GESAMP
Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection

GESAMP 49/4/1
1 August 2022
ENGLISH ONLY

49th session
Agenda item 4

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

**Report of the Chair of 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 by IMO on 13 February 2004 in response to the increasing concern of the international community with regard to the transfer of invasive aquatic species in ships' ballast water. On 8 September 2017, the Ballast Water Management Convention entered into force. Currently, the ratification status is that the combined tonnage of contracting States to the treaty adds up to 92.40% with 92 contracting Parties (status as of 1 August 2022).

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 GESAMP Ballast Water Working Group (WG 34). There is a third step, the type approval, but this 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) every 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, the task of WG 34 is to evaluate the risks of the BWMS for the crew, the ship's safety, the risk for the public at large and the environment. 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. GESAMP may recall that the Methodology of WG 34 (GESAMP R&S report No. 101) was presented at the 50th anniversary of GESAMP during its 46th meeting in New York.

7 WG 34 had one regular meeting since GESAMP 48 to evaluate proposed BWMS; GESAMP-BWWG 42 took place from 18 to 22 July 2022 in London, UK, where three BWMS were evaluated for MEPC 79. Of these three BWMS, two were submitted for Final Approval and one for Basic Approval.

8 WG 34 agreed that the two ballast water management systems submitted for Final Approval would be recommended to be granted Final Approval at MEPC 79.

9 With respect to the system submitted for Basic Approval the Group considered that the BWMS was not yet sufficiently developed to be recommended Basic Approval with this application.

10 MEPC has not yet decided on the recommendations of WG 34 for these three systems because MEPC 79 will take place from 12 to 16 December 2022. An overview of the BWMS evaluated at this meeting is presented in Annex 2 to this report.

11 WG 34 was able to clear the whole stock of BWMS submitted for evaluation before the meeting of MEPC for which the evaluation was requested. WG 34 recognized that the number of BWMS presented to WG 34 had increased compared to recent reporting periods. WG 34 does expect that more BWMS will have to be evaluated for freshwater as there are still several BWMS that received only Final Approval for marine and brackish water.

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

12 The evaluation Methodology of WG 34 has been determined to be a living document based on increasing experience in the evaluation of BWMS and international developments in risk assessment of chemicals. GESAMP-BWWG used to develop its Methodology using the instrument of stocktaking workshops in which specific topics could be discussed without the pressure of the delivery of BWMS evaluations as well. After a few years without such a workshop, WG 34 felt the need to have a ninth STW as several subjects had to be discussed and decided upon.

13 MEPC 77 endorsed the proposal of GESAMP-BWWG 41 to hold a ninth Stock-taking workshop (STW 9). The workshop was held virtually from 24 to 28 January 2022. The agenda of the ninth Stock-taking workshop is attached as Annex 3. The chair of GESAMP, Prof. David Vousden, provided the members with an update on the activities of GESAMP, which was well received by the members. A copy of his lecture is attached as Annex 4.

14 Annex 5 to this report contains the results of the STW 9, whilst below some highlights are presented for the three specific agenda points:

.1 WG 34 was able to prepare draft guidelines for re-evaluations in cases where modifications had been made, for consideration by the Committee at a future session, as requested by MEPC 75 (MEPC 75/4/18, paragraph 4.7). WG 34 defined a procedure (see Annex 4 to Annex 5) to be inserted in the existing Methodology as Chapter 12. Several modifications have been determined that may influence the earlier results achieved in WG 34's evaluations considering risks to the environment, human health, including the crew. and risks to the ship. WG 34 developed a decision tree and a table with which an applicant

may determine which data should be submitted for a re-evaluation based on a modification performed;

.2 WG 34 reviewed its position on how to evaluate TRO sensors, including required properties of amperometric TRO sensors used in BWMS. WG 34 concluded that in the test reports several improvements were achieved that diminish WG 34's concern with amperometric sensors compared to colorimetric sensors. It was decided to accept in the future amperometric TRO sensors on an equal basis compared to the colorimetric TRO sensors, with the understanding that on a regular basis the amperometric measurements should be compared with the results of a handheld colorimetric method; and

.3 WG 34 concluded and recommended not to include new test organisms, e.g. bacteria, for laboratory ecotoxicity testing and WET test in WG 34's Methodology. The reason is that insufficient scientific support and a lack of test protocols were available. WG 34 is of the opinion that, if sufficient scientific information will be available in the future, such an inclusion may be reconsidered.

15 It was the intention of WG 34 to hold this STW in addition to a regular meeting at the first possible opportunity. Due to the fact that there were no submissions of applications for BWMS approvals to MEPC 78, and therefore no regular meeting of WG 34 reporting to that session, the STW took place as a stand-alone event.

16 During its seventy-ninth session, the MEPC approved the draft guidelines for the re-evaluation in cases where modifications have been made to a ballast water management system as contained in the STW 9 report of WG 34 (see Annex 4 to Annex 5). The guideline was included in the Methodology of WG 34 as chapter 12 with the understanding that the guideline will take effect immediately after MEPC 78.

17 MEPC 78 endorsed the view of WG 34 that for re-evaluations of ballast water management systems which make use of Active Substances to be conducted in cases where the recommendation of the GESAMP-BWWG may be challenged by the Committee:

.1 the Administration requesting a re-evaluation should provide sound scientific justification and clear rationale for the Committee's consideration;

.2 the re-evaluation should not require substantial new information (in such a case a new application would instead need to be submitted); and

.3 an additional fee of USD 20,000 would be payable if the recommendation of the GESAMP-BWWG does not change as a result of the re-evaluation and is subsequently endorsed by the Committee.

**Planning ahead**

18 The next meeting of WG 34 is scheduled, from 20 to 24 February 2023. Of course, the number of days of the meetings depends on the number of submissions. In case there is only one submission the applicant may decide to postpone its submission and in case of no submissions the meeting will be cancelled.

**Acknowledgement**

19 WG 34 is 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 improved as a result of the 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**

20 GESAMP is invited to review this document and to 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)).

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 48**

| Name of the System/Manufacturer | Brief description of the System | Date of Approval | Specifications |
|---|---|---|---|
| 1. RADClean® BWMS<br><br>Rahavaran Ayandeh Darya Company, Islamic Republic of Iran, submitted by the Islamic Republic of Iran. | Disinfection with Active Substance sodium hypochlorite by in situ electrolysis. Filtration is used as pre-treatment and neutralization as post-treatment. This system requires the storage of the neutralizer sodium thiosulfate on board. | Final Approval recommended but decision pending for MEPC 79. | The flag State Administration was invited to ensure that the recommendations provided in annex 4 of the report of the GESAMP-BWWG 42 meeting were fully addressed before issuing the Type Approval Certificate. The recommendations mainly relate to updating the Operational Management and Safety Manual (OMSM), the safe handling of the BWMS under low temperatures and the venting of hydrogen. |
| 2. ECS-Hychlor 2.0 BWMS<br><br>TechCross Inc. Republic of Korea, submitted by the United Kingdom. | Disinfection with Active Substance sodium hypochlorite by in situ electrolysis. The system is designed without filtration as pre-treatment but with neutralization as post-treatment. This system requires the storage of the neutralizer sodium thiosulfate on board. | Final Approval recommended but decision pending for MEPC 79. | The flag State Administration was invited to ensure that the recommendations provided in annex 5 of the report of the GESAMP-BWWG 42 meeting were fully addressed before issuing the Type Approval Certificate. The recommendations mainly relate to updating the OMSM and reducing the delay time for the detection of the high TRO levels. |
| 3. AirTree BWMS ABWOT<br><br>AirTree Europe GmbH, Germany, submitted by Germany. | Disinfection with Active Substance ozone formed in situ. Filtration is used as pre-treatment and neutralization as post-treatment. This system requires the | Basic Approval not recommended but decision pending for MEPC 79. | The WG 34 considered that this system was not yet fully developed to be considered as promising for Final Approval. The Group recommended that the concerns and |

| Name of the System/Manufacturer | Brief description of the System | Date of Approval | Specifications |
|---|---|---|---|
| | storage of the neutralizer sodium thiosulfate on board. | | recommendations provided in annex 6 of the report of the GESAMP-BWWG 42 meeting should be fully addressed before any future re-submission for Basic Approval. The recommendations relate to safe handling of the ozone as Active Substance and the development of a monitoring system for the MADC. |

