



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

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

Background and introduction

1 The International Convention for the Control and Management of Ships' Ballast Water and Sediments, (hereafter referred to as the BWM Convention) was adopted at IMO on 13 February 2004, in response to the increasing concern of the international community with regard to the transfer of invasive species in ships' ballast water. To date, 26 March 2012, 33 of the required minimum of 30 countries representing 26.46% of the required 35% of the world's tonnage have ratified the BWM Convention. Last year it was anticipated that the conditions for entry into force would be met before the end of 2011. This goal was however not achieved. Although the number of countries' criterion was met, the percentage of world's tonnage is still less than the required 35%. Concern was expressed at MEPC 63 that 8 years after the adoption of the Convention it still had not entered into force.

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

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.

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

'Active Substances'

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 systems using such substances is described in resolution MEPC.169(57) adopted in 2008. However, not only 'Active Substances' are evaluated by the WG 34. Also all other substances considered relevant are taken into account

in the evaluation report. The Procedure for approval of ballast water management systems that make use of Active Substances (G9) contained in resolution MEPC.169(57) under the BWM Convention distinguishes also 'Relevant Chemicals' and 'Other Chemicals'.

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

7 WG 34 convened three times since GESAMP 38 to evaluate proposed BWMS and also held a Stocktaking Workshop (STW) to discuss items related to the Methodology. However, another session of WG34 is scheduled for the week of GESAMP 39 which is not yet included in this report. This meeting will now be included in the next report of WG 34 to GESAMP 40. During these meetings 14 BWMS were discussed and evaluated. Of these BWMS, five received a recommendation for Basic Approval (BA) and seven received a recommendation for Final Approval (FA). One system was denied a recommendation for BA and also one system was denied a recommendation for FA. The system that was denied recommendation for BA could not demonstrate that the system would not have unacceptable effects on the receiving aquatic environment. The working, control and monitoring of the neutralization process could not guarantee a safe and successful operation for the system that was denied FA. During its meeting in July 2011 and in March 2012, MEPC endorsed the pending recommendations of WG 34 in all cases and granted the approvals accordingly. An overview of the systems evaluated in these meetings is presented in Annex 2 to this report.

8 Again it was not possible to clear the stock of pending BWMS applications, as three additional systems were submitted in time to MEPC 63, have yet to be evaluated. This will take place in the meeting of WG 34 in April 2012.

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

9 The evaluation Methodology of WG 34 has been determined to be a living document based on increasing experience in the evaluation of BWMS. During three Stock Taking Workshops WG 34 further developed the Methodology by adding: 1) quantitative methods for the evaluation of human risk assessment including exposure assessment for professionals and the general public; 2) quantitative assessment of the environmental effects by using a specific ballast water model, MAMPEC 3.0 BW; and 3) finalization of the first version of the data base for 17 specific disinfection by-products (DBP) in which the physic-chemical data, the toxicological data and the environmental fate and effect data are included.

10 During MEPC 63, which was held from 27 February to 2 March 2012 at IMO Headquarters, the updated Methodology of WG 34 was reviewed and finally endorsed. The new Methodology will be applied for the BA submissions to MEPC 65 and subsequent submissions for the FA of those systems. Proposals for approval submitted to the Committee prior to MEPC 65 may be evaluated in accordance with the current Methodology. However, proponents are encouraged to use the updated Methodology for all applications prior to MEPC 65. Doing so will facilitate the work of the GESAMP-BWWG. For BWMS already in the pipeline, *i.e.* for Final Approval, the new Methodology may be used but must be used for submissions to MEPC 66.

11 According to the proposal of GESAMP to hold an STW each year, which was endorsed by MEPC 62, WG 34 has scheduled its fourth stock-taking workshop from 14 to 17 August 2012 in Busan (Republic of Korea). The draft annotated agenda is attached to this report (Annex 3). It should be noted that the agenda and its annotations are not yet finalized. GESAMP may recognize that its suggested agenda points are included in the draft agenda.

