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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.

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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

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

UNEP

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	**Common name**	Tributyltin compounds
1.2	**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
1.3	**Trade names and names of preparations**	Anti fouling paints INTERSMOOTH HISOL BFA253 SPC INTERSWIFT BKA007 TRI-LUX II T COPOLYMER ANTIFOULING PAINT Manufacturing concentrates BIOMET 303/60 Antifouling Agent BIOMET 304/60 Antifouling Agent BIOMET 300/60 Antifouling Agent
1.4	**Code numbers**	
1.4.1	**CAS number**	Tributyltin oxide 56-35-9 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

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OR

Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

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	☒ This is a first time notification of final regulatory action on this chemical.
1.5.2	❑ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ❑ 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 ☒ **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 ❑ **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:	C24H54OSn2
Molecular Weight	596.07 g
Boiling point:	173°C

	Melting point: <-45°C Relative density (water = 1): 1.17 at 20°C Vapour pressure, Pa at 20°C: 0.001 Flash point: 190°C c.c. Solubility: low, <1.0 - > 100 mg/L depending on pH, temperature, anions) Octanol/water partition coefficient as log Pow: 3.19-3.84 (distilled water) 3.54 sea water
	REF: World Health Organisation. 1999. Concise International Chemical Assessment Document 14. (www.inchem.org/documents/cicads/cicads/cicad14.htm). International Programme on Chemical Safety. 1990. Environmental Health Criteria No. 116: Tributyltin Compounds (www.inchem.org/documents/ehc/ehc/ehc116.htm)

1.8.2	**Description of toxicological properties of the chemical**
	The special review focussed on the environmental risks associated with the tributyltin compounds. An exhaustive review of the human health considerations and risks was not undertaken. However, for the purpose the review, the hazards associated with the tributyltins have been summarized predominantly from available monographs (International Programme on Chemical Safety Environmental Health Criteria 116 Tributyltin Compounds, 1990). Acutely, tributyltin is moderately to highly toxic in laboratory animals via the oral route. Effects of acute exposure have been reported to include alterations in blood lipid levels, the endocrine system, liver and spleen and transient deficits in brain development. Acute dermal toxicity is low. Tributyltin is very hazardous as an inhaled aerosol producing lung irritation and edema but is relatively innocuous as a vapour. It is severely irritating to the skin, an extreme irritant to the eye but does not appear to be a skin sensitizer. In short- and long-term studies, structural effects on endocrine organs, mainly the pituitary and thyroid have been reported. Changes in circulating hormone concentrations and altered response to physiologic stimuli (pituitary trophic hormones) have been reported primarily in short-term studies, suggesting some adaptive response with prolonged exposure. The liver and bile duct have also been identified as target organs on the rat, mouse and dog with short-term oral exposure. Likewise, effects on erythrocyte parameters leading to anemia have been documented in rats and mice. The most characteristic toxic effect is on the immune system. Due to effects on the thymus, cell-mediated function is impaired; non-specific resistance is also affected. While effects on the immune system of rats and dogs have been reported, the rat appears to be the most sensitive species tested, particularly with effects on host resistance to infection following short-term oral exposure. It has been postulated that TBT is metabolized to a more active dibutyltin salt. The dibutyltin then impedes the maturation of immature thymocytes by inhibiting action/binding with thymic epithelial cells. Carcinogenicity data are limited but suggest elevated incidences of tumors in the endocrine organs of the rat at high doses (ie. pituitary, adrenal in both sexes, parathyroid in males only). Negative results have been obtained in the vast majority of genotoxicity studies suggesting little potential for genotoxic activity. In developmental studies in the rat, rabbit and mouse, no sensitivity of the fetuses was observed. Malformations (ie. cleft palate) were noted in rat and mouse fetuses but only at doses that were overtly toxic to the mothers. Scant information is available on reproductive toxicity but it appears that TBT did not affect reproductive parameters in a rat multi-generation reproduction study. No information is available on the neurotoxic potential of the tributyltins. Occupational exposure of workers to tributyltins has resulted in irritation of the upper respiratory tract, severe dermatitis and eye irritation. The lack of an immediate dermal response exacerbates this

