DEVELOPMENT OF GUIDELINES AND OTHER DOCUMENTS FOR UNIFORM IMPLEMENTATION OF THE 2004 BWM CONVENTION

Draft Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention

Submitted by Brazil, the Netherlands, New Zealand and the United Kingdom

SUMMARY

Executive summary: This document provides the text of the draft “Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention”

Strategic direction: 7.1

High-level action: 7.1.2

Planned output: 7.1.2.2

Action to be taken: Paragraph 5

Related documents: MEPC 56/23 and BLG 12/5/3

1 Regulation B-3.7 of the International Convention for the Control and Management of Ships’ Ballast Water and Sediments (the BWM Convention) allows for other methods of ballast water management provided that “such methods ensure at least the same level of protection to the environment, human health, property or resources, and are approved in principle by the Committee”.

2 Having considered document MEPC 56/2/11 (Saudi Arabia and India) on an alternative ballast water management method, MEPC 56 agreed on the need to develop the “Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention”. Consequently, MEPC 56 instructed the BLG Sub-Committee to develop such a procedure.
3 BLG 12 discussed the first draft proposal in document BLG 12/5/3 (United Kingdom) and decided that the proposal should be further developed. BLG 13 noted that the delegation of the Netherlands offered to coordinate the development of a co-sponsored document for submission to BLG 14.

4 The annex to this document contains the draft “Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention” for further review and revision by the Sub-Committee.

**Action requested of the Sub-Committee**

5 The Sub-Committee is invited to consider the draft procedure contained in the annex and decide as it deems appropriate.

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ANNEX

DRAFT PROCEDURE FOR APPROVING OTHER METHODS OF BALLAST WATER MANAGEMENT IN ACCORDANCE WITH REGULATION B-3.7 OF THE BWM CONVENTION

1 INTRODUCTION

1.1 Regulation B-3.7 of the International Convention for the Control and Management of Ships’ Ballast Water and Sediments, 2004 (the BWM Convention) permits the use of other methods of ballast water management to achieve at least the same level of protection to the environment, human health, property or resources as provided for under regulations B-3.1 to B-3.5.

1.2 The Procedure for approving other methods of ballast water management, in accordance with regulation B-3.7 of the BWM Convention (hereafter referred to as “the Procedure”), aims at providing criteria for the evaluation and approval of other methods of ballast water management (hereafter referred to as “Other Methods”), as permitted by regulation B-3.7 of the BWM Convention.

1.3 This Procedure has been developed to ensure that these Other Methods as permitted by regulation B-3.7 provide at least the same level of protection to the environment, human health, property or resources as those methods permitted under regulations B-3.1 to B-3.5.

1.4 Other Methods of ballast water management permitted under regulation B-3.7 are to be approved in principle by the Committee prior to Type Approval or Prototype Approval of a system by the Administration that implements such Other Method.

1.5 An Other Method that uses a system where Active Substances and Preparations are added to the ballast water, or are generated on board ships by the system, should also be subject to the approval by the Committee in accordance with the “Procedure for approval of ballast water management systems that make use of Active Substances (G9)”, as amended.

1.6 All systems based on an Other Method will also have to gain Type Approval or Prototype Approval, as appropriate, under the Guidelines for approval of ballast water management systems (G8), as amended. It should be noted, however, that there may be certain tests or standards under the Guidelines (G8) that cannot be undertaken due to the nature of the technology (e.g., land-based testing for a flow through ballast water exchange system or the use of potable water for ballast). In such cases, the Applicant should provide theoretical modelling or alternative tests as a substitute to the test needed under the Guidelines (G8).

1.7 The environmental impacts of any chemical by-products formed by a system based on an Other Method will also have to be evaluated by the Administration during the type approval process, in accordance with the procedure described in paragraph 1.6.4 of part 1 of the annex to Guidelines (G8), as amended, with respect to safety to the environment.