12 The newly developed tools will be submitted to MEPC and GESAMP.

Planning ahead

13 The reports of the 17th, 18th, 19th, and 20th sessions of WG 34 have already been reviewed by GESAMP before these were forwarded to MEPC 62 (report 17), MEPC 63 (reports 18, 19 and 20). In addition, the report of the 21st meeting (16 to 20 April 2012) will be forwarded to the members of the GESAMP at the earliest opportunity. The next two meetings of WG 34 are planned as follows: GESAMP-BWWG(22) from 7 to 11 May 2012 and GESAMP-BWWG(23) from 25 to 29 June 2012.

Acknowledgement

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

Action requested of GESAMP

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

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 G9* for consideration by MEPC 56.

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 G9);
- .2 scientific evaluation of the assessment report contained in the proposal for approval (see paragraph 4.3.1 of 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 G9);
- .4 scientific evaluation of any further information submitted (see paragraph 8.1.2.6 of G9);
- .5 scientific review of the risk characterization and analysis contained in the proposal for approval (see paragraph 5.3 of 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 G9); and
- .7 preparation of a Report addressing the above-mentioned aspects for consideration by MEPC (see paragraph 8.1.2.10 of 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 MEPC (see paragraph 8.2 of G9).

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

* G9 stands equivalent for MEPC 53/2/1 annex, as amended: Procedure for approval of ballast water management systems that make use of Active Substances (G9).

ANNEX 2

LIST OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES IN ACCORDANCE WITH PROCEDURE (G9) SINCE GESAMP 37

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
1. AquaStar BWMS AQUA Eng. Co., Ltd., Republic of Korea	Filtration by Smart Pipe and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralisation with sodium thiosulfate. This system requires the storage of chemicals on-board.	Final Approval, Not Recommended, May 2011	The dose of TRO was considered not controlled very well nor the discharge of neutralized ballast water was guaranteed to be below the Maximum Allowed Discharge Concentration (MADC). Recommendations to improve the system were given in Annex 4 of the report of GESAMP-BWWG17.
2. HiBallast BWMS Hyundai Heavy Industries Co., Ltd. (HHI), Republic of Korea	Filtration, disinfection with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.	Final Approval, Recommended, May 2011	Flag State Administration was invited to ensure that the recommendations contained in Annex 5 of the report of GESAMP-BWWG17 were verified prior to issuance of a Type Approval Certificate. The recommendations mainly focus on maintaining the dose and the maximum allowable discharge concentration (MADC).
3. Purimar BWMS Techwin Eco Co., Ltd. (TWEKO), Republic of Korea	Filtration and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.	Final Approval, Recommended, May 2011	Flag State Administration was invited to ensure that the recommendations presented in Annex 6 of the report of the GESAMP-BWWG17 were verified prior to issuance of a Type Approval Certificate. The recommendations mainly focus on maintaining the dose and the maximum allowable discharge concentration (MADC).

