

This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

**► B      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)**  
**(OJ L 174, 1.7.2011, p. 88)**

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Delegated Directive 2012/50/EU of 10 October 2012	L 348	16	18.12.2012
► <u>M2</u>	Commission Delegated Directive 2012/51/EU of 10 October 2012	L 348	18	18.12.2012
► <u>M3</u>	Commission Delegated Directive 2014/1/EU of 18 October 2013	L 4	45	9.1.2014
► <u>M4</u>	Commission Delegated Directive 2014/2/EU of 18 October 2013	L 4	47	9.1.2014
► <u>M5</u>	Commission Delegated Directive 2014/3/EU of 18 October 2013	L 4	49	9.1.2014
► <u>M6</u>	Commission Delegated Directive 2014/4/EU of 18 October 2013	L 4	51	9.1.2014
► <u>M7</u>	Commission Delegated Directive 2014/5/EU of 18 October 2013	L 4	53	9.1.2014
► <u>M8</u>	Commission Delegated Directive 2014/6/EU of 18 October 2013	L 4	55	9.1.2014
► <u>M9</u>	Commission Delegated Directive 2014/7/EU of 18 October 2013	L 4	57	9.1.2014
► <u>M10</u>	Commission Delegated Directive 2014/8/EU of 18 October 2013	L 4	59	9.1.2014
► <u>M11</u>	Commission Delegated Directive 2014/9/EU of 18 October 2013	L 4	61	9.1.2014
► <u>M12</u>	Commission Delegated Directive 2014/10/EU of 18 October 2013	L 4	63	9.1.2014
► <u>M13</u>	Commission Delegated Directive 2014/11/EU of 18 October 2013	L 4	65	9.1.2014
► <u>M14</u>	Commission Delegated Directive 2014/12/EU of 18 October 2013	L 4	67	9.1.2014
► <u>M15</u>	Commission Delegated Directive 2014/13/EU of 18 October 2013	L 4	69	9.1.2014
► <u>M16</u>	Commission Delegated Directive 2014/14/EU of 18 October 2013	L 4	71	9.1.2014
► <u>M17</u>	Commission Delegated Directive 2014/15/EU of 18 October 2013	L 4	73	9.1.2014
► <u>M18</u>	Commission Delegated Directive 2014/16/EU of 18 October 2013	L 4	75	9.1.2014

