QUESTIONS & ANSWERS

REGARDING A DRAFT COMMISSION REGULATION AMENDING REGULATION (EC) NO 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON PERSISTENT ORGANIC POLLUTANTS AS REGARDS ANNEXES I AND III

This document aims to cover some of the most relevant questions that may arise in relation to the draft proposal to implement the COP4 decisions in Union law. Some important considerations and choices reflected in the proposal are not necessarily included in the text, as there is no "Explanatory Memorandum" and the recitals are meant to cover only what is strictly speaking covered by the legislative proposal.

Disclaimer: This document reflects the Commission services' current thinking on the issues raised. Member State representatives and POP CAs are invited to take note of the content of this document.

GENERAL

1. Questions:

What is the legal framework for the draft regulation?

Answer:

The draft regulation amends Regulation (EC) No 850/2004 on POPs (hereinafter referred to as "the POPs Regulation"). The POPs Regulation implements in Union law the international commitments expressed in the Stockholm Convention and in the UN-ECE POPs Protocol. The key provisions particularly relevant for the draft regulation are Articles 3 (control of production, placing on the market and use), 4 (exemptions from control measures) and 7 (waste management).

The POPs Regulation and the Convention list substances in different Annexes (Annex I, prohibition; Annex II, restriction, Annex III unintentional releases). The Regulation's remaining Annexes (IV and V on waste management) are not in the Convention but are necessary for the transposition of the obligation that flows from the listing of substances to the Convention.

Substances subject to prohibition or restriction are not allowed to be produced, used, imported or exported. The Convention does allow exemptions from the restrictions for those uses expressly listed in the Convention Annexes. The Convention Annex A can contain "specific exemptions". These exemptions can be open to specific Parties or to all Parties. A common feature is that they only remain valid for five years. The exemption can be renewed, subject to approval by the COP.

Annex B contains similar provisions, as well as exemptions for "acceptable purpose". The latter provision is open to all Parties and is available without predefined time limits.

2. 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.

3. 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.

4. Question:

Reference is made in Annex I (both for PBDEs and PFOS entries) to 'articles'. What is the definition of articles in this case? Should that be interpreted as in ROHS and WEEE where 0,1% is calculated on the homogenous material, i.e. not the whole product?

Answer:

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OJ L 396, 30.12.2006, p.1.

The term 'article' is defined in Art 2 of the POPs Regulation as "an object composed of one or more substances and/or preparations which during production is given a specific shape, surface or design determining its end use function to a greater extent than its chemical composition does". Article 3(3) of the REACH Regulation defines "article" as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition."

A definition is not set out in RoHS, however, in the Annex it is established that "For the purposes of Article 5(1)(a), a maximum concentration value of 0,1 % by weight in homogeneous materials for ... polybrominated diphenyl ethers (PBDE)... shall be tolerated."

There is no guidance on the interpretation of the "article" definition in the POPs Regulation, since the notion of "article" has been less relevant for the substances currently listed in Annex I (mainly plant protection products).

Once the draft regulation is adopted, the Commission and the POP CAs can consider if there is a need to develop guidance on the term "article" in the POPs Regulation. In this regard it must be borne in mind that the PBDE derogation does not refer to "articles" but to the "flame-retarded parts of articles" and for PFOS the prohibition of articles applies to the "mass of structurally and micro-structurally distinct parts that contain PFOS" or for textiles or other coated materials to the surface of the coated material. The interpretation of the mass of structurally and micro-structurally distinct parts is the same as under REACH².

THE POPS REGULATION AND REACH

5. Question:

What will happen with substances already listed in REACH Annex XVII that will be listed in the POPs Regulation?

Answer:

Substances already listed in REACH Annex XVII that will be listed in the POPs Regulation will be removed from Annex XVII by a separate amendment to REACH. Having two different restrictions in force at the same time covering the same substances would lead to legal uncertainty. The Commission therefore intends to adopt, in tandem with the amendments to the POPs Regulation, a revision of REACH Annex XVII so that pentaBDE and PFOS in the future are restricted / prohibited exclusively by the POPs Regulation.

The Commission is currently working on the REACH Annex XVII proposal, which will be subject to a later vote in the REACH Committee.

PBDES ENTRY

6. Question:

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² http://ec.europa.eu/enterprise/sect<u>ors/chemicals/files/reach/restr_faq_jan_2010_en.pdf</u>

Why do we list the PBDEs differently from in the COP 4 Decisions and REACH Annex XVII and why is octaBDE not added to the draft regulation?