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
<p>4. NeoPurimar BWMS</p> <p>Samsung Heavy Industries Co., Ltd. (SHI), Republic of Korea</p>	<p>Filtration and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by further treatment with sodium hypochlorite at discharge and neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.</p>	<p>Basic Approval, Recommended, May 2011</p>	<p>Flag State Administration was invited to ensure that the recommendations presented in Annex 7 of the report of the GESAMP-BWWG17 were verified prior to submission for Final Approval. The recommendations mainly focus on the safety of the second treatment for the environment.</p>
<p>5. Smart Ballast BWMS</p> <p>STX Metal Co., Ltd. Republic of Korea</p>	<p>Disinfection with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.</p>	<p>Basic Approval, Recommended, September 2011</p>	<p>The Flag State Administration was invited to ensure that the recommendations provided in Annex 4 of the report of the GESAMP-BWWG18 meeting were fulfilled prior to submission for Final Approval.</p>
<p>6. SEI Ballast Water Management System</p> <p>Sumitomo Electric Industries Ltd. Japan</p>	<p>Filtration and UV irradiation, followed by further UV irradiation.</p>	<p>Basic Approval, Recommended, September 2011</p>	<p>The Flag State Administration was invited to conduct future evaluations in accordance with the Guidelines for approval of ballast water management systems (G8) taking into account the review contained in Annex 5 of GESAMP-BWWG18.</p>
<p>7. SiCURE Ballast Water Management System</p> <p>Siemens AG, Germany</p>	<p>Filtration and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by an optional neutralization with sodium sulphite. This system requires the storage of chemicals on-board.</p>	<p>Final Approval, Recommended, September 2011</p>	<p>Flag State Administration was invited to ensure that the recommendations contained in Annex 6 of the report of GESAMP-BWWG18 were all taken into account were verified prior to issuance of a Type Approval Certificate. The recommendations mainly focus on ensuring that a sufficient holding time will be used in cases where no</p>

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
			neutralization is applied.
8. DMU OH Ballast Water Management System Environment Engineering Institute of Dalian Maritime University (DMU-EEI), China	Filtration, ultrasonic treatment and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, and optional neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.	Basic Approval, Recommended, November 2011	The Flag State Administration was invited to ensure that the recommendations provided in Annex 4 of the report of the GESAMP-BWWG19 meeting were fulfilled prior to submission for Final Approval.
9. ERMA FIRST Ballast Water Management System ERMA FIRST ESK S.A., Greece	Filtration, cyclonic separation and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium bisulphite. This system requires the storage of chemicals on-board.	Final Approval, Recommended, November 2011	The Flag State Administration was invited to ensure that the recommendations provided in Annex 5 of the report of the GESAMP-BWWG19 meeting were fulfilled prior to issuance of a Type Approval Certificate. The recommendation focused on the formation of hydrogen gas as a potential safety item because the applicant was not able to determine hydrogen in the development phase.
10. MicroFade Ballast Water Management System Kuraray Co Ltd, Japan	Filtration and disinfection with Active Substance calcium hypochlorite, followed by neutralization with sodium sulphite. This system requires the storage of chemicals on-board. In this case the Active substance calcium hypochlorite and the neutralizer sodium sulphite.	Final Approval, Recommended, November 2011	The Flag State Administration was invited to ensure that the recommendations provided in Annex 6 of the report of the GESAMP-BWWG19 meeting were fulfilled prior to issuance of a Type Approval Certificate. The recommendation focuses on the monitoring of the Active Substance during discharge (MADC).
11. AquaStar BWMS AQUA Eng. Co., Ltd., Republic of	Cavitation (Smart Pipe), Disinfection with Active Substance Sodium Hypochlorite Formed by	Final Approval, Recommended, November 2011	Flag State Administration was invited to ensure that the recommendations

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
Korea	In situ electrolysis, followed by neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.		presented in Annex 7 of the report of the GESAMP-BWWG19 meeting were verified before re-application for Final Approval. The recommendation focuses on the monitoring of the Active Substance during treatment (dose) and discharge (MADC).
12. EcoGuardian BWMS Hanla IMS Co Ltd, Republic of Korea	Filtration and disinfection with Active Substance TRO formed by electrolysis, followed by neutralisation with sodium thiosulfate. This system requires the storage of chemicals on-board.	Basic Approval, Recommended, December 2011	Flag State Administration was invited to ensure that the recommendations presented in Annex 4 of the report of the GESAMP-BWWG20 meeting were verified before application for Final Approval. The recommendations focus on the residual toxicity at discharge.
13. HS-BALLAST BWMS HWASEUNG R&A Co., Ltd., Republic of Korea	Disinfection with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by neutralization with sodium thiosulfate. This system requires the storage of chemicals on-board.	Basic Approval, not recommended, December 2011	Flag State Administration was invited to ensure that the recommendations presented in Annex 5 of the report of the GESAMP-BWWG20 meeting were verified before a new application for Basic Approval. The recommendations focus on the missing information on the unit operations determining the exposure of the crew and the environmental effects after discharge.
14. BWMS with Peraclean Ocean (SKY-system) Katayama Chemical, Inc., Japan	Filtration and treatment with Active Substance sodium hypochlorite formed by in situ electrolysis, followed by further treatment with sodium hypochlorite and neutralisation with sodium thiosulfate This system requires the storage of chemicals on-	Final Approval, Recommended, December 2011	Flag State Administration was invited to ensure that the recommendations presented in Annex 6 of the report of the GESAMP-BWWG20 meeting were prior to issuance of a Type Approval Certificate. The recommendations

