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

Methodology for information gathering and conduct of work of the GESAMP*-BWWG

1 Regulation D-3 of the Ballast Water Management Convention provides that ballast water management systems which make use of Active Substances shall be approved by the Organization. The Marine Environment Protection Committee (MEPC), at its fifty-third session (July 2005), adopted the *Procedure for approval of ballast water management systems that make use of Active Substances* (G9) by resolution MEPC.126(53), and agreed with the establishment of a Technical Group under the auspices of GESAMP to evaluate such systems and advise the Committee accordingly. At the same session the GESAMP-Ballast Water Working Group was also requested to develop a Methodology for information gathering and conduct of its work (the Methodology).

2 The MEPC, at its fifty-sixth session (July 2007), having recognized that the Methodology was a living document, which may be further refined taking into account the best practices and lessons learned during the evaluation process, agreed that the Methodology, as drafted at that time, should be suitable for use as technical guidance by applicants submitting applications for approval of ballast water management systems.

3 Having adopted resolution MEPC.169(57), which revokes resolution MEPC.126(53) and contains the revised *Procedure for approval of ballast water management systems that make use of Active Substances* (G9), MEPC 57 requested the GESAMP-BWWG to update its Methodology in accordance with the revised Procedure (G9). The updated Methodology was subsequently circulated by means of BWM.2/Circ.13.

4 Taking into account the lessons learned and the experience gained, the GESAMP-BWWG has carried out thorough reviews of the Methodology and prepared revised versions which were approved by the MEPC and circulated as revisions to BWM.2/Circ.13.

5 The GESAMP-BWWG, at its Ninth Stocktaking Workshop in January 2022, prepared draft guidelines for re-evaluations in cases where modifications have been made to a ballast water management system, including a decision tree, as a potential addition to the Methodology. The MEPC, at its seventy-eighth session (June 2022), approved the guidelines and instructed the Secretariat to issue the revised Methodology, incorporating the aforementioned guidelines as a new chapter 12, by means of BWM.2/Circ.13/Rev.5.

* GESAMP stands for "IMO/FAO/UNESCO-IOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO/ISA Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection".

6 MEPC 78 further noted that the revised Methodology incorporating these guidelines would be applicable to all cases where modifications are made after that session to an already approved ballast water management system.

7 As the existing parts of the Methodology (chapters 1 to 11), relating to new applications for Basic or Final Approval, were not affected by this revision, the revised Methodology retains the applicability of BWM.2/Circ.13/Rev.4 with regard to such applications, namely it is applicable to all submissions for Basic Approval to MEPC 74 and onwards, and subsequent submissions for Final Approval of those systems.

8 Member Governments are invited to bring the revised Methodology to the attention of all parties concerned and, in particular, manufacturers of ballast water management systems that make use of Active Substances.

9 This circular revokes BWM.2/Circ.13/Rev.4.

ANNEX

REVISED METHODOLOGY FOR INFORMATION GATHERING AND CONDUCT OF
WORK OF THE GESAMP-BWWG

Approved by MEPC 78 on 10 June 2022

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1 INTRODUCTION

This document contains the Methodology for information gathering and conduct of work of the GESAMP-BWWG when undertaking technical evaluations 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), as revised, hereinafter referred to as Procedure (G9)).

1.1 Terms and definitions

For the purpose of this Methodology, these definitions are intended to supplement those in the Ballast Water Management Convention to facilitate a consistent evaluation of submissions:

- .1 **Ballast Water Management Convention** (the Convention) means the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004.
- .2 **Ballast Water Management** means mechanical, physical, chemical and biological processes – either singularly or in combination – to remove, render harmless, or avoid the uptake or discharge of harmful aquatic organisms and pathogens within ballast water and sediments.
- .3 **Ballast Water Management System** (BWMS) means any system which processes ballast water such that meets or exceeds the ballast water performance standard in regulation D-2. The BWMS includes ballast water treatment equipment, all associated control equipment, piping arrangements as specified by the manufacturer, control and monitoring equipment and sampling facilities. For the purpose of this Methodology, BWMS does not include the ship's ballast water fittings, which may include piping, valves, pumps, etc., that would be required if the BWMS was not fitted.
- .4 **Preparation** means any commercial formulation containing one or more Active Substances including any additives. This term also includes any Active Substances generated on board for purposes of ballast water management and any Relevant Chemicals formed in the ballast water management system that makes use of Active Substances to comply with the Convention.
- .5 **Active Substance** (AS) means a substance or organism, including a virus or a fungus, that has a general or specific action (chemical or biological) on or against harmful aquatic organisms and pathogens.
- .6 **Relevant Chemical** (RC) means transformation or reaction product that is produced during and after employment of the ballast water management system in the ballast water or in the receiving environment and that may be of concern to the ship's safety, aquatic environment and/or human health.
- .7 **Other Chemical** (OC) means any other substance, other than the Active Substance(s) or Relevant Chemicals, potentially associated with the system either intentionally or resulting from the treatment of ballast water.

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- .8 **Basic Approval (BA)** means the preliminary approval of Active Substances and the ballast water management system that uses them in order to comply with the Ballast Water Management Convention. Basic Approval should confirm that the available information does not indicate possible unacceptable adverse effects or a potential for unreasonable risk to environment, human health, property or resources. This should include consideration of potential risks associated with the Active Substance during full-scale deployment on commercial ships when possible.
- .9 **Final Approval (FA)** means the approval of a ballast water management system using an Active Substance or Preparation to comply with the Convention and includes an evaluation of the whole effluent toxicity (WET) tests performed as part of the land-based Type Approval process in accordance with the *Guidelines for approval of ballast water management systems* (G8). The review does not include the re-evaluation of efficacy testing results conducted by Administrations under the 2016 Guidelines (G8). The Final Approval should confirm that previous evaluations of risks to ship, crew and the environment including storage, handling and application of Active Substances or Preparations remain valid and the concerns expressed during the Basic Approval process have been addressed, as well as that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval.
- .10 **GESAMP-Ballast Water Working Group (GESAMP-BWWG)**, also being referred to as the Group, means the Technical Group consisting of independent experts acting in their individual capacity that review the proposals for approval of ballast water management systems that make use of Active Substances submitted by the Administration and report, through the GESAMP, to the MEPC. When reviewing the proposals, the Group should take account of any other relevant data as well as other relevant information submitted to it, or the Group is aware of, because of its members' expertise.
- .11 **GESAMP** is the IMO/FAO/UNESCO-IOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, an advisory and multi-disciplinary body consisting of specialized experts nominated by the sponsoring agencies. Experts working for the GESAMP act independently in their individual capacity.
- .12 **Land-based testing** means a test of the BWMS carried out in a laboratory, equipment factory or pilot plant including a moored test barge or test ship, according to parts 2 and 3 of the annex to the 2016 Guidelines (G8), to confirm that the BWMS meets the standard described in regulation D-2 of the Convention.
- .13 **Major components** means those components that directly affect the ability of the system to meet the ballast water performance standard described in regulation D-2.
- .14 **System Design Limitations (SDL)** of a BWMS means the water quality and operational parameters, determined in addition to the required type approval testing parameters, that are important to its operation, and, for each such parameter, a low and/or a high value for which the BWMS is designed to achieve the performance standard of regulation D-2. The System Design Limitations should be specific to the processes being employed by

the BWMS and should not be limited to parameters otherwise assessed as part of the type approval process. The System Design Limitations should be identified by the manufacturer and validated under the supervision of the Administration in accordance with the 2016 Guidelines (G8).

- .15 **Holding time** means the total time during which treated ballast water will be held in a simulated ballast water tank for the purpose of verifying biological efficacy under the 2016 Guidelines (G8).
- .16 **Storage period** means the total time during which treated ballast water will be held in a simulated ballast water tank for the purpose of identifying the worst-case concentrations of Relevant Chemicals in treated and discharged ballast water.

1.2 Abbreviations used in the text

<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
μg	microgram
AS	Active Substance
ASF	interspecies allometric scaling factor
ASTM	American Society for Testing and Materials
BA	Basic Approval
BCF	bioconcentration factor
BIO _{inh}	bioavailability factor for inhalation
BMD	benchmark dose
b.p.	boiling point
Bw	body weight
BWMS	ballast water management system
°C	degree Celsius (Centigrade)
CAS	Chemical Abstracts Service
Cc	cubic centimeter
CEC	cation exchange capacity
CF _{abs}	correction factor for absorption
CF _{dr}	correction factor for dose regime
CMR	carcinogenicity, mutagenicity and reproductive toxicity
D	day(s)
DNEL	Derived No-Effect Level
DMEL	Derived Minimal Effect Level
DOC	dissolved organic carbon
DT ₅₀	half-life of a substance
EC ₅₀	effect concentration, 50% (median effective concentration)
EHC	environmental health criteria
EHS	Evaluation of Hazardous Substances
ESF	observed effect scaling factor
EU	European Union

FA	Final Approval
G	gram
G9	<i>Procedure for approval of ballast water management systems that make use of Active Substances (G9)</i> , as revised, adopted by resolution MEPC.169(57) in April 2008
GESAMP	IMO/FAO/UNESCO-IOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
GESAMP-BWWG	GESAMP-Ballast Water Working Group
GHS	Globally Harmonized System
GLP	good laboratory practice
H	hour(s)
HES	human exposure scenario
IARC	International Agency for Research on Cancer
IC ₅₀	inhibition concentration, 50%
IMO	International Maritime Organization
IR	ingestion rate
ISF	intraspecies differences factor
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K _d	sorption coefficient
Kg	kilogram
K _{oc}	organic carbon-water partition coefficient
K _{ow}	octanol/water partitioning coefficient (also P _{ow})
K _p	sorption coefficient for ionic substances
L	litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	lethal dose, 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOD	Limit of Detection
LOEL	lowest observed effect level
Log P _{ow}	logarithm of the octanol/water partition coefficient
MADC	Maximum Allowable Discharge Concentration
MAMPEC	Marine anti-foulant model for PEC calculation
MAMPEC-BW	Marine anti-foulant model for PEC calculation for ballast water
MARPOL	International Convention for the Prevention of Pollution from Ships
MEPC	Marine Environment Protection Committee
Mg	milligram
mL	millilitre
m.p.	melting point
Ng	nanogram
NOAEC	No Observed Adverse Effect Concentration
NOEC	No Observed Effect Concentration
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
NTP	National Toxicological Programme

OC	Other Chemical
OECD	Organisation for Economic Co-operation and Development
Organization	the International Maritime Organization
OSF	other interspecies scaling factor
PBT	Persistence, Bioaccumulation and Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
POC	Particulate organic carbon
POEM	UK Predictive Operator Exposure Model
P _{ow}	Octanol/water partition coefficient (also K _{ow})
PPE	protective personal equipment
QAPP	Quality Assurance Project Plan
QA/QC	Quality Assurance/Quality Control
QFC	quantity of fish consumed
QSAR	Quantitative Structure-Activity Relationship
RC	Relevant Chemical
RCR	Risk Characterization Ratio
SDL	System Design Limitation
SF _{dur}	scaling factor for exposure duration
SOLAS	The International Convention for the Safety of Life at Sea
TLV	threshold limit value
TOC	Total Organic Carbon
TRC	total residual chlorine
TRO	total residual oxidant
US EPA	United States Environmental Protection Agency
WET	whole effluent toxicity test
WHO	World Health Organization
Wt	weight

2 GENERAL

2.1 Legal provision

Regulation D-3.2 of the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004, stipulates that ballast water management systems (BWMS) that make use of Active Substances to comply with the Convention shall be approved by the Organization. During its fifty-third session, the Marine Environment Protection Committee (MEPC) adopted the *Procedure for approval of ballast water management systems that make use of Active Substances* (G9) (resolution MEPC.126(53)). Resolution MEPC.169(57) revoked the initial Procedure and provided a revised version of it.

2.2 Principles of acceptability of BWMS that make use of Active Substances

This section describes the principles of acceptability of BWMS that make use of Active Substances, required in section 3 of Procedure (G9).

2.2.1 A ballast water management system that makes use of Active Substances accomplishes its intended purpose through action on potentially harmful aquatic organisms and pathogens in ships' ballast water and sediments. However, if the ballast water is still toxic at the time of discharge into the environment, the organisms in the receiving water may suffer unacceptable harm. Both the Active Substance itself or the Preparation, as well as the treated ballast water, should be subjected to toxicity testing in order to determine if an Active Substance or Preparation can be used and under which conditions the potential for harming the receiving environment or human health is acceptably low (G9: 3.2).

2.2.2 Any system that makes use of, or generates, Active Substances, Relevant Chemicals or free radicals during the treatment process to eliminate harmful organisms and pathogens in order to comply with the Convention should be subject to Procedure (G9) (G9: 3.3).

2.2.3 Ballast water management systems that make use of Active Substances and Preparations must be safe in terms of the ship, its equipment and the personnel to comply with the Convention (G9: 3.4).

2.2.4 The Administration should determine if a BWMS that uses UV irradiation produces Active Substances and decide whether it needs to make a proposal for approval to the Committee or not (MEPC 59/24, paragraph 2.17).

2.3 Submission of an application for approval

This section describes the procedure to submit an application for approval specified in sections 8.1 and 8.2 of Procedure (G9).