► <b><u>M19</u></b>	Commission Delegated Directive 2014/69/EU of 13 March 2014	L 148	72	20.5.2014
► <b><u>M20</u></b>	Commission Delegated Directive 2014/70/EU of 13 March 2014	L 148	74	20.5.2014
► <b><u>M21</u></b>	Commission Delegated Directive 2014/71/EU of 13 March 2014	L 148	76	20.5.2014
► <b><u>M22</u></b>	Commission Delegated Directive 2014/72/EU of 13 March 2014	L 148	78	20.5.2014
► <b><u>M23</u></b>	Commission Delegated Directive 2014/73/EU of 13 March 2014	L 148	80	20.5.2014
► <b><u>M24</u></b>	Commission Delegated Directive 2014/74/EU of 13 March 2014	L 148	82	20.5.2014
► <b><u>M25</u></b>	Commission Delegated Directive 2014/75/EU of 13 March 2014	L 148	84	20.5.2014
► <b><u>M26</u></b>	Commission Delegated Directive 2014/76/EU of 13 March 2014	L 148	86	20.5.2014
► <b><u>M27</u></b>	Commission Delegated Directive (EU) 2015/573 of 30 January 2015	L 94	4	10.4.2015
► <b><u>M28</u></b>	Commission Delegated Directive (EU) 2015/574 of 30 January 2015	L 94	6	10.4.2015
► <b><u>M29</u></b>	Commission Delegated Directive (EU) 2015/863 of 31 March 2015	L 137	10	4.6.2015
► <b><u>M30</u></b>	Commission Delegated Directive (EU) 2016/585 of 12 February 2016	L 101	12	16.4.2016
► <b><u>M31</u></b>	Commission Delegated Directive (EU) 2016/1028 of 19 April 2016	L 168	13	25.6.2016
► <b><u>M32</u></b>	Commission Delegated Directive (EU) 2016/1029 of 19 April 2016	L 168	15	25.6.2016
► <b><u>M33</u></b>	Commission Delegated Directive (EU) 2017/1009 of 13 March 2017	L 153	21	16.6.2017
► <b><u>M34</u></b>	Commission Delegated Directive (EU) 2017/1010 of 13 March 2017	L 153	23	16.6.2017
► <b><u>M35</u></b>	Commission Delegated Directive (EU) 2017/1011 of 15 March 2017	L 153	25	16.6.2017
► <b><u>M36</u></b>	Commission Delegated Directive (EU) 2017/1975 of 7 August 2017	L 281	29	31.10.2017
► <b><u>M37</u></b>	Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017	L 305	8	21.11.2017
► <b><u>M38</u></b>	Commission Delegated Directive (EU) 2018/736 of 27 February 2018	L 123	94	18.5.2018
► <b><u>M39</u></b>	Commission Delegated Directive (EU) 2018/737 of 27 February 2018	L 123	97	18.5.2018
► <b><u>M40</u></b>	Commission Delegated Directive (EU) 2018/738 of 27 February 2018	L 123	100	18.5.2018
► <b><u>M41</u></b>	Commission Delegated Directive (EU) 2018/739 of 1 March 2018	L 123	103	18.5.2018
► <b><u>M42</u></b>	Commission Delegated Directive (EU) 2018/740 of 1 March 2018	L 123	106	18.5.2018
► <b><u>M43</u></b>	Commission Delegated Directive (EU) 2018/741 of 1 March 2018	L 123	109	18.5.2018
► <b><u>M44</u></b>	Commission Delegated Directive (EU) 2018/742 of 1 March 2018	L 123	112	18.5.2018
► <b><u>M45</u></b>	Commission Delegated Directive (EU) 2019/169 of 16 November 2018	L 33	5	5.2.2019
► <b><u>M46</u></b>	Commission Delegated Directive (EU) 2019/170 of 16 November 2018	L 33	8	5.2.2019
► <b><u>M47</u></b>	Commission Delegated Directive (EU) 2019/171 of 16 November 2018	L 33	11	5.2.2019
► <b><u>M48</u></b>	Commission Delegated Directive (EU) 2019/172 of 16 November 2018	L 33	14	5.2.2019