Name of the System/Manufacturer	Brief description of the System	Date of Approval	Specifications
	board.		focus on a sufficient time window for the Active Substance to take effect for the second treatment.

ANNEX 3**PROVISIONAL ANNOTATED AGENDA
FOURTH STOCKTAKING WORKSHOP ON THE ACTIVITY OF
THE GESAMP-BALLAST WATER WORKING GROUP**

**Pusan Test Facility, Pusan (Republic of Korea)
from 14 to 17 August 2012, starting at 9:00 a.m.**

Note: the agenda is subject to change.

1. Adoption of the agenda
2. Introduction and ways of working during the meeting (including house-keeping)
3. Outcome of MEPC 63
 - i. Which information should be on the non-confidential report (also shorter formatting for it)
 - ii. Corrosion issue
 - iii. Amended methodology
 - iv. What should be needed in Assessment report by the administration
 - v. Practicalities and impracticalities
 - vi. Add scientific explanation to methodology where appropriate.
4. GESAMP comments and suggestions to improve the methods of work
5. BWMS using fresh and/or cold water and residual toxicity, including salinity
6. Dealing with CMR substances (HH only)
7. Validity criteria for ecotoxicity testing of microalgae
8. Structure of risk assessments – environment and human health
9. Use of the database (from JC) in our evaluations
10. MAMPEC calculations by the Group
11. TRO sensors, types, etc.
12. Neutralization in the BWMS – should it be used in all cases?
13. Evaluation of UV-systems
14. Dealing with PBT assessment (Env only)
15. Development of Glossary
16. Any other business -

Other suggestions:

- invite Korean Register (KR)
- ask Martin Schabert for comments on table: done, comments come early April
- invite Barbara Werschkun (BfR, Germany)
- invite Korean professor to present overview of TRO-equipment, reliability, reaction time
- invite Korean expert (test facility) on micro algae tests

Annotations to the Agenda STW4

1. Adoption of the agenda

The order of the agenda is according to my ideas about the importance of the items. These can be adjusted any time during the preparation of the workshop or during the workshop.

2. Introduction and ways of working during the meeting (including house-keeping)

The workshop is intended to last 3 full days – Tuesday to Thursday. The start is on Tuesday at 9.00AM and each day lasts until 6.00PM. Lunchtime is from 12.30PM until 1.30PM with a coffee and tea break at 11.00AM and 3.30PM. Bathroom and security facilities will be indicated by our host.

3. Outcome of MEPC 63

During MEPC63 a Ballast Water Review Group (BWRG) has been established with the intention to agree on the Methodology. The document has been worked through paragraph by paragraph and every delegation present was given the opportunity to bring up items to discuss and improve. At the end there was available a final document, which is now ready for the BWWG to be used for the evaluation of BWMS. Most changes proposed by the BWWG have been considered acceptable by the BWRG but there were also changes proposed by the BWRG. The final methodology as accepted by MEPC is not yet attached and is one of the documents for the BWWG to consider. I have the feeling that all changes proposed and endorsed by MEPC should be considered mandatory to us. There is still a lot to do for us during the STW4. Some items that are mentioned below. The topics brought forward to the WG will be dealt with according to the appearance in the methodology unless already on the agenda.

