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Interim Chemical Review Committee

Fourth session

Rome, 3 – 7 March 2003

Item 5 a) iv) of the provisional agenda*

**INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT
PROCEDURE - REVIEW OF NOTIFICATIONS OF FINAL REGULATORY ACTIONS
TO BAN OR SEVERELY RESTRICT A CHEMICAL**

Tributyltin Compounds

Note from the Secretariat

1. In line with Article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two interim PIC regions, that contain the information required in Annex I of the Convention, it shall forward the notifications and accompanying documentation to the members of the Interim Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure and a decision guidance document drafted.
2. The Intergovernmental Negotiating Committee, in decision INC.7/6, adopted a process for drafting decision guidance documents. The process is based on that developed by the Interim Chemical Review Committee at its first session in Geneva, February 2000. An excerpt of the decision is contained in document UNEP/FAO/PIC/ICRC.4/INF.5.
3. The Secretariat has identified two verified notifications from two interim PIC regions relating to tributyltin compounds (Asia - Japan and Europe – European Community). Summary of the notification provided by Japan was included in PIC Circular XI June 2000 and summary of the notification submitted by the European Community will be published in PIC Circular XVII June 2003.
4. This note contains the two notifications as they were circulated to the members of the Interim Chemical Review Committee in a letter the week of 15 December 2002 in line with Article 5 of the Convention.

* UNEP/FAO/PIC/ICRC.4/1

5. The relevant documentation provided by Japan and the European Community in conjunction with their respective notifications were circulated to members of the Interim Chemical Review Committee with a letter the week of XX November 2002 and are available as an addendum to this note (UNEP/FAO/PIC/ICRC.4/17/Add.1 and UNEP/FAO/PIC/ICRC.4/17/Add.2 respectively).



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

IMPORTANT: See instructions before filling in the form

COUNTRY: JAPAN

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL		
1.1	Common name	Bis(tributyltin)oxide
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	Bis(tri-n-butyltin) oxide; Tributyltin oxide; TBTO; hexabutylstannoxane; Bis(tributyltin)oxide; Bis(tri-normal-butyltin) oxide; bis(tributyltin) oxide of tin; bis(tributylstannyl) oxide; BTO; hexabutyltin; oxybis(tributyltin); tri-n-butylstannane oxide; TBOT; Hexabutylstannoxane; Tributyltin trioxide; Bis(tri-n-tributyltin)oxide
1.3	Trade names and names of preparations	biomet tbto; Butinox; C-SN-9; L.S. 3394; Interlux Micron; Interswift BKA007; Super Sea Jacket; Sigmaplane 7284; Navicote 2000; AF-SeafloZ-100; HBD; AW 75-D; Biomet; Biomet 75
1.4	Code numbers	
1.4.1	CAS number	56-35-9
1.4.2	Harmonized System customs code	2931.00
1.4.3	Other numbers (specify the numbering system)	

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

1.6 Information on hazard classification where the chemical is subject to classification requirements
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PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention Plant Protection Service Plant Production and Protection Division, FAO Viale delle Terme di Caracalla 00100 Rome, Italy Tel: (+39 06) 5705 3441 Fax: (+39 06) 5705 6347 E-mail: pic@fao.org	OR	Interim Secretariat for the Rotterdam Convention UNEP Chemicals 11-13, Chemin des Anémones CH - 1219 Châtelaine, Geneva, Switzerland Tel: (+41 22) 917 8183 Fax: (+41 22) 797 3460 E-mail: pic@unep.ch
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International classification systems	Hazard class
UN Recommendations on the Transport of Dangerous Goods	Class 6.1 (No.2788)
Other classification systems	Hazard class

1.7 Use or uses of the chemical	
1.7.1	<p><input checked="" type="checkbox"/> Pesticide</p> <p>Describe the uses of the chemical as a pesticide in your country:</p> <p>Used to be used for preservatives; anti-mold agents; anti-fouling paints and anti-foulants for fishing nets</p> <p>Note: This discription is following the idea that the category "Pesticide" includes biocides.</p>
1.7.2	<p><input checked="" type="checkbox"/> Industrial</p> <p>Describe the industrial uses of the chemical in your country:</p> <p>Used to be used for producing other TBTs.</p>