► <b><u>M49</u></b>	Commission Delegated Directive (EU) 2019/173 of 16 November 2018	L 33	17	5.2.2019
► <b><u>M50</u></b>	Commission Delegated Directive (EU) 2019/174 of 16 November 2018	L 33	20	5.2.2019
► <b><u>M51</u></b>	Commission Delegated Directive (EU) 2019/175 of 16 November 2018	L 33	23	5.2.2019
► <b><u>M52</u></b>	Commission Delegated Directive (EU) 2019/176 of 16 November 2018	L 33	26	5.2.2019
► <b><u>M53</u></b>	Commission Delegated Directive (EU) 2019/177 of 16 November 2018	L 33	29	5.2.2019
► <b><u>M54</u></b>	Commission Delegated Directive (EU) 2019/178 of 16 November 2018	L 33	32	5.2.2019
► <b><u>M55</u></b>	Commission Delegated Directive (EU) 2019/1845 of 8 August 2019	L 283	38	5.11.2019
► <b><u>M56</u></b>	Commission Delegated Directive (EU) 2019/1846 of 8 August 2019	L 283	41	5.11.2019
► <b><u>M57</u></b>	Commission Delegated Directive (EU) 2020/360 of 17 December 2019	L 67	109	5.3.2020
► <b><u>M58</u></b>	Commission Delegated Directive (EU) 2020/361 of 17 December 2019	L 67	112	5.3.2020
► <b><u>M59</u></b>	Commission Delegated Directive (EU) 2020/364 of 17 December 2019	L 67	122	5.3.2020
► <b><u>M60</u></b>	Commission Delegated Directive (EU) 2020/365 of 17 December 2019	L 67	125	5.3.2020
► <b><u>M61</u></b>	Commission Delegated Directive (EU) 2020/366 of 17 December 2019	L 67	129	5.3.2020
► <b><u>M62</u></b>	Commission Delegated Directive (EU) 2021/647 of 15 January 2021	L 133	54	20.4.2021
► <b><u>M63</u></b>	Commission Delegated Directive (EU) 2021/884 of 8 March 2021	L 194	37	2.6.2021
► <b><u>M64</u></b>	Commission Delegated Directive (EU) 2021/1978 of 11 August 2021	L 402	65	15.11.2021
► <b><u>M65</u></b>	Commission Delegated Directive (EU) 2021/1979 of 11 August 2021	L 402	69	15.11.2021
► <b><u>M66</u></b>	Commission Delegated Directive (EU) 2021/1980 of 11 August 2021	L 402	73	15.11.2021
► <b><u>M67</u></b>	Commission Delegated Directive (EU) 2022/274 of 13 December 2021	L 43	25	24.2.2022
► <b><u>M68</u></b>	Commission Delegated Directive (EU) 2022/275 of 13 December 2021	L 43	29	24.2.2022
► <b><u>M69</u></b>	Commission Delegated Directive (EU) 2022/276 of 13 December 2021	L 43	32	24.2.2022
► <b><u>M70</u></b>	Commission Delegated Directive (EU) 2022/277 of 13 December 2021	L 43	35	24.2.2022
► <b><u>M71</u></b>	Commission Delegated Directive (EU) 2022/278 of 13 December 2021	L 43	38	24.2.2022
► <b><u>M72</u></b>	Commission Delegated Directive (EU) 2022/279 of 13 December 2021	L 43	41	24.2.2022
► <b><u>M73</u></b>	Commission Delegated Directive (EU) 2022/280 of 13 December 2021	L 43	44	24.2.2022

► <b><u>M74</u></b>	Commission Delegated Directive (EU) 2022/281 of 13 December 2021	L 43	47	24.2.2022
► <b><u>M75</u></b>	Commission Delegated Directive (EU) 2022/282 of 13 December 2021	L 43	51	24.2.2022
► <b><u>M76</u></b>	Commission Delegated Directive (EU) 2022/283 of 13 December 2021	L 43	54	24.2.2022
► <b><u>M77</u></b>	Commission Delegated Directive (EU) 2022/284 of 16 December 2021	L 43	57	24.2.2022
► <b><u>M78</u></b>	Commission Delegated Directive (EU) 2022/287 of 13 December 2021	L 43	64	24.2.2022
► <b><u>M79</u></b>	Commission Delegated Directive (EU) 2022/1631 of 12 May 2022	L 245	45	22.9.2022
► <b><u>M80</u></b>	Commission Delegated Directive (EU) 2022/1632 of 12 May 2022	L 245	48	22.9.2022
► <b><u>M81</u></b>	Commission Delegated Directive (EU) 2023/171 of 28 October 2022	L 24	33	26.1.2023
► <b><u>M82</u></b>	Commission Delegated Directive (EU) 2023/1437 of 4 May 2023	L 176	14	11.7.2023
► <b><u>M83</u></b>	Commission Delegated Directive (EU) 2023/1526 of 16 May 2023	L 185	26	24.7.2023

Corrected by:

- **C1** Corrigendum, OJ L 44, 14.2.2014, p. 55 (2011/65/EU)
- **C2** Corrigendum, OJ L 285, 1.11.2017, p. 32 (2017/1975)
- **C3** Corrigendum, OJ L 188, 27.7.2023, p. 59 (2023/1526)

**▼B****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)***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.

**▼M37****▼B**

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;

**▼B**

- (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;

**▼M37**

- (k) pipe organs.

