Rotterdam Convention

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

Revised Decision Guidance Document

Tributyltin compounds

Food and Agriculture
Organization of the
United Nations

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

180717

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. However, in the case of tributyltin compounds, only one notification has been received by the Secretariat in the industrial category. 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 from 27 to 31 October 2008 the Conference of the Parties agreed to list all tributyltin compounds in Annex III of the Convention under pesticides category and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure. The decision-guidance document related to that decision was communicated to designated national authorities on 1 February 2009 in accordance with Articles 7 and 10 of the Rotterdam Convention. The decision guidance document was amended to include information relevant to the industrial category.

At its eighth meeting, held in Geneva from 24 April to 5 May 2017, the Conference of the Parties agreed to list tributyltin compounds in Annex III of the Convention under industrial chemicals category, as well and adopted the revised decision-guidance document including both pesticides and industrial chemicals categories 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 15 September 2017, 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).

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[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.

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.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ATSDR	Agency for Toxic Substances Disease Registry
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
CSTEE	Scientific Committee for Toxicity, Ecotoxicity and the Environment (European Commission)
CTV	Critical Toxicity Value
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EINECS	European Inventory of Existing Commercial Chemical Substances
ECHA	European Chemicals Agency
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal

STANDARD CORE SET OF ABBREVIATIONS

L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	metre
m.p.	melting point
mg	milligram
mL	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	maximum tolerated dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PNEC	predicted no effect concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
RTECS	Registry of Toxic Effects of Chemical Substances
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TBT	tributyltin
TBTO	tributyltin oxide
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision-guidance document for a banned or severely restricted chemical

Tributyltin (TBT) compounds[3] including: **Published: September 2017**
Tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.

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

Common name

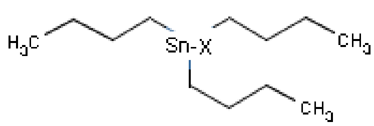
Tributyltin (TBT) compounds including: tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.

Chemical name and other names or synonyms

Tributyltin oxide (TBTO)
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	2931.20 (pure substance) 3808.50 (mixture)
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, Industrial
Regulated category	Pesticide (Canada and European Union), Industrial chemical (Canada)
Use(s) in regulated category	Pesticide (Canada and European Union): Used in non-agricultural biocide pest control products. The most common use of TBT was in antifouling 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. Industrial chemical (Canada): Tributyltins in their pure form are currently not in commercial use in Canada, but they may be found in products that are mainly used in the PVC processing industry, and as pesticides.Minor uses of products containing tributyltin compounds include glass coating and catalysts.
Trade names	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 *This list is an indicative list of trade names. It is not intended to be exhaustive.*
Formulation types	Canada and European Union / pesticide: Formulated as paints (biocides) Canada / industrial chemicals: All formulation types (see section 2.1)
Uses in other categories	The European Union also 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	Pesticide: 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 both the pesticide and industrial category. The group of compounds is listed on the basis of the final regulatory actions that severely restrict their use as pesticide and industrial chemical, notified by Canada and the European Union.

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

Canada / pesticide: Registrations of all TBT-based antifouling paints, and the associated registered active ingredients and concentrates, were phased out by 31 October 2002. The registrant agreed to recall from the market all unsold stocks to ensure that there were no products in trade after 1 January 2003. There are no longer any TBT pesticides registered in Canada.

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

European Union / pesticide: 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).

Canada / industrial chemical: Severe restriction of the manufacture, use, sale, offer for sale or import of non-pesticidal TBT compounds with the exemption of: a) tetrabutyltins containing a concentration of less than or equal to 30 % by weight of tributyltins; and b) mono- and dibutyltins, because tributyltins are incidentally present in these products. Entry into force of the final regulatory action was March 14, 2013.

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

2.2 Risk evaluation (see Annex 1 for further details)

Canada / Pesticide: Because of concerns regarding the impact of TBT (pesticidal use) on the aquatic environment, Canada had limited application of TBT antifouling paints to vessels greater than 25 metres in length and to vessels (ofany 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 (*Pest Control Products Act*) 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 antifouling paints in Canada had not eliminated the problem by 1995.

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

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.

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 Union / Pesticide: The results of a study on the risks to health and to the environment of antifouling 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 antifouling 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.

Canada / Industrial: A detailed review conducted by the government of Canada in 2009[5] concluded that non-pesticidal use of tributyltin compounds have toxic effects to aquatic organisms at low concentrations, and have a high potential to cause environmental harm due to their high persistence and bioaccumulative properties.

