



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

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English only

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 action: Tributyltin compounds

ADVANCE COPY

**Tributyltin compounds: Verified Final Regulatory Actions by
European Union and Canada on Pesticides and the Rationale
adopted by the Chemical Review Committee**

Note by the Secretariat

The Secretariat has the honour to provide, in the annex to the present note, verified notifications of final regulatory actions from European Union and Canada on tributyltin compounds under the category of pesticides reviewed by the Chemical Review Committee at its second meeting and the rationale adopted to recommend that tributyltin compounds should be included in Annex III to the Rotterdam Convention as a pesticide. The documentation has not been formally edited.

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

Annexes

- Notifications of Final Regulatory Actions by European Union and Canada on tributyltin compounds under the category of pesticides reviewed by the Chemical Review Committee at its second meeting;
- The rationale adopted by the Chemical Review Committee at its second meeting to recommend that tributyltin compounds should be included in Annex III to the Rotterdam Convention as a pesticide.

Notifications of Final Regulatory Actions by European Union and Canada on tributyltin compounds under the category of pesticides reviewed by the Chemical Review Committee at its second meeting



**United Nations
Environment Programme**

**Food and Agriculture Organization
of the United Nations**

Distr.: General
8 November 2005

English only

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

Second meeting
Geneva, 13–17 February 2006
Item 5 (b) of the provisional agenda*

**Listing of chemicals in Annex III of the Rotterdam Convention:
Review of notifications of final regulatory action to ban
or severely restricted a chemical: Tributyl tin**

Tributyl tin

Note by the Secretariat

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 from each of two prior informed consent (PIC) regions that contain the information required in 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 documentation provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III and a decision guidance document drafted.
2. The Secretariat has received four notifications from three PIC regions relating to tributyl tin compounds that meet the information requirements of Annex I (Asia – Japan and Republic of Korea; Europe – European Community; and North America – Canada). Summaries of those notifications were included in PIC Circular XI of June 2000, PIC Circular XVII of December 2002, PIC Circular XX of December 2004 and PIC Circular XXII of December 2005 respectively.
3. The notifications from the European Community and Japan had been considered by the Interim Chemical Review Committee. At its fourth session, the Interim Chemical Review Committee agreed that the notification from the European Community had met all the criteria of Annex II of the Convention, while the notification from Japan did not meet those criteria. That information may be found in the report of the session (document UNEP/FAO/PIC/ICRC4/18, paragraphs 72 to 74).
4. At its first meeting, the Chemical Review Committee considered the notifications from the Republic of Korea and Japan 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 Annex.

* UNEP/FAO/RC/CRC.2/1.

It also endorsed the conclusion that the notification from the European Community fulfilled all the criteria of Annex II. That information may be found in the report of the meeting (document UNEP/FAO/RC/CRC.1/28, paragraphs 103 to 107).

5. The Secretariat is forwarding the new notification from Canada and the notification from the European Community for review by the Chemical Review Committee. Those notifications as they were received from the notifying Parties are annexed to the present note.

6. The supporting documentation provided by Canada and the European Community, where available, may be found in documents UNEP/FAO/RC/CRC.2/11/Add.1 and Add.2 respectively.

Annex



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

IMPORTANT: See instructions before filling in the form

COUNTRY: CANADA

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL							
1.1	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; padding: 5px;">Common name</td> <td style="padding: 5px;">Tributyltin compounds</td> </tr> </table>	Common name	Tributyltin compounds				
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1.2	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; padding: 5px;">Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists</td> <td style="padding: 5px;"> Tributyltin compounds used in antifouling paints in Canada included: Tributyltin oxide (TBTO) IUPAC: bis(tributyltin)oxide CAS: hexabutyldistannoxane Tributyltin fluoride (TBTF) IUPAC: tributyl-fluoro stannane CAS: tributyltin fluoride Tributyltin methacrylate (TBTM) IUPAC: tributyltin methacrylate CAS: tributyl-(2-methyl-1-oxo-2-propyl)oxystannane </td> </tr> </table>	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	Tributyltin compounds used in antifouling paints in Canada included: Tributyltin oxide (TBTO) IUPAC: bis(tributyltin)oxide CAS: hexabutyldistannoxane Tributyltin fluoride (TBTF) IUPAC: tributyl-fluoro stannane CAS: tributyltin fluoride Tributyltin methacrylate (TBTM) IUPAC: tributyltin methacrylate CAS: tributyl-(2-methyl-1-oxo-2-propyl)oxystannane				
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Tributyltin fluoride	1983-10-4						

