# INTERNATIONAL CONVENTION ON THE CONTROL OF HARMFUL ANTI-FOULING SYSTEMS ON SHIPS, 2001

#### THE PARTIES TO THIS CONVENTION.

**NOTING** that scientific studies and investigations by Governments and competent international organizations have shown that certain anti-fouling systems used on ships pose a substantial risk of toxicity and other chronic impacts to ecologically and economically important marine organisms and also that human health may be harmed as a result of the consumption of affected seafood,

**NOTING IN PARTICULAR** the serious concern regarding anti-fouling systems that use organotin compounds as biocides and being convinced that the introduction of such organotins into the environment must be phased-out,

**RECALLING** that Chapter 17 of Agenda 21 adopted by the United Nations Conference on Environment and Development, 1992, calls upon States to take measures to reduce pollution caused by organotin compounds used in anti-fouling systems,

**RECALLING ALSO** that resolution A.895(21), adopted by the Assembly of the International Maritime Organization on 25 November 1999, urges the Organization's Marine Environment Protection Committee (MEPC) to work towards the expeditious development of a global legally binding instrument to address the harmful effects of anti-fouling systems as a matter of urgency,

**MINDFUL OF** the precautionary approach set out in Principle 15 of the Rio Declaration on Environment and Development and referred to in resolution MEPC.67(37) adopted by MEPC on 15 September 1995,

**RECOGNIZING** the importance of protecting the marine environment and human health from adverse effects of anti-fouling systems,

**RECOGNIZING ALSO** that the use of anti-fouling systems to prevent the build-up of organisms on the surface of ships is of critical importance to efficient commerce, shipping and impeding the spread of harmful aquatic organisms and pathogens,

**RECOGNIZING FURTHER** the need to continue to develop anti-fouling systems which are effective and environmentally safe and to promote the substitution of harmful systems by less harmful systems or preferably harmless systems,

## **HAVE AGREED** as follows:

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# **ARTICLE 1**

**General Obligations** 

- (1) Each Party to this Convention undertakes to give full and complete effect to its provisions in order to reduce or eliminate adverse effects on the marine environment and human health caused by anti-fouling systems.
- (2) The Annexes form an integral part of this Convention. Unless expressly provided otherwise, a reference to this Convention constitutes at the same time a reference to its Annexes.
- (3) No provision of this Convention shall be interpreted as preventing a State from taking, individually or jointly, more stringent measures with respect to the reduction or elimination of adverse effects of anti-fouling systems on the environment, consistent with international law.
- (4) Parties shall endeavour to co-operate for the purpose of effective implementation, compliance and enforcement of this Convention.

(5) The Parties undertake to encourage the continued development of anti-fouling systems that are effective and environmentally safe.

#### ARTICLE 2

Definitions

For the purposes of this Convention, unless expressly provided otherwise:

- (1) "Administration" means the Government of the State under whose authority the ship is operating. With respect to a ship entitled to fly a flag of a State, the Administration is the Government of that State. With respect to fixed or floating platforms engaged in exploration and exploitation of the sea-bed and subsoil thereof adjacent to the coast over which the coastal State exercises sovereign rights for the purposes of exploration and exploitation of their natural resources, the Administration is the Government of the coastal State concerned.
- (2) "Anti-fouling system" means a coating, paint, surface treatment, surface, or device that is used on a ship to control or prevent attachment of unwanted organisms.
- (3) "Committee" means the Marine Environment Protection Committee of the Organization.
- (4) "Gross tonnage" means the gross tonnage calculated in accordance with the tonnage measurement regulations contained in Annex 1 to the International Convention on Tonnage Measurement of Ships, 1969, or any successor Convention.
- (5) "International voyage" means a voyage by a ship entitled to fly the flag of one State to or from a port, shipyard, or offshore terminal under the jurisdiction of another State.
- (6) "Length" means the length as defined in the International Convention on Load Lines,
- 1966, as modified by the Protocol of 1988 relating thereto, or any successor Convention.
- (7) "Organization" means the International Maritime Organization.