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**ANNEX 3**

**AGENDA**

**NINTH STOCKTAKING WORKSHOP ON THE ACTIVITY OF THE GESAMP-BALLAST WATER WORKING GROUP**

**to be held remotely**
**from 24 to 28 January 2022**

**(Session commences at 11 a.m. on Monday, 24 January 2022)**

1 Adoption of the agenda

2 Introduction and ways of working during the Workshop, housekeeping, timetable and GESAMP presentation

3 Draft guidelines for re-evaluations in cases where modifications have been made, as requested by MEPC 75

4 Evaluation of the Group's position on TRO sensors

5 Recommended test organisms for laboratory ecotoxicity testing and WET tests

6 Any other business

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**ANNEX 4**

Presentation of David Vousden to the ninth Stock-taking Workshop of GESAMP-BWWG
On 24 January 2022

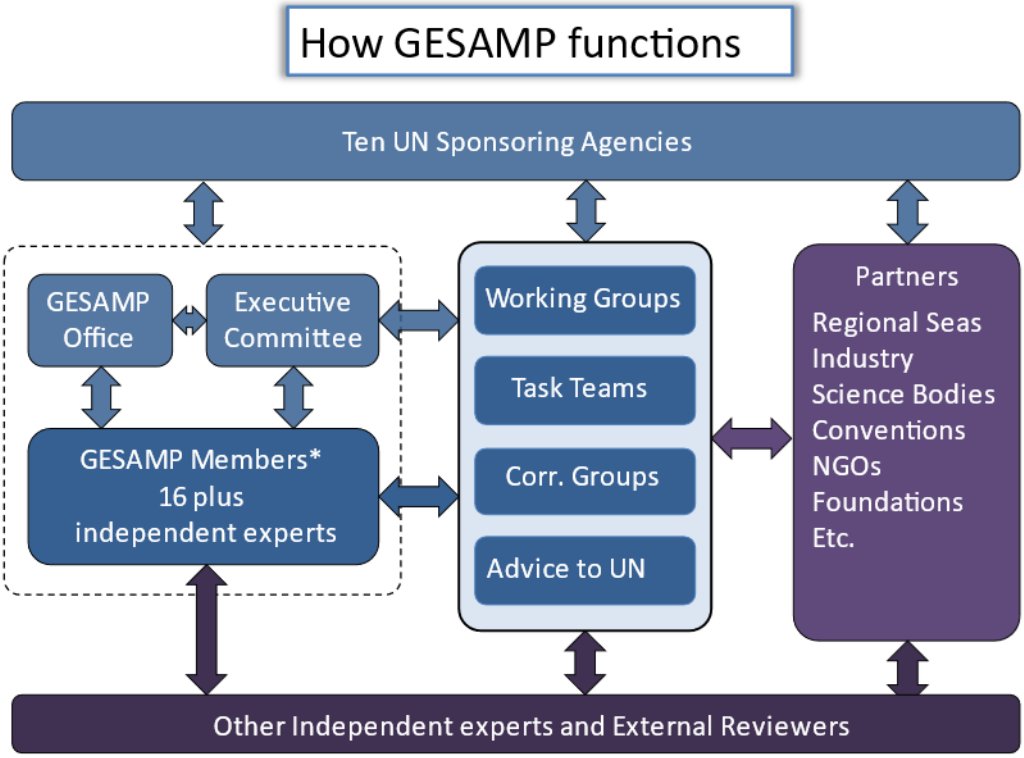
GESAMP

The Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection

An inter-agency body of the United Nations established in 1969

Purpose: *'to provide authoritative, independent, interdisciplinary scientific advice to organizations and governments to support the protection and sustainable use of the marine environment.'*

IMO FAO UNESCO IOC WMO UNIDO IAEA UN UNEP UNDP ISA

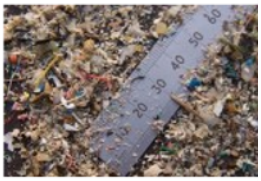
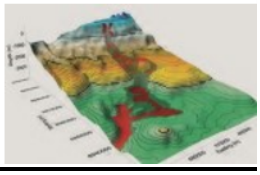



* Membership (as of January 2022): Australia, Canada, Fiji, India, Netherlands, New Caledonia, Nigeria, South Africa, Jamaica, UK, USA,

## GESAMP Working Groups

- Working Groups are set up by GESAMP to carry out individual studies and assessments requested by of one or more of its Sponsoring Organizations.
- WGs are proposed, established and supported by a UN Sponsoring Organisation to address an issue of concern identified by the Organisation, by the Members or by a Member State and to carry out individual studies and assessments
- These groups are chaired by a GESAMP Member and are made up of leading global experts who are not necessarily members of GESAMP itself. This broadens the GESAMP network activities and allows Working Group expertise to be tailored to specific projects.
- WGs have formal Terms of Reference and Membership as agreed with the Sponsoring Organisation
- Reports of the Working Groups are normally considered for publication in the GESAMP Reports and Studies series after peer review and approval by GESAMP



## GESAMP Working Groups

**WG 1** – evaluation of the hazards from harmful substances carried by ships IMO (self-funded)

**WG 34** – review of applications for 'active substances' in ballast water management systems – IMO (self-funded)

**WG 38** – atmospheric inputs of chemicals to the ocean – WMO

**WG 40** – sources, fate & effects of plastics and microplastics - IOC-UNESCO, UNEP

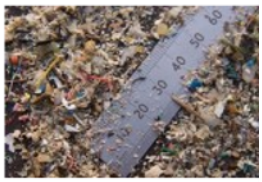
**WG 41** –Ocean interventions for climate change mitigation - WMO, IOC-UNESCO, UNEP

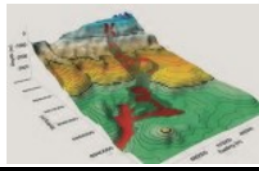
**WG 42** – impacts of wastes and other matter in the marine environment from mining operations including marine mineral mining - IMO, UNEP, ISA