2.3.1 The manufacturer should evaluate the system, the Active Substances or Preparations and the potential discharge in accordance with the approval criteria specified in the *Procedure for approval of ballast water management systems that make use of Active Substances* (G9).

2.3.2 Upon completion of the evaluation the manufacturer should prepare an application on the system that makes use of Active Substances or Preparations and submit it to the Member of the Organization concerned. An application should only be made when the ballast water management system using Active Substance or Preparations has been sufficiently designed, developed and tested to provide the full data necessary for Basic or Final Approval as appropriate (G9: 8.1.2.2).

2.3.3 For systems that have previously received Basic Approval, the provisions of the *Framework for determining when a Basic Approval granted to one BWMS may be applied to another system that uses the same Active Substance or Preparation* should apply (BWM.2/Circ.27).

2.3.4 Upon receipt of an application, the concerned Administration should conduct a careful completeness check to ensure that the application satisfies all the provisions contained in Procedure (G9) and that it is presented in the format recommended in this Methodology. Administrations should check the quality and completeness of any application against the latest version of the Methodology for information gathering and conduct of work of the GESAMP-BWWG, agreed by the Organization, prior to its submission to the MEPC. For Final Approval applications, the Administration should ensure that all the recommendations given by the GESAMP-BWWG during the Basic Approval process have been addressed to its complete satisfaction.

2.3.5 When the Administration is satisfied with the application received in accordance with paragraph 3.6 of Procedure (G9), it should submit a proposal for approval to the Organization consisting of the following:

- .1 a description of the ballast water management system containing the non-confidential data in the usual format for dissemination as an MEPC document (preferably less than 50 pages). Administrations should aim at submitting the non-confidential descriptions of their ballast water management systems at the MEPC session, which precedes the MEPC session expected to decide on the approval of the systems. If this is not possible, the non-confidential description should be submitted at the earliest opportunity to the MEPC session expected to decide on the approval of the systems, but not later than the 28-week deadline established as indicated in paragraph 2.3.7 below. Documents containing non-confidential descriptions of BWMS, which contain more than 20 pages, will not be translated into all working languages in their entirety. They should include, for translation purposes, a summary of the document not longer than four pages, with the technical content submitted as an annex in the language (e.g. English) that may be needed, for example, by working groups. Proponents seeking approval of BWMS that use Active Substances should thoroughly observe the provisions of paragraph 8.1.1 of Procedure (G9), bearing in mind that failure to provide the non-confidential information could result in Member States having insufficient data to approve the proposals when requested by the Committee. INF documents could be used in conjunction with proposals for approval to ensure that all safety and environmental protection data are made available;
- .2 a Letter of Agreement concerning the arrangements between IMO and the submitting Administrations for the evaluation of the respective system. A template of such a letter is provided in appendix 1;
- .3 the complete application dossier in accordance with Procedure (G9) consisting of the full description of the system, tests results, study reports, references and copies of the literature referenced and any other information relevant to that system. A summary of the key data should be provided in a tabular format. The complete application dossier should contain a list of contents indicating the location of the information in the application. Pursuant to paragraphs 4.2.2, 8.1.1 and 8.1.2.7 of Procedure (G9), the information mentioned above will be treated as confidential. It should be noted, however, that all information related to safety and environmental protection, including physical/chemical properties, environmental fate and toxicity, will be treated as non-confidential; and
- .4 the assessment report in accordance with paragraph 4.3 of Procedure (G9).

2.3.6 Proposals for approval of ballast water management systems that make use of Active Substances that need to be evaluated by the GESAMP-BWWG should be addressed to:

Marine Environment Division
International Maritime Organization
4 Albert Embankment
London SE1 7SR
United Kingdom

2.3.7 A non-refundable registration fee to cover the costs related to the services provided by the GESAMP-BWWG should be paid upon receipt of the invoice issued by the Organization in this respect. It should be noted that the evaluation of a proposal for approval cannot be initiated before the payment of the fee mentioned above.

2.3.8 The GESAMP-BWWG aims to hold its meetings 20 weeks before the MEPC session expected to decide on the approval of the proposals made by the Member Governments. Consequently, a 28-week deadline has been established for the submission of the proposal for approval (including the complete application dossier). This allows eight weeks for the preparation of the meeting and enables interested parties to provide information that is relevant to the evaluation in accordance with the provisions of paragraph 8.1.2.6 of Procedure (G9). A timetable used for planning the activities related to the GESAMP-BWWG meetings is shown in appendix 2.

2.3.9 When due to the time constraints the GESAMP-BWWG is not able to evaluate all the proposals for approval submitted before the deadline established as indicated in paragraph 2.3.8 above, an extraordinary meeting of the GESAMP-BWWG may be convened, subject to the availability of the Group and with the authorization of the Secretary-General of the Organization.

2.3.10 The GESAMP-BWWG will endeavour to evaluate as many proposals for approval as possible received before the deadline described in paragraph 2.3.8 above. When due to the time limitations between two consecutive sessions of the MEPC, the GESAMP-BWWG is not able to evaluate all the proposals for approval received before the above deadline, the remaining proposals will be evaluated on a "priority basis", in accordance with the order of submission during the subsequent meetings of the GESAMP-BWWG. Proposals for approval received after the established deadline will be referred to the MEPC session following the session used to establish the deadline and will be considered after any priority proposals not considered at previous meetings.

2.3.11 Upon receipt of a complete proposal for approval, the Organization will issue a confirmation letter indicating the date and the time the proposal has been received. In order to ensure complete transparency and a fair and impartial treatment of all the submissions, the proposals for approval are evaluated in the chronological order of their receipt.

2.3.12 Face-to-face meetings between the GESAMP-BWWG and applicants/Administrations should be conducted at the request of the Administrations prior to the meeting and solely during Final Approval evaluations. Face-to-face meeting should be limited to one hour per Final Approval application.

2.3.13 Clarification of certain aspects identified during the preparation for, or in the process of, an evaluation of a proposal for approval may be requested by the GESAMP-BWWG, if it becomes evident that clarification is found to be necessary in order to finalize the evaluation. The clarifications should be received in a timely manner so that the GESAMP-BWWG is able to take the information into account during its evaluation of the system. A time limit for response to any request for clarifications should not exceed 24 hours unless otherwise agreed with the GESAMP-BWWG. Applicants may wish to designate a technical representative to provide clarifications on request during the Group's meeting.

2.3.14 After completion of the GESAMP-BWWG report, relevant annexes containing the results of the evaluation will be forwarded to the respective Administrations for confirmation that no confidential data are being disclosed. Unless the Administration advises otherwise before the deadline indicated in the request for confirmation (normally one week), the Secretariat will assume that the respective evaluation does not contain confidential data and will process the report according to the timetable shown in appendix 2.

2.3.15 If after the revision of the draft report of the GESAMP-BWWG the GESAMP provides comments on the findings of the Group, the Chair of the GESAMP-BWWG, in consultation with the members of the Group, as appropriate, will address the respective comments.

The GESAMP provides confirmation of peer review and approval to the Organization for the information of the MEPC.

2.3.16 In case an Administration that has submitted a proposal for approval disagrees with the recommendations of the GESAMP-BWWG, such an Administration should be given the option to submit a document indicating the reasons for disagreement to the session of the MEPC expected to decide on the respective proposal. The explanatory document should be considered by the Committee in conjunction with the GESAMP-BWWG report.

2.3.17 Any supplementary data regarding a proposal not recommended for approval that was provided to the GESAMP-BWWG after the completion of its meeting will be considered as a new proposal, subject to a new deadline for evaluation according to the procedure described in this Methodology and subject to a new registration fee.

2.3.18 The Secretariat will endeavour to forward all the requests for clarification regarding the published reports of the GESAMP-BWWG received from the Administrations concerned to the Chairman of the GESAMP-BWWG and to the IMO consultant responsible for the respective meeting for response as appropriate.

2.4 Confidentiality and data protection

This section describes the confidentiality and data protection specified in paragraphs 8.1.1 and 8.1.2.7 of Procedure (G9).

The confidential information in the submitted documents should be clearly identified. All information related to safety and environmental protection, including physical/chemical properties, environmental fate and toxicity, will be treated as non-confidential with the understanding that original proprietary test reports and studies, with the exception of the summary of the results and test conditions to be prepared by the applicant and validated by the GESAMP-BWWG, are considered confidential (G9: 8.1.1). Once an approval procedure is completed and the system using the Active Substance is approved, the following data should not be regarded as confidential:

- .1 the name and address of the Administration;
- .2 the names and addresses of the Administrations of the Active Substance and/or the Preparation (if different);
- .3 the names and amount of the Active Substance(s) in the Preparations and the name of the Preparation;
- .4 the names of other components of Preparations, in particular those that are regarded as dangerous according to the UN GHS or relevant IMO regulations and contribute to the hazard documentation of the Preparation;
- .5 the names of Relevant Chemicals that may be formed during or after application of the BWMS and that may be of concern for the receiving environment or human health;
 - .1 the names of other chemicals that may be formed during or after the application of the BWMS with a technical justification as to why they should not be treated as Relevant Chemicals;
- .6 methods of chemical analysis, including the Limit of Detection (LOD);

- .7 physical and chemical data concerning the Active Substance, the Preparation and its components and Relevant Chemicals;
- .8 a summary of the results of the tests conducted pursuant to section 4.2 of the Procedure (G9) to establish the effects of the substance(s) or Preparation(s) on humans and the environment;
- .9 a summary of the results of the tests conducted on the treated ballast water pursuant to section 5.2 of Procedure (G9);
- .10 recommended methods and precautions against dangers resulting from handling, storage, transport and fire;
- .11 any means of rendering the Active Substance or Preparation harmless;
- .12 methods of disposal of the product and of its packaging;
- .13 procedures to be followed and measures to be taken in the case of spillage or leakage;
- .14 first aid and medical advice to be given in the case of injury to persons;
- .15 Safety Data Sheets, which should contain the information required of items .7 to .14;
- .16 all results of the Persistence, Bioaccumulation and Toxicity (PBT) assessment and the risk characterization pursuant to sections 5.1 and 5.3 of Procedure (G9); and
- .17 the uncertainty analysis specified in paragraph 6.4.3 of Procedure (G9).

2.5 Test methods

This section describes the test methods specified in paragraphs 4.2.3 to 4.2.4 of Procedure (G9).

2.5.1 Tests, which are described in 3.3.2, 3.3.3 and 6.1.3., should be carried out under internationally recognized guidelines (preferably OECD or equivalent) (G9: 4.2.3), and according to an internationally recognized quality assurance system (G9: 4.2.4) (e.g. Good Laboratory Practice (GLP)). Information may be derived from existing data where an acceptable justification is provided. Full copies of sources of data (e.g. literature papers) and relevant documents for QA/QC (i.e. QAPP) should be provided electronically and in hard copy. The relevant document should include validity criteria for all tests.

2.5.2 Care should be taken to provide full supporting references and copies of the appropriate test laboratory reports in support of each application electronically and in hard copy. If submissions are lacking relevant information, it may not be possible for the GESAMP-BWWG to conduct its risk assessment.

2.5.3 Many substances have acquired large databases for many of the hazards concerned and a weight of evidence approach has become necessary to ensure that the rating reflects the body of data rather than simply using the most conservative value. This, however, means that the submission of all available end-point data for Active Substances and Relevant Chemicals is necessary to enable a review.

2.6 Alternatives to testing and non-submission of data

2.6.1 Alternative methods to testing on live organisms, e.g. in vitro testing methods, Quantitative Structure-Activity Relationship (QSAR), extrapolation by analogy to known chemicals, or grouping of similar substances, may be used whenever justified. Sufficient documentation or references to documentation on the validity of the method should be provided, as well as documentation that the substance or Preparation lies within the applicability domain of the method.

2.6.2 Information that is not necessary, owing to the nature of the substance, need not be supplied. The same applies where it is not scientifically justified or technically feasible to supply the information. In such cases, a justification for not supplying such information should be submitted.

2.7 Additional data

2.7.1 If, in the course of the review by the GESAMP-BWWG, the Group considers that additional data are found to be necessary to finalize the evaluation, the Group may, in exceptional circumstances, request that such data are provided to facilitate the review.

2.7.2 The applicant should not submit any additional data after the dossier has been submitted to the Organization for evaluation unless such data have been requested by the Group.

2.8 Retrospective requirement

Once a ballast water management system has received Final Approval under this procedure, then the respective applicant should not have to retrospectively submit new data in accordance with this revised Methodology (paragraph 8.2.3 of Procedure (G9)).

3 APPLICATION DATA-SET

3.1 General

This section describes the general requirement for the application data-set specified in sections 4.2, 5.2 and 5.3 of Procedure (G9).

3.1.1 The dossier should contain the information specified in Procedure (G9). In cases where information requested in accordance with Procedure (G9) has not been submitted and no justification for non-submission is provided, the GESAMP-BWWG may not be able to judge the reasons for not submitting the information that may influence its evaluation and development of recommendations. A model for the presentation of the application data-set is given in appendix 3.

3.1.2 For Active Substances and/or Preparations, including any of its components as appropriate, data on properties should be included. For Relevant Chemicals, data should be provided as well.