1.8 This Procedure specifies the requirements for the information to be provided, identifies the responsible parties for providing such information, and outlines the approval processes required by the Organization.
1.9 The use of Other Methods of ballast water management should be consistent with the objectives of the Convention “to prevent, minimize and ultimately eliminate the risks to the environment, human health, property and resources arising from the transfer of harmful aquatic organisms and pathogens through the control and management of ships’ ballast water and sediments, as well as to avoid unwanted side effects from that control, and to encourage developments in related knowledge and technology”.

1.10 However, under the BWM Convention, an Active Substance means a substance or organism, including a virus or fungus, that has a general or specific action on or against harmful aquatic organisms and pathogen. For this Procedure, the option of using organisms is specifically excluded as the intention is for Other Methods to exclude the transfer of hazardous aquatic organisms.

2 PURPOSE

2.1 The Procedure ensures that the consideration of Other Methods is consistent with the standards contained in the BWM Convention. The Procedure will be kept under review and updated by the Organization in light of the experience gained during its application and as the state of knowledge and technology may require.

2.2 The purposes of this Procedure are as follows:

.1 to provide a uniform interpretation and application of the requirements for the approval of other methods permitted under regulation B-3.7;

.2 to ensure that systems approved by an Administration based on an Other Method are capable of at least achieving equivalence with the standards required by regulations B-3.1 to B-3.5;

.3 to assist in determining the information necessary for the approval in principle of Other Methods being developed under regulation B-3.7 of the BWM Convention and identify the roles and responsibilities in providing such information;

.4 to assist Administrations in assessing Type Approval or Prototype Approval of systems based on an Other Method;

.5 to provide guidance to manufacturers, shipowners and other interested parties involved in determining the suitability of systems based on an Other Method to meet the requirements of the BWM Convention; and

.6 to provide the approval process required by the Organization.

3 DEFINITIONS

3.1 Method means a process developed and designed to reduce the transfer of harmful aquatic organisms through ships’ ballast water to meet the standards specified under regulations B-3.1 to B-3.5 of the BWM Convention.
3.2 Other Method means an alternative to a Method defined under regulation 3.1, which provides a level of protection equivalent to that provided by the standards specified under regulations B-3.1 to B-3.5 of the BWM Convention and the additional requirements outlined in this Procedure.

3.3 System means any equipment installed on a ship that processes ballast water and implements an Other Method.

4 APPLICABILITY

4.1 The Procedure applies to Administrations either seeking, assessing or granting approval in principle for an Other Method and Type Approval or Prototype Approval for a system implementing such Other Methods under regulation B-3.7 of the BWM Convention.

4.2 Equipment manufacturers wanting to seek approval of an Other Method should also consult this Procedure.

4.3 Other Methods that base an equivalent level of protection on any, or any combination, of the conditions specified in regulation A-4.1 of the BWM Convention, should not be dealt with by this Procedure.

5 GENERAL CRITERIA FOR AN APPLICATION FOR APPROVAL IN PRINCIPLE OF AN OTHER METHOD

5.1 The information provided to support the application for approval in principle should be complete, of sufficient quality, and in accordance with this Procedure.

5.2 The applicant, for approval in principle of an Other Method of ballast water management, is required to provide theoretical and/or operational proof that the Other Method being submitted:

.1 provides a level of protection at least equivalent to that provided by the standards specified under regulations B-3.1 to B-3.5 of the BWM Convention; and

.2 is capable of providing a consistent level of protection at all times in all environments/locations.

Equivalence and benchmark criteria for an application for approval in principle of an Other Method

5.3 A fully developed theoretical approach for assessing the level of protection against the transfer of harmful aquatic organisms and pathogens (article 2.1 of the BWM Convention) should be part of the description of an Other Method that sets the benchmark for the performance of systems, based on Other Method, and enables a transparent comparison of this level of protection with that provided by the standards in regulations B-3.1 to B-3.5 of the BWM Convention and the additional requirements outlined in this Procedure, as appropriate.