- i. Which information should be on the non-confidential report (also shorter formatting for it)

Explanation: Germany is preparing (has prepared) a submission to MEPC63 outlining the minimal data requirements in the non-confidential dossier. The aim of the submission is that the risk assessment for chemicals in the BWMSs as carried out by the WG can be followed by the Administrations' experts. To some extent I have already commented on this submission and during MEPC it has been checked whether the final version conflicts with the current version of the methodology. This was not the case. Therefore, we do not need another discussion paper here nor an invited external expert. My current opinion is even that we do not have to discuss this further.

- ii. Corrosion issue

Explanation: the International Corrosion Society NACE has commented on the corrosion proposals as currently stated in document MEPC59/2/16. NACE developed a protocol for the measurement of corrosion in BWMSs. They will send the endorsed version of this protocol to GESAMP-BWWG for its consideration around April 1, 2012. In addition the International Paint and Printing Ink Council (IPPIC) has carried out corrosion studies with different levels of TRO, between 5 and 15 mg TRO/L as Cl₂. The final results of this study will be sent to GESAMP-BWWG for its consideration as well, probably in April. I made the following appointment with representatives of NACE and IPPIC: both documents of NACE and IPPIC will be sent in April. The BWWG will study these documents and decide how important the corrosion issue should be on the agenda of the STW4. If it is to be expected that it would take more than half a day of discussion a representative of NACE and of IPPIC will be invited to the meeting to add to our discussion. If we think corrosion will be a less important issue, less than 0.5 day of discussion, no invitations should be issued. Both organizations cover their own expenses. The WG should discuss the documents of NACE and IPPIC and come to a final approach on corrosion.

I propose that **Hongtian** and **Shinichi** prepare a discussion paper for STW4 when the documents are available. It should be kept in mind that Hongtian already prepared a short comparison of the draft NACE document and the BWWG-approach. This document is attached and may serve as a basis for the final discussion paper.

- iii. Amended methodology

As stated above the Methodology has been discussed paragraph for paragraph during MEPC and at the end of the meeting it has been endorsed. The new endorsed Methodology will be

made available as soon as possible. Some discussion at MEPC considered the human exposure scenarios. It was felt that especially the exposure scenarios for ballast water tank inspections were too worst case. If such a scenario does not lead to unacceptable exposure, based on our RA-approach, it is my feeling that we should not change the scenario. I have asked a rather independent expert, Martin Schabert, Lloyd's Register Denmark (LRD), to comment on the table in chapter 2 of Appendix 4 of the Methodology. He promised his comments early April 2012.

I propose that **Jan** will present an overview of all changes during the STW4 and we can discuss each change according to the need taking into account the comments of LRD.

iv. What should be needed in Assessment Report by the administration

Explanation: in the Methodology and also in Procedure G9 an assessment report is mentioned to be part of the dossier. Up to now the WG has not paid much attention to this report and should discuss the usefulness and the potential contents of this section. This Assessment Report was probably added to the requirements of applicants because it has a role in the assessment of veterinary drugs as an "independent" assessment of the available data. This item has been a discussion point at MEPC on the request of Japan as to whom should be responsible for the drafting of the AR, the applicant or the Administration. According to Japan, it could not be the Administration. It has been decided by MEPC to leave this open and each Administration can act as they think appropriate.

I suggest that **Shinichi** prepares a discussion paper in consultation with **Jan** for the workshop. However, in the light of the discussion at MEPC, my personal opinion is that we could delete this point from our agenda.

v. Practicalities and impracticalities

This item was brought up during a small meeting during MEPC of all the GESAMP-BWWG-members attending. I am not sure anymore what was the intention of this suggestion nor I do know who came up with this. Could the member responsible for this suggestion send to me a short description of his intention to put here in the annotations? Action: **David, Kitae, Shinichi** or **Stephan**. Probably, here also to potential invitation for the Korean Register expert comes in.

vi. Add scientific explanation to methodology where appropriate.