Answer:

The PBDEs are listed in the draft regulation using the same approach as in REACH Annex XVII, i.e. using the chemical formula. The popular names for the substances have been taken from the COP4 decisions as they more accurately describe what is covered by the formula than the wording used in REACH.

The basis for the COP4 decisions was the nominations. <u>Commercial</u> mixtures of octaBDE and pentaBDE were nominated, but during the evaluation it was proved that it was more correct and precise to list those of the individual congeners of the commercial mixtures that in fact were proven to meet the POPs criteria rather than just the commercial mixtures.

<u>Commercial</u> octaBDE will *de facto* be prohibited as it contains BDE-congeners meeting the POP criteria, e.g. heptaBDE. However, the specific octaBDE congener does not meet the POPs criteria in its own right. OctaBDE will continue to stay in REACH Annex XVII as it meets the PBT criteria.

7. 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?

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 <u>trace</u> contamination.

8. 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.

9. Question:

In Annex I and in exemption 1 for Tetra, Penta, Hexa & Hepta BDE's it states that: "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 or as constituents of the flame-retarded parts of articles. Are "articles" as such not covered (as is the case in REACH)?

Answer:

The Convention and the POPs Regulation use the term "prohibition" of POP substances listed in their respective Annex I (or A). In some cases, a POP substance can be present in an article, even if not intended. A special provision has been inserted that allows the presences of "unintentional trace contaminants" (UTC).

The Commission has not been able to find any written evidence to the justification for the provision. Taking into account that the majority of the listed substances are plant protection products for which the provision is of less relevance it is logical to assume that it probably more was intended to address problems with unintentional releases. For example dioxin can be present in the ambient environment and thus can contaminate a given product. This product may still comply with the POP Regulation as the dioxin is there without it being the <u>intention</u> of the manufacture and assuming that it is only present in quantities equal to <u>traces</u>.

Therefore, in the context of the Convention, and consequently also the POPs Regulation, the distinction between "article" and "the flame retardant parts of articles" is of insignificant relevance as a given substance must not be present except if it exists as described above.

The draft regulation aims to supplement the above with supporting provisions in order to facilitate uniform enforcement and control within the EU by setting a fixed threshold determining when a substance can be considered only present as a trace contaminant. The justification for this provision is further reinforced by the fact that the relevant substances are already restricted in the EU with such fixed thresholds.

The REACH Annex XVII restriction on pentaBDE applies equally to "articles and flame retardant parts thereof". However, the Commission is of the view that the term "flame retardant parts of articles" in fact achieves the same result, assuming that the substance can only be used as a flame-retardant.

10. 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.

PFOS ENTRY

11. Questions:

Why do we put PFOS in Annex I and not in Annex II?

Answer:

The COP4 decided to list eight of the substances in Annex A (elimination) to the Convention. Perfluorooctane sulfonic acid and its derivatives 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 in Annex I (prohibition) and Annex II (restriction).

The placing on the market and use of PFOS is restricted in the Union by virtue of Annex XVII to REACH. The existing restriction on PFOS in the Union contains only a 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.

12. Question:

Why is the wording of the PFOS definition different from the one in Annex XVII to REACH?

Answer:

The term "Perfluorooctane sulfonates (PFOS) C8F17SO2X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers" was replaced by "Perfluorooctane sulfonic acid and its derivatives (PFOS) C8F17SO2X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers".

The change has no effect on the scope of the prohibition. In Annex XVII, the term "perfluorooctane sulfonates" also included the acid (molecular formula C8F17SO2OH), which is not strictly correct according to the chemical nomenclature. With this amendment of the POPs Regulation, the relationship between the names and the associated molecular formulas is made clearer (i.e. "perfluorooctane sulfonic acid" is the name attributed to chemical formula "C8F17SO2OH" and "its derivatives" is a general name attributed to "Metal salt (O-M+), halide, amide, and other derivatives including polymers".

13. Question:

How is the new PFOS definition to be interpreted and how are the limits of concentration to *be calculated?*

Answer:

The definition is to be interpreted and the limits of concentration are to be calculated the same way as under REACH³:

The definition covers any substance containing the PFOS moiety (C8F17SO2) with the potential to degrade to the anionic form C₈F₁₇SO₃ in the environment. These substances include the acid form of PFOS, the metal salts and the halides of PFOS and the amides. Polymers including the PFOS moiety are also within the scope of the entry.

The limit values in the entry mean the concentration of extractable PFOS measured with CEN methods and expressed as the corresponding amount of PFOS acid.

