Rotterdam Convention

Operation of the prior informed consent procedure for banned or severely restricted chemicals

Decision Guidance Document

Tributyltin compounds

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

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its fourth meeting, held in Rome on 27-31 October 2008 the Conference of the Parties agreed to list all tributyltin compounds in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on 1 February 2009 in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

---

[1] According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Acronyms and abbreviations	
<	less than
>	greater than
µg	microgram
µm	micrometre
ADI	acceptable daily intake
ATSDR	Agency for Toxic Substances Disease Registry
BCF	bioconcentration factor
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CSTEE	Scientific Committee for Toxicity, Ecotoxicity and the Environment (European Commission)
d	day
EC	European Community
EC_{50}	effect concentration, 50%
ED_{50}	effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Chemical Substances
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
k	kilo- (x 1000)
kg	kilogram
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
mg	milligram
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
Pa	pascal
PEC	predicted environmental concentration
PNEC	predicted no effect concentration
Pow	octanol-water partition coefficient
RTECS	Registry of Toxic Effects of Chemical Substances
TWA	time weighted average
UNEP	United Nations Environment Programme
US EPA	United States of America Environmental Protection Agency

Acronyms and abbreviations	
WHO	World Health Organization
wt	weight

Decision-guidance document for a banned or severely restricted chemical

Tributyltin (TBT) compounds[3] including: Tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.	**Published:** **February 2009**

1. Identification and uses (see annex 1 for further details)

Common name — Tributyltin (TBT) compounds including: tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.

Chemical name and other names or synonyms

Tributyltin oxide
IUPAC: hexabutyldistannoxane
CAS: bis(tributyltin)oxide

Tributyltin benzoate
IUPAC: (benzyloxy) tributyl stannane
CAS: tributyltin benzoate

Tributyltin chloride
IUPAC: tributyl-chloro stannane
CAS: tributyltin chloride

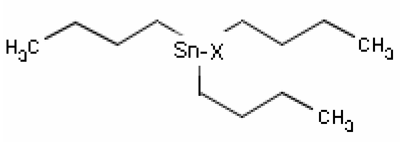
Tributyltin fluoride
IUPAC: tributyl-fluoro stannane
CAS: tributyltin fluoride

Tributyltin linoleate
IUPAC: tributyl-(l-oxo-9,l2-octadecadienyl)oxy-stannane
CAS: tributyltin linoleate

Tributyltin methacrylate
IUPAC: tributyltin methacrylate
CAS: tributyl-(2-methyl-l -oxo-2-propyl)oxystannane

Tributyltin naphthenate
IUPAC: tributyl-mono(naphthenoyloxy) stannane
CAS: tributyltin naphthenate

Chemical structure — Tributyltin derivatives $C_{12}H_{27}SnX$



3 “TBT” is used in the present document to represent all tributyltin derivatives (or compounds), as the active form is the same for all compounds. “TBTO” is used where the information is specific to tributyltin oxide as in, for example, section 2 of annex 1, relating to toxicological properties.

CAS number(s)	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
Other CAS numbers that may be used	None
Harmonized System Customs Code	3808-90-90
Other numbers	**EC:** Index number 050-008-00-3 (common number for all TBT compounds) **EINECS:** 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. **RTECS:** Tributyltin oxide: JN8750000; tributyltin benzoate: WH6710000: tributyltin chloride: WH6820000; tributyltin fluoride: WH8275000; tributyltin linoleate: WH8585000; tributyltin methacrylate: WH8692000.
Category	Pesticide
Regulated category	Pesticide
Use(s) in regulated category	Used in non-agricultural biocide pest control products. The most common use of TBT was in anti-fouling paints for ship hulls. It was also used as a biocide to prevent the fouling of appliances and equipment submerged in coastal and marine aquatic environments. TBT continues to be used in material and wood preservatives and as a slimicide.
Trade names	Anti fouling paints: Intersmooth Hisol BFA253 SPC Interswift BKA007 Tri-Lux II T copolymer anti-fouling paint Manufacturing concentrates: BIOMET 303/60 Anti-fouling agent BIOMET 304/60 Anti-fouling agent BIOMET 300/60 Anti-fouling agent *This list is an indicative list of trade names. It is not intended to be exhaustive.*
Formulation types	Formulated as paints
Uses in other categories	The European Community reported uses in the industrial chemicals category, such as: use as an auxiliary agent in stereo selective intermediate synthesis in the pharmaceutical industry; use as a modifier for synthetic rubber polymers; and niche applications for some drugs.
Basic manufacturers	Witco GmbH (now Chemtura Organmetallics GmbH), Song Woun, Elf Atochem, Sigma Coatings, International Paints, Hempel, Jotun, Ameron, Chugoku and Kansai. *This is an indicative list of current and former manufacturers of TBT and TBT paints. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Tributyltin compounds (TBT) are included in the PIC procedure in the pesticide category. The group of compounds is listed on the basis of the final regulatory actions that severely restrict their use, notified by Canada and the European Community.

While the use of anti-fouling paints containing TBT has been banned, they continue to be used in material and wood preservatives and as a slimicide.

