

COMMISSION REGULATION (EU) No 757/2010**of 24 August 2010****amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC ⁽¹⁾, and in particular Article 14(1) thereof,

Whereas:

(1) Regulation (EC) No 850/2004 implements in the law of the Union the commitments set out in the Stockholm Convention on Persistent Organic Pollutants (hereinafter 'the Convention') approved by Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants ⁽²⁾ and in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (hereinafter 'the Protocol') approved by Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants ⁽³⁾.

(2) Following nominations of substances received from the European Union and its Member States, Norway and Mexico, the Persistent Organic Pollutants Review Committee established under the Convention has concluded its work on the nine proposed substances, which have been found to meet the criteria of the Convention. At the fourth meeting of the Conference of the Parties to the Convention on 4–8 May 2009 (hereinafter 'COP4') it was agreed to add all nine substances to the Annexes to the Convention.

(3) In view of the decisions taken at COP4 it is necessary to update Annexes I and III to Regulation (EC) No 850/2004. Annex I to Regulation (EC) No 850/2004 should be amended to take into account that substances can be listed only in the Convention.

(4) The COP4 decided to list eight of the substances in Annex A (elimination) to the Convention. The ninth substance, Perfluorooctane sulfonic acid and its derivatives (hereinafter PFOS) is still widely used worldwide and COP4 decided to list it in Annex B (restriction) with a range of exemptions. Regulation (EC) No 850/2004 has a similar structure with Annex I (prohibition) and Annex II (restriction). The Convention contains obligations to prohibit or restrict production, use, import and export of the substances listed in its Annexes A and B. By listing the substance covered by the COP4 decisions in Regulation (EC) No 850/2004, the scope of the restriction is brought in conformity with the COP4 decision as Regulation (EC) No 850/2004 includes conditions for production, use and waste management in addition to restricting placing on the market.

(5) Placing on the market and use of PFOS has been restricted in the Union by virtue of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ⁽⁴⁾. The existing restriction on PFOS in the Union contains only few exemptions compared to those included in the COP4 decision. PFOS was also listed in Annex I to the revised Protocol adopted on 18 December 2009. Therefore PFOS should be listed together with the other eight substances in Annex I to Regulation (EC) No 850/2004. Derogations that were applicable for PFOS when listed in Annex XVII are carried over and listed in Annex I to Regulation (EC) No 850/2004 with only few amendments. The derogations should be subject to the use of best available technique where applicable. The specific derogation to use PFOS as wetting agents for use in controlled electroplating systems is time limited in accordance with the COP4 decision. If technically justified the deadline can be prolonged, subject to approval by the Conference of the Parties to the Convention. Member States must report every four years on the use of the allowed derogations. The European Union as a Party to the Convention should report to it based on the Member State reports. The Commission should continue to review the remaining derogations and the availability of safer alternative substances or technologies.

(6) The provisions in Article 4(1)(b) of Regulation (EC) No 850/2004 regarding substances occurring as an unintentional trace contaminant should be defined for PFOS to ensure a harmonised enforcement and control of that Regulation, while at the same time guaranteeing conformity with the Convention. By virtue of Annex XVII to Regulation (EC) No 1907/2006 PFOS was

⁽¹⁾ OJ L 158, 30.4.2004, p. 7.

⁽²⁾ OJ L 209, 31.7.2006, p. 1.

⁽³⁾ OJ L 81, 19.3.2004, p. 35.

⁽⁴⁾ OJ L 396, 30.12.2006, p. 1.

allowed to be used in quantities below certain thresholds. Until further information becomes available, the thresholds in Annex XVII to Regulation (EC) No 1907/2006 for PFOS in articles correspond to a level below which PFOS can not be meaningfully used while enabling control and enforcement through existing methods. These thresholds should therefore limit the use of PFOS to a level corresponding to unintentional trace contaminants. For PFOS as substances or in preparations, this Regulation should establish a threshold corresponding to a similar level. To rule out intentional use, this level should be lower than the level applied in Regulation (EC) No 1907/2006.

