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COMMISSION OF THE EUROPEAN COMMUNITIES

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2008/0240 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(recast)

{SEC(2008) 2930}
{SEC(2008) 2931}



EXPLANATORY MEMORANDUM

Context of the proposal

- **Grounds for and objectives of the proposal**

Directive 2002/95/EC (RoHS Directive) aims to restrict hazardous substances in electrical and electronic equipment so as to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. Its review is being carried out for two main reasons:

1. The Commission is committed to developing a better regulatory environment, one that is simple, understandable, effective and enforceable. The regulatory environment in which businesses operate influences their competitiveness, and their ability to grow and create jobs. The aim for better regulation is an important element in the EU's Partnership for Growth and Jobs (Lisbon) strategy. There is room to improve the Directive in terms of implementation, enforcement and coherence.

2. The RoHS Directive calls on the Commission to review the measures provided for in the Directive in particular with regard to the inclusion of two additional categories of equipment in the scope (categories 8&9 : medical devices and monitoring and control instruments) and the adaptation of the list of restricted substances. The objectives of the proposal are a clearer Directive that is simpler in its operation, improved enforcement at national level, adaptation to technical and scientific progress and coherence with other pieces of Community legislation.

- **General context**

Uncertainty about the scope, lack of clarity on legal provisions and definitions as well as disparities in Member States' approaches to product compliance and potential duplication of procedure with other pieces of EU legislation such as REACH generate unnecessary administrative costs. If the RoHS Directive is not reviewed, environmental benefits reaped from the legislation will remain sub-optimal; uncertainty among manufacturers about legal requirements for demonstrating compliance with the RoHS Directive and about enforcement methodologies in the 27 Member States will persist, maintaining or increasing administrative burden.

- **Existing provisions in the area of the proposal**

The acts related to the present proposal are the RoHS Directive itself.

- **Consistency with the other policies and objectives of the Union**

The RoHS review will enhance its complementarity and coherence with other relevant Community legislation, such as the "Marketing of Products Package"¹ of legislation

¹ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Decision 93/465/EEC (OJ L 218, 13.8.2008,

(regarding definitions and enforcement), REACH² (regarding the use of substances), the EuP Directive³ (regarding the design of electrical and electronic equipment (EEE)) and legislation related to management of waste from EEE. It is aimed to reduce the administrative burden and make the RoHS Directive more cost effective.

Consultation of interested parties and impact assessment

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

Two stakeholder consultations have been launched via the EUROPA website. The first stakeholder consultation (22 March – 22 May 2007) invited for comments and information supply on potential RoHS Directive review topics. A second stakeholder consultation (13 December 2007 – 13 February 2008) was held with the main purpose of receiving feedback and information on proposed policy options during the first stakeholder event.

Summary of responses and how they have been taken into account

The responses to the consultations covered a large stakeholder and geographical spectrum and there were considerable variations in the extent and quality of the contributions.

In the first consultation (49 respondents), industry stakeholders focused on the need of streamlined and harmonised implementation (in particular with regard to scope and demonstration of compliance) and that of speeding up the exemptions mechanism. NGOs called for enhancing the environmental and health benefits of the Directive.

In the second consultation (62 respondents) stakeholders responded in detail giving a clear idea as to their preferences on the individual options, and on the future orientations of the RoHS Directive in general. Some suggested phasing out of the RoHS Directive and entrusting the hazardous substances management to REACH, but the vast majority of stakeholders did not share this view. In general, stakeholders submitted ideas for clarifying concepts and reducing uncertainties.

The results of the consultations are available at
http://ec.europa.eu/environment/waste/weee/events_rohs2_en.htm.

- **Collection and use of expertise**

p. 82) and Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

² OJ L 396, 30.12. 2006, p. 1.

³ OJ L 191, 22.7.2005, p. 29.

Scientific/expertise domains concerned

A study regarding the possibility of including medical devices monitoring and control instruments, as requested by Article 6 of the RoHS Directive, was carried out in 2006⁴.

A study examining the need and feasibility of regulating under RoHS additional hazardous substances as required by Articles 4(3) and 6 of RoHS Directive, was finalised in June 2008.

A service contract to assist the Commission services with technical aspects of the impact assessment was finalised in July 2008.

A study focusing on innovation and competition aspects of the WEEE and RoHS review was finalised in April 2008⁵.

The only substance for which updated science justified examining whether it should be removed from the ban is Deca-BDE. Since 2002, the use of Deca-BDE in EEE has been restricted by the RoHS Directive. In 2005 Deca-BDE was exempted from the restriction of use by Commission Decision 2005/717/EC.⁶ On 1st April 2008, the European Court of Justice annulled the exemption decision in this respect, but maintained its effects until 30 June 2008 inclusive⁷.

Since the 1st of July 2008 the original restriction of use of Deca-BDE in EEE applies again. In the present proposal, Deca-BDE remains included in the list of banned substances (Annex IV). There remain uncertainties about its toxicity and degradation to other banned substances (debromination to PBT/vPvB substances). The risk assessment concluded that there is no need for risk reduction measures beyond those which are being applied already with regard to risk to consumers, human health (physico-chemical properties), risks to the atmosphere and risks to micro-organisms in the sewage treatment plant, and that there is a need for further information and or testing with respect to risks to workers, to humans exposed via the environment and to the aquatic and terrestrial ecosystem, in order to adequately characterise the concerns regarding the persistent, bio-accumulative and toxic properties of the substance.⁸ Commission Regulation 565/2006 required further studies to be carried out for the purpose of risk evaluation, including on developmental neurotoxicity, human bio-monitoring and environmental monitoring programmes.⁹ The risks caused by the use of Deca-BDE in EEE are aggravated by recent findings¹⁰ about uncontrolled dumping of waste in the EU and in particular about illegal trade of WEEE to countries with sub-standard waste management conditions. User industry can apply for temporary exemptions from the ban following the criteria of Article 5(1)(b) of the present proposal. In line with what is envisaged in Recital 7 of the present proposal, the current restriction of use will be kept under review and, if necessary, will be adjusted to take account of new technical and scientific information.

⁴ Final Report available at http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

⁵ Final Report available at http://ec.europa.eu/enterprise/environment/reports_studies/index.htm.

⁶ OJ L 271, 15.10.2005, p. 48.