	potential hazard. Overall, it would appear that the primary health hazards include endocrine disruption, immunotoxicity and severe irritation. REF: International Programme on Chemical Safety Environmental Health Criteria 116 Tributyltin Compounds, 1990www.inchem.org/documents/ehc/ehc/ehc116.htm)
1.8.3	**Description of ecotoxicological properties of the chemical** 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 A detailed review of the persistence, bioaccumulation and toxicity of TBT was conducted by Environment Canada. 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. The octanol–water partition coefficient (*K*ow) for TBT indicates a potential for bioaccumulation, as the log *K*ow 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. 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. 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)

PART II: FINAL REGULATORY ACTION

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** Use of TBT antifouling paints represent an unacceptable risk to the marine environment. Alternative products currently registered in Canada offer an adequate period of control of fouling organisms to meet the needs of Canadian users. As a result of the review, the registrations of all tri-*N*-butyl tin based TBT antifouling paints, and their associated registered concentrates and active ingredient, were phased out during 2002. The registrant had agreed to conduct a recall of any unsold product to ensure that there is no product in the channels of trade after January 1, 2003.
2.2.2	**Reference to the regulatory document** 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)
2.2.3	**Date of entry into force of the final regulatory action** October 31, 2002

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☒ **Yes**	☐ **No**
	If yes, give information on such evaluation Because of concerns regarding the impact of TBT on the aquatic environment, Canada and many other countries limited application of TBT antifouling paints to vessels greater than 25 m in length and to vessels (of any length) with aluminum hulls, the latter because many non-tin alternatives contain forms of copper which can cause corrosion of aluminum hulls. A maximum daily tin release rate was imposed for these applications. In Canada, these regulatory controls have been only partially effective in reducing concentrations of TBT in the aquatic environment. In some locations, TBT was found in fresh water much less frequently in 1994 than in 1982–1985, and at much lower concentrations than a decade earlier. In 1994, TBT was found in fresh water sediments at similar concentrations to those found a decade earlier, but was found more frequently. In sea water, TBT was found more frequently in 1994 compared to samples taken between 1982 and 1985. In every case, the concentrations exceeded acute and chronic toxicity endpoints, indicating a high potential for adverse effects in the particular locations. In marine sediments, TBT was found more frequently in 1994 than a decade earlier, although at greatly reduced concentrations. In about half of all marine sediments in which TBT was found, its concentration exceeded chronic toxicity thresholds, indicating a high potential for adverse effects in the particular locations. Using the effect of imposex on molluscs to monitor recovery from TBT contamination in Canadian waters, it was found that whelks (various species) before 1989 had high frequencies of imposex in the Juan de Fuca Strait and the Strait of Georgia, and lower frequencies on the west coast of Vancouver Island. By 1994, a reduction in imposex was evident on the west coast of Vancouver Island and in some locations in the Strait of Georgia. However, there was no clear evidence of recovery near Victoria, and Vancouver Harbour did not have whelks in any abundance. Similarly, in Atlantic Canada, imposex in *Nucella lapillus* was found in 13 of 34 sites sampled in 1995. These results indicate that the		

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.

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.

Reference to the relevant documentation

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)

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

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	❑ **Yes** ☒ **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?**	☒ **Yes** ❑ **No**

If yes, give summary of the known hazards and risks to the environment

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.

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.

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.

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.

Reference to the relevant documentation

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

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)

	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**	☐ **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**	☒ **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. - Material preservative - Wood preservative - Slimicide	

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-*N*-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**

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.

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.

2.7.3	**Relevant additional information**

Based on text prepared by Marine Environment Protection Committee, International Marine Organization Assembly adopted resolution A.895(21), *Anti-fouling Systems Used on Ships*, 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.