Official controls for the enforcement of the limits mentioned in the entry will make use of CEN standards (currently under development). The limits in the entry will therefore eventually mean the PFOS content as measured by the CEN methods. The analytical methods under consideration by CEN are Liquid Chromatography/Mass Spectroscopy (LC/MS) for anionic PFOS species, and Gas Chromatography/ Mass Spectroscopy (GC/MS) for non-ionic PFOS species. As both methods require liquid samples, for semi-finished products and articles, solvent extraction of PFOS will be required and a CEN method for this will be developed. The extracted PFOS species are expected to be mainly anionic, but non-ionic species may also be present in the liquid samples.

In practice, samples may well contain several PFOS species and they must all be taken into account in calculating the total PFOS concentration. However, the molecular weights of the various PFOS species in a sample can cover a wide range of values. Aggregation of the amounts of the different species is therefore best achieved by first calculating the corresponding amounts of a reference species, i.e. PFOS acid C8F17SO3H.

14. Questions:

Why do we have the notion of "microstructurally distinct parts" for PFOS and what does it refer to?

Answer:

The notion of "the mass of structurally and microstructurally distinct parts" was taken over from the provisions of Annex XVII to REACH.

The interpretation of this term should be the same as under REACH⁴: The PFOS entry in Annex XVII places various limits on the concentration of PFOS in substances, in mixtures,

³ http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/restr_faq_jan_2010_en.pdf

⁴ Questions and agreed answers concerning the implementation of Annex XVII to REACH on the restrictions on the manufacturing, placing on the market, and use of certain dangerous substances, mixtures and articles, Version 2, 22 January 2010, http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/restr_fag_jan_2010_en.pdf

articles, semi-finished products, textiles and coated materials in order to protect the environment. For example, paragraph 2 reads as follows:

"2. Shall not be produced, placed on the market or used in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or greater than 0,1 % by weight calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or greater than $1 \mu g/m2$ of the coated material."

One of the principal uses of PFOS in articles, semi-finished products, textiles and coated materials is in surface coatings. Risk reduction measures must therefore target the release of PFOS to the environment from surface coating, either during use or at the end of the service life. This is to be achieved by limiting the concentration of PFOS in such layers, which may be invisible to the naked eye, and can only be seen with the aid of a microscope. It follows that the limit on the concentration of PFOS in coated articles should not be calculated in relation to the entire article, but rather in relation to that part of the article that contains the PFOS.

The terms "structurally or microstructurally distinct part" were introduced as a generic way of referring to the part of the article that contains PFOS, and which is intended to avoid uncertainties that might arise by referring simply to, for example, "articles or parts thereof".

PFOS in small parts

For example, a car is an article, but an electronic item in a car – e.g. the radio – can arguably be considered to be either an article in its own right, or to be a part of the car. Furthermore, an integrated circuit used in a car radio is a part of an article when installed in the radio, but the same integrated circuit was an article in its own right when first placed on the market. Clearly, none of these distinctions is of any relevance to the release of PFOS into the environment. What is important is the concentration of PFOS in the integrated circuit. The integrated circuit can be extracted from the radio, so it is a **structurally distinct part**. The PFOS concentration should therefore be calculated with reference to the mass of the smallest structurally distinct part i.e. to the mass of the integrated circuit, not to the mass of the radio, nor to the mass of the car.

PFOS in coatings other than textiles

The above considerations also apply to PFOS in coatings as well as to PFOS in small parts. However, the coatings are not structurally distinct in the sense that they cannot be easily separated from the substrate. Nevertheless, they are **microstructurally distinct** in the sense that they can be identified when a cross-section of the coated surface is viewed though a microscope.

PFOS in textiles

Coatings on textiles usually concern mainly the surface fibres. Each of the surface fibres could be considered either to be a **structurally distinct part**, or the coating on each fibre could be considered to be **a microstructurally distinct part**, as described above. However, analysis for control purposes using either of those two approaches would be difficult to achieve in practice. The analysis is therefore simplified by calculating the concentration per square meter using sampling, extraction and analysis methods developed by CEN.

15. 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.
- o 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.

16. 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%.

17. 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:

- O 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.
- O 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 CCD⁵ 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:

- o It is not clear what the lowest possible effective concentrations really are;
- o 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;
- o 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.