1.8 Properties	
1.8.1	<p>Description of physico-chemical properties of the chemical</p> <p>Chemical Formula C₂₄H₅₄O₂Sn₂</p> <p>Molecular Weight 596.07</p> <p>Water Solubility 50 mg/l</p> <p>1-Octanol/Water Partition Coefficient(log value) 3.31</p>
1.8.2	<p>Description of toxicological properties of the chemical</p>

1.8.3	<p>Description of ecotoxicological properties of the chemical</p> <p>Degree of Biodegradation 2% by BOD (4 weeks, 100 mg/l substance, 30 mg/l sludge - according to the OECD Guidelines for Testing of Chemicals 301C, 302C)</p> <p>Bioaccumulation in carp (<i>Cyprinus carpio</i>) 0.5 µg/l conc. BCF* 2550-12100 0.05 µg/l conc. BCF 2880-11200 (according to the OECD Guidelines for Testing of Chemicals ,305C) (Acute toxicity test for Orange red-killifish 20.8 µg/l (8h LC50) *BCF(Bioconcentration Factor) =concentration of test substance in fish / concentration of test substances in water</p>

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	<p>The chemical is: <input type="checkbox"/> banned OR <input checked="" type="checkbox"/> severely restricted</p>
2.2 Information specific to the final regulatory action	
2.2.1	<p>Summary of the final regulatory action</p> <p>Authorization to manufacture and import. Restrictions on import of products and on use. There is so far no allowed use. Regulations mentioned above, except the restriction on import of products, do not apply to foodstuffs prescribed in the Foodstuffs Sanitation Law (1947); agricultural chemicals prescribed in the Agricultural Chemicals Control Law(1948); ordinary fertilizers prescribed in the Fertilizers Control Law(1950); animal feed or additives in animal feed prescribed in the Law on Security of Animal Feed Safety and Improvement of Quality(1953); or medical supplies or medical implements prescribed in the Pharmaceutical Law(1960).</p> <p>This substance is referred to as "Bis(n-tributyltin) oxide" in the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances.</p>
2.2.2	<p>Reference to the regulatory document</p> <p>The Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances The Enforcement Order under the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances</p>
2.2.3	<p>Date of entry into force of the final regulatory action</p> <p>6 January, 1990</p>

2.3	<p>Was the final regulatory action based on a risk or hazard evaluation?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
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	<p>If yes, give information on such evaluation</p> <p>This substance is hardly changed chemically by natural effect and is easily accumulated in living organisms and may be harmful to human health when ingested continuously.</p>
	<p>Reference to the relevant documentation</p> <p>Chemicals Inspection & Testing Institute Japan(ed.) <i>Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL (Chemical Substances Control Law) Japan</i>, 1992, pp. 2-119 (referred to as Bis(n-tributyltin) oxide) OR Http://www.citi.or.jp/e_index.htm</p>

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	<p>If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers</p> <p>It is based on the result that existing toxic data were evaluated synthetically.</p>	
	<p>Reference to the relevant documentation</p>	
	<p>Expected effect of the final regulatory action</p> <p>Should result in reduced exposure in humans to Tributyltin oxide as it is phased out of use.</p>	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	<p>If yes, give summary of the known hazards and risks to the environment</p>	

	<p>This substance is hardly changed chemically by natural effect and is easily accumulated in living organisms.</p>
	<p>Reference to the relevant documentation</p> <p>Chemicals Inspection & Testing Institute Japan(ed.) <i>Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL (Chemical Substances Control Law) Japan</i>, 1992, pp. 2-119 (referred to as Bis(n-tributyltin) oxide)</p> <p>OR</p> <p>Http://www.citi.or.jp/e_index.htm</p>
	<p>Expected effect of the final regulatory action</p> <p>Should result in reduced level of Tributyltin oxide in the environment in the long term.</p>

2.5 Category or categories where the final regulatory action has been taken	
2.5.1	<p>Final regulatory action has been taken for the chemical category <input checked="" type="checkbox"/> Industrial</p> <p>Use or uses prohibited by the final regulatory action</p> <p>All uses except below</p> <p>Use or uses that remain allowed</p> <p>Use for testing and research purposes, use as a reagent (used for the detection or estimation of a substance, for experiments in synthesis of a substance, or for measurement of the physical characteristics of a substance). There is so far no use designated in the Enforcement Order under the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances.</p>