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- (8) "Secretary-General" means the Secretary-General of the Organization.
- (9) "Ship" means a vessel of any type whatsoever operating in the marine environment and includes hydrofoil boats, air-cushion vehicles, submersibles, floating craft, fixed or floating platforms, floating storage units (FSUs) and floating production storage and off-loading units (FPSOs).
- (10) "Technical Group" is a body comprised of representatives of the Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization, and non-governmental organizations in consultative status with the Organization, which should preferably include representatives of institutions and laboratories that engage in anti-fouling system analysis. These representatives shall have expertise in environmental fate and effects, toxicological effects, marine biology, human health, economic analysis, risk management, international shipping, anti-fouling systems coating technology, or other fields of expertise necessary to objectively review the technical merits of a comprehensive proposal.

#### **ARTICLE 3**

Application

- (1) Unless otherwise specified in this Convention, this Convention shall apply to:
- (a) ships entitled to fly the flag of a Party;
- (b) ships not entitled to fly the flag of a Party, but which operate under the authority of a Party; and
- (c) ships that enter a port, shipyard, or offshore terminal of a Party, but do not fall within subparagraph (a) or (b).
- (2) This Convention shall not apply to any warships, naval auxiliary, or other ships owned or operated by a Party and used, for the time being, only on government non-commercial service. However, each Party shall ensure, by the adoption of appropriate measures not impairing operations or operational capabilities of such ships owned or operated by it, that such ships act in a manner consistent, so far as is reasonable and practicable, with this Convention.
- (3) With respect to the ships of non-Parties to this Convention, Parties shall apply the requirements of this Convention as may be necessary to ensure that no more favourable treatment is given to such ships.

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#### **ARTICLE 4**

Controls on Anti-Fouling Systems

- (1) In accordance with the requirements specified in Annex 1, each Party shall prohibit and/or restrict:
- (a) the application, re-application, installation, or use of harmful anti-fouling systems on ships referred to in article 3(1)(a) or (b); and
- (b) the application, re-application, installation or use of such systems, whilst in a Party's port, shipyard, or offshore terminal, on ships referred to in article 3(1)(c),
- and shall take effective measures to ensure that such ships comply with those requirements.
- (2) Ships bearing an anti-fouling system which is controlled through an amendment to

Annex 1 following entry into force of this Convention may retain that system until the next scheduled renewal of that system, but in no event for a period exceeding 60 months following application, unless the Committee decides that exceptional circumstances exist to warrant earlier implementation of the control.

#### **ARTICLE 5**

Controls of Annex 1 Waste Materials

Taking into account international rules, standards and requirements, a Party shall take appropriate measures in its territory to require that wastes from the application or removal of an anti-fouling system controlled in Annex 1 are collected, handled, treated and disposed of in a safe and environmentally sound manner to protect human health and the environment.

#### **ARTICLE 6**

Process for Proposing Amendments to Controls on Anti-Fouling Systems

- (1) Any Party may propose an amendment to Annex 1 in accordance with this article.
- (2) An initial proposal shall contain the information required in Annex 2, and shall be submitted to the Organization. When the Organization receives a proposal, it shall bring the proposal to the attention of the Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization and non-governmental organizations in consultative status with the Organization and shall make it available to them.
- (3) The Committee shall decide whether the anti-fouling system in question warrants a more indepth review based on the initial proposal. If the Committee decides that further review is warranted, it shall require the proposing Party to submit to the Committee a comprehensive proposal containing the information required in Annex 3, except where the initial proposal also includes all the information required in Annex 3. Where the Committee is of the view that there is a threat of serious or irreversible damage, lack of full scientific certainty shall not be used as a

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reason to prevent a decision to proceed with the evaluation of the proposal. The Committee shall establish a technical group in accordance with article 7.