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

		Tributyltin methacrylate	2155-70-6
1.4.2	Harmonized System customs code	3808-90-90	
1.4.3	Other numbers (specify the numbering system)	RTECS: JN8750000 EINECS: 200-268-0	

1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____
	<input type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
UN	UN Hazard Class : 6.1 UN Pack Group: II
EC	T; R25-48/23/25; Xn; R21; Xi; R36/38
Other classification systems	Hazard class
US EPA PC Code	083001

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide
	Describe the uses of the chemical as a pesticide in your country: _____ TBT compounds are used in non-agricultural biocide pest control products. The most common use of TBT compounds was in antifouling paints for ship hulls. TBT compounds continue to be used in material and wood preservatives, and as a slimicide.
1.7.2	<input type="checkbox"/> Industrial
	Describe the industrial uses of the chemical in your country: _____

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical
	Data for tributyltin oxide is provided as the most commonly reported form used in antifouling paints. In seawater, tributyltin compounds exist as three species (hydroxide, chloride and carbonate) under normal conditions. Similar data for other forms is also available.
	IUPAC name: bis(tributyltin)oxide
	Molecular Formula: C ₂₄ H ₅₄ OSn ₂
	Molecular Weight 596.07 g
	Boiling point: 173°C

	<p>potential hazard.</p> <p>Overall, it would appear that the primary health hazards include endocrine disruption, immunotoxicity and severe irritation.</p> <p>REF: International Programme on Chemical Safety Environmental Health Criteria 116 Tributyltin Compounds, 1990www.inchem.org/documents/ehc/ehc/ehc116.htm)</p>
1.8.3	<p>Description of ecotoxicological properties of the chemical</p> <p>In seawater, tributyltin compounds exist as three species (hydroxide, chloride and carbonate) under normal conditions. Ecotoxicological information is presented simply as TBT since this is the moiety of concern regardless of the form used in antifouling paint</p> <p>A detailed review of the persistence, bioaccumulation and toxicity of TBT was conducted by Environment Canada.</p> <p>The persistence of TBT in water is slight to moderate with half-lives of a few days to a few months. In sediments, it is significantly more persistent. Several studies from different parts of the world indicate half-lives for TBT in sediment of up to 15 years.</p> <p>The octanol–water partition coefficient (<i>K_{ow}</i>) for TBT indicates a potential for bioaccumulation, as the log <i>K_{ow}</i> values range from 3.2 to 4.1. Studies with algae, aquatic invertebrates, and fish have confirmed that bioaccumulation of TBT in these organisms is substantial. The bioconcentration factor (BCF) values range up to 10 000 in periwinkles, 50 000 in fish, and 500 000 in clams. Although TBT does not appear to significantly biomagnify up the food chain in some studies conducted to date, it is found in the tissues of marine mammals and other organisms in open ocean areas.</p> <p>TBT is toxic to many aquatic organisms, including fish. Acute toxicity, to some fish, occurs at a few milligrams per litre, while chronic toxicity can be found at concentrations in the order of micrograms per litre. It is highly toxic to molluscs, with chronic toxicity in oysters and clams occurring at fractional micrograms per litre concentrations. Evidence of the disruption of the endocrine system, e.g., the induction of imposex (the imposition of male sexual characteristics on females) is seen at 0.5 ng Sn/L in dogwhelks. Some marine benthic invertebrates are also very sensitive to TBT in sediments. Populations of benthic invertebrates such as polychaetes and amphipods have been shown to be reduced as a result of exposure to TBT in sediments.</p> <p>REF: Pest Management Regulatory Agency Special Review Decision: Tributyltin Antifouling Paints for Ship Hulls (SRD2002-01). (www.pmra-arla.gc.ca/english/pdf/srd/srd2002-01-e.pdf)</p>

	<p>regulatory control of TBT antifouling paints in Canada had not eliminated the problem by 1995. Because of the long persistence of TBT in sediment, TBT concentrations in marine sediments in some locations may exceed chronic toxicity thresholds for years to come.</p> <p>In consideration of the foregoing, it was determined that the use of TBT in antifouling paints poses an unacceptable risk to Canadian waters, based on non-target toxicity to aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.</p>
	<p>Reference to the relevant documentation</p> <p>Pest Management Regulatory Agency Special Review Decision: Tributyltin Antifouling Paints for Ship Hulls (SRD2002-01). (www.pmra-arla.gc.ca/english/pdf/srd/srd2002-01-e.pdf)</p> <p>Review of the Persistence, Bioaccumulation, and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, Water Qual. Res. J. Canada, 2000, Volume 35, No.4, 633-679</p>

