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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*
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.13/Rev.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 chaired by Mr. Jan Linders. Prof. David Vousden, Chair 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 the 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, Chair of the GESAMP-BWWG.

* 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.

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 recommended test organisms for laboratory ecotoxicity testing and whole effluent toxicity (WET) tests.

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 manufacturing system (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 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 disinfection by-products (DBPs);

.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 DBPs and, therefore, in the discharge concentrations to the environment at deballasting. The exposure concentrations to aquatic organisms may change and thus the ratio of predicted environmental concentrations to predicted no-effect concentrations (PEC/PNEC ratios) may change as well.

10 With respect to human health, increasing concentrations of DBPs 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 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 should meet 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 analysed the different modification possibilities and identified the potential effects. The results of this analysis are 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, while 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. However, 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 would be required in the case that a neutralizer was chosen other than sodium thiosulfate or sodium bisulfite (including sodium sulfite and sodium metabisulfite). The reason for this was that these compounds act in a chemically similar way and the Group has gained sufficient experience with these neutralizers but not with other potential neutralizers.

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 paragraphs 25 to 32. The Group agreed to recognize amperometric TRO sensors as practical alternatives to DPD colorimetric sensors for use in the online 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 on board 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 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 a 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

	Re-evaluation after a significant modification to the BWMS				
	Partial FA submission[1]				**Full FA submission**
Significant changes to:	**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 provided by Norway regarding TRO sensor methodology. The Group recognized the advances that had been made in online 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 online 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 (ISO standard DIS 23780-1) 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 are 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 online monitoring of TRO in 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 are 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 DBPs have carcinogenic, mutagenic or toxic for reproduction (CMR) properties. The Workshop had 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, had 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 had 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 had 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 had also reiterated its standpoint from STW 5 that the inclusion of any additional tests would require the revision of Procedure (G9).

35 The agenda item on 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 item on "supplementary tests with ballast water" appeared, however, due to time constraints the Workshop had not considered 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 is 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 tests with bacteria *Vibrio fischeri* (also, *Aliivibrio fischeri*) is well established (ISO, 2007). The Group also recognized that the bioluminescent inhibition test with *Vibrio* produces 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 relevant references are available.

40 The Workshop investigated the possibility of suggesting 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 basis 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 online monitoring of TRO in future BWMS applications, provided the method used is part of a control system which reliably monitors and regulates the TRO dose during the uptake of ballast water and also controls the neutralizer dose at discharge to maintain the MADC at all times (paragraph 30);

.4 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

.5 note the Group's conclusion that bacteria should not be introduced as a new test organism at this time (paragraphs 38 to 40).

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ANNEX 1

AGENDA

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

held remotely
from 24 to 28 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

LIST OF PARTICIPANTS

GESAMP-BWWG Experts

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ANNEX 3

ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	Meaning
AS	Active Substance
BA	Basic Approval
BWMS	Ballast water management system
CMR	Carcinogenic, mutagenic or toxic for reproduction
DBP	Disinfection by-products
DPD	N,N-diethyl-p-phenylenediamine
FA	Final Approval
GESAMP	Joint Group of Experts on the Scientific Aspects of Marine Environmental 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

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

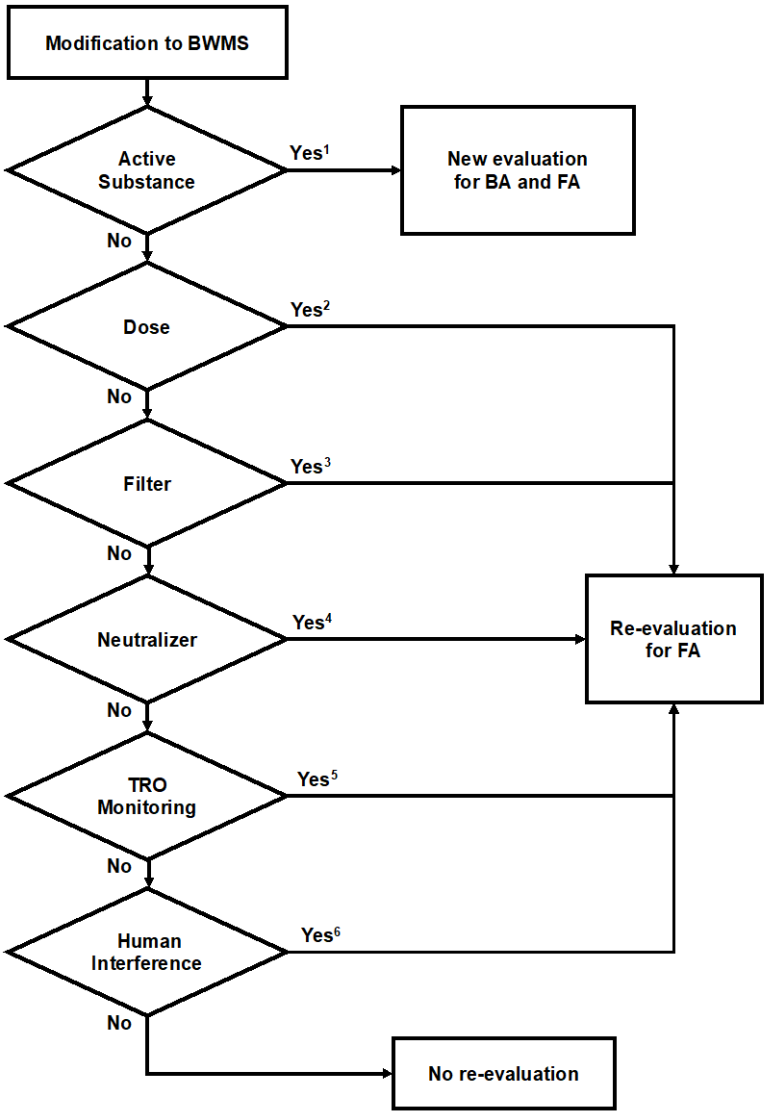
The following new chapter is inserted after chapter 11 of the *Methodology for information gathering and conduct of work of the GESAMP-BWWG* (BWM.2/Circ.13, as revised):

"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 the 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 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 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.

Procedure for submission of an application for re-evaluation after a significant change

12.6 Upon determination by the Administration that a new submission 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 this 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 previous 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

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): The Group considered the formulation in Procedure (G9) to be 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 the draft 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. 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 assessments:

.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 that a re-evaluation of a new submission for Final Approval would be necessary.

.4 Increase in dose of the 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 in 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 the 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 would 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 being able to maintain the MADC at all times.

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