- (4) The technical group shall review the comprehensive proposal along with any additional data submitted by any interested entity and shall evaluate and report to the Committee whether the proposal has demonstrated a potential for unreasonable risk of adverse effects on non-target organisms or human health such that the amendment of Annex 1 is warranted. In this regard:
- (a) The technical group's review shall include:
- (i) an evaluation of the association between the anti-fouling system in question and the related adverse effects observed either in the environment
- or on human health, including, but not limited to, the consumption of affected seafood, or through

controlled studies based on the data described in Annex 3 and any other relevant data which come to light;

- (ii) an evaluation of the potential risk reduction attributable to the proposed control measures and any other control measures that may be considered by the technical group;
- (iii) consideration of available information on the technical feasibility of control measures and the cost-effectiveness of the proposal;
- (iv) consideration of available information on other effects from the introduction of such control measures relating to:
- the environment (including, but not limited to, the cost of inaction and the impact on air quality);
- shipyard health and safety concerns (i.e. effects on shipyard workers);
- the cost to international shipping and other relevant sectors; and
- (v) consideration of the availability of suitable alternatives, including a consideration of the potential risks of alternatives.
- (b) The technical group's report shall be in writing and shall take into account each of the evaluations and considerations referred to in subparagraph (a), except that the technical group may decide not to proceed with the evaluations and considerations described in subparagraph (a) (ii) through (a)(v) if it determines after the evaluation in subparagraph (a)(i) that the proposal does not warrant further

consideration.

(c) The technical group's report shall include, *inter alia*, a recommendation on whether international controls pursuant to this Convention are warranted on the anti-fouling system in question, on the suitability of the specific control measures suggested in the comprehensive proposal, or on other control measures which it believes to be more suitable.

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- (5) The technical group's report shall be circulated to the Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization and non-governmental organizations in consultative status with the Organization, prior to its consideration by the Committee. The Committee shall decide whether to approve any proposal to amend Annex 1, and any modifications thereto, if appropriate, taking into account the technical group's report. If the report finds a threat of serious or irreversible damage, lack of full scientific certainty shall not, itself, be used as a reason to prevent a decision from being taken to list an anti-fouling system in Annex 1. The proposed amendments to Annex 1, if approved by the Committee, shall be circulated in accordance with article 16(2)(a). A decision not to approve the proposal shall not preclude future submission of a new proposal with respect to a particular anti-fouling system if new information comes to light.
- (6) Only Parties may participate in decisions taken by the Committee described in paragraphs (3) and (5).

## **ARTICLE 7**

Technical Groups

- (1) The Committee shall establish a technical group pursuant to article 6 when a comprehensive proposal is received. In circumstances where several proposals are received concurrently or sequentially, the Committee may establish one or more technical groups as needed.
- (2) Any Party may participate in the deliberations of a technical group, and should draw on the relevant expertise available to that Party.
- (3) The Committee shall decide on the terms of reference, organization and operation of the technical groups. Such terms shall provide for protection of any confidential information that may be submitted. Technical groups may hold such meetings as required, but shall endeavour to conduct their work through written or electronic correspondence or other media as appropriate.
- (4) Only the representatives of Parties may participate in formulating any recommendation to the Committee pursuant to article 6. A technical group shall endeavour to achieve unanimity among the representatives of the Parties. If unanimity is not possible, the technical group shall communicate any minority views of such representatives.

## **ARTICLE 8**

Scientific and Technical Research and Monitoring

(1) The Parties shall take appropriate measures to promote and facilitate scientific and technical research on the effects of anti-fouling systems as well as monitoring of such effects. In particular, such research should include observation, measurement, sampling, evaluation and analysis of the effects of anti-fouling systems.

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(5) The technical group's report shall be circulated to the Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization and non-governmental organizations in consultative status with the Organization, prior to its consideration by the Committee. The Committee shall decide whether to approve any proposal to amend Annex 1, and any modifications thereto, if appropriate, taking into account the technical group's report. If the report finds a threat of serious or irreversible damage, lack of full scientific certainty shall not, itself, be used as a reason to prevent a decision from being taken to list an anti-fouling system in Annex 1. The proposed amendments to Annex 1, if approved by the Committee, shall be circulated in accordance with article 16(2)(a). A decision not to approve the proposal shall not preclude future submission of a new proposal with respect to a particular anti-fouling system if new information comes to light.