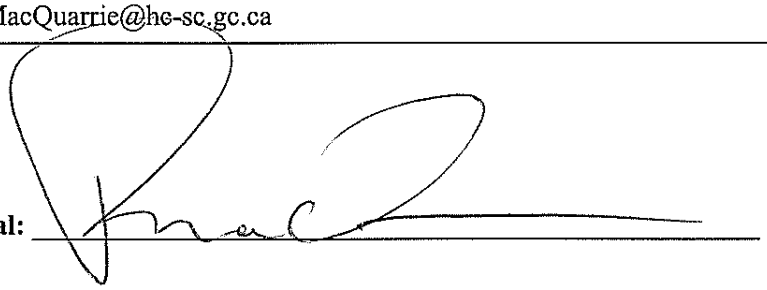
Non-pesticidal organotin compounds were included on the first Priority Substances List under the 1988 Canadian Environmental Protection Act for assessment of potential risks to the environment and human health. The non-pesticidal organotin compounds considered in the assessment were primarily those of 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.

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)

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)

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: 

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

UNEP

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): TBTCl; - 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

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CH – 1219 Châtelaine, Geneva, Switzerland

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

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.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☐ 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 25th 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	☒ **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	☒ **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
	* 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: • 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:** Acute toxicity o LD_{50} (rat, oral): 94 – 234 mg/kg bw (TBT) o LD_{50} (rat, oral): 165 – 277 mg/kg bw (TBTO*) o LD_{50} (mouse, oral): 44 – 230 mg/kg bw (TBT) o LD_{50} (rabbit, dermal): > 9000 mg/kg bw (TBT) o LC_{50} (rat, inhalation, 4 h): 65 mg/L bw (TBTO*, respirable particles) o 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** o Mutagenicity: There is no evidence that TBTO* has any mutagenic potential. o Carcinogenicity: 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). o Reproductive toxicity: 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. o Immunotoxicity: the characteristic effect of TBTO* is on the immune system. Due to effects on the thymus, the cell-mediated function is impaired.

	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.
	* TBTO: See point 1.8.1 • 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**	
	Fate and behaviour • TBTO is strongly adsorbed to sediments. • The principal degradation pathway for TBT is biodegradation to dibutyltin and monobutyltin and eventually to tin oxide. **Ecotoxicology** Acute effects (TBTO*) • Mollusc: LC_{50} (48h, adult *Mytilus edulis*) = 300 µg TBTO/L LC_{50} (48h, juvenile *Mytilus edulis*) = 0.97 µg TBT/L LC_{50} (48h, larvae *Mytilus edulis*) = 2.3 µg TBTO/L • Fish: LC_{50} (96h, *Salmo gairdneri*) = 3.44 µg TBTO/L • Bacteria: EC_{10} (18h, *Pseudomonas putida*) = 24 µg TBT/L Chronic effects (TBT compounds): • 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 *Nucella lapillus* 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 (*Crassostrea gigas*) have been observed at concentrations < 2 ng TBT/L.	
	* TBTO: See point 1.8.1 • 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:**	☐ **banned**	**OR**	☒ **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 20th day following that of its publication in the Official Journal of the European Communities (*i.e.* 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?**	☒ Yes ☐ No

If yes, give information on such evaluation

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.

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.

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.

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.

Reference to the relevant documentation

- 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?**	☒ Yes ☐ 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

Hazards: see classification in point 1.6

In the risk assessment conducted for the European Commission, unacceptable health risks were identified in the following areas:

- 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.

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.

Reference to the relevant documentation

- 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?**	☒ Yes ☐ No

If yes, give summary of the known hazards and risks to the environment

Hazards: see classification in point 1.6

In the risks assessment conducted for the European Commission, unacceptable environmental risks were identified in the following areas:

- 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.

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.

Reference to the relevant documentation

- 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

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.

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**	☐ **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**	☒ **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. Reference: 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
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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
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Date, signature of DNA and official seal: 25.11.02