UNITED
NATIONS

EP

United Nations
Environment
Programme

Distr.
GENERAL

UNEP/POPS/INC.4/4
30 December 1999

ORIGINAL: ENGLISH

INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR AN
INTERNATIONAL LEGALLY BINDING INSTRUMENT
FOR IMPLEMENTING INTERNATIONAL ACTION ON
CERTAIN PERSISTENT ORGANIC POLLUTANTS
Fourth session
Bonn, 20-25 March 2000
Item 4 of the provisional agenda*

ORGANIZATIONAL MATTERS: REPORT BY THE SECRETARIAT ON INTER-SESSIONAL WORK REQUESTED BY THE COMMITTEE

Analysis of the terms "de minimis contaminant", "constituent of article" and "closed-system intermediate"

Note by the secretariat

INTRODUCTION

1. At its third session, held in Geneva from 6 to 11 September 1999, the Intergovernmental Negotiating Committee considered possible general exemptions to the draft international legally binding instrument for implementing international action on certain persistent organic pollutants (POPs). In this regard, as recorded in paragraph 93 of the report of the Committee's third session (UNEP/POPS/INC.3/4), the Committee asked the secretariat to develop an analysis of the use of the terms: "de minimis contaminant"; "constituent of articles"; and "closed-system intermediate" as they might apply to POPs.

2. In response to that request, the secretariat has prepared the present analysis for the consideration of the Committee at its fourth session. The document is presented without prejudice to any other approach that the Committee may wish to consider.

* UNEP/POPS/INC.4/1.

3. The analysis takes into account the fact that these terms are being considered in the context of establishing general exemptions, meaning that they would apply to each chemical addressed by the POPs instrument, unless otherwise stated.

4. The present note begins with a review of the relevant discussions at the third session of the Intergovernmental Negotiating Committee and its related contact group. It then considers how those three, or similar, terms are defined and used in international agreements related to the management of chemicals, as well as in technical dictionaries and other resource materials. Because relevant references in international texts are limited in number, the note also takes into account the use of the terms in regional and national laws and regulations readily available in English. Consequently, most of the regional and national references are from Canada, the European Union and the United States of America.

5. Following the discussion of relevant international and national texts, the note considers the application of the three terms as possible general exemptions to a legally binding instrument on POPs.

6. The note does not attempt to provide a complete survey of all legal instruments containing the three terms; rather it provides pertinent examples in order to facilitate discussions in the Intergovernmental Negotiating Committee. Neither does it address the technical and scientific questions related to whether specific POPs could create a risk to human health or the environment when they are found as de minimis contaminants or as constituents of an article, or when being used as closed-system intermediates.

I. BACKGROUND

7. The request by the Intergovernmental Negotiating Committee for this analysis arose from the discussions, at the Committee's third session, in the contact group on paragraphs 1 and 2 of draft article D and its associated annexes. The contact group considered, inter alia, the issue of general exemptions. One representative submitted a text for consideration by the contact group and noted that the proposed exemptions could help to ensure that the instrument would be as cost-effective and legally workable for as many countries as possible (UNEP/POPS/INC.3/4, annex III, paragraphs 6-8).

8. As a result of its discussions, the contact group submitted a bracketed proposal to the plenary related to general exemptions, which stated that, unless otherwise specified in the Convention, paragraphs 1 and 2 of Article D should not apply to quantities of a substance, inter alia: "(b) Occurring as de minimis contaminants in products; (c) Occurring as constituents of articles manufactured or already in use as of the implementation date of the relevant obligation; [or] (d) To be used as a closed-system intermediate that is chemically transformed in the manufacture of other chemicals" (UNEP/POPS/INC.3/4, appendix to annex III).