**▼B***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;
- (10) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

**▼B**

- (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>(1)</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 disjointed 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>(2)</sup>;

<sup>(1)</sup> OJ L 204, 21.7.1998, p. 37.

<sup>(2)</sup> OJ L 189, 20.7.1990, p. 17.

**▼B**

- (24) ‘industrial monitoring and control instruments’ means monitoring and control instruments designed for exclusively industrial or professional use;
- (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;

**▼M37**

- (28) ‘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.

**▼B***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.

**▼M37**

3. 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.

**▼B**

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;



**▼B**

- (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;

**▼M37**

- (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;

**▼B**

- (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.

**▼M37**

5. 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.

**▼B**

6. Paragraph 1 shall not apply to the applications listed in Annexes III and IV.

*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:

**▼B**

- 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.

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.

**▼M37**

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.

**▼B**

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;

**▼M37**

- (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;

**▼B**

- (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.

►M37 ————— ◀ 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.

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).

#### *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;

**▼B**

- (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.

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;

**▼B**

- (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;
- (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,

**▼B**

- 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;
- (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, ►C1 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.

**▼B***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 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.
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.



**▼B**

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.

*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.

**▼B**

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

**▼B***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.

*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*.

*Article 28***Addressees**

This Directive is addressed to the Member States.

*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.

**▼ M29***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 %)

Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)

Butyl benzyl phthalate (BBP) (0,1 %)

Dibutyl phthalate (DBP) (0,1 %)

Diisobutyl phthalate (DIBP) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.

The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.

**▼B***ANNEX III***Applications exempted from the restriction in Article 4(1)**

	Exemption	Scope and dates of applicability
<b>▼M69</b>		
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1(a)	For general lighting purposes < 30 W: 2,5 mg	Expires on 24 February 2023
1(b)	For general lighting purposes $\geq$ 30 W and < 50 W: 3,5 mg	Expires on 24 February 2023
1(c)	For general lighting purposes $\geq$ 50 W and < 150 W: 5 mg	Expires on 24 February 2023
1(d)	For general lighting purposes $\geq$ 150 W: 15 mg	Expires on 24 February 2023
1(e)	For general lighting purposes with circular or square structural shape and tube diameter $\leq$ 17 mm: 5 mg	Expires on 24 February 2023
<b>▼M74</b>		
1(f) – I	For lamps designed to emit mainly light in the ultraviolet spectrum: 5 mg	Expires on 24 February 2027
1(f) – II	For special purposes: 5 mg	Expires on 24 February 2025
<b>▼M70</b>		
1(g)	For general lighting purposes < 30 W with a lifetime equal or above 20 000 h: 3,5 mg	Expires on 24 August 2023
<b>▼M77</b>		
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): 4 mg	Expires on 24 February 2023
2(a)(2)	Tri-band phosphor with normal lifetime and a tube diameter $\geq$ 9 mm and $\leq$ 17 mm (e.g. T5): 3 mg	Expires on 24 August 2023
2(a)(3)	Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and $\leq$ 28 mm (e.g. T8): 3,5 mg	Expires on 24 August 2023
2(a)(4)	Tri-band phosphor with normal lifetime and a tube diameter > 28 mm (e.g. T12): 3,5 mg	Expires on 24 February 2023
2(a)(5)	Tri-band phosphor with long lifetime ( $\geq$ 25 000 h): 5 mg.	Expires on 24 February 2023
<b>▼B</b>		
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
<b>▼M75</b>		
2(b)(3)	Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9): 15 mg	Expires on 24 February 2023; 10 mg may be used per lamp from 25 February 2023 until 24 February 2025