2.1 Final regulatory action (see annex 2 for further details)

Canada: Registrations of all TBT-based anti-fouling paints, and the associated registered active ingredients and concentrates, were phased out by 31 October 2002. The registrant agreed to recall all unsold stocks to ensure that there were no products in trade after 1 January 2003.

Reason: Environment (concerns with regard to non-target aquatic organisms, persistence in the environment and bioaccumulation in aquatic organisms).

European Community: The use of TBT was prohibited, with effect from 1 January 2003, 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; any totally or partially submerged appliance or equipment; and industrial water treatment.

Reason: Human health and environment (concerns with regard to occupational exposure, consumption of contaminated food and risks to non-target aquatic organisms)

2.2 Risk evaluation (see annex 1 for further details)

Canada: Because of concerns regarding the impact of TBT on the aquatic environment, Canada had limited application of TBT anti-fouling paints to vessels greater than 25 metres in length and to vessels (of any length) with aluminium hulls, the latter because many non-tin alternatives contain forms of copper which can cause corrosion of aluminium hulls. A maximum daily tin release rate was imposed for these applications (1989).

These regulatory controls were only partially effective in reducing concentrations of TBT in the aquatic environment. Monitoring for levels of TBT was undertaken in 1994. For some locations, TBT was found in freshwater much less frequently than in 1982–1985, and at much lower concentrations. In freshwater sediments, TBT was found at similar concentrations to those found a decade earlier, but was found more frequently. In seawater, 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 these particular locations. In marine sediments, TBT was found more frequently in 1994 than a decade earlier, and 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 these particular locations.

Using the effect of imposex[4] 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. There was no clear evidence, however, of recovery near Victoria, and Vancouver Harbour did not have whelks in any abundance. Similarly, in Atlantic Canada, imposex in the dog whelk (*nucella lapillus)* was found in 13 of 34 sites sampled in 1995. These results indicate that the regulatory control of TBT in anti-fouling 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.

[4] Imposex is the development of male sexual characteristics by female gastropods, which in severe cases can cause reproductive failure and death.

In consideration of the foregoing, it was determined that the use of TBT in anti-fouling 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.

The risk evaluation is based on TBT as the toxic species, rather than the specific tributyltin compounds that were registered in Canada (tributyltin oxide, tributyltin fluoride and tributyltin methacrylate). This evaluation is therefore valid for all tributyltin compounds.

European Community: The results of a study on the risks to health and to the environment of anti-fouling paints containing tin organic compounds were reviewed in November 1998 by the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission. Unacceptable risks were identified in the following areas:

Human health

Occupational: A health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere during mixing. Measurements of atmospheric concentrations at paint mixing plants have shown levels during the transfer period to be double the acceptable short-term occupational exposure limit, which is set at three times the value of the most stringent 8 hour time-weighted average (TWA). The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain.

Food consumption: A potential health risk was also identified from the ingestion of contaminated seafood. Using worst case values for bioaccumulation, daily fish consumption and acceptable daily intake (ADI), a TBT concentration in water necessary to keep the dietary exposure to TBT below acceptable daily intake levels was calculated. It was found that this concentration would be exceeded in areas close to shipping ports, although it was unlikely in more distant locations and the open sea. The use of TBT can result in concentrations in water that pose an unacceptable risk to human health where daily intake of fish comes from shellfish raised in waters near commercial harbours.

Environmental impact

Four exposure scenarios were examined and the predicted environmental concentration (PEC), predicted no effect concentration (PNEC) and PEC/PNEC ratios were identified for each of the following four environmental release scenarios:

1. Release to surface water from the manufacture of tributyltin oxide (TBTO);
2. Release to surface water from the manufacture of TBT self-polishing co-polymer paints;
3. Release to surface water from dockyard procedures;
4. Release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment.

Although it was not possible to determine the exact water concentrations arising from the release of TBT from shipping, sufficient evidence was available to suggest that, where shipping intensity was high, the PEC for TBT in surrounding water was greater than the PNEC, giving a ratio in all of the four exposure scenarios of >1, thus indicating an unacceptable environmental risk.

The freshwater environment was considered to be the most sensitive to TBT, because it has the most sensitive species and because TBT releases have greater potential for accumulation owing to lower rates of water exchange in lakes as compared to the open sea. Unacceptable environmental risk may also occur in other areas where exchange of water is low, which is common in large harbours such as in Rotterdam (where there is also a high influx of organic rich anoxic sediment) and in large bodies of brackish water such as the Baltic Sea.

It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. Releases of TBT from shipping, however, are more difficult to control because it has 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. To reduce the TBT input from this source, it is necessary to restrict the use of TBT paints in the aquatic environment.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada	The use of TBT anti-fouling paints, the main source of TBT to the aquatic environment, was banned. Although persistence in the marine environment at some locations will maintain elevated for some time, removing this source of input will allow recovery to occur.
European Community	The ban of TBT in anti-fouling paints is expected to reduce significantly the input of TBT to the aquatic environment. 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.

3.2 Other measures to reduce exposure

None reported by the notifying Parties

General: The International Convention on the Control of Harmful Anti-fouling Systems on Ships prohibits the use of harmful organotins in anti-fouling paints used on ships and establishes a mechanism to prevent the potential future use of other harmful substances in anti-fouling systems. Under the terms of the Convention, Parties to the Convention are required to prohibit or restrict the use of harmful anti-fouling systems on ships. By 1 January 2008 (effective date), ships either:

- Shall not bear such compounds on their hulls or external parts or surfaces; or
- Shall bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant anti-fouling systems.