II. USE OF THE THREE TERMS IN OTHER INSTRUMENTS

A. "De minimis contaminant"

1. Definitions

9. The precise term "de minimis contaminant" has not been found in a relevant international legal instrument. The term "de minimis" is Latin and means "of minimum importance". 1/ The term "de minimis noncurat lex" is used under the law to indicate that the law does not take notice of small or trifling matters. 2/

10. The term "contaminant" has been defined in chemicals and other environmental regulations to mean a substance or material that enters a system (the environment, human body, food, etc.) where it is not normally found. 3/ It can include any kind of substance or material, e.g., a gas, liquid or solid, an odour, an organism, energy or a combination of contaminants. 4/ It is sometimes used to imply that the substance has an adverse effect on the environment. 5/

11. The 1998 Protocol to the 1979 Convention on Long-range Transboundary Air Pollution on Persistent Organic Pollutants, prepared under the auspices of the United Nations Economic Commission for Europe (ECE) (hereinafter referred to as the "POPs Protocol") represents an important reference document for the Committees' consideration of general exemptions: it addresses the same target chemicals as those addressed by the Committee; it is one of the most recent international instruments dealing with hazardous chemicals; and, in paragraph 10 of its decision 19/13 C, the Governing Council recommended that due consideration be given to the Protocol during the negotiation of the global instrument on POPs.

1/ Latin-English Dictionary (Http://hermes.arts.cuhk.edu.hk) (Research Institute for the Humanities, the Chinese University of Hong Kong). Law.com: On-line Legal Dictionary: (http://dictionary.law.com) (NLP IP Company, 1999)

2/ Black's Law Dictionary (Seventh edition, 1999).

3/ US Agency for Toxic Substances and Disease Registry: Glossary of Terms (http://www.atsdr.cdc.gov/glossary.html) (US Department of Health and Human Services, 1999).

4/ Queensland Consolidated Acts: Environmental Protection Act 1994, Section 11 (http://www.austlii.edu.au/).

5/ Environmental Dictionary About.Com http:/environment.about.com/culture/environment/library/weekly/blgloss3a.htm)(About.com, Inc. , 1999).

12. The POPs Protocol does not include relevant general exemptions in the main body of the text. In Annexes I and II, however, (containing the list of substances targeted for elimination or for restrictions on use, respectively), there is the following statement:

> "Unless otherwise specified in the present Protocol, this annex shall not apply to the substances listed below when they occur: (i) as contaminants in products; or (ii) in articles manufactured or in use by the implementation date; or (iii) as site-limited chemical intermediates in the manufacture of one or more different substances and are thus chemically transformed."

Neither the Protocol, nor the Convention on Long-range Transboundary Air Pollution, contains definitions of the terms used in this statement on exemptions.

13. It should also be recognized that the POPs Protocol does not apply the exemptions to the substances or groups of substances listed in Annex III as subject to reduction of emission (i.e., PAHs, dioxins/furans and hexachlorobenzene).

14. Notwithstanding the exemption in its article 7, the POPs Protocol contains a call for Parties to make determined efforts that are economically feasible to reduce levels of substances contained as contaminants in other substances, chemical products or manufactured articles, as soon as the relevance of the source has been established.

15. A related term - "trace contaminant" - has been used in some international instruments. For example, the Protocol for the Prevention of Pollution of the South Pacific Region by Dumping (1986) (hereinafter referred to as the Noumea Protocol) establishes an obligation on Parties to take all appropriate measures to prevent, reduce and control pollution in the Protocol Area by dumping. It prohibits dumping of wastes or other matter listed in Annex I except as otherwise provided. That annex establishes an exemption to the prohibition in the case where certain identified substances exist as trace contaminants. These trace contaminants are nevertheless subject to less restrictive regulation.

