

ANNEX 4

RESOLUTION MEPC.126(53)

Adopted on 22 July 2005

**PROCEDURE FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS
THAT MAKE USE OF ACTIVE SUBSTANCES (G9)**

THE MARINE ENVIRONMENT PROTECTION COMMITTEE,

RECALLING Article 38(a) of the Convention on the International Maritime Organization concerning the functions of the Marine Environment Protection Committee conferred upon it by the international conventions for the prevention and control of marine pollution,

RECALLING ALSO that the International Conference on Ballast Water Management for Ships held in February 2004 adopted the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004 (the Ballast Water Management Convention) together with four Conference resolutions,

NOTING that Regulation A-2 of the Ballast Water Management Convention requires that discharge of ballast water shall only be conducted through Ballast Water Management in accordance with the provisions of the Annex to the Convention,

NOTING FURTHER that Regulation D-3.2 of the Annex to the Ballast Water Management Convention provides that Ballast Water Management systems that make use of Active Substances or Preparations containing one or more Active Substances used to comply with this Convention, shall be approved by the Organization based on a Procedure developed by the Organization,

NOTING ALSO that resolution 1 adopted by the International Conference on Ballast Water Management for Ships invited the Organization to develop this Procedure as a matter of urgency,

HAVING CONSIDERED, at its fifty-third session, the draft Procedure for Approval of Ballast Water Management systems that make use of Active Substances developed by the Ballast Water Working Group,

1. ADOPTS the Procedure for approval of Ballast Water Management Systems that make use of Active Substances, as set out in the Annex to this resolution;
2. INVITES Governments to apply the Procedure as soon as possible, or when the Convention becomes applicable to them; and
3. AGREES to keep the Procedure under review.

ANNEX

**PROCEDURE FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS
THAT MAKE USE OF ACTIVE SUBSTANCES (G9)**

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PROCEDURE FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES (G9)

1 INTRODUCTION

1.1 This procedure describes the approval and withdrawal of approval of Ballast Water Management systems that make use of Active Substances to comply with the Convention and their manner of application as set out in Regulation D-3 of the “International Convention for the Control and Management of Ships’ Ballast Water and Sediments”. The Convention requires that at withdrawal of approval, the use of the relevant Active Substance or Substances shall be prohibited within 1 year after the date of such withdrawal.

1.2 To comply with the Convention, Ballast Water Management systems that make use of Active Substances or Preparations containing one or more Active Substances shall be approved by the Organization, based on a procedure developed by the Organization.

1.3 The objective of this procedure is to determine the acceptability of Active Substances and Preparations containing one or more Active Substances and their application in Ballast Water Management systems concerning ship safety, human health and the aquatic environment. This procedure is provided as a safeguard for the sustainable use of Active Substances and Preparations.

1.4 This procedure is not intended for the evaluation of the efficacy of Active Substances. The efficacy of Ballast Water Management systems that make use of Active Substances should be evaluated in accordance with the “Guidelines for Approval of Ballast Water Management Systems”.

1.5 The goal of the procedure is to ensure proper application of the provisions contained in the Convention and the safeguards required by it. As such the procedure is to be updated as the state of knowledge and technology may require. New versions of the procedure will be circulated by the Organization following their approval.

2 DEFINITIONS

2.1 For the purposes of this procedure, the definitions in the Convention apply and:

- .1 “Active Substance” means a substance or organism, including a virus or a fungus that has a general or specific action on or against Harmful Aquatic Organisms and Pathogens.
- .2 “Ballast Water Discharge” means the ballast water as would be discharged overboard.
- .3 “Preparation” means any commercial formulation containing one or more Active Substances including any additives. This term also includes any Active Substances generated onboard for purposes of Ballast Water Management and any relevant chemicals formed in the Ballast Water Management system that make use of Active Substances to comply with the Convention.

- .4 “Relevant Chemicals” means transformation or reaction products that are produced during the treatment process or in the receiving environment and may be of concern to the aquatic environment and human health when discharged.

3 PRINCIPLES

3.1 Active Substances and Preparations may be added to the ballast water or be generated on board ships by technology within the Ballast Water Management system using an Active Substance to comply with the Convention.

3.2 Active Substances and Preparations accomplish their intended purpose through action on Harmful Aquatic Organisms and Pathogens in ships’ ballast water and sediments. However, if the ballast water is still toxic at the time of discharge into the environment, the organisms in the receiving water may suffer unacceptable harm. Both the Active Substance or Preparation as well as the Ballast Water Discharge should be subjected to toxicity testing in order to protect the receiving environment or human health from toxic effects due to the discharges. Toxicity testing is needed to determine if an Active Substance or Preparation can be used and under which conditions the potential of harming the receiving environment or human health is acceptably low.