This applies to all ships (including fixed and floating platforms, floating storage units and floating production storage and offtake units).

3.3 Alternatives

It is essential that, before a country considers substituting alternatives, it ensures that the use is relevant to its national needs and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Canada: Since 1989, several non-TBT anti-fouling paints have been evaluated and registered for use in Canada. These non-tin products contain copper active ingredients that offer anti-fouling properties similar to those of the TBT anti-fouling paints. Presently, there are more than 50 copper-based anti-fouling paints registered for use by either small ship owners or professional paint applicators. These copper anti-fouling paints offer protection periods ranging from 12 to 36 months. There are two copper thiocyanate products that are suitable for application on ships with aluminium hulls, as they do not cause corrosion like other copper-containing paints.

The International Convention on Control of Harmful Anti-fouling Systems on Ships requires that each Party undertakes to communicate information regarding any anti-fouling systems approved, restricted or prohibited under its domestic law. In order to fulfil this obligation, information is available on the website of Canada's Pest Management Regulatory Agency, at www.pmra-arla.gc.ca./english/intern/imo-e.html, which provides a listing of products registered in Canada.

European Community: A number of alternative tin-free anti-fouling 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. Several reviews, however, have been or are being carried out. The performances of most alternatives tend to be lower and the price is generally higher than that of TBT-based paints.

3.4 Socio-economic effects

Canada: There was no detailed assessment conducted on the socio-economic effects of the final regulatory action to ban the use of TBT based anti-fouling paints.

Organotin anti-fouling paints were registered for a range of anti-fouling needs including deep seagoing ships and smaller ships which travel primarily in coastal waters (e.g. ferries and sailboats with aluminium hulls). Registrations at the time of the regulatory action included three paint products (two of which had not been used in the previous year), the associated concentrates and the active ingredient tri-n-butyltin methacrylate. The only TBT anti-fouling paint that was in use at the time was labelled for use on ships with aluminium hulls. Based on information obtained from International Paint Co., at the time the regulatory action was taken, Canadian paint applicators were no longer applying TBT paints to vessels that travel in deep seawater. 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 were available.

European Community: There was no detailed assessment conducted on the socio-economic effects of a severe restriction, although the risk evaluation suggested that a ban would have a significant cost to the economy. It should also be noted that, without anti-fouling, the fuel consumption of large ships may be increased by 50 per cent.

4. Hazards and risks to human health and the environment

4.1 Hazard classification

European Community	**Classification** is (Commission directive 2004/73/EC of 29 April 2004): **T** toxic; **N** dangerous for the environment; **Xn** harmful; **Xi** irritant. **Risk phrases:** **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 effects in the aquatic environment

4.2 Exposure limits of TBTO

United States of America Environmental Protection Agency (USEPA 1997):
- Oral reference dose of 0.3 µg/kg body weight/day.

Agency for Toxic Substances Disease Registry (ATSDR 2005):
- Chronic oral minimal risk level of 0.3 µg/kg body weight/day.

World Health Organization (WHO 1999):
- Guidance value for oral exposure of 0.3 µg/kg body weight/day.

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard class and packing group:	United Nations number: 2786 Hazard class: 6.1. Poisonous substance Packing group: II
International Maritime Dangerous Goods Code	Severe marine pollutant.
Transport emergency card	61G41 (Organotin pesticide, solid)

4.4 First aid

Note: The following advice is based on information available from the World Health Organization and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Signs and symptoms of acute poisoning include abdominal cramps, cough, diarrhoea, laboured breathing, nausea, vomiting and redness and pain at point of exposure.

First aid procedures:
Inhalation: Fresh air, rest. Half-upright position. Seek medical attention.
Skin: Rinse and then wash skin with water and soap. Seek medical attention.
Eyes: First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to doctor.
Ingestion: Induce vomiting (only in conscious persons). Give plenty of water to drink. Seek medical attention.

International Programme on Chemical Safety (IPCS) (2004). International safety card on tributyltin oxide, available at www.inchem.org/pages/icsc.html.

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticide stocks the guidelines available include the FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (1995), the FAO Pesticide Storage and Stock Control Manual (1996) and the FAO/WHO/UNEP Guidelines for the Management of Small Quantities of Unwanted and Obsolete Pesticides (1999).

Canada and the European Community adopted the same risk management strategy to deal with the existing stocks, by allowing a short phase-out period following adoption of their regulatory actions. This was seen as the lowest risk option for disposing of existing stocks in the light of risk associated with product recall, storage and disposal. It also allowed users time to change over to alternatives (see annex 2 to the present document).

In all cases, waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, any guidelines thereunder and any other relevant regional agreements.

It should be noted that the recommended disposal and destruction methods are often not available in, or suitable for, all countries, e.g. high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in the FAO/WHO/UNEP Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (1996).

In the event of spillage of TBTO, do not wash away into a sewer. Carefully collect the remainder, then remove it and take it to a safe place. Do not let TBTO enter the environment. Wear a chemical protection suit, including self-contained breathing apparatus.

