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Proposal for a

**COUNCIL DECISION**

**on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A to the Stockholm Convention on Persistent Organic Pollutants**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

The Stockholm Convention on Persistent Organic Pollutants (the Convention), which was approved by Council Decision 2006/507/EC<sup>1</sup>, entered into force on 17 May 2004. The aim of the Convention is to protect human health and the environment from persistent organic pollutants (POPs). The Convention provides a framework, based on the precautionary principle, for elimination of production, use, import and export of currently twenty-three priority POPs, their safe handling and disposal and elimination or reduction of releases of certain unintentional POPs.

Regulation (EC) No 850/2004 on persistent organic pollutants<sup>2</sup> implements in Union law the commitments set out in the Convention and in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (the Protocol), approved by Council Decision 259/2004/EC<sup>3</sup>.

Article 8(1) of the Convention stipulates that any Party may submit a proposal to the Secretariat for listing a chemical in Annexes A, B or C to the Convention which will then be reviewed by the Persistent Organic Pollutants Review Committee (POP RC) following Article 8(3) and (4). The proposal shall contain the information specified in Annex D. The procedure for the adoption of amendments to Annexes is governed by Article 22 of the Convention.

According to available scientific information and review reports, as well as taking due account of the screening criteria laid down in Annex D to the Convention, perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances that can be degraded to PFOA under environmental conditions exhibit characteristics of POPs. In the following, reference to “PFOA and its compounds” denotes all forms described pertaining to this paragraph.

A recent market analysis<sup>4</sup>, conducted on behalf of the European Commission, revealed only one company manufacturing ammonium pentadecafluorooctanoate (APFO) was active in the Union in 2010. This company announced cessation of production of APFO as per August 2010 and cessation of its commercialisation as per November 2010. The market analysis also showed that PFOA and APFO are mainly used in the Union in the production of fluoropolymers and fluoroelastomers<sup>5</sup> and that entry into the environment occurs at this stage.

On 20 June 2013, following unanimous agreement of the EU's Member State Committee under Regulation (EC) No 1907/2006 of the European Parliament and the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>6</sup>, PFOA and APFO were added to the EU's Candidate List for authorisation<sup>7</sup> having been identified as Substances of Very High Concern (SVHCs). The identification of PFOA

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<sup>1</sup> OJ L 209, 31.7.2006, p. 1.

<sup>2</sup> OJ L 158, 30.4.2004, p. 7.

<sup>3</sup> OJ L 81, 19.3.2004, p. 35.

<sup>4</sup> van der Putte I, Murin M, van Velthoven M, Affourtit F. 2010. Analysis of the risks arising from the industrial use of Perfluorooctanoic Acid (PFOA) and Ammonium Perfluorooctanoate (APFO) and from their use in consumer articles. Evaluation of the risk reduction measures for potential restrictions on the manufacture, placing on the market and use of PFOA and APFO. European Commission, DG Enterprise and Industry.

<sup>5</sup> Fluoropolymers are high performance plastic materials and fluoroelastomers are high performance synthetic rubbers.

<sup>6</sup> OJ L 396, 30.12.2006, p. 1.

<sup>7</sup> ED/69/2013 - Available at: <http://echa.europa.eu/documents/10162/b54352de-0f2f-454c-bc83-04f191c560b7>

and APFO as a SVHC was based on an information dossier<sup>8</sup> prepared by Germany pursuant to Annex XV of Regulation (EC) No 1907/2006. The scientific data presented in this dossier showed that PFOA and APFO met the criteria of Article 57(c) of REACH as toxic for reproduction 1B and in particular, that they also met the criteria of Article 57(d) of REACH as a substance which is persistent, bioaccumulative and toxic (PBT).

In October 2013, PFOA and APFO received a harmonised classification in Annex VI of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)<sup>9</sup>, as amended by Commission Regulation (EU) No 944/2013<sup>10</sup>, as carcinogen category 2, toxic for reproduction category 1B and specific target organ toxicants on liver following repeated exposure category 1 (STOT RE 1 liver). Following this classification, the placing on the market and use of PFOA and APFO as substances or in mixtures for supply to the general public are banned in the Union since 1 January 2015, in accordance with Regulation (EC) 1907/2006 as amended by Regulation (EU) No 317/2014<sup>11</sup>.