**▼ B**

	Exemption	Scope and dates of applicability
<b>▼ M78</b>		
2(b)(4)- I	Lamps for other general lighting and special purposes (e.g. induction lamps): 15 mg	Expires on 24 February 2025
2(b)(4)- II	Lamps emitting mainly light in the ultraviolet spectrum: 15 mg	Expires on 24 February 2027
2(b)(4)- III	Emergency lamps: 15 mg	Expires on 24 February 2027
<b>▼ M67</b>		
3	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes used in EEE placed on the market before 24 February 2022 not exceeding (per lamp):	
3(a)	Short length ( $\leq 500$ mm): 3,5 mg	Expires on 24 February 2025
3(b)	Medium length ( $> 500$ mm and $\leq 1\,500$ mm): 5 mg	Expires on 24 February 2025
3(c)	Long length ( $> 1\,500$ mm): 13 mg	Expires on 24 February 2025
<b>▼ M73</b>		
4(a)	Mercury in other low pressure discharge lamps (per lamp): 15 mg	Expires on 24 February 2023
4(a)-I	Mercury in low pressure non-phosphor coated discharge lamps, where the application requires the main range of the lamp-spectral output to be in the ultraviolet spectrum: up to 15 mg mercury may be used per lamp	Expires on 24 February 2027
<b>▼ M76</b>		
4(b)	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 80$ : $P \leq 105$ W: 16 mg may be used per burner	Expires on 24 February 2027
4(b)-I	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$ : $P \leq 155$ W: 30 mg may be used per burner	Expires on 24 February 2023
4(b)-II	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$ : $155$ W $< P \leq 405$ W: 40 mg may be used per burner	Expires on 24 February 2023
4(b)-III	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$ : $P > 405$ W: 40 mg may be used per burner	Expires on 24 February 2023
<b>▼ M68</b>		
4(c)	Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner):	



**▼ M68**

Exemption		Scope and dates of applicability
4(c)-I	$P \leq 155 \text{ W}$ : 20 mg	Expires on 24 February 2027
4(c)-II	$155 \text{ W} < P \leq 405 \text{ W}$ : 25 mg	Expires on 24 February 2027
4(c)-III	$P > 405 \text{ W}$ : 25 mg	Expires on 24 February 2027

**▼ B**

4(d)	Mercury in High Pressure Mercury (vapour) lamps (HPMV)	Expires on 13 April 2015
------	--	--------------------------

**▼ M71**

4(e)	Mercury in metal halide lamps (MH)	Expires on 24 February 2027
------	------------------------------------	-----------------------------

**▼ M72**

4(f) -I	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	Expires on 24 February 2025
4(f) -II	Mercury in high pressure mercury vapour lamps used in projectors where an output $\geq 2000$ lumen ANSI is required	Expires on 24 February 2027
4(f) -III	Mercury in high pressure sodium vapour lamps used for horticulture lighting	Expires on 24 February 2027
4(f) -IV	Mercury in lamps emitting light in the ultraviolet spectrum	Expires on 24 February 2027

**▼ M26**

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
------	--	-----------------------------

**▼ B**

5(a)	Lead in glass of cathode ray tubes	
5(b)	Lead in glass of fluorescent tubes not exceeding 0,2 % by weight	

**▼ M41**

6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Expires on: — 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments; — 21 July 2023 for category 8 in vitro diagnostic medical devices; — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
------	--	---

**▼ M41**

	Exemption	Scope and dates of applicability
6(a)-I	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2021 for categories 1-7 and 10.

**▼ M42**

6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	Expires on: — 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments, — 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices, — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
6(b)-I	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling	Expires on 21 July 2021 for categories 1-7 and 10.
6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight	Expires on 18 May 2021 for categories 1-7 and 10.