3.1.3 Fate and effect testing should be performed in the laboratory with Active Substances and Preparations (G9: 5.3.1). However, the GESAMP-BWWG notes that normally assessment of fate (including degradation, bioaccumulation) is not feasible for Preparations, but only for individual substances. Therefore, degradation and fate testing of Preparations may not be appropriate. However, fate of individual substances of the Preparation should be demonstrated.

3.1.4 For treated ballast water, the Administration should provide both acute and chronic toxicity data (G9: 5.2.2) at Basic Approval application. The discharge toxicity tests at Final Approval should include acute and chronic toxicity test methods and results performed as part of the land-based type approval process with test species (fish, crustacea and algae). The results should include acute LC₅₀ values and chronic NOECs (G9: 5.2.5). One hundred per cent concentrations of samples of ballast water discharge should be tested (G9: 5.2.6), if appropriate.

3.1.5 Any reference to specific test methods in the following is indicative with the purpose of providing guidance to an Administration on possible methods that may be considered. Any other internationally recognized test method may be used as well.

3.2 Identification of the substance or Preparation

This section describes the identification of the substance or Preparation specified in paragraph 4.1 of Procedure (G9).

3.2.1 Preparations

For each Preparation, the application should include the following information (G9: 4.2.2):

- .1 the Trade name;
- .2 compositional information of the Preparation; including:
 - .1 the chemical (IUPAC) name of each component;
 - .2 the concentration of each component (liquids in g/L; solids in %w/w; gases in %v/v);
 - .3 the CAS number of each component;
 - .4 the UN number and proper shipping name of each component (where relevant);
 - .5 an indication of whether the component is an Active Substance or an additive, e.g. stabilizer or inhibitor or solvent, etc.; and
 - .6 particle size distribution, if in powder and/or granular form, as smaller particles (< 10 µm) present a greater hazard in potential cases of inhalation.

3.2.2 Active Substances

For each Active Substance, the applicant should provide the following information:

- .1 the Trade name (where relevant);

- .2 the chemical (IUPAC) name;
- .3 the CAS number;
- .4 the UN number and proper shipping name (where relevant);
- .5 the molecular mass;
- .6 the empirical formula;
- .7 the structural formula;
- .8 the classification in accordance with the UN GHS system;
- .9 the purity of the technical material and identification of impurities (chemical name and CAS-numbers, etc.); and
- .10 the identity of any stabilizers or necessary additives.

3.2.3 Relevant Chemicals

3.2.3.1 For identification of all possible Relevant Chemicals that have been produced by the use of the BWMS, and the corresponding worst case concentrations in treated and discharged ballast water, chemical analysis should be performed in conjunction with the efficacy test according to Guidelines (G8), both at Basic Approval and Final Approval.

3.2.3.2 If chemical analyses were performed during more than one test run, the number of test runs should be stated and results should be reported in the form of individual measurements for each test run. Analytical results should be provided for both treated and control samples.

3.2.3.3 If the tests regarding biological efficacy under Guidelines (G8) are performed for a shorter period than the storage period according to Procedure (G9) (i.e. 5 days), it is recommended that the applicant prepares additional treated ballast water to be kept in a separate tank for the purpose of testing according to Procedure (G9) (hereafter "5-day storage tank"). In such a case, the same BWMS, including the same test water, as the one being used during the biological efficacy test, should be used in order to simulate the ballast water.

3.2.3.4 It is recommended that the volume of the 5-day storage tank should be above 5 m³. Making use of an airtight and dark tank is recommended to prevent any unexpected photochemical reaction and vaporization of the Relevant Chemicals. The applicant should verify the representativeness of the treated water that is being kept in the 5-day storage tank in terms of water quality parameters (i.e. salinity, DOC, POC and TSS).

3.2.3.5 For identification of the worst case concentrations of Relevant Chemicals during the testing period, the applicant should collect test water samples at different times (24 and 48 hours), in addition to the sampling and analysis at 120 hours. The reason is that some Relevant Chemical concentrations may peak already at 24 or 48 hours.

3.2.3.6 It is recommended that for Basic Approval the tests should be carried out in ambient temperature conditions.

3.2.3.7 If any post-treatment, such as neutralization, is applied at discharge, sampling and analysis should be performed both before and after treatment. While making use of a small-scale BWMS, post-treatment prior to discharge should not be performed manually.

3.2.3.8 The substances listed in the Database of chemicals most commonly associated with treated ballast water (hereinafter the Database, appendix 6) should be regarded as the minimum set of Relevant Chemicals to be analysed if the BWMS uses an Active Substance that can be characterized as TRO. The detection limit of each target substance has to be chosen such that it is possible to perform a PEC/PNEC assessment (that is the detection limit cannot be higher than the respective PNEC). For other types of BWMS, the applicant should provide their own target list of Relevant Chemicals including scientific justification. In appendix 7 an overview is given of the recommended detection limits for the Relevant Chemicals listed in the Database.

3.2.3.9 For Basic Approval the minimum number of sets of samples for Relevant Chemical identification should be 18, as indicated in the table below.

Table 1: Test waters needed for Relevant Chemical identification in conjunction with the 2016 Guidelines (G8) for Basic Approval

Parameter	Requirements
Test water type (3)	seawater, brackish water and fresh water
Sample timing (3)	24, 48 and 120 hours
Treatment (2)	before and after neutralization process
Temperature (1)	ambient

Note: The numbers in brackets show the minimum number of sets of samples for each parameter.

3.2.3.10 The minimum holding time for evaluation of Guidelines (G8) efficacy, can be shorter than five days, as stated in paragraph 2.4.5 in Part 2 of the annex of the 2016 Guidelines (G8). Regardless of the length of holding time, test facilities carrying out identification of Relevant Chemicals of treated ballast water from test cycles with a holding time that is shorter than five days should ensure that a sufficient volume of treated water is reserved after the efficacy testing. The reason is that other Relevant Chemical concentrations may peak after five days.

3.2.3.11 It is recommended to identify all possible Relevant Chemicals for the Final Approval in conjunction with the cycle aimed at evaluation of regrowth during the holding time (2016 Guidelines (G8), annex, paragraph 2.6.1).

3.2.3.12 The full-scale BWMS from the land-based test set-up should be used to prepare test water for the Relevant Chemical identification. The recommendations described in paragraphs 3.2.3.6 to 3.2.3.8 should apply. For physicochemical properties of the test water refer to paragraphs 3.6.17 to 3.6.19.

3.2.3.13 For Final Approval the minimum number of sample situations for Relevant Chemical identification should be 18 as described under Basic Approval.

3.2.3.14 It is important that the applicant makes use of test water that does not contain anthropogenic pollutants.

3.2.3.15 All chemicals detected at least once in any test water, stated in paragraph 3.2.3.9 or 3.2.3.13, should be classified as Relevant Chemicals. The applicant should select the

highest concentration for each Relevant Chemical among all samples as the concentration to be taken forward to the risk assessment.

3.2.3.16 Applicants may propose two worst-case concentrations, one for occupational assessment (in a ballast water tank) and the other for environmental and general public risk assessment (in the discharged ballast water).

3.2.3.17 The applicant should provide the following information for those chemicals deemed to be Relevant Chemicals:

- .1 the Chemical (IUPAC) name;
- .2 the CAS number;
- .3 the molecular mass;
- .4 the empirical formula;
- .5 the structural formula; and
- .6 the classification in accordance with the GHS system.

3.2.4 Other Chemicals

Unless a justification can be provided for not doing so, the following information should be supplied for Other Chemicals:

- .1 the Chemical (IUPAC) name;
- .2 the CAS number;
- .3 the molecular mass;
- .4 the empirical formula;
- .5 the structural formula;
- .6 the classification in accordance with the GHS system; and
- .7 if relevant particle size distribution, if in powder and/or granular form, as smaller particles (< 10 µm) present a greater hazard in potential cases of inhalation exposure.

3.3 Data on effects on aquatic plants, invertebrates and fish, and other biota, including sensitive and representative organisms

This section describes the data on effects on aquatic plants, invertebrates and fish, and other biota, including sensitive and representative organisms specified in paragraph 4.2.1.1 of Procedure (G9).

3.3.1 General

For every Active Substance or Preparation including any of its components, data should be presented and discussed either on the basis of toxicological tests or published toxicological knowledge for each end point listed.

3.3.2 Acute aquatic toxicity

3.3.2.1 Short-term L(E)C₅₀ from freshwater or marine representatives of three taxa (algae, crustacean and fish) representing three trophic levels by internationally standardized tests, e.g. OECD guidelines 201 (Algae, Growth Inhibition Test), 202 (*Daphnia* sp. Acute Immobilization Test), 203 (Fish, Acute Toxicity Test), US EPA 850.1035 (Mysid shrimp acute toxicity test), and Mysid shrimp acute toxicity test (US EPA 850.1035) should be accepted. To reduce further any remaining uncertainty, applicants should, preferably, also submit data for two additional marine taxa (e.g. echinoderms, molluscs), ISO 10253 (Micro algae), ISO 7346-2, ISO 7346-3 (fish), and ISO 10706 (*Daphnia*).

3.3.2.2 Such acute aquatic toxicity data should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances;
- .3 Relevant Chemicals; and
- .4 discharged ballast water (G9: 5.2.3).

3.3.2.3 For algal toxicity testing, it is recommended that:

- .1 two species of algae be used in toxicity testing for marine and brackish water. The same two species should be used for Basic Approval and Final Approval;
- .2 *Skeletonema* sp.¹ be used as one of the test species for marine and brackish water. Test facilities should identify the strains of *Skeletonema* sp. used;
- .3 the second test species not be a diatom for marine and brackish water;
- .4 *Phaeodactylum tricornutum* not be used as a test species; and
- .5 for fresh water, another species rather than those described in the previous points should be selected.

3.3.3 Chronic aquatic toxicity

3.3.3.1 Long-term NOECs or EC₁₀ from three freshwater or marine species (normally algae and/or crustacea and/or fish), representing three trophic levels by internationally standardized tests, e.g. OECD guidelines 201 (algae), 210, 215, or 212 (fish), and 211 (*Daphnia*), should be acceptable. To reduce any further remaining uncertainty, applicants should preferably also submit two long-term NOECs from additional marine taxa (e.g. echinoderms, molluscs), ISO 10253 (micro algae), ISO 20666 (rotifer), and ISO 10229 (fish).

¹ Recent taxonomic reviews have resulted in new identification of *Skeletonema costatum* in *Skeletonema* sp. (refer to ISO 10253:2016).

3.3.3.2 Short-term methods by US EPA and ISO for estimating the chronic toxicity of substances and discharge provide acceptable alternatives, since the identification of the sensitive sub-lethal endpoints and vulnerable life stages is the ultimate aim of the long-term testing.

3.3.3.3 Such chronic aquatic toxicity data should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances;
- .3 Relevant Chemicals; and
- .4 discharged ballast water (fish, invertebrate, plant) (G9: 5.2.3).

3.3.3.4 For the chronic aquatic toxicity testing using discharged ballast water (paragraph 3.1.4), based on the experience gained in the evaluation process of BWMS, it has been shown that, where the BWMS uses an Active Substance that can be characterized as TRO, there is no need to evaluate the results of chronic ecotoxicity testing using discharged ballast water. This is because the levels of Relevant Chemicals, such as THMs and HAAs, have been found to remain in similar concentration ranges that lead to PEC/PNEC ratios < 1. It is also recognized that with these types of BWMS, Relevant Chemicals other than the range of well-known chlorinated and brominated low molecular weight substances are not produced. Therefore, it is considered appropriate that such BWMS could fully be evaluated at Basic Approval without the results of chronic ecotoxicity testing. It should be emphasized that this waiver would not apply to BWMSs other than those systems mentioned and this waiver does not extend to Final Approval.

3.3.4 Endocrine disruption

3.3.4.1 Regarding the risks connected to endocrine disruption, non-standardized *in vivo* as well as *in vitro* tests may be conducted as long as no internationally standardized tests are available (e.g. full-life-cycle test on fish or amphibian metamorphosis assay). When substantial evidence on such effects is available, this should be taken into account on a case-by-case basis and in the effect assessment for each compartment of relevance. If there is no indication for endocrine disruption – e.g. due to the structure of the substance or results of other available studies – these tests may be waived.

3.3.4.2 Such information on endocrine disruption should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.3.5 Sediment toxicity

3.3.5.1 Substances that are potentially capable of depositing on or adsorbing to sediments to a significant extent should be assessed for toxicity to sediment-dwelling organisms. Testing is considered relevant only if $\log K_{ow} > 3$ or if there is similar adsorption behaviour and should include a maximum of three long-term tests with species representing different living and feeding conditions, e.g. *Chironomus* sp. (OECD 218), *Lumbriculus variegatus*, including a minimum of two tests with marine species. If sediment toxicity tests are not available, toxicity

should be assessed using established internationally recognized methods such as the equilibrium partitioning method (EPM) according to the "Technical Guidance Document on Risk Assessment" (TGD) to the European Biocides Regulation 1107/2009/EC.

3.3.5.2 For substances that are persistent in marine waters or may accumulate in sediments, a specific marine sediment assessment is necessary.

