE WITH ITS SUCCESSIVE AMENDMENTS

(referred to in Article 26)

Directive 2002/95/EC of the European Parliament and of the Council	(OJ L 37, 13.2.2003, p. 19).
Commission Decision 2005/618/EC	(OJ L 214, 19.8.2005, p. 65).
Commission Decision 2005/717/EC	(OJ L 271, 15.10.2005, p. 48).
Commission Decision 2005/747/EC	(OJ L 280, 25.10.2005, p. 18).
Commission Decision 2006/310/EC	(OJ L 115, 28.4.2006, p. 38).
Commission Decision 2006/690/EC	(OJ L 283, 14.10.2006, p. 47).
Commission Decision 2006/691/EC	(OJ L 283, 14.10.2006, p. 48).
Commission Decision 2006/692/EC	(OJ L 283, 14.10.2006, p. 50).
Directive 2008/35/EC of the European Parliament and of the Council	(OJ L 81, 20.3.2008, p. 67).
Commission Decision 2008/385/EC	(OJ L 136, 24.5.2008, p. 9).
Commission Decision 2009/428/EC	(OJ L 139, 5.6.2009, p. 32).
Commission Decision 2009/443/EC	(OJ L 148, 11.6.2009, p. 27).
Commission Decision 2010/122/EU	(OJ L 49, 26.2.2010, p. 32).
Commission Decision 2010/571/EU	(OJ L 251, 25.9.2010, p. 28).

### PART B

#### LIST OF TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW

(referred to in Article 26)

Directive	Deadline for transposition
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2002/95/EC	12 August 2004
2008/35/EC	—

## ANNEX VIII

## CORRELATION TABLE

<b>Directive 2002/95/EC</b>	<b>This Directive</b>
Article 1	Article 1
Article 2(1)	Article 2(1), 2(2), Annex I
Article 2(2)	Article 2(3)
Article 2(3)	Article 2(4), introductory wording
—	Article 2(4)
Article 3(a)	Article 3(1),(2)
Article 3(b)	—
—	Article 3(6)-(28)
Article 4(1)	Article 4(1), Annex II
—	Article 4(3)-(4)
Article 4(2)	Article 4(6)
Article 4(3)	—
Article 5(1), introductory wording	Article 5(1), introductory wording
Article 5(1)(a)	Article 4(2)
Article 5(1)(b)	Article 5(1)(a), first and third indents
—	Article 5(1)(a), second indent Article 5(1)(a), final paragraph
Article 5(1)(c)	Article 5(1)(b)
—	Article 5(2) Article 5(3)-(6)
Article 5(2)	Article 5(7)
—	Article 5(8)
Article 6	Article 6
—	Article 7-18
Article 7	Articles 19-22
Article 8	Article 23
Article 9	Article 25
—	Article 26

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Article 10	Article 27
Article 11	Article 28
—	Annexes I-II
Annex, points 1-39	Annex III, points 1-39
—	Annexes IV, V, VI-VIII

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- (1) OJ C 306, 16.12.2009, p. 36.
- (2) OJ C 141, 29.5.2010, p. 55.
- (3) Position of the European Parliament of 24 November 2010 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.
- (4) OJ L 37, 13.2.2003, p. 19.
- (5) OJ L 312, 22.11.2008, p. 3.
- (6) OJ C 30, 4.2.1988, p. 1.
- (7) OJ L 158, 30.4.2004, p. 7.
- (8) OJ L 37, 13.2.2003, p. 24.
- (9) OJ L 396, 30.12.2006, p. 1.
- (10) OJ L 285, 31.10.2009, p. 10.
- (11) OJ L 266, 26.9.2006, p. 1.
- (12) OJ L 140, 5.6.2009, p. 16.
- (13) OJ L 169, 12.7.1993, p. 1.
- (14) OJ L 331, 7.12.1998, p. 1.
- (15) OJ L 218, 13.8.2008, p. 82.
- (16) OJ L 218, 13.8.2008, p. 30.
- (17) OJ L 55, 28.2.2011, p. 13.
- (18) OJ C 321, 31.12.2003, p. 1.
- (19) OJ L 204, 21.7.1998, p. 37.
- (20) OJ L 189, 20.7.1990, p. 17.
- (21) OJ L 174, 1.7.2011, p. 88.