5.4 Applications for Other Methods need to specify the benchmark against which the performance of any system based on an Other Method can be measured. This would operate in the same way that regulations D-1 and D-2 provide a measurable benchmark that can be evaluated for Type Approval and port State control (regulation D-1 being a process evaluation, while regulation D-2 is a measurable performance standard). The benchmark would need to be
contained in the application, agreed by the Committee, and then be used for consideration of Type Approval through Guidelines (G8) and compliance testing by port State control. The benchmark provides an assurance that systems based on an Other Method are providing the same level of protection for the environment as the Other Method that has received the approval of the Committee in principle.

5.5 Benchmarks should be based on a recognized international standard, where appropriate.

5.6 Other Methods designed to provide equivalence to D-1 standard and/or D-2 standard should demonstrate, by risk assessment, theoretical physical and biological modelling, operational testing of this modelling and full-scale operational testing, where applicable, that the Other Method is capable of meeting at all times a level of protection that is, at least equivalent to, or better than, regulation(s) D-1 and/or D-2 of the Convention as applicable.

5.7 An Other Method may provide the same level of protection for the environment, human health, property or resources where:

.1 the ballasting and deballasting process does not transfer harmful aquatic organisms and pathogens (e.g., a rapid flow through system that results in a minimal residence time for the water on board so that organisms are not transported at a biologically meaningful distance, and should be addressed through the Guidelines for risk assessment under regulation A-4 of the BWM Convention (G7)); or

.2 the ballast water discharge contains no harmful aquatic organisms and pathogens (e.g., a system that uses potable water); and

.3 for flow through systems, it is necessary to have a performance standard that limits the amount of viable organisms and indicator microbes from one bioregion being discharged through ballast water in another bioregion that is equivalent to the D-1 or D-2 performance standard. Such a standard could potentially be used on trade routes with well defined bioregions.

5.8 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.

**Sampling protocol criteria for an application for approval in principle of an Other Method**

5.9 The description of the Other Method should contain a ballast water sampling and analysis protocol that, where appropriate, satisfies the requirements of Guidelines for ballast water sampling (G2).

**Ship and personnel safety criteria for an application for approval in principle of an Other Method**

5.10 A Formal Safety Assessment or a Safety Case should be developed to ensure that the Other Method or system based on an Other Method is safe for installation on board ship and any risks to the ship’s crew resulting from the system are identified and adequately addressed. This Formal Safety Assessment or Safety Case should be consistent, where appropriate, with part 3 of the annex to Guidelines (G8), as amended, and approved by the Administration.
6 SUBMISSION PROCESS

6.1 The manufacturer should evaluate the Other Method in accordance with the approval criteria specified in this Procedure according to a protocol that is approved by an Administration.

6.2 Upon completion, the manufacturer should prepare an application for the Other Method and submit it to the Member of the Organization concerned.

6.3 The Member of the Organization having received an application should review the application to ensure it is satisfactory (i.e. contains all of the information that is required and the information provided is of a sufficient standard to enable a decision to be made by the Committee). If the application is satisfactory then the Member should submit the application to the Organization at least 28 weeks prior to the MEPC at which approval in principle is to be sought.

6.4 When in session the Organization should decide if the proposal is acceptable for consideration by the Organization and set the time frame for the evaluation of the proposal, as follows:

.1 The Organization may commission an independent review of the risk assessment method, data and assumptions in order to ensure that a scientifically rigorous analysis has been conducted. The review should be undertaken by independent experts with ecological, aquatic biology and risk assessment expertise.

.2 The reviewers’ 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.

.3 Other Methods making use of Active Substances or preparations to comply with the BWM Convention should also be evaluated according to Procedure (G9).

.4 Other methods that do not make use of Active Substances should be evaluated for environmental acceptability according to Guidelines (G8).

6.5 All proprietary data should be treated as confidential by the Organization, the competent Authorities involved, and the evaluating regulatory scientists, if any. However, all information related to safety and environmental protection, including physical/chemical properties and data on environmental fate and toxicity, should be treated as non-confidential.