3.3.5.3 Such information on sediment toxicity should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.3.6 Food web/population effects

3.3.6.1 The biomagnification and persistence in the food web should be discussed based on the results from aquatic toxicity testing, mammalian toxicity evaluation and bioaccumulation and biodegradation data.

3.3.6.2 An assessment of secondary poisoning is redundant if, for the substance of concern, the absence of bioaccumulation potential can be demonstrated ($BCF < 500$ L/kg wet weight for the whole organism at 5% fat). If not, testing should include:

- .1 one long-term NOEC based on reproduction studies with a bird species; and
- .2 two NOECs from long-term studies with two mammalian species (from section 3.4 below).

3.3.6.3 Such information related to the food web/population effects should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.4 Data on mammalian toxicity

This section describes the data on mammalian toxicity specified in paragraph 4.2.1.2 of Procedure (G9).

3.4.1 General

3.4.1.1 Information that is deemed to be scientifically not justified or technically not feasible need not be supplied. However, in such cases, a scientific justification should be submitted in order to explain why the data have not been provided. In general, testing with vertebrate animals should be avoided if another type of information is available that allows an assessment of hazards and risks to humans. Such alternative information may be obtained by validated *in vitro* methods, Quantitative Structure Activity Relationships (QSAR), and grouping or read-across with similar substances. If available, human cases or epidemiological evidence should be presented and discussed.

3.4.1.2 In general, information should be provided on the Active Substance and the Preparation, including any of its components, as appropriate. Information on Relevant Chemicals formed during or after application of the BWMS should be provided as well.

3.4.2 Acute toxicity

3.4.2.1 The acute toxicity data should be known for at least two routes of exposure, one of which should be the oral route. Active Substances or Preparations that are gases should be assessed in terms of inhalation toxicity.

3.4.2.2 The submission of dermal and/or inhalation studies instead of or in addition to oral studies may be requested depending on the physico-chemical properties of the substance, the proposed or potential application of the substance/products.

3.4.2.3 Such information on acute toxicity should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.3 Effects on skin and eye

3.4.3.1 Data should provide information on the degree and nature of skin, eye and associated mucous membrane irritation, especially with regard to the reversibility of responses. Data should provide sufficient information to assess the potential to cause skin sensitization reactions. Submitted data should concern testing with the Active Substance(s) or Preparation(s).

3.4.3.2 Data should include available information concerning a study on acute dermal irritation/corrosion and a study on acute eye irritation/corrosion. The recommended tests are OECD guidelines 404 (Acute Dermal Irritation/Corrosion) and 405 (Acute Eye Irritation/Corrosion). Results from validated *in vitro* test methods may be submitted.

3.4.3.3 The recommended test guideline for Skin Sensitization is OECD guideline 406. While the guinea-pig Maximization test is considered to be the preferred adjuvant technique in certain cases, there may be good reasons for choosing the Buehler test or OECD TG 442A the Local Lymph Node Assay (LLNA) and OECD TG 442B (Lymph Node Assay: BrdU-ELISA). However, scientific justification should be given when either of the two latter mentioned is used. Information regarding hazard classification as a sensitizer should be submitted, if available.

3.4.3.4 Such information related to the effects on skin and eyes should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.4 Repeated-dose toxicity

3.4.4.1 Repeated-dose toxicity should be assessed based on data from a sub-chronic toxicity study (90-day) in two species, one rodent and one other mammalian species, using the oral route unless another one is more appropriate.

3.4.4.2 Such information on repeated-dose toxicity should be provided for:

- .1 Preparation including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.5 Chronic toxicity

3.4.5.1 There is a need for a chronic toxicity assessment based on a study of a minimum duration of 12 months in two species – one rodent and one other mammalian species – unless a full justification demonstrates that this test is not necessary.

3.4.5.2 Any chronic study can be combined with a carcinogenicity study.

3.4.5.3 Such information on chronic toxicity should be provided for:

- .1 Preparation including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.6 Developmental and reproductive toxicity

3.4.6.1 Data should include information from:

- .1 a two-generation reproduction and fertility study (OECD guideline 416 – Two-Generation Reproduction Toxicity Study); and
- .2 a prenatal developmental toxicity (teratogenicity) study in two species (OECD guideline 414 – Prenatal Developmental Toxicity).

3.4.6.2 However, this information can be waived provided that an argument is submitted based on structural relationships with a known reproductive toxicant, the results of other toxicity studies (including toxicokinetics), and concerns for endocrine disruption. Such information on developmental and reproductive toxicity should be provided for:

- .1 Preparation including any of its components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.7 Carcinogenicity

3.4.7.1 Carcinogenicity data should be submitted based on studies performed with one rodent and one other mammalian species. In case this information is not provided, a scientific justification should be submitted.

3.4.7.2 Such information on carcinogenicity should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.8 Mutagenicity/genotoxicity

3.4.8.1 This information should address at least three tests: a bacterial gene mutation test, an *in vitro* mammalian cell cytogenicity study and an *in vitro* mammalian cell gene mutation assay. In case of positive or equivocal results, further *in vivo* mutagenicity data are necessary i.e. bone marrow assay for chromosomal damage or a micronucleus test. In case this information is not provided, a scientific justification should be submitted.

3.4.8.2 Such information on mutagenicity and genotoxicity should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.4.9 Toxicokinetics

Basic data on the toxicokinetics of Active Substances and other components of a Preparation as well as Relevant Chemicals should be included. Information on absorption, distribution, metabolism and elimination (e.g. OECD guideline 417) should be presented, if available, to allow better understanding of toxic effects and a reduction of animal testing. The potential for dermal absorption should be evaluated preferably *in vitro* or by physico-chemical data to reduce the need for any specific dermal toxicity testing.

3.5 Data on environmental fate and effect under aerobic and anaerobic conditions

This section describes the data on environmental fate and effect under aerobic and anaerobic conditions specified in paragraph 4.2.1.3 of Procedure (G9).

3.5.1 General

3.5.1.1 The rate and route of abiotic and biotic degradation of the Active Substances, components of a Preparation and Relevant Chemicals under aerobic and anaerobic conditions should be assessed, resulting in the identification of relevant metabolites in the relevant media (ballast water, marine and fresh waters) (G9: 5.3.4).

3.5.1.2 The solids-water partition coefficient (K_d) and/or organic carbon normalized distribution coefficient (K_{oc}) of the Active Substances, components of a Preparation and Relevant Chemicals should be determined (G9: 5.3.6).

3.5.1.3 The data submitted in accordance with this paragraph should clarify, in addition to the degradation of the substance, other relevant routes of dispersion in and from water, such as volatilization, adsorption, sedimentation and transformation into bound residues. Accordingly, the exposure of organisms living in water and the sediment should be established.

3.5.2 Modes of degradation (biotic; abiotic)

3.5.2.1 Testing should include:

- .1 a study on hydrolysis at pH 5, 7, and 9 under aerobic conditions according to OECD guideline 111;
- .2 a study on ready biodegradability according to OECD guideline 301 (Ready Biodegradability) or equivalent guidelines if the Active Substance is discharged only into fresh water;
- .3 a study on ready biodegradability according to OECD guideline 306 (Biodegradability in Seawater) or equivalent guidelines if the Active Substance is discharged only into marine water;
- .4 studies on ready biodegradability according to OECD guideline 301 (or equivalent guidelines) and OECD guideline 306 (or equivalent guidelines) if the Active Substance is discharged into estuarine water (e.g. inland harbour with contact to seawater); and
- .5 evaluating the fate of Active Substances and Relevant Chemicals in fresh water (PSU < 1), brackish water (PSU 10-20) and in marine water (PSU 28-36) each in a range of 0°C to 40°C (2°C to 40°C for fresh water) and a mid-range temperature of 10°C to 20°C subject to an assessment verified by the Administration.

3.5.2.2 If the Active Substance is not readily biodegradable, then the following higher Tier studies should be conducted:

- .1 a study on aerobic and anaerobic transformation in aquatic sediment systems according to OECD guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) or equivalent guidelines if $K_{oc} > 500$ L/kg, using fresh or marine water depending on the kind of aquatic ecosystem where discharge is intended. At least one system with high organic matter/nutrient content and one with low organic matter/nutrient content should be tested;
- .2 a study on aerobic transformation of low concentrations of organic contaminants according to OECD guideline 309 (Aerobic Mineralization in Surface Water – Simulation Biodegradation Test) or equivalent guidelines, using fresh or marine water depending on the kind of aquatic ecosystem where discharge is intended; and
- .3 where relevant, a study on photo-transformation in water, e.g. US EPA OPPTS 835.2210 (1998) and/or OECD Guidance document on photo-transformation in water (1997).

3.5.2.3 Such information on the modes of degradation should be provided for:

- .1 Active Substances;
- .2 Other Chemicals; and
- .3 Relevant Chemicals.

3.5.3 *Persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters)*

3.5.3.1 The route of degradation in the higher Tier simulation tests specified under section 3.5.2 of this Methodology should be characterized based on a mass balance, including mineralization and formation of bound residues. Reaction or transformation products formed that may be considered as Relevant Chemicals should be identified.

3.5.3.2 Such information on persistence and metabolites should be provided for:

- .1 Active Substances;
- .2 Other Chemicals; and
- .3 Relevant Chemicals.

3.5.4 *Bioaccumulation, partition coefficient, octanol/water partition coefficient*

3.5.4.1 Data should include:

- .1 information on bioconcentration and biomagnification, which have already been detailed earlier in this Methodology;
- .2 a study into the log P_{ow} according to OECD guideline 107 (Partition Coefficient (n-octanol/water): Shake Flask Method), OECD guideline 117 (Partition coefficient – n-octanol/water HPLC Method) or equivalent test guidelines. For very hydrophobic compounds, a slow stirring method is appropriate (e.g. OECD 123 (Partition coefficient – Slow Stirring Method)); and
- .3 the partition coefficient between solids and liquids should be determined, e.g. according to EU Technical Guidance Document on Risk Assessment (2003) for at least three inocula, including fresh water sediment, marine sediment, and particulate matter (sludge) (OECD 106). If no measured data are available for a specific adsorbing material, it is assumed that all adsorption can be related to the organic matter of the medium, viz. standardization to K_{oc} . This is only valid for non-ionic substances. For ionic substances, the K_p values and the test characteristics (% clay, CEC, % o.c., pH) should be reported.

3.5.4.2 Such information on bioaccumulation and partition coefficients should be provided for:

- .1 Active Substances;
- .2 Other Chemicals; and
- .3 Relevant Chemicals.

3.5.5 Bioavailability/biomagnification/bioconcentration

3.5.5.1 If $\log P_{ow} > 3$, testing of the bioaccumulation potential should be considered taking into account the following points:

- .1 one bioconcentration factor (BCF) determined in a bioconcentration study (at two dosing levels) with fish (e.g. OECD 305) or bivalves. The BCF should be based on uptake/elimination kinetics (k_1/k_2). The half-life for elimination should be reported. Fat content in marine fish typically ranges between 0.5 and 15% of the whole body weight. BCF should be normalized to 5% fat. The BCF, could e.g. be calculated with formulae 74 and 75 of the TGD (see 3.3.5) using the $\log K_{ow}$;
- .2 the biomagnification and persistence in the food web should be discussed based on the results from aquatic toxicity testing, mammalian toxicity evaluation and bioaccumulation and biodegradation data; and
- .3 there are no data provisions on bioavailability since it is considered that the bioavailability in the toxicity test systems is equivalent to the conditions under assessment. If the bioavailability of the Active Substance or Relevant Chemical in the discharge or the receiving environment is to be assessed, consequently, the bioavailability in the toxicity testing is to be reconsidered.

3.5.5.2 Such information on bioavailability/biomagnification/bioconcentration should be provided for:

- .1 Active Substances;
- .2 Other Chemicals; and
- .3 Relevant Chemicals.

3.5.6 Reaction with organic matter

3.5.6.1 The reaction of radicals produced by the action of Active Substances with organic matter should be addressed qualitatively as to identify products of concern to the environment and, where possible, quantitatively as to identify environmental concentrations. In cases where this information is not available, a scientific justification should be submitted.

3.5.6.2 Radical producing chemicals are capable of forming halogenated (chlorinated, brominated) hydrocarbons that may be of concern to environment or human health, in the presence of organic matter. For these substances, the freely and otherwise reasonably available information should be presented and discussed in relation to the proposed manner of application, since they are subject to the decision making criteria.

3.5.6.3 Such information on the reaction with organic matter should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.5.7 Potential physical effects on wildlife and benthic habitats

3.5.7.1 Data requirements consisting of physical/chemical properties are also required under other headings. Further guidance can be found in the MEPC-approved hazard evaluation procedure published as GESAMP Reports and Studies No.64. In cases where this information is not available, a scientific justification should be submitted.

3.5.7.2 Such data on the potential physical effects on wildlife and benthic habitats should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances;
- .3 Relevant Chemicals; and
- .4 discharged ballast water.

3.5.8 Potential residues in seafood

3.5.8.1 As appropriate, data should be submitted to assess the potential presence of residues of the Active Substance in seafood, the possible impact on consumer safety, and the level of residues that may be tolerated in seafood. Any available monitoring data on residues of the substance in seafood should be submitted.