16. Another related term used in the context of chemicals control is "impurity". The 1982 Organisation for Economic Cooperation and Development (OECD) publication entitled Chemicals Control Legislation: An International Glossary of Key Terms (hereinafter referred to as the OECD Glossary) 6/ defines "impurity" as a chemical substance present with, but not intentionally added to, the desired substance or substances. The Glossary explains that this definition is intended to

---

6/ Chemicals Control Legislation: An International Glossary of Key Terms (Paris, 1982), OECD piblication.

identify chemical substances that may be subject to legal requirements because of their presence with a desired substance or substances. It further clarifies the definition by noting that impurity covers contaminants as well as substances that may be carried through or arise in the manufacturing process. 7/

17. Council Directive 88/364/EEC of the Council of the European Communities (hereinafter referred to as the Council Directive) seeks to protect workers against risks to their health by means of a ban on certain specific chemicals and/or certain work activities. 8/ The Directive defines "impurities" as "substances which are a priori present in insignificant amounts in other substances". It therefore incorporates by definition two characteristics of de minimis contaminants: unintentional and insignificant presence in another substance.

18. The Council Directive states that the ban does not apply to specific chemicals if these chemicals are present in a substance or a preparation in the form of impurities or by-products, or as a constituent of waste products, provided that their individual concentration therein is less than 0.1 per cent weight/weight.

19. The United States Regulations concerning: Reporting and Recordkeeping Requirements under Section 8 (a) of the Toxic Substances Control Act (hereinafter referred to as the TSCA Section 8 (a) Regulations)9/ define "impurity" as a chemical substance which is unintentionally present with another chemical substance. The regulations state that a person who manufactures, imports, processes, or proposes to manufacture, import or process a substance identified in this part solely as an impurity is exempt from the reporting requirements.

20. Two instruments related to the implementation of the Montreal Protocol on Substances that Deplete the Ozone Layer may also be relevant to the discussions in the Intergovernmental Negotiating Committee. In the proposal for a European Union regulation on substances that deplete the ozone layer, an exception to limits on controlled substances is made for "insignificant quantities of any controlled substance, originating from inadvertent or coincidental production during a manufacturing process... or from use as processing agent which is present in chemical substances as trace impurities". 10/

7/ OECD Glossary, p. 31.

8/ Council Directive 88/364/EEC of 9 June 1988 on the protection of workers by the banning of certain specified agents and/or certain work activities (Official Journal L 179 (9/7/1988), pp. 44-47.

9/ 40 CFR Part 704.

10/ Proposal for a Council regulation on substances that deplete the ozone layer (98/C 286/06) COM (1998) 398 final 98/0228 (SYN).

21. The 1998 Ozone-depleting Substances Regulations under the Canadian Environmental Protection Act 11/ address the application of the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer, as amended. The section on "Non-application" states that the Regulations 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."

2. Application of the term "de minimis contaminant" to POPs

22. In applying the term "de minimis contaminant" to POPs, it should first be recognized that the UNEP Governing Council specifically stated that the instrument being developed by the Intergovernmental Negotiating Committee would address unintentionally produced by-products and contaminants. The Governing Council decision 19/13 C incorporates, in paragraph 5, one primary characteristic of a contaminant, i.e., that it is part of a product or system that is inadvertent.

23. There are several examples of legal instruments in which "impurities" or "contaminants" are exempted from regulatory requirements. In others, impurities or contaminants are subject to controls - albeit, in some cases, less restrictive controls (including, for example, the Noumea Protocol, which maintains some controls for trace contaminants). The POPs Protocol provides for an exemption for contaminants in products, with respect to the substances in annexes I and II.

24. There are, however, no examples in other texts of the specific term "de minimis contaminant" and, therefore, no guidance on how such contaminants can be identified or quantified in practice. As indicated above, "de minimis" means of minimal importance, and, therefore, a de minimis contaminant implies, by definition, that the impacts of the contaminant should not be of concern. Several underlying questions remain, relating to what types and concentrations of contaminants should be considered "de minimis" remain. These include, inter alia:

(a) Whether trace contaminants (or impurities) consisting of POPs create a potential hazard to human health or the environment, taking into account manufacture, handling, use and disposal;

11/ Ozone-depleting Substances Regulations, 1998 (P.C. 1998-2251, 16 December 1998).

