

CRC-10/4: Short-chained chlorinated paraffins

The Chemical Review Committee,

Recalling Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for short-chained chlorinated paraffins submitted by Norway and Canada¹ meet the criteria set out in Annex II to the Rotterdam Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Recommends*, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties should list short-chained chlorinated paraffins in Annex III to the Convention as industrial chemicals;

4. *Decides*, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for short-chained chlorinated paraffins;

5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2, that the composition of the intersessional drafting group to prepare the draft decision guidance document for short-chained chlorinated paraffins and the workplan of the group shall be as set out in annexes II and III to the report of the Committee's tenth meeting, respectively.

Annex to decision CRC-10/4

Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Norway and Canada in respect of short-chained chlorinated paraffins meet the criteria of Annex II to the Rotterdam Convention

1. In reviewing the notifications of final regulatory action by Norway and Canada to ban the use of short-chained chlorinated paraffins (SCCPs) as industrial chemicals, together with the supporting documentation provided by those parties, the Committee confirmed that those actions had been taken to protect the environment (both notifications) and human health (the Canadian notification). The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

2. The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.10/6, UNEP/FAO/RC/CRC.10/INF/10 and UNEP/FAO/RC/CRC.10/INF/11.

I. Norway

(a) Scope of the notified regulatory action

3. The final regulatory action was taken for the category "industrial chemicals" to protect the environment. The use of SCCPs is banned by the final regulatory action, which states that production, import, export, sale and use of SCCPs in pure form, in preparations or in products containing > 0.1 per cent SCCPs is prohibited (UNEP/FAO/RC/CRC.10/6, annex I, sect. 2.1, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6, annex I, sect. 2.5.1).

(b) Annex II paragraph (a) criterion

¹ UNEP/FAO/RC/CRC.10/6, UNEP/FAO/RC/CRC.10/INF/10 and UNEP/FAO/RC/CRC.10/INF/11.

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

4. The Committee confirmed that the final regulatory action to ban SCCPs had been taken to protect the environment.

5. In Norway, SCCPs have mainly been used as softeners in paints, plastics, fillers and coatings, as flame inhibitors in rubber, plastics and textiles and as additives in other chemical substances and products. There has also been limited use in metal-working fluids as well as in certain lubricants and car care products. SCCPs are also used in leather processing; this was not known to be the case in Norway, however (UNEP/FAO/RC/CRC.10/6, sect. 1.7.2).

6. In the notification, various hazards to the environment are reported. These include high toxicity to aquatic organisms, slow degradation in the environment and a high potential for bioaccumulation. The negative long-term effects in the aquatic environment, the risk of secondary poisoning of predators through the food chain and the potential for long-range transport of SCCPs via air and water gave rise to serious concerns (UNEP/FAO/RC/CRC.10/6, sect. 1.8.3, 2.3, 2.4.2).

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- (i) Data have been generated according to scientifically recognized methods;*
- (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

7. Norway undertook research studies prior to the regulatory action and published the results in national reports and an international journal (Borgen et al., 2003). Furthermore, reference is made to the internationally recognized reports of the OSPAR Commission (OSPAR, 2001 and OSPAR, 2009) and the European Chemicals Bureau (ECB, 2000). As a European Environment Agency member State, Norway was involved in the process of preparing the European Union risk assessment report.

8. The Committee established that the data upon which the hazard identification and risk assessment were based originated from recognized testing methods, peer-reviewed literature and peer-reviewed scientific reports and were reviewed according to recognized scientific principles and procedures.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

9. Prevailing conditions in Norway have been taken into account. In a material flow analysis for SCCPs in Norway published by the Norwegian Pollution Control Authority SFT in 1999, data on production, use and emissions have been summarized (UNEP/FAO/RC/CRC.10/INF/10, pp. 222–226).

10. Risks for aquatic organisms have been identified in the European Union risk assessment report on SCCPs, which was published in 2000 (UNEP/FAO/RC/CRC.10/INF/10, pp. 3–176). In the draft OSPAR background document on SCCPs, monitoring data in ringed seal near Svalbard (belonging to Norway) from 1981 is reported, as well as in many other biota from Scandinavia and the Arctic (UNEP/FAO/RC/CRC.10/INF/10, pp. 204/205). Although this draft report was published in 2001, its content contributed to the Norwegian final regulatory action; this is evident because the draft report is mentioned in the relevant section of the notification and because it is likely that earlier drafts of the report were discussed between the OSPAR contracting parties such as Norway.

11. Further monitoring data on SCCPs from Norway are reported in the study by Borgen et al. (2003) and by SFT (1996, 2001 and 2002): samples of sediment from landfills were collected from six different parts of Norway. Samples of cod liver and blue mussels were collected from three different parts of the Oslofjord to indicate a spatial distribution of polychlorinated alkane (PCA) accumulation in these species. Furthermore, three samples of moss were analysed and indicated a potential for atmospheric spread of PCA. All samples were analysed for SCCPs. High concentrations of SCCPs in some sediments have been detected, presumably due to waste disposal from mechanical or shipping industry. These concentrations are in the same range as those from industrial areas of the United Kingdom.