3.5.8.2 Such data on potential residues in seafood should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.5.9 Any known interactive effects

3.5.9.1 Any knowledge (or absence of this knowledge) on interactive effects of the substances identified with the ballast water, with other Preparations to be used in ballast water, with other physical or chemical management of the ballast water, or with the receiving environment, should be reported. In cases where this information is not available, a scientific justification should be submitted.

3.5.9.2 Such information on known interactive effects should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.6 Physical and chemical properties for the Active Substances and Preparations and treated ballast water, if applicable

This section describes the physical and chemical properties specified in paragraph 4.2.1.4 of Procedure (G9).

3.6.1 General

Data should be submitted for the Active Substances, Preparations including any of its components, the treated ballast water on board and the Relevant Chemicals to allow for the identification of hazards to the crew, the ship and the environment.

3.6.2 Melting point

Data on the melting point should be provided for Active Substances.

3.6.3 Boiling point

Data on the boiling point should be provided for Active Substances.

3.6.4 Flammability (flash point)

Data on the flash point should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.5 Density (relative density)

Data on the density should be provided for:

- .1 Active Substances; and
- .2 discharged ballast water.

3.6.6 Vapour pressure, vapour density

Data on the vapour pressure and vapour density should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.7 Water solubility/dissociation constant

Data on the water solubility and dissociation constant should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.8 Oxidation/reduction potential

Data on the oxidation/reduction potentials should be provided for:

- .1 Preparations including any of their components;
- .2 Active Substances;

- .3 Relevant Chemicals; and
- .4 discharged ballast water.

3.6.9 Corrosivity and chemical influence on the materials or equipment of normal ship construction

3.6.9.1 For the dataset, at least the corrosivity and chemical influence to low carbon steel and other metals (e.g. stainless steel, Cu alloys and Ni alloys) and non-metals (e.g. gasket, coatings and seal materials) as may be found in a ship's seawater piping, fittings and structures that will be exposed to the Active Substance and Relevant Chemicals should be provided.

Data required for Basic Approval

3.6.9.2 For Basic Approval it is sufficient that the data from publicly available sources are submitted.

Data required for Final Approval

3.6.9.3 For Final Approval evaluation, the risk to the Safety of Ships should be assessed (see chapter 7.1).

3.6.10 Auto-ignition temperature

Data on the auto-ignition temperature should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.11 Explosive properties

Data on the explosive properties should be provided for:

- .1 Active Substance; and
- .2 Relevant Chemicals.

3.6.12 Oxidizing properties

Data on the oxidizing properties should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.13 Surface tension

Data on the surface tension should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.14 Viscosity

Data on the viscosity should be provided for:

- .1 Active Substances; and
- .2 Relevant Chemicals.

3.6.15 Thermal stability and identity of relevant breakdown products

Data on thermal stability and identity of relevant breakdown products should be provided for Active Substances.

3.6.16 Reactivity towards materials

Data on the reactivity towards materials, e.g. piping, gaskets and containers, should be provided for:

- .1 Preparations;
- .2 Active Substances; and
- .3 Relevant Chemicals.

3.6.17 pH

Since the pH of test waters can influence the formation of disinfection by-products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of the pH. Data on the pH should be provided for uptake water and discharged water.

3.6.18 Salinity

Since the salinity of test waters can influence the formation of disinfection by products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of the salinity. If water of different sources was mixed or any additives were added to natural test water to achieve the given salinity, this should be specified. Data on the salinity should be provided for uptake water and discharged water.

3.6.19 TOC, DOC, percentage of particulate matter

Since the organic carbon and particulate matter content of test waters can influence the formation of disinfection by-products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of TOC, DOC, and total suspended solids (TSS). Data on the TOC, DOC and percentage of particulate matter should be provided for uptake water and discharged water. If any additives were added to natural test water, the information submitted under Procedure (G9) should include all details regarding the selection and validation of additives as specified in paragraph 2.4.21 of the annex to the 2016 Guidelines (G8). In particular, any information on the results of measuring Specific UV Absorbance at 254 nm should be provided.

3.6.20 Other known relevant physical or chemical hazards

Data on the any other known relevant physical or chemical hazards should be provided for:

- .1 Active Substances;
- .2 Relevant Chemicals; and
- .3 discharged ballast water.

3.7 Analytical methods at environmentally relevant concentrations

This section describes the analytical methods at environmentally relevant concentrations, stated in paragraphs 4.2.1.5 and 5.3.15 of Procedure (G9).

3.7.1 Recognizing that some methods may only cover a range of chemicals, e.g. TRO, analytical methods at environmentally relevant concentrations should be provided for:

- .1 Active Substance; and
- .2 Relevant Chemicals.

3.7.2 If the BWMS needs any monitoring system for the Active Substance, the analytical methods and product name of the monitoring equipment should be provided.

4 USE OF THE ACTIVE SUBSTANCE OR THE PREPARATION

4.1 The manner of application

This section describes the manner of application specified in paragraph 4.2.6 and sections 7.1 and 7.3 of Procedure (G9).

4.1.1 The proposal for Basic Approval and Final Approval should include the intended minimum and maximum dosage and maximum allowable discharge concentrations of Active Substances, if applicable.

4.1.2 The proposal should also include the manner of application of the Active Substance or the Preparation by the BWMS to ensure the dosage and concentrations mentioned in paragraph 4.1.1 above.

4.1.3 For Basic Approval submissions, the applicant should prepare all the information on the manner of application after receiving the results on 'Readiness evaluation (refer to paragraph 1.5 of Part 1 of the annex to the 2016 Guidelines (G8))' from the relevant Administration (refer to paragraph 8.1.2.2 of Procedure (G9)). Furthermore, the application dossier should include information on the major components, as identified in paragraph 3.9 of the 2016 Guidelines (G8), in the proposed BWMS. This is understood to mean that the neutralization process to ensure the MADC is not such a component, because it does not directly affect the ability of the BWMS to meet the ballast water performance standard described in regulation D-2 of the Convention.

4.1.4 The description of the manner of application should include a control scheme showing that the Active Substance dose and the MADC can be maintained effectively in the BWMS at all times, in particular at the beginning of discharge. An overdose against stoichiometric demand is needed in this regard.

4.1.5 MADC should be ensured even under extreme conditions of SDLs (such as lower temperature) (refer to paragraph 2.5.1 of Part 2 of the annex to the 2016 Guidelines (G8)). Under extreme low temperatures an additional overdose of the neutralizer is needed.

4.1.6 To verify the reliability and completion of the control scheme of the neutralizer together with Active Substance monitoring, it is recommended that at Basic Approval applicants should perform a simulation of discharge immediately after treatment (when the maximum amount of neutralizer will be needed). The raw monitored data shown below should be provided in the application:

- .1 Active Substance concentration at, prior to and after the neutralization process;
- .2 calculated overdose ratio against the stoichiometric demand;
- .3 dose of the neutralization; and
- .4 measurement results on Active Substance and on the residual concentration of the neutralizer discharged by using manual methods.

4.1.7 In relation to section 7 of Procedure (G9), the dossier should contain the necessary data addressing the following items:

- .1 the technical manual or instructions by the Administration, including the product specification, process description, operational instructions, details of the major components and materials used, technical installation specifications, system limitations, and routine maintenance should be provided. The technical manual should also clearly specify the dosage to be added to ballast water and the maximum discharge concentration of the Active Substance therein;
- .2 recommended methods and precautions concerning handling, use, storage, and transport;
- .3 procedures to be followed in case of fire, and the nature of reaction products, combustion gases, etc.;
- .4 measures to be taken in emergency situations;
- .5 an indication of the possibility of destruction or decontamination following emergency release in the marine environment;
- .6 procedures for the management of wastes that may be generated during the operation of the BWMS;
- .7 the manner or procedure of reuse or recycling of Active Substances or Preparations, if applicable;
- .8 the possibility of neutralization;
- .9 conditions for controlled discharge;

- .10 minimum retention time² of treated water on board before discharge (see paragraph 5.2.7 of Procedure (G9));
- .11 the amount of substance on board ship; and
- .12 if an Active Substance is used that is convertible to TRO, the dose should be expressed as mg/L as Cl₂.

4.1.8 The discharge concentration of Active Substance should be continuously monitored in an appropriate manner at all times. The monitoring point of Active Substance should be positioned prior to the sampling facility, as specified in the 2016 Guidelines (G8). If the sampling facility is placed prior to the monitoring point of the Active Substance, the MADC may not yet have been reached, due to insufficient chemical reaction time.

4.1.9 Appropriate risk management measures (e.g. for neutralization of the Active Substance in case of emergency or if PEC/PNEC at discharge > 1) should be described. These management measures are an integral part of the ballast water management system and should be evaluated in the assessment.

5 RISK CHARACTERIZATION – HUMAN HEALTH

This section describes the risk characterization on human health specified in paragraphs 5.3.12, 5.3.13 and section 6.3 of Procedure (G9).

5.1 In risk characterization for human health, the procedure is to compare the exposure levels to which the target groups are exposed or likely to be exposed with those levels at which no toxic effects from the chemicals are expected to occur.

5.2 A quantitative risk assessment is an iterative process and normally includes four steps:

- .1 **Hazard identification** – what are the substances of concern and what are their effects?
- .2 **Dose (concentration)** – response (effect) relation – what is the relationship between the dose and the severity or the frequency of the effect?
- .3 **Exposure assessment** – what is the intensity, and the duration or frequency of exposure to an agent?
- .4 **Risk characterization** – how to quantify the risk from the above data?

5.3 In assessing an acceptable level of a particular substance, the procedure usually follows moving from animal experiments or preferably human data (e.g. epidemiological studies) giving a No Observed Adverse Effect Level (NOAEL) or a Lowest Observed Adverse Effect Level (LOAEL) to derive an exposure limit above, which humans should not be exposed to (Derived No Effect Level – DNELs). Taking into account the critical health effect that can be exerted by a threshold mode of action, the lowest DNEL for each exposure route should be established by dividing the value of the critical dose descriptor, e.g. N(L)OAEL, by an assessment factor (AF) to allow for extrapolation from experimental data to real human exposure situations. Comparison of this exposure limit with a measured or estimated exposure level is then used to judge whether the situation is satisfactory or whether risk management measures are required.

² The original wording used in paragraph 5.2.7 of Procedure (G9) is "holding time". However, since the term "holding time" is also being used under another definition in the 2016 Guidelines (G8), this term has been given another designation (retention time) in this version of the Methodology.

5.4 Based on the most suitable N(L)OAEL, a DNEL for further risk assessment is derived. Generally, the DNEL is determined by applying an Assessment Factor (AF) according to the formula:

$$DNEL = \frac{N(L)OAEL}{AF}$$

5.5 Two groups of potentially exposed persons are distinguished as follows:

- .1 workers (crew and port State control officers); and
- .2 general public.

5.6 Particularly in case of occupational exposure, it is of primary importance to fully understand the processes and unit operations in which exposure occurs, and the actual activities resulting in exposure (potentially exposed individuals, frequency and duration of the routes of concern, what personal protective equipment and control measures are used to reduce or mitigate exposure, and how effective they are).

5.7 It is useful to conduct an assessment using "worst-case" assumptions. If this indicates a risk of no concern, the assessment needs no further refinement.

5.8 Exposure should always be assessed in the first instance for the unprotected worker and, if appropriate, a second assessment, should be made taking personal protective equipment (PPE) into account.

5.9 In the risk characterization, these estimates are combined with the results of the effects assessment and conclusions are drawn whether or not there is a concern for any scenarios assessed (Risk Characterization Ratio (RCR) = Exposure/DNEL).

5.10 When a risk assessment results in the conclusion that there is an unacceptable risk (RCR > 1), a second Tier assessment should be performed by considering specific risk control measures in order to lower this risk to acceptable levels (protective clothing, respirators and self-contained breathing apparatus, crew training, good operational practices, etc.).

5.11 The effect assessment of the Active Substances, Preparations and Relevant Chemicals should include a screening on carcinogenic, mutagenic and endocrine disruptive properties, taking into account available information. There is no requirement for additional testing. If the screening results give rise to concerns, this should give rise to a further assessment.

5.12 As a general rule, exposure in the workplace must be avoided or minimized as far as technically feasible. In addition, a risk for the general public from secondary exposure to a non-threshold carcinogenic substance is also unacceptable.

5.13 Carcinogens can have a threshold or non-threshold mode of action. When it comes to threshold carcinogens, these can be assessed by using a Derived No-Effect Level (DNEL) approach, however in the case of the non-threshold carcinogens a different approach to risk assessment is recommended. In these cases, a Derived Minimal Effect Level (DMEL) should be determined.

5.14 Cancer risk levels between 10^{-4} to 10^{-6} are normally seen as indicative tolerable risk levels when setting DMELs. Where these values are available from internationally recognized bodies, they can be used to set DMELs for risk assessment purposes.

5.15 The assessment of the carcinogenicity, mutagenicity and reproductive toxicity properties of the Active Substance and the Relevant Chemicals takes place as part of the PBT assessment (see paragraph 6.1 of this Methodology).