Annexes

Annex 1	**Further information on the substance**
Annex 2	**Details of final regulatory action**
Annex 3	**Address of designated national authorities**
Annex 4	**References**

Annex 1 Further information on the substance

Introduction

The information presented in the present annex reflects the conclusions of the two notifying Parties, namely Canada and the European Community. Where possible, information provided by these two Parties on hazards has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions banning tributyltin compounds. The notification from Canada was first reported in PIC Circular XXII of December 2005 and the notification from the European Community in PIC Circular XVII of June 2003.

There have been two reviews on TBT, both published by WHO: the International Programme on Chemical Safety Environmental Health Criteria, No. 116: Tributyltin compounds (1990); and the Concise International Chemical Assessment Document, No. 14: Tributyltin oxide (1999). These reviews had been taken into consideration in the final regulatory actions of Canada and the European Community and are referenced in the present document. Some conclusions from these reviews have been used in the present document, for example, those relating to carcinogenicity and neurotoxicity set out in section 2.2. These do not differ substantially from the information provided by the notifying Parties.

Further information - tributyltin compounds

1. Physico-chemical properties

1.1	**Identity**	Data for tributyltin oxide is provided as the most commonly reported form used in anti-fouling paints. In seawater, tributyltin compounds exist as three species (hydroxide, chloride and carbonate) under normal conditions. Similar data for other forms are available.
1.2	**Formula**	Tributyltin oxide (TBTO): $C_{24}H_{54}OSn_2$; Tributyltin benzoate: $C_{19}H_{32}O_2Sn$; Tributyltin chloride: $C_{12}H_{27}ClSn$; Tributyltin fluoride: $C_{12}H_{27}FSn$; Tributyltin linoleate: $C_{30}H_{58}0_2Sn$; Tributyltin methacrylate: $C_{16}H_{32}O_2Sn$; Tributyltin naphthenate: $C_{23}H_{34}O_2Sn$.
1.3	**Molecular weight**	596.07 g
1.4	**Appearance**	Colourless liquid
1.5	**Boiling point**	173°C
1.6	**Melting point**	<-45°C
1.7	**Density (g/cm^3)**	1.17 at 20 °C
1.8	**Vapour pressure, Pa at 20°C**	$1x10^{-3}$ Pa at 20°C
1.9	**Flash point**	190°C
1.10	**Solubility in water**	71.2 mg/l at 20°C (1–100 mg/l, depending on pH, temperature, anions)
1.11	**Solubility in organic solvents**	TBTO is soluble in lipids and very soluble in a number of organic solvents (ethanol, ether, halogenated hydrocarbons)
1.12	**Log Pow**	3.19–3.84 (distilled water), 3.54 (sea water)
1.13	**Decomposition**	>230°C

(Atkins International Ltd. 1998; IPCS, 1990)

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of action**	Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT and, as such, a number of acceptable and tolerable daily intake values have been determined for this endpoint. The cell-mediated function is impaired due to effects on the thymus. The mechanism of action is unknown but may involve the metabolic conversion to dibutyltin compounds. Non-specific resistance is also affected (IPCS, 1990).

2.1.2 Symptoms of poisoning

Effect of short-term exposure is severe irritation to the eyes and the skin. Inhalation of the aerosol may cause lung oedema which often do not become apparent until several hours have passed. They are exaggerated by physical effort. TBTO[5] may cause effects on the thymus, resulting in depression of the immune function (IPCS, 2004).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

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; IPCS, 1990).

2.2 Toxicology studies

2.2.1 Acute toxicity

LD_{50} (rat, oral): 94–234 mg/kg bw (TBT)
LD_{50} (rat, oral): 165–277 mg/kg bw (TBTO)
LD_{50} (mouse, oral): 44–230 mg/kg bw (TBT)
LD_{50} (rabbit, dermal): > 9000 mg/kg bw (TBT)
LC50 (rat, inhalation, 4 h): 65 mg/l bw (TBTO, respirable particles)
(IPCS, 1990)

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. TBT is very hazardous as an inhaled aerosol, producing lung irritation and oedema, but is relatively innocuous as a vapour. It is severely irritating to the skin and is an extreme irritant to the eye but does not appear to be a skin sensitizer. Severe dermatitis can result after direct contact with TBT concentrations greater than 0.01% (IPCS, 1990).

2.2.2 Short term toxicity

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 anaemia have been documented in rats and mice (IPCS, 1990).

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 or binding with thymic epithelial cells (IPCS, 1990).

Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT, and as such, acceptable daily intake (ADI) values have been determined for this endpoint. The setting of ADI values is discussed in section 2.2.7.

[5] 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). TBT in the aquatic environment is in the same form regardless of the TBT compound from which it was derived**.**

2.2.3 Genotoxicity (including mutagenicity)

There is no evidence that TBTO has any mutagenic potential (IPCS, 1990).

A wide range of both in vitro and in vivo mutagenicity assays have been carried out on TBTO with the conclusion that there is no convincing evidence that TBTO has any mutagenic potential (IPCS 1990).