(6) Only Parties may participate in decisions taken by the Committee described in paragraphs (3) and (5).

## **ARTICLE 9**

Communication and Exchange of Information

- (1) Each Party undertakes to communicate to the Organization:
- (a) a list of the nominated surveyors or recognized organizations which are authorized to act on behalf of that Party in the administration of matters relating to the control of anti-fouling systems in accordance with this Convention for circulation to the Parties for the information of their officers. The Administration shall therefore notify the Organization of the specific responsibilities and conditions of the authority delegated to nominated surveyors or recognized organizations; and
- (b) on an annual basis, information regarding any anti-fouling systems approved, restricted, or prohibited under its domestic law.
- (2) The Organization shall make available, through any appropriate means, information communicated to it under paragraph (1).
- (3) For those anti-fouling systems approved, registered or licensed by a Party, such Party shall either provide, or require the manufacturers of such anti-fouling systems to provide, to those Parties which request it, relevant information on which its decision was based, including information provided for in Annex 3, or other information suitable for making an appropriate evaluation of the anti-fouling system. No information shall be provided that is protected by law.

# **ARTICLE 10**

Survey and Certification

A Party shall ensure that ships entitled to fly its flag or operating under its authority are surveyed and certified in accordance with the regulations in Annex 4.

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## **ARTICLE 11**

Inspections of Ships and Detection of Violations

(1) A ship to which this Convention applies may, in any port, shipyard, or offshore terminal of a Party, be inspected by officers authorized by that Party for the purpose of determining whether the ship is in compliance with this Convention. Unless there are clear grounds for believing that a ship

is in violation of this Convention, any such inspection shall be limited to:

- (a) verifying that, where required, there is onboard a valid International Anti-fouling System Certificate or a Declaration on Anti-fouling System; and/or
- (b) a brief sampling of the ship's anti-fouling system that does not affect the integrity, structure, or operation of the anti-fouling system taking into account guidelines developed by the Organization.\* However, the time required to process the results of such sampling shall not be used as a basis for preventing the movement and departure of the ship.
- (2) If there are clear grounds to believe that the ship is in violation of this Convention, a thorough inspection may be carried out taking into account guidelines developed by the Organization.\*
- (3) If the ship is detected to be in violation of this Convention, the Party carrying out the inspection may take steps to warn, detain, dismiss, or exclude the ship from its ports. A Party taking such action against a ship for the reason that the ship does not comply with this Convention shall immediately inform the Administration of the ship concerned.
- (4) Parties shall co-operate in the detection of violations and the enforcement of this Convention. A Party may also inspect a ship when it enters the ports, shipyards, or offshore terminals under its jurisdiction, if a request for an investigation is received from any Party, together with sufficient evidence that a ship is operating or has operated in violation of this Convention. The report of such investigation shall be sent to the Party requesting it and to the competent authority of the Administration of the ship concerned so that the appropriate action may be taken under this Convention.

#### **ARTICLE 12**

Violations

(1) Any violation of this Convention shall be prohibited and sanctions shall be established therefore under the law of the Administration of the ship concerned wherever the violation occurs.

If the Administration is informed of such a violation, it shall investigate the matter and may request the reporting Party to furnish additional evidence of the alleged violation. If the Administration is satisfied that sufficient evidence is available to enable proceedings to be brought in respect of the alleged violation, it shall cause such proceedings to be taken as soon as possible, in accordance with its laws. The Administration shall promptly inform the Party that reported the alleged violation, as well as the Organization, of any action taken. If the Administration has not taken any action within one year after receiving the information, it shall so inform the Party which reported the alleged violation.

Guidelines to be developed. AFS/CON

## **ARTICLE 13**

Undue Delay or Detention of Ships

- (1) All possible efforts shall be made to avoid a ship being unduly detained or delayed under article 11 or 12.
- (2) When a ship is unduly detained or delayed under article 11 or 12, it shall be entitled to compensation for any loss or damage suffered.

