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**INTERNATIONAL CONVENTION FOR THE CONTROL AND
MANAGEMENT OF SHIPS' BALLAST WATER AND
SEDIMENTS, 2004**

**Framework for determining when a Basic Approval granted to one ballast water
management system may be applied to another system that uses
the same Active Substance or Preparation**

1 The Marine Environment Protection Committee, at its sixty-first session (27 September to 1 October 2010), approved the Framework for determining when a Basic Approval granted to one ballast water management system may be applied to another system that uses the same Active Substance or Preparation developed by the BLG Sub-Committee at its fourteenth session (8 to 12 February 2010), as set out in the annex.

2 Member Governments are invited to bring this circular to the attention of all parties concerned.

ANNEX

FRAMEWORK FOR DETERMINING WHEN A BASIC APPROVAL GRANTED TO ONE BALLAST WATER MANAGEMENT SYSTEM MAY BE APPLIED TO ANOTHER SYSTEM THAT USES THE SAME ACTIVE SUBSTANCE OR PREPARATION

1 INTRODUCTION

1.1 The "Procedure for approval of ballast water management systems that make use of Active Substances (G9)" (**Procedure (G9)**) provides that, subject to evaluation against the criteria developed by the Organization, an Active Substance or Preparation may be used for Prototype or Type Approval testing for the approval of different ballast water management systems (BWMS).

1.2 The objective of this document is to provide guidance for the manufacturers and the Administration, and for other interested parties, in preparing an application based on the use of an original Basic Approval and, for its subsequent evaluation by the GESAMP-BWWG for Final Approval according to Procedure (G9).

1.3 An Active Substance or Preparation should be identical to the Active Substance or Preparation that has already received Basic Approval and its treatment concentration should be less than or equal to the original Basic Approval. In addition, any recommendations by the MEPC for the Basic Approval, including neutralization and maximum allowable discharge concentration (MADC) considerations, should be applied.

1.4 The document provides a framework including criteria to enable direct comparison of the physical nature of the system, the chemical nature of the Active Substance or Preparation, and the legal and commercially sensitive nature of the information and data being transferred.

1.5 When considering an application, the use of an Active Substance or Preparation should be substantially similar to the original application that has gained Basic Approval, as this needs to be considered in the context of the BWMS within which it is used. This is because of the way different systems use the Active Substance or Preparation, that may change the nature of the Active Substance or Preparation itself. For example, hydrogen peroxide can be used as a chemical treatment on its own or as a catalyst in combination with a secondary method.

1.6 Any BWMS that has been granted approval to use a Basic Approval from another system is still subject to the Final Approval process, as set out in Procedure (G9).

1.7 Any BWMS seeking to use the Basic Approval from another system should also meet conditions or requirements placed on the original Basic Approval by the Committee.

1.8 Before considering the development of an application to use a Basic Approval from another system, an applicant should consider that the less similarity between the two systems, the more data that will need to be supplied to evaluate the application.

2 DEFINITIONS

For the purpose of this guidance, the definitions in Procedure (G9) apply and:

2.1 "**Applicant**" means any manufacturer or developer working with the Member State or Administration, in the development of a BWMS that intends to use the original Basic Approval for a certain Active Substance in the development of the BWMS.

2.2 "Substantially similar" in relation to "use" of an Active Substance or Preparation means the method of application and point of injection of the Active Substance or Preparation to the BWMS are not significantly different to that in the system granted approval.

3 PROCEDURE TO BE FOLLOWED

3.1 The manufacturer seeking to use an original Basic Approval for a BWMS that makes use of an Active Substance or Preparation for the purpose of obtaining a subsequent Final Approval for a BWMS using the same Active Substance or Preparation, should evaluate the extent to which the BWMS meets the criteria specified in this guidance document.

3.2 Proof that legal issues have been properly dealt with should be provided to the Administration by the manufacturer seeking to use the original approval.

3.3 The Administration having received a submission to use an original Basic Approval should review the application, taking into account the guidance in this document. If the Administration is satisfied that such utilization is acceptable, it should advise the Organization of its determination as appropriate. The Organization should circulate the information accordingly.

3.4 The Administration should submit the application for Final Approval to the Organization, as soon as possible in accordance with section 8.2 of Procedure (G9).

3.5 If the GESAMP-BWWG agrees that the application is complete and appropriate, it should proceed to consider the application for Final Approval of the BWMS.

3.6 If the GESAMP-BWWG finds that the application is not complete or is inappropriate, (or both), the GESAMP-BWWG should report their findings, as provided for in Procedure (G9), for consideration by the Committee.

3.7 Under Procedure (G9), the Committee of the Organization will make the final decision on whether to accept the recommendations of the GESAMP-BWWG to reject an approval of any proposal.

4 CRITERIA FOR ASSESSING WHETHER THE ACTIVE SUBSTANCES OR PREPARATIONS ARE IDENTICAL

4.1 The description of Active Substances and Preparations should include chemicals associated with the system, as required by the Procedure (G9) in section 4.1 and listed in detail in relevant sections of the GESAMP-BWWG Methodology, applicable at the time of this assessment.

4.2 If any of the identified chemicals is not listed in the original Basic Approval application, then utilization of Basic Approval is not appropriate.

4.3 The stated concentrations for storage, generation and treatment, as appropriate, of the Active Substances and Preparations should be equal to or less than those in the original Basic Approval application.

4.4 The maximum allowable discharge concentration or the worst case discharge concentration should be equal to or less than those in the original Basic Approval application.

4.5 Analytical data about the composition and structure of the Active Substances or Preparations should be provided to substantiate that the Active Substances and Preparations are identical.

5 MANNER OF APPLICATION OF ACTIVE SUBSTANCE OR PREPARATION

5.1 The BWMS design should be substantially similar including all physical processes used in the system: including method or methodology for dosing ballast water, any mechanical separation used, pumps and pipe work, phase of treatment (e.g., on uptake, discharge or both) and any necessary neutralization.

5.2 Application of the Active Substance and Preparation within the BWMS should be substantially similar, including:

- point of introduction of the Active Substance or Preparation; and
- method of application or generation of the Active Substance or Preparation (e.g., electrolytic generation).

6 GUIDANCE ON LEGAL ISSUES

6.1 A legally binding agreement under which access to information within an original Basic Approval is granted could include:

- .1 name and address of the person to whom the Basic Approval rights are being shared;
- .2 identification of each item of Basic Approval data being shared including:
 - .1 the name of the Active Substance and Preparation or item of data;
 - .2 whether the agreement is an exclusive use agreement, and, if so, when the period of exclusive use protection expires;
 - .3 the name of the person or laboratory that conducted the study;
 - .4 a statement that the applicant and approval holder understand that any false statement may be punishable under international, national or local legislation; and
 - .5 the names, signatures and titles of the applicant and the approval holder, and the date signed;
- .3 in addition, the approval holder should submit to the Administration a notarized statement affirming that the person signing the agreement is authorized by the approval holder to bind the applicant.

6.2 The manufacturer seeking to use the Basic Approval for a BWMS that makes use of an Active Substance or Preparation for the purpose of Final Approval, should ensure that all relevant international, national and local legislation has been complied with.
