Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (Text with EEA relevance)

DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

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

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having regard to the opinion of the Committee of Regions[(2)],

Acting in accordance with the ordinary legislative procedure[(3)],

Whereas:

(1) A number of substantial changes are to be made to Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment[(4)]. In the interest of clarity, that Directive should be recast.

(2) The disparities between the laws or administrative measures adopted by the Member States regarding the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) could create barriers to trade and distort competition in the Union and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to lay down rules in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE.

(3) Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in its scope equipment which falls within certain categories and to study the need to adapt the list of restricted substances on the basis of scientific progress, taking into account the precautionary principle, as endorsed by Council Resolution of 4 December 2000.

(4) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste[(5)] gives first priority to prevention in waste legislation. Prevention is defined, inter alia, as measures that reduce the content of harmful substances in materials and products.

(5) Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium[(6)] invited the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable alternatives do not exist.

(6) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants[(7)] recalls that the objective of protecting the environment and human health from persistent organic pollutants cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, and can therefore be better achieved at Union level. Pursuant to that Regulation, releases of persistent organic pollutants, such as dioxins and furans, which are unintentional by-products of industrial processes, should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible.

(7) The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste EEE as set out in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)[(8)] are necessary to reduce the waste management problems associated with the heavy metals and flame retardants concerned. In spite of those measures, however, significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union. Even if waste EEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions.

(8) Taking into account technical and economic feasibility, including for small and medium sized enterprises (SMEs), the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials. Restricting the use of those hazardous substances is likely to enhance the possibilities and economic profitability of recycling of waste EEE and decrease the negative impact on the health of workers in recycling plants.

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

(10) The measures provided for in this Directive should take into account existing international guidelines and recommendations and should be based on an assessment of

available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information. The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency[(9)]. In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments, in accordance with the new criteria set out in this Directive as part of the first review.

(11) This Directive supplements the general Union waste management legislation, such as Directive 2008/98/EC and Regulation (EC) No 1907/2006.

(12) A number of definitions should be included in this Directive in order to specify its scope. In addition, the definition of ‘electrical and electronic equipment’ should be complemented by a definition of ‘dependent’, to cover the multipurpose character of certain products, where the intended functions of EEE are to be determined on the basis of objective characteristics, such as the design of the product and its marketing.

(13) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products[(10)] enables specific ecodesign requirements to be set for energy-related products which may also be covered by this Directive. Directive 2009/125/EC and the implementing measures adopted pursuant to it are without prejudice to Union waste management legislation.

(14) This Directive should apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators[(11)] and Regulation (EC) No 850/2004.

(15) The technical development of EEE without heavy metals, PBDE and PBB should be taken into account.

(16) As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. To this end, the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies

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

(17) The development of renewable forms of energy is one of the Union's key objectives, and the contribution made by renewable energy sources to environmental and climate objectives is crucial. Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources[(12)] recalls that there should be coherence between those objectives and other Union environmental legislation. Consequently, this Directive should not prevent the development of renewable energy technologies that have no negative impact on health and the environment and that are sustainable and economically viable.

(18) Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured. The decision on exemptions and on the duration of possible exemptions should take into account the availability of substitutes and the socioeconomic impact of substitution. Life-cycle thinking on the overall impacts of exemptions should apply, where relevant. Substitution of the hazardous substances in EEE should also be carried out in such a way as to be compatible with the health and safety of users of EEE. The placing on the market of medical devices requires a conformity assessment procedure, according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(13)] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(14)], which could require the involvement of a notified body designated by competent authorities of Member States. If such a notified body certifies that the safety of the potential substitute for the intended use in medical devices or in vitro diagnostic medical devices is not demonstrated, the use of that potential substitute will be deemed to have clear negative socioeconomic, health and consumer safety impacts. It should be possible, from the date of entry into force of this Directive, to apply for exemptions for equipment, even before the actual inclusion of that equipment in the scope of this Directive.

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

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

(21) Procedures for assessing the conformity of EEE subject to this Directive should be consistent with relevant Union legislation, in particular Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework

for the marketing of products[15]. Harmonising conformity assessment procedures should give manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Union.

(22) The conformity marking applicable for products at Union level, CE marking, should also apply to EEE that is subject to this Directive.

(23) The market surveillance mechanisms laid down by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[16] provide the safeguard mechanisms to check compliance with this Directive.

(24) In order to ensure uniform conditions for the implementation of this Directive, particularly with regard to the guidelines and format of applications for exemptions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[17].

(25) For the purposes of achieving the objectives of this Directive the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation of Annexes III and IV to technical and scientific progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(26) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(27) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex VII, Part B.

(28) When reviewing this Directive, a thorough analysis of its coherence with Regulation (EC) No 1907/2006 should be carried out by the Commission.

(29) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making[18], Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and their transposition measures, and to make those tables public.

(30) Since the objective of this Directive, namely to establish restrictions on the use of hazardous substances in EEE, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the problem and its implications in respect of other Union legislation on recovery and disposal of waste and areas of common interest, such as human health protection, be better achieved at Union level, the Union may

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

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 306, 16.12.2009, p. 36.

(**2**) OJ C 141, 29.5.2010, p. 55.

(**3**) Position of the European Parliament of 24 November 2010 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.

(**4**) OJ L 37, 13.2.2003, p. 19.

(**5**) OJ L 312, 22.11.2008, p. 3.

(**6**) OJ C 30, 4.2.1988, p. 1.

(**7**) OJ L 158, 30.4.2004, p. 7.

(**8**) OJ L 37, 13.2.2003, p. 24.

(**9**) OJ L 396, 30.12.2006, p. 1.

(**10**) OJ L 285, 31.10.2009, p. 10.

(**11**) OJ L 266, 26.9.2006, p. 1.

(**12**) OJ L 140, 5.6.2009, p. 16.

(**13**) OJ L 169, 12.7.1993, p. 1.

(**14**) OJ L 331, 7.12.1998, p. 1.

(**15**) OJ L 218, 13.8.2008, p. 82.

(**16**) OJ L 218, 13.8.2008, p. 30.

(**17**) OJ L 55, 28.2.2011, p. 13.

(**18**) OJ C 321, 31.12.2003, p. 1.