Since this point, the German and Norwegian Competent Authorities have jointly compiled a dossier under Annex XV of REACH with the intention of proposing PFOA compounds for inclusion in the restriction process under REACH. This Restriction dossier<sup>12</sup> was submitted to ECHA on 17 October 2014 and proposes a restriction on the manufacture, use or placing on the market of PFOA compounds as substances on their own, or as constituents of other substances, in mixtures or articles.

Due to their outstanding technical properties (to provide water, oil, and grease repellency) PFOA compounds are used in various consumer products as well as in industrial applications. These uses lead to the wide-dispersive release of PFOA, its salts and related substances into the environment. Globally, the sources of PFOA have been significantly reduced in the USA, Japan and the Union. However, it is important to note, that the manufacture of fluoropolymers is shifting to countries such as Russia and China, where it is assumed that a large share of fluoropolymers is still produced using PFOA. This can be seen from consumer articles containing PFOA which are often imported from outside the Union. The global fluoropolymer market is continuously growing (5-6% per year globally).

The dossier estimates, based on available information, that 40 tonnes per annum (t/a) of PFOA and its salts are currently imported into the Union. In addition, it estimates that 100 - 1000 t/a of PFOA-related substances are manufactured in the Union and that a further 100 – 1000 t/a are imported into the Union. In addition, the PFOA-related substances enter the Union via imported articles, such as textiles, which are expected to account for significant volumes of PFOA-related substances.

In addition to their proven PBT qualities, as evidenced in the REACH and CLP classifications noted above, the Annex XV Restriction dossier also investigates the long-range environmental transport (LRT) potential of PFOA and its compounds. The dossier makes reference to a report conducted by the OECD in 2006 that concluded that PFOA and its compounds are subject to long range environmental transport and have been found in remote

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<sup>8</sup> Available at: <http://echa.europa.eu/documents/10162/1b26b219-6783-4981-9acf-154d620937b4>

<sup>9</sup> OJ L 353, 31.12.2008, p. 1.

<sup>10</sup> Commission Regulation (EU) No 944/2013 (5th Adaption to Technical Progress (ATP) to Regulation (EC) 1272/2008) (OJ L 261, 03.10.2013, p. 5).

<sup>11</sup> Commission Regulation (EU) No 317/2014 amending Regulation (EC) No 1907/2006 as regards Annex XVII (CMR substances) (OJ L 93, 28.03.2014, p. 24).

<sup>12</sup> Restriction Report for PFOA, compiled by DE and NO, published on ECHA website on 17/12/14. Available at: <http://www.echa.europa.eu/web/guest/restrictions-under-consideration>

areas such as the Arctic<sup>13</sup>. The dossier concludes that this confirms emissions of PFOA and its compounds as a transboundary pollution problem.

Given the information currently available regarding the PBT and LRT qualities of PFOA and its compounds and, on the basis of the studies and reports outlined above, it is proposed that PFOA and its compounds meet the criteria of Annex D to the Convention and therefore could be considered as a POP.

PFOA and its compounds are still produced, used or unintentionally emitted in significant amounts in third countries. Due to the potential for long-range environmental transport of these chemicals, the measures taken nationally or at the Union level are not sufficient to safeguard the high level of protection of the environment and human health and wider international action is necessary.

With a view to the next POPRC meeting in October 2015, it is appropriate that the Commission submit on behalf of the Union a proposal for the listing of PFOA and its compounds for inclusion in Annex A to the Secretariat of the Stockholm Convention. This constitutes a position to be adopted on the Union's behalf for the purpose of Article 218(9) TFEU.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS**

A paper<sup>14</sup> concerning the common understanding between the Convention, the Protocol and REACH was endorsed by the Competent Authorities of the EU Member States in July 2014.

The decision to submit a proposal for the listing of PFOA and its compounds in Annex A to the Convention is based on the conclusions of this common understanding paper in which it states that the process for including a substance in Annex XVII (Restriction) of REACH can run concurrently with the process of including a substance in one of the Annexes to the Convention and, furthermore, that the completion of the REACH Restriction process for a substance could facilitate the development of the EU position for the Conference of Parties when the listing of that substance will have to be decided.