⁷ Joined cases C-14/06 and 295/06. The Court found that the decision did not meet the criteria for granting exemptions (Article 5). First, the decision was not based on “technical or scientific progress”, since the draft conclusions of the risk assessment used to justify the exemption dated from 2002 and the conclusions had not changed since then; secondly, the Commission did not assess whether or not

Methodology used

The methodology used for the above mentioned studies included surveys, literature research, interviews with industry and Member States' enforcement authorities' and industry representatives. Moreover, technical workshops with stakeholders were held.

Main organisations/experts consulted

Industry federations and individual companies, NGOs and Member States.

Summary of advice received and used

Key points of advice received and used include harmonisation of requirements, clarification and simplification of the Directive, improvement of exemptions' mechanism and inclusion of medical devices and control and monitoring instruments in the scope.

Means used to make the expert advice publicly available

Publication of final reports on the EUROPA website.

• **Impact assessment**

The options considered included: not to make any clarifications or additions in the scope or definitions; to repeal the Directive altogether; to release a substance (DecaBDE) from the ban and to extend the list of restricted substances.

They were rejected because the impact assessment showed that they would result in suboptimal benefits from the review of the Directive or because the potential costs outweighed the benefits. It is recommended to introduce clarifications and enforcement-related clauses, to align provisions where possible with other pieces of Community legislation such as REACH, to adapt the exemption mechanism and to include two new categories of equipment. The expected benefits are environmental (reduction of quantities of hazardous substances released in the environment from medical devices and control and monitoring instruments, reduction of number of non-compliant products in the market) and economic (reduction of administrative burden, avoidance of duplication of procedures, and increase of legal certainty).

The proposal has been subject to an impact assessment listed in the Commission's Legislative and Work Programme.

substitutes are available and what are the impacts of the substitutes compared to Deca-BDE; thirdly, the exemption was too wide.

OJ C131/7 of 29.5.2008

OJ L 99/3 of 7.4.2006

See Commission Staff Working Document accompanying document to the Proposal for a Directive of the European Parliament and of the Council amending Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), page 99.

Legal elements of the proposal

- **Summary of the proposed action**

It should be noted that the basic objectives and mechanisms of this Directive have not been changed. The ultimate aim is the elimination of certain hazardous substances from electrical and electronic equipment; where this is temporarily not possible, exemptions are granted. No new substances are proposed to be banned.

The main proposed modifications are as follows:

Article 2 (scope): Two new annexes describing the Directive scope are added, the first describing the broad product categories and the second, amendable by the Commission, providing binding product lists within each category. A harmonised scope improves implementation of the Directive and reduces administrative burden. Medical devices and control and monitoring instruments are included to reap the environmental and health benefits from the reduction of use of hazardous substances in such equipment but in a staged manner so that adverse socioeconomic impacts are avoided

Article 3 (definitions): The definitions for economic operators are aligned to the "Marketing of products" package and new definitions, such as for "medical devices" and "homogeneous material" are added. Harmonised definitions, coherent with related Community legislation enhance legal clarity and reduce administrative cost.

Article 4 (substance ban): Maximum concentration values for the banned substances are set (incorporation in the Directive of a Commission Decision) and permission to use non-compliant spare parts is extended to equipment benefitting from an exemption when placed on the market, to prevent premature withdrawal of equipment from use; a new annex with exemptions specific to the new product categories (medical devices and control and monitoring instruments) is added for cases where substitution is currently not feasible; a mechanism for introducing new substance bans in line with the REACH methodology is inserted to ensure coherence and maximise synergy with the work carried out under the chemicals' legislation. Detailed rules of this process will be developed through comitology. When developing these detailed rules, the Commission will give priority to using the expertise available at the European Chemicals Agency (ECHA). The Commission will invite ECHA to evaluate the substances concerned as a priority.

Article 5 (exemptions mechanism) : a 4-year maximum validity period for the exemptions is set to stimulate substitution efforts, provide legal security and shift the burden of proof to the applicant, in line with REACH. New criteria such as availability and reliability for granting exemptions are introduced to take into account broader socio-economic aspects; a mandate is given to the Commission for establishing detailed rules for the applicants to apply when requesting an exemption for facilitating them and speeding the scrutiny process.

Articles 6-8 are new and introduce product conformity assessment requirements and market surveillance mechanisms in line with the "Marketing of products" package. Reducing number of non-compliant products through strengthened and harmonised market surveillance is a cost effective way for increasing the environmental benefit of the Directive; harmonised conformity assessment requirements increase legal certainty

and reduce administrative cost for Member States and manufacturers

- **Legal basis**

Article 95 of the Treaty.

- **Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons:

Environmental impacts of electrical and electronic products and their free movement in the internal market are shared competences between the Community and the Member States;

Reduced environmental protection and problems in the internal market might result in case of individual initiatives from the Member States.

Community action will better achieve the objectives of the proposal for the following reasons:

The transnational nature of the problems makes them appropriate for being regulated at Community level; harmonisation of requirements for manufacturers and authorities throughout the Community will increase cost-efficiency and foster simplification.

The need for more advanced harmonisation of the RoHS requirements can only be addressed through a recast of the Directive; simplification of EU legislation can only take place at Community level.

Fragmented national RoHS-related administrative requirements would increase cost of compliance for manufacturers.

This recast is an integral part of developing a better regulatory environment at Community level.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reasons:

The proposed measure is the recast of an existing Directive on the points indicated by Council and European Parliament. It is also part of the simplification exercise and increases coherence and synergies with other relevant Community legislation affecting the same products.

The clarifications on scope and definitions, the introduction of harmonised enforcement-related clauses and the improvement of the mechanism for granting exemptions to the restrictions will increase legal certainty and reduce administrative

burden.

- **Choice of instruments**

Proposed instruments: Directive.

Other means would not be adequate for the following reasons:

The proposed measure is a recast of an existing Directive; it incorporates, as necessary, elements from guidance documents, the harmonisation effect of which was deemed insufficient. Self-regulatory activities only would not be sufficient for achieving the policy objectives; the option of repealing the Directive was examined and discarded during the impact assessment.

Budgetary implication

The proposal has no implication for the Community budget.

Additional information

- **Simplification**

The recast proposal provides for simplification of legislation: simplification of administrative procedures for public authorities (EU and national); simplification of administrative procedures for private parties.

