



**Rotterdam Convention on the Prior
Informed Consent Procedure for
Certain Hazardous Chemicals and
Pesticides in International Trade**

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Chemical Review Committee

Tenth meeting

Rome, 21–24 October 2014

Item 4(c)(iii) of the provisional agenda*

**Technical work: Review of notifications of final regulatory actions:
Tributyltin compounds**

ADVANCE COPY

Tributyltin compounds: Notifications of final regulatory action

Note by the Secretariat

I. Introduction

1. Under Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the Secretariat has received at least one notification of final regulatory action regarding a particular chemical from each of two prior informed consent (PIC) regions that it has verified meet the requirements of Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be made subject to the Prior Informed Consent (PIC) procedure and be listed in Annex III to the Convention. In accordance with Article 7, for each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document.

2. The Secretariat has received six notifications relating to tributyltin compounds from three PIC regions, that meet the requirements of Annex I (Asia – Japan and Republic of Korea; Europe – European Union; and North America–Canada). Summaries of these notifications were included in PIC Circular XI, June 2000; PIC Circular XVII, June 2003; PIC Circular XX, December 2004; PIC Circular XXI, June 2005; PIC Circular XXII, December 2005; and PIC Circular XXXVIII, December 2013.

* UNEP/FAO/RC/CRC.10/1.

3. The notifications from the European Union and Japan had been considered by the Interim Chemical Review Committee at its fourth session, which agreed that the notification from the European Union was complete and had met all the criteria, while the notification from Japan did not meet those criteria. That information may be found in the report of the session.¹
4. At its first meeting, the Chemical Review Committee considered the notifications from the Republic of Korea and Japan (new submission) and agreed that both notifications had met the criteria of Annex II of the Convention with the exception of the criterion set forth in subparagraph (b) (iii) of that Annex².
5. The Chemical Review Committee at its second meeting considered a notification from Canada under the pesticides category and concluded that the notification of final regulatory actions by the European Union and Canada met the information requirements of Annex I and the criteria set out in Annex II to the Convention. It was recommended that tributyltin compounds should be included in Annex III to the Rotterdam Convention as a pesticide. The recommendation and draft decision guidance document were forwarded to the Conference of the Parties by the third meeting of the Chemical Review Committee³.
6. The Secretariat is forwarding a new notification from Canada on Final Regulatory Actions under the industrial chemicals category, for review by the Chemical Review Committee. The notification as it was received from the notifying Party is annexed to the present note.
7. The supporting documentation provided by Canada is set out in document UNEP/FAO/RC/CRC.10/INF/12. The verified notifications from European Union and Canada on tributyltin compounds under the category of pesticides and the rationale adopted by the Chemical Review Committee at its second meeting are available as annexes to UNEP/FAO/RC/CRC.10/INF/13.

II. Proposed action

The Committee may wish:

- (a) To review the information provided in the notifications and the respective supporting documentation from Canada related to Tributyltin compounds, in accordance with the criteria set out in Annex II to the Convention,
- (b) If there are notifications from at least two PIC regions meeting the criteria of Annex II to the Convention, to recommend to the Conference of the Parties that the chemical in question should be included in Annex III to the Convention within the industrial chemicals category and a decision guidance document should be drafted.

¹ UNEP/FAO/PIC/ICRC/4/18, paragraphs 73 and 74

² UNEP/FAO/RC/CRC.1/28, paragraphs 103 to 107

³ UNEP/FAO/RC/CRC.3/15, annex I. Annex III of the Convention was amended to list tributyltin compounds by decision RC-4/5 adopted by the fourth meeting of the Conference of the Parties

Annex

Notification of final regulatory action for Tributyltin compounds submitted by Canada



ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE



FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country:

Canada

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1 Common name

Tributyltins

1.2 Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists

Tributyltins, which contain the grouping $(C_4H_9)_3Sn$

1.3 Trade names and names of preparations

1.4 Code numbers

1.4.1 CAS number

Final Regulatory Action applies to all CAS numbers representing compounds that contain the grouping $(C_4H_9)_3Sn$.

