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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. Annexed to this note is a revised notification for tributyltin oxide from Japan dated 23 January 2003. This shall replace the previous notification for the chemical, which is contained in document UNEP/FAO/PIC/ICRC.4/17.

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



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

COUNTRY: JAPAN

IMPORTANT: See instructions before filling in the form

**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; hexabutyldistannoxane; Bis(tributyltin) oxide; Bis(tri-normal-butyltin) oxide ; bis(tributyloxi)de of tin; bis(tributylstannyl) oxide; BTO; hexabutylditin; oxybis(tributyltin); tri-n-butylstannane oxide; TBOT; Hexabutyldistannoxane; 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.            |   |

**PLEASE RETURN THE COMPLETED FORM TO:**

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

OR

Interim Secretariat for the Rotterdam Convention  
UNEP Chemicals

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

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

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

|              |  |
|--------------|--|
| <b>1.5.2</b> | <input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical.<br>The sections modified are: _____                  |
|              | <input checked="" type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.<br>Date of issue of the previous notification: _____ |

| <b>1.6 Information on hazard classification where the chemical is subject to classification requirements</b> |                     |
|--|---------------------|
| <b>International classification systems</b>  | <b>Hazard class</b> |
| UN Recommendations on the Transport of Dangerous Goods   | Class 6.1 (No.2788) |
|  |                     |
|  |                     |
|  |                     |
| <b>Other classification systems</b>  | <b>Hazard class</b> |
|  |                     |
|  |                     |
|  |                     |
|  |                     |

| <b>1.7 Use or uses of the chemical</b> |   |
|--|---|
| <b>1.7.1</b>                           | <input type="checkbox"/> <b>Pesticide</b>   |
|  | <b>Describe the uses of the chemical as a pesticide in your country:</b>  |
| <b>1.7.2</b>                           | <input checked="" type="checkbox"/> <b>Industrial</b>   |
|  | <b>Describe the industrial uses of the chemical in your country:</b><br>Used to be used for preservatives; anti-mold agents; anti-fouling paints and anti-foulants for fishing nets |

| <b>1.8 Properties</b> |  |
|-----------------------|--|
| <b>1.8.1</b>          | <b>Description of physico-chemical properties of the chemical</b>  |
|                       | Chemical Formula C <sub>24</sub> H <sub>54</sub> OSn <sub>2</sub><br>Molecular Weight 596.07<br>Water Solubility 50mg/l<br>1-Octanol/Water Partition Coefficient(log value) 3.31 |

|              |   |
|--------------|---|
| <b>1.8.2</b> | <b>Description of toxicological properties of the chemical</b>  |
| <b>1.8.3</b> | <b>Description of ecotoxicological properties of the chemical</b><br>Degree of Biodegradation<br>2% by BOD (4 weeks, 100mg/l substance, 30mg/l sludge – according to the OECD Guidelines for Testing of Chemicals 301C, 302C)<br><br>Bioaccumulation in carp ( <i>Cyprinus carpio</i> )<br>0.5 µg/l conc. BCF* 2550-12100<br>0.05µg/l conc. BCF 2880-11200<br>(according to the OECD Guidelines for Testing of Chemicals, 305C)<br>(Acute toxicity test for Orange red-killifish 20.8µg/l (8h LC50)<br>*BCF (Bioconcentration Factor)<br>=concentration of test substance in fish / concentration of test substances in water |

## PART II: FINAL REGULATORY ACTION

|                                   |   |
|-----------------------------------|---|
| <b>2. FINAL REGULATORY ACTION</b> |   |
| <b>2.1</b>                        | <b>The chemical is:</b> <input checked="" type="checkbox"/> <b>banned</b> <b>OR</b> <input type="checkbox"/> <b>severely restricted</b>   |
| <b>2.2</b>                        | <b>Information specific to the final regulatory action</b>  |
| <b>2.2.1</b>                      | <b>Summary of the final regulatory action</b><br>Authorization to manufacture and import. Banned on imports of products and on use.<br>There is so far no allowed use.<br>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).<br><br>This substance is referred to as “Bis(n-tributyltin) oxide” in the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances. |
| <b>2.2.2</b>                      | <b>Reference to the regulatory document</b><br>The Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances<br>The Enforcement Order under the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances   |
| <b>2.2.3</b>                      | <b>Date of entry into force of the final regulatory action</b><br>6 January, 1990   |

|            |  |   |
|------------|--|---|
| <b>2.3</b> | <b>Was the final regulatory action based on a risk or hazard evaluation?</b>   | <input checked="" type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> |
|            | <b>If yes, give information on such evaluation</b>   |   |
|            | 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.   |   |
|            | <b>Reference to the relevant documentation</b>   |   |
|            | Chemical 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)<br>OR<br><a href="http://www.citi.or.jp/e_index.htm">http://www.citi.or.jp/e_index.htm</a> |   |

