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Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Sixth meeting
Geneva, 11–15 October 2010
Item 8 of the provisional agenda*

Other matters

Information related to quantities of a chemical occurring as unintentional trace contaminants in products and articles

Note by the Secretariat

1. Annex I to the present note contains a letter from the European Commission to the Secretariat of the Stockholm Convention enquiring how the notion of "unintentional trace contaminants" in note (i) of part I of Annexes A and B to the Convention should be applied to the persistent organic pollutants listed by the Conference of the Parties at its fourth meeting.

2. In response to this letter and in order to gather information for consideration by the Persistent Organic Pollutants Review Committee, the Secretariat requested parties and observers to provide information on how national regulations define unintentional trace contaminants in products and articles, in addition to information on experiences in applying this clause in practice. Annex II to the present note contains a compilation of responses received. The responses have not been formally edited.

3. As at 23 September 2010, 11 parties and two observers had submitted responses. Six countries replied that they lacked regulations on or definitions of unintentional trace contaminants. Six countries indicated that they did not use the term "unintentional trace contaminants" in their regulations, but applied threshold limits regarding particular substances to determine persistent organic pollutant contamination in products and articles. Concentration limits are a means to facilitate enforcement, and in some cases regulatory measures are linked to them. In three of these six countries, terms such as "impurities" or "incidental presence" are used in regulations.

4. The European Commission has amended its regulations to define the concept of unintentional trace contaminants in substances, preparations or articles. This is the only entity that provided information with regard to setting specific threshold limits for the newly listed persistent organic pollutants. Annex III to the present note contains questions and answers developed by the European Commission in connection with the amendment to its regulation to implement the decisions by the Conference of the Parties at its fourth meeting relevant to the listing of new persistent organic pollutants. The annex has not been formally edited by the Secretariat.

5. No country reported any specific experience of applying regulations on unintentional trace contaminants to the newly listed persistent organic pollutants. One country did, however, report its experience in evaluating dioxin concentrations in products and articles.

* UNEP/POPS/POPRC.6/1/Rev.1.

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Annex I

Letter from the European Commission

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate D - Water, Chemicals & Biotechnology
ENV.D.3 – Chemicals and Nanomaterials

Brussels, 25 -02- 2010
AS D(2010) 102954

Mr. Donald Cooper, Executive Secretary
Secretariat of the Stockholm Convention
United Nations Environment Programme
International Environment House I
11 – 13 Chemin des Anemones
1219 Chatelaine, Geneva
Switzerland
Email: ssc@pops.int

Dear Mr. Cooper,

The European Union was pleased with the outcome of the fourth Conference of the Parties to the Stockholm Convention and particularly the listing of the new substances. It demonstrated that the Convention is well functioning and that the recommendations from the POP Review Committee were sound and well founded. We hope this progress will continue and that the next COP will finally decide on the important compliance mechanism.

As you may be aware, the EU has not taken advantage of the provisions set out in the Article 25 (4) in the Convention. We are therefore working expeditiously to implement the COP4 outcome in Union law by no later than 26 August 2010.

In the context of the related preparatory work a question has arisen on which we are seeking your assistance. With the addition of PFOS, commercial octaBDE and pentaBDE, the Convention is now restricting substances which are still widely used in a variety of articles. In the case of PFOS it is known that it may even be used in very small quantities while still providing the intended effects. For such substances in articles the EU normally establishes a fixed maximum concentration limit below which the substances are not considered restricted. These limits are usually expressed as an absolute figure in percentage or in parts per million (ppm). This is done to create legal certainty and enable uniform application and enforcement of the restrictions.

The problem we are struggling with relates to the existing notes (i) listed in both Annexes A and B to the Convention reading "*Except as otherwise specified in this Convention, quantities of a chemical occurring as unintentional trace contaminants in products and articles shall not be considered to be listed in this Annex*". For the substances listed

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hitherto this note has not raised any real problems since the Convention's original Annex A and B mainly contained substances used as pesticides. One key exception is PCB for which the Convention has established rather detailed risk management provisions to support the implementation, in particular by introducing some concentration limits.