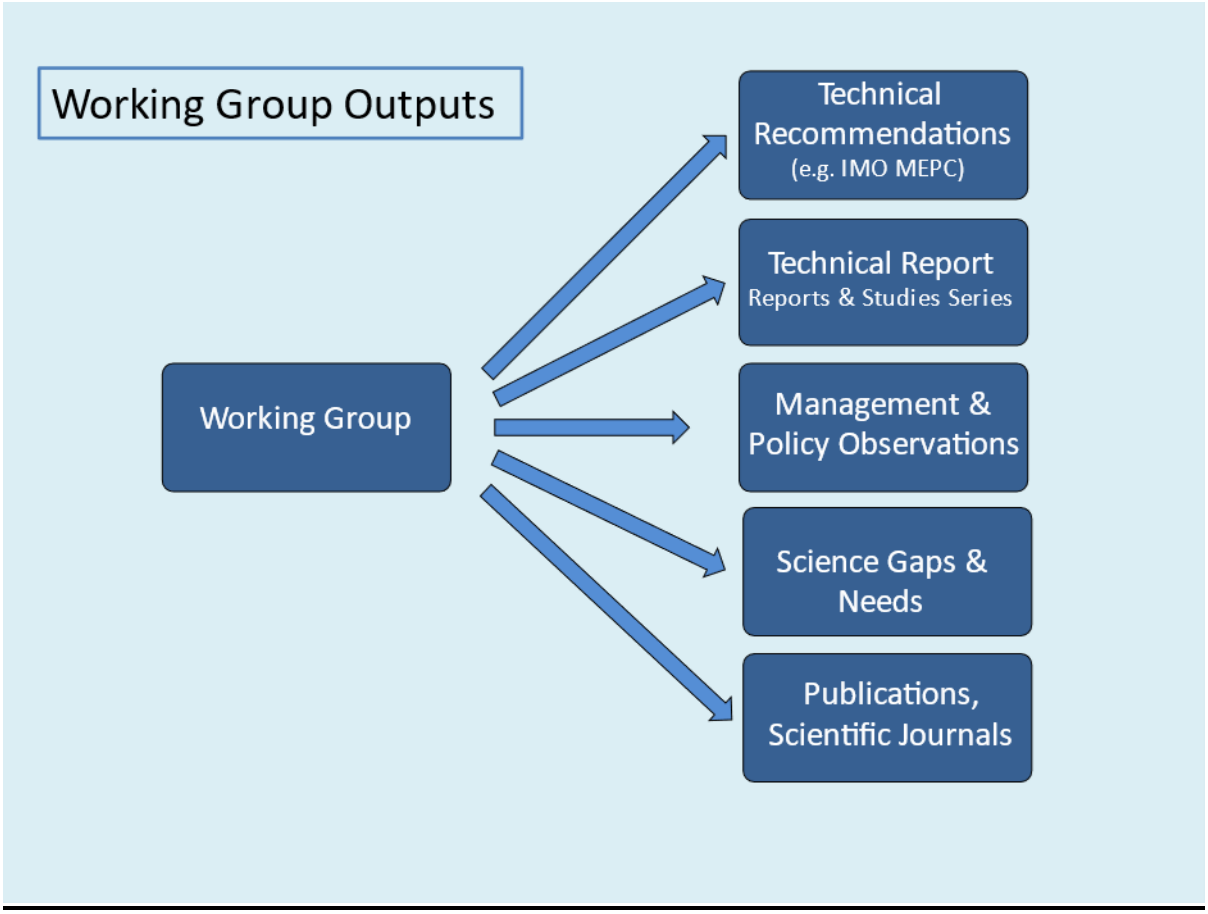
**WG 43** – Sea-based sources of marine litter including fishing gear and other shipping-related litter – FAO, IMO, UNEP

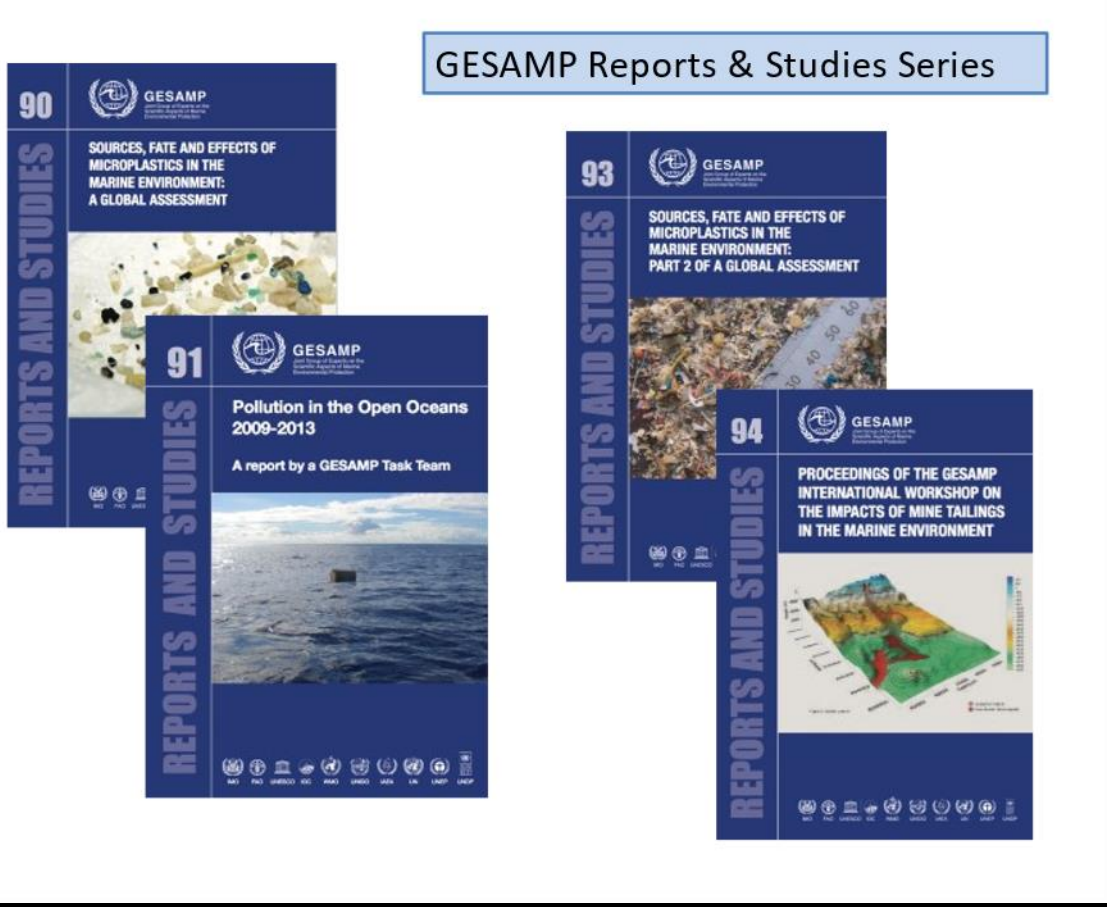
**WG 44** – Biofouling Management – IOC-UNESCO, IMO, UNDP

**WG45** – Climate change and greenhouse gas related impacts on contaminants in the ocean – IAEA, IOC-UNESCO, WMO, IMO






Working Group Outputs
Working Group
Technical Recommendations
(e.g. IMO MEPC)
Technical Report
Reports & Studies Series
Management & Policy Observations
Science Gaps & Needs
Publications, Scientific Journals


GESAMP Reports & Studies Series
90
GESAMP
SOURCES, FATE AND EFFECTS OF MICROPLASTICS IN THE MARINE ENVIRONMENT: A GLOBAL ASSESSMENT
REPORTS AND STUDIES
91
GESAMP
Pollution in the Open Oceans 2009-2013
A report by a GESAMP Task Team
REPORTS AND STUDIES
93
GESAMP
SOURCES, FATE AND EFFECTS OF MICROPLASTICS IN THE MARINE ENVIRONMENT: PART 2 OF A GLOBAL ASSESSMENT
REPORTS AND STUDIES
94
GESAMP
PROCEEDINGS OF THE GESAMP INTERNATIONAL WORKSHOP ON THE IMPACTS OF MINE TAILINGS IN THE MARINE ENVIRONMENT
REPORTS AND STUDIES

## GESAMP Correspondence Groups

Correspondence Groups are established to review a particular situation or concern and advise ExCom if they see a need for further action

- Relevance of inputs of disinfection byproducts into the marine environment
- The causes and impacts of massive outbreaks of Sargassum seaweed in the Caribbean and West Africa
- Sand and gravel mining in the marine environment – new insights on a growing environmental problem
- Updating the information on sources and levels of the main pollutants impacting the global marine environment
- Impact of armed conflicts on the marine environment and sustainable development
- Decade of Ocean Science for Sustainable Development





## GESAMP Task Teams

These are established at the request of the Sponsoring Organisations

- To carry out specific tasks that do not require the establishment of a long term Working Group, or
- If a significant event related to marine environmental protection requires the prompt attention of GESAMP.