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment	
	<p>TBT is an exclusively anthropogenic chemical. A detailed review conducted by Environment Canada concluded that TBT is extremely toxic to aquatic organisms, and is sufficiently persistent and bioaccumulative to warrant virtual elimination from the Canadian environment.</p> <p>Using the effect of imposex on molluscs to monitor recovery from TBT contamination, studies indicate that regulatory control of TBT antifouling paints in Canada prior to 1999 had not eliminated the problem.</p> <p>It was determined that the continued use of TBT in antifouling paints poses an unacceptable risk to Canadian waters, based on non-target toxicity to aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.</p> <p>Because of the long persistence of TBT in sediment, TBT concentrations in marine sediments in some locations may exceed chronic toxicity thresholds for years to come.</p>	
	Reference to the relevant documentation	
	<p>Review of the Persistence, Bioaccumulation, and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, Water Qual. Res. J. Canada, 2000, Volume 35, No.4, 633-679</p> <p>Pest Management Regulatory Agency Special Review Decision: Tributyltin Antifouling Paints for Ship Hulls (SRD2002-01). (www.pmra-arla.gc.ca/english/pdf/srd/srd2002-01-e.pdf)</p>	

	Expected effect of the final regulatory action
	Regulatory action will remove this source of TBT to the aquatic environment. Although persistence in the marine environment at some locations will maintain elevated levels for some time, removing this source of input will allow recovery to occur.

2.5 Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category <input type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action
	Use or uses that remain allowed
2.5.2	Final regulatory action has been taken for the chemical category <input checked="" type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action
	All formulations of antifouling paint containing tributyltin compounds are prohibited from import, sale or use in Canada.
	Formulation(s) and use or uses that remain allowed
	Formulations for the pest control uses in the following categories are registered in Canada. <ul style="list-style-type: none"> - Material preservative - Wood preservative - Slimeicide

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced		
Imported		
Exported		
Used		

2.6 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions	
	TBT antifouling paints can cause harm to the environment. Preventing use on ship hulls therefore protects the aquatic environment from this exposure wherever such ships may travel.

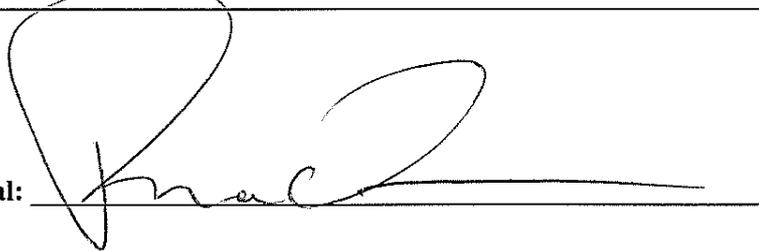
2.7 Other relevant information that may cover:	
2.7.1	Assessment of socio-economic effects of the final regulatory action
	Organotin antifouling paints were registered for a range of antifouling needs including deep seagoing ships and smaller ships which travel primarily in coastal waters (e.g., ferries, sailboats with aluminum hulls). Registrations at the time of the regulatory action included three paint products (two of which had not been used in the last year), the associated three concentrates, and the active ingredient tri- <i>N</i> -butyltin methacrylate. The only TBT antifouling paint that was in use at the time was labelled for use on ships with aluminum hulls. Based on information obtained from International Paint Co., Canadian paint applicators were no longer applying TBT paints to vessels that travel in deep sea water. It was confirmed that past users of TBT paints, such as the Department of National Defence, were no longer applying tin products on their ships, which would indicate that adequate alternative paints are available.