2.2.4 Long term toxicity and carcinogenicity

In a two-year rat test, TBTO was considered to have produced no relevant malignant tumours at oral concentrations of up to 50 mg/kg body weight/day. The presence of elevated numbers of tumours in the endocrine organs (pituitary and adrenal in both sexes, parathyroid in males only) at lower doses and kidney and pancreatic tumours were not considered biologically relevant, as there was no dose dependent response (IPCS, 1990). TBTO was not carcinogenic in a study in mice (IPCS, 1999).

There is insufficient evidence to suggest that TBTO is a possible human carcinogen (IPCS, 1990).

2.2.5 Effects on reproduction

In developmental studies in the rat, rabbit and mouse, no sensitivity of the foetuses was observed. Malformations (i.e. cleft palate) were noted in rat and mouse foetuses, but only at doses that were overtly toxic to the mothers. TBTO is not considered to be teratogenic. The lowest no-observed effect level (NOEL), with regard to embryotoxicity and foetotoxicity for mice, rats and rabbits, was 1.0 mg/kg body weight (IPCS, 1990).

Little information is available on reproductive toxicity but it appears that TBT did not affect reproductive parameters in a rat multi-generation reproduction study (IPCS, 1990).

2.2.6 Special studies where available

Neurotoxicity/ delayed neurotoxicity

There is no evidence that neurotoxicity is likely to be a critical effect (IPCS, 1999).

2.2.7 Summary of mammalian toxicity and overall evaluation

TBT has moderate to high acute oral toxicity, low dermal toxicity and is very hazardous as inhaled aerosols resulting in lung irritation and oedema. They are severely irritating to the skin and extremely irritating to the eye.

TBT leads to endocrine changes in experimental animals, particularly to pituitary trophic hormones.

The most characteristic toxic effect is on the immune response, with effects on cell mediated function due to effects on the thymus. Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT, and as such, a number of acceptable and tolerable daily intake values have been determined based on this toxic endpoint.

There is no convincing evidence of mutagenicity and insufficient data to suggest carcinogenic potential in humans. It is not considered to be teratogenic but there is little information on reproductive effects. Neurotoxicity is not likely to be a critical effect.

The effects of TBT on the immune system, and particularly on host resistance, have proved the most sensitive parameter of toxicity in the rat, the most sensitive species tested. The no-observed effect level (NOEL), for immuno-suppression following long-term oral exposure in rats is 0.025 mg/kg body weight/day (IPCS 1999).

Based on the application of an uncertainty factor of 100, WHO proposed a guidance value for oral exposure of 0.3 µg/kg body weight/day (IPCS, 1999).

USEPA currently reports a guidance value of 0.3 µg/kg body weight/day based on a benchmark does analysis (BMD10) of the same study data. (USEPA, 1997).

The ADI used by Atkins International Ltd. (1998) in its assessment for the European Community was 1.6 µg/kg body weight/day (CSTEE, 1998). This figure was derived from a NOEL-based on a different toxicological endpoint (lymphoid weight and function studies). In the final decision, the European Community adopted an ADI of 0.3 µg/kg body weight/day based on the same NOEL and endpoint as the WHO.

3 Human exposure/risk evaluation

3.1 Food

The risk evaluation of Canada suggested that data were inadequate to characterize meaningfully the total intake of organotin compounds from food.

The risk evaluation of the European Community identified a potential health risk from the ingestion of contaminated seafood. Using an exposure scenario with a value for bioaccumulation of 7,000 (*mytilus edulis*), a daily fish intake of 115 g and an acceptable daily intake value of 1.6 µg/kg body weight/day, it was calculated that the quantity of TBT that would be consumed by a man weighing 70 kg would be in the order of 112 µg. Calculating back from this value, it was determined that, in order to keep consumption of TBT at or below this level, the concentration in water should be in the order of 139 ng/l. It was considered that this concentration could be exceeded in areas close to the shipping ports, although it was unlikely in more distant locations and the open sea. If the consumption estimate was repeated with the more conservative ADI of 0.3 µg/kg body weight/day, the concentration in water would correspondingly be lower.

Therefore, the level of TBT use may pose an unacceptable risk to human health where daily intake of fish comes from shellfish raised in waters near commercial harbours.

3.2 Air

Data on the concentration of organotin compounds in either indoor or ambient air were not identified in the risk evaluation of Canada.
While systematic review of exposure to air has not been undertaken, the risk evaluation of the European Community identified inhalation exposure during the mixing of ingredients in the manufacture of anti-fouling paint to be a potential risk to human health.

3.3 Water

Levels of TBT released from shipping and from use in dockyards can result in levels in water in the ng/l range. A potential risk was identified by the European Community from the consumption of fish and shellfish raised in water contaminated with TBT.

Human exposure to TBT through the consumption of water containing residues in the ng/l range is considered negligible.

3.4 Occupational exposure

Occupational exposure of workers to TBT 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.

WHO describes skin lesions, dermatitis and skin and eye irritancy in workers exposed dermally to TBT and irritation of the upper respiratory tract and lower chest symptoms in rubber vulcanizing workers using TBTO (IPCS, 1990).

In the risk evaluation of the European Community, a health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere during mixing. Measurement of atmospheric concentrations at paint mixing plants have shown levels during the transfer period of 0.049 to 0.195 mg/m^3 as TBT. This exposure only occurs for approximately 15 minutes, however it can be over double the acceptable short-term occupational exposure limit of 0.072 mg/m^3 set at three times the value of the most stringent 8-hour time-weighted average (TWA: 3 x 0.024 mg/m^3). The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain.