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

In the risk assessment a risk quotient was calculated on the basis of modelled as well as measured exposure and the toxicity. The exposure was based firstly, on concentrations of tributyltin compounds in water and sediment modelled for Canada, and secondly, on measured concentrations of tributyltin compounds in water and sediment in Canada. It was concluded that estimated and measured concentrations of non-pesticidal uses of tributyltins in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, tributyltins meet the criteria for persistence and bioaccumulation set out in Canada`s national regulation, and high concentrations of tributyltin compounds in the environment, e.g. in the sediment, are known to cause imposex on molluscs and appear to have the potential to induce sex reversal in some marine fish.

The risk evaluation took into account that Canadian PVC processing facilities which use organotin stabilizers have adopted product stewardship practices that have led to a decrease in the quantity of organotins that could potentially be released to the environment. Because of the unique concerns relating to persistent and bioaccumulative substances, the potential for tributyltin compounds to cause environmental harm was evaluated separately from organotins as a group. The risk evaluation took into account these modelled and measured exposure data[6] and the ecotoxicological endpoints for tributyltin compounds and indicates a high risk to the most sensitive aquatic organisms.

[6] UNEP/FAO/RC/CRC.10/INF/13.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada / pesticide	The use of TBT in antifouling paints, which is the main source of TBT to the aquatic environment, was banned. Although persistence in the marine environment at some locations will cause it to remain elevated for some time, removing this source of input will allow recovery to occur.
European Union / pesticide	The ban of TBT in antifouling 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.
Canada / industrial	The industrial use of TBT was banned with certain exceptions because there are other initiatives in place to manage any potential releases of these substances or these other uses have limited environmental impact. TBT's for non-pesticidal uses are not currently manufactured or used as pure substances in Canada. However, adding them to the Prohibition Regulations would prevent their introduction (and of products containing them) into the Canadian market, thereby eliminating the risk of their release to the aquatic environment.

3.2 Other measures to reduce exposure

The following initiatives are currently in place to manage any potential release of substances where TBTs may be present:

- An Environmental Performance Agreement 2015-2020 Respecting the Use of Tin Stabilizers in the Vinyl Industry is in place to manage the potential releases of mono- and di-organotins (referred to as tin stabilizers used in the vinyl industry) which may contain incidentally some TBT (this new agreement replaces the former one that covered the period of 2008-2013) http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=2F52E977;
- A Code of Practice (CoP)was published under section 54 of CEPA 1999 to manage releases of tetrabutyltin to the aquatic environment for all facilities involved with tetrabutyltin in Canada. Given that TBT may also be present incidentally in tetrabutyltin, this Code also indirectly manages the potential release of TBT.

General: The International Convention on the Control of Harmful Antifouling Systems on Ships prohibits the use of harmful organotins in antifouling paints used on ships and establishes a mechanism to prevent the potential future use of other harmful substances in antifouling systems. Under the terms of the Convention, Parties to the Convention are required to prohibit or restrict the use of harmful antifouling 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 antifouling 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 / pesticide: 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 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 Antifouling Systems on Ships requires that each Party undertakes to communicate information regarding any antifouling 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 Union / pesticide: 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.

Canada / industrial chemical: PVC stabilizers: Substitutes for PVC tin stabilizers include lead or mixed metals such as calcium and zinc. Characteristics of lead stabilizers include low costs and well-documented environmental concerns. Lead stabilizers are currently being phased out in Europe. It is expected that lead will be replaced by lighter metals like calcium or zinc, as well as organic stabilizers. Mixed metal stabilizers are more expensive than their tin-based counterparts and are less effective in stabilization.
Use of Tributyltins as a Starting Material: Tributyltins are known to be used in the manufacture of other chemicals, one of which is a material preservative. Although no alternatives as a starting material are known to exist for this application, other non-tributyltin material preservatives registered under the *Pest Control Products Act* may be available.

3.4 Socio-economic effects

Canada / pesticide: 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 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 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 antifouling 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 Union / pesticide: 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 antifouling, the fuel consumption of large ships may be increased by 50 per cent.

Canada / industrial: The severe restriction was not expected to result in any incremental costs to industry, as TBT compounds were not manufactured or used as industrial chemicals in their pure form in Canada and activity involving tributyltins which may be present in other compounds was not prohibited.