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

|       |  |   |
|-------|--|---|
| 2.4.2 | <b>Is the reason for the final regulatory action relevant to the environment?</b>  | <input checked="" type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> |
|       | <b>If yes, give summary of the known hazards and risks to the environment</b>  |   |
|       | This substance is hardly changed chemically by natural effect and is easily accumulated in living organisms.   |   |
|       | <b>Reference to the relevant documentation</b>   |   |
|       | Chemical 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)<br>OR<br><a href="http://www.citi.or.jp/e_index.htm">http://www.citi.or.jp/e_index.htm</a> |   |
|       | <b>Expected effect of the final regulatory action</b>  |   |
|       | Should result in reduced level of Tributyltin oxide in the environment in the long term.   |   |

|            |   |   |
|------------|---|---|
| <b>2.5</b> | <b>Category or categories where the final regulatory action has been taken</b>  |   |
| 2.5.1      | <b>Final regulatory action has been taken for the chemical category</b>   | <input checked="" type="checkbox"/> <b>Industrial</b> |
|            | <b>Use or uses prohibited by the final regulatory action</b>  |   |
|            | All uses except below   |   |
|            | <b>Use or uses that remain allowed</b>  |   |
|            | 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).<br>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. |   |

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

| 2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available. |                        |      |
|--|------------------------|------|
|  | Quantity per year (MT) | Year |
| Produced   | 0                      | 2001 |
| Imported   | 0                      | 2001 |
| Exported   | 0                      | 2001 |
| Used   | 0                      | 2001 |

|     |   |
|-----|---|
| 2.6 | <b>Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions</b> |
|     |   |

|       |  |
|-------|--|
| 2.7   | <b>Other relevant information that may cover:</b>                          |
| 2.7.1 | <b>Assessment of socio-economic effects of the final regulatory action</b> |
|       |  |



|              |   |  |
|--------------|---|--|
| <b>2.7.2</b> | <b>Information on alternatives and their relative risks</b> |  |
| <b>2.7.3</b> | <b>Relevant additional information</b>                      |  |

### PART III : GOVERNMENT AUTHORITIES

| Ministry/Department and authority responsible for issuing/enforcing the final regulatory action |  |
|---|--|
| <b>Institution</b>  | Ministry of Economy, Trade and Industry (METI), Ministry of Health, Labour and Welfare (MHLW) & Ministry of the Environment (MOE)  |
| <b>Address</b>  | METI: 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8901, Japan<br>MHLW: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916, Japan<br>MOE: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8975, Japan |
| <b>Telephone</b>  | METI: +81-3-3501-0080, MHLW: +81-3-3595-2298,<br>MOE: +81-3-5521-8260  |
| <b>Telefax</b>  | METI: +81-3-3580-6347, MHLW: +81-3-3593-8913,<br>MOE: +81-3-3580-3596  |
| <b>E-mail address</b>   |  |
| Designated National Authority   |  |
| <b>Institution</b>  | Global Environment Division, Multilateral Cooperation Department, Ministry of Foreign Affairs  |
| <b>Address</b>  | 2-11-1 Shibakoen, Minato-ku, Tokyo 105-8519, Japan   |
| <b>Name of person in charge</b>   | Mr. Katsuhiko Araiike  |
| <b>Position of person in charge</b>   | Official   |
| <b>Telephone</b>  | +81-3-6402-2540  |
| <b>Telefax</b>  | +81-3-6402-2538  |
| <b>E-mail address</b>   | <a href="mailto:katsuhiko.araiike@mofa.go.jp">katsuhiko.araiike@mofa.go.jp</a>   |

Date, signature of DNA and official seal: 21 January, 2003