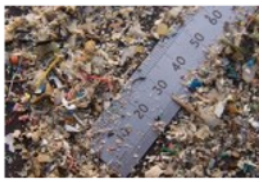
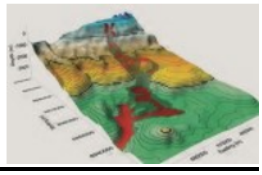
With the support of the Sponsoring Organisation(s), the Chair of GESAMP may establish a Task Team to investigate such an issues and prepare a draft GESAMP statement

One of the more recent examples would be the Task Team on Open Ocean Pollution which was set up to support the Group of Experts that prepared the UN Regular Process

Another would be the Task Team for the review of Exhaust Gas Cleaning Systems for Ships which advises the Marine Environmental Protection Committee of IMO

More recently, GESAMP agreed to establish a Task Team for the Decade of Ocean Science to act as an interface between the various GESAMP Working Groups and the 'Decade' Coordination Body (IOC-UNESCO)



## GESAMP Functional Timetable - Sessional

Annual Session of GESAMP

Hosted by one of the UN Sponsoring Organisations

Members and Executive Committee meet separately first and then together

Agenda Items broadly include:

- Annual Reports from Chair and Administrative Secretary
- Status of Funding, Support Arrangements and Membership
- Planning of GESAMP Activities (Progress of WGs)
- Contributions to other UN Processes (Regular Process, SDGs, Decade)
- Identification of New and Emerging Issues and Proposed Actions
- Scoping Activities (Correspondence Groups and Task Teams)
- Future Work Programme

## GESAMP Functional Timetable - Intersessional

Executive Committee Intersessionals
Usually once a year between Annual Sessions
Primarily to follow up on Matters Arising from the Annual Session

Member's Intersessionals
As required – so far twice a year between Annual Sessions
Follow up on Matters Arising
Ongoing Activities
Emerging Issues
Specific Topics as selected by the Members

Working Group Meetings
As required

Also
GESAMP attendance/input to scientific gatherings, particularly where they relate to Working Groups (e.g. WG 38 on Atmospheric Input of Chemicals and SCOR)
GESAMP representation to UN Sponsoring Organisations and other bodies

## External Independent Review of GESAMP's Work

An Independent Review of GESAMP undertaken in 2005 noted that GESAMP provides an approach to ocean sustainability by the UN agencies that is:

- Cross-sectoral and interdisciplinary
- Based on scientific understanding of marine ecosystems and human activities that affect them
- Avoids duplication within the agencies while identifying areas of common interest

The Independent Review further noted that:

'GESAMP has been praised for its rigorous scientific assessments and reporting and is held in considerable esteem by the scientific community'

# Scoping Activities

During its Annual and Intersessional meetings, GESAMP Members consider and discuss issues of growing concern and newly emerging issues.

These are then brought to the attention of the Sponsoring Organisations for them to propose further action as necessary.

If the SOs feel that the concern needs action they will request a Scoping Paper from the Members

Some Examples of Recent Arising Concerns

- Light & Noise Pollution (e.g. from coastal development, offshore renewables, shipping, deep sea mining)– considered to have major impact on migratory species
- Impacts from New Energy Sources (e.g. Bulk transport of Hydrogen & Ammonia plus their proposed use as a maritime fuel)
- Impacts from Armed Conflict on Ocean and Coasts

N.B All of these issues have implications relating to socioeconomics and marine law which are also addressed by GESAMP

# Ballast Water Working Group - Progress

Since it's establishmentin November 2005, the BWWG has:

Held 41 meetings

9 Stock-taking workshops

Recommended basic approval to 61 and final approval to 52 ballast water management systems, Recommended 5 (?) extensionsfor freshwater.

As of 2019, 23 experts had served on the WG

4 Technical Secretaries

7 BWWG consultants

Four GESAMP Chairs

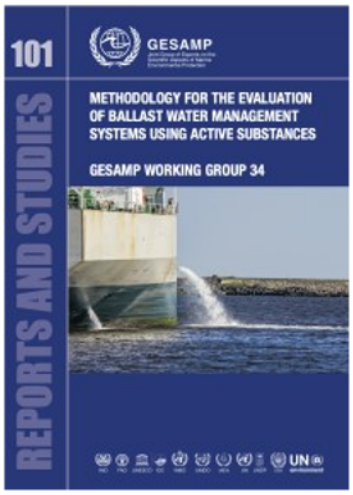
Three IMO Secretary-Generals

.... But only three WG Chairs in 17 years!

## Role and Significance of WG 34

- The importance of this WG for the regulatory work of IMO cannot be stressed enough, as it directly supports the implementation of the Ballast Water Management Convention
- It was also an instrumental part of the work leading up to the Convention's entry into force in September 2017, by building trust in the BWM systems and their approval process both from the perspective of manufacturers and Administrations, but also the wider community (scientific)
- GESAMP Reports & Studies No.101 published in 2019 provides an excellent account of the methodology used by the WG

**So, a HUGE 'Thank You' to the Chair and Members of this vitally important GESAMP Working Group 34!!!**



# More on GESAMP

GESAMP would be more than pleased to discuss its work with interested parties

And GESAMP would be happy to demonstrate how it might offer assistance and advise, through the Sponsoring Organisations, in relation to any areas of Marine Environmental Protection

http://www.gesamp.org/

Thank You for Your Interest

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**ANNEX 5**

**Report of GESAMP-BWWG to MEPC 78 on STW 9**

INTERNATIONAL MARITIME ORGANIZATION

***E***

MARINE ENVIRONMENT PROTECTION COMMITTEE
78th session
Agenda item 4

MEPC 78/4/2
4 March 2022
Original: ENGLISH
Pre-session public release: ☒

**HARMFUL AQUATIC ORGANISMS IN BALLAST WATER**

**Ninth Stocktaking Workshop on the activity of the GESAMP-Ballast Water Working Group**

**Note by the Secretariat**


**SUMMARY**

| | |
|---|---|
| *Executive summary:* | This document provides a summary of the outcome of the Ninth Stocktaking Workshop on the activity of the GESAMP-Ballast Water Working Group[1] |
| *Strategic direction, if applicable:* | 2 |
| *Output:* | 2.2 |
| *Action to be taken:* | Paragraph 41 |
| *Related documents:* | MEPC 77/18, MEPC 77/4/4, MEPC 75/18 and BWM.2/Circ.13Rev.4 |


## INTRODUCTION

1 In considering the report of the forty-first meeting of the GESAMP-Ballast Water Working Group (the Group), the Marine Environment Protection Committee, at its seventy-seventh session, noted the recommendation of the Group contained in document MEPC 77/4/4 (Secretariat) to hold a ninth Stocktaking Workshop )STW 9) and endorsed the proposal of the Group.

2 The Ninth Stocktaking Workshop on the activity of the GESAMP-BWWG was held virtually from 24 to 28 January 2022 under the chairmanship of Mr. Jan Linders. Prof. David

1 Following a decision of MEPC 58, only the main body of the GESAMP-BWWG report is translated in all three working languages with the annexes being submitted in English only.

Vousden, chairman of GESAMP represented the GESAMP and made a presentation providing an update of the activities of GESAMP in recent years. The agenda, as adopted by the Workshop, is set out in annex 1, and a list of participants is set out in annex 2. Abbreviations used by the Group are set out in annex 3. A summary record of the Workshop is provided below.

3 The Workshop was opened by Ms. Megan Jensen, Technical Officer, Marine Environment Division; and Mr. Jan Linders, Chairman of the GESAMP-BWWG.

4 The terms of reference for the Workshop, as noted by MEPC 77, were as follows:

.1 prepare draft guidelines for re-evaluations in cases where modifications have been made, for consideration by the Committee at a future session, as requested by MEPC 75 (MEPC 75/4/18, paragraph 4.7);

.2 evaluate the Group's position on total residual oxidant (TRO) sensors, including required properties of amperometric TRO sensors used in BWMS; and

.3 recommend test organisms for laboratory ecotoxicity testing and whole effluent toxicity (WET) test.