3.3 Ballast Water Management systems that make use of Active Substances and Preparations must be safe in terms of the ship, its equipment and the personnel to comply with the Convention.

3.4 The approval of Active Substances and Preparations using viruses or fungi for use in Ballast Water Management Systems is not addressed in this procedure. The approval of such substances for Ballast Water Management should require an additional consideration by the Organization in compliance with Regulation D-3 of the Convention if the use of such substances is proposed.

4 GENERAL REQUIREMENTS

4.1 Identification

4.1.1 The proposal for approval of an Active Substance or a Preparation should include a chemical identification and description of the chemical components even if generated onboard. A chemical identification should be provided for any Relevant Chemicals.

4.2 Data-set for Active Substances and Preparations

4.2.1 A proposal for approval should include information on the properties or actions of the Preparation including any of its components as follows:

- .1 Data on effects on aquatic plants, invertebrates, fish, and other biota, including sensitive and representative organisms:
- acute aquatic toxicity;
 - chronic aquatic toxicity;
 - endocrine disruption;

- sediment toxicity;
- bioavailability/biomagnification/bioconcentration; and
- food web/population effects.

.2 Data on mammalian toxicity:

- acute toxicity;
- effects on skin and eye;
- chronic and long-term toxicity;
- developmental and reproductive toxicity;
- carcinogenicity; and
- mutagenicity.

.3 Data on environmental fate and effect under aerobic and anaerobic conditions:

- modes of degradation (biotic; abiotic);
- bioaccumulation, partition coefficient, octanol/water coefficient;
- persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters);
- reaction with organic matter;
- potential physical effects on wildlife & benthic habitats;
- potential residues in seafood; and
- any known interactive effects.

.4 Physical and chemical properties for the Active Substances and Preparations and the treated ballast water, if applicable:

- melting point;
- boiling point;
- flammability;
- density (relative density);
- vapour pressure, vapour density;
- water solubility / dissociation constant (pKa);
- oxidation/reduction potential;
- corrosivity to the materials or equipment of normal ship construction;
- autoignition temperature; and
- other known relevant physical or chemical hazards.

.5 Analytical methods at environmentally relevant concentrations.

4.2.2 A proposal for approval should include the above data set either for the Preparation or for each component separately, and a list of the name and relative quantities (in volumetric percentages) of the components should be also attached. As described in section 8.1, all proprietary data should be treated as confidential.

4.2.3 The tests for Active Substances and Preparations should be carried out in accordance with internationally recognized guidelines⁵.

4.2.4 The testing process should contain a rigorous quality control/quality assurance programme consisting of:

- .1 Both a Quality Management Plan (QMP) and a Quality Assurance Project Plan (QAPP). Guidance on preparation of these plans, along with other guidance documents and other general quality control information are available for download from the International Organization for Standardization (ISO) (www.iso.org).
- .2 The QMP addresses the quality control management structure and policies of the Test Organization (including subcontractors and outside laboratories).
- .3 The QAPP is a project specific technical document reflecting the specifics of the system to be tested, the test facility, and other conditions affecting the actual design and implementation of the required experiments.

4.2.5 Dossiers already used for registration of chemicals can be submitted by the applicant to satisfy the required data needed for the evaluation of Active Substances and Preparations according to this procedure.

4.2.6 The proposal should describe the manner of application of the Preparation for Ballast Water Management, including required dosage and retention time.

4.2.7 A proposal for approval should include (Material) Safety Data Sheets ((M)SDS).

4.3 Assessment report

4.3.1 A proposal for approval should include an assessment report. The assessment report should address the quality of the test reports, the risk characterization and a consideration of the uncertainty associated with the assessment.

5 RISK CHARACTERIZATION

5.1 Screening for persistency, bioaccumulation and toxicity

5.1.1 An assessment on the intrinsic properties of the Active Substance and/or Preparation such as persistency, bioaccumulation and toxicity should be conducted (see Table 1 in section 6).

- .1 Persistence tests:
Persistence should preferably be assessed in simulation test systems that determine the half-life under relevant conditions. Biodegradation screening tests may be used to show that the substances are readily biodegradable. The determination of the half-life should include assessment of relevant chemicals.

⁵ Preferably Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals (1993) or other equivalent tests.

- .2 Bioaccumulation tests:
The assessment of the (potential for) bioaccumulation should use measured bioconcentration factors in marine (or freshwater) organisms. Where these tests are not applicable, or if $\log P_{ow} < 3$, Bio Concentration Factor (BCF) values may be estimated using (Quantitative) Structure-Activity Relationship ((Q)SAR) models.
- .3 Toxicity tests:
Acute and/or chronic ecotoxicity data, ideally covering the sensitive life stages, should in principle be used for the assessment of the toxicity criterion.