2.7.2	Information on alternatives and their relative risks
<p>Since 1989, several non-TBT antifouling paints have been evaluated and registered for use in Canada. These non-tin products contain copper active ingredients that offer antifouling properties similar to those of the TBT antifouling paints. Presently there are more than 50 copper-based antifouling paints registered for use by either small ship owners or professional paint applicators. These copper antifouling paints offer protection periods ranging from 12 months to 36 months. There are two copper thiocyanate products that are suitable for application on ships with aluminum hulls, since they do not cause corrosion like other copper-containing paints.</p> <p>In October 2001, the International Maritime Organisation (IMO) held a Diplomatic Conference at the end of which the text for a global treaty on "Control of Harmful Antifouling Systems on Ships" was agreed upon, and requires that each Party undertakes to communicate information regarding any anti-fouling systems approved, restricted, or prohibited under its domestic law. In order to fulfill this obligation, information is available (at www.pmra-arla.gc.ca/english/intern/imo-e.html), which provides a listing of products registered in Canada.</p>	
2.7.3	Relevant additional information
<p>Based on text prepared by Marine Environment Protection Committee, International Marine Organization Assembly adopted resolution A.895(21), <i>Anti-fouling Systems Used on Ships</i>, in November 1999. This resolution called for development of a global, legally binding instrument to address the harmful effects of antifouling systems and indicates that the instrument should ensure a prohibition on the application of organotin antifouling paints.</p> <p>Non-pesticidal organotin compounds were included on the first Priority Substances List under the 1988 Canadian Environmental Protection Act for assessment of potential risks to the environment and human health. The non-pesticidal organotin compounds considered in the assessment were primarily those of monomethyltin, dimethyltin, monobutyltin, dibutyltin, mono-octyltin and dioctyltin. Non-pesticidal organotin compounds are imported into Canada mainly for use as poly(vinyl chloride) (PVC) stabilizers and as industrial catalysts. The assessment of effects on the environment focused on aquatic biota since they are the most likely to be exposed to non-pesticidal organotin compounds. On the basis of available data, non-pesticidal organotin compounds are not considered to have adverse effect to the Canadian environment. Further, the compounds that were assessed are not volatile and are not expected to contribute to phenomena such as ozone depletion, global warming, or the formation of ground-level ozone. It was also concluded that, based on available data, non-pesticidal organotin compounds are not entering the environment in a quantity or conditions that may constitute a danger to human health or life. The assessment report recommended that future uses of these compounds should continue to be monitored to ensure that exposure does not increase to any significant extent, and any relevant data should be considered upon development of more sensitive testing strategies for endocrine disrupting effects.</p> <p>Ref: Priority Substances List Assessment Report - Non-pesticidal Organotin Compounds, Government of Canada, Environment Canada, Health and Welfare Canada, 1993. (www.hc-sc.gc.ca/hecs-sesc/exsd/pdf/non_pesticidal_organotin_compounds.pdf)</p> <p>Follow-up Report on a PSL1 Substance for Which Data Were Insufficient to Conclude Whether the Substance Was "Toxic" to Human Health - Non-pesticidal Organotin Compounds, May 2003. (www.ec.gc.ca/substances/ese/eng/psap/assessment/PSL1_organotin_followup.pdf)</p>	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish_MacQuarrie@hc-sc.gc.ca
Designated National Authority	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Name of person in charge	Trish MacQuarrie
Position of person in charge	Director, Alternative Strategies and Regulatory Affairs Division
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish MacQuarrie@hc-sc.gc.ca

Date, signature of DNA and official seal:





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

COUNTRY: EUROPEAN COMMUNITY
(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL		
1.1	Common name	Tri-organnostannic compounds, in particular Tributyl tin (TBT) compounds including Tributyltin oxide (Bis (tributyltin) oxide); Tributyltin benzoate; Tributyltin chloride; Tributyltin fluoride; Tributyltin linoleate; Tributyltin methacrylate; Tributyltin naphthenate.
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	- Tributyltin oxide (Bis (tributyltin) oxide): TBTO; - Tributyltin benzoate ((benzyloxy) tributyl stannane): TBTB; - Tributyltin chloride (Tributyl-chloro stannane): TBTCI; - Tributyltin fluoride (Tributyl-fluoro stannane): TBTF; - Tributyltin linoleate (Tributyl-(1-oxo-9,12-octadecadienyl)oxy-stannane): TBTL; - Tributyltin methacrylate (Tributyl-(2-methyl-1-oxo-2-propyl)oxy-stannane): TBTM; - Tributyltin naphthenate (Tributyl-mono(naphthenoyloxy) stannane): TBTN.
1.3	Trade names and names of preparations	---
1.4	Code numbers	
1.4.1	CAS number	Tributyltin oxide (Bis (tributyltin) oxide): 56-35-9; Tributyltin benzoate: 4342-36-3; Tributyltin chloride: 1461-22-9; Tributyltin fluoride: 1983-10-4; Tributyltin linoleate: 24124-25-2; Tributyltin methacrylate: 2155-70-6; Tributyltin naphthenate: 85409-17-2.
1.4.2	Harmonised System Customs Code	3808-90-90
1.4.3	Other numbers (specify the numbering system)	EC: 050-008-00-3 (common number for all TBT compounds) EC: Tributyltin oxide (Bis (tributyltin) oxide): 200-268-0; Tributyltin benzoate: 224-399-8; Tributyltin chloride: 215-958-7; Tributyltin fluoride: 217-847-9; Tributyltin linoleate: 246-024-7; Tributyltin methacrylate: 218-452-4; Tributyltin naphthenate: 287-083-9.