## DRAFT GUIDELINES FOR RE-EVALUATIONS IN CASES WHERE MODIFICATIONS HAVE BEEN MADE

### Introduction

5 At its thirty ninth session, the GESAMP-BWWG discussed the possibility of ballast water management systems (BWMS) manufacturers carrying out revisions after Final Approval was granted by MEPC and/or after type approval by an Administration. The Group recognized that these revisions could include changes to the original specifications of their equipment and which could potentially introduce or increase risks to the environment, ship safety, and/or human health. The Group further recognized that the general terms of reference for the GESAMP-BWWG did not include re-evaluations in such cases (MEPC 75/4/6, paragraph 3.7 and paragraphs 5.2 and 5.3 of the annexed report).

6 Subsequently, MEPC 75 noted the view of the GESAMP-BWWG that a unified approach was needed to determine when a change to a BWMS after Final Approval or type approval should be considered a significant change in accordance with paragraph 8.4.2 of Procedure (G9), and requested the GESAMP-BWWG to prepare draft guidelines for re-evaluations in cases where modifications had been made, for consideration by the Committee at a future session (MEPC 75/18, paragraph 4.7).

7 The Group noted that, in accordance with Procedure (G9), re-evaluations due to significant changes or modifications to a BWMS making use of Active Substances or Preparations would require a new application for Final Approval to be submitted to MEPC and to be evaluated by the GESAMP-BWWG.

### Modifications considered

8 The Group limited its discussions to modifications to a BWMS that might affect the risks to the environment, human health and safety of the ship. Consequently, the workshop considered only modifications that could lead to:

.1 changing the composition and concentration of disinfectant by-products (DBP);

.2 changing any exposure of the crew to chemicals stored and handled on board;

.3 compromising ensuring the Maximum Allowable Discharge Concentration (MADC) at all times; or

.4 changing risks for ship safety.

9 In considering the environmental risks, modifications in the BWMS may cause an increase in the formation of DBP and, therefore, in the discharge concentrations to the environment at de-ballasting. The exposure concentrations to environmental aquatic organisms may change and thus the ration of predicted environmental concentration to predicted no-effect concentrations (PEC/PNEC-ratios) may change as well.

10 With respect to human health, increasing concentrations of DBP may also result in increased risk assessment ratios for several activities of the crew (e.g. delivery, loading, mixing or adding chemicals to the BWMS, ballast water sampling, ballast tank inspections, and normal work on deck) and for the general public, (e.g. swimming and consumption of contaminated seafood.

11 An important starting point of the evaluation of the GESAMP-BWWG was that the discharged ballast water meets the MADC at all times. Due to modifications in the BWMS, adjustments may be needed to meet the MADC at all times.

12 The introduction of modifications may lead to an increase of explosive risk due to localized dust formation during handling or hydrogen concentration increase during Active Substance generation. Additionally, an increase in dose of the Active Substance to a level above 10 mg TRO/L as $Cl_2$ may lead to enhanced corrosion effects on the ship's structure and fittings.

13 The workshop decided that if potential modifications in the BWMS would lead to effects that could impact the evaluation according to Procedure (G9) a re-evaluation by GESAMP-BWWG would be appropriate. These modifications may occur in the three areas mentioned in the terms of reference of the GESAMP-BWWG: environment, human health and ship safety.

14 The Group analyzed the different modification possibilities and identified the potential effects. The results of this analysis is set out in annex 5.

**Conclusions**

15 The Group identified all parameters for which modifications could influence the outcome of the risk assessment for the environment, human health or ship safety, as set out in annex 5. In addition, the Group considered that aspects relating to changes in the Active Substance, the Preparation and the physical state could be considered together. Changes in the Active Substance and/or the Preparation would, in the opinion of the Group, require a new submission for Basic Approval and subsequently Final Approval, whilst for a change of physical state a re-evaluation of a new submission for Final Approval would be sufficient.

16 The Group proposed that a modification of the dose should lead to a new submission for Basic Approval and subsequently Final Approval, because of a potential difference

in DBP formation. An increase of the dose to above 10 mg TRO/L should also lead to a re-evaluation of a new submission for Final Approval in which a corrosion test should be included.

17 Modification to or removal of an existing filtration situation should, in the view of the Group, lead to a new submission for Final Approval evaluation. In the case where a new filter was added, no new submission for Final Approval would be required.

18 With respect to neutralization, the Group was of the opinion that a new application for Final Approval should be required in the case that a neutralizer was chosen different from sodium thiosulfate or sodium bisulfite (including sodium sulfite and sodium metabisulfite). The reason for this was that these compounds act chemically similar and the Group has gained sufficient experience with these neutralizers but not with a potential other neutralizer.

19 The Group wished to stress that paragraph 30 introduced the new opinion of the Group with respect to monitoring of TRO. The matter is dealt with in more detail in the paragraphs 25 to 32. The Group agreed to recognize amperometric TRO sensors as practical alternatives to DPD colorimetric sensors for use in the on-line monitoring of TRO in any future BWMS applications. Regarding changes made to a BWMS after Final Approval, the Group concluded that changing the TRO sensor to a type other than colorimetry or amperometry would require a new submission for Final Approval.

20 The Group concluded further that, in case the human interference in the handling of the chemicals onboard was changed from automated to manual and where no countermeasures were applied, a re-evaluation of a new submission for Final Approval would be required.

21 The Group developed a decision tree for ease of reference that depicts the proposals referred to in paragraphs 15 to 20, as set out in figure 1 of annex 4.

22 Although in the course of its work, the Group had evaluated several BWMS where modifications to applications were made between the submission of an application for Basic Approval and the submission of an application for Final Approval, the Group recalled that these modifications were accompanied by, in the opinion of the Group, an adequate justification based on scientific evidence. The Group recommended that any change should be accompanied with a scientific reasoning.

23 The Group recognized that a full application for Final Approval would not be required in all cases for a re-evaluation set out in the paragraphs above. Table 1 details the elements of an application that should be included in an new submission for Final Approval, based on the type of significant modifications made to a BWMS.

**Table 1. Required elements for new submission for re-evaluation for Final Approval after a significant modification**

| Significant changes to: | Re-evaluation after a significant modification to the BWMS | | | | |
|---|---|---|---|---|---|
| | Partial FA submission[1] | | | | Full FA submission |
| | Chemical identification | Environmental assessment | Human health assessment | Ship safety (including OMSM) | |
| Physical state | No | No | Yes | Yes[2] | N/A |
| Filtration[3] | N/A | N/A | N/A | N/A | Yes |

| | | | | | |
|---|---|---|---|---|---|
| Neutralizer | Yes | Yes[4] | Yes | Yes[2] | Yes[5] |
| TRO monitoring | No | No | No | Yes[2] | N/A |
| Human interference | No | No | Yes | Yes[2] | N/A |

1 For chemical identification, only samples from full-scale tests should be used, regardless of living organisms, only at day 5, with and without neutralization for three salinity ranges during the treatment.
2 All modifications proposed would require an updated OMSM.
3 Filter removal or modification of existing filtration system.
4 PEC/PNEC only.
5 If other than colorimetric or amperometric sensors.

24 Based on the considerations outlined above, the Workshop developed the draft Guidelines for re-evaluations for Final Approval in cases where modifications had been made to a BWMS, in the form of a new chapter 12 to be inserted into the *Methodology for information gathering and conduct of work of the GESAMP-BWWG* (the Methodology, BWM.2/Circ.13, as revised), as set out in annex 4.

**THE GROUP'S POSITION ON TRO SENSORS USED IN BWMS**

25 During the STW, the Group considered documents and information presented by Norway regarding TRO sensor methodology. The Group recognized the advances that had been made in on-line amperometric sensing and measuring technology for use in BWMS. These advances include the positioning of the sensor directly into the ballast line and the use of a bare electrode sensor instead of a membrane-based instrument as used in conventional amperometric measurement methods.