For the above-mentioned substances (PFOS, commercial octaBDE and pentaBDE), in the EU's draft implementing legislation we would like to translate the notion of "*unintentional trace contaminants*", ideally by fixing the maximum concentration limits referred to above in such a way that it can be considered to reflect this notion. However, especially applying this concept to substances that may be used in so minuscule quantities as is the case for PFOS is neither easy nor straightforward. The ideal solution from our perspective would be to establish a fixed threshold that would represent the administrative interpretation of what is to be understood as an "*unintentional trace contaminant*". However, we understand that this is not easy as there is no international agreement or any literature on what is meant by this notion. What constitutes a "*trace*" and when is it a "*contaminant*"? We believe that most people intuitively understand what is covered by the concept of "*unintentional*", but its use in administrative law it is likewise difficult.

It is likely that other Parties may have similar difficulties as we have. With this in mind, we would appreciate it if you could provide us with your thoughts on the above matter so that our implementing provisions correctly reflect note (i) to Annexes A and B. Beyond any initial reflections you may be able to offer, we believe that the interpretation may require advanced technical knowledge about the individual substances listed and could benefit from expert analysis, possibly by the POPRC.

We look forward to hearing from you and should you have any questions please do not hesitate to contact us.

Yours sincerely,

Astrid Schomaker
Head of Unit

CC.: Sylvain Bintein, Peter Korytar and Henrik Laursen (DG ENV)

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Annex II

Responses from parties and observers

The table below is a compilation of responses from parties and observers to the request from the Secretariat to provide information on how national regulations define unintentional trace contaminants in products and articles, in addition to information on experiences in applying this clause in practice.

Country or entity	Response
Canada	**1. How your national regulation defines unintentional trace contaminants in products and articles:** The following are the regulations under *Canadian Environmental Protection Act, 1999* (CEPA) which apply the term "incidental presence": **A. *Ozone-depleting Substances Regulations, 1998:*** http://canadagazette.gc.ca/archives/p2/1999/1999-01-06/html/sor-dors7-eng.html Ozone-depleting Substances controlled under these Regulations are listed in Schedule 2 of the Regulations. The Regulations control their manufacture, import, export, use, sale and offer for sale. In certain instances, these same activities for equipment containing or designed to contain these substances are also controlled. *How the unintentional trace is defined within the text of the Regulation:* Section2: The ODSR 1998 do not apply to a controlled substance if: (a) the controlled substance is produced incidentally in the manufacture of substances other than controlled substances; or (b) the controlled substance is incidentally present in a mixture, a product or equipment. **B. *Prohibition of Certain Toxic Substances Regulations, 2005*** http://canadagazette.gc.ca/archives/p2/2005/2005-03-09/html/sor-dors41-eng.html The Prohibition Regulations apply to the substances listed in the Regulations and mixtures and products containing them. The Regulations prohibit the manufacture, use, sale, offer for sale and import of the toxic substances listed in Schedules 1 and 2 to the Regulations. Schedule 1 lists prohibited toxic substances subject to total prohibition, with the exception of incidental presence. Schedule 2 includes toxic substances that are subject to prohibitions related to concentration or use. *How the unintentional trace is defined within the text of the Regulation*: Section 4: Subject to section 6, no person shall manufacture, use, sell, offer for sale or import a toxic substance set out in Schedule 1 or a mixture or product containing any such toxic substance unless the substance is incidentally present. **C. *Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations:*** http://canadagazette.gc.ca/rp-pr/p2/2008/2008-06-11/html/sor-dors178-eng.html The *Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations* (PFOS Regulations) prohibit the manufacture, use, sale, offer for sale and import of PFOS, as well as products containing PFOS, unless the PFOS is incidentally present. The PFOS Regulations include a limited number of exemptions that are identified as critical uses in Canada. *How the unintentional trace is defined within the text of the Regulation:* Section 4: Subject to sections 5 to 7, no person shall manufacture, use, sell, offer for sale or import any substance referred to in section 1 or a product containing any such substance unless the substance is incidentally present.