(b) Whether the levels at which contaminants are considered "de minimis" or not of concern could be identified, for example, in terms of an absolute level - e.g., ppm - or relative to a regulatory level;

(c) Whether it is useful to consider different approaches among different types or classes of POPs; and

(d) Whether it is technically and economically feasible to detect or control de minimis or trace contaminants.

B. "Constituent of article"

1. Definitions

25. In ordinary language, the term "constituent" means an essential part, component, or an element. 12/ "Article" has been defined, for the purposes of chemicals regulation, as a manufactured item specifically shaped or formed with a function depending on shape or design. 13/ Some definitions include the idea that the design is intended for specific end-uses. Certain definitions also specify that an article does not release, or result in exposure to, a hazardous material in normal use or that the chemical composition does not significantly change during end-use.

26. The OECD Glossary defines "article" as something fabricated to a specific form and states further that an article is a type of product that is usually not directly regulated under chemical control laws. It also notes in its summary analysis that articles can contain chemical substances and, as such, may be subject to certain legal requirements. 14/

27. As indicated above, the POPs Protocol exempts from regulation substances defined in Annexes I and II when they occur "in articles manufactured or in use by the implementation date", although the term "article" is not defined.

28. The International Labour Organization (ILO) Convention concerning Safety in the Use of Chemicals at Work defines "article" to mean "an object which is formed to a specific shape or design during its manufacture or which is in its natural shape, and whose use in that form is dependent in whole or in part on its shape or design." 15/ The Convention exempts from its controls articles which will not expose workers to a hazardous chemical

---

12/ Merriam-Webster Dictionary (http://www.m-w.com) (Merriam-Webster, Inc. 1999).

13/ Glossary of Common MSDS Terms (http://www.pp.okstate.edu/ehs/hazcom/) (Oklahoma State University, Environmental Health and Safety Dept., 1999).

14/ OECD Glossary, p.22.

15/ ILO Convention 170, Article 2(e).

under normal or reasonably foreseeable conditions of use. 16/ Thus, the exemption is limited to those cases where there is little or no likelihood of adverse consequences to human health.

29. The 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal does not define the terms "article" or "constituent of an article". It does, however, establish that wastes subject to control under the Convention include waste substances and articles containing or contaminated with polychlorinated biphenyls (PCBs), and/or polychlorinated terphenyls (PCTs) and/or polybrominated biphenyls (PBBs), as well as wastes having as constituents any of 27 identified substances or classes of substances listed in Annex I, unless they do not possess any of the hazardous characteristics identified in Annex III. Thus, the Basel Convention includes within its scope articles containing certain specified substances as constituents, except where no harm could result since they do not have hazardous characteristics.

30. Similarly, the 1991 Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa defines hazardous wastes for purposes of the Convention as including waste substances and articles containing or contaminated with PCBs, PCTs and or PCBs, and wastes having as constituents identified substances and classes of substances. Unlike the Basel Convention, it does not contain an exemption for such articles that do not have specified hazardous characteristics.

31. The 1987 Decision-Recommendation of the OECD Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls 17/ distinguishes between new uses of PCBs, on the one hand, and products, articles and equipment contaminated by PCBs, on the other. With respect to contamination by PCBs, member countries agreed to apply control measures to products, articles or equipment contaminated by PCBs in order to reduce contamination in such items to levels that do not endanger human health or the environment. 18/

32. The United States TSCA Section 8 (a) Regulations also contain a definition of "article", namely, "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or

---

16/ There are similar references in the ILO Code of Practice on Safety in the Use of Chemicals at Work.

17/ C(87)2(Final).

18/ The Act recommends that member countries ensure that, for contaminated fluids and soils, the level of contamination is not greater than 50 ppm.

design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design." 19/

33. These regulations exempt from reporting requirements a person who imports, processes, or proposes to import or process a substance identified solely as part of an article.