An indicative (non-exhaustive) list of CAS numbers covered by this regulatory action would include:

- 56-35-9
- 688-73-3
- 1461-22-9

1.4.2 Harmonized System
customs code

1.4.3 Other numbers
(specify the numbering
system)

- 1983-10-4
- 2155-70-6
- 4027-18-3
- 4342-30-7
- 67701-37-5

EC: Index number 050-008-00-3 (common
number for all TBT compounds).

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action
on this chemical **for industrial chemical uses.**

1.5.2 ☐ This notification replaces all previously submitted notifications
on this chemical.

Date of issue of the previous notification: _____

SECTION 2

FINAL REGULATORY ACTION

2.1 The chemical is: ☐ banned OR ☒ severely restricted

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

A person must not manufacture, use, sell, offer for sale or import tributyltins or a product containing them unless the toxic substance is incidentally present.

This prohibition does not apply to the following:

(a) tetrabutyltin containing a concentration of less than or equal to 30% by weight of tributyltins; and

(b) mono- and dibutyltins (in applications such as PVC processing, glass coating or as catalysts), because tributyltins are incidentally present in these products.

Furthermore, the Regulations, do not apply to tributyltins for pesticidal uses within the meaning of section 2 of the *Pest Control Products Act*.

A person who is a manufacturer or importer of tributyltins, or a product containing them, on the day on which the Regulations come into force may continue that activity if they have been issued a permit under section 10 of the Regulations.

A person may use, sell, or offer for sale a product containing tributyltins if they are manufactured or imported before the day on which these Regulations come into force.

- 2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Prohibition of Certain Toxic Substances Regulations, 2012
Canada Gazette, Part II, Vol. 147, No. 1 — January 2, 2013.
<http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html>

- 2.2.3 Date of entry into force of the final regulatory action

March 14, 2013

2.3 Category or categories where the final regulatory action has been taken

- 2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Tributyltins in their pure form were not in commercial use in Canada, but they may be found in products that are mainly used in the polyvinyl chloride (PVC) processing industry, and as pesticides. Minor uses of products containing tributyltins include glass coatings and catalysts.

Tributyltins for non-pesticidal uses may be present in tetrabutyltin (up to 30%) and in mono- and dibutyltin compounds (less than 1%). During the manufacturing of the mono- and dibutyltins, the tributyltins contained in the tetrabutyltin, along with the tetrabutyltin, are converted into the mono- and dibutyltins with a large part of the tributyltins eliminated. Therefore, tributyltins were present in tetrabutyltin as a by-product.

- 2.3.2 Final regulatory action has been taken for the category ☒ Industrial

Use or uses prohibited by the final regulatory action

All manufacture, use, sale, offer for sale or import of tributyltins, or a product containing them, is prohibited unless they are incidentally present.

Use or uses that remain allowed (only in case of a severe restriction)

This prohibition does not apply to the following:

- (a) tetrabutyltin containing a concentration of less than or equal to 30% by weight of tributyltins; and

(b) mono- and dibutyltins (in applications such as PVC processing, glass coating or as catalysts), because tributyltins are incidentally present in these products.

Furthermore, the Regulations, do not apply to tributyltins for pesticidal uses within the meaning of section 2 of the *Pest Control Products Act*.

A person who is a manufacturer or importer of tributyltins, or a product containing them, on the day on which the Regulations come into force may continue that activity if they have been issued a permit under section 10 of the Regulations.

A person may use, sell, or offer for sale a product containing tributyltins if they are manufactured or imported before the day on which these Regulations come into force.

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

N/A

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

N/A

2.4 Was the final regulatory action based on a risk ☒ Yes
or hazard evaluation?

☐ No (If no, you may also
complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or

risk evaluation

Government of Canada. 2009. Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List. Ottawa, Ontario.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☐ Yes

☒ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

N/A

Expected effect of the final regulatory action

N/A

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Tributyltins are harmful to many aquatic organisms at low concentrations. They are present in the environment as a result of human activity. They have been shown to impose male sexual characteristics on females of some marine gastropods and appear to have the potential to induce sex reversal in some marine fish. Estimated and measured concentrations of tributyltins in some locations in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, tributyltins meet the criteria for persistence and bioaccumulation set out in the *Persistence and Bioaccumulation Regulations*, a regulation made under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Tributyltins are present as a contaminant in commercial tetrabutyltin formulations and probably at much lower levels in mono- and dibutyltin formulations.