6.6 The Committee should evaluate the application for approval in principle of an Other Method based on the criteria in this Procedure.
7 APPROVAL

Criteria for assessing approval in principle

7.1 The application for approval in principle should be assessed by the Committee to ascertain whether:

.1 the application for approval in principle is complete, of sufficient quality, and in accordance with this Procedure;

.2 the Other Method does not cause any unacceptable adverse effects to environment, human health, property or resources;

.3 the Other Method does not contravene the other regulations in the BWM Convention, or any other convention or code applicable to the ship type; and

.4 the Other Method affords at least the same level of protection to the environment, human health, property or resources as those methods permitted under regulations B-3.1 to B-3.5.

7.2 The absence of, or uncertainty in, any information should not be considered a reason to grant approval.

7.3 The Committee should decide whether to approve in principle the proposal, introduce any modifications thereto, if appropriate, taking into account the reviewers’ report.

7.4 The Member of the Organization that submitted the application to the Organization should inform the applicant in writing about the decision made by the Organization with regard to the Other Method in question.

7.5 Once the Other Method is approved in principle by the Committee all systems using the Other Method will also have to gain Type Approval or Prototype Approval, as appropriate.

Assessment of equivalence

7.6 The Committee should review the benchmarks detailed in the application and use them as the basis for assessing equivalence to the level of protection for the environment, human health, property or resources as provided for under regulations B-3.1 to B-3.5.

7.7 Other Methods designed to provide equivalence to the D-1 standard (e.g., flow through systems) are as follows:

.1 Other Methods, designed to provide equivalence to D-1 standard until the vessel needs to comply with D-2 standard, should demonstrate, through risk assessment, theoretical physical and biological modelling, operational testing of this modelling and full-scale operational testing of systems based on other methods, where applicable, that the Other Method is capable of meeting at all times a level of protection that is, at least equivalent to, or better than, regulation D-1 of the BWM Convention:
1. ballast water exchange with an efficiency of at least 95 per cent volumetric exchange of ballast water; or

2. exchanging ballast water by the pumping-through method, pumping through three times the volume of each ballast water tank.

Pumping through less than three times the volume may be accepted provided the ship can demonstrate that at least 95 per cent volumetric exchange is met. If there is a question about the environmental impact of an Other Method during the development of those other methods, such approval should be split in that same way as it is in Procedure (G9). Other Methods should be approved by the Administration and Organization based on theoretical data prior to them being tested at sea.

3. With respect to the same characteristics as the recipient waters, the relevant water quality parameters (suspended solids, salinity, oxygen concentration, particulate organic matter, to be extended, if necessary) should be reasonably the same in the incoming as well as in the outflowing water.

7.8 Other Methods designed to provide equivalence to D-2 standard (e.g., potable water systems) are as follows:

1. Other Methods designed to provide equivalence to D-2 standard should demonstrate, by risk assessment, theoretical physical and biological modelling, operational testing of this modelling and full-scale operational testing of systems based on other methods, where applicable, that the Other Method is capable of meeting a level of protection at all times that is at least equivalent to, or better than, regulation D-2 of the BWM Convention.

2. Where appropriate, benchmarks should be based on recognized international standards, e.g., WHO Guidelines for drinking water quality.

3. The description of the main characteristics of the ballast water as well as the absence/presence of harmful aquatic organisms is to be supported by independent verification (e.g., a certificate from the local water authorities, or information on the ship's potable water-generating system) if communal potable water is used.

4. If potable water is used then the following should be available on board ship for inspection: generated potable water onboard test results, equipment specification and quality assurance.

7.9 Other Methods designed to provide equivalence to both D-1 and D-2 standards should demonstrate by risk assessment, theoretical physical and biological modelling, operational testing of this modelling and full-scale operational testing, where applicable, that the Other Method is capable of meeting a level of protection at all times that is, at least equivalent to, or better than, regulation D-2 of the BWM Convention.

7.10 Risk assessment is the logical process for assigning the likelihood and consequences of specific events, such as entry, establishment or spread of harmful aquatic organism and pathogens in situations where a direct comparison of application benchmarks with D-1 and D-2 standards is not possible.
7.11 In undertaking risk assessment to consider and evaluate the equivalence of an Other Method with D-1 and D-2 standards, the risk assessment principles outlined in Guidelines (G7), as amended, should be carefully applied. The lack of full scientific certainty should be carefully considered in the decision-making process.