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH - 1219 Châtelaine, Geneva, Switzerland

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____
	<input type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
UN Hazard class (Pack group)	6.1 (II)
	Severe marine pollutant.
Classification in the EC in accordance with Directive 67/548/EEC (as amended by Commission Directive 98/98/EC, adapting to technical progress for the 25 th time Council Directive 67/548/EC)	T (toxic), N (dangerous for the environment), Xn (harmful), Xi (irritant). R25 Toxic if swallowed. R48/23/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. R21 Harmful in contact with skin. R36/38 Irritating to eyes and skin. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effect in the aquatic environment
Other classification systems	Hazard class

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide
	Describe the uses of the chemical as a pesticide in your country: _____
	TBT compounds are used for their biocidal action as non-agricultural pesticides. They were mainly used as marine anti-fouling agents or in industrial water treatment. Anti-fouling paints containing TBT oxide (TBTO) were the most important application and were particularly effective against barnacles (the most important fouling organism). They are also used as wood preservatives.
1.7.2	<input checked="" type="checkbox"/> Industrial
	Describe the industrial uses of the chemical in your country: _____
	TBT is used as an auxiliary agent in stereo selective intermediate synthesis in the pharmaceutical industry. It is also employed to modify synthetic rubber polymers. Niche applications exist for some drugs.

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical
Formula	Tributyltin oxide (Bis (tributyltin) oxide) (TBTO): $C_{24}H_{54}OSn_2$; Tributyltin benzoate: $C_{19}H_{132}O_2Sn$; Tributyltin chloride: $C_{12}H_{27}ClSn$; Tributyltin fluoride: $C_{12}H_{27}FSn$; Tributyltin linoleate: $C_{30}H_{58}O_2Sn$; Tributyltin methacrylate: $C_{16}H_{32}O_2Sn$; Tributyltin naphthenate: $C_{23}H_{34}O_2Sn$.
Molecular weight	596 g/mol (TBTO*)
Appearance	Colourless liquid (TBTO*)
Tin content	38.7 – 39.7 % (TBTO*)
Melting point	< - 45 °C (TBTO*)
Boiling point	173 °C at 130 Pa (TBTO*)
Decomposition	> 230°C
Relative density	1.17 – 1.18 g.cm ⁻³ at 20°C (TBTO*)
Vapour pressure	1 x 10 ⁻³ Pa at 20°C (TBTO*)
Solubility in water	71.2 mg.L ⁻¹ at 20°C
Solubility in organic solvents	TBTO is soluble in lipids and very soluble in a number of organic solvents (ethanol, ether, halogenated hydrocarbons, etc...)
Partition coefficient	3.2 – 3.8
<p>* Data applying to TBTO is principally reported, as this was the main chemical form used in anti-fouling paints. TBTO is hydrolysed to TBT ions in the water column. The principal forms of TBT in the aquatic environment are hydroxides, chlorides and carbonates, the proportion of each depending on the properties of the water body (e.g. pH, salinity, etc...). Complementary data on the other TBT compounds may be found in the supporting documentation:</p> <ul style="list-style-type: none"> • Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A) April 1998 (copy attached). • International Programme on Chemical Safety, 1990. Environmental Health Criteria No.116: Tributyltin compounds. (available at: http://www.inchem.org/documents/ehc/ehc/ehc116.htm) 	

1.8.2	Description of toxicological properties of the chemical
Metabolism	
TBT is absorbed through the gut (20-50%) and via the skin of mammals (about 10%), and can be transferred across the blood-brain barrier. Absorbed material is rapidly and widely distributed amongst tissues (principally liver and kidneys).	
Toxicological properties:	
<u>Acute toxicity</u>	
<ul style="list-style-type: none"> ○ LD₅₀ (rat, oral): 94 – 234 mg/kg bw (TBT) ○ LD₅₀ (rat, oral): 165 – 277 mg/kg bw (TBTO*) ○ LD₅₀ (mouse, oral): 44 – 230 mg/kg bw (TBT) ○ LD₅₀ (rabbit, dermal): > 9000 mg/kg bw (TBT) ○ LC₅₀ (rat, inhalation, 4 h): 65 mg/L bw (TBTO*, respirable particles) ○ TBT is a skin and eye irritant and severe dermatitis can result after direct contact with TBT concentrations greater than 0.01%. 	
Short-term and long term toxicity	
<ul style="list-style-type: none"> ○ <u>Mutagenicity</u>: There is no evidence that TBTO* has any mutagenic potential. ○ <u>Carcinogenicity</u>: In a two-year rat test TBTO* induced no malignant tumours at oral concentrations of up to 50 mg/kg. A second study has shown some increased incidence of malignant pancreatic tumours in rats. There is insufficient evidence to suggest that TBTO is a possible human carcinogen (IPCS, 1990). ○ <u>Reproductive toxicity</u>: TBTO* is not considered to be teratogenic. The lowest NOEL, with regard to embryotoxicity and foetotoxicity for mice, rats and rabbits, was 1.0 mg/kg body weight. ○ <u>Immunotoxicity</u>: the characteristic effect of TBTO* is on the immune system. Due to effects on the thymus, the cell-mediated function is impaired. 	