Expected effect of the final regulatory action

The proposed risk management objective for tributyltins is to achieve the lowest level of releases that are technically and economically feasible.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

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2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

At the time the Regulations came into effect, tributyltins for non-pesticidal uses were not manufactured or used in their pure form in Canada. Furthermore, current activities involving tributyltins which are present in other organotin compounds are not prohibited. As a result, the Regulations are not expected to result in any incremental costs to industries.

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

N/A

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

N/A

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

Canada previously notified of regulatory action for tributyltins for pesticide purposes and a summary of that notification was included in PIC Circular XXII of December 2005. The present notification concerns regulatory action for the "industrial chemical" category and is additional to the regulatory action for the pesticide category.

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification
systems
e.g. WHO, IARC, etc.

Hazard class

UN	UN Number: 2786 UN Hazard Class: 6.1 UN Pack Group: II

Other classification systems
e.g. EU, USEPA

Hazard class

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Tributyltins are represented by the formula $(C_4H_9)_3SnL$ where "L" may be halogens (chloride, fluoride, etc.) or other sulphur- or oxygen-based organic moieties.

Reference

Government of Canada. 2009. Proposed Risk Management Approach for Non-Pesticidal Organotin Compounds. Ottawa, Ontario.

3.2.2 Description of toxicological properties of the chemical

N/A

Reference

N/A

3.2.3 Description of ecotoxicological properties of the chemical

For tributyltins, the most sensitive freshwater organism is the guppy, *Poecilia reticulata*, with a 90-day NOEC of 0.01 µg/L (from hexabutyldistannoxane) (Becker, 1992; data presented in ECOTOX). The 110-day Lowest-Observed-Effect Concentration (LOEC) for rainbow trout, *Oncorhynchus mykiss*, yolk sac fry was 0.173 µg/L (from tributyltin chloride), based on increased mortality and decreased resistance to *Aeromonas* (de Vries et al., 1991). Induction of "imposex" (the imposition of male sexual characteristics on females) has been reported for dogwhelks, *Nucella lapillus*, a marine gastropod, at tributyltin concentrations of 0.001 µg/L, whereas sterilization of females is initiated at 0.007–0.012 µg/L (Bryan et al., 1988; Gibbs et al., 1988). Shimasaki et al. (2003) reported that tributyltin oxide induced sex reversal of genetic female Japanese flounders, *Paralichthys olivaceus*, into phenotypic males when they were exposed to the substance in food at concentrations of 0.1 µg/g (25.7% sex reversal) and 1.0 µg/g (31.1% sex reversal). In sediments, the 21-day IC50, for the mayfly, *Hexagenia spp.*, based on growth, was 1.5 µg/g dry weight (from tributyltin chloride) (Day et al., 1998). This is consistent with the observation of Meador (2000) that chronic effects on benthos may occur at tributyltin concentrations in the range 0.1–1 µg/g dry weight of

sediment. According to Meador (2000), tributyltin toxicity may result from several specific modes of action, including endocrine disruption, as well as alterations in energy production, the P-450 enzyme system and heme metabolism.

Tributyltin compounds meet both persistence and bioaccumulation criteria specified in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Government of Canada, 2000).

There are special concerns with such highly persistent and bioaccumulative substances. Although current science is unable to accurately predict the long-term ecological effects of these substances, they are generally acknowledged to have the potential to cause serious and possibly irreversible impacts. Assessments of such substances must therefore be performed using a preventative, proactive approach, to ensure that such harm does not occur.

Evidence that a substance is persistent and bioaccumulative when taken together with potential for environmental release or formation and potential for toxicity to organisms provides a significant indication that it may be entering the environment under conditions that may have harmful long-term ecological effects. Persistent substances remain in the environment for long periods of time, increasing the probability and the duration of exposure. Persistent substances that are subject to long-range transport are of particular concern because they can result in low-level, regional contamination. Releases of extremely small amounts of persistent and bioaccumulative substances may lead to relatively high concentrations in organisms over wide areas. Very bioaccumulative and persistent substances may also biomagnify through the food chain, resulting in especially high internal exposures for top predators. Because they are widespread, several different persistent and bioaccumulative substances may be present simultaneously in the tissues of organisms, increasing the likelihood and potential severity of harm.