26 However, the Group noted that the data and information presented during the STW were limited to measurements of TRO in simulated ballast water only during a land-based test, and data showing the justification measurement of TRO by amperometric sensors in variable natural waters and during actual ballast water treatment had not been reviewed by the Group. The Group reviewed data on shipboard tests with amperometric sensors but the Group considered that a significant overdose of neutralizer was used and therefore this data was not considered to be fully representative.

27 To this end, the Group encouraged rigorous scientific studies based on reliable methods of TRO measuring in natural waters. These studies could compare different methods of on-line TRO measurement in variable natural waters to increase the body of knowledge on the subject and increase confidence in existing and newly developed TRO sensors. The Group would value an extension of the method currently under development by ISO to include natural waters.

28 The Group also recognized that in a recent evaluation of a BWMS by the Group, and after thorough review of the information submitted by the applicant, the Group agreed to recommend Final Approval using the amperometric method proposed by the applicant.

29 The Group noted that, when advanced amperometric sensors were employed in a BWMS TRO control system, there may be a specific need for the application of an additional overdose of neutralizer to compensate for any system design limits such as potential sensor divergence at lower detection levels during the discharge process (paragraphs 4.1.4 and 4.1.5 of the Methodology (BWM.2/Circ.13/Rev.4)).

30 Subsequently, it was agreed by the Group that it would recognize amperometric TRO sensors as practical alternatives to DPD colorimetric sensors for use in the on-line mon-

itoring of TRO in any future BWMS applications. It should be noted that this is always subject to any application employing either technology, categorically demonstrating that the method used was part of a control system which reliably monitored and regulated the TRO dose during the uptake of ballast water and also controlled the neutralizer dose at discharge to maintain the MADC at all times.

31 The Group also noted that a DPD or amperometric TRO measurement sensor in a BWMS may be changed from one to another (such as DPD to amperometric or vice versa). When such a change of measurement method occurs after Final Approval, the Group noted that both the compatibility with and reliability of any resultant change to the BWMS TRO control system should be verified on a case-by-case basis by the type-approving Administration.

32 The Group recommended that, when amperometric sensors were employed in a BWMS, there should be a manual DPD meter provided for the periodical verification of the effective operation of such sensors to control the appropriate TRO concentrations.

**RECOMMENDED TEST ORGANISMS FOR LABORATORY ECOTOXICITY TESTING AND WET TESTS**

33 At its fifth Stocktaking Workshop (MEPC 66/2/6) the Group had discussed the need for additional tests that would take into consideration the fact that some disinfection by-products have carcinogenic, mutagenic or toxic for reproduction (CMR) properties. The Workshop further discussed the need for higher tier and CMR properties testing and noted that some internationally recognized methods were available to achieve this. The Workshop, however, concluded that for further consideration, more information and scientific justification were needed before any changes to the Methodology were to be suggested, and also that a revision of Procedure (G9) would be necessary in that regard.

34 At its sixth Stocktaking Workshop (MEPC 68/2/8) the Group further discussed the need for additional tests that would address mixture toxicity. To this end, the Workshop had discussed that WET testing using in vitro tests targeted at relevant endpoints, e.g. mutagenicity might be a way to address this matter. The Workshop however, had considered that no established test procedures were available for performing in vitro genotoxicity tests in saline waters. The Workshop agreed to invite a representative of the company developing the test system “Mutatox” to the next Stocktaking workshop to further explore the issue. The Workshop also reiterated its standpoint from STW5 that the inclusion of any additional tests would require the revision of Procedure (G9).

35 The agenda item of additional tests (WET testing using in vitro tests targeted at relevant endpoints) was part of the report of Stocktaking workshop 7 under the headline “Future activities”.

36 At its eighth Stocktaking Workshop, the agenda point on “supplementary tests with ballast water” appeared, however, due to time constraints the Workshop did not consider it. However, the agenda item was retained for future workshops.

37 During this STW, the Group discussed the introduction of bacteria as the addition of a new test organism. Bacteria are widely used as test organisms for the evaluation of genotoxicity and ecotoxicity on toxic substances for administrative management and scientific research, e.g. wastewater management.

38 The Group noted that there are limited test protocols for genotoxicity tests with bacteria in the environment. The Group also recognized that the genotoxicity test basically used

for screening purposes, and, therefore it is not appropriate to use in Procedure (G9) evaluations.

39 The Group recognized the protocol of ecotoxicity test with Bacteria, *Vibrio fischeri* (also, *Aliivibrio fischeri*) is well established (ISO, 2007). The Group also recognized that the bioluminescent inhibition test with *Vibrio* produce a quantified ecotoxicity end-point. However, the Group also noted that the references to evaluate toxicity of this test in connection with other toxicity tests with algae, crustaceans and fish for discharge water are limited at the present time. Therefore, the Group agreed that the addition of bacteria for ecotoxicity evaluation would be postponed until the available references are available.

40 The Workshop investigated the possibility to suggest a test with *Vibrio fischeri* as a possible additional test to further address mixture toxicity. The Workshop, however, concluded that there was not enough scientific support to suggest any addition of a test using bacteria to the Methodology.

**Action requested of the Committee**

41 The Committee is invited to note the outcome of the ninth Stocktaking Workshop of the GESAMP-BWWG and in particular to:

.1 consider the proposed guidelines for re-evaluations in cases where modifications had been made to a BWMS, as set out in annex 4, including a decision tree, as a potential addition to the *Methodology for information gathering and conduct of work of the GESAMP-Ballast Water Working Group* (paragraph 24);

.2 endorse the Group's encouragement of rigorous scientific studies based on reliable methods of TRO measurement in variable natural waters (paragraph 27);

.3 note the Group's conclusion that it would recognize amperometric TRO sensors as practical alternatives to DPD colorimetric sensors for use in the on-line monitoring of TRO in any future BWMS applications, provided the method used was part of a control system which reliably monitors and regulates the TRO dose during the uptake of ballast water and also controlled the neutralizer dose at discharge to maintain the MADC at all times (paragraph 30);

.5 endorse the Group’s recommendation that when amperometric sensors are employed in a BWMS, there should be a manual DPD meter provided for the periodic verification of the effective operation of such sensors to control the appropriate TRO concentrations (paragraph 32); and

.6 note the Group’s conclusion that bacteria should not be introduced as a new test organism at thid time (paragraph 38 to 40).

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**ANNEX 1 to ANNEX 5**

**AGENDA**

**NINTH STOCKTAKING WORKSHOP ON THE ACTIVITY OF THE GESAMP-BALLAST WATER WORKING GROUP**

**to be held remotely
from 24 to 28 January 2022**

**(Session commences at 11 a.m. on Monday, 24 January 2022)**

1 Adoption of the agenda

2 Introduction and ways of working during the Workshop, housekeeping, timetable and GESAMP presentation

3 Draft guidelines for re-evaluations in cases where modifications have been made, as requested by MEPC 75

4 Evaluation of the Group's position on TRO sensors

5 Recommended test organisms for laboratory ecotoxicity testing and WET tests

6 Any other business

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**ANNEX 2 to ANNEX 5**

**LIST OF PARTICIPANTS**

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**ANNEX 3 to Annex 5**

## ABBREVIATIONS AND ACRONYMS

| Abbreviation / Acronym | Meaning |
|---|---|
| AS | Active Substance |
| BA | Basic Approval |
| BWMS | Ballast water management system |
| BWRG | Ballast Water Review Group |
| CMR | Carcinogenicity, mutagenicity and reproduction toxicity |
| DBP | Disinfection by-products |
| DPD | N,N-diethyl-p-phenylenediamine |
| FA | Final Approval |
| GESAMP | United Nations' Group of Experts on the Scientific Aspects of Marine Protection |
| ISO | International Organization for Standardization |
| MADC | Maximum allowable discharge concentration |
| MEPC | Marine Environment Protection Committee |
| OMSM | Operational Management and Safety Manual |
| PEC | Predicted environmental concentration |
| PNEC | Predicted no-effect concentration |
| QA/QC | Quality assurance / quality control |
| STW | Stocktaking Workshop |
| TRO | Total Residual Oxidant |
| WET | Whole effluent toxicity |