It clarifies definitions and scope; harmonises compliance assessment of products and market surveillance activities; adapts and improves the efficiency of the mechanism for granting exemptions to technical and scientific progress.

Structured coordination of market surveillance authorities and activities (including exchange of information), clarification of scope and definitions and streamlining of the mechanism for granting exemptions will facilitate the work of the authorities in implementing and enforcing the Directive.

Clarifications on scope and definitions will facilitate decisions on whether a given product falls within and the scope and which measures must be taken for achieving compliance; harmonising conformity assessment procedures gives to manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Community.

The proposal is included in the Commission's rolling programme for up-date and simplification of the *acquis communautaire* and its Work and Legislative Programme under the reference 2008/ENV/001.

- **Recast of existing legislation**

The adoption of the proposal will lead to the recast of existing legislation, namely the existing Directive 2002/95/EC. As the Annex V listing exemptions from the substance ban of Article 4(1) of the RoHS Directive is being updated on regular basis according to technical and scientific progress through the comitology procedure, this Annex is not

part of the current co-decision proposal.

- **Review/revision/sunset clause**

The proposal does not include a review clause. However, the Commission will closely monitor the need for revision, in light of the outcome of the review carried out under Article 138(6) of Regulation (EC) No 1907/2006.

- **Correlation table**

The Member States are required to communicate to the Commission the text of national provisions transposing the Directive as well as a correlation table between those provisions and this Directive.

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹¹,

Having regard to the opinion of the Economic and Social Committee¹²,

Having regard to the opinion of the Committee of Regions¹³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ~~in the light of the joint text approved by the Conciliation Committee on 8 November 2002~~¹⁴,

Whereas:

↓ new

- (1) (1) A number of substantial changes are to be made to Directive 2002/95/EC of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment¹⁵. In the interest of clarity, that Directive should be recast.

↓ 2002/95/EC

- (24) The disparities between the laws or administrative measures adopted by the Member States as regards the restriction of the use of hazardous substances in electrical and

¹¹ OJ C ~~⊗~~ , , p. ~~⊗~~ 365 E, 19.12.2000, p. 195 and OJ C 240 E, 28.8.2001, p. 303.

¹² OJ C ~~⊗~~ , , p. ~~⊗~~ 116, 20.4.2001, p. 38.

¹³ OJ C ~~⊗~~ , , p ; ~~⊗~~ 148, 18.5.2001, p. 1.

¹⁴ ~~⊗~~ OJ C , , p ~~⊗~~ Opinion of the European Parliament of 15 May 2001 (OJ C 34 E, 7.2.2002, p. 109), Council Common Position of 4 December 2001 (OJ C 90 E, 16.4.2002, p. 12) and Decision of the European Parliament of 10 April 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.

¹⁵ OJ L 37, 13.2.2003, p 19.

electronic equipment could create barriers to trade and distort competition in the Community and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to approximate the laws of the Member States in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment.

↓ 2002/95/EC (adapted)
⇒ new

- ~~(3)(2)~~ ~~The European Council at its meeting in Nice on 7, 8 and 9 December 2000~~
⇒ Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in the scope, equipment which falls under certain categories and to study the need to adapt the list of substances on the basis of scientific progress, taking into account the precautionary principle, as ~~endorsed~~ ⇒ by ~~the~~ Council Resolution of 4 December 2000. ~~on the precautionary principle.~~
- ~~(3)~~ ~~The Commission Communication of 30 July 1996 on the review of the Community strategy for waste management stresses the need to reduce the content of hazardous substances in waste and points out the potential benefits of Community wide rules limiting the presence of such substances in products and in production processes.~~
- ~~(4)~~ ~~The Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium¹⁶ invites the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable and safer alternatives do not exist.~~
- ~~(4)(5)~~ The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste electrical and electronic equipment (WEEE) as set out in Directive 2002/96/EC of 27 January 2003 of the European Parliament and of the Council on waste electrical and electronic equipment¹⁷ are necessary to reduce the waste management problems linked to the heavy metals concerned and the flame retardants concerned. In spite of those measures, however, significant parts of WEEE will continue to be found in the current disposal routes. Even if WEEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, PBB and PBDE would be likely to pose risks to health or the environment.
- ~~(5)(6)~~ Taking into account technical and economic feasibility, ⇒ including for small and medium sized enterprises (SMEs) ⇐ the most effective way of ensuring the significant reduction of risks to health and the environment relating to those substances which can achieve the chosen level of protection in the Community is the substitution of those substances in electrical and electronic equipment by safe or safer materials. Restricting

¹⁶ OJ C 30, 4.2.1988, p. 1.

¹⁷ See page 24 of this Official Journal

the use of these hazardous substances is likely to enhance the possibilities and economic profitability of recycling of WEEE and decrease the negative health impact on workers in recycling plants.

~~(6)(7)~~ The substances covered by this Directive are scientifically well researched and evaluated and have been subject to different measures both at Community and at national level.

~~(7)(8)~~ The measures provided for in this Directive take into account existing international guidelines and recommendations and are based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human and animal health and the environment, having regard to the risks which the absence of measures would be likely to create in the Community. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information.

↓ new

(8) This Directive supplements the general Community waste management legislation, such as Directive 2008/[...]/EC of the European Parliament and of the Council on waste.

(9) Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of eco-design requirements for energy-using products¹⁸ enables the adoption of specific eco-design requirements for energy using products which may also be covered by this Directive. Directive 2005/32/EC and the implementing measures adopted pursuant to it are without prejudice to Community waste management legislation.

↓ 2002/95/EC (adapted)

⇒ new

~~(10)(9)~~ This Directive should apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation, in particular ~~⊗~~ Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators ~~⊗~~ ~~Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances~~¹⁹ ⇒ and Regulation (EC) 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants²⁰. ⇐

↓ 2002/95/EC (adapted)

⇒ new

~~(11)(10)~~ The technical development of electrical and electronic equipment without heavy metals, PBDE and PBB should be taken into account.

¹⁸ OJ L 191, 22.7.2005, p. 29-58

¹⁹ 7 OJ L ~~⊗~~ 266, 26.9.2006, p.1. ~~⊗~~ 78, 26.3.1991, p. 38. Directive as amended by Commission Directive 98/101/EC (OJ L 1, 5.1.1999, p. 1).