- (7) Placing on the market and use of pentabromodiphenyl ether and octabromodiphenyl ether have been restricted in the Union by virtue of Annex XVII to Regulation (EC) No 1907/2006 with a maximum concentration limit of 0,1 % by weight below which it is not considered restricted. The COP4 decided to list congeners present in the commercial forms of pentabromodiphenyl ethers and octabromodiphenyl ethers having POPs characteristics. For reasons of coherence the listing in Regulation (EC) No 850/2004 should follow the approach of Annex XVII to Regulation (EC) No 1907/2006 for those derivatives identified by COP4 as having POP characteristics; therefore hexabromodiphenyl ether, heptabromodiphenyl ether, tetrabromodiphenyl ether and pentabromodiphenyl ether derivatives should be listed in Annex I to Regulation (EC) No 850/2004.
- (8) The provisions in Article 4(1)(b) of Regulation (EC) No 850/2004 regarding substances occurring as an unintentional trace contaminant should be defined for polybrominated diphenyl ethers (PBDEs) to ensure a harmonised enforcement and control of that Regulation, while at the same time guaranteeing conformity with the Convention. This Regulation should establish a fixed threshold for considering unintentional trace contaminants regarding PBDEs in substances, preparations and articles. Subject to further information that becomes available and a review by the Commission, in line with the objectives of this Regulation, the thresholds in Annex XVII to Regulation (EC) No 1907/2006 for PBDEs in articles produced from recycled materials should limit the use of PBDEs to unintentional trace contaminants in that they are considered to correspond to a level below which PBDEs can not be meaningfully used while enabling control and enforcement through existing methods. For PBDEs as substances, in preparations or in articles, this Regulation should establish a threshold corresponding to a similar level.
- (9) It is necessary to clarify that the prohibition in Article 3 of Regulation (EC) No 850/2004 does not apply to

articles containing PBDEs and PFOS already in use on the date of entry into force of this Regulation.

- (10) DDT and Hexachlorocyclohexanes (HCH), including lindane, should be listed without derogations. Part A of Annex I to Regulation (EC) No 850/2004 allows Member States to maintain existing production and use of DDT for the production of dicofol. No Member State is currently using the derogation. In addition, dicofol was denied for inclusion in Annex I to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹⁾ as well as in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽²⁾. That derogation should therefore be deleted. HCH, including lindane, is listed in Part B of Annex I Regulation (EC) No 850/2004, with two specific derogations for certain specific uses. The derogations expired on 1 September 2006 and on 31 December 2007 and should therefore be deleted.
- (11) In conformity with the COP4 decisions pentachlorobenzene should be added to Annexes I and III to Regulation (EC) No 850/2004 so that it becomes subject to a general prohibition as well as the release reduction provisions in that Regulation. Chlordecone and hexabromobiphenyl should be moved to Annex I, Part A as they are now listed to both international instruments.
- (12) In accordance with Article 22 of the Convention, amendments to Annexes A, B and C thereto enter into force one year from the date of communication by the depositary of an amendment, which will fall on 26 August 2010. Consequently and for reasons of coherence this Regulation should apply from the same date. This Regulation should therefore enter into force as a matter of urgency.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Directive 67/548/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and III to Regulation (EC) No 850/2004 are amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 26 August 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

(1) Annex I to Regulation (EC) No 850/2004 is replaced by the following:

ANNEX I

Part A — Substances listed in the Convention and in the Protocol as well as substances listed only in the Convention

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Tetrabromodiphenyl ether $C_{12}H_6Br_4O$			<ol style="list-style-type: none"> 1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of Tetrabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: <ol style="list-style-type: none"> (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of tetrabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use; (b) electrical and electronic equipment within the scope of Directive 2002/95/EC of the European Parliament and Council (*). 3. Use of articles already in use in the Union before 25 August 2010 containing Tetrabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Pentabromodiphenyl ether $C_{12}H_5Br_5O$			<ol style="list-style-type: none"> 1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of pentabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: <ol style="list-style-type: none"> (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of pentabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			<p>(b) electrical and electronic equipment within the scope of Directive 2002/95/EC.</p> <p>3. Use of articles already in use in the Union before 25 August 2010 containing Pentabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.</p>
Hexabromodiphenyl ether <chem>C12H4Br6O</chem>			<p>1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of hexabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles.</p> <p>2. By way of derogation, the production, placing on the market and use of the following shall be allowed:</p> <p>(a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of hexabromobiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;</p> <p>(b) electrical and electronic equipment within the scope of Directive 2002/95/EC.</p> <p>3. Use of articles already in use in the Union before 25 August 2010 containing Hexabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.</p>
Heptabromodiphenyl ether <chem>C12H3Br7O</chem>			<p>1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of heptabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles.</p> <p>2. By way of derogation, the production, placing on the market and use of the following shall be allowed:</p> <p>(a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of heptabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;</p>

