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PLANNING OF GESAMP ACTIVITIES: REVIEW OF APPLICATIONS FOR 'ACTIVE SUBSTANCES' TO BE USED IN BALLAST WATER MANAGEMENT SYSTEMS

Report of the GESAMP Ballast Water Working Group (Working Group 34)

Background and introduction

1 The International Convention for the Control and Management of Ships' Ballast Water and Sediments (hereafter referred to as the BWM Convention) was adopted at IMO on 13 February 2004, in response to the increasing concern of the international community with regard to the transfer of invasive species in ships' ballast water. On 8 September 2017, the Ballast Water Management Convention entered into force. Currently, there are 73 contracting Parties to the treaty, the combined tonnage of which adds up to 75.35% of the world's tonnage.

2 Within this framework, an approval procedure has been set up for those ballast water management systems that make use of an Active Substance or Preparation to comply with the Convention. The procedure consists of a two-step approach for granting Basic Approval and Final Approval. The approval is granted by the Marine Environment Protection Committee (MEPC) based on the advice provided by the Ballast Water Working Group of the GESAMP (WG 34). There is a third step, the type approval granted by an Administration, but that is outside the remit of WG 34.

3 The more general outline, scope and aim of the BWM Convention have been addressed in the report to the GESAMP 35 (see document GESAMP 35/5/1) and will only be referred to here. The Terms of Reference of WG 34 have been added as Annex 1 to this report. As the terms of reference of WG 34 have not changed, several parts of this report have been kept unchanged. For the readability of the report these sections are kept in the report with apologies to the experienced reader.

4 This report focuses on the main activities of WG 34, which consist of the evaluation of several ballast water management systems (hereafter BWMS) and the further development of the Methodology of the Group, which has been accepted as a 'living' document. This means that the Methodology will be a discussion item at (almost) each meeting of the Group and changes and improvements are made, as appropriate (see further below).

Ballast water management systems

5 'Active Substances' are defined by the Convention as "substances or organisms, including a virus or a fungus, that have a general or specific action on or against harmful aquatic organisms and pathogens" and the approval of BWMS using such substances is described in resolution MEPC.169(57) adopted in 2008. However, not only 'Active Substances' are evaluated by the WG 34. Also all other substances considered relevant are taken into account in the evaluation report. The Procedure for approval of ballast water management systems that make use of Active Substances (G9) contained in resolution MEPC.169(57) under the BWM Convention distinguishes also 'Relevant Chemicals' and 'Other Chemicals'.

6 Therefore, WG 34's task is to evaluate the risks for the crew, the ships' safety, the public at large and the environment from the operation of the BWMS. It is furthermore the intention of WG 34 to perform these evaluations in a consequent, consistent and transparent manner, which helps Administrations to prepare a concise dossier, containing all the necessary data. The Methodology, as developed by WG 34 in the course of its work process, serves as guidance in the evaluation.

7 WG 34 was convened twice since GESAMP 44 to evaluate proposed BWMS, both times for a regular meeting, the first from 8 to 10 November 2017, where one BWMS has been evaluated, and the second from 4 to 7 June 2018 with two BWMS to be evaluated. Of these three BWMS, one received a recommendation for Basic Approval, one was not recommended for Final Approval and one received a recommendation for Final Approval. During its meeting in April 2018, MEPC 72 agreed with the recommendation of WG 34 for the first Final Approval not to be granted. The agreement and endorsement of the Basic Approval and the second Final Approval are still pending until the MEPC 73 meeting in October 2018. An overview of the BWMS evaluated since GESAMP 44 is presented in Annex 2 to this report.

8 One of the BWMS evaluated had made use of the provisions of 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* (BWM.2/Circ.27), based on the Basic Approval granted to another variation of this BWMS (Envirocleanse inTank™ BWTS) at MEPC 71. In this regard, the Group had a thorough examination of whether these provisions were indeed applicable, which would allow it to proceed with the evaluation of this proposal for Final Approval without having previously reviewed a Basic Approval application for the same variation of this system.