On the request of Japan, MEPC agreed to add a scientific explanation why CMR is now included in the RA-approach of GESAMP-BWWG. It was a general feeling that, where changes are proposed by the BWWG, as much as possible a scientific explanation for the proposed change should be included in the Methodology. As the Methodology is endorsed by MEPC as it stands now we could take this suggestion on board for future changes. What is the feeling of the BWWG on this point? Action: **All**.

4. GESAMP comments and suggestions to improve the methods of work

At the moment no comments or suggestions have been received from GESAMP. It is not very likely that additional comments will be received as Tim indicated that no time was available for this action.

I propose that **Tim** prepares a discussion paper on the Methodology as representative of GESAMP for the workshop. I will approach him for this action. This could be an extensive agenda point. As Tim is invited anyway no external expert would be needed to help us in the discussion. If Tim is not available we could invite the vice chair of GESAMP, Peter Kershaw or Mike Huber.

GESAMP made several comments on our reports related to more general items:

- Publication of the methodology as a GESAMP report
- Glossary and acronyms see point 13. Andrew offered to make a start on this.
- Some concerns about the consistency of approach and presentation among the different system evaluations within BWWG reports and also from one report to another.
- Inconsistency regarding the holding times before water is used before toxicity testing, note for example in the evaluation in one Annex there was an issue regarding whether toxicity data were immediately after treatment/neutralization and then 5-day old water was used for toxicity tests, then in another Annex the holding time before testing is not specified. Is there an issue of not holding the water if the toxicity evaluation is on water held for 5 days? I will not specify this as requiring action for report approval but suggest

the Group considers this to ensure they are comfortable that holding times viz. toxicity testing is being dealt with appropriately and consistently.

- The issue of operation of systems dependent on electrolysis of seawater in brackish water conditions (such as major estuaries, semi-enclosed seas and the Great Lakes) may require further consideration by the group.
- The issue of cumulative effects of treated discharged ballast water in large volumes from multiple sources into relatively confined water bodies remains a concern, if not strictly within the scope of the BWWG remit for dealing with individual submissions.
- More items may come.

5. BWMS using fresh and/or cold water and residual toxicity, including salinity

Up to now we have adopted the proposals of the applicant if certain limitations to the application of the BWMS were considered appropriate. Sometimes we mention these limitations, sometimes we do not. We all remember the Peraclean Ocean case as also MEPC does. Therefore, we should make it more clear what our own opinion on the limitations are. For G8 testing of 2 salinities, being more than 10 psu apart, should be tested. What is the opinion of BWWG if no fresh water has been tested? Should residual toxicity be measure at different temperatures? Should degradation rates be tested at different temperatures or can these be extrapolated using the Arrhenius equation? For a salinity extrapolation no established method is available only the Canadian paper on Peraclean Ocean. Is this sufficient for a scientific extrapolation to other temperatures? This kind of questions should be considered here.

In addition, mentioning the limitations of a BWMS clearly has also been suggested by GESAMP. I suggest that **Kitae**, supported by **Shinichi** and **Jan**, provides a discussion paper on this topic.

6. Dealing with CMR substances (HH only)

The potential CMR substances are a new item for our evaluation and therefore, we should need and use ample time to discuss this agenda point. CMR discusses the inherent hazardous properties of a substance without a risk assessment. It has been decided by regulatory agencies, including the EU, that humans should not be exposed to CMR substances. If we adopt this opinion, it would become impossible to grant approval to BWMSs that produce CMR substances. Only when we apply a risk assessment to these CMRs some discharge could be allowed. During MEPC, CMR has been discussed to some extent as a table on how to determine whether a substance has to be considered a CMR substance was missing. I have drafted such a table on the spot and that table is now inserted in the Methodology. I propose that the STW4 discusses this table.