12. The studies by SFT were in Norwegian only and were therefore not analysed in detail. However, tables from those studies show PCA measurements in various environmental samples. Norway confirms that the results published in the SFT study from 2002 and in the study by Borgen et al. (2003) were known before the final regulatory action was taken (UNEP/FAO/RC/CRC.10/INF/10, p. 2).

13. The Committee concluded that the final regulatory action was based on a risk evaluation involving prevailing conditions in Norway.

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

14. The final regulatory action states that production, import, export, sale and use of SCCPs in pure form, in preparations or in products containing > 0.1 per cent SCCPs is prohibited (UNEP/FAO/RC/CRC.10/6, sect. 2.2.1). In the notification and supporting documentation, data were presented on the import, export and use of SCCPs in Norway (UNEP/FAO/RC/CRC.10/6, sect. 2.5.3).

15. Since the regulatory action bans the use of SCCPs (UNEP/FAO/RC/CRC.10/6, sect. 2), it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

16. It is expected that since the regulatory action to ban the use of SCCPs significantly reduces the quantity of the chemical used, the risks to the environment will be significantly reduced.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

17. In the notification, reference is made to OSPAR and ECB reports (OSPAR, 2001, OSPAR, 2009 and ECB, 2000) and to OSPAR decision 95/1 (UNEP/FAO/RC/CRC.10/6, sect. 2.2.3). Both the OSPAR and ECB reports mention high concentrations of SCCPs in environmental media, e.g., in the Baltic Sea, Lake Ontario, in the United Kingdom, Germany, the Czech Republic and Sweden. Furthermore, SCCPs are recognized to be of possible concern with regard to long-range atmospheric transport (UNEP/FAO/RC/CRC.10/INF/10, pp. 136, 187, 188). Therefore, similar environmental problems are likely to be encountered in other countries. The Committee concluded that the relevance of the final regulatory action was not limited to Norway.

(iv) Whether there is evidence of ongoing international trade in the chemical;

18. In the notification, reference is made to an OSPAR report (OSPAR, 2009) that

states that in 2005 the usage of SCCPs in Sweden had decreased to 14 tonnes in 18 products (Kemi-Stat, 2008).

19. In France, several thousand tonnes were used in the beginning of the 1990s but only 222 tons in 2002; 147 tonnes were used for metal-working fluid, a use that was expected to end in 2004 (INERIS, 2005; see UNEP/FAO/RC/CRC.10/INF/10, p. 186).

20. Furthermore, it is stated in the notification that the use of SCCPs is allowed for research and analytical purposes (UNEP/FAO/RC/CRC.10/6, sect. 2.5.1).

21. In addition, information from the draft risk profile prepared by the Stockholm Convention's Persistent Organic Pollutants Review Committee indicates that SCCPs were used and traded internationally until 2010 (UNEP/POPS/POPRC.6/11/Rev.1, sect. 2.2.1).

22. The Committee concluded that there was evidence of ongoing international trade in SCCPs.

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

23. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

(f) Conclusion

24. The Committee concluded that the notification of final regulatory action by Norway met all criteria set out in Annex II of the Convention.

II. Canada

(a) Scope of the notified regulatory action

25. The final regulatory action was taken for the category "industrial chemicals" to protect human health and the environment. The use of SCCPs is banned by the final regulatory action, which states that all manufacture, use, sales, offering for sale or import of SCCPs or products containing them is prohibited, except for SCCPs incidentally present in a product or used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.1, 2.2.1 and 2.2.3).

(b) Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

26. The Committee confirmed that the final regulatory action to ban SCCPs had been taken to protect human health and the environment.

27. SCCPs were primarily used in Canada as extreme pressure additives in metalworking fluids. Products containing SCCPs, including paints, adhesives, sealants, rubber and plastics, could have been imported into Canada; the volume of such imports was believed to be small (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.3.1).

28. In the notification, hazards to human health are reported, including possible carcinogenicity (first Priority Substances List (PSL1) assessment) (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.4.2.1). In addition, the draft risk profile prepared by the Persistent Organic Pollutants Review Committee discusses the carcinogenicity of SCCPs (UNEP/POPS/POPRC.6/11/Rev.1).

29. In the supporting documentation, the latest follow up-report to the Priority Substances List assessment report (2008) concludes that SCCPs are entering, or may

enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).

30. In the notification, hazards to the environment are reported, including persistence in various environmental media and a high potential for bioaccumulation.