34. The use of the concept of a "constituent of a product" (rather than an "article") appears in the Chlorobiphenyls Regulations under the Canadian Environmental Protection Act 20/. These regulations prohibit the manufacture, process, use, offer for sale or import of chlorobiphenyls for specified commercial, manufacturing or processing uses. These include, inter alia, as a constituent of any product, machinery or equipment manufactured in or imported into Canada on or after 1 September 1977, other than electrical capacitors and electrical transformers and associated electrical equipment; and as a constituent of electrical capacitors and electrical transformers and associated electrical equipment manufactured in or imported into Canada on or after 1 July, 1980. An exemption exists when the chlorobiphenyls are unintentionally present in any product, machinery or equipment and the quantity of concentration of chlorobiphenyls in the product, machinery, or equipment is not inconsistent with good manufacturing practice.

B. Application of the term "constituent of article" to POPs

35. As indicated above, a constituent usually implies that the substance is meant to be part of the article, and not an unintentional component. In some cases, use of the term "article" implies that there is no release or exposure to a hazardous material in normal use of the article. There are examples, consequently, in which articles are exempted from control where the aim of the legislative instrument is to protect the user of the article.

36. In other instruments, including those that address hazardous waste, constituents of articles may be subject to controls in order to safeguard human health or the environment. Still other instruments exempt from some or all requirements only those articles containing controlled substances manufactured before a certain date.

37. In the case of POPs, there is a very broad-based concern, i.e., to protect workers and the general public (including users of the articles), as well as the environment. Thus, in establishing the scope of a legal instrument, consideration is given to the full life-cycle of the chemicals of concern from production, through use, handling,

---

19/ 40 CFR Part 704.

20/ Chlorobiphenyls Regulations (SOR/91-152, 21 February 1991).

transport and ultimate disposal.

38. Based on the examples given above, some questions arise including, e.g., whether:

(a) POPs which are constituents of articles may harm human health and the environment through exposure during production of the articles, use, handling or disposal; and

(b) It might be useful to distinguish between individual chemicals as constituents of articles, or between types of chemicals or articles.

C. "Closed-system intermediate"

1. Definitions

39. A closed-system intermediate is, by definition, a chemical that is consumed in the process of manufacturing a product or a substance, and which is not released to the environment. Specifically, "closed-system" has been defined as a chemical or biological system which does not exchange matter with the outside environment. Some definitions state that it might exchange energy with the surroundings; others state that energy is not exchanged in a closed system.21/

40. "Intermediate" has been defined in the following manner: "any chemical substance produced during the conversion of some reactant to a product. Most synthetic processes involve transformation of some readily available and often inexpensive substance to some desired product through a succession of steps. All the substances generated by one step and used for the succeeding step are considered intermediates." 22/

21/ The following sources were compared:

UK Pest Management Resource Centre, Pest Management Glossary (http://www.pestmanagement.co.uk/library/glossary.html) (DR Dent and R Allcott, 1996)

Gray Laboratory On-line Medical Dictionary (http://www.graylab.ac.uk) (Gray Laboratory Cancer Research Trust, 1999)

Biotech Life Science Dictionary http://biotech.icmb.utexas.edu) (University of Texas at Austin, 1999)

UK Statutory Instruments 1999 No 437 "The Control of Substances Hazardous to Health Regulations 1999" Part III Containment Measures for Industrial Processes.

22/ Encyclopedia Britannica (http://www.Britannica.com), 1999.

41. As previously noted, the POPs Protocol provides an exemption in Annexes I and II for "site-limited chemical intermediates in the manufacture of one or more different substances and are thus chemically transformed." It is not clear from the language of the POPs Protocol whether "site-limited chemical intermediates" would, when applied, be synonymous with "closed-system intermediate."

42. A related term used in some instruments is "feedstock". For example, it has been used in the context of the control of ozone-depleting chemicals. The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer defines production as "the amount of controlled substances produced, minus the amount destroyed by technologies to be approved by the Parties and minus the amount entirely used as feedstock in the manufacture of other chemicals. The amount recycled and reused is not to be considered as 'production'".