Other factors can increase concerns regarding the potential for persistent and bioaccumulative substances to cause environmental harm. For example, there is a particular concern for substances that have the potential to harm organisms at relatively low concentrations and/or that have specific modes of toxic action (in addition to narcosis). Evidence that a substance does not occur in the environment naturally may also indicate an elevated potential to cause harm, since organisms will not have had very long to develop specific strategies for mitigating the effects of exposures. Evidence from monitoring studies indicating that a substance is widespread in the environment and/or that concentrations have been increasing over time is an indicator of elevated exposure potential.

Although risk quotients may also be used to indicate potential to cause

environmental harm for persistent and bioaccumulative substances, risks are likely to be underestimated using this approach. For example, if steady state has not been achieved in the environment and concentrations are continually increasing, measured Predicted Environmental Concentrations (PECs) will be too low. In addition, Predicted No-Effect Concentrations (PNECs) may be too high because of the long time needed to achieve steady state and the lack of exposure through food consumption in typical short-term laboratory toxicity tests.

Nevertheless, risk quotients for tributyltins were calculated for comparison purposes. Predicted Environmental Concentration (PEC)/PNEC ratios for tributyltin compounds, based on both modelled and measured PECs in water and sediment, are shown in Table 1. The Canadian Water Quality Guideline for the Protection of Freshwater Aquatic Life of 0.008 µg/L (CCME, 1999) was used as the PNEC for tributyltins in water. The most sensitive benthic organism reported was the mayfly, *Hexagenia spp.*, with a 21-day IC50 (growth) of 1.5 mg tributyltin/kg dry weight. Dividing this toxicity value by an assessment factor of 100 (10 to extrapolate from an acute to a chronic no-effect level, and 10 to account for extrapolation from laboratory to field conditions and for inter- and intraspecies variability) gives a chronic PNEC of 0.015 mg/kg dry weight for tributyltins in sediment. All risk quotients in Table 11 are significantly greater than 1.

Table 1: PEC/PNEC Ratios for Tributyltin Substances

	PEC	CTV	PNEC	PEC/PNEC
Water: modelled PEC ^a	0.22 µg/L	--	0.008 µg/L	28
Water: measured PEC ^b	0.043 µg/L	--	0.008 µg/L	5.4
Sediment: modelled PEC ^a	7.8 mg/kg dry weight	1.5 mg/kg dry weight	0.015 mg/kg dry weight	520
Sediment: measured PEC ^b	2.4 mg/kg dry weight	1.5 mg/kg dry weight	0.015 mg/kg dry weight	160

^a Highest environmental concentrations predicted for new and/or transitional tributyltins associated with chemical manufacturing, expressed as hydrolyzed tributyltin.

^b Highest concentrations measured in Canada.

Based on the various lines of evidence presented above, it is concluded that tributyltin compounds have the potential to cause environmental harm.

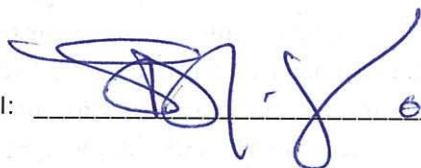
Reference

Government of Canada. 2009. Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List. Ottawa, Ontario.

SECTION 4**DESIGNATED NATIONAL AUTHORITY**

Institution	Environment Canada
Address	351 St. Joseph Blvd., Gatineau, Quebec. K1A 0H3
Name of person in charge	Ms. Lucie Desforbes
Position of person in charge	Director, Chemical Production Division
Telephone	819-994-4404
Telefax	819-994-5030
E-mail address	Lucie.Desforbes@ec.gc.ca

Date, signature of DNA and official seal: _____

 OCT. 16, 2013**PLEASE RETURN THE COMPLETED FORM TO:**

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.