3.5	**Medical data contributing to regulatory decision**	The effects of TBT in humans are not well documented, except for the induction of apoptosis in granulocytes and human thymocytes. No information has been located regarding toxicity of TBTO in humans following oral exposure. Summary of the human data suggests that TBTO is a potent non-allergenic dermal irritant (see section 3.4 above). Impairment of the immune system is considered the most sensitive parameter for systemic effects of TBT. There have been no cases of acute systemic poisoning (IPCS, 1990).
3.6	**Public exposure**	No detailed risk evaluations of public exposure have been undertaken by Canada or the European Community, other than the potential risk to consumers of fish and shellfish raised in waters contaminated with TBT.
3.7	**Summary-overall risk evaluation**	Occupational exposure of workers to TBT 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. In the risk evaluation of the European Community, a health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere. The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain. Levels of TBT released from shipping and from use in dockyards can result in levels in water in the ng/l range. A potential risk was identified by the European Community from the consumption of fish and shellfish raised in areas close to shipping ports contaminated with TBT. Human exposure to TBT through the consumption of water containing residues in the ng/l range was considered negligible.

4 Environmental fate and effects

4.1	**Fate**	
4.1.1	**Soil**	There are no soil persistence values in the risk evaluations of the notifying countries.
4.1.2	**Water**	Irrespective of their original structure, tributyltin compounds exist in seawater as three species (hydroxide, chloride and carbonate) under normal conditions. TBT slowly degrades to dibutyltin and monobutyltin in the aquatic environment (Atkins International Ltd., 1998). Levels of TBT released from shipping result in levels in water in the ng/l range. Persistence of TBT in water is slight to moderate with a half-life in water reported as a few days to a few months.
4.1.3	**Air**	No available data.
4.1.4	**Bioconcentration**	Studies with algae, aquatic invertebrates and fish have confirmed that bioaccumulation of TBT in these organisms is substantial. The bioconcentration factor (BCF) values reach up to 10,000 in periwinkles, 50,000 in fish, and 500,000 in clams. Although TBT does not appear to biomagnify significantly 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 (Maguire, 2000).

4.1.5 Persistence

The persistence of TBT in water is slight to moderate with half-lives of a few days to a few months. TBT shows significant persistence in sediments, however. Several studies from different parts of the world indicate half-lives for TBT in sediment of up to 15 years. The levels of TBT in the sediments of dockyards around the world varies widely from 10–2000 μg/kg dry weight (Atkins International Ltd., 1998).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

There have been few detailed studies on terrestrial species. WHO reports that exposure to terrestrial organisms results primarily from its use as a wood preservative. There was some indication of toxicity to bats exposed topically or via feeding on treated wood. TBT is moderately toxic to wild mice (IPCS, 1990).

4.2.2 Aquatic species

TBT is toxic to many aquatic organisms.

Mollusc:	LC_{50} (48h, adult *mytilus edulis)* = 300 μg TBTO/l
	LC_{50} (66d, 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 TBTOl
Bacteria:	EC_{10} (18h, *pseudomonas putida)* = 24 μg TBT/l

Daphnia magna: NOEC (21 d) = 0.078 μg TBT/l

(Atkins International Ltd., 1998)

Effects on the shell development of the Pacific oyster *(crassostrea gigas)* have been observed at concentrations < 2 ng TBT/l (Atkins International Ltd., 1998).

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 (Maguire, 2000).

The dog whelk (*nucella lapillus)* has been shown to suffer from imposex[6] at TBT concentrations at less than 1 ng TBT/l. This impairment of reproduction was also observed in numerous other marine species (Maguire, 2000).

4.2.3 Honeybees and other arthropods

TBT is toxic to bees housed in hives made from wood treated with TBT. There was some indication of toxicity to insects exposed topically or via feeding on treated wood.

4.2.4 Earthworms

No available data

4.2.5 Soil microorganisms

No available data

4.2.6 Terrestrial plants

No available data

[6] Imposex is the development of male sexual characteristics by female gastropods, which in severe cases can cause reproductive failure and death.

5 Environmental exposure/risk evaluation

5.1 Terrestrial vertebrates

No risk evaluation

5.2 Aquatic species

Canada: TBT is an exclusively anthropogenic chemical. A detailed review conducted concluded that TBT is extremely toxic to aquatic organisms, and is sufficiently persistent (half life of up to 15 years in sediment) and bioaccumulative (BCF values up to 500,000) to warrant further regulatory action. The dog whelk (*nucella lapillus)* has been shown to suffer from imposex at TBT concentrations at less than 1 ng TBT/l. TBT has been detected in surface water at levels greater than 1 ng/l thus representing an unacceptable risk to non-target aquatic species.

It was determined that the continued use of TBT in anti-fouling paints poses an unacceptable risk to the Canadian environment, based on toxicity to non-target 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.