**▼ M43**

6(c)	Copper alloy containing up to 4 % lead by weight	Expires on: — 21 July 2021 for categories 1-7 and 10, — 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments, — 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices, — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
------	--	--

**▼ M44**

7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)	Applies to categories 1-7 and 10 (except applications covered by point 24 of this Annex) and expires on 21 July 2021.  For categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments expires on 21 July 2021.  For category 8 <i>in vitro</i> diagnostic medical devices expires on 21 July 2023.  For category 9 industrial monitoring and control instruments, and for category 11 expires on 21 July 2024.
------	---	--

**▼ B**

7(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications	
------	---	--

**▼ B**

	Exemption	Scope and dates of applicability
<b>▼ <u>M38</u></b>		
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	<p>Applies to categories 1-7 and 10 (except applications covered under point 34) and expires on 21 July 2021.</p> <p>For categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments expires on 21 July 2021.</p> <p>For category 8 <i>in vitro</i> diagnostic medical devices expires on 21 July 2023.</p> <p>For category 9 industrial monitoring and control instruments, and for category 11 expires on 21 July 2024.</p>
<b>▼ <u>M45</u></b>		
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	<p>Does not apply to applications covered by point 7(c)-I and 7(c)-IV of this Annex.</p> <p>Expires on:</p> <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10;</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
<b>▼ <u>B</u></b>		
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
<b>▼ <u>M46</u></b>		
7(c)-IV	Lead in PZT based dielectric ceramic materials for capacitors which are part of integrated circuits or discrete semiconductors	<p>Expires on:</p> <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10;</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
<b>▼ <u>B</u></b>		
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

**▼ B****▼ M47**

	Exemption	Scope and dates of applicability
8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11 and expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
8(b)-I	Cadmium and its compounds in electrical contacts used in: <ul style="list-style-type: none"> <li>— circuit breakers,</li> <li>— thermal sensing controls,</li> <li>— thermal motor protectors (excluding hermetic thermal motor protectors),</li> <li>— AC switches rated at: <ul style="list-style-type: none"> <li>— 6 A and more at 250 V AC and more, or</li> <li>— 12 A and more at 125 V AC and more,</li> </ul> </li> <li>— DC switches rated at 20 A and more at 18 V DC and more, and</li> <li>— switches for use at voltage supply frequency <math>\geq 200</math> Hz.</li> </ul>	Applies to categories 1 to 7 and 10 and expires on 21 July 2021.
<b>▼ M58</b>		
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution	Applies to categories 8, 9 and 11 and expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments,</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices,</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
9(a)-I	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators (including minibars) designed to operate fully or partly with electrical heater, having an average utilised power input $< 75$ W at constant running conditions	Applies to categories 1-7 and 10 and expires on 5 March 2021.
9(a)-II	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: <ul style="list-style-type: none"> <li>— designed to operate fully or partly with electrical heater, having an average utilised power input <math>\geq 75</math> W at constant running conditions,</li> <li>— designed to fully operate with non-electrical heater.</li> </ul>	Applies to categories 1-7 and 10 and expires on 21 July 2021.
<b>▼ M81</b>		
9(a)-III	Up to 0,7 % hexavalent chromium by weight, used as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of gas absorption heat pumps for space and water heating	Applies to category 1 and expires on 31 December 2026.

**▼ B**

	Exemption	Scope and dates of applicability
<b>▼ M34</b>		
9(b)	Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	Applies to categories 8, 9 and 11; expires on: <ul style="list-style-type: none"> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices,</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11,</li> <li>— 21 July 2021 for other subcategories of categories 8 and 9.</li> </ul>
9(b)-(I)	Lead in bearing shells and bushes for refrigerant-containing hermetic scroll compressors with a stated electrical power input equal or below 9 kW for heating, ventilation, air conditioning and refrigeration (HVACR) applications	Applies to category 1; expires on 21 July 2019.
<b>▼ B</b>		
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
<b>▼ M35</b>		
13(a)	Lead in white glasses used for optical applications	Applies to all categories; expires on: <ul style="list-style-type: none"> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;</li> <li>— 21 July 2021 for all other categories and subcategories</li> </ul>
<b>▼ M33</b>		
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11; expires on: <ul style="list-style-type: none"> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;</li> <li>— 21 July 2021 for other subcategories of categories 8 and 9</li> </ul>
13(b)-(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10
13(b)-(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-(III)	Cadmium and lead in glazes used for reflectance standards	
<b>▼ B</b>		
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