5.16 Forty-one chemicals most commonly associated with treated ballast water (see appendix 6) have been already assessed by the GESAMP-BWWG. The DNEL and DMEL values can be found online in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water (<https://gisis.imo.org/>).

5.17 The human risk assessment approach is described in more detail in appendix 4.

6 RISK CHARACTERIZATION – ENVIRONMENT

The environmental risk assessment approach is set up according to the following principles:

- .1 **Hazard identification** – what are the substances of concern and what are their effects?
- .2 **Dose (concentration)** – response (effect) relation – what is the relationship between the dose and the severity or the frequency of the effect?
- .3 **Exposure assessment** – what is the intensity, and the duration or frequency of exposure to an agent?
- .4 **Risk characterization** – how to quantify the risk from the above data?

6.1 Screening for persistence, bioaccumulation and toxicity

This section describes the screening for persistence, bioaccumulation and toxicity specified in paragraphs 5.3.12, 5.3.13 and section 6.3 of Procedure (G9).

6.1.1 Persistence

6.1.1.1 Persistence is preferably assessed in simulation test systems to determine the half-life under relevant conditions. Biodegradation screening tests may be used to show that the substances are readily biodegradable. The determination of the half-life should include assessment of Relevant Chemicals.

6.1.1.2 For persistence and degradation data, see sections 3.5.2 and 3.5.4 of this Methodology.

6.1.2 Bioaccumulation

6.1.2.1 The assessment of the bioaccumulation potential should use measured bioconcentration factors in marine (or freshwater organisms). Where test results are not available, the assessment of the bioaccumulation potential of an organic substance may be based on the $\log P_{ow}$.

6.1.2.2 For bioaccumulation data, see sections 3.3.6 and 3.5.3 of this Methodology.

6.1.3 Toxicity tests

6.1.3.1 Acute and/or chronic ecotoxicity data, ideally covering the sensitive life stages, should be used for the assessment of the toxicity criterion.

6.1.3.2 For ecotoxicity data, see section 3.3 of this Methodology.

6.1.3.3 It is necessary to consider, whether an effect assessment based on tests in freshwater species offers sufficient certainty that sensitive marine species will be covered by any risk assessment.

6.1.4 Does the Active Substance and/or Relevant Chemicals meet all three criteria for PBT?

Table 2: Criteria for identification of PBT Substances

Criterion	PBT criteria
Persistence	Half-life: > 60 days in marine water, or > 40 days in fresh water,* or > 180 days in marine sediments, or > 120 days in freshwater sediments
Bioaccumulation	Experimentally determined BCF > 2,000, or if no experimental BCF has been determined, $\log P_{ow} \geq 3$
Toxicity (environment) Toxicity (human health, CMR)	Chronic NOEC < 0.01 mg/L carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A, 1B or 2) According to GHS classification.

* For the purpose of marine environmental risk assessment, half-life data in fresh water and freshwater sediment can be overruled by data obtained under marine conditions.
See also table 1 in Procedure (G9).

6.1.4.1 Active Substances, Relevant Chemicals or Preparations identified as PBT substances will not be recommended for approval in accordance with paragraph 6.4.1 of Procedure (G9).

6.1.4.2 The CMR assessment is based on new regulations in several jurisdictions as part of the PBT assessment. This is a new development in the risk assessment methods as applied by jurisdictions to register pesticides, biocides and industrial chemicals. Therefore, it is considered appropriate that including CMR into the methodology of the evaluation of BWMS is necessary to be in line with these jurisdictions.

6.1.4.3 Based on the appropriate toxicological studies on carcinogenicity, mutagenicity and reproductive toxicity, the Relevant Chemicals should be scored on these three items, using 1 (one) if the substance showed the hazard under consideration and 0 (zero) if the substance did not show the hazard under consideration.

6.1.4.4 For any Relevant Chemical showing at least one of the hazards, carcinogenicity, mutagenicity or reproductive toxicity, exposure should be avoided or relevant risk mitigation measures should be proposed to minimize exposure to an acceptable level using appropriate extrapolation methods.

6.2 Evaluation of the discharged ballast water

This section describes the evaluation of the discharged ballast water specified in paragraphs 5.2 and 8.2.2 of Procedure (G9).

6.2.1 General

6.2.1.1 The advantage of toxicity testing on the ballast water discharge is that it integrates and addresses the potential aquatic toxicity of the Active Substance, Preparation including any of its components and Relevant Chemicals formed during and after application of the BWMS.

6.2.1.2 For ecotoxicity data, see sections 3.3.2 and 3.3.3 of this Methodology.

6.2.1.3 The validity criteria should be clearly established during planning and the results of the validation should be stated in the report.

6.2.1.4 For the growth inhibition test using algae, the following three criteria should be taken into account:

- .1 The biomass should increase exponentially by a factor of at least 16 within the 72-hour test period. This corresponds to a specific growth rate of 0.92 d^{-1} .
- .2 The mean coefficient of variation (mCV) for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) must not exceed 35% in accordance with OECD 201, even if ISO 10253 is used.
- .3 The coefficient of variation of average specific growth rates in the replicates during the whole test period must not exceed 7% for ISO10253 or 10% for OECD 201.

6.2.2 Basic Approval

6.2.2.1 Testing should be performed in the laboratory using a sample prepared by simulation of the BWMS (G9: 5.2.1).

6.2.2.2 It is required that the residual toxicity of treated ballast water is assessed in marine, brackish and fresh water to provide certainty as to acceptability when the treated water is discharged because discharge of ballast water may occur in all three salinities and, therefore, risk assessment in three salinities is needed. Any limitations as to environmental acceptability should be clearly indicated in the submission.

6.2.2.3 The sampled water for Relevant Chemical identification, described in paragraph 3.2.3, should be used for the ecotoxicity testing at Basic Approval. The applicant does not need to make use of the test water that has been sampled prior to neutralization.

6.2.2.4 It is recommended to use water from the 5-day storage tank for the WET tests.

Table 3: Test waters needed for laboratory ecotoxicity testing in conjunction with the 2016 Guidelines (G8) for Basic Approval

Parameter	Requirements
Test water type (3)	seawater, brackish water and fresh water
Sample timing (1)	120 hours
Treatment (1)	after neutralization process
Temperature (1)	ambient

Note: The numbers in brackets show the minimum number of sets of samples for each parameter.

6.2.3 Final Approval

6.2.3.1 Toxicity tests (Whole Effluent Toxicity test) with samples of ballast water treated with the BWMS from the land-based test set-up should be conducted (G9: 5.2.1.2, 5.2.2 and 5.2.3).

6.2.3.2 The full-scale BWMS from the land-based test set-up should be used to prepare test water for WET testing. The recommendations described in paragraphs 6.2.2.3 to 6.2.2.4 should apply.

6.2.3.3 From a pragmatic standpoint, the submission of WET tests on growth inhibition using algae (plants), and acute toxicity for invertebrates and fish, would provide adequate safeguards for the environment.

6.2.4 Comparison of effect assessment with discharge toxicity

The results of the effect assessment of the substances that are likely to be present in the treated ballast water at discharge are compared to the results of the toxicity testing of the treated ballast water. Any unpredicted results (e.g. lack of toxicity or unexpected toxicity in the treated ballast water at discharge) should give rise to a further elaboration on the effect assessment (G9: 5.3.14).

6.2.5 Determination of retention time³

6.2.5.1 The test data should be used to determine the no adverse-effect concentration upon discharge, i.e. the necessary dilution of the treated ballast water. The dosage rates and transformation half-life, system parameters and toxicity should be used to determine the retention time needed to hold the treated ballast water before discharge (G9: 5.2.7). An indication of the uncertainty of the retention time to protect environmental acceptability should be given, taking into account different variables (e.g. temperature, salinity, DOC/POC/TSS concentration and any SDL of the BWMS).

6.2.5.2 In general, for BWMS with a neutralization process where the MADC of Active Substance at any discharge can be ensured, no minimum retention time is required. For other BWMSs, the GESAMP-BWWG should determine a minimum retention time to ensure the environmental acceptability. It should be noted that if the retention time determined in this paragraph is longer than the minimum holding time at determined according to paragraph 2.4.5 in part 2 of the annex to the 2016 Guidelines (G8) for attaining biological efficacy, the BWMS should not discharge any treated ballast water before the end of the retention time in accordance with this paragraph (a clarification regarding the definition of the term "retention time" is given in the table below).

³ The original wording used in paragraph 5.2.7 of Procedure (G9) is "holding time". However, since the term "holding time" is also being used under another definition in the 2016 Guidelines (G8), this term has been given another designation (retention time) in this version of the Methodology.

Table 4: Clarification of the terms "tank holding time", "storage period" and "retention time"

	Terminology	Meaning
G8	Tank holding time	The total time during which treated ballast water will be held in a simulated ballast water tank for the purpose of evaluating biological efficacy
	Minimum tank holding time	The amount of time needed to hold the treated ballast water in the BW tank to achieve D-2 standard (refer to paragraph 2.4.5 in part 2 of the annex to the 2016 Guidelines (G8))
G9	Storage period	The total time during which treated ballast water will be held in a simulated ballast water tank for the purpose of identifying the worst-case concentrations of Relevant Chemicals in treated and discharged ballast water
	Retention time	The amount of time needed to hold the treated ballast water in the BW tank before discharge

6.3 Risk characterization and analysis

This section describes the risk characterization and analysis specified in paragraphs 5.3.1 to 5.3.14 and paragraphs 6.4.2 to 6.4.4 of Procedure (G9).

6.3.1 Prediction of discharge and environmental concentrations

6.3.1.1 Based on measured data of the Active Substances, Preparations including any of its components, and Relevant Chemicals, the worst-case concentration at discharge should be established.

6.3.1.2 Environmental concentrations after discharge of treated ballast water under controlled conditions during development and type approval tests should be estimated and provided in the application dossier for Basic Approval.

6.3.1.3 Environmental concentrations, under suitable emission scenarios developed describing typical full-scale use and discharge situations, should also be estimated for treated ballast water, Active Substances, Relevant Chemicals and other components of Preparations, as appropriate.

6.3.1.4 MAMPEC-BW, latest available version, should be used to calculate PEC values with its standard settings. All information about MAMPEC-BW can be found through the information given in appendix 5.

6.3.1.5 The MAMPEC-BW, latest available version, will calculate the stationary concentration in the harbour after discharge of ballast water. To account for local effects, near the ship at discharge, the local concentration at near ship is estimated using the formulae suggested in Zipperle et al., 2011 (Zipperle, A., Gils J. van, Heise S., Hattum B. van, Guidance for a harmonized Emission Scenario Document (ESD) on Ballast Water discharge, 2011):

$$C_{\max} = \frac{C_{BW} + (S - 1) \cdot C_{\text{mean}}}{S}$$

where:

$C_{\max}$	=	the maximum concentration due to near ship exposure (µg/L)
C_{BW}	=	the concentration found in the discharged ballast water (µg/L)
S	=	dilution factor based on sensitivity analysis with a higher Tier model, default value = 5
C_{mean}	=	the mean concentration as output from MAMPEC-BW

6.3.1.6 The concentration calculated with this formula will be compared to acute toxicity data for the Active Substances and Relevant Chemicals to evaluate the short-term effects on aquatic organisms.

6.3.1.7 It is further recommended that the effect of cold and/or fresh water to the natural degradation process of the Active Substances and Relevant Chemicals is considered.

6.3.1.8 It is not necessary to undertake further assessment of temperature effects on the degradation rate of Active Substances and Relevant Chemicals if the PEC/PNEC ratio is found to be acceptable assuming no degradation.

6.3.1.9 If the PEC/PNEC ratio is not found to be acceptable assuming no degradation, further analysis is required. In the literature, the degradation rate of the Active Substance and Relevant Chemicals is typically determined at mid-range temperatures of 10°C to 20°C. Because the degradation rate is slower in cold environments, the risk should be assessed at a temperature of 0°C (2°C for fresh water).

6.3.1.10 Extrapolation of the temperature effect for a difference less than or equal to 10°C is generally scientifically accepted when assessed by application the Q10 approach according to the Arrhenius equation. Extrapolation of the temperature effect for a difference greater than 10°C should also be undertaken as a best estimate using the Arrhenius equation.

6.3.2 Effects assessment

6.3.2.1 The effect assessment of the Active Substances, Preparations including any of their components, and Relevant Chemicals is initially based on a data-set of acute and/or chronic ecotoxicity data for aquatic organisms, being primary producers (e.g. algae), consumers (e.g. crustacean), and predators (e.g. fish) (G9: 5.3.9).

6.3.2.2 An effect assessment could also be prepared on secondary poisoning to mammalian and avian top-predators where relevant. Only toxicity studies reporting on dietary and oral exposure are relevant, as the pathway for secondary poisoning refers exclusively to the uptake of chemicals through the food chain. It might be necessary to extrapolate threshold levels for marine species from terrestrial species assuming there are interspecies correlations between laboratory bird species and marine predatory bird species and between laboratory mammals (e.g. rats) and the considerably larger marine predatory mammals. An assessment of secondary poisoning is redundant if the substance of concern demonstrates a lack of bioaccumulation potential (e.g. BCF < 500 L/kg wet weight for the whole organism at 5% fat) (G9: 5.3.10).