European Community: In the risk evaluation of the European Community, four aquatic exposure scenarios were examined and the predicted environmental concentration (PEC), predicted no effect concentration (PNEC) and PEC/PNEC ratios were identified for each of the identified releases to the aquatic environment. The PNEC derived for freshwater, based on toxicity to freshwater snails (*biomphalaria glabrata*), was 0.024 ng/l and for marine water, based on toxicity to the dog whelk (n*ucella lapillus*), 1.2 ng/l. The four scenarios were:

1. Release to surface water from the manufacture of TBTO;
2. Release to surface water from the manufacture of TBT self-polishing co-polymer paints;
3. Release to surface water from dockyard procedures;
4. Release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment.

Table 1 PEC, PNEC and PEC:PNEC ratio for each of the aquatic exposure scenarios (Atkins International Ltd., 1998)

Release source	PEC (ng/l)	PNEC (ng/l)	PEC:PNEC
Manufacture of TBTO	17.5	0.024	729
Manufacture of TBT self-polishing co-polymer paints	2	0.024	83
Release of TBT from dockyard into freshwater	20	0.024	833
Release of TBT from dockyard into marine water	2	1.2	1.6
Release from shipping over 25m into marine water	>1.2[1]	1.2	>1
Release from shipping over 25m into brackish water	>1.2[1]	1.2	>1
Release of TBT from shipping over 25m into freshwater	>1[1]	0.024	>40

[1]Not able to quantify

In this evaluation, PEC, PNEC and PEC/PNEC ratios were derived for each of the aquatic exposure scenarios. Sufficient evidence was available to suggest that where shipping intensity is high and in dockyards, the potential concentration of TBT in the surrounding waters represented by the PEC is greater than the PNEC (derived from no effect levels on sensitive species together with an assessment factor: the dog whelk (*nucellus lapillus)* for marine water and freshwater snails (*biomphalaria glabrata)* for freshwater) giving a ratio in all the above areas of >1, thus indicating an unacceptable environmental risk.

It was concluded that releases of TBT to the aquatic environment from shipping and dockyards are difficult to control. The minimum TBTO release rate required to maintain anti-fouling efficiency still resulted in a substantial release to the aquatic environment in the case of large ships. To reduce the TBT input to the aquatic environment from this source, it would be necessary to restrict the use of TBT anti-fouling paints.

5.3	**Honey bees**	No risk evaluation
5.4	**Earthworms**	No risk evaluation
5.5	**Soil microorganisms**	No risk evaluation
5.6	**Summary – overall risk evaluation**	**Canada:** It was concluded that the use of TBT in anti-fouling paints posed an unacceptable risk to the Canadian environment, based on toxicity to non-target aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.

European Community: Unacceptable risks to non-target aquatic organisms were identified in the release to surface waters both from the manufacture of TBT and TBT-containing anti-fouling paints and the hulls of ships painted with anti-fouling paints.

Annex 2 – Details of final regulatory actions reported

Party name: Canada

1	**Effective date(s) of entry into force of actions**	31 October 2002
	Reference to the regulatory document	Pest Management Regulatory Agency special review decision on tributyltin antifouling paints for ship hulls (SRD2002-01). (www.pmra-arla.gc.ca/english/pdf/srd/srd2002-01-e.pdf).
2	**Succinct details of the final regulatory action(s)**	The registrations of all tri-n-butyl tin-based TBT anti-fouling paints, and their associated registered concentrates and active ingredient, were phased out during 2002. The registrant agreed to conduct a recall of any unsold product to ensure that there is no product in the channels of trade after 1 January 2003.
3	**Reasons for action**	Using the effect of imposex on molluscs to monitor recovery from TBT contamination, studies indicated that regulatory control of TBT anti-fouling paints in Canada prior to 1999 had not eliminated the problem. It was determined that the continued use of TBT in anti-fouling paints posed an unacceptable risk to non-target 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.
4	**Basis for inclusion into Annex III**	Final regulatory action that severely restricts the use of TBT compounds based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	The review concluded that there were unacceptable risks to the aquatic environment.
4.2	**Criteria used**	Risks to the environment.
	Relevance to other States and Region	TBT anti-fouling paints can cause harm to the aquatic environment. Preventing use on ship hulls therefore protects the aquatic environment from this exposure wherever such ships may travel.
5	**Alternatives**	Since 1989, several non-TBT anti-fouling paints have been evaluated and registered for use in Canada. These non-tin products contain copper active ingredients that offer anti-fouling properties similar to those of the TBT anti-fouling paints. Presently, there are more than 50 copper-based anti-fouling paints registered for use by either small ship owners or professional paint applicators. These copper anti-fouling 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 aluminium hulls, as they do not cause corrosion like other copper-containing paints.
6	**Waste management**	No specific measures outlined.
7	**Other**	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 polyvinylchloride (PVC) stabilizers and as industrial catalysts. The assessment of effects on the environment focused on aquatic biota since they are 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. Furthermore, 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 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.