I propose that **Teresa** and **Annette** provide a discussion paper how the BWWG should deal with CMR substances. If we look at the substances currently in our data base several chemicals have CMR properties and are therefore considered CMR substances. Barbara Werschkun (BfR, Germany) is proposed to be invited for the STW4. Maybe she could also assist in the drafting of a discussion paper.

7. Validity criteria for ecotoxicity testing of microalgae

During our evaluations of laboratory treated BW tests and also land-based WET tests we have found that the validity criteria for algae were often not met, especially the 16-fold growth rate in the control test. Algae are generally considered as the most sensitive species in these tests, whereas they are considered the least suitable for petting compared to fish and crustacean. This has also to do with the fast growth rates of algae for which a 96 hour toxicity test may already be considered as a chronic test. Also other validity criteria should be taken into account by the BWWG.

I propose that **Kitae** prepares a discussion paper on this item and also proposes an external expert to be invited. If needed **Jan** can assist.

8. Structure of risk assessments – environment and human health

Environment: Basic Approval and Final Approval evaluation can be considered as a tiered approach in the risk assessment. In addition, at BA and at FA different ecotoxicological data are available to the BWWG to perform the risk assessment. Of course, first of all the ecotoxicological information from the literature is available for the specific chemicals. These data

together with the results of the MAMPEC calculation are sufficient to carry out a risk assessment by comparing the PEC from MAMPEC and the PNEC based on the toxicological data provided. At BA also the data from the laboratory testing with treated BW is available, which may also be used for a risk assessment by considering the PEC from MAMPEC and the concentration used in the laboratory tests. What is the status of both approaches; is there a hierarchy in these 2 approaches; what decides for the one or the other? AT FA there is the same kind of problem. Again the data from the literature are available and the MAMPEC results, but also the results of the WET tests at full scale. Which approach is preferred by the BWWG; on what grounds; what is the status of the near sea calculation; what happens if contradictory results are achieved? I propose that **Jan** will draft a discussion paper on this topic with decision criteria for the BWWG.

Human: in the risk assessment for humans there is not such a hierarchy problem as defined under environment. There is only the RA for crew and PSC and the general public. Do we have to discuss the by-stander exposure? Therefore, I do not see an analogy here between human exposure and environmental exposure. What we could discuss, however, is how we want to report the results of the human RA in our evaluation report; what kind of tables and what kind of text.

Unless, Teresa and Annette provide a different reasoning here I suggest that **Teresa** and **Annette** provide a discussion paper about the way the RA for humans could consistently be reported.

9. Use of the database (from JC) in our evaluations

As discussed during the BWWG20 in the presence of John Crayford the data can be used as an absolute tool in the risk assessment. A theoretical value can be derived based on the (eco)toxicological information and the appropriate assessment factors (AF) below which the concentration or dose of a chemical will not pose any unacceptable risk. The only thing the BWWG has to do during its evaluation meetings is to decide whether the concentration or dose is below or above that critical value. Another approach is to report the real values of the assessment and to report whether these are acceptable or not. The same approach can be taken for human exposure and for the environmental exposure.

I propose that **John**, in addition to his preparation of a user manual and technical description of the data base is also providing a discussion paper on the approach to be taken in the evaluation reports.

10. MAMPEC calculations by the Group

Especially during the last BWWG20 meeting it became very clear how much time it may cost to perform MAMPEC calculations. At the moment the applicants may use 3 different versions of MAMPEC (2.0, 2.5 and 3.0). Sometimes different harbors or different variables in the harbors are used. First the BWWG checks the results of the applicant by performing a recalculation, secondly the PEC is determined if the right GESAMP-BWWG harbor and scenario is used. If the BWWG has to do that for all substances relevant in an application and / or the applicant made mistakes a lot of time has to be devoted during the meeting in establishing the correct values to be used in the risk assessment. The calculation is quite critical as the PEC base on MAMPEC has to be used for the human RA as well as the environmental RA. The question is how the efforts of the BWWG may be reduced to a more sensible amount of time? Taking into account the results of the discussion under point 7 (environment) we may conclude that MAMPEC calculations are only necessary at BA as at FA we have the results of the WET tests available for a higher tier RA. Is this a workable way forward?