	<p>ADI This should be based on the impairment of the immune system (the most sensitive parameter for systemic effects). Its value is still open to debate. The lowest reported value is 0.3 µg/kg b.w.</p>
	<p>* TBTO: See point 1.8.1</p> <ul style="list-style-type: none"> • Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A) April 1998 (copy attached). • International Programme on Chemical Safety, 1990. Environmental Health Criteria No.116: Tributyltin compounds. (available at: http://www.inchem.org/documents/ehc/ehc/ehc116.htm) • Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html).

1.8.3	Description of ecotoxicological properties of the chemical	
	<p>Fate and behaviour</p> <ul style="list-style-type: none"> • TBTO is strongly adsorbed to sediments. • The principal degradation pathway for TBT is biodegradation to dibutyltin and monobutyltin and eventually to tin oxide. <p>Ecotoxicology</p> <p><u>Acute effects (TBTO*)</u></p> <ul style="list-style-type: none"> • Mollusc: LC₅₀ (48h, adult <i>Mytilus edulis</i>) = 300 µg TBTO/L LC₅₀ (48h, juvenile <i>Mytilus edulis</i>) = 0.97 µg TBT/L LC₅₀ (48h, larvae <i>Mytilus edulis</i>) = 2.3 µg TBTO/L • Fish: LC₅₀ (96h, <i>Salmo gairdneri</i>) = 3.44 µg TBTO/L • Bacteria: EC₁₀ (18h, <i>Pseudomonas putida</i>) = 24 µg TBT/L <p><u>Chronic effects (TBT compounds):</u></p> <ul style="list-style-type: none"> • Daphnia magna NOEC (21 d) = 0.078 µg TBT/L • TBT has a log P_{ow} greater than 3 and may be bioaccumulated. • The dogwhelk <i>Nucella lapillus</i> has been shown to suffer from imposex (imposed sex) at TBT concentrations at less than 1 ng TBT/L. This impairment of the reproduction was also observed in numerous other marine species. • Effects on the shell development of the Pacific oyster (<i>Crassostrea gigas</i>) have been observed at concentrations < 2 ng TBT/L. 	
	<p>* TBTO: See point 1.8.1</p> <ul style="list-style-type: none"> • Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). • International Programme on Chemical Safety, 1990. Environmental Health Criteria No.116: Tributyltin compounds. (available at: http://www.inchem.org/documents/ehc/ehc/ehc116.htm) 	

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	The chemical is: <input type="checkbox"/> banned OR <input checked="" type="checkbox"/> severely restricted
2.2	Information specific to the final regulatory action
2.2.1	Summary of the final regulatory action As from 1 January 2003, the use of tri-organostannic compounds is banned in all paints and products to prevent the fouling of all craft intended for use in marine, coastal, estuarine and inland waterways and lakes, appliances and equipment used for fish or shellfish farming, and any totally or partially submerged appliance or equipment; and in industrial water treatment.
2.2.2	Reference to the regulatory document Commission Directive 2002/62/EC of 9 July 2002 adapting to technical progress for the ninth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (organostannic compounds) (Official Journal of the European Communities (OJ) L183 of 12/07/2002, p. 58) (available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_183/l_18320020712en00580059.pdf). Other relevant regulatory actions: Council Directive 89/677/EEC of 21 December 1989 (OJ L398 of 30/12/1989, p. 19), Commission Directive 1999/51/EC of 26 May 1999 (OJ L142 of 5/06/1999, p. 22)
2.2.3	Date of entry into force of the final regulatory action The regulatory action entered into force on the 20 th day following that of its publication in the Official Journal of the European Communities (<i>i.e.</i> 12/07/2002). The Member States of the European Community were required to adopt and publish the provisions necessary to comply with this Directive by 31 October 2002 at the latest and apply the measures as from 1 January 2003.