Country or entity	Response
	D. ***PCB Regulations*****:** http://canadagazette.gc.ca/rp-pr/p2/2008/2008-09-17/html/sor-dors273-eng.html This Regulation applies to products and would not be subject to products where toxic substances are incidentally present. *How the unintentional trace is defined within the text of the Regulation:* Section 11: (1) A person may manufacture, export, import, offer for sale, sell, process and use a colouring pigment containing PCBs produced incidentally if the concentration of the PCBs is less than 50 mg/kg (2) despite subsection (1), the annual average concentration of PCBs produced incidentally in colouring pigment that a person may manufacture, export, import, offer for sale, sell, process and use shall not exceed 25 mg/kg. **2. Your experience in applying this clause in practice** In general the words "incidentally present" refer to the presence of the substance in a final product when it is present as a residual, a trace contaminant or impurity and was not added to the formulation intentionally. Although the term "incidentally present" was identified as an enforcement issue, we are not aware of any other issues related to the promotion of compliance or general implementation with the use of "incidentally present". Consideration is being given to establishing thresholds in certain cases to facilitate enforcement of regulations that apply the use of incidental presence.
Chile	(1) The Agriculture and Livestock Service, a public institution under the Ministry of Agriculture, by Resolution No. 1032, set maximum limits for dioxins and dioxin-like PCBs in products intended for animal feed. This regulation: a) prohibits the manufacture, processing, import, export, storage, sale and transport of products intended for animal feed which contain levels of dioxins and dioxin-like PCBs over the provisions of this resolution; b) sets maximum limits of these contaminants in products intended for animal feed. (See Res.Ex.N No. 1032, attached) (2) The Ministry of Health by Resolution N º 499 of 16/08/2008, stated that all pork and its by-products containing concentrations equal to or greater than 2 picograms per gram of fat, presumably harmful to health. (See Res.Ex.N No. 449, attached)
European Commission	The Stockholm Convention on Persistent Organic Pollutants is implemented in the European Union by Regulation (EC) No 850/2004 of 29 April 2004 on persistent organic pollutants (POP Regulation). The provisions of Note (i) of Part I of Annex A as well as of Annex B of the Convention, which states that: "*Except as otherwise specified in this Convention, quantities of a chemical occurring as unintentional trace contaminants in products and articles shall not be considered to be listed in this Annex"* are reflected in the EU's implementing legislation which provides exemptions for substances occurring as unintentional trace contaminants in substances, preparations or articles. Amendments to the POPs Regulation (Regulation (EC) 757/2010) entered into force on 26 August 2010 implementing the decisions made at COP4 regarding the nine new substances. The amended Regulation defines the concept of unintentional trace contaminants in substances, preparations or articles for perfluorinated sulfonic acid and its derivatives (PFOS) and polybrominated diphenyl ethers (PBDEs). A substance is considered to be an unintentional trace contaminant if it is present in quantities equal to or below a fixed threshold set in the POPs Regulation. The thresholds were set to correspond to a level below which the substance can not be meaningfully used and above detection limit of existing detection methods to enable control and enforcement.