5.2 Toxicity testing of the treated Ballast Water

5.2.1 Toxicity testing is necessary for the Active Substance, or Preparations (see sections 4.2.1 and 5.3) and the treated Ballast Water Discharge as covered in this section. The advantage of conducting toxicity testing on the Ballast Water Discharge is that it integrates and addresses the potential for interactions of the Active Substances and Preparations with the possible by-products.

- .1 For the basic approval process, the discharge testing should be performed in a laboratory using techniques and equipment to simulate Ballast Water Discharge following treatment by the Preparation.
- .2 For final approval, the discharge testing should be performed as part of the land-based type approval process using the treated ballast water discharge.

5.2.2 The applicant should provide both acute and chronic toxicity test data using standardized test procedures to determine the toxicity of the Preparation and Relevant Chemicals as used in conjunction with the Ballast Water Management System. This testing approach should be performed on the treated Ballast Water Discharge, as the Ballast Water Management system could either mitigate or enhance the adverse effects of the Preparation or Relevant Chemicals.

5.2.3 The discharge toxicity tests should be conducted on samples drawn from the land-based test set-up, which would be representative of the discharge from the Ballast Water Management system.

5.2.4 These toxicity tests should include chronic test methods with multiple test species (a fish, an invertebrate and a plant) that address the sensitive life-stage. The preference is to include both a sub-lethal endpoint (growth) and a survival endpoint. Either freshwater or marine test methods should be tested⁶.

5.2.5 The test results to be provided include: acute 24-hour, 48-hour, 72-hour, and 96-hour Lethal Concentration at which x % of the test organisms die (LCx), No Observed Adverse Effect Concentrations (NOAECs), chronic No Observed Effect Concentration (NOEC) and/or Effect Concentration at which x % of test organisms show effect (ECx), as appropriate based on the experimental design.

⁶ Currently there is no compelling physiological or empirical proof that marine organisms are more sensitive than freshwater organisms or vice versa. Should this however be demonstrated for the substance under consideration, this should be taken into account.

5.2.6 A dilution series including a 100% ballast water discharge would be tested to determine the no adverse effect level using the statistical endpoints (NOEC or EC_x). An initial analysis could use a conservative approach where the dilution capacity would not be taken into consideration (no modelling or plumes analysis would be used). The rationale for taking a conservative approach is that there could be multiple discharges into one location (even though this is not necessarily the case).

5.2.7 The acute and chronic toxicity test data in conjunction with the information in Section 4.2.1 should be used to determine the holding time necessary to achieve the no adverse effect concentration upon discharge. Knowing the half-life (days), decay rate, dosage rate, volume of system and toxicity tests with time series, then a computational model can be used to determine the amount of time needed to hold the treated ballast water before discharge.

5.3 Risk characterization and analysis

5.3.1 For the basic approval process, fate and effect testing should be performed in the laboratory with Active Substances and Preparations. This section lists information that could be useful for a preliminary risk characterization.

5.3.2 Both the Active Substance or Preparation as well as the treated Ballast Water Discharge should be subject to toxicity testing in order to protect the receiving environment from toxic effects due to discharges.

5.3.3 The reaction with organic matter of Active Substances and Preparations that produce free radicals, should be addressed qualitatively so as to identify products of concern to the environment.

5.3.4 The rate of abiotic and biotic degradation of the Active Substances and Preparations under aerobic and anaerobic conditions should be assessed, resulting in the identification of relevant metabolites in the relevant media (ballast water, marine and fresh waters).

5.3.5 The rate of abiotic and biotic degradation of the Active Substances and Preparations under aerobic and anaerobic conditions should be assessed, resulting in the characterization of the persistence of the Active Substances, Preparations and Relevant Chemicals in terms of degradation rates under specified conditions (e.g. pH, redox, temperature).

5.3.6 The partition coefficients (solids-water partition coefficient (K_d) and/or organic carbon normalized distribution coefficient (K_{oc})) of the Active Substances, Preparations and Relevant Chemicals should be determined.

5.3.7 For Active Substances and Preparations, the potential for bioaccumulation should be assessed in marine or freshwater organisms (fish or bivalves) if the logarithm octanol/water partition coefficient (logP_{ow}) is >3.

5.3.8 Based on the information on fate and behavior of Active Substances and Preparations, the discharge concentrations at selected time intervals should be predicted.