18. Question

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REACH currently permits articles in use before 27^{th} June 2008 to remain on the market. The POPs Regulation Article 4 (2) has a similar provision allowing articles in use before entry in force (May 2004) – subject to notification if such articles are found to be in use. Is it correct that this is also applicable to the new additions, with obviously the August entry into force date? If this is the case, if the articles are found on the market (pre-June 2008 articles), do

⁵ Charge-coupled-device = technology for capturing digital images

such articles have to be notified to the Commission (in view of the wider exemptions for PFOS in the Convention whereby such articles may not have to be notified to the Convention Secretariat)?

Answer:

Yes, the provision allowing articles already in use (in this case before August 2010) remains applicable to the new entries. The notification obligation will apply equally regardless of the provisions in the Convention. Such information is useful in identifying sources of contamination and minimizing contamination via recycling.

REGARDING A DRAFT COMMISSION REGULATION AMENDING REGULATION (EC) NO 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON PERSISTENT ORGANIC POLLUTANTS AS REGARDS ANNEXES VI AND V

1. Question:

We are concerned that in the Stockholm Convention listing there is no derogation for the recycling of PFOS as there is for BDEs. However, recital (6) of the draft regulation amending the POP Regulation presumes that we have this. Can you clarify to us your position on this as it seems that we are relying on a derogation to allow the continued recycling of PFOS containing articles, when this would be in breach of our international obligations. The concentration should be equivalent to "unintentional trace contaminants".

Answer:

Article 6.1 of the Stockholm Convention stipulates that "In order to ensure that stockpiles (...) and wastes, including products and articles upon becoming wastes, consisting of, containing or contaminated with a chemical listed in Annex A, B or C, are managed in a manner protective of human health and the environment, each Party shall (...) (d) Take appropriate measures so that such wastes, including products and articles upon becoming wastes, are: (i) Handled, collected, transported and stored in an environmentally sound manner; (ii) Disposed of in such a way that the *persistent organic pollutant content is destroyed* or irreversibly transformed (...) *or otherwise disposed of* in an environmentally sound manner *when* destruction or irreversible transformation does *not* represent the *environmentally preferable* option *or the persistent organic pollutant content is low* (..); (iii) Not permitted to be subjected to disposal operations that may lead to recovery, recycling, reclamation, direct reuse or alternative uses of persistent organic pollutants;"

This means that for wastes with a low POP content, other options than destruction or irreversible transformation are allowed. This principle was kept when drafting the POP Regulation (Article 7.4 (a)) and applies to *wastes containing any kind of POPs* – and not just to wastes containing PFOS and BDE. By contrast, as regards *POP substances*, Article 7.3 stipulates that operations leading to recycling, recovery or reuse of the POP substances shall be prohibited (e.g. in cases a process leads to a separation from a POP substance from the rest of the waste, the POP substance has to be destroyed (or irreversibly transformed)).

2. Question:

In Article 7 of the POP Regulation the derogation in Article 7.4 is related to Article 7.2 only and not to Article 7.3. Therefore, there can be no derogation from Article 7.3 which states:

'Disposal or recovery options that may lead to recovery, recycling, reclamation or re-use of the substances listed in Annex IV shall be prohibited'. So in effect, despite the derogation in Annex IV to allow recycling, this would still be prohibited in the body of the Regulation.

Answer:

A distinction has to be made between the POP substance and wastes containing POPs.

- 1. POP substances have to be destroyed or irreversible transformed (Article 7.3).
- 2. For wastes containing POPs, Article 7.2 lays down a general rule, according to which these wastes should be treated in such a way that the POP content is destroyed (or irreversibly transformed). However, by way of derogation from Article 7.2, Article 7.4 (a) stipulates that for wastes with a low POP content (i.e. below the concentration limits set in Annex IV), other treatments leading to a destruction of the POP content or not are possible. This means e.g. that plastic wastes containing POPs below the concentrations defined in Annex IV can be recycled. It has to be noted that Article 7.3 is also applicable to wastes containing POPs: this means that operations aimed at recovering POP substances (contained in the wastes) are explicitly forbidden.

It can be concluded that destruction of all wastes containing or contaminated by POPs regardless of the concentration of the POPs in the wastes is not required by the POP Regulation. In line with Article 6.1 d (ii) of the Stockholm Convention, POP containing wastes "may be otherwise disposed of [i.e. by operations not leading to destruction] in an environmentally sound manner when (...) the persistent organic pollutant content is low".

3. Question:

Is the Commission satisfied that Article 7.3 of the POPs Regulation will permit the recycling for example of WEEE plastics containing BDEs? In other words, does Article 7(3) apply only to the POPs and not the waste stream containing the POPs per se?