I propose that **Jan** is preparing a discussion paper on this topic using the expertise of **Stephan** and **Emmanuel** in the application of MAMPEC. An additional external expert is not needed for this topic.

11. TRO sensors, types, etc.

Shinichi, could you provide some text for this annotated agenda to clarify what your intention was in proposing this topic? A colleague of Kitae was proposed to be invited for this agenda point. He is an expert in TRO-equipment. Kitae will ask him about his availability.

12. Neutralization in the BWMS – should it be used in all cases?

Could I invite the proposer to draft some text for this annotated agenda?

13. Evaluation of UV-systems

Again, during MEPC63, it was re-established that UV-systems used as BWMS, are not considered subject to Procedure (G9). It is still not clear what the position of the BWWG should be when a UV-system is sent to the Organization for review by GESAMP-BWWG. Up to now we have considered these systems and advice in an inconsistent way: we have mentioned our inability to judge these systems as not subject to G9, we have given BA and we have given BA and FA from the viewpoint that if an Administration does want the opinion of the BWWG we had an obligation to do so. Dandu has a different view with his opinion that the BWWG simply could say that UV-systems are not subject to G9 and should be referred back to the Administration for further decision making under G8. During the STW4 a clear approach should be determined. I propose that **Jan** will draft a discussion paper with the help of **Dandu** on this item.

14. Dealing with PBT assessment (Env only)

According to me personally there is no need for this agenda point. The way PBT substances are identified is quite clearly described in the available guidance from the US EPA and the EU REACH program. Unless, I completely miss the point here, I propose to delete this agenda point. **I would like to invite members with different points of view to draft text for this annotated agenda to clarify the need for this point.**

15. Development of Glossary

The need for a Glossary was brought up by some members of GESAMP. We have discussed it some time ago, I think during STW2 or STW3, but we decided that insufficient time was available to the members to do this. An external consultant could provide a start with this item. It would help the outside world to better understand our work. From that point of view I am still in favor of getting a glossary out. I also propose to include acronyms. Andrew offered to make a start on this. So, at the meeting we will have a draft available to discuss. **I invite Andrew to prepare a draft Glossary and list of acronyms.**

16. Any other business -

None identified yet.

Summary of actions

Agenda point	Action	First responsible member	Supporting member(s)
3,ii	Discussion paper on corrosion	Hongtian	Shinichi
3,iii	Overview of all changes during MEPC	Jan	
3,iv	Assessment Report	Shinichi	Jan
3,v	Prepare annotation	D, K, Sh or St	
3,vi	Add scientific explanation to methodology	All	
4	Discussion paper on the Methodology by GESAMP	Tim	Jan
5	Limitations of BWMS	Kitae	Shinichi & Jan
6	Dealing with CMR substances	Teresa	Annette & Barbara
7	Discussion paper on validity criteria for ecotoxicity testing of microalgae	Kitae	Jan & Korean expert
8,env	Structure of risk assessments – environment	Jan	
8,hh	Structure of risk assessments –human health	Annette	Teresa & Barbara
9	User manual and technical description of the data base	John	
10	MAMPEC calculations	Jan	Stephan & Emmanuel
11	Annotation on TRO sensors, types	Shinichi	
12	Annotation Neutralization	Proposer?	
13	Evaluation of UV-systems	Jan	Dandu
14	Dealing with PBT assessment (Env only)	All	
15	Development of Glossary	Andrew	
16			