²⁰ OJ L 229, 30.4.2004, p.5 amending Directive 79/117/EEC

(12) As soon as scientific evidence is available and taking into account the precautionary principle, the prohibition of other hazardous substances and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined \Rightarrow , paying attention to coherency with other Community legislation, and in particular to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)²¹. Specific account should be taken of the potential impact on SMEs. \Leftarrow

~~(13)~~~~(14)~~ Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view \Rightarrow , taking specific account of the situation of SMEs \Leftarrow or if the negative environmental, ~~or~~ health \Rightarrow or socio-economic \Leftarrow impacts caused by substitution are likely to outweigh ~~the human~~ the health, and environmental \Rightarrow or socio-economic \Leftarrow benefits of the substitution. \Rightarrow or the availability and reliability of substitutes is not ensured. \Leftarrow Substitution of the hazardous substances in electrical and electronic equipment should also be carried out in a way so as to be compatible with the health and safety of users of electrical and electronic equipment \Rightarrow The placing on the market of medical devices requires a conformity assessment procedure, according to Directives 93/42/EC and 98/79/EC, which could require the involvement of a notified body designated by Competent Authorities of Member States. If such a notified body certifies that the safety of the potential substitute for the intended use in medical devices or in vitro medical devices is not demonstrated, this will be viewed as a clear negative socio-economic, health and consumer safety impact \Leftarrow ~~(EEE)~~. \Rightarrow It should be possible to apply for exemptions of equipment coming under the scope of this Directive from the date of its entry into force, even when that is before the actual inclusion in the scope of that equipment. \Leftarrow

\Downarrow new

(14) Exemptions from the prohibition for certain specific materials or components should be limited in their scope, in order to achieve a gradual phase-out of hazardous substances in electrical and electronic equipment, given that the use of those substances in such applications should become avoidable.

\Downarrow 2002/95/EC

~~(15)~~~~(12)~~ As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available.

\Downarrow new

(16) Procedures for assessing the conformity of electrical and electronic equipment subject to this Directive should be consistent with the Community relevant legislation and in particular Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC²². Harmonising conformity assessment procedures should give manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Community.

²¹ OJ L 396 of 30.12. 2006, p. 1–849.

²² OJ L 218, 13.8.2008, p 82-128.

- (17) The conformity marking applicable for products at Community level, CE marking, should also apply to electrical and electronic equipment subject to this Directive.
- (18) The market surveillance mechanisms laid down by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93²³ would ensure the safeguard mechanisms to check compliance with this Directive.

↓ new

- ~~(13) The adaptation to scientific and technical progress of the exemptions from the requirements concerning phasing out and prohibition of hazardous substances should be effected by the Commission under a committee procedure.~~

↓ 2002/95/EC

- ~~(19)~~⁽¹⁴⁾ The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²⁴.

↓ new

- (20) In particular the Commission should be empowered to adapt Annexes II, III, IV, V and VI to technical and scientific progress and to adopt other necessary implementing measures. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/95/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (21) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (22) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directives set out in Annex VIII, Part B,
- (23) Since the objectives of the action to be taken, namely to establish restrictions on the use of hazardous substances in electrical and electronic equipment cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level by reason of the scale of the problem and its implications in respect of other Community legislation on recovery and disposal of waste and areas of common interest, such as human health protection, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the

²³ OJ L 218, 13.8.2008, p.30-47

²⁴ OJ L 184, 17.7.1999, p. 23.

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

↓ 2002/95/EC (adapted)
⇒ new

HAVE ADOPTED THIS DIRECTIVE:

Article 1

⊗ Subject matter ⊗ Objectives

~~The purpose of this Directive is to approximate the laws of the Member States on the restrictions of the use of hazardous substances in electrical and electronic equipment and~~

⇒ This Directive lays down rules on the restriction of use of hazardous substances in electric and electronic equipment with a view ⇐ to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment.

Article 2

Scope

1. ~~Without prejudice to Article 6, ¶~~ This Directive shall apply to electrical and electronic equipment falling under the categories ~~1, 2, 3, 4, 5, 6, 7 and 10~~ set out in Annex I~~A~~ as
⇒ specified in Annex II ⇐ ~~to Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaires in households.~~

↓ 2002/95/EC
⇒ new

2. This Directive shall apply without prejudice to ⇐ requirements of ⇐ Community legislation on safety and health, ⇐ on chemicals, in particular Regulation (EC) 1907/2006 as well as of ⇐ ~~requirements and~~ specific Community waste management legislation.

3. This Directive does not apply to: ~~spare parts for the repair, or to the reuse, of electrical and electronic equipment put on the market before 1 July 2006.~~

- (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 which is specifically designed as part of another type of equipment that does not fall within the scope of this Directive and can fulfill its function only if it is part of that equipment; ⇐
- (c) ⇐ equipment which is not intended to be placed on the market as a single functional or commercial unit. ⇐

Article 3

Definitions

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

(a) ‘electrical and electronic equipment’ ~~or~~ ⇒ (hereinafter ⇔ ‘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 ~~falling under the categories set out in Annex IA to Directive 2002/96/EC (WEEE)~~ and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current;

~~(b) ‘producer’ means any person who, irrespective of the selling technique used, including by means of distance communication according to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts²⁵;~~

~~(i) manufactures and sells electrical and electronic equipment under his own brand;~~

~~(ii) resells under his own brand equipment produced by other suppliers, a reseller not being regarded as the ‘producer’ if the brand of the producer appears on the equipment, as provided for in subpoint (i); or~~

~~(iii) imports or exports electrical and electronic equipment on a professional basis into a Member State.~~

~~Whoever exclusively provides financing under or pursuant to any finance agreement shall not be deemed a ‘producer’ unless he also acts as a producer within the meaning of subpoints (i) to (iii).~~

↓ new

(b) "manufacturer" means any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured under his name or trademark;

(c) "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;

(d) "importer" means any natural or legal person established within the Community, who places an EEE from a third country on the Community market;

(e) "making available on the market" means any supply of an EEE for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

(f) "placing on the market" means the first making available of an EEE on the Community market;

²⁵ ~~OJ L 144, 4.6.1997, p. 19. Directive as amended by Directive 2002/65/EC (L 271, 9.10.2002, p. 16).~~

- (g) "harmonised standard" means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC;
- (h) "authorised representative" means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (i) "CE marking" means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonization legislation providing for its affixing;
- (j) "conformity assessment" means the process demonstrating whether the requirements of the present Directive relating to an EEE, are met;
- (k) "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 do not endanger health, safety or other issues of public interest protection ;
- (l) "homogeneous material" means a material of uniform composition throughout that can not be mechanically disjointed into different materials, meaning that the materials can not, in principle, be separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes;
- (m) "medical device" means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EC;
- (n) "in vitro diagnostic medical device" means in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;
- (o) "active implantable medical device" means any active implantable medical device within the meaning of point (c) of Article 1(2) of Directive 90/385/EEC .
- (p) "industrial monitoring and control instruments" mean monitoring and control instruments designed for exclusively industrial or professional use.