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes, give information on such evaluation		
<p>Commission Directive 2002/62/EC was the latest in a series of regulatory actions, dating back to 1989, when use of TBT compounds in treatment of industrial waters was banned, because large quantities of water are used in many installations such as cooling systems, power station cooling towers, pulp and paper mills leading to significant releases in surface water, and when controls on anti-fouling applications were first introduced. These latter restrictions have progressively been extended. Use of TBT in free association paints was banned in 1999. In this type of paint the TBT is only physically incorporated into the paint matrix and has a significant potential for early release. The ban has now been extended to all other forms of anti-fouling products.</p> <p>The final regulatory action is based on an independent risk evaluation. The European Commission commissioned a study that was issued in April 1998. The aim of the project was to investigate the risks to health and to the environment of antifouling paints for shipping containing tin organic compounds and to examine the advantages and the drawbacks of further restrictions on their marketing and use.</p> <p>The findings of that study were reviewed by the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission in November 1998.</p> <p>The final regulatory action also took into account developments within the International Maritime Organisation (IMO), and in particular the IMO International Convention on the Control of Harmful Anti-fouling Systems, agreed at an IMO Diplomatic conference in October 2001. This includes a global prohibition on the application or reapplication of organotin compounds which act as biocides in anti-fouling systems on ships by 1 January 2003. It also requires that by 1 January 2008 ships either shall not bear such compounds on their hulls etc or shall bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant anti-fouling systems.</p>		
Reference to the relevant documentation		
<ul style="list-style-type: none"> • Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). • Opinion on The report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html). • International Convention on the Control of Harmful Anti-fouling Systems on Ships (available at: http://www.imo.org/home.asp?topic_id=161) 		

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers		
<p>Hazards: see classification in point 1.6</p> <p>In the risk assessment conducted for the European Commission, unacceptable health risks were identified in the following areas:</p> <ul style="list-style-type: none"> - exposure to atmospheric TBT during the transfer of ingredients to the mixing vessel during anti-fouling paint manufacture; - ingestion of contaminated food (e.g. mussels) where TBT concentrations are high. <p>It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. However, releases of TBT from shipping are more difficult to control because it as been shown that even when the TBTO release rate is reduced to the minimum required to maintain anti-fouling efficiency, the amount released from a large ship is still considerable, leading to possible contamination of food.</p>		

Reference to the relevant documentation	
<ul style="list-style-type: none"> Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). Opinion on The report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html). 	
Expected effect of the final regulatory action	
Reduction of the levels of exposure from the application of TBT based paints in dockyards, and reduced levels of indirect exposure through contaminated food.	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, give summary of the known hazards and risks to the environment			
<p>Hazards: see classification in point 1.6</p> <p>In the risks assessment conducted for the European Commission, unacceptable environmental risks were identified in the following areas:</p> <ul style="list-style-type: none"> - release to surface water from the manufacture of TBTO; - release to surface water from the manufacture of TBT self polishing co-polymer paints; - release to surface water from dockyard procedures; - release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment. <p>It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. However, releases of TBT from shipping are more difficult to control because it as been shown that even when the TBTO release rate is reduced to the minimum required to maintain anti-fouling efficiency, the amount released from a large ship is still considerable.</p>			
Reference to the relevant documentation			
<ul style="list-style-type: none"> Risk Assessment for the European Commission . "Assessment of the Risks to health and to the environment of tin organic compounds in ant-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). Opinion on The report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html). 			
Expected effect of the final regulatory action			
<p>A ban of TBT in anti-fouling paints is expected to significantly reduce input of TBT to the aquatic environment. The timescale over which effects will be seen is likely to be biphasic. Initially, a significant drop in water concentrations will be seen and this should result in reduced levels of risks for exposed environments. However, there are likely to be some residual concentrations of TBT in water for some time after implementation of a ban of its use, because of continuing releases from ship hulls and the TBT reservoirs that have accumulated in the sediment of contaminated areas. Considering the long half time of degradation for TBT, it is likely that TBT will remain in the water column and sediment for up to twenty years after the cessation of TBT inputs to the environment. These residual concentrations should not present a threat to population sustainability.</p>			

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action	
	Not relevant.	

	Use or uses that remain allowed	
	Not relevant.	
2.5.2	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	After 1 January 2003, tri-organostannic compounds 1. May not be placed on the market for use as substances and constituents of preparations when acting as biocides in free association paint. 2. May not be placed on the market or used as substances and constituents of preparations which act as biocides to prevent the fouling by microorganisms, plants or animals of: (a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes; (b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming; (c) any totally or partly submerged appliance or equipment. 3. May not be used as substances and constituents of preparations intended for use in the treatment of industrial waters.	
	Formulation(s) and use or uses that remain allowed	
	All uses, including use as preservative for wood, not covered by the Directive 2002/62/EC remain allowed.	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (kT)	Year
Produced	3000 *	1996
Imported	30 *	
Exported	1700 *	
Used*	1330 (EU apparent consumption) *	

* TBTO data. (Source: Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached)).