2.5.2	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	0	1998
Imported	0	1998
Exported	0	1998
Used	0	1998

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

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action

2.7.2	Information on alternatives and their relative risks
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of International Trade and Industry (MITI) & Ministry of Health and Welfare (MHW)
Address	MITI: 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8901, Japan MHW: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8045, Japan
Telephone	MITI: +81-3-3501-0080 MHW: +81-3-3595-2298
Telefax	MITI: +81-3-3580-6347 MHW: +81-3-3593-8913
E-mail address	
Designated National Authority	
Institution	Ministry of Foreign Affairs
Address	2-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8919, JAPAN
Name of person in charge	Mr. Makito Takahashi
Position of person in charge	Director
Telephone	+81-3-3581-3882
Telefax	+81-3-3592-0364
E-mail address	

Date, signature of DNA and official seal:

22. Sep



[Handwritten signature]



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

COUNTRY: EUROPEAN COMMUNITY

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

PART I: PROPERTIES, IDENTIFICATION AND USES

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

PLEASE RETURN THE COMPLETED FORM TO:

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

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtellaine, Geneva, Switzerland

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

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

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

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

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

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

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

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

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

PART II: FINAL REGULATORY ACTION

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

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

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	<p>Hazards: see classification in point 1.6</p> <p>In the risk assessment conducted for the European Commission, unacceptable health risks were identified in the following areas:</p> <ul style="list-style-type: none"> - exposure to atmospheric TBT during the transfer of ingredients to the mixing vessel during anti-fouling paint manufacture; - ingestion of contaminated food (e.g. mussels) where TBT concentrations are high. <p>It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. However, releases of TBT from shipping are more difficult to control because it as been shown that even when the TBTO release rate is reduced to the minimum required to maintain anti-fouling efficiency, the amount released from a large ship is still considerable, leading to possible contamination of food.</p>	
	Reference to the relevant documentation	
	<ul style="list-style-type: none"> • Risk Assessment for the European Commission. "Assessment of the Risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). • Opinion on The report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html). 	
	Expected effect of the final regulatory action	
	Reduction of the levels of exposure from the application of TBT based paints in dockyards, and reduced levels of indirect exposure through contaminated food.	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment	
	<p>Hazards: see classification in point 1.6</p> <p>In the risks assessment conducted for the European Commission, unacceptable environmental risks were identified in the following areas:</p> <ul style="list-style-type: none"> - release to surface water from the manufacture of TBTO; - release to surface water from the manufacture of TBT self polishing co-polymer paints; - release to surface water from dockyard procedures; - release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment. <p>It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. However, releases of TBT from shipping are more difficult to control because it as been shown that even when the TBTO release rate is reduced to the minimum required to maintain anti-fouling efficiency, the amount released from a large ship is still considerable.</p>	
	Reference to the relevant documentation	
	<ul style="list-style-type: none"> • Risk Assessment for the European Commission . "Assessment of the Risks to health and to the environment of tin organic compounds in ant-fouling paint and of the effects of further restrictions on their marketing and use. WS Atkins International Ltd (vol. A), April 1998 (copy attached). • Opinion on The report by WS Atkins International Ltd (vol. A) "Assessment of the Risks to Health and to the Environment of Tin Organic Compounds in Anti-fouling Paint and of the Effects of Further Restrictions on their Marketing and Use", opinion expressed at the 6th CSTEE plenary meeting, Brussels, 27 November 	

	1998 (available at http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html).
	<p>Expected effect of the final regulatory action</p> <p>A ban of TBT in anti-fouling paints is expected to significantly reduce input of TBT to the aquatic environment. The timescale over which effects will be seen is likely to be biphasic. Initially, a significant drop in water concentrations will be seen and this should result in reduced levels of risks for exposed environments. However, there are likely to be some residual concentrations of TBT in water for some time after implementation of a ban of its use, because of continuing releases from ship hulls and the TBT reservoirs that have accumulated in the sediment of contaminated areas. Considering the long half time of degradation for TBT, it is likely that TBT will remain in the water column and sediment for up to twenty years after the cessation of TBT inputs to the environment. These residual concentrations should not present a threat to population sustainability.</p>

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

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

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

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

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

PART III : GOVERNMENT AUTHORITIES

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

Date, signature of DNA and official seal: _____