5.3.9 The effect assessment of the Active Substances, Preparations and Relevant Chemicals is initially based on a dataset of acute and/or chronic ecotoxicity data for aquatic organisms, being primary producers (algae or sea grasses), consumers (crustaceans), predators (fish), and should

include secondary poisoning to mammalian and avian top-predators, as well as data for sediment species.

5.3.10 An assessment of secondary poisoning is redundant if the substance of concern demonstrates a lack of bioaccumulation potential (e.g., BCF <500 L/kg wet weight for the whole organism at 6% fat).

5.3.11 An assessment of sediment species is redundant if the potential of the substance of concern to partition into the sediment is low (e.g., K_{oc} <500 L/kg).

5.3.12 The effect assessment of the Active Substances, Preparations and Relevant Chemicals should include a screening on carcinogenic, mutagenic and endocrine disruptive properties. If the screening results give rise to concerns, this should give rise to a further effect assessment.

5.3.13 The effect assessment of the Active Substances, Preparations and Relevant Chemicals, taking the indicated information into account, should be based on internationally recognized guidance⁷.

5.3.14 The results of the effect assessment are compared to the results of the discharge toxicity testing. Any unpredicted results (e.g., lack of toxicity or unexpected toxicity in the discharge assessment) should give rise to a further elaboration on the effect assessment.

5.3.15 An analytical method suitable for monitoring Active Substances and Preparations in ballast water discharges should be available.

6 EVALUATION CRITERIA

The Organization should evaluate the application for approval based on the criteria in this section.

6.1 The information that has been provided should be complete, of sufficient quality and in accordance with this procedure.

6.2 That this information does not indicate possible unacceptable adverse effects to environment, human health, property or resources.

6.3 Ship and personnel safety

6.3.1 In order to protect the ship and personnel safety the technical group should evaluate the physical and chemical hazards (see paragraph 4.2.1.4) to ensure that potential hazardous properties of the Active Substances, Preparations or Relevant Chemicals formed in the treated ballast water should not create any unreasonable risk to the ship and personnel. Proposed procedures for the use and technical equipment introduced needs to be taken into account.

6.3.2 For the protection of personnel involved in the handling and storage of the Active Substances and Preparations, the proposal should include relevant ((M)SDS). The Organization should evaluate (M)SDS, mammalian toxicity data and chemical properties hazards (see paragraphs 4.2.1.2 and 4.2.1.4) and ensure that potential hazardous properties of the Active

⁷ Such as relevant OECD guidelines or equivalent.

Substances, Preparations or Relevant Chemicals should not create any unreasonable risk to the ship or personnel. This evaluation should take into account the different circumstances that a ship or personnel may face in its trade (e.g., ice, tropical, humidity, etc.).

6.4 Environmental protection

6.4.1 In order to approve the application, the Organization should determine that the Active Substances, Preparations or Relevant Chemicals are not Persistent, Bioaccumulative and Toxic (PBT). Preparations that exceed all these criteria (Persistence, Bioaccumulation and Toxicity) in the table below are considered PBT.

Table 1 Criteria for identification of PBT substances

Criterion	PBT criteria
Persistence	Half-life: > 60 days in marine water, or > 40 days in freshwater*, or > 180 days in marine sediment, or > 120 days in freshwater sediment*
Bioaccumulation	BCF > 2,000 or LogP _{octanol/water} ≥ 3
Toxicity	Chronic NOEC < 0.01 mg/l

* For the purpose of marine environmental risk assessment half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.

6.4.2 The Organization should determine the overall acceptability of the risk the Preparation may pose in its use for Ballast Water Management. It should do so by comparing the information provided and the undertaken assessment of PBT and the discharge with scientific knowledge of the Active Substances, Preparations and Relevant Chemicals concerned. The risk evaluation should qualitatively take into account cumulative effects that may occur due to the nature of shipping and port operations.

6.4.3 The risk evaluation should consider the uncertainties involved in the application for approval, and as appropriate, provide advice on how these uncertainties can be dealt with.

7 REGULATION OF THE USE OF ACTIVE SUBSTANCES AND PREPARATIONS

7.1 Handling of Active Substances and Preparations

7.1.1 The proposal for approval of Active Substances and Preparations should include information on their intended use and application. The quantity of Active Substances and Preparations to be added to the ballast water and the maximum allowable concentration of the Active Substances therein should be described in the instructions provided by the manufacturer. The system should ensure that the maximum dosage and maximum allowable discharge concentration are not exceeded at any time.

7.2 Hazard documentation and labelling

7.2.1 The proposal should include ((M)SDS) as required. The (M)SDS should describe appropriate storage and handling together with the effects of degradation and chemical reactivity during storage and should be included in the instructions provided by the manufacturer.