4. Hazards and risks to human health and the environment

4.1 Hazard classification

European Union	**CLP Classification** (Annex VI to Regulation (EC) 1272/2008): Acute Tox. 3, H301 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 **Classification** (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 numbers: 2786, 2787, 2788, 3019, 3020, 3146 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 Union 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 two Parties notifying TBTs as pesticides, namely Canada and the European Union, and one Party, Canada, notifying TBTs as industrial chemicals. Where possible, information provided by these Parties on hazards has been presented together, while the risk assessments, which are specific to the use category and 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 as pesticide was first reported in PIC Circular XXII of December 2005, the notification from the European Union (at that time it was the European Community) in PIC Circular XVII of June 2003 and the notification from Canada as industrial chemicals was published in PIC Circular XXXVIII of December 2013.

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 relating to the pesticide category of Canada and the European Union 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 antifouling 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 does not become apparent until several hours have passed. They are exaggerated by physical effort. TBTO[7] 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.

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).

[7] 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.

2.2.4 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 Union 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 Union 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 Union identified a potential health risk from the ingestion of contaminated seafood. Using an exposure scenario with a value for bioaccumulation of 7000 (*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 Union identified inhalation exposure during the mixing of ingredients in the manufacture of antifouling 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 Union 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 Union, 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 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 Union, 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 Union, 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 Union 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/ Bioaccumulation

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 10000 in periwinkles, 50000 in fish, and 500000 in clams. Tributyltins are highly bioaccumulative, with reported BAFs (bioaccumulation factor) of up to 900000. Concentrations in tissues of top predators are also high (up to 4 µg/g wet weight). Limited evidence of biomagnification has been reported for some marine food chains with biomagnification factors typically less than 10 (Government of Canada, 2009).

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 TBTO/L NOEC (90 day, *Poecilia reticulata*) = 0.01 µg hexabutyldistannoxane /L (Atkins International Ltd., 1998) The 110-day Lowest-Observable-Effect Concentration (LOEC) for rainbow trout (*Oncorhynchus mykiss*) yolk sac fry was 0.173 µg tributyltin chloride/L, based on increased mortality and decreased resistence to *Aeromonas*. Tributyltins are toxic at low concentrations. Furthermore, several specific modes of toxic action are possible, including endocrine disruption (Government of Canada, 2009). *Daphnia magna*: NOEC (21 d) = 0.078 µg TBT/L (Atkins International Ltd., 1998) *Hexagenia spp*. LC_{50} (mayfly, 21-d, sediment): 1.5 µg TBTchloride/g dry weight, based on growth (Government of Canada, 2009) Bacteria: EC_{10} (18h, *Pseudomonas putida)* = 24 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). Chronic effects on benthos may occur at TBT concentrations in the range of 0.1-1 µg/g dry weight of sediment (Government of Canada, 2009). 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 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

5 Environmental exposure/risk evaluation

5.1	**Terrestrial vertebrates**	No risk evaluation
5.2	**Aquatic species**	**Canada / pesticide:** TBT is an exclusively anthropogenic chemical. A detailed review 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 500000) 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 antifouling 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 Union / pesticide: In the risk evaluation of the European Union, 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 (*Nucella 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 antifouling 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 antifouling paints.

Canada / industrial chemical: A detailed review conducted by the government of Canada (Proposed risk management approach for Non-Pesticidal Organotin Compounds (Organotins), 2009) concluded that tributyltin compounds are toxic to aquatic organisms at low concentrations, and have a high potential to cause environmental harm due to their high persistence and bioaccumulative properties.

In the risk assessment a risk quotient was calculated on the basis of modelled as well as measured exposure and the toxicity. The exposure was based firstly, on concentrations of tributyltin compounds in water and sediment modelled for Canada, and secondly, on measured concentrations of tributyltin compounds in water and sediment in Canada. It was concluded that estimated and measured concentrations of tributyltins in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, tributyltins meet the criteria for persistence and bioaccumulation set out in Canada`s national regulation, and high concentrations of tributyltin compounds in sediments are known to cause imposex (imposition of male characteristics on female organisms) on molluscs and appear to have the potential to induce sex reversal in some marine fish.

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

Nevertheless, risk quotients for tributyltins were calculated for comparison purposes. PEC/PNEC ratios for tributyltin compounds, based on both modelled and measured PECs in water and sediment, are shown in Table 2. The Canadian Water Quality Guideline for the Protection of Freshwater Aquatic Life of 0.008 µg/L was used as the PNEC for tributyltins in water. The most sensitive benthic organism reported was the mayfly, *Hexagenia* spp., with a 21-day IC_{50} (growth) of 1.5 mg tributyltin/kg dry weight. Dividing this toxicity value by an assessment factor of 100 (10 to extrapolate from an acute to a chronic no-effect level, and 10 to account for extrapolation from laboratory to field conditions and for inter- and intraspecies variability) gives a chronic PNEC of 0.015 mg/kg dry weight for tributyltins in sediment. All risk quotients in Table 2 are significantly greater than 1, thus indicating a potentially high risk.