Party name: European Community		
1	**Effective date(s) of entry into force of actions**	The regulatory action entered into force on 12 July 2002. The Member States of the European Community were required to apply the measures as from 1 January 2003.
	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 July 2002, p. 58) (available at http://europa.eu.int/eur-Iex/pri/en/oj7dat/2002/l_183/l_1 8320020712en00580059.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	**Succinct details of the final regulatory action(s)**	As from 1 January 2003, the use of tri-organostannic compounds, including TBT 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; any totally or partially submerged appliance or equipment; and in industrial water treatment.
3	**Reasons for action**	In the risk assessment conducted for the European Commission, unacceptable health risks were identified in the following areas: **Human health** • Occupational: Inhalation and dermal exposure to atmospheric TBT during the transfer of ingredients to the mixing vessel during anti-fouling paint manufacture. • Food consumption: Ingestion of contaminated food (e.g. mussels) where TBT concentrations are high. It was concluded that the occupational risk arising from manufacture and application processes may be reduced by increased control of the process. Releases of TBT to the aquatic environment from shipping, however, are more difficult to control because it has 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. **Environmental impact** 1. Release to surface water from the manufacture of TBT; 2. Release to surface water from the manufacture of TBT self polishing co-polymer paints; 3. Release to surface water from dockyard procedures; 4. 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. Releases of TBT from shipping, however, are more difficult to control because it has been shown that, even when the TBT release rate is reduced to the minimum required to maintain anti-fouling efficiency, the amount released from a large ship is still considerable. To reduce the TBT input from this source, it was necessary to restrict the use of TBT paints in the aquatic environment.

4	**Basis for inclusion in Annex III**	Final regulatory action to severely restrict use of TBT based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	The evaluation concluded that there were unacceptable risks to human health and to the environment.
4.2	**Criteria used**	Risks to human health and the environment.
	Relevance to other States and regions	Protection of the aquatic environment and human health. Global relevance is confirmed by the International Convention on the Control of Harmful Anti-fouling Systems. 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 or shall bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant anti-fouling systems.
5	**Alternatives**	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 (extracts of natural products, e.g. sponge).
6	**Waste management**	No specific measures outlined
7	**Other**	Commission Directive 2002/62/EC is the latest in a series of regulatory actions, dating back to 1989, when use of TBT 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. Commission Directive 2002/62/EC extended the ban to all other forms of anti-fouling products.

Annex 3 – Addresses of designated national authorities

Canada
P

Pest Management Regulatory Agency, Health Canada 2720 Riverside Drive Ottawa, Ontario K1A 0K9 *Trish MacQuarrie* *Director, Alternative Strategies and Regulatory Affairs Division*	**Phone** +1 613-736-3660 **Fax** +1 613-736-3659 **E-mail** trish_macquarrie@hc-sc.gc.ca

European Commission
CP

DG Environment European Commission Rue de la Loi, 200 B-1049 Brussels Belgium *Leena Yla-Mononen* *Deputy Head of Unit*	**Phone** +322 299 48 60 **Fax** +322 296 69 95 **E-mail** Leena.Yla-Mononen@cec.eu.int

CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References

Regulatory actions

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/2002/1_18320020712en00580059.pdf).

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).

PMRA (2002). *Pest Management Regulatory Agency special review decision: Tributyltin anti-fouling paints for ship hulls* (SRD2Q02-01). (www.pmra-arla.gc.ca/english/pdf/srd/srd2002-01-e.pdf).

Other documents

Atkins International Ltd. (1998). 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.* W.S. Atkins International Ltd. (vol. A), April 1998.

ATSDR (2005). Agency for Toxic Substances and Disease Registry. *Toxicological profiles: Tin and tin compounds* (available at: http://www.atsdr.cdc.gov/).

CSTEE (1998). *Opinion on the report by W.S. 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 sixth CSTEE plenary meeting, Brussels, 27 November 1998 (available at: http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html).

Environment Canada, Health and Welfare Canada (1993) *Priority substances list assessment report: Non-pesticidal organotin compounds* (available at: www.hc.sc.gc.ca/hecs-sesc/exsd/pdf/non_pesticial_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 (available at: www.hc.gc.ca/substances/ese/eng/psap/assessment/PSL1_organotin_followup.pdf).

International Convention on the Control of Harmful Anti-fouling Systems on Ships (available at: http://www.imo.org/home.asp?topic_id=161).

IPCS (1990). *Environmental Health Criteria No. 116 Tributyltin Compounds,* WHO, Geneva (available at http://www.inchem.org/documents/ehc/ehc/ehc116.htm).

IPCS (1999). *Concise International Chemical Assessment Document 14: Tributyltin Oxide.* WHO, Geneva (available at: http://www.inchem.org/pages/cicads.html).

IPCS (2004). *International chemical safety card: tributyltin oxide* (available at: http://www.inchem.org/pages/icsc.html).

Maguire (2000). *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 Quality Research Journal, Canada, 2000, Volume 35, No.4, 633-679.

USEPA (1997). United States Environmental Protection Agency Integrated Risk Information System (IRIS) (available at: http://www.epa.gov/iris).

Relevant guidelines and reference documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996) (available at: www.basel.int).

FAO (1990). Guidelines for personal protection when working with pesticides in tropical countries. FAO, Rome (available at: http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.htm).

FAO (1995). Revised guidelines on good labelling practices for pesticides. FAO, Rome (available at: see above)

FAO (1995). Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks. FAO, Rome (available at: see above).

FAO (1996). Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. FAO, Rome (available at: see above)

FAO (1996). Pesticide Storage and Stock Control Manual. FAO, Rome (available at: see above)