<table>
<tr><th>Country or entity</th><th>Response</th></tr>
<tr><td></td><td>
<table>
<tr><th>Substance</th><th>Threshold</th></tr>
<tr><td>Tetrabromodiphenyl ether</td><td>• 10 mg/kg (0.001% by weight) when it occurs in substances, preparations, articles or as constituents of the flame retarded parts of articles</td></tr>
<tr><td>Pentrabromodiphenyl ether</td><td>• 10 mg/kg (0.001% by weight) when it occurs in substances, preparations, articles or as constituents of the flame retarded parts of articles</td></tr>
<tr><td>Hexabromodiphenyl ether</td><td>• 10 mg/kg (0.001% by weight) when it occurs in substances, preparations, articles or as constituents of the flame retarded parts of articles</td></tr>
<tr><td>Heptabromodiphenyl ether</td><td>• 10 mg/kg (0.001% by weight) when it occurs in substances, preparations, articles or as constituents of the flame retarded parts of articles</td></tr>
<tr><td>Perfluorooctane sulfonic acid and its derivates (PFOS)</td><td>• 10 mg/kg (0.001% by weight) when it occurs in substances or in preparations;
• In semi-finished products or articles, or parts thereof, 0.1% by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS;
• For textiles or other coated materials 1 µg/m^2 of the coated material</td></tr>
</table>
</td></tr>
<tr><td>Germany</td><td>Germany provides the comment, that in the European regulation the terms “products and articles” are not in use, at least not in this context. It is a kind of duplication, because the term “products” already includes the term “articles”. It is more common to refer to substances, preparations or articles, as done so in the European regulation on POPs (850/2004/EC).

As the concept of unintentional trace contaminants is a specialty of the POP regulations, there is no such definition on national level. Usually substance specific concentration limits are in use.

On the national level the Chemicals Prohibition Ordinance1 deals with unintentional traces of polychlorinated and polybrominated Dioxins and Furans in substances, preparations or articles. Therefore concentration limits (1 to 100 µg/kg) were set, depending on the properties of the different chemicals and their congeners (e.g. toxicity, persistency). For substances, preparations or articles with concentration above permissible limits, placing on the market is prohibited.</td></tr>
<tr><td>Ghana</td><td>Ghana is currently in the process of developing a legal framework for the Stockholm Convention and will take steps to incorporate provisions relating to quantities of a chemical occurring as unintentional trace contaminants in products and articles. We shall collaborate with relevant national agencies such as the Ghana Standards Board on this issue.</td></tr>
<tr><td>Mexico</td><td>The Secretariat of Environment and Natural Resources (SEMARNAT) does not have information related to quantities of chemicals occurring as unintentional trace contaminants.

The Secretariat of Health provided through the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) the following information:
• The general law on health defines in Article 207: “Products or material is considered contaminated if these contain microorganism, hormones, bacteriostatics, pesticides, radioactive particles, strange matter, as well as any other substance in quantities exceeding threshold limits established by the Secretariat of Health.” The later has the authority to establish these limits.
• Concerning the determination of presence of POPs in unintentional trace quantities, there is only experience in the evaluation of dioxin concentration in the pesticide 2,4-D, where the dioxins are produced because of secondary reactions in the production process. The evaluation is carried out in form of an evaluation of five batches in order to establish equivalents. COFEPRIS compares the results of the analyses of five batches, determining if the dioxin content is above international standards.

The Secretariat of Economy has no legal framework regulating trace contaminants.</td></tr>
<tr><td>Monaco</td><td>The Government of Monaco does not have any specific regulation in regards to these chemicals and, therefore, no experience in applying this clause in practice.</td></tr>
<tr><td>Nepal</td><td>Among the nine chemicals in the new list except Lindane, no other chemicals are use in Nepal. Lindane has been in use in Nepal only for public health purpose but not as pesticide. Our National Regulations, Pesticide Act 1991 and Pesticide Regulations 1994 have banned the use of Lindane as pesticide. Accordingly, during COP 4 meeting in Geneva, Nepal has requested for an exemption to use only for public health purpose until there is a safer alternative is available.</td></tr>
</table>