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**ANNEX 4 to Annex 5**

**DRAFT GUIDELINES FOR RE-EVALUATIONS IN CASES WHERE MODIFICATIONS HAVE BEEN MADE TO A BWMS**

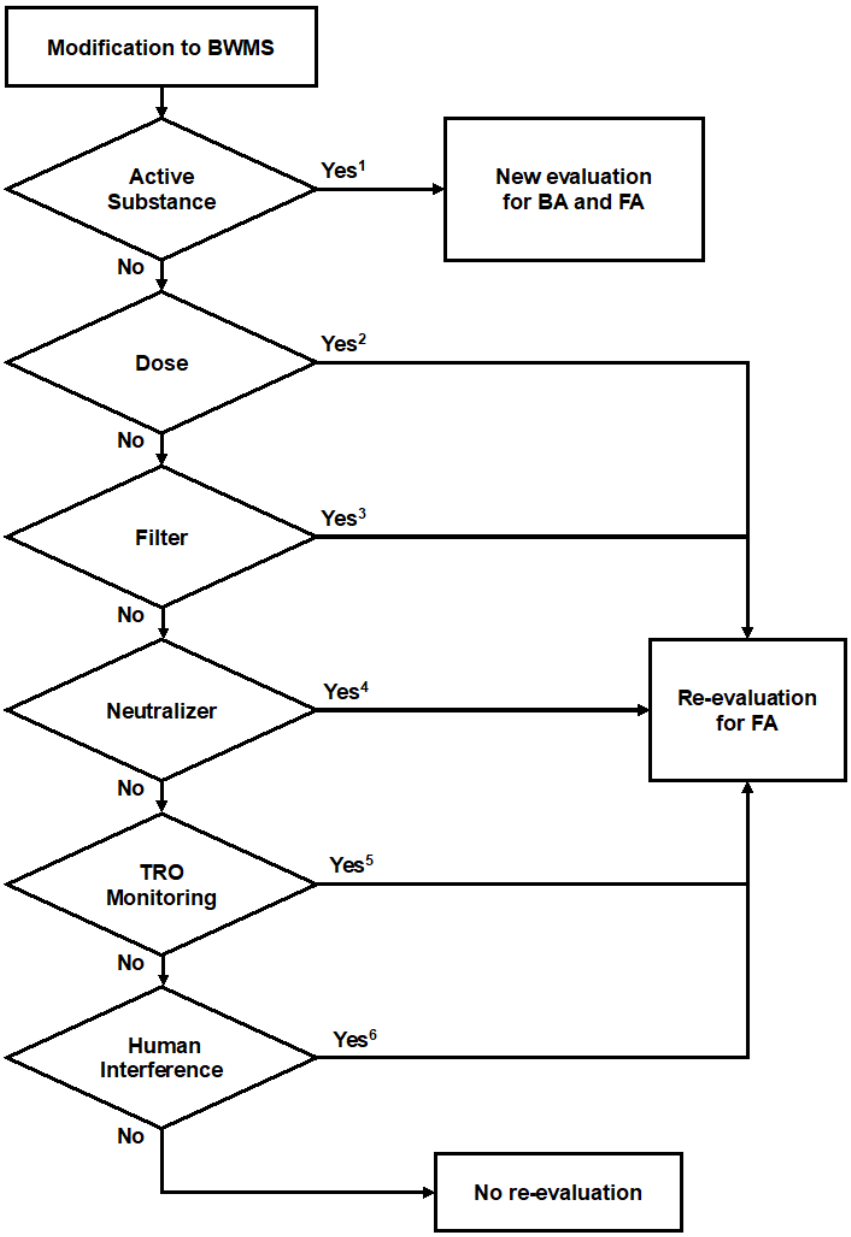
The following new chapter is inserted after chapter 11 of the *Methodology for information gathering and conduct of work of the GESAMP-BWWG* (BWM.2/Circ.13, as revised):

"**12 GUIDELINES FOR RE-EVALUATIONS IN CASES WHERE MODIFICATIONS HAVE BEEN MADE TO A BWMS**

**Determining if re-evaluation after a modification is required**

12.1 The GESAMP-BWWG identified all parameters for which modifications could influence the outcome of the risk assessment for the environment, human health or ship safety, including changes to the Active Substance, its dose, filtration, neutralization, TRO sensor(s), and human interference, and whether potential changes would require a new application for re-evaluation for Final Approval only, both Basic Approval and subsequently Final Approval, or no re-evaluation. For ease of reference, a decision tree detailing these potential modifications is shown in figure 1.

12.2 For additional details regarding potential modifications and new applications for re-approval, please see the report of the GESAMP-BWWG's Ninth Stocktaking Workshop (MEPC 78/4/2, paragraphs 15 to 20 and annex 5).




1 Except physical state – in that case re-evaluation for Final Approval only is sufficient
2 If increase of dose
3 If removal or modification of existing filter system
4 If other neutralizer than sodium thiosulfate or sodium bisulfite (including sodium sulfite and sodium metabisulfite)
5 If other monitoring method than colorimetric or amperometric sensors
6 If automated to manual or where no countermeasures were applied

**Figure 1: Proposed decision tree for re-evaluations in cases where modifications have been made to a BWMS**

## Criteria for evaluation

12.3 Modifications to ballast water management systems (BWMS) after Final Approval has been granted may affect the risk assessments of GESAMP-BWWG for the environment, human health and ship safety. However, the Group considered that modifications may not affect risk assessment of all the items involved. Therefore, a subset of required elements as indicated in the table below clarify what new data should be included in the submission for a re-evaluation for Final Approval following a significant modification.

**Table 1. Required elements for a submission for re-evaluation for Final Approval after a significant modification**

| Significant changes to: | Re-evaluation after a significant modification to the BWMS | | | | |
|---|---|---|---|---|---|
| | Partial FA submission[1] | | | | Full FA submission |
| | Chemical identification | Environmental assessment | Human health assessment | Ship safety (including OMSM) | |
| Physical state | No | No | Yes | Yes[2] | N/A |
| Filtration[3] | N/A | N/A | N/A | N/A | Yes |
| Neutralizer | Yes | Yes[4] | Yes | Yes[2] | N/A |
| TRO monitoring | No | No | No | Yes[2] | Yes[5] |
| Human interference | No | No | Yes | Yes[2] | N/A |

1 For chemical identification, only samples from full-scale tests should be used, without living organisms, only at day 5, with and without neutralization for three salinity ranges during the treatment.
2 All modifications proposed would require an updated OMSM.
3 Filter removal or modification of existing filtration system.
4 PEC/PNEC only.
5 If other than colorimetric or amperometric sensors.

12.4 All changes proposed by the applicant should be accompanied by a scientific reasoning as to why the change was considered necessary.

12.5 All tests listed in table 1 should be carried out with the relevant QA/QC as was required at the original Final Approval, including the evaluation of the quality criteria for each test. If these quality criteria are breached in the study results, the test reports will not be acceptable for the GESAMP-BWWG.

12.6 Upon determination by the Administration that a new submission for FA is required, the manufacturer should prepare a new submission for re-evaluation after a modification and submit it to the Member of the Organization concerned.

12.7 Upon receipt of a submission, the concerned Administration should conduct a careful completeness check to ensure that the submission satisfies the relevant provisions contained in Procedure (G9), as specified in paragraphs 12.1 and 12,2 and that it is presented in the format recommended in the Methodology. Administrations should check the quality and completeness of any submission against the latest version of the Methodology, regardless of the version that had been used for the Basic and Final Approval of the BWMS.