**Type Approval**

7.12 A system based on an Other Method, having received approval in principle from the Committee, is to be Type Approved by an Administration according to Guidelines (G8) and Procedure (G9) as appropriate.

7.13 The Administration may need to assess an application for Type Approval of a system based on an Other Method through a modified version of the Guidelines (G8) (e.g., the use of the application benchmark in place of D-2 standard).

7.14 The evaluation for safety to human health, property, or resources of systems based on an Other Method not making use of Active Substances or preparations, to comply with the BWM Convention, should be based on the following criteria applied for Methods:

1. systems based on an Other Method should be evaluated for safety to human health, property or resources, according to the guidance on Type Approval contained in Guidelines (G8); and

2. systems based on an Other Method not making use of Active Substances or Preparations to comply with the BWM Convention should be evaluated according to the procedure described in paragraph 1.6.4 of part 1 of the annex to Guidelines (G8), as amended, with respect to safety to the environment.

7.15 Systems based on an Other Method making use of Active Substances or preparations to comply with the BWM Convention, should be evaluated according to Procedure (G9), as amended, for safety to the environment, human health, property or resources.

7.16 If there is a question about the environmental impact of a system based on an Other Method and using Active Substances during the development of that system, such approval should be split in that same way as it is in Procedure (G9). Other Methods should be approved by the Administration and Organization based on theoretical data prior to them being at sea.

8 **NOTIFICATION OF APPROVAL**

8.1 The Organization will record the approval in principle of Other Methods and circulate the list once a year including the following information:

- name of ballast water management system that make use of the Other Method;
- date of approval;
- name of manufacturer;
- the benchmark that the Other Method is designed to meet;
- copies of or access routes to test reports, test methods, etc. (as resolution MEPC.175 (58); and

- any other specifications, if necessary.

8.2 Administrations, when approving a system based on an Other Method should report to the Organization in accordance with resolution MEPC.175(58) on Information reporting on Type-Approved ballast water management systems.

9 MODIFICATION

9.1 Manufacturers should report any modifications in the system, based on an Other Method approved by the Organization, to the Member of the Administration.

9.2 Manufacturers intending to make changes to the mode of operation of the system based on an Other Method that has been approved by the Organization should submit the changes for approval to the Member State. In case the changes fall outside the original Approval in principle, a new application should be submitted to the Organization.

10 WITHDRAWAL OF APPROVAL

10.1 The Organization may withdraw any approval in principle in the following circumstances:

.1 if the Other Method or system based on an Other Method no longer conforms to requirements due to amendments of the BWM 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 criteria;

.3 if a request for withdrawal of approval is made by the Member of the Organization on behalf of the manufacturer; and

.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 an approved system based on the Other Method.

10.2 The decision to withdraw an approval in principle should specify all necessary further details, at least the date upon which the withdrawal takes effect.

10.3 The authority of Member States regarding type approvals issued under their jurisdiction remains unaffected.

11 INSTALLATION ON SHIPS

11.1 Ships employing a system based on an Other Method under regulation B-3.7 of the BWM Convention, to meet their obligations under the Convention, can only do so once the Other Method has been approved by the Organization and the system has been granted Type Approval by the Administration following Guidelines (G8).
11.2 Ships employing a system based on an Other Method under regulation B-3.7 of the BWM Convention should provide equivalent protection to either D-1 or D-2 standard up until the dates set out in paragraphs 1 to 5 of regulation B-3 of the BWM Convention. After which, the ship should employ a system based on an Other Method that provides equivalent protection to D-2.

11.3 Type-Approved systems should be installed in line with the dates in regulation B-3 of the BWM Convention.

11.4 When a Type-Approved system based on an Other Method is installed on board ship, an installation survey in accordance with section 8 of Guidelines (G8), as amended, should be carried out.