Table 2: PEC/PNEC Ratios for Tributyltin Substances

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

[a] highest environmental concentrations predicted for new and/or transitional tributyltins associated with chemical manufacturing, expressed as hydrolysed tributyltin
[b] highest concentration measured in Canada (Follow-up report on a PSL1 substance..,. 2003)

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 / pesticide: It was concluded that the use of TBT in antifouling 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 Union / pesticide: Unacceptable risks to non-target aquatic organisms were identified in the release to surface waters both from the manufacture of TBT and TBT-containing antifouling paints and the hulls of ships painted with antifouling paints.

Canada / industrial chemical: It was concluded that the use of TBT as an industrial chemical posed an unacceptable risk to the Canadian environment, based on toxicity to aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.

Annex 2 – Details of final regulatory actions reported

Category: Pesticide

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). (http://www.hc-sc.gc.ca/contact/order-pub-commande-eng.php?title=PMRA%20%28srd2002-01%29%20Tributyltin%20Antifouling%20Paints%20for%20Ship%20Hulls).
2	**Succinct details of the final regulatory action(s)**	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 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 antifouling paints in Canada prior to 1999 had not eliminated the problem. It was determined that the continued use of TBT in antifouling 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. For more details please see Annex I, 5.2.
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 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 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 stabilizers during the processing of polyvinylchloride (PVC) resins 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 Union

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 Union 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_l 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 antifouling 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 antifouling 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 antifouling 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 antifouling 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 antifouling 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 antifouling products.

Category: Industrial

Party name: Canada

1	**Effective date(s) of entry into force of actions**	14 March 2013
	Reference to the regulatory document	*Prohibition of Certain Toxic Substances Regulations, 2012* *Canada Gazette*, Part II, Vol. 147 No. 1 – Jan. 2, 2013 http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html
2	**Succinct details of the final regulatory action(s)**	Severe restriction of the use of TBT compounds. All manufacture, use, sale, offer for sale or import is prohibited with the exception of: a) tetrabutyltins containing a concentration of less than or equal to 30 % by weight of tributyltins; and b) mono- and dibutyltins, because tributyltins are incidentally present in these products.
3	**Reasons for action**	Protection of the environment. Tributyltins are harmful to many aquatic organisms at low concentrations. They are present in the environment as a result of human activity. They have been shown to impose male sexual characteristics on females of some marine gastropods and appear to have the potential to induce sex reversal in some marine fish. Estimated and measured concentrations of tributyltins in some locations in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, non-pesticidal use of tributyltins meet the criteria for persistence and bioaccumulation set out in the *Persistence and Bioaccumulation Regulations*, a regulation made under the *Canadian Environmental Protection Act, 1999*.
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 risk evaluation took into account industry stewardship practices. In light of this, and with consideration of the persistent and bioaccumulative properties of tributyltins, the review concluded that there were unacceptable risks to aquatic organisms.
4.2	**Criteria used**	Risks to the environment.
	Relevance to other States and Region	TBT can cause harm to the aquatic environment. Preventing input from industrial uses protects the aquatic environment from this exposure.
5	**Alternatives**	No information was presented in the Notification of Final Regulatory Action. The supporting information provided the following on alternatives: PVC Stabilizers: Substitutes for PVC tin stabilizers include lead or “mixed metals” such as calciumzinc. Mixed metal stabilizers are more expensive than their tin-based counterparts and are less effective in stabilization Tributyltins are known to be used in the manufacture of other chemicals, one of which is a material preservative. Although no alternatives as a starting material are known to exist for this application, other non-tributyltin material preservatives registered under the *Pest Control Products Act* may be available.
6	**Waste management**	No specific measures outlined.
7	**Other**	

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 Union
CP

Directorate General Environment, Unit D3-Chemicals, Biocides, Nanomaterials European Commission Avenue de Beaulieu 9 Office BU 9, 05/166 B-1049 Brussels Belgium *Jürgen Heinrich Helbig* *Principal Policy Officer*	**Phone** +322 298 8521 **Fax** +322 298 8874 **E-mail** Juergen.Helbig@ec.europa.eu

Canada
C

Environment Canada 351 St. Joseph Blvd., Gatineau Quebec. K1A 0H3 *Ms. Lucie Desforges* *Director, Chemical Production Division*	**Phone** +1 819-938-4209 **Fax** +1 819-938-4218 **E-mail** Lucie.Desforges@ec.gc.ca

CP Pesticides and industrial chemicals
P Pesticides
C Industrial chemicals

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).

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