Country or entity	Response
Suriname	Suriname has no guidelines nor regulation nor legislation about unintentional trace contaminants in products and articles.
Switzerland	The legislation on chemicals (Chemicals Ordinance, ChemO, RS 813.11, http://www.admin.ch/ch/f/rs/c813_11.html) mentions "impurities" (= unintentional trace contaminants)" but does not provide a definition or more detailed information. The term impurity is mentioned in relation to: 1) A new substance is considered being composed of a single element if each impurity is less than 10%. If an impurity is > 10%, the substance must be considered to be a mixture. 2) When classifying a substance or mixture, dangerous impurities have to be taken into consideration for the classification if they exceed the concentration of classification (usually 0.1%). Concerning halogenated organic compounds, the Ordinance on Risk Reduction related to Chemical Products (ORRChem, SR 814.81, http://www.admin.ch/ch/f/rs/c814_81.html) mentions in its Annex 1.1: Halogenated organic compounds 1. Prohibitions 1.1 Substances and preparations It is prohibited to manufacture, place on the market, import in a private capacity, or use: a. halogenated organic compounds within the meaning of section 3 (i.e. POPs); b. substances and preparations that contain halogenated organic compounds within the meaning of section 3 that are not merely unavoidable impurities. We have no other experience in relation to "impurities" of chemicals.
Thailand	Thailand national regulation does not define unintentional trace contaminants in products and articles.
United Arab Emirates	1. How your national regulation defines unintentional trace contaminants in products and articles: We do not have regulations .Our NIP project will clarify this. 2. Your experience in applying this clause in practice: We do not have experience in applying it.
United States of America	Since the United States is not a Party to the Convention and the phase “unintentional trace contaminants” does not appear in EPA regulations, certain other terms applied in EPA regulations are reviewed below. **a. Industrial Chemicals** EPA does not have regulations that interpret the exact type of exemption in the Convention and hence does not have any experience in implementing the exemption. The term “de minimis” is often used to refer to a trace contamination level; however, there is no regulation which defines “de minimis” or “trace amount” as a certain amount for all regulatory purposes under TSCA. Currently, when EPA takes regulatory action under TSCA, EPA may also determine that it is appropriate to establish a de minimis concentration of the chemical substance, below which the regulatory action would not apply. The U.S. does have regulatory approaches in certain regulations for industrial chemicals that exclude "impurities" (note that "impurity" has no "trace" qualifier) and certain regulations have "de minimis"-type exemptions, where levels below a certain concentration are excluded (e.g., TSCA Sec. 12(b) export regulations and the Toxics Release Inventory (TRI) under the Emergency Planning and Community Right to Know Act (EPCRA) Sec. 313) regulations have an exemption that excludes chemicals below a certain percentage in products/mixtures). For example, the regulations at Title 40 of the Code of Federal Regulation (CFR) Sec. 704.3 (TSCA Sec. 8(a) Information Gathering rules reporting regulation), defines impurity as: “Impurity means a chemical substance which is unintentionally present with another chemical substance.” The regulation exempts from reporting anyone who manufactures, imports, processes, or proposes to manufacture, import, or process a substance identified in section 704.3 solely as an impurity is exempt from the reporting requirements of this part. **b. Pesticides** EPA requires information in support of a pesticide’s registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). The U.S. EPA’s regulations for the pesticide’s product chemistry data requirements can be found at Title 40 of the Code of Federal Regulations (CFR) §158.300-158.355.