#### **ARTICLE 14**

Dispute Settlement

Parties shall settle any dispute between them concerning the interpretation or application of this Convention by negotiation, enquiry, mediation, conciliation, arbitration, judicial settlement, resort to regional agencies or arrangements, or other peaceful means of their own choice.

# **ARTICLE 15**

Relationship to International Law of the Sea

Nothing in this Convention shall prejudice the rights and obligations of any State under

 customary international law as reflected in the United Nations Convention on the Law of the Sea.F/26

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#### **ARTICLE 16**

Amendments

- (1) This Convention may be amended by either of the procedures specified in the following paragraphs.
- (2) Amendments after consideration within the Organization:
- (a) Any Party may propose an amendment to this Convention. A proposed amendment shall be submitted to the Secretary-General, who shall then circulate it to the Parties and Members of the Organization at least six months prior to its consideration. In the case of a proposal to amend Annex 1, it shall be processed in accordance with article 6, prior to its consideration under this article.
- (b) An amendment proposed and circulated as above shall be referred to the Committee for consideration. Parties, whether or not Members of the Organization, shall be entitled to participate in the proceedings of the Committee for consideration and adoption of the amendment.
- (c) Amendments shall be adopted by a two-thirds majority of the Parties present and voting in the Committee, on condition that at least one-third of the Parties shall be present at the time of voting.
- (d) Amendments adopted in accordance with subparagraph (c) shall be communicated by the Secretary-General to the Parties for acceptance.
- (e) An amendment shall be deemed to have been accepted in the following circumstances:
- (i) An amendment to an article of this Convention shall be deemed to have been accepted on the date on which two-thirds of the Parties have notified the Secretary-General of their acceptance of it.
- (ii) An amendment to an Annex shall be deemed to have been accepted at the end of twelve months after the date of adoption or such other date as determined by the Committee. However, if by that date more than one-third of the Parties notify the Secretary-General that they object to the amendment, it shall be deemed not to have been accepted.
- (f) An amendment shall enter into force under the following conditions:
- (i) An amendment to an article of this Convention shall enter into force for those Parties that have declared that they have accepted it six months after the date on which it is deemed to have been accepted in accordance with subparagraph (e)(i).

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- (ii) An amendment to Annex 1 shall enter into force with respect to all Parties six months after the date on which it is deemed to have been accepted, except for any Party that has:
- (1) notified its objection to the amendment in accordance with subparagraph
- (e) (ii) and that has not withdrawn such objection;
- (2) notified the Secretary-General, prior to the entry into force of such amendment, that the amendment shall enter into force for it only after a subsequent notification of its acceptance; or
- (3) made a declaration at the time it deposits its instrument of ratification, acceptance or approval of, or accession to, this Convention that amendments to Annex 1 shall enter into force for it only after the

notification to the Secretary-General of its acceptance with respect to such amendments.

- (iii) An amendment to an Annex other than Annex 1 shall enter into force with respect to all Parties six months after the date on which it is deemed to have been accepted, except for those Parties that have notified their objection to the amendment in accordance with subparagraph (e)(ii) and that have not withdrawn such objection.
- (g) (i) A Party that has notified an objection under subparagraph (f)(ii)(1) or (iii) may subsequently notify the Secretary-General that it accepts the amendment. Such amendment shall enter into

force for such Party six months after the date of its notification of acceptance, or the date on which the amendment enters into force, whichever is the later date.

- (ii) If a Party that has made a notification or declaration referred to in subparagraph (f)(ii)(2) or (3), respectively, notifies the Secretary-General of its acceptance with respect to an amendment, such amendment shall enter into force for such Party six months after the date of its notification of acceptance, or the date on which the amendment enters into force, whichever is the later date.
- (3) Amendment by a Conference:
- (a) Upon the request of a Party concurred in by at least one-third of the Parties, the Organization shall convene a Conference of Parties to consider amendments to this Convention.
- (b) An amendment adopted by such a Conference by a two-thirds majority of the Parties present and voting shall be communicated by the Secretary-General to all Parties for acceptance.
- (c) Unless the Conference decides otherwise, the amendment shall be deemed to have been accepted and shall enter into force in accordance with the procedures specified in paragraphs (2)(e) and (f) respectively of this article.