7.2.2 Documentation of hazards or the (M)SDS should conform to the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the relevant IMO regulations (e.g. the IMDG Code) and guidelines (e.g. the GESAMP Hazard Evaluation Procedure). Where these regimes are not applicable, relevant national or regional regimes should be followed.

7.3 Procedures and use

7.3.1 Detailed procedures and information for safe application of Active Substances and Preparations on board should be supplied and comply with the approval conditions such as maximum allowable concentration and maximum discharge concentration, if any.

8 APPROVAL

8.1 Basic approval

8.1.1 All proprietary data should be treated as confidential by the Organization and its Technical Group, the Competent Authorities involved, and the evaluating regulatory scientists, if any.

8.1.2 Procedure to be followed:

- .1 The manufacturer should evaluate the Active Substances or Preparations and the potential discharge in accordance with the approval criteria specified in this procedure.
- .2 Upon completion, the manufacturer should prepare an Application on the Active Substances and Preparations and submit it to the Member of the Organization concerned.
- .3 The Administration having received a satisfactory application should as soon as possible propose an approval to the Organization.
- .4 Members of the Organization may propose an approval.
- .5 The Organization should announce and set the time frame for the evaluation of Active Substances and Preparations.
- .6 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 may submit information that is relevant to the evaluation.

- .7 The Organization should establish a Technical Group in accordance with its rules of procedure ensuring that proprietary data should be treated as confidential.
- .8 The Technical Group should review the comprehensive proposal along with any additional data submitted and report to the Organization whether the proposal has demonstrated a potential for unreasonable risk for environment, human health, property or resources in accordance with the criteria specified in this procedure.
- .9 The Technical Group's report should be in written form and 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 competent Committee.
- .10 The Committee of the Organization should decide whether to approve any proposal, introduce any modifications thereto, if appropriate, taking into account the Technical Group's report.
- .11 The Member of the Organization that submitted the application to the Organization should inform in writing the applicant about the decision made with regard to the respective Active Substance or Preparation and their manner of application.
- .12 Active Substances or Preparations receiving basic approval by the Organization may be used for prototype or type approval testing based on the guidelines developed by the Organization⁸. An Active Substance or Preparation may be used for Prototype or Type Approval testing for the approval of different BWMS without going through basic approval again.

8.2 Final approval

8.2.1 In accordance with Regulation D-3.2, a Ballast Water Management system using an Active Substance or Preparation to comply with the Convention (which received basic approval) must be approved by the Organization. For this purpose, the Member of the Organization submitting an application should conduct the Type Approval tests in accordance with Guidelines for Approval of Ballast Water Management Systems. The results should be conveyed to the Organization for confirmation that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval. This would result in Final Approval of the Ballast Water Management system in accordance with Regulation D-3.2. Active Substances or Preparations that have received Basic Approval by the Organization may be used for evaluation of Ballast Water Management systems using Active Substances or Preparations for Final Approval.

⁸ Guidelines for approval of prototype ballast water treatment technologies and Guidelines for approval of Ballast Water Management Systems.

8.3 Notification of approval

8.3.1 The Organization will record the Basic and Final Approval of Active Substances and Preparations and Ballast Water Management systems that make use of Active Substances and circulate the list once a year including the following information:

- Name of Ballast Water Management system that make use of Active Substances and Preparations;
- Date of approval;
- Name of manufacturer; and
- Any other specifications, if necessary.

8.4 Modification

8.4.1 Manufacturers should report any modifications in names, including trade and technical name, composition or use of the Active Substances and Preparations in the Ballast Water Management systems approved by the Organization, to the Member of the Organization. The Member of the Organization should inform the Organization accordingly.

8.4.2 Manufacturers intending to significantly change any part of a Ballast Water Management System that has been approved by the Organization or the Active Substances and Preparations used in it should submit a new application.

8.5 Withdrawal of approval

8.5.1 The Organization may withdraw any approval in the following circumstances:

- .1 If the Active Substances and Preparations or Ballast Water Management system that make use of Active Substances no longer conforms to requirements due to amendments of the Convention.
- .2 If any data or test records differ materially from data relied upon at the time of approval and are deemed not to satisfy the approval condition.
- .3 If a request for withdrawal of approval is made by the Member of the Organization on behalf of the manufacturer.
- .4 If unreasonable harm to environment, human health, property or resources is demonstrated by any Member of the Organization or observer to have been caused by the approved Ballast Water Management system that make use of Active Substances or Preparations.

Appendix

Approval Scheme for Active Substance or Preparation and Ballast Water Management systems that make use of Active Substances