**▼ B****▼ M48**

	Exemption	Scope and dates of applicability
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11 and expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: <ul style="list-style-type: none"> <li>— a semiconductor technology node of 90 nm or larger;</li> <li>— a single die of 300 mm<sup>2</sup> or larger in any semiconductor technology node;</li> <li>— stacked die packages with die of 300 mm<sup>2</sup> or larger, or silicon interposers of 300 mm<sup>2</sup> or larger.</li> </ul>	Applies to categories 1 to 7 and 10 and expires on 21 July 2021.
<b>▼ B</b>		
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 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
<b>▼ M53</b>		
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)	Expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10;</li> <li>— 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>

**▼ M53**

	Exemption	Scope and dates of applicability
18(b)-I	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb) when used in medical phototherapy equipment	Applies to categories 5 and 8, excluding applications covered by entry 34 of Annex IV, and expires on 21 July 2021.

**▼ B**

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

**▼ M49**

21	Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	Applies to categories 8, 9 and 11 and expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
21(a)	Cadmium when used in colour printed glass to provide filtering functions, used as a component in lighting applications installed in displays and control panels of EEE	Applies to categories 1 to 7 and 10 except applications covered by entry 21(b) or entry 39 and expires on 21 July 2021.
21(b)	Cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	Applies to categories 1 to 7 and 10 except applications covered by entry 21(a) or 39 and expires on 21 July 2021.
21(c)	Lead in printing inks for the application of enamels on other than borosilicate glasses	Applies to categories 1 to 7 and 10 and expires on 21 July 2021.

**▼ B**

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
----	--	--

**▼B**

	Exemption	Scope and dates of applicability
<b>▼M39</b>		
24	Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	Expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10,</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments,</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices,</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
<b>▼B</b>		
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
<b>▼M50</b>		
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC (?)	Expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10;</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
<b>▼B</b>		
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)	



▼ **B**

	Exemption	Scope and dates of applicability
▼ <b>M51</b>		
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes	Expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10,</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments,</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices,</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
▼ <b>B</b>		
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
▼ <b>M40</b>		
34	Lead in cermet-based trimmer potentiometer elements	Applies to all categories; expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10,</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments,</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices,</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
▼ <b>B</b>		
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
▼ <b>M52</b>		
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	Expires on: <ul style="list-style-type: none"> <li>— 21 July 2021 for categories 1-7 and 10;</li> <li>— 21 July 2021 for categories 8 and 9 other than <i>in vitro</i> diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 <i>in vitro</i> diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
▼ <b>B</b>		
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
▼ <b>M36</b>		
39(a)	Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0,2 µg Cd per mm <sup>2</sup> of display screen area)	► <b>C2</b> Expires for all categories on 31 October 2019 ◀

**▼ B**

	Exemption	Scope and dates of applicability
<b>▼ M2</b>		
40	Cadmium in photoresistors for analogue opto-couplers applied in professional audio equipment	Expires on 31 December 2013
<b>▼ M60</b>		
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>(1)</sup> )	Applies to all categories and expires on: <ul style="list-style-type: none"> <li>— 31 March 2022 for categories 1 to 7, 10 and 11;</li> <li>— 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li> <li>— 21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>— 21 July 2024 for category 9 industrial monitoring and control instruments.</li> </ul>
<b>▼ M54</b>		
42	Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment: <ul style="list-style-type: none"> <li>— with engine total displacement <math>\geq 15</math> litres;</li> <li>or</li> <li>— with engine total displacement <math>&lt; 15</math> litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications.</li> </ul>	Applies to category 11, excluding applications covered by entry 6(c) of this Annex. Expires on 21 July 2024.
<b>▼ M55</b>		
43	Bis(2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use and provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin and the concentration value of bis(2-ethylhexyl) phthalate does not exceed: <p>(a) 30 % by weight of the rubber for</p> <ul style="list-style-type: none"> <li>(i) gasket coatings;</li> <li>(ii) solid-rubber gaskets; or</li> <li>(iii) rubber components included in assemblies of at least three components using electrical, mechanical or hydraulic energy to do work, and attached to the engine.</li> </ul> <p>(b) 10 % by weight of the rubber for rubber-containing components not referred to in point (a).</p> <p>For the purposes of this entry, 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.</p>	Applies to category 11 and expires on 21 July 2024.