↓ 2002/95/EC (adapted)
⇒ new

Article 4

Prevention

1. Member States shall ensure that, ~~from 1 July 2006, new electrical and electronic equipment~~ ☒ EEE ☒ ⇒ including spare parts for its repair or its reuse placed ☒ put on the market does not contain ⇒ the substances listed in Annex IV. ☒ ~~lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE).~~
~~National measures restricting or prohibiting the use of these substances in electrical and~~

~~electronic equipment which were adopted in line with Community legislation before the adoption of this Directive may be maintained until 1 July 2006.~~

↓ 2002/95/EC, Annex, pt 29
⇒ new

2. For the purposes of ~~Article 5(1)(a)~~ ⇒ this Directive ⇐ , ~~the~~ maximum concentration value ⇐ of 0,1 % by weight in homogeneous materials as specified in Annex IV shall be tolerated ⇐ of 0,1 % by weight in homogeneous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) and of 0,01 % by weight in homogeneous materials for cadmium shall be tolerated.

↓ new

3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 1st January 2014, to in vitro medical devices which are placed on the market from 1st January 2016 and to industrial monitoring and control instruments which are placed on the market from 1st January 2017.

4. Paragraph 1 shall not apply to spare parts for the repair or to the reuse of the following:

(a) EEE placed on the market before 1 July 2006.

(b) Medical devices placed on the market before 1st January 2014.

(c) In vitro diagnostic medical devices placed on the market before 1st January 2016.

(d) Monitoring and control instruments placed on the market before 1st January 2014.

(e) Industrial monitoring and control instruments placed on the market before 1st January 2017.

(f) EEE which benefited from an exemption and was placed on the market before that exemption expired.

5. Paragraph 1 shall not apply to active implantable medical devices. By 2020 the Commission shall review the exclusion of active implantable medical devices with a view to propose inclusion.

↓ 2002/95/EC (adapted)
⇒ new

26. Paragraph 1 shall not apply to the applications listed in ~~the Annexes II~~ ⇒ V and VI ⇐.

~~3. On the basis of a proposal from the Commission, the European Parliament and the Council shall decide, as soon as scientific evidence is available, and in accordance with the principles on chemicals policy as laid down in the Sixth Community Environment Action Programme, on the prohibition of other hazardous substances and the substitution thereof by more environment friendly alternatives which ensure at least the same level of protection for consumers.~~

↓ new

7. When there is an unacceptable risk to human health or the environment, arising from the use of substances, and in particular the substances listed in Annex III, which needs to be addressed on a Community-wide basis, the list of prohibited substances in Annex IV shall be reviewed using a methodology based on the process set out in Articles 69 to 72 of Regulation (EC) No 1907/2006. Those measures designed to amend non essential elements of this Directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2)

↓ 2002/95/EC (adapted)
⇒ new

Article 5

Adaptation ☒ of the Annexes ☒ to scientific and technical progress

↓ 2008/35/EC Art. 1.1(a)
(adapted)
⇒ new

⇒ 1. The Commission shall, for the purposes of adapting the annexes to scientific and technical progress, adopt the following measures: ⇐

~~1.(a) Any ☒ necessary ☒ amendments which are necessary in order to adapt the Annex~~
~~⇐ II ⇐ to scientific and technical progress for the following purposes shall be adopted:~~

~~(a) establishing, as necessary, maximum concentration values up to which the presence of the substances referred to in Article 4(1) in specific materials and components of electrical and electronic equipment shall be tolerated;~~

(b) ~~exempting~~ ⇐ Include ⇐ materials and components of ~~of electrical and electronic equipment~~ ☒ EEE ☒ ~~from Article 4(1)~~ ⇐ in Annexes V and VI where either 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 referred to in Article 4(1) is ☒ scientifically or technically ☒ impracticable;
- ⇐ the availability and reliability of substitutes is not ensured, ⇐
- the negative environmental health consumer safety ⇐ or socio-economic ⇐ impacts caused by substitution are likely to outweigh the environmental, health or consumer safety ⇐ and/or socio-economic ⇐ benefits thereof;

~~(c) carrying out a review of each exemption in the Annex at least every four years or four years after an item is added to the list with the aim of considering deletion of materials and components of electrical and electronic equipment from the Annex if their elimination or substitution via design changes or materials and components~~

~~which do not require any of the materials or substances referred to in Article 4(1) is technically or scientifically possible, provided that the negative environmental, health and/or consumer safety impacts caused by substitution do not outweigh the possible environmental, health and/or consumer safety benefits thereof.~~

↓ 2008/35/EC Art. 1.1(b)

~~The measures referred to in points (a), (b) and (c) of the first subparagraph, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(2).~~

↕ new

(c) delete materials and components of EEE from Annexes V and VI where the conditions set out in point (b) are no longer fulfilled.

Those measures designed to amend non essential elements of this directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2).

2. Measures adopted in accordance with point b of paragraph 1 shall have a maximum validity period of four years and may be renewed. The Commission shall decide in due time on any application for renewal that is submitted no later than 18 months before an exemption expires.

↓ 2002/95/EC (adapted)

⇒ new

~~32. Before the Annex is~~ ⇒ Annexes are ⇐ amended ~~pursuant to paragraph 1~~, the Commission shall *inter alia* consult producers of electrical and electronic equipment, recyclers, treatment operators, environmental organisations and employee and consumer associations. ~~Comments shall be forwarded to the Committee referred to in Article 7(1). The Commission shall provide an account of the information it receives.~~

⇒ 4. As long as materials or components are included in Annexes V and VI to this Directive, on the basis of Article 5(1)(b) of this Directive, those applications shall also be considered exempted from the authorisation requirements set out in Article 58(2) of the regulation (EC) No 1907/2006. ⇐

↕ new

Article 6

Implementing measures

The Commission shall adopt detailed rules for:

- applications for the exemption including a format and types of information to be provided when introducing those applications, including analysis of the alternatives and, if suitable alternatives are available, substitution plans as referred to in Regulation (EC) 1907/2006.
- Complying with the maximum concentration values of Article (4) (2)

- The implementation of Article 5(2), taking into account the need for legal certainty for economic operators pending a Commission Decision on renewal of exemptions.