Answer:

Article 7.3 reiterates the prohibition to intentionally recover, reclaim, recycle or re-use POP substances. Article 7.3 applies to the *POP substance*. This means in practice that recycling of *WEEE plastic wastes with a BDE content below the threshold* to be established in Annex IV will still be possible.

4. Question

Recital (6), page 3 appears to imply that by not including concentration limits in Annexes IV & V that the recycling of articles containing PFOS is permitted. Does this mean that a Member State Competent Authority (MS-CA) can apply 'concentration limits' or technical requirements to allow recovery in line with relevant Union legislation? If the MS-CA does not specify these requirements, does this mean that articles containing PFOS (which can continue to be used if on the market pre-June 2008) when they become waste must therefore be destroyed?

Answer:

From a legal point of view, in the absence of a concentration limit, the default concentration limit would be equal to zero. A similar situation (absence of concentration limits) occurred when the POP Regulation was adopted in 2004. Some MS-CA *applied* 'concentration limits' for a transitional period until concentration limits were set at EU level (as foreseen in Article 7.4(a)).

A study has been launched aimed at providing data for setting concentration limits for the new POPs. The interim report containing first results will be available and circulated to the MS in August and will be discussed with the MS in a meeting in September. In order to ensure legal certainty, MS-CA could set or apply temporary concentration limits. Based on the results of the interim report of the study, the Commission will *recommend* the concentration limits that cand be applied by the MS-CA.

Once the results of the study have been discussed with the MS, the procedure for a new amendment of the POP Regulation will be launched, so as to include the concentration limits for the new POPs.

5. Question

Recital (9): For those substances for which no limit values have been set in Annexes IV & V, does this mean the MS-CA can apply limits/technical requirements to allow wastes be 'otherwise dealt with'?

Answer:

Yes. The MS-CA can set or apply temporary concentration limits/technical requirements to allow wastes be 'otherwise dealt with' until concentration limits are set in the POP Regulation (see question above). However, in order to avoid a confusion amongst authorities and industry and a potential market distortion, it would be convenient to have the same temporary concentration limits across the EU. To that end, the Commission will distribute the results of the study to the Member States and recommend the limit values to be applied by the CA-MS

6. Question:

Annex IV, PFOS entry, page 6: Does Article 7.3 of Regulation 850/2004 mean that if PFOS is 'recovered' or 'extracted' from a waste (such as a solvent?) arising from an 'acceptable purpose use', it cannot be reused for that 'acceptable purpose'?

Answer:

If "pure" PFOS is extracted from a waste, according to Article 7.3 it will have to be destroyed or irreversibly transformed. This may be in contradiction with the acceptable uses foreseen in the amendment as regards Annexes I and III. However, Article 7.3 leaves no room for other interpretations. In order to allow recovery or re-use of PFOS for acceptable purposes, an amendment by Co-decision procedure would be required.

7. Question:

Recital (7), page 3 implies that Regulation 850/2004 will be amended to take on board the Part IV requirements of the Stockholm Convention COP4 Decisions. Is this correct? If so,

what timelines are envisaged? By not including any limits, does this mean that the MS-CA can apply technical requirements to allow recycling in line with Community legislation? If the MS does not specify those requirements, does this mean that articles containing BDEs (which can continue to be used if placed on the market pre-August 2004 & the RoHS Directive's scope permits the use of spare parts containing Penta & Octa for the repair of EEE that was placed on the market prior to July 2006) must be destroyed once they become waste?

Answer:

Once the results of the study have been discussed and an agreement reached with the Member States, Regulation 850/2004 will be amended again (tentative timeline for the adoption: Q1 of 2011) including limit values for the new POPs. No additional measures in order to allow recycling of BDEs are intended. Once the present amendment enters into force and until concentration limits have been set for BDEs, CA-MS can set or apply concentration limits. Otherwise, the concentration limit can be interpreted as being zero, in which case wastes containing BDEs would have to be destroyed.

8. Question:

Does the study currently being performed on behalf of the Commission include an assessment of the impacts on current recycling and recovery schemes as a result of the application of any proposed limit values? Such an assessment should also address the application of any proposed temporary limit values.

Answer:

The study will include an assessment of the impacts (including economic implications) of any proposed measures (particularly concentration limits). The study will take into account waste and recycling issues, as well as diverging standards across the EU. The workshop to be held in September 2010 will allow reaching a consensus with the Member States on the concentration limits. Active participation of the Member States is highly appreciated.