**▼ B**

	Exemption	Scope and dates of applicability
<b>▼ M56</b>		
44	Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council <sup>(3)</sup> , installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users	Applies to category 11 and expires on 21 July 2024.
<b>▼ M62</b>		
45	Lead diazide, lead styphnate, lead dipicramate, orange lead (lead tetroxide), lead dioxide in electric and electronic initiators of explosives for civil (professional) use and barium chromate in long time pyrotechnic delay charges of electric initiators of explosives for civil (professional) use	Applies to category 11 and expires on 20 April 2026

**▼ B**

- **M22** <sup>(1)</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). ◀
- **M50** <sup>(2)</sup> Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 36). ◀
- **M56** <sup>(3)</sup> Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53). ◀

**▼B***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.
- 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.

**▼M11**

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.

**▼B**

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.

**▼ B**

19. Lead in Liquid crystal on silicon (LCoS) displays.
20. Cadmium in X-ray measurement filters.

**▼ M4**

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.

**▼ M5**

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.

**▼ M3**

23. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.

**▼ M6**

24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.

**▼ M8**

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.

**▼ M31**

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;
- (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.

**▼ M9**

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,
  - (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,

**▼ M80**

- (c) MRI non-integrated coils, for which the Declaration of Conformity of this model is issued for the first time before 23 September 2022, or
- (d) MRI devices including integrated coils, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, for which the Declaration of Conformity is issued for the first time before 30 June 2024.

Expires on 30 June 2027.

**▼ M10**

28. Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards. Expires on 31 December 2017.

**▼ M12**

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.

**▼ M13**

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.

**▼ M30**

- 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.

**▼ M14**

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.

**▼ M15**

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.

**▼ M18**

34. Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP ( $\text{BaSi}_2\text{O}_5\text{:Pb}$ ) phosphors. Expires on 22 July 2021.

**▼ M25**

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.

**▼ M24**

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.

**▼ M57**

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  $\pm 1\%$  of the sample range and where high corrosion resistance of the electrode are required for any of the following:
    - (i) solutions with an acidity  $< \text{pH } 1$ ;
    - (ii) solutions with an alkalinity  $> \text{pH } 13$ ;
    - (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 2025.

**▼ M21**

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.

**▼ M20**

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  $149 \text{ mm}^2$ ;
    - (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  $314 \text{ mm}^2$  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.

**▼ M19**

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.

**▼ M61**

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 March 2022.

**▼ M83**

- 41a. Lead as a thermal stabilizer 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 creatinine and blood urea nitrogen in whole blood.

Applies to category 8 and expires on 31 December 2023.

**▼ M28**

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

**▼ M63**

Expires on 30 June 2026.

**▼ M32**

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.

**▼ M59**

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

Applies to category 9. Expires on 31 March 2027.

**▼ M66**

45. Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids

Expires on 21 July 2028.

**▼ M65**

46. Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils.

Expires on 1 January 2024.

**▼ M64**

47. Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, 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 21 July 2028.



**▼ M79**

48. Lead in bismuth strontium calcium copper oxide (BSCCO) superconductor cables and wires and lead in electrical connections to these wires

Expires on 30 June 2027.

**▼ M82**

49. Mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and pressures over 1 000 bar

Applies to category 9 and expires on 31 December 2025.

*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 (\*):
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):

---

(\*) OJ L 174, 1.7.2011, p. 88.



## 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
2002/95/EC	12 August 2004
2008/35/EC	—



## ANNEX VIII

## Correlation table

Directive 2002/95/EC	This Directive
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
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