## **ARTICLE 17**

Signature, Ratification, Acceptance, Approval and Accession

- (1) This Convention shall be open for signature by any State at the Headquarters of the Organization from 1 February 2002 to 31 December 2002 and shall thereafter remain open for accession by any State.
- (2) States may become Parties to this Convention by:
- (a) signature not subject to ratification, acceptance, or approval; or
- (b) signature subject to ratification, acceptance, or approval, followed by ratification, acceptance, or approval; or
- (c) accession.
- (3) Ratification, acceptance, approval, or accession shall be effected by the deposit of an instrument to that effect with the Secretary-General.
- (4) If a State comprises two or more territorial units in which different systems of law are applicable in relation to matters dealt with in this Convention, it may at the time of signature, ratification, acceptance, approval, or accession declare that this Convention shall extend to all its territorial units or only to one or more of them and may modify this declaration by submitting another declaration at any time.
- (5) Any such declaration shall be notified to the Secretary-General and shall state expressly the territorial units to which this Convention applies.

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#### **ARTICLE 18**

Entry into force

- (1) This Convention shall enter into force twelve months after the date on which not less than twenty-five States, the combined merchant fleets of which constitute not less than twenty-five percent of the gross tonnage of the world's merchant shipping, have either signed it without reservation as to ratification, acceptance or approval, or have deposited the requisite instrument of ratification, acceptance, approval or accession in accordance with article 17.
- (2) For States which have deposited an instrument of ratification, acceptance, approval or accession in respect of this Convention after the requirements for entry into force thereof have been met, but prior to the date of entry in force, the ratification, acceptance, approval or accession shall take effect on the date of entry into force of this Convention or three months after the date of deposit of instrument, whichever is the later date.
- (3) Any instrument of ratification, acceptance, approval or accession deposited after the date on which this Convention enters into force shall take effect three months after the date of deposit.
- (4) After the date on which an amendment to this Convention is deemed to have been accepted under article 16, any instrument of ratification, acceptance, approval or accession

deposited shall apply to the Convention as amended.

#### **ARTICLE 19**

Denunciation

- (1) This Convention may be denounced by any Party at any time after the expiry of two years from the date on which this Convention enters into force for that Party.
- (2) Denunciation shall be effected by the deposit of written notification with the Secretary-General, to take effect one year after receipt or such longer period as may be specified in that notification.

#### **ARTICLE 20**

Depositary

- (1) This Convention shall be deposited with the Secretary-General, who shall transmit certified copies of this Convention to all States which have signed this Convention or acceded thereto.
- (2) In addition to the functions specified elsewhere in this Convention, the Secretary-General shall:
- (a) inform all States which have signed this Convention or acceded thereto of:
- (i) each new signature or deposit of an instrument of ratification, acceptance, approval, or accession, together with the date thereof;

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- (ii) the date of entry into force of this Convention; and
- (iii) the deposit of any instrument of denunciation of this Convention, together with the date on which it was received and the date on which the denunciation takes effect; and
- (b) as soon as this Convention enters into force, transmit the text thereof to the

Secretariat of the United Nations for registration and publication in accordance with Article 102 of the Charter of the United Nations.

## **ARTICLE 21**

#### Languages

This Convention is established in a single original in the Arabic, Chinese, English, French, Russian and Spanish languages, each text being equally authentic.

IN WITNESS WHEREOF the undersigned being duly authorized by their respective Governments for that purpose have signed this Convention.

DONE AT LONDON, this fifth day of October, two thousand and one.