Those measures designed to amend non essential elements of this directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2)

↓ 2002/95/EC

~~Article 6~~

~~Review~~

~~Before 13 February 2005, the Commission shall review the measures provided for in this Directive to take into account, as necessary, new scientific evidence.~~

~~In particular the Commission shall, by that date, present proposals for including in the scope of this Directive equipment which falls under categories 8 and 9 set out in Annex IA to Directive 2002/96/EC (WEEE).~~

~~The Commission shall also study the need to adapt the list of substances of Article 4(1), on the basis of scientific facts and taking the precautionary principle into account, and present proposals to the European Parliament and Council for such adaptations, if appropriate.~~

~~Particular attention shall be paid during the review to the impact on the environment and on human health of other hazardous substances and materials used in electrical and electronic equipment. The Commission shall examine the feasibility of replacing such substances and materials and shall present proposals to the European Parliament and to the Council in order to extend the scope of Article 4, as appropriate.~~

↓ new

Article 7

Obligations of manufacturers

1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 4.

2. Manufacturers shall draw up the required technical documentation and carry out the internal production control procedure set out in module A of Annex II to Decision No 768/2008/EC or have it carried out.

Where compliance of an EEE with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for ten years after the EEE has been placed on the market.

4. Manufacturers shall 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 an EEE is declared shall be adequately taken into account.

5. When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed EEE, investigate, and, if necessary, keep a register of complaints, of non-conforming EEE and product recalls, and shall keep distributors informed of any such monitoring.

6. Manufacturers shall ensure that their EEE bear a type, batch or serial number or other element allowing their 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.

7. Manufacturers shall 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.

8. Manufacturers who consider or have reason to believe that a EEE which they have placed on the market is not in conformity with the applicable Community harmonisation legislation shall immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the EEE presents a risk, manufacturers shall 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.

9. Manufacturers shall, 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, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by EEE which they have placed on the market.

Article 8

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 7(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for ten years ;

(b) 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 ;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EEE covered by their mandate.

Article 9

Obligations of importers

1. Importers shall place only compliant products on the Community market.

2. Before placing an EEE on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6) .

Where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, he shall not place the EEE on the market until it has been brought into conformity. Furthermore, where the EEE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall 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.

4. Importers shall ensure that, while an EEE is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 4.

5. When deemed appropriate with regard to the risks presented by an EEE, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed EEE, investigate, and, if necessary, keep a register of complaints, of non-conforming EEE and EEE recalls, and shall keep distributors informed of such monitoring.

6. 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 shall immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the EEE presents a risk, importers shall 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.

7. Importers shall, for ten years, keep a copy of the EC 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.

8. Importers shall, 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 in a language which can be easily understood by that authority. They shall cooperate

with that authority, at its request, on any action taken to eliminate the risks posed by EEE which they have placed on the market.

Article 10

Obligations of distributors

1. When making an EEE available on the market distributors shall act with due care in relation to the requirements applicable.

2. Before making an EEE available on the market distributors shall verify 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 Article 7(5) and (6) and Article 9(3).

Where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, he shall not make the EEE available on the market until it has been brought into conformity. Furthermore, where the EEE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while an EEE is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 4.

4. 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 shall make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the EEE presents a risk, distributors shall 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.

5. Distributors shall, 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. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by EEE which they have made available on the market.

Article 11

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 7, where he places an EEE on the market under his name or trademark or modifies an 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

Economic operators shall, on request, identify the following to the market surveillance authorities, for ten years:

(a) any economic operator who has supplied them with an EEE;

(b) any economic operator to whom they have supplied an EEE.

Article 13

EC declaration of conformity

1. The EC declaration of conformity shall state that the fulfilment of requirements specified in Article 4 has been demonstrated.

2. The EC declaration of conformity shall have the model structure and shall contain the elements specified in Annex VII and shall be updated.

3. By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EEE.

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 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, where the legislation concerned provides for such documents.

2. The CE marking shall be affixed before the EEE is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the 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

Member States shall presume electrical and electronic equipment bearing the CE marking as conforming to this Directive.

Electrical and electronic equipment on which tests and measurements have been performed 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 all the relevant requirements of this Directive to which such standards relate.

↓ new

Article 17

Market surveillance and controls of EEE entering the Community market

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

↓ 2008/35/EC Art. 1.2 (adapted)

Article 18~~7~~

Committee

1. The Commission shall be assisted by the Committee set up by Article 18 of European Parliament and Council Directive ~~75/442/EEC of 15 July 1975~~ on waste ☒ 2006/12/EC of 5 April 2006 ☒ ²⁶.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

²⁶ OJ L ☒ 114, 27.4.2006, p. 9 ☒ 194, 25.7.1975, p. 39. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

Article ~~19~~⁸

Penalties

~~Member States shall determine penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties thus provided for shall be effective, proportionate and dissuasive.~~

☒ 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 the date specified in Article 12 at the latest and shall notify it without delay of any subsequent amendment affecting them. ☒

Article ~~20~~⁹

Transposition

~~1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 13 August 2004. They shall immediately inform the Commission thereof.~~

↓ .

1. Member States shall adopt and publish, by at the latest [18 month after this Directive's publication in the Official Journal of the European Union], the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [...].

↓ 2002/95/EC (adapted)

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

2. Member States shall communicate to the Commission ~~all laws, regulations and administrative provisions adopted~~ ☒ the text of the main provisions of national law which they adopt ☒ in the field covered by this Directive.

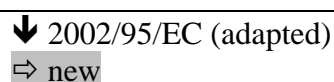


Article 21

Repeal

Directive 2002/95/EC as amended by the acts listed in Annex VIII Part A is repealed with effect from the day after the date mentioned in the first subparagraph of Article 20(1) 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 VIII, 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 IX..