43. In the 1998 proposal for Council regulation on substances that deplete the ozone layer, "feedstock" is defined as "any controlled substance that undergoes transformation in a process in which it is entirely converted from its original composition". The proposal exempts from its regulations relating to placing on the market and use of controlled substances those substances used for feedstock or as a processing agent. 23/

44. In the Ozone-depleting Substances Regulations under the Canadian Environmental Protection Act 24/ "feedstock" is defined as "any controlled substance that is used and the molecular structure of which is transformed in the manufacture of another chemical substance". The regulations prohibit the manufacture, use, sale, import or export of controlled substances. There are limited exemptions for chemicals used as feedstock.

45. Some worker protection regulations address the issue of intermediates. For example, the 1971 ILO Benzene Convention, designed to limit exposure of workers to benzene and to products containing benzene (exceeding 1 per cent by volume) states that whenever harmless or less harmful substitute products are available, they shall be used instead of benzene or products containing benzene. It further states that this restriction does not apply to, inter alia, the production of benzene or the use of benzene for chemical synthesis. 25/

46. In addition, the ILO Benzene Convention calls on Parties to prohibit the use of benzene and of products containing benzene in certain work processes. It states that the prohibitions shall at least include the use of benzene and of products containing benzene as a solvent or diluent, except where the process is carried out in an enclosed system or where

---

23/ Proposal for an EU Council Regulation on substances that deplete the ozone layer. (98/C 286/06) COM (1998) 398 final 98/0228 (SYN).

24/ Ozone-Depleting Substances Regulations, P.C. 1998 - 2251 (16 December 1998).

25/ ILO Convention 136.

there are other equally safe methods of work. The Convention also states that work processes involving the use of benzene or products containing benzene shall as far as practicable be carried out in an enclosed system.

47. Council Directive 98/24/EC of the Council of the European Communities on the protection of the health and safety of workers from the risks related to chemical agents at work lays down the minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. 26/ Among the permissible reasons for derogation from the requirements is the production of certain chemicals for use as intermediates and for such use. The directive also states, in its article 9, that the exposure of workers must be prevented, in particular by providing that that the production and use of such chemicals agents as intermediates must take place in a single closed system, from which the chemical can only be removed to the extent necessary to monitor the process or service the system.

48. The United States laws related to new chemical notification also address the question of intermediates. The TCSA Section 8 (a) Regulations 27/ contain the following definitions of intermediate, non-isolated intermediate and enclosed process:

> "Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rate of such chemical reactions.
>
> "Non-isolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured.
>
> "Enclosed process means a manufacturing or processing operation that is designed and operated so that there is no intentional release into the environment of any substance present in the operation. An

26/ EU Council Directive 98/24/EC of 7 April 1998. Office Journal L 131, 5/5/98, pp11-23.

27/ 40 CRF Part 704.

operation with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases."

49. The section of the Regulations relating to "Exemptions" states that a person who manufactures or proposes to manufacture a substance identified in this part solely as a non-isolated intermediate is exempt from the reporting requirements of this part.

50. The United States TSCA Chemical Information Rules 28/ contain the same definitions for intermediate and non-isolated intermediate. They state that persons are not subject to certain reporting requirements if they manufactured or imported the chemical substance during the reporting period as a by-product, a non-isolated intermediate or an impurity.

2. Application of the term "closed-system intermediate" to POPs

51. Since the term "closed-system" implies that there will be no release to the environment, and "intermediates" are generally defined as substances consumed during a chemical process, the expectation is that chemicals which occur as closed-system intermediates should pose no risk to human health or the environment. A number of examples have been provided where chemical intermediates, feedstocks and chemicals in enclosed systems have been exempted from international and national requirements, including worker protection laws and reporting requirements.

52. Depending upon how the term is defined, however, there may be risks involved in the original production or importation of the intermediate, or as a result of an accidental release. It might also be necessary to consider whether distinctions should be made among the different POPs, or classes of POPs.

28/ 40 CFR Part 712.