

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.

^{F1}2

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

4 This Directive does not apply to:

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

^{F3}k pipe organs.]

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Textual Amendments

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

Article 3

Definitions

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

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

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

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

Textual Amendments

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

Article 4

Prevention

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

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

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

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

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

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[^{F3}ea all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019;]

f EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

[^{F2}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.]

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

Textual Amendments

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

Article 5

Adaptation of the Annexes to scientific and technical progress

1 For the purposes of adapting Annexes III and IV to scientific and technical progress, and in order to achieve the objectives set out in Article 1, the Commission shall adopt by means of individual delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, the following measures:

- a inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled:
 - their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,
 - the reliability of substitutes is not ensured,
 - the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

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

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

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

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

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

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

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

4 The Commission shall:

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

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

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

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

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

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

Textual Amendments

- F1** Deleted by [Directive \(EU\) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Text with EEA relevance\)](#).
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Article 6

Review and amendment of list of restricted substances in Annex II

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

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

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

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

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

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

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

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

Article 7

Obligations of manufacturers

Member States shall ensure that:

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

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

Article 8

Obligations of authorised representatives

Member States shall ensure that:

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

Article 9

Obligations of importers

Member States shall ensure that:

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

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- (b) importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, [X¹and that the manufacturer has complied with the requirements set out in points (g) and (h) of Article 7;]
- (c) where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;
- (d) importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;
- (e) importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- (f) importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (g) importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;
- (h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

Editorial Information

- X1** Substituted by [Corrigendum to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment \(Official Journal of the European Union L 174 of 1 July 2011\)](#).

Article 10

Obligations of distributors

Member States shall ensure that:

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

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

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

Article 11

Cases in which obligations of manufacturers apply to importers and distributors

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

Article 12

Identification of economic operators

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

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

Article 13

EU declaration of conformity

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

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

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

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

Article 14

General principles of the CE marking

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

Article 15

Rules and conditions for affixing the CE marking

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

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

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

Article 16

Presumption of conformity

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

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

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Article 17

Formal objection to a harmonised standard

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

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

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

Article 18

Market surveillance and controls of EEE entering the Union market

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

Article 19

Committee procedure

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

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

Article 20

Exercise of the delegation

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

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

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

Article 21

Revocation of the delegation

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

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

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

Article 22

Objections to delegated acts

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

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

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

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

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

Article 23

Penalties

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

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Article 24

Review

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

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

Article 25

Transposition

1 Member States shall adopt and publish, by 2 January 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 26

Repeal

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

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

Article 27

Entry into force

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

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Article 28

Addressees

This Directive is addressed to the Member States.

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- (1) [OJ L 204, 21.7.1998, p. 37.](#)
- (2) [OJ L 189, 20.7.1990, p. 17.](#)