9 Concerns were expressed with regard to certain provisions of BWM.2/Circ.27 not being fully satisfied, notably the criteria for assessing whether the Active Substance is identical and the manner of application of the Active Substance. In particular, it was noted that this variation of the system has on-board storage of the Active Substance, which appears to be in contrast with paragraph 4.3 of the circular, and it incorporates a fundamental change to the source of the Active Substance from electrolysis to chemical injection, which may be in contrast with paragraph 5.2 of the circular.

10 The Group noted that the fundamental concept of the system's operation was substantially similar, ensuring continuity between the two evaluations, and that, while the source of the Active Substance is different, the method of its application is substantially similar. In addition, the Group was of the view that a separate Basic Approval application for this variation would not have necessarily provided more information on the remaining issues, which may be addressed at Final Approval only in any case. In conclusion, recognizing also that the objective of the circular is to provide guidance that can be interpreted based on expert judgement, the Group agreed that the two variations of this BWMS were sufficiently substantially similar therefore allowing the use of this circular, and that the application for Final Approval could be evaluated on this basis.

11 WG 34 was able to clear the stock of BWMS submitted for evaluation before the meeting of MEPC for which the evaluation was requested. The Group recognized that the number of BWMS presented to it have been less than in other reporting periods. Whether or not this trend will continue in the future has to be seen.

Revision of Procedure (G9)

12 During the first meeting the revision of resolution MEPC.169(57) (commonly known as Procedure (G9)) was also discussed as a follow-up of the revision of resolution MEPC.174(58), commonly known as Guidelines (G8). Guidelines (G8) deals with the procedures to follow to determine the biological efficacy of the BWMS under consideration, while Procedure (G9) deals with the procedures for the evaluation of a BWMS with Active Substances in terms of the risks

outlined in paragraph 6. As such the Procedure (G9) is the basis for the GESAMP-BWWG Methodology.

13 The consideration of the need for a revision of Procedure (G9) was a specific request of MEPC and was based on the revision of Guidelines (G8), which moreover became mandatory in the form of a Code, with the purpose to streamline the relation between the two. WG 34 reviewed the document from two different angles. On the one hand from the minimum changes necessary to streamline the interactions between the two, specifically in the area of mandatory wording, and on the other hand a more thorough revision based on the current status of the scientific knowledge. At MEPC 72, the Committee decided that Procedure (G9) should be revised as a consequence of the revision of Guidelines (G8), and that it was not necessary to make Procedure (G9) into a code under the Convention. Therefore, a more thorough revision of Procedure (G9) was not necessary.

Methodology for information gathering and the conduct of work of WG 34

14 The evaluation Methodology of WG 34 has been determined to be a living document based on increasing experience in the evaluation of BWMS. WG 34 added two more substances to the database of chemicals commonly associated with BWMS, based on the regularly occurring Active Substance sodium dichloroisocyanurate (NaDCC) that breaks down giving isocyanuric acid as the main metabolite, and chlorate that also often is occurring as a disinfection by-product (DBP). The current version of the database now contains 43 specific chemicals, including an AS and a neutralizer frequently used in BWMS. For these 43 substances the applicants do not have to submit the physico-chemical characteristics and the (eco-)toxicological data anymore to IMO as the Group is of the opinion that sufficient relevant information is already available. If, however, new data becomes available, it has to be submitted to IMO in any application dossier.

Planning ahead

15 The deadline for the submission of proposals for approval of BWMS to MEPC 74 is on 26 October 2018, which is relatively far in the future and therefore no applications were received to date. WG 34 scheduled two meetings to accommodate potential applications: BWWG 37 (regular) from 26 to 30 November 2018 and BWWG 38 (additional) from 14 to 18 January 2019, if needed. Of course, the number of meetings depends on the number of submissions. Both meetings are foreseen to be held at IMO Headquarters in London.

Acknowledgement

16 WG 34 is very thankful to all the members of GESAMP that took the time to critically review the work of WG 34. The quality of the work has been improved as a result of this peer review process and the comments made were brought to the attention of the consultant involved in the drafting of the reports for future use.