Article ~~22~~¹⁰

Entry into force

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

Article ~~23~~¹¹

Addressees

This Directive is addressed to the Member States.

ANNEX I

Categories of electrical and electronic equipment 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 (with the exception of large-scale stationary industrial tools)
7. Toys, leisure and sports equipment
8. Medical devices.
9. Monitoring and control instruments including industrial monitoring and control instruments
10. Automatic dispensers

ANNEX II

Binding list of products which fall under the Categories listed in Annex I:

1. Large household appliances, including

Washing machines

Clothes dryers

Dish washing machines

Large household appliances used for refrigeration, conservation and storage of food, such as:

Large cooling appliances, Refrigerators, Freezers

Large household appliances used for cooking and other processing of food, such as:

Cooking, Electric stoves, Electric hot plates,

Microwaves

Large appliances for heating rooms, beds, seating furniture, such as:

Electric heating appliances, Electric radiators,

Fanning, exhaust ventilation and conditioning equipment such as:

Electric fans

Air conditioner appliances

2. Small household appliances, including

Appliances for cleaning, such as vacuum cleaners, carpet sweepers

Appliances used for sewing, knitting, weaving and other processing for textiles

Irons and other appliances for ironing, mangling and other care of clothing

Toasters

Fryers

Grinders, coffee machines and equipment for opening or sealing containers or packages

Electric knives

Appliances for hair-cutting, hair drying, tooth brushing, shaving, massage and other body care appliances

Clocks, watches and equipment for the purpose of measuring, indicating or registering time

Scales

3. IT and telecommunications equipment, including

Products and equipment for the collection, storage, processing, presentation or communication of information by electronic means, such as: centralised data processing(Mainframes, Minicomputers, Printer units) and personal computing (Personal computers (CPU, mouse, screen and keyboard included), Laptop computers (CPU, mouse, screen and keyboard included), Notebook computers, Notepad computers, Printers, Copying equipment, Electrical and electronic typewriters, Pocket and desk calculators)

Products or equipment of transmitting sound, images or other information by telecommunications, such as User terminals and systems, Facsimile, Telex, Telephones, Pay telephones, Cordless telephones, cellular telephones, Answering systems

4. Consumer equipment, including products or equipment for the purpose of recording or reproducing sound or images, including signals or other technologies for the distribution of sound and image than by telecommunications, such as Radio sets, Television sets, Videocameras, Video recorders, Hi-fi recorders, Audio amplifiers, Musical instruments (excluding pipe organs installed in churches)

5. Lighting equipment, including

lighting or equipment for the purpose of spreading or controlling light, such as Luminaires for fluorescent lamps, Straight fluorescent lamps, Compact fluorescent lamps, High intensity discharge lamps, including pressure sodium lamps and metal halide lamps, Low pressure sodium lamps

6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools), including

Drills

Saws

Sewing machines

Equipment for turning, milling, sanding, grinding, sawing, cutting, shearing, drilling, making holes, punching, folding, bending or similar processing of wood, metal and other materials

Tools for riveting, nailing or screwing or removing rivets, nails, screws or similar uses

Tools for welding, soldering or similar use

Equipment for spraying, spreading, dispersing or other treatment of liquid or gaseous substances by other means

Tools for mowing or other gardening activities

7. Toys, leisure and sports equipment, including

Electric trains or car racing sets

Hand-held video game consoles

Video games

Computers for biking, diving, running, rowing, etc.

Sports equipment with electric or electronic components

Coin slot machines

8. Medical devices (MD):

– Electrical equipment within the scope of Directive 93/42/EEC

– Electrical equipment within the scope of Directive 98/79/EC

9. Monitoring and control instruments, including

Smoke detector

Heating regulators

Thermostats

Measuring, weighing or adjusting appliances for household or as laboratory equipment

Industrial monitoring and control instruments

10. Automatic dispensers, including all appliances which deliver automatically all kind of products, such as automatic dispensers for hot drinks, automatic dispensers for hot or cold bottles or cans, automatic dispensers for solid products, automatic dispensers for money

ANNEX III: Substances referred to in Article 4(7)

1. Hexabromocyclododecane (HBCDD)
2. Bis (2-ethylhexyl) phthalate (DEHP)
3. Butyl benzyl phthalate (BBP)
4. Dibutylphthalate (DBP)

ANNEX IV

Prohibited substances referred to in Article 4(7) 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%)

↓ 2005/717/EC Art. unique and Annex .1 (adapted)

ANNEX VII

Applications ☒ exempted from the ban in Article 4(1) ☒ of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) which are exempted from the requirements of Article 4(1)

↓ 2002/95/EC

1. Mercury in compact fluorescent lamps not exceeding 5 mg per lamp.
2. Mercury in straight fluorescent lamps for general purposes not exceeding:

— halophosphate	10 mg
— triphosphate with normal lifetime	5 mg
— triphosphate with long lifetime	8 mg.

3. Mercury in straight fluorescent lamps for special purposes.
 4. Mercury in other lamps not specifically mentioned in this Annex.
 5. Lead in glass of cathode ray tubes, electronic components and fluorescent tubes.
 6. Lead as an alloying element in steel containing up to 0,35 % lead by weight, aluminium containing up to 0,4 % lead by weight and as a copper alloy containing up to 4 % lead by weight.
-

↓ 2005/747/EC Art. 1 and Annex .1

- 7. -Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead),
- -lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission as well as network management for telecommunications,
- -lead in electronic ceramic parts (e.g. piezoelectronic devices).

↓ 2005/747/EC Art. 1 and Annex .2

8. Cadmium and its compounds in electrical contacts and cadmium plating except for applications banned under Directive 91/338/EEC²⁷ amending Directive 76/769/EEC²⁸ relating to restrictions on the marketing and use of certain dangerous substances and preparations.

↓ 2002/95/EC

9. Hexavalent chromium as an anti-corrosion of the carbon steel cooling system in absorption refrigerators.

↓ 2005/717/EC Art. unique and Annex .2, Judgement of the ECJ (in joined cases C-14/06 and C-295/06) (adapted)

~~9a. DecaBDE in polymeric applications.~~

↓ 2005/717/EC Art. unique and Annex .3

~~109b. Lead in lead-bronze bearing shells and bushes.~~

↓ 2002/95/EC (adapted)

~~10. Within the procedure referred to in Article 7(2), the Commission shall evaluate the applications for:~~

- ~~– Deca BDE,~~
- ~~– mercury in straight fluorescent lamps for special purposes,~~
- ~~– lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission as well as network management for telecommunications (with a view to setting a specific time limit for this exemption), and~~
- ~~– light bulbs,~~

~~as a matter of priority in order to establish as soon as possible whether these items are to be amended accordingly.~~

²⁷ OJ L 186, 12.7.1991, p. 59.