Country or entity	Response
	Specifically: ♦ **40 CFR §158.300 (Definitions) This regulation** provides definitions for two relevant terms: • *Impurity* means any substance (or group of structurally similar substances if specified by the Agency), in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products. • *Impurity associated with an active ingredient* means: o Any impurity present in the technical grade of active ingredient; and o Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product. ♦ **40 CFR §158.320 (Product Identity and Composition)** This section requires submission of specific details of all parts of the pesticide's composition. Among other things, it requires the identification of impurities in Confidential Statements of Formula (CSFs) by name and amount. • §158.320(c) Impurities of toxicological significance associated with the active ingredient must be identified by name and quantity in the pesticide. US EPA determines on a case by case basis whether or not a pesticide can be registered when such impurities are present at the levels certified by the applicant. There is no minimum level below which such impurities must be reported. • §158.320(d) Other impurities associated with the active ingredient must be identified by name and quantity if they are present in any sample of the pesticide at concentrations of 0.1 percent or higher. • §158.320(e) Impurities associated with an inert ingredient. [Reserved]. ♦ **40 CFR §158.340 (Discussion of Formulation of Impurities)** An applicant for registration must provide a detailed discussion of the impurities that may be present in the product, and why they may be present. ♦ **40 CFR §158.345 (Preliminary Analysis) –** (1) If the product consists solely of the technical grade active ingredient (TGAI) or is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI (the Agency recognizes that this may not be appropriate for certain biological pesticides). The preliminary analysis of 5 batches (if batch production) or 5 samples (if continuous production) should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. (2) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted. ♦ **40 CFR §158.350 (Certified Limits) –** The applicant must propose certified limits for the ingredients in the product including impurities of toxicological significance. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date. The regulations at 40 CFR §§158.300-158.355 can be downloaded at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=013b05537f6069487ae3f2252ae1d5a0&rgn=div5&view=text&node=40:23.0.1.1.9&idno=40#40:23.0.1.1.9.4 The regulations at 40 CFR §158.320, §158.340, §158.345, and §158.350 are further described in EPA's Test Guidelines available at this website: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm

Country or entity	Response

Product chemistry requirement	EPA regulation citation	EPA's Product Properties Test Guideline citation
Product Identity and Composition	40 CFR §158.320	830.1550
Discussion of Formulation of Impurities	40 CFR §158.340	830.1670
Preliminary Analysis	40 CFR §158.345	830.1700
Certified Limits	40 CFR §158.350	830.1750

In the preamble to the final product chemistry regulations discussed above, EPA discussed the chemicals that could be impurities of toxicological concern and that must be reported to EPA regardless of the concentration present in a pesticide product. (53 Federal Register 15951, May 4, 1988.) In addition, EPA issued Pesticide Registration (PR) Notice 96-8 on 31 October 1996 entitled, "Toxicologically Significant Levels of Pesticide Active Ingredients." PR Notice 96-8 defines toxicologically significant levels of impurities that are active ingredients in other products. In the 1996 PR Notice, the EPA provided background information for evaluating the presence in a product of an active ingredient from another product based on the understanding that cross-contamination could occur in pesticide manufacturing facilities. However, since pesticide registrants are responsible for the composition of their products, the PR Notice identifies the levels at which discrete categories of active ingredients would be toxicologically significant as impurities, and provides guidance for registrants (i.e., those with registrations for formulating pesticide products) to take action once they become aware that their pesticide product contains a "toxicologically significant level" of such impurities. PR Notice 96-8 can be downloaded at: http://www.epa.gov/PR_Notices/pr96-8.pdf.

Annex III

Questions and answers related to the notion of unintentional trace contaminants in Commission Regulation amending Regulation (EC) No. 850/2004 on persistent organic pollutants to implement in European Union law the decisions of the Conference of the Parties of the Stockholm Convention at its fourth meeting

Commission Regulation (EU) No 757/2010 of 24 August 2010:

http://eur-lex.europa.eu/lexuriserv/lexuriserv.do?uri=oj:l:2010:223:0029:0036:en:pdf

This "Questions and Answers" was developed by the European Commission in 2010 in connection with the amendment to the EC regulation No.850/2004 on POPs to implement the decisions of the fourth meeting of the Conference of the Parties to the Stockholm Convention.

1. Questions:

Why do we now need to define a threshold for "unintentional trace contaminants"? How are we actually implementing the COP 4 decisions by doing this, since these decisions do not contain thresholds?

Answer:

The Convention and the POPs Regulation (cf. Art 4 (1) (b)) generally exempt "substances occurring as an unintentional trace contaminant in substances, preparations or articles". This notion is not applied in other pieces of EU chemicals legislation, which instead set fixed values below which a substance is not considered restricted. A fixed threshold facilitates uniform enforcement and control and provides legal certainty to economic operators.