Action requested of GESAMP

17 GESAMP is invited to review this document and comment, as it deems appropriate.

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ANNEX 1

TERMS OF REFERENCE FOR THE TECHNICAL GROUP (GESAMP-BWWG/ WG 34)

1 Consideration of development of necessary methodologies and information requirements in accordance with the "Procedure for approval of ballast water management systems that make use of Active Substances (G9)" (adopted by resolution MEPC 169(57)) for consideration by MEPC 65.

2 For Basic Approval, the Group should review the comprehensive proposal submitted by the Member of the Organization along with any additional data submitted as well as other relevant information available to the Group and report to the Organization.

In particular, the Group should undertake:

.1 scientific evaluation of the data set in the proposal for approval (see paragraphs 4.2, 6.1, 8.1.2.3, 8.1.2.4 of Procedure (G9));

.2 scientific evaluation of the assessment report contained in the proposal for approval (see paragraph 4.3.1 of Procedure (G9));

.3 scientific evaluation of the risks to the ship and personnel to include consideration of the storage, handling and application of the Active Substance (see paragraph 6.3 of Procedure (G9));

.4 scientific evaluation of any further information submitted (see paragraph 8.1.2.6 of Procedure (G9));

.5 scientific review of the risk characterization and analysis contained in the proposal for approval (see paragraph 5.3 of Procedure (G9));

.6 scientific recommendations on whether the proposal has demonstrated a potential for unreasonable risk to the environment, human health, property or resources (see paragraph 8.1.2.8 of Procedure (G9)); and

.7 preparation of a report addressing the above-mentioned aspects for consideration by MEPC (see paragraph 8.1.2.10 of Procedure (G9)).

3 For Final Approval, the Group should review the discharge testing (field) data and confirm that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval and that the previous evaluation of the risks to the ship and personnel including consideration of the storage, handling and application of the Active Substance remains valid. The evaluation will be reported to the MEPC (see paragraph 8.2 of Procedure (G9)).

4 The Group should keep confidential all data, the disclosure of which would undermine protection of the commercial interests of the applicant, including intellectual property.

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ANNEX 2

LIST OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES IN ACCORDANCE WITH PROCEDURE (G9) SINCE GESAMP 43

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
1. Envirocleanse inTank BWTS (Bulk Chemical Variation) Envirocleanse, LLC United States but submitted by Norway	Disinfection with Active Substance sodium hypochlorite and doses ballast water after uptake based on a concentration-time (CT) treatment approach. This system requires the storage of the Active Substance and the neutralizer on board.	Final Approval, not granted, April 2018	The Flag State Administration was invited to ensure that the recommendations provided in annex 4 of the report of the GESAMP-BWWG 35 meeting were fully addressed during the further development of this ballast water management system before any new submission for FA. The recommendations mainly relate to uncertainties in the results of the chemical analyses, the quality of the whole effluent toxicity tests.
2. BioBallast 1000 BWMS Biomarine S.r.l, Italy but submitted by Germany	Disinfection with Active Substance ozone formed in situ by an ozone generator and subsequent neutralization with sodium thiosulfate. The system contains prior to treatment a filtration. This system requires the storage of the neutralizer on board.	Basic Approval recommended, pending for MEPC 73, October 2018	If MEPC agrees: The Flag State Administration was invited to ensure that the recommendations provided in annex 4 of the report of the GESAMP-BWWG 36 meeting were fully addressed during the further development of this ballast water management system before any submission for FA. The recommendations mainly relate to the stability of the TRO monitoring and the consideration of the exposure route to crew via the headspace of the BW tanks.
3. Envirocleanse inTank BWTS (Electrochlorination Variation)	Disinfection with Active Substance hypochlorite ion formed by in situ electrolysis and doses ballast water after uptake based on a	Final Approval recommended, pending for MEPC 73, October 2018	If MEPC agrees: The Flag State Administration was invited to ensure that the recommendations provided in annex 5 of

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
Envirocleanse, LLC United States but submitted by Norway	concentration-time (CT) treatment approach. This system requires the storage of the neutralizer on board.		the report of the GESAMP-BWWG 36 meeting were fully addressed during the further development of this ballast water management system prior to the issuance of the Type Approval Certificate. The recommendations mainly relate to improve the reliability of the MADC monitoring and to determine the neutralization time.