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions
	Protection of the aquatic environment and human health.

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action
2.7.2	Information on alternatives and their relative risks A number of alternative tin-free anti-foulant systems are commercially available (copper acrylate, other copper systems, with or without booster, non-stick biocide-free products). Others are still under development (natural products extracts, e.g. sponge). The toxicity and the long-term environmental impact of all alternatives are not fully assessed. However, several reviews have been or are being carried out. It should be noted that, without anti-fouling, the fuel consumption of large ships may be increased by 50%. The performances of most alternatives tend to be lower and the price is generally higher than that of TBT based paints. <u>Reference:</u> Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached).
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 48 60
Telefax	+322 296 69 95
E-mail address	klaus.berend@cec.eu.int
Designated National Authority	
Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Name of person in charge	Klaus BEREND
Position of person in charge	Administrator
Telephone	+322 299 48 60
Telefax	+322 296 69 95
E-mail address	klaus.berend@cec.eu.int

Date, signature of DNA and official seal:

Klaus Berend

25.11.02



The rationale adopted by the Chemical Review Committee at its second meeting to recommend that tributyltin compounds should be included in Annex III to the Rotterdam Convention as a pesticide

Tributyl tin

1. Rationale for the recommendation that all tributyl tin compounds should become subject to the prior informed consent procedure and to establish an intersessional drafting group to prepare a draft decision-guidance document

1. In reviewing the notifications of final regulatory action by the European Community and Canada to severely restrict tributyl tin compounds, together with the supporting documentary information provided by those Parties, the Chemical Review Committee was able to confirm that the regulatory actions had been taken in order to protect both human health and the environment in the case of the European Community and the environment in that of Canada. The European Community action was based on an international environmental health criteria document, an independent risk assessment and expert opinion within the European Community. These reviews concluded that immune system toxicity of tributyltin compounds represented the main concern for human health, and that tributyl tin compounds were highly toxic to aquatic organisms, including imposex in dogwhelks and effects on shell development in Pacific oysters.

2. The Canadian regulatory action was based on two environmental risk assessment reviews, which concluded that tributyl tin compounds were highly toxic to aquatic organisms, including imposex in dogwhelks, effects on molluscs and benthic invertebrates. Both notifications indicated the persistence of tributyl tin compounds in sediment and identified anti-fouling paints as the main source of tributyl tin compounds toxicity in the marine environment.

3. The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. It also showed that the final regulatory actions had been based on chemical-specific risk evaluations, taking into account the conditions of exposure within the European Community (including exposure scenarios from European Union dockyards, ports, and major North Sea shipping lanes) and Canada (monitoring of effects as a consequence of exposure in the environment – in particular imposex in molluscs – on Canada's Pacific and Atlantic coasts).

4. The Committee concluded that the final regulatory actions provided a sufficiently broad basis to merit including tributyl tin compounds in Annex III of the Rotterdam Convention in the pesticide category. As there was no indication that there were any significant other pesticidal or industrial uses for tributyl tin compounds, it noted that the actions by the European Community and Canada would lead to a significant decrease in the quantities and uses of tributyl tin compounds, and the risk to human health and the environment in the European Community and the environment in Canada was expected to be significantly reduced.

5. The Committee also took into account that the considerations underlying the final regulatory action were not of limited applicability but of wider relevance, since the use of anti-fouling paints containing tributyl tin compounds on the hulls of ships could lead to risk to the marine environment in any area of the world. On the basis of information provided to the members at the second session of the Chemicals Review Committee and other available information, the Committee concluded also that there was evidence of ongoing international trade in tributyl tin compounds.

6. The Committee noted that the final regulatory actions were not based on concerns about intentional misuse of tributyl tin compounds.

7. At its second meeting, the Committee concluded that the notification of final regulatory actions by the European Community and Canada met the information requirements of Annex I and the criteria set out in Annex II to the Convention. It was recommended that tributyl tin compounds should be included in Annex III to the Rotterdam Convention as a pesticide. Compounds that would be covered by the decision-guidance document would be:

“All tributyl tin compounds, including:

Tributyl tin oxide (CAS 56-35-9)
Tributyl tin fluoride (CAS 1983-10-4)
Tributyl tin methacrylate (CAS 2155-70-6)
Tributyl tin benzoate (CAS 4342-36-3)
Tributyl tin chloride (CAS 1461-22-9)
Tributyl tin linoleate (CAS 24124-25-2)
Tributyl tin naphthenate (CAS 85409-17-2) ...”