6.3.2.3 An assessment of effects to sediment species should be conducted unless the potential of the substance of concern to partition into the sediment is low (e.g. $K_{oc} < 500 \text{ L/kg}$) (G9: 5.3.11).

6.3.2.4 The effect assessment of the Active Substances, Preparations and Relevant Chemicals, taking the indicated information into account, should be based on internationally recognized guidance (G9: 5.3.13).

6.3.3 Effects on aquatic organisms

6.3.3.1 For assessment of effects to the aquatic environment, appropriate Predicted No-Effect Concentrations (PNEC) should be derived. A PNEC is typically derived at a level that, when not exceeded, protects the aquatic ecosystem against toxic effects of long-term exposures. However, for situations where only short-term exposures are expected, an additional PNEC for short-term (or near ship) exposure may be useful. PNEC values are normally derived from acute and/or chronic aquatic toxicity results for relevant aquatic species by dividing the lowest available effect concentration with an appropriate assessment factor. For the aquatic effect assessment, the assessment factors, given in Table 5, should provide guidance although these may be altered on a case-by-case basis based on expert judgment. In cases where a comprehensive data-set is available, the PNEC may be derived with a mathematical model of the sensitivity distribution among species.

Table 5: Assignment of Assessment Factors (AF) used for deriving PNEC values

Data-set	Assessment Factor		Rule number
	PNEC general	PNEC near ship	
Lowest* short-term L(E)C ₅₀ from freshwater or marine species representing one or two trophic levels	10,000	1,000	1
Lowest* short-term L(E)C ₅₀ from three freshwater or marine species representing three trophic levels	1,000	100	2
Lowest* short-term L(E)C ₅₀ from three freshwater or marine species representing three trophic levels + at least two short-term L(E)C ₅₀ from additional marine taxonomic groups	100	10	3
Lowest* chronic NOEC from one freshwater or marine species representing one trophic level, but not including micro-algae	100		4
Lowest* chronic NOEC from two freshwater or marine species representing two trophic levels, which may include micro-algae	50		5
Lowest* chronic NOEC from three freshwater or marine species representing three trophic levels, which may include micro-algae	10		6

- Notes:***
- .1 If the lowest value is not used, based on expert judgement, a scientific rationale should be submitted.
 - .2 AF assigned to chronic data may be lowered if sufficient (for instance three different trophic levels) acute values are available.
 - .3 See section 3.3.3 of this Methodology for information on suitable chronic testing.

- .4 For the determination of the assessment factor for the NOEC values in Table 5 micro-algae have been excluded because of the short duration of the chronic test for algae (4 days) and, therefore, it is not considered by some jurisdictions as a real chronic test.
- .5 The rule numbers are used in the GESAMP-BWWG Database containing the 41 substances as indicated in appendix 6 to this Methodology to determine the PNEC taking into account the indicated Assessment Factor (see paragraph 6.3.3.7).

6.3.3.2 In some cases, the $PNEC_{\text{near ship}}$ may be substantially lower than the $PNEC_{\text{harbour}}$ due to insufficient availability of acute ecotoxicity data. In such cases, the $PNEC_{\text{near ship}}$ should be set equal to the $PNEC_{\text{harbour}}$. This would still be considered a worst-case PNEC.

6.3.3.3 PNEC values should be derived for any substances that may be found in treated ballast water in concentrations that may be of concern for the aquatic environment. The relevance of deriving PNEC values for Active Substances, any other components of Preparations and/or Relevant Chemicals should thus be considered.

6.3.3.4 Currently there is no compelling physiological or empirical proof that marine organisms are more sensitive than freshwater organisms or vice versa and, therefore, an additional assessment factor is not applied. Should this, however, be demonstrated for the substance under consideration, an additional assessment factor should be taken into account.

6.3.3.5 Where data are available for additional marine taxa, for example, rotifers, echinoderms or molluscs, the uncertainties in the extrapolation are reduced and the magnitude of the assessment factor applied to a data-set can be lowered.

6.3.3.6 Because sediment constitutes an important compartment of ecosystems, it may be important to perform an effects assessment for the sediment compartment for those substances that are likely to transfer substantially into the sediment.

6.3.3.7 Forty-one chemicals most commonly associated with treated ballast water (see appendix 6) have been already assessed by the GESAMP-BWWG. The PNEC values can be found in the online GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water (<https://gis.imo.org/>).

6.3.4 Comparison of effect assessment with discharge toxicity

The results of the effect assessment of the substances that are likely to be present in the treated ballast water at discharge are compared to the results of the toxicity testing of the treated ballast water. Any unpredicted results (e.g. lack of toxicity or unexpected toxicity in the treated ballast water at discharge) should give rise to a further elaboration on the effect assessment (G9: 5.3.14).

7 RISK ASSESSMENT

7.1 Risk to safety of ship

This section describes the risk to safety of ship specified in section 6.3 and chapter 7 of Procedure (G9).

7.1.1 The potential risk to the safety of the ship raised by the operation of the BWMS should be assessed, taking into account the identified risk mitigation measures to be applied and any relevant legislative requirements such as provided in SOLAS and MARPOL. Potential risks to the ship may include, inter alia:

- .1 increased corrosion;

- .2 fire and explosion; and
- .3 storage and handling of the substances.

7.1.2 The operations manual provided for the BWMS should include suitable and sufficient information regarding the safe operation of the system under normal use. If there are operational errors then the control system should give appropriate alarms alerting the crew to instigate corrective actions or shutdown procedures. Potential hazards arising from operational misuse of the BWMS are not evaluated.

7.1.3 Increased corrosion

7.1.3.1 The introduction of Active Substances into ship operating equipment and ballast tanks may give rise to detrimental corrosion effects. In paragraphs 7.1.3.2 to 7.1.3.7 the criteria are stated for instigating a prescribed corrosion assessment along with the standard test procedure to be adopted and the resultant minimum acceptable values.

7.1.3.2 The BWMS that make use of an Active Substance (such as hypochlorite electrolysis, chlorine dioxide, sodium hypochlorite, peroxyacetic acid or ozone) may have a direct effect on organic material like epoxy tank coatings. Depending on the dose and degradation rate of Active Substance there could be an impact on the coating system. For a BWMS with a TRO dose ≥ 10 mg/L, expressed as Cl_2 mg/L, the compatibility with coating systems is to be validated by the testing described in paragraphs 7.1.3.3 and 7.1.3.4.

7.1.3.3 Testing should be conducted in accordance with the NACE TM0112-2012 Standard Test Method with two series of test panels and the coating should be applied in accordance with Table 1 of the *Performance standard for protective coatings for dedicated seawater ballast tanks in all types of ships and double-side skin spaces of bulk carriers* (PSPC) (resolution MSC.215(82)). One set of panels should be exposed to treated ballast water. Other test conditions are described in the table below.

Table 6: Test conditions corrosion

Parameters	Quantification	Reference ¹ /Remark
The size of each test panel	200 mm x 400 mm x 3 mm	NACE standard TM0112-2012
Depth of immerse	250 $\pm$ 10 mm	NACE standard TM0112-2012
Water temperature in tanks for exposure	35 $\pm$ 2 °C	NACE standard TM0112-2012
The total test duration	182 days	NACE standard TM0112-2012
Ballast water	Natural seawater (> 32 PSU)	Preferred by GESAMP/BWWG but artificial seawater <u>prepared using demineralized water</u> is accepted
Active Substance Dose	At maximum dose, which is evaluated by the Group at Basic Approval	Modified from NACE standard TM0112-2012
Renewal frequency	Every 7 days	Modified from NACE standard TM0112-2012

7.1.3.4 Testing of corrosion should take place in the laboratory, but it is recommended to make use of the full-scale BWMS which is to be used for efficacy testing in accordance with the 2016 Guidelines (G8), for the preparation of treated ballast water for this purpose. However, if it is impractical to maintain the renewal frequency described in the table, ballast water may be prepared by a separate treatment using an identical BWMS.

7.1.3.5 After the exposure duration, several corrosion relevant measurements as listed in paragraph 7.1.3.7 should be scored against the PSPC criteria and reported.

Acceptance criteria

7.1.3.6 In order to determine whether the BWMS has influenced the coating's properties as evaluated according to ISO standards, the principles and acceptance criteria mentioned in paragraph 7.1.3.7 should be employed. Paint coatings evaluation should be carried out on treated ballast water. Paint coatings for BWMS compliance testing will already be required to have PSPC approval and this additional evaluation is to employ the NACE TM0112-2012 Standard Test Method to assess any potential detrimental effects on a coating system resulting from the use of a particular BWMS.

7.1.3.7 For the BWMS to be found suitable for Final Approval, it should not fail in any test evaluation of epoxy based coating systems as specified below:

- .1 ISO 4624: Adhesion: "Fail" if the adhesive or cohesive values at the treated panel are below those required in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1;
- .2 ISO 4628-2: Blistering: "Fail" if any blisters occur;
- .3 ISO 4628-3: Rusting: "Fail" if any rusting occurs;
- .4 ISO 4628-4: Cracking: "Fail" if any cracking occurs;
- .5 ISO 4628-8: Delamination and corrosion around a scribe: "Fail" if the delamination at the treated panel is greater than that specified in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1; and
- .6 ISO 15711: Cathodic protection – disbondment from artificial holiday (NACE TM0112-2012 Method B – Sacrificial Anode): "Fail" if the values at the treated panel are greater than those required in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1.

7.1.3.8 The criteria expressed in 7.1.3.7, subparagraphs .1, .5 and .6 may be revised in the future based on new scientific insights based on test experiences gained, including information on degradation of TRO during the tests.

7.1.4 Fire and explosion

Where ship safety may be affected by potential fire or explosion arising from the use of a BWMS, the outline procedures to prevent such occurrence and consequent mitigating emergency actions to be taken should be included in the dossier as expressed in paragraphs 4.1.7.3 and 4.1.7.4 of this Methodology.

7.1.5 Storage and handling

Where a BWMS has operational features requiring the loading, storage and handling of ancillary substances, the potential hazards arising from the improper handling or storage on board a ship of such substances should be addressed as required in section 4.1.7.2 of this Methodology. The hazards associated with the possible creation of atmospheric dusts should also be included.

7.2 Risks to human health

This section describes the risk to human health specified in section 6.3 and chapter 7 of Procedure (G9).

7.2.1 General

The human health risk assessment should follow generally accepted guidelines including acute/short-term and long-term exposure situations. The risk assessment should entail hazard identification and, as appropriate, dose (concentration) – response (effect) assessment, exposure assessment and risk characterization as indicated in section 5.2 of this Methodology. The population groups deemed to be at risk and so to be examined should include crew, port State control officers and general public. The evaluation of the risks to human health should include risk reduction (risk management) by specific measures proposed by the manufacturer and of the ballast water management system.

7.2.2 Health effects in humans

The effect assessment of the Active Substances, Preparations and Relevant Chemicals should include a screening on carcinogenic, mutagenic and reproductive toxic properties. If the screening results give rise to concerns, this should give rise to a further effect assessment (G9: 5.3.12) (see also section 6.1.4 of this Methodology).

7.2.3 Human Exposure Scenario

7.2.3.1 A Human Exposure Scenario (HES) should be provided by the applicant as part of the risk assessment procedure for ballast water management systems (G9: 6.3.3).

7.2.3.2 The risk assessment should include a description of the ballast water treatment process associated with the system as a set of unit operations, i.e. in doing so, identifying clearly which individual system components of a BWMS are likely to lead to human exposure to Active Substances, Relevant Substances and by-products. For each system five scenarios have been defined as follows:

- .1 delivery, loading, mixing or adding chemicals to the BWMS;
- .2 ballast water sampling;
- .3 periodic cleaning of ballast tanks;
- .4 ballast tank inspections; and
- .5 normal work on deck.

The way the risk assessment is performed is elaborated in appendix 4 of this Methodology.

7.2.3.3 For the general public two scenarios have been defined:

- .1 swimming in seawater contaminated with treated ballast water where exposure may be via ingestion (accidental swallowing), inhalation and dermal contact; and
- .2 consumption of seafood which has been exposed to Relevant Chemicals in the treated ballast water.

The risk assessment approach is also given in appendix 4.

7.2.3.4 In cases where RCR is above 1, then, to demonstrate that there is no unacceptable risk, the applicant should provide scientific justification, which may include potential risk mitigation measures.

7.3 Risks to the aquatic environment

This section describes the risk to safety of ship specified in section 6.4 and chapter 7 of Procedure (G9).

7.3.1 The potential risks to the aquatic environment should be assessed for both Basic and Final Approval.

7.3.2 When no aquatic toxicity of the treated ballast water at discharge is found either through direct testing of the treated ballast water or if the estimated ratios between predicted concentrations of the Active Substance, components of Preparations or Relevant Chemicals, described in paragraph 6.3.3 and the respective PEC/PNEC ratios are less than 1, no further assessment of direct toxic effects to the aquatic environment is necessary.

7.3.3 In cases where a PEC/PNEC ratio is above 1, then, to demonstrate that there is no unacceptable risk, the applicant should provide scientific justification, which may include potential risk mitigation measures.