12.8 When the Administration is satisfied with the application received, it should submit a proposal for approval to the Organization in accordance with the procedure in paragraphs 2.3.5 to 2.3.18. For such applications, a non-refundable registration fee should be paid in accordance with paragraph 2.3.7, immediately following receipt of the Letter of Agreement by the Organization.

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## ANNEX 5 to ANNEX 5

## DETAILED CONSIDERATIONS OF THE GESAMP-BWWG REGARDING MODIFICATIONS TO A BWMS AFTER FINAL APPROVAL

### Documents considered

1 The Group took into account the following documents and evaluated them for their relevance to developing draft Guidelines in cases where modifications have been made to a BWMS:

.1 Procedure (G9) (MEPC: The Group considered the formulation in Procedure (G9) not precise enough concerning the identification of the significant modifications to be considered. The intention of the Group's discussion was to clearly define what constitutes a significant change and to identify criteria eliciting the levels of changes, e.g. major vs minor changes. A decision tree was proposed covering the potential changes leading to whether the change would trigger a completely new submission of a BWMS application (Basic Approval and Final Approval), require a new submission for a re-evaluation for Final Approval, or not require further evaluation by the Group;

.2 The GESAMP-BWWG Methodology, chapter 11 (BWM.2/Circ.13/Rev.4):
The freshwater procedure set out in chapter 11 of the Methodology was considered useful as a basis upon which to base the draft Guidelines.

.3 Report of MEPC 75 (MEPC 75/18, paragraph 4.7): The report of MEPC 75 clearly referred to changes in the BWMS after Final Approval or type approval with the request to define what should be considered a significant change in the BWMS where modifications had been made. To the opinion of the Group the emphasis was on the term ‘unified approach’.

.4 Comments by Norway in relation to terms of reference for the Ballast Water Review Group established by MEPC 77 (MEPC 77/1/1/Add.1, paragraph 8). These comments were not relevant to this Stocktaking Workshop, as they referred to cases where MEPC may request the GESAMP-BWWG to give further consideration to a BWMS application in which no new submission for Final Approval was required, as was agreed by MEPC 75 (referred to as a re-evaluation in document MEPC 77/16). This is in contrast to the re-evaluations discussed by the GESAMP-BWWG STW 9 in which a new evaluation for Final Approval might be required after significant modifications to a BWMS have been made.

### Modifications and potential effects

2 The Group took into account the following possibilities and potential effects and evaluated them for their relevance in cases where modifications have been made to a BWMS:

.1 Chemical identity of the Active Substance: The chemical identity of the Active Substance used in a BWMS is the defining characteristic as well as the starting point for any evaluation and risk assessment according to Procedure (G9) and the Methodology, respectively. Therefore, a modification of the chemical identity of the Active Substance itself would require a submission of new applications for both Basic Approval and subsequently Final Approval.

.2 Chemical identity or composition of a Preparation: In many cases, the Active Substance is generated on board a ship from a preparation or physical treatment of a suitable water source (*e.g.* electrolysis) or ambient air (*e.g.* ozone generation). If the method of generation of the Active Substance / Preparation is changed, this may have an impact on factors relevant for risk assessment:

.1 a modification from seawater electrolysis to a chemical precursor of the Active Substance introduces potential new risks from the storage and handling of the precursor chemicals on board;

.2 the reverse modification from a chemical precursor to seawater electrolysis introduces potential new risks from the formation of hydrogen; and

.3 a modification from one chemical precursor to another e.g. from sodium hypochlorite to sodium dichloroisocyanurate is associated with a change in the list of chemicals considered during risk assessment, which may have an impact on the outcome of the risk assessment.

The Group concluded that this type of modifications would require the same consequence as for a change in Active Substance, and thus the submission of new applications for both Basic Approval and subsequently Final Approval.

.3 Physical state of the Active Substance or Preparation: The Active Substance or Preparation can be applied as a solid in different forms (powder, granulate etc.) or as a solution of a certain concentration in water. Modifications of the physical state of the Active Substance / Preparation may have an impact on the risk assessment for the crew and for ship safety:

.1 powders can form dust that is associated with specific risks for inhalation toxicity and/or explosion risks;

.2 storage facilities and mixing procedures will be different for solid preparations as compared to solutions; and

.3 an increase in the concentration of a solution may lead to increased risks for the crew during handling and storage or for ship safety in terms of corrosion.

In this case the Group considered a re-evaluation of a new submission for Final Approval was considered necessary.

.4 Increase in dose of Active Substance:

.1 DBPs: The Group was of the opinion that an increase of dose would require the submission of new applications for both Basic Approval and subsequently Final Approval, as an increase of the formation of DBPs could be expected and that would affect the results of the risk assessment for the environment and human health.

.2 Corrosion: If the dose is increased from a value below 10 mg TRO/L to a value greater than or equal to 10 mg TRO/L, a

corrosion test will be required. If the dose is increased from a value greater than or equal to 10 mg TRO/L to an even higher value, this may also have an additional impact on corrosion. The existing corrosion test may no longer be valid and, therefore, a new submission for Final Approval would be required.

.5 Filtration: With respect to the filter of an existing BWMS, the Group was of the opinion that in cases of filter removal or modification of the existing filter situation, a re-evaluation of a new application for Final Approval would be required. In the case where a new filter was added, no new submission for Final Approval would be required.

.1 Removal: If the filtration unit is removed from a BWMS after approval, a substantially larger amount of organic and inorganic matter will pass through the BWMS into the downstream installations, including the ballast water tanks. The following consequences can be expected:

.1 potential increased formation of DBPs, especially due to increased nitrogen contents in the non-filtered water, which can be expected to have an impact on human health and environmental risk assessment; and

.2 increased sedimentation inside the ballast tanks, and possibly also increased obstruction of pipes for sampling / monitoring, resulting in a higher frequency of cleaning and maintenance procedures. This would also result in increased human contact with potentially toxic residues. However, as the current risk assessment relies on fixed scenarios for procedures such as ballast tank cleaning without taking into account any system-specific parameters, it would be difficult to take such changes into account.

.2 Modification: If a filtration system is modified, this would be considered a substantial modification as factors such as mesh pore size and filtration velocity may affect the ability of an existing electrolyser unit to produce and maintain the required concentrations of Active Substance.

.6 Neutralization: Neutralizers are regarded as “other chemicals” and as such must be considered in the risk assessment for human health and the environment. The most commonly used neutralizers are sodium thiosulfate or sodium bisulfite (including sodium sulfite and sodium metabisulfite), and the Group has gained sufficient experience in their risk assessment. Any other neutralizers are less well studied and require a new submission for Final Approval with regard to neutralization efficiency and potential toxicity of the neutralizer itself and any residues.

.7 TRO Monitoring: The reliable monitoring and control of the Active Substance being used in a BWMS is an important factor influencing the range of risk assessments carried out by the Group in conjunction with chemical characterization and WET testing of the discharge water. The Group concluded that a new submission for Final Approval would be required for a BWMS that would propose to change its fundamental method of Active Substance determination from those already accepted by the Group (colorimetric or amperometric).

.8 Human interference (automated vs manual operations): Modifications from automatic procedures to manual operations and where no countermeasures were applied, may be associated with the following potential impacts on risk assessment or the safe operation of the BWMS:

.1 An increased potential of human exposure to hazardous chemicals. This is the case, for instance, if the loading and mixing of the Active Substance, preparation or neutralizer is switched from an automated procedure, which is recommended, to a manual one.

.2 An increased potential of inaccuracies or mistakes that may affect the safe operation of the BWMS. This might be the case, for instance, if an automated monitoring procedure is replaced by manual operations. If the result of the monitoring in turn, influences the dosing of the neutralizer, this could have an impact on maintaining MADC at all times.

The Group concluded that in these cases a new submission for Final Approval would be required.