

CRC-10/5: Tributyltin compounds

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,

Taking into account the conclusion by the Chemical Review Committee that the notifications of final regulatory action for tributyltin compounds under the pesticide category submitted by Canada and the European Union met the criteria in Annex II¹ and recalling decision RC-4/5, by which the Conference of the Parties, having considered the recommendation of the Committee, decided to amend Annex III to the Convention to list tributyltin compounds as pesticides and adopted the decision guidance document for those substances,²

1. *Concludes* that the notification of final regulatory action for tributyltin compounds under the industrial category submitted by Canada³ meets 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 tributyltin compounds 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 tributyltin compounds for the industrial category by revising the decision guidance document adopted by the Conference of the Parties in decision RC-4/5⁴ to include information relevant to the industrial category;
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 revise the decision guidance document for tributyltin compounds 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-10/5

Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by Canada in respect of tributyltin compounds under the industrial category meets the criteria of Annex II to the Rotterdam Convention

1. In reviewing the notification of final regulatory action by Canada to severely restrict tributyltin compounds as industrial chemicals, together with the supporting documentation provided by Canada, the Committee was able to confirm that the final regulatory action had been taken to protect the environment. The notification from this party was found to meet the information requirements of Annex I 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.10/7 and UNEP/FAO/RC/CRC.10/INF/13. Information on ongoing international trade was provided by the European Union and made available in document

¹ UNEP/FAO/RC/CRC.2/20, annex II, section B.

² UNEP/FAO/RC/COP.4/10, annex V.

³ UNEP/FAO/RC/CRC.10/7, UNEP/FAO/RC/CRC.10/INF/13.

⁴ UNEP/FAO/RC/COP.4/10, annex V.

(a) Scope of the notified regulatory action

3. The notified regulatory action relates to tributyltin compounds and their use as industrial chemicals. The decision made was to severely restrict those uses (Prohibition of Certain Toxic Substances Regulations, 2012). This action was based on the results of a risk evaluation.

(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;

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

5. Tributyltin compounds have been used as industrial chemicals in the polyvinyl chloride (PVC) processing industry. Minor uses of products containing tributyltins include glass coating and catalysts, and tributyltins are present in tetrabutyltin compounds as a by-product.

6. The notification identifies uses that remain allowed under the severe restriction. The notification describes the specific risks and outlines that a severe restriction of industrial uses of tributyltin compounds significantly reduces the exposure of aquatic organisms. This is stated in section 2.4.2.2 of the notification (UNEP/FAO/RC/CRC.10/7) and supporting documentation (UNEP/FAO/RC/CRC.10/INF/13).

(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. A detailed review conducted by the Government of Canada concludes that tributyltin compounds are toxic to aquatic organisms at low concentrations and have a high potential to cause environmental harm due to their high persistence and bioaccumulative properties (Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List, 2009 (UNEP/FAO/RC/CRC.10/INF/13)). In the follow-up risk assessment, risk quotients were calculated on the basis of modelled as well as measured exposure and hazard data; this is an internationally applied methodology. There is an extensive list of references cited in the follow-up risk assessment document from a wide range of sources, including well-known international journals.

8. Thus, the Committee established that the data reviewed for the risk evaluation were generated according to scientifically recognized methods and that the data reviews were performed according to generally 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. The exposure was based, first, on concentrations of tributyltin compounds in water and sediment modelled for Canada, and, second, on measured concentrations of tributyltin compounds in water and sediment in Canada. It was concluded that estimated and measured concentrations of tributyltin compounds in Canada were high enough to

cause adverse effects in sensitive organisms. Furthermore, tributyltin compounds meet the criteria for persistence and bioaccumulation set out in Canada's national regulation, and high concentrations of tributyltin compounds in sediments are known to cause imposex (imposition of male characteristics on female organisms) in molluscs and appear to have the potential to induce sex reversal in some marine fish.

10. The risk evaluation took into account these modelled and measured exposure data in Canada and the ecotoxicological endpoints for tributyltin compounds and indicated a high risk to the most sensitive aquatic organisms. Therefore the Committee concluded that this criterion was met.

(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;

11. The final regulatory action severely restricts the use of tributyltin compounds as industrial chemicals, mainly in the polyvinyl chloride (PVC) processing industry. The severe restriction is expected to lead to a decrease in the quantity of the chemical used and consequently to a further reduction of the environmental risks associated with the use of tributyltin compounds as industrial chemicals.

(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;

12. Since the regulatory action will significantly reduce the contamination of the aquatic environment from tributyltin compounds, it is expected that it will lead to a significant reduction of the risk to the environment. Although persistence in the aquatic environment at some locations will result in elevated levels for some time, removing this source of input will allow recovery to occur.

(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;

13. Similar environmental exposure and risks are likely to be found in other countries where tributyltin compounds are used as industrial chemicals. Therefore, the relevance of the final regulatory action is not limited to Canada.

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

14. Information from the European Union on international trade in chemicals shows recent information on trade between European Union member States and other countries from 2012 to 2014 (UNEP/FAO/RC/CRC.10/INF/6).

(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.

15. There is no indication in the notification or supporting documentation that concerns about intentional misuse prompted the final regulatory action.

(f) Conclusion

The Committee concluded that the notification of final regulatory action by Canada related to the industrial uses of tributyltin compounds met the criteria set out in Annex II to the Convention.