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			<p>(b) electrical and electronic equipment within the scope of Directive 2002/95/EC.</p> <p>3. Use of articles already in use in the Union before 25 August 2010 containing Heptabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.</p>
<p>Perfluorooctane sulfonic acid and its derivatives (PFOS)</p> <p>$C_8F_{17}SO_2X$</p> <p>(X = OH, Metal salt (O-M⁺), halide, amide, and other derivatives including polymers)</p>			<p>1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of PFOS equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances or in preparations.</p> <p>2. For the purposes of this entry, Article 4(1) (b) shall apply to concentrations of PFOS in semi-finished products or articles, or parts thereof, if the concentration of PFOS is lower than 0,1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is lower than 1 µg/m² of the coated material.</p> <p>3. Use of articles already in use in the Union before 25 August 2010 containing PFOS as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.</p> <p>4. Fire-fighting foams that were placed on the market before 27 December 2006 may be used until 27 June 2011.</p> <p>5. If the quantity released into the environment is minimised, production and placing on the market is allowed for the following specific uses provided that Member States report to the Commission every four years on progress made to eliminate PFOS:</p> <p>(a) until 26 August 2015, wetting agents for use in controlled electroplating systems;</p> <p>(b) photoresists or anti reflective coatings for photolithography processes;</p> <p>(c) photographic coatings applied to films, papers, or printing plates;</p>

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			<p>(d) mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems;</p> <p>(e) hydraulic fluids for aviation.</p> <p>Where derogations in points (a) to (e) above concern the production or use in an installation within the scope of Directive 2008/1/EC of the European Parliament and of the Council (**), the relevant best available techniques for the prevention and minimisation of emissions of PFOS described in the information published by the Commission pursuant to Article 17(2), second subparagraph, of Directive 2008/1/EC shall apply.</p> <p>As soon as new information on details of uses and safer alternative substances or technologies for the uses in points (b) to (e) becomes available, the Commission shall review the derogations in the second subparagraph so that:</p> <p>(i) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible,</p> <p>(ii) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on,</p> <p>(iii) releases of PFOS into the environment have been minimised by applying best available techniques.</p> <p>6. Once standards are adopted by the European Committee for Standardisation (CEN) they shall be used as the analytical test methods for demonstrating the conformity of substances, preparations and articles to paragraphs 1 and 2.</p>
DDT (1,1,1-trichloro-2,2-bis(4-chlorophenyl)ethane)	50-29-3	200-024-3	—
Chlordane	57-74-9	200-349-0	—
Hexachlorocyclohexanes, including lindane	58-89-9 319-84-6 319-85-7 608-73-1	200-401-2 206-270-8 206-271-3 210-168-9	—

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Dieldrin	60-57-1	200-484-5	—
Endrin	72-20-8	200-775-7	—
Heptachlor	76-44-8	200-962-3	—
Hexachlorobenzene	118-74-1	200-273-9	—
Chlordecone	143-50-0	205-601-3	—
Aldrin	309-00-2	206-215-8	—
Pentachlorobenzene	608-93-5	210-172-5	—
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1 and others	Without prejudice to Directive 96/59/EC, articles already in use at the time of the entry into force of this Regulation are allowed to be used
Mirex	2385-85-5	219-196-6	—
Toxaphene	8001-35-2	232-283-3	—
Hexabromobiphenyl	36355-01-8	252-994-2	—

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

(**) OJ L 24, 29.1.2008, p. 8.

Part B — Substances listed only in the Protocol

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
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(2) In Annex III the following substance is added:

'Pentachlorobenzene (CAS No 608-93-5)'