In the event that PFOA and its compounds are nominated for listing in Annex A to the Convention, a further period of consultation and assessment will commence with interested stakeholders and any other interested Parties to the Convention.

## **3. LEGAL ELEMENTS OF THE PROPOSAL**

This proposal will result in the compilation of an information dossier pursuant to the provisions of Article 8(1) and criteria of Annex D to the Convention upon which a proposal will be submitted to the Convention's Secretariat to add PFOA and its compounds to Annex A of the Convention.

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<sup>13</sup> OECD, 2006. SIDS Initial Assessment Report after SIAM 22 - Ammonium Perfluorooctanoate & Perfluorooctanic Acid, pp. 1-210.

<sup>14</sup> CA/29/2014 – endorsed at the 15<sup>th</sup> Meeting of the Competent Authorities for REACH and CLP (CARACAL) in July 2014.

Proposal for a

## COUNCIL DECISION

### **on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A to the Stockholm Convention on Persistent Organic Pollutants**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 191(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union ratified the Stockholm Convention on Persistent Organic Pollutants (the Convention) on 16 November 2004 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<sup>15</sup>.
- (2) As a Party to the Convention, the Union may make proposals for amendment of the Annexes to the Convention. Annex A to the Convention lists persistent organic pollutants (POPs) to be eliminated.
- (3) With regard to available scientific information and review reports as well as taking due account of the screening criteria laid down in Annex D to the Convention, perfluorooctanoic acid (PFOA), its salts and PFOA-related substances that can be degraded to PFOA under environmental conditions (hereinafter PFOA and its compounds) exhibit characteristics of POPs.
- (4) In accordance with Article 59(1) and an Annex XV dossier<sup>16</sup> of Regulation (EC) No 1907/2006 of the European Parliament and the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>17</sup>, PFOA and its ammonium salt (APFO) have been included in the Candidate List of substances of very high concern having been identified as meeting the criteria of Article 57(c) of that regulation as toxic for reproduction 1B and in particular, that it also met the criteria of Article 57(d) of that regulation as a substance which is persistent, bioaccumulative and toxic.
- (5) Further to the provisions of Article 69(4) of REACH, PFOA and its compounds are currently the subject of an Annex XV dossier<sup>18</sup>, submitted to the European Chemical Agency, aiming to restrict the manufacture, use or placing on the market of PFOA and

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<sup>15</sup> OJ L 209, 31.7.2006, p. 1.

<sup>16</sup> Available at: <http://echa.europa.eu/documents/10162/1b26b219-6783-4981-9acf-154d620937b4>

<sup>17</sup> Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 369, 30.12.2006, p. 1).

<sup>18</sup> Restriction Report for PFOA, compiled by DE and NO, published on ECHA website on 17/12/14. Available at: <http://www.echa.europa.eu/web/guest/restrictions-under-consideration>

its compounds on their own, or as constituents of other substances, in a mixture or articles.

- (6) PFOA and its compounds are substances with worldwide dispersive uses and are ubiquitously detected in the environment. Due to the potential for long-range environmental transport of PFOA, the measures taken at Union level are not sufficient to safeguard the high level of protection of the environment and human health and wider international action is necessary.
- (7) The Union should therefore submit a proposal to the Secretariat of the Convention for the listing of PFOA and its compounds in Annex A to the Convention. This proposal and the Union's position regarding the conditions for listing PFOA and its compounds in Annex A to the Convention should take account of any relevant information obtained in the course of the on-going restriction procedure under Articles 68 to 73 of REACH.

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Union shall submit a proposal for the listing of PFOA and its compounds in Annex A to the Stockholm Convention on Persistent Organic Pollutants (the Convention).
2. The Commission shall communicate the proposal on behalf of the Union to the Secretariat of the Convention with all the information required under Annex D to the Convention.

*Article 2*

This Decision shall enter into force on the day of its adoption.

Done at Brussels,

*For the Council  
The President*