The draft regulation aims to bridge the gap between the two approaches by using fixed thresholds as an interpretation of what is to be understood by an unintentional trace contaminant. The concrete threshold must be based on the specific properties of the restricted substance. The original 12 substances in the Convention were mainly pesticides while the COP4 decisions contain substances used in consumer products. An interpretation is therefore needed. The thresholds are an interpretation of the Convention that fits into an EU law context.

The Commission has asked the Convention Secretariat to consider the challenges that will inevitably arise when implementing the notion of "unintentional trace contaminants". However, the Convention could not provide an answer in time for the draft regulation, as only the 2011 COP would be able to take a decision to start the work.

2. Question:

Reference is made in Annex I (both for PBDEs and PFOS entries) to 'preparations' which is defined in Regulation 850/2004 with a link to Article 2 of Directive 67/548. Is this definition still acceptable or has the term "mixtures" now taken over (as per Regulation 1272/2008)? If the latter is the case, is there any legal issue if "preparation" remains in use?

Answer:

The POPs and Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH[1].) originally contained the term "preparation" (cf. Art. 2 (d) and Art 3 (2) respectively). However, the formulation in REACH was later amended through Regulation (EC) 1272/2008 (CLP) pursuant to Art. 57 (11) where after "preparation" and "preparations" are replaced by "mixture" or "mixtures". No similar changes have been made to the POPs Regulation, hence the term "preparation" remains.

3. Question:

The threshold concentration for substances and preparations was lowered to 10 mg/kg (0.001 % by weight) in POPs Regulation compared to 1000 mg/kg (0.1 % by weight) in Annex XVII to REACH. Why was the threshold lowered?

[1] OJ L 396, 30.12.2006, p.1.

Answer:

The threshold for PBDEs is introduced in the draft regulation as an interpretation of unintentional trace contamination for which a general exemption is given in Article 4(1)(b). The threshold of 0.1% specified in Annex XVII of REACH is too high to be credibly considered as an unintentional trace contamination.

4. Questions:

Why do we introduce a threshold of 0.1% for new materials manufactured from recycled materials?

Answer:

Derogation 2 (a) for "articles containing concentrations below 0.1% of [tetra-, penta-, hexa- or hepta]-bromodiphenyl ether by weight when produced from recycled materials" is introduced to allow continuation of recycling of materials (including materials not within the scope of Directive 2002/95/EC) as the threshold for the flame-retarded parts of articles produced from non-recycled materials was lowered to 0.001%.

It was recognised by the COP that recycling of plastic would become a special challenge when adding the PBDEs to the list of prohibited substances. Parties are therefore allowed to have special provisions in this regard, see also the Q&A for Annexes IV and V.

5. Question:

Annex I, exemption 2(a): regarding the respective entries for Tetra, Penta, Hexa & Hepta BDEs, whilst it is acknowledged that the language used (such as 'recycling') is aligned with the respective 'COP4 Decisions', should this exemption 2(a) not only apply to 'recycling' but also to 'preparing for reuse' activities that are higher up the waste hierarchy as per Directive 2008/98 on Waste? Should this exemption 2(a) also extend to 'recovery' activities, for example: R2, R5?

Answer:

The distinction in the text between the general rule and the rule applicable for recycled articles is made to protect the continued recycling in the EU i.e. by maintaining the current restrictions already in place in the EU by virtue of REACH Annex XVII. Since paragraph 2 of the relevant entries for the PBDEs in fact covers "*production, placing on the market and use*," the entire waste handling phase is assumed to be covered by the derogation.

The proposal is in conformity with the corresponding COP4 decisions. Reuse is not covered by the said decisions and most therefore be assumed to be covered by the general obligations.

6. Question:

The threshold concentration for substances and preparations was lowered to 10 mg/kg (0.001 % by weight) in POPs Regulation compared to 50 mg/kg (0.005 % by weight) in Annex XVII to REACH. Why was the threshold lowered?

Answer:

The threshold was lowered to rule out the intentional use of PFOS-related substances, as there is evidence to suggest that PFOS-related substances might be intentionally used at concentrations very close to or even below the previous threshold of 0.005% in preparations.