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#### ANNEX 2

# **REQUIRED ELEMENTS FOR AN INITIAL PROPOSAL**

- (1) An initial proposal shall include adequate documentation containing at least the following:
- (a) identification of the anti-fouling system addressed in the proposal: name of the anti-fouling system; name of active ingredients and Chemical Abstract Services Registry Number (CAS number), as applicable; or components of the system which are suspected of causing the adverse effects of concern;
- (b) characterization of the information which suggests that the anti-fouling system or its transformation products may pose a risk to human health or may cause adverse effects in non-target organisms at concentrations likely to be found in the environment (e.g., the results of toxicity studies on representative species or bioaccumulation data);
- (c) material supporting the potential of the toxic components in the anti-fouling system, or its transformation products, to occur in the environment at concentrations which could result in adverse effects to non-target organisms, human health, or water quality (e.g., data on persistence in the water column, sediments and biota; the release rate of toxic components from treated surfaces in studies or under actual use conditions; or monitoring data, if available);
- (d) an analysis of the association between the anti-fouling system, the related adverse effects and the environmental concentrations observed or anticipated; and
- (e) a preliminary recommendation on the type of restrictions that could be effective in reducing

the risks associated with the anti-fouling system.

(2) An initial proposal shall be submitted in accordance with rules and procedures of the Organization.

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### ANNEX 3

# REQUIRED ELEMENTS OF A COMPREHENSIVE PROPOSAL

- (1) A comprehensive proposal shall include adequate documentation containing the following:
- (a) developments in the data cited in the initial proposal;
- (b) findings from the categories of data set out in paragraphs (3)(a), (b) and (c), as applicable, depending on the subject of the proposal and the identification or description of the methodologies under which the data were developed;
- (c) a summary of the results of studies conducted on the adverse effects of the anti-fouling system;
- (d) if any monitoring has been conducted, a summary of the results of that monitoring, including information on ship traffic and a general description of the area monitored;
- (e) a summary of the available data on environmental or ecological exposure and any estimates of environmental concentrations developed through the application of mathematical models, using all available environmental fate parameters, preferably those which were determined experimentally, along with an identification or description of the modelling methodology;
- (f) an evaluation of the association between the anti-fouling system in question, the related adverse effects and the environmental concentrations, either observed or expected;
- (g) a qualitative statement of the level of uncertainty in the evaluation referred to in subparagraph (f);
- (h) a recommendation of specific control measures to reduce the risks associated with the anti-fouling system; and
- (i) a summary of the results of any available studies on the potential effects of the recommended control measures relating to air quality, shippard conditions, international shipping and other relevant sectors, as well as the availability of suitable alternatives.
- (2) A comprehensive proposal shall also include information on each of the following physical and chemical properties of the component(s) of concern, if applicable:
- melting point;
- boiling point;
- density (relative density);
- vapour pressure;

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- water solubility / pH / dissociation constant (pKa);
- oxidation/reduction potential;
- molecular mass:
- molecular structure: and
- other physical and chemical properties identified in the initial proposal.
- (3) For the purposes of paragraph (1)(b) above, the categories of data are:
- (a) Data on environmental fate and effect:
- modes of degradation/dissipation (e.g., hydrolysis/photodegradation/biodegradation);
- persistence in the relevant media (e.g., water column/sediments/biota);
- sediments/water partitioning;
- leaching rates of biocides or active ingredients;
- mass balance;
- bioaccumulation, partition coefficient, octanol/water coefficient; and
- any novel reactions on release or known interactive effects.
- (b) Data on any unintended effects in aquatic plants, invertebrates, fish, seabirds, marine mammals, endangered species, other biota, water quality, the seabed, or habitat of non-target organisms, including sensitive and representative organisms:

- acute toxicity;
- chronic toxicity;
- developmental and reproductive toxicity;
- endocrine disruption;
- sediment toxicity;
- bioavailability/biomagnification/bioconcentration;
- food web/population effects;
- observations of adverse effects in the field/fish kills/ strandings/ tissue analysis; and
- residues in seafood.

These data shall relate to one or more types of non-target organisms such as aquatic plants, invertebrates, fish, birds, mammals and endangered species.

- (c) Data on the potential for human health effects (including, but not limited to, consumption of affected seafood).
- (4) A comprehensive proposal shall include a description of the methodologies used, as well as any relevant measures taken for quality assurance and any peer review conducted of the studies.

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