31. Based on the information available, it is proposed that SCCPs are entering the environment in quantities or concentrations or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (UNEP/FAO/RC/CRC.10/6, sect. 2.4.2.2).

(c) **Annex II paragraph (b) criteria**

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- (i) Data have been generated according to scientifically recognized methods;*
- (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

32. Canada undertook research studies prior to the regulatory action and published the results (Government of Canada 1993a, 2004, 2004a, 2008 and Environment Canada and Health Canada, 2008).

33. The Priority Substances List assessment report on chlorinated paraffins (Government of Canada, 1993a) provides an extensive review of international peer-reviewed literature. The report itself underwent international (external) peer review (UNEP/FAO/RC/CRC.10/INF/11, p. 34).

34. In the follow-up reports (Government of Canada 2004, 2004a and 2008), newer data on SCCPs were identified and the hazards of the substance were reassessed.

35. The Committee established that the data upon which the hazard identification and risk assessment were based originated from recognized testing methods, peer-reviewed literature and peer-reviewed scientific reports and had been reviewed according to recognized scientific principles and procedures.

- (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;*

36. Canada undertook research studies involving the prevailing conditions in Canada (Government of Canada 1993a, 2004, 2004a, 2008 and Environment Canada, 2008). Anthropogenic releases of SCCPs into the Canadian environment have been confirmed (UNEP/FAO/RC/CRC.10/INF/11, p. 163). SCCPs have been detected in environmental media in Canada, including air, wastewater effluents, surface waters and sediments, as well as in aquatic organisms (plankton, mussels, fish and marine mammals). Risk quotients for several organism groups in Canada were presented in the supporting documentation. The risk quotients compare toxicity data (estimated no-effect values) to estimated exposure values based on empirical data from Canada. In conjunction with the fact that SCCPs are considered to be both highly persistent and bioaccumulative, it was concluded that SCCPs might be causing long-term ecological harm in Canada (UNEP/FAO/RC/CRC.10/INF/11, pp. 160–163).

37. In the notification, hazards to human health are reported, including possible carcinogenicity (PSL1 assessment) (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.4.2.1).

38. In the supporting documentation, the latest follow-up report of the Priority Substances List assessment report (2008) concludes that SCCPs are entering, or may

enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).

39. The Committee concluded that the final regulatory action was based on a risk evaluation involving prevailing conditions in Canada.

(d) Criteria Annex II (c)

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

40. The notification of final regulatory action states that all use, sale, offer for sale or import of SCCPs, or a product containing them, is prohibited by the final regulatory action, unless the toxic substance is incidentally present, and therefore is expected to lead to a significant decrease in the quantity of the chemical used (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.1, 2.2.1, 2.3.1).

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

41. It is expected that since the regulatory action to ban the use of SCCPs significantly reduces the quantity of the chemical used, the risks to human health and the environment will also be significantly reduced.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

42. In the supporting documentation (Government of Canada 2008, sects. 4.2 and 4.3) reference is made to SCCPs being detected in environmental samples from various countries (Canada, the United Kingdom, Norway, the United States of America, Germany, the Czech Republic, Chile, Greece, Iceland, France and Sweden). Furthermore, the presence of SCCPs in remote Arctic regions suggests that long-range atmospheric transport of SCCPs is occurring (UNEP/FAO/RC/CRC.10/INF/11, p. 66). The task group concluded that the considerations that led to the final regulatory action being taken were applicable to a wide geographical area and circumstances.

(iv) Whether there is evidence of ongoing international trade in the chemical;

43. In the supporting documentation, it is stated that the total reported annual usage of chlorinated paraffins in Canada (production + imports - exports) was approximately 2.8 kilotonnes in 2000 and 2001. As production of chlorinated paraffins (CPs) in Canada has stopped, CPs are now imported into Canada as chemical formulations from foreign producers or as formulations in products such as paints, sealants, plastics and metalworking fluids (UNEP/FAO/RC/CRC.10/INF/11, pp.67 and 90).

44. The notification states that the use of SCCPs is allowed for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6, annex II, sect. 2.2.1).

45. Additionally, information from the draft risk profile prepared by the Persistent Organic Pollutants Review Committee indicates that SCCPs were used and traded internationally until 2010 (UNEP/POPS/POPRC.6/11/Rev.1, sect. 2.2.1).

46. The Committee concluded that there was evidence of ongoing international trade in SCCPs.

(e) Criterion Annex II (d)

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

47. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

(f) Conclusion

48. The Committee concluded that the notifications of final regulatory action by Norway and Canada met the criteria set out in Annex II to the Rotterdam Convention.

49. The Committee also concluded that the final regulatory actions taken by Norway and Canada provided a sufficient basis to merit including short-chained chlorinated paraffins in Annex III to the Rotterdam Convention in the industrial chemicals category and that a decision guidance document should be drafted on the basis of the notifications.