²⁸ OJ L 262, 27.9.1976, p. 201.

↓ 2005/747/EC Art. 1 and Annex .3

- 11. Lead used in compliant pin connector systems.
- 12. Lead as a coating material for the thermal conduction module c-ring.
- 13. Lead and cadmium in optical and filter glass.
- 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.
- 15. Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit Flip Chip packages.

↓ 2006/310/EC Art. 1 and Annex

- 16. Lead in linear incandescent lamps with silicate coated tubes.
- 17. Lead halide as radiant agent in High Intensity Discharge (HID) lamps used for professional reprography applications.
- 18. 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 ($\text{BaSi}_2\text{O}_5\text{:Pb}$) as well as when used as speciality lamps for diazo-printing reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ($(\text{Sr,Ba})_2\text{MgSi}_2\text{O}_7\text{:Pb}$).
- 19. Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact Energy Saving Lamps (ESL).
- 20. Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCD).

↓ 2006/691/EC Art. 1 and Annex

- 21. Lead and cadmium in printing inks for the application of enamels on borosilicate glass.
- 22. Lead as impurity in RIG (rare earth iron garnet) Faraday rotators used for fibre optic communications systems.
- 23. Lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with NiFe lead frames and lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with copper lead frames.
- 24. Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors.
- 25. Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer,

the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring as well as in print pastes.

26. Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

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.

↓ 2006/692/EC Art. 1 (adapted)

~~28. Hexavalent chromium in corrosion preventive coatings of unpainted metal sheetings and fasteners used for corrosion protection and Electromagnetic Interference Shielding in equipment falling under category three of Directive 2002/96/EC (IT and telecommunications equipment). Exemption granted until 1 July 2007.~~

↓ 2006/690/EC Art. 1

29. Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC²⁹.

↓ 2005/618/EC Art. 1 (adapted)

~~For the purposes of Article 5(1)(a), a maximum concentration value of 0,1 % by weight in homogeneous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) and of 0,01 % by weight in homogeneous materials for cadmium shall be tolerated.~~

↓ 2008/385/EC Art. 1 and Annex

30. Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more.

31. Lead in soldering materials in mercury free flat fluorescent lamps (which e.g. are used for liquid crystal displays, design or industrial lighting).

32. Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes.

²⁹ OJ L 326, 29.12.1969, p. 36. Directive as last amended by 2003 Act of Accession.

ANNEX VI

Applications exempted from the ban in Article 4(1) as regards Categories 8 and 9

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 (plus item 1)
 - 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 adsorption spectroscopy lamps
- 11 Lead in alloys as a superconductor and thermal conductor in MRI
- 12 Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors
- 13 Lead in counterweights
- 14 Lead in single crystal piezoelectric materials for ultrasonic transducers

- 15 Lead in solders for bonding to ultrasonic transducers
- 16 Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay
- 17 Lead in solders in portable emergency defibrillators
- 18 Lead in solders of high performance infrared imaging modules to detect in the range 8 – 14 μm
- 19 Lead in Liquid crystal on silicon (LCoS) displays
- 20 Cadmium in X-ray measurement filters

ANNEX VII

EC 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...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 specifications in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate: ...

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

ANNEX VIII

Part A

Repealed Directive with its successive amendments

(referred to in Article 12)

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. 219)
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)

Part B

List of time-limits for transposition into national law

(referred to in Article 13)

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

ANNEX IX

Correlation table

Directive 2002/95/EC	This Directive
Article 1	Article 1
Article 2(1)	Article 2(1)
Article 2(2)	Article 2(2)
Article 2(3)	Article 2(3), introductory wording
-	Article 2(3)(a) and (b)
Article 3(a)	Article 3(a)
Article 3(b)	-
-	Article 3(b)-(o)
Article 4(1)	Article 4(1)
-	Article 4(3)-(6)
Article 4(2)	Article 4(7)
Article 4(3)	-
-	Article 4(8)
-	Article 5(1), introductory wording
Article 5(1), first subparagraph, introductory wording	Article 5(1)(a)
Article 5(1), first subparagraph, (a)	-
Article 5(1), first subparagraph, (b)	Article 5(1)(b), introductory wording and first and third indents
-	Article 5(1)(b), second indent
Article 5(1), first subparagraph, (c)	-
Article 5(1), second subparagraph	-
Article 5(2)	Article 5(2)
-	Article 5(3)

Article 6	-
-	Article 6-17
Article 7	Article 18
Article 8	Article 19
Article 9	Article 20
-	Article 21
Article 10	Article 22
Article 11	Article 23
-	Annex I- IV
Annex, points 1-28	Annex V, points 1-28
Annex, point 29, first subparagraph	Annex V, point 29, first subparagraph
Annex, point 29, second subparagraph	Article 4(2)
Annex, points 30-32	Annex, points 30-32
-	Annex VI-IX

**LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS HAVING A
BUDGETARY IMPACT EXCLUSIVELY LIMITED TO THE REVENUE SIDE**

1. NAME OF THE PROPOSAL:

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment repealing Directive 2002/95/EC

2. BUDGET LINES:

Chapter and Article:

Amount budgeted for the year concerned:

3. FINANCIAL IMPACT

☒ Proposal has no financial implications

☐ Proposal has no financial impact on expenditure but has a financial impact on revenue – the effect is as follows:

(€million to one decimal place)

Budget line	Revenue ³⁰	12 month period, starting dd/mm/yyyy	[Year n]
Article ...	<i>Impact on own resources</i>		
Article ...	<i>Impact on own resources</i>		

Situation following action					
	[n+1]	[n+2]	[n+3]	[n+4]	[n+5]
Article ...					

³⁰ Regarding traditional own resources (agricultural duties, sugar levies, customs duties) the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % of collection costs.

Article ...					
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4. ANTI-FRAUD MEASURES

...

5. OTHER REMARKS

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