Information on concentrations used in preparations and articles can be found in the draft Guidance on alternatives to PFOS and its derivatives. The draft guidance was prepared by a contractor for the Stockholm Convention Secretariat and has been made available to CAs via CIRCA. The document for example states:

- *A PFOS derivative often used in cleaning agents, floor polish and auto polish products has been potassium N-ethyl-N-[(heptadecafluorooctyl)sulfonyl] glycinate (CAS-no. 2991-51-7). The concentration of that substance in the final product was in general between **0.005% and 0.01%** but might have been ten times higher.*
- *PFOS derivatives have had several historical uses (before year 2000 about 18% of the PFOS use in EU) in coating, paint and varnishes at reduction of surface tension, for example for substrate wetting, levelling, as dispersing agents, and for improving gloss and antistatic properties. They can be used as additive in dyestuff and ink, e.g. as foam generators. Furthermore, they can be used as pigment grinding aids or as agents to combat pigment flotation problems. The concentrations used were **below 0.01%** (w/w)*

- *According to information from the OECD 2006 survey sulfluamid was used in insecticides at a concentration of **0.01-0.1%** at an annual volume of up to 17 tons.*

7. Question:

The threshold concentration for substances and preparations was lowered to 10 mg/kg (0.001 % by weight) in draft regulation compared to 50 mg/kg (0.005 % by weight) in Annex XVII of REACH. Is there a standard currently available for testing below this new threshold?

Answer:

Currently there is no adopted standard analytical method for testing of PFOS-related substances in preparations or articles. However, in 2006 the Commission mandated CEN to develop such a method. The technical specification has been prepared and is expected to be adopted in spring 2010. It will describe a method applicable for analyses and it can already be applied today. However, before the method is an official standard it must still be tested in an inter-laboratory comparison which is expected to take some 1-2 years.

The Commission has consulted the task force of CEN in charge of the mandate and it has confirmed that the analytical method described in the technical specification can be used for the proposed lower threshold of 0.001%.

8. Question:

Are there any uses of PFOS in articles below the thresholds specified in the draft regulation and why were the thresholds for articles not lowered compared to Annex XVII of REACH as was done for preparations?

Answer:

There are some indications of uses of PFOS-related substances below the thresholds specified e.g. certain medical devices such as in vitro diagnostic kits and colour filters for endoscopes, but the Commission has never seen any written evidence.

The draft Guidance on alternatives to PFOS and its derivatives prepared by a contractor for the Stockholm Convention Secretariat, in question 16, states:

- *Historical uses of PFOS in electric and electronic parts include belts and rollers in printers and copying machines. For most of these not well-known uses, alternatives are available or are under development. However, several uses have been identified by industry, for which alternatives will not soon be available. One such use is in the intermediate transfer belt and PFA rollers of colour copiers and printers. Intermediate transfer belts contain up to **100 ppm** of PFOS, while PFOS in the amount of **8×10^{-4} ppm** is contained in an additive used in producing PFA rollers.*
- *Video endoscopes are used to examine and treat patients at hospitals. Around 70% of the video endoscopes used worldwide or about 200 000 endoscopes contain a CCD[2] colour filter that contains a small amount of (**150 ng**) PFOS. According to submission from the Japanese delegation, repairing such video endoscopes requires a CCD colour filter containing PFOS.*

The thresholds for articles were not lowered in the draft regulation because:

- It is not clear what the lowest possible effective concentrations really are;
- the CEN task force in charge of the mandate to develop an EU standard method which complies with the limit values of PFOS in preparations and in articles responded that the method currently under preparation cannot be applied for lower concentrations in articles;
- unknown impacts on the recycling sector.

More information is needed to be able to set new, lower thresholds. The Commission will launch a project to identify the appropriate thresholds. This may eventually lead to a revision of the current proposal.

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[2] Charge-coupled-device = technology for capturing digital images