7.4 Hierarchy of the Environmental Risk Assessment

7.4.1 During the Basic Approval evaluation priority is given to the PEC/PNEC ratios above the laboratory effluent toxicity testing (STW 5) whilst at the Final Approval evaluation priority is given at the results of the WET testing above the PEC/PNEC ratios.

7.4.2 In Table 7 an overview is given of the different data that are available at Basic Approval and Final Approval in relation to the risk assessment possibilities.

Table 7: Overview of data availability and risk assessment possibilities

Basic Approval			Final Approval		
Data	Available/ Method	Remark	Data	Available/ Method	Remark
Physico-chemical	Yes	-	Physico-chemical	Yes	-
Fate, e.g. biodegradation	No	Sometimes available	Fate, e.g. biodegradation	No	Sometimes available
MAMPEC-BW modelling	Yes	-	MAMPEC-BW modelling	Yes	-

Basic Approval			Final Approval		
Data	Available/ Method	Remark	Data	Available/ Method	Remark
Near ship scenario	Yes	-	Near ship scenario	Yes	-
Ecotoxicity Literature	Yes	Not always complete	Ecotoxicity Literature	Yes	Not changed compared to Basic Approval
Ecotoxicity Lab studies	Yes	-	Ecotoxicity WET tests	Yes	-
Full chemical analysis	Yes	Sufficiently low MDL	Full chemical analysis	Yes	Sufficiently low MDL
Risk assessment Tier 1	PEC/PNEC, incl. near ship PEC/PNEC	Using modelling and literature data	Risk assessment Tier 1	PEC/PNEC, incl. near ship PEC/PNEC	Using modelling and literature data
Risk assessment Tier 2	Effects in lab tests	-	Risk assessment Tier 2	Effects in WET tests	-
Risk assessment Tier 3	Tiers 1 and 2 in agreement?	Yes/No	Risk assessment Tier 3	Tiers 1 and 2 in agreement?	Yes/No
Conclusion, if Risk assessment Tier3 indicated No	Preference for the results of Risk assessment Tier 1 rather than that of Tier 2		Conclusion if Risk assessment Tier3 indicated No	Preference for the results of Risk assessment Tier 2 rather than that of Tier 1	

7.4.3 As indicated in table 7, there are only differences between Basic Approval and Final Approval with respect to the results of the effluent testing and the conclusion. The laboratory ecotoxicity tests at Basic Approval are considered indicative for potential effects but are not yet final and decisive. The WET tests at Final Approval are intended to be final and to give decisive information on the hazards of the discharge. If the discharge shows no effects in the WET tests, the discharge should be considered safe. Therefore, the preferred method of risk assessment changes between Basic Approval and Final Approval. The risk assessment based only on the PNEC determined and literature data is not considered sufficient for a final decision, at least not for Final Approval. For Basic Approval such assessment result gives an indication where to search for improvements in the system leading to a lower PEC/PNEC ratio.

8 ASSESSMENT REPORT

The Assessment Report referred to in section 4.3 of Procedure (G9) should be presented by the concerned Administration.

9 MODIFICATION TO THE APPLICATION

9.1 Manufacturers should report any modifications in names, including trade and technical name, composition or use of the Active Substances and Preparations in the ballast water management systems approved by the Organization, to the Member of the Organization. The Member of the Organization should inform the Organization accordingly (G9: 8.4.1).

9.2 Manufacturers intending to significantly change any part of a ballast water management system that has been approved by the Organization or the Active Substances and Preparations used in it should submit a new application (G9: 8.4.2).

10 FINAL APPROVAL

10.1 In accordance with paragraph 5.2.1 of Procedure (G9) for Final Approval, the discharge testing should be performed as part of the land-based type approval process using the treated ballast water discharge.

10.2 In order to obtain Final Approval in accordance with section 8.2 of Procedure (G9), the following criteria have to be met:

- .1 Basic Approval has to be granted first;
- .2 the Member of the Organization submitting an application should conduct the Type Approval tests in accordance with the Guidelines for approval of ballast water management systems (G8). The results should be conveyed to the Organization for confirmation that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval. This would result in Final Approval of the ballast water management system in accordance with regulation D-3.2. Active Substances or Preparations that have received Basic Approval by the Organization may be used for evaluation of ballast water management systems using Active Substances or Preparations for Final Approval (G9: 8.2.1) in accordance with the provisions of the framework "For determining when a Basic Approval granted to one BWMS may be applied to another system that uses the same Active Substance or Preparation";
- .3 it is to be noted that from section 2.4 of the annex to the 2016 Guidelines (G8), on land-based testing, only the results of the residual toxicity tests should be included in the proposal for Final Approval in accordance with Procedure (G9). All other Guidelines (G8) testing remains for the assessment and attention of the Administration. Although Basic Approval under Procedure (G9) should not be a pre-requisite for Type Approval testing, as an Administration can regulate discharges from its own ships in its own jurisdiction, Basic Approval should still be required when the technology is used on ships trading in other States' jurisdiction (G9: 8.2.2);
- .4 it should be noted that once a system has received Final Approval under Procedure (G9), the respective applicant should not have to retrospectively submit new data if there is a change in the Methodology agreed by the Organization (G9: 8.2.3);
- .5 WET testing should be carried out using discharge water at three salinities at 120 hours after treatment;
- .6 all information related to Total Residual Oxidants (TROs) and the chemicals included in such groupings, including their concentrations, should be provided to the GESAMP-BWWG for Final Approval;
- .7 in addition to the basic data-set needed for the treated ballast water and the individual Relevant Chemicals a new meaningful PEC/PNEC ratio would be required, using confirmed worst case concentrations with full scaled BWMS and verified PNEC; and
- .8 the application for Final Approval should address the concerns identified during the consideration for Basic Approval.

11 PROCEDURE FOR THE SUBMISSION OF NEW DATA ON FRESH WATER TESTING OF BALLAST WATER MANAGEMENT SYSTEMS WITH FINAL APPROVAL

Testing method and criteria for evaluation

11.1 For the evaluation of new data on fresh water testing of BWMS with Final Approval, WET tests with three organisms from three different trophic levels, e.g. a micro-algae, a crustacean and a fish, are required in accordance with section 5.2 of Procedure (G9). The tests should be carried out according to the description in section 6.2.

11.2 In addition, the identification of Relevant Chemicals is required in accordance with section 4.1 of Procedure (G9) and should be carried out according to the description in section 3.2.3.

11.3 The tests mentioned in paragraphs 11.1 and 11.2 should be carried out taking into account all relevant QA/QC, 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.

11.4 The GESAMP-BWWG evaluates the fresh water testing separately from the evaluation of new BWMS proposals for Basic and Final Approval, with the understanding that priority is always given to the new BWMS. If four or more new BWMS are submitted, the evaluation of new fresh water data will take place in a separate meeting of the GESAMP-BWWG.

Procedure for submission of new data on fresh water testing of ballast water management systems with Final Approval

11.5 The manufacturer should evaluate the results of fresh water testing in accordance with the criteria specified in paragraphs 11.1 and 11.2.

11.6 Upon completion of the evaluation in paragraph 11.5, the manufacturer should prepare an application for fresh water data evaluation and submit it to the Member of the Organization concerned. An application should only be made when the BWMS has previously received Final Approval. The Administration should be satisfied that there is no modification of the BWMS from the previous Final Approval at the submission of an application for fresh water data evaluation.

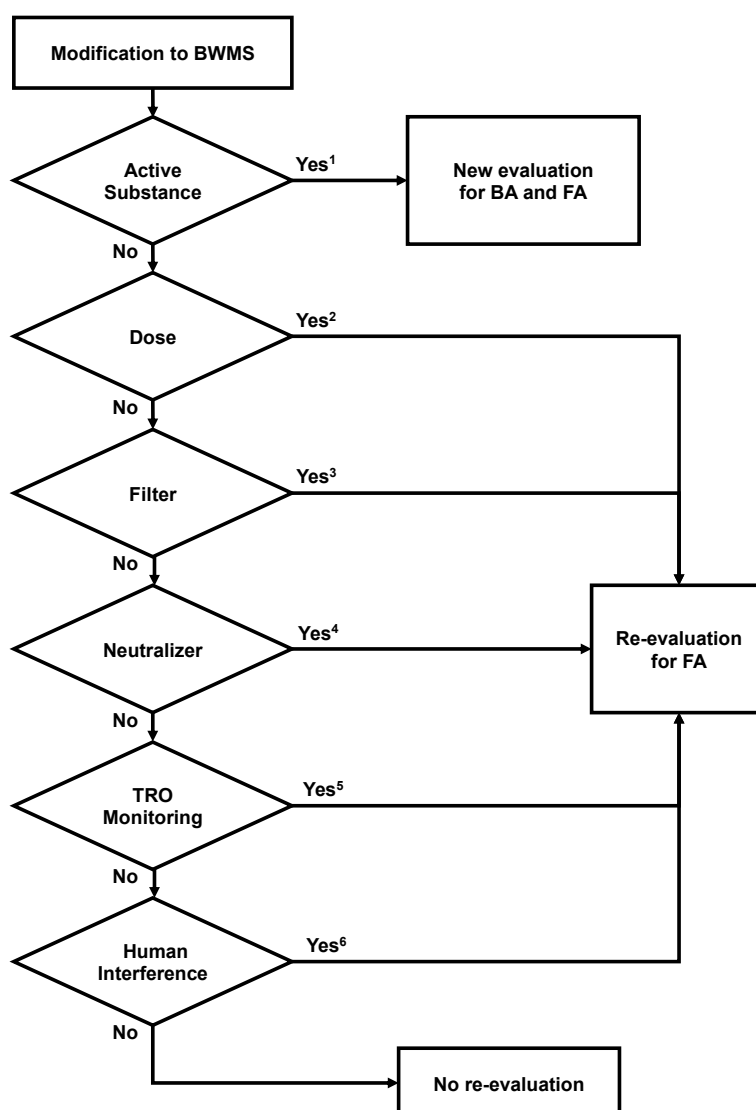
11.7 Upon receipt of an application, the concerned Administration should conduct a careful completeness check to ensure that the application satisfies the relevant provisions contained in Procedure (G9), as specified in paragraphs 11.1 and 11.2, and that it is presented in the format recommended in this Methodology. Administrations should check the quality and completeness of any application against the latest version of the Methodology, regardless of the version that had been used for the Basic and Final Approval of the BWMS.

11.8 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.

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.



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

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).

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 Table 8 below, clarify what new data should be included in the submission for a re-evaluation for Final Approval following a significant modification.

Table 8: 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 8 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.

APPENDIX 1

LETTER OF AGREEMENT

[relating to a ballast water management system that makes use of Active Substances proposed for approval in accordance with regulation D-3, paragraph 2, of the Ballast Water Management Convention]

[relating to new data on freshwater testing of a ballast water management system with Final Approval in accordance with regulation D-3, paragraph 2, of the Ballast Water Management Convention]

Having received a satisfactory application on **[please insert the name of the ballast water management system]** produced by **[please insert the name of the manufacturer]**, the undersigned hereby confirms, on behalf of the maritime Administration of **[please insert the name of the submitting country]**, that the application dossier regarding [the ballast water management system that makes use of Active Substance(s)] [new data on freshwater testing of the ballast water management system with Final Approval] mentioned above is subject to the following conditions:

1. **Financial arrangements:** The fee paid in connection with this proposal for approval is based on the recovery of costs incurred by the International Maritime Organization (Organization) in respect of the services provided by the GESAMP-Ballast Water Working Group.

For an application for Basic or Final Approval of a ballast water management system that makes use of Active Substance(s), fees will be invoiced in up to three tranches:

- US\$50,000 immediately following receipt of this Letter of Agreement by the Organization;
- an additional US\$50,000 immediately following the deadline for submissions, if only one submission has been made; and/or
- a final invoice to recover costs over the initial cost estimate, if required.

For an application for approval of new data on freshwater testing of a ballast water management system with Final Approval, a fee of US\$20,000 will be invoiced immediately following receipt of this Letter of Agreement by the Organization.

For a re-evaluation of a BWMS in cases where the recommendation of the GESAMP-BWWG has been challenged in MEPC, a fee of US\$20,000 will be invoiced if the recommendation of the GESAMP-BWWG does not change as a result of the re-evaluation and is subsequently endorsed by MEPC.

All fees paid as described above will be retained in a Trust Fund established for this purpose.

2. **Intellectual Property Rights:** The Organization and the members of the GESAMP-Ballast Water Working Group will make every reasonable effort to prevent the disclosure of information which is clearly and prominently identified as being subject to an intellectual property right, subject to the

condition that sufficient detail must be provided to the Marine Environment Protection Committee (MEPC) of the Organization to enable that body to perform its functions under resolution MEPC.169(57) and, in particular, to approve the proposed ballast water management systems that make use of Active Substances. In this respect the members of the Group will be required to sign a declaration concerning the confidentiality of information acquired as a result of their affiliation with the Group. In any case, neither the Organization nor the members of the GESAMP-Ballast Water Working Group can accept liability for damage or loss, which may result from disclosure of such information in the exercise of their responsibilities.

3. **Settlement of disputes:** The submitting Administration, the Organization, and the GESAMP-Ballast Water Working Group shall use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to the process established for reviewing Active Substances used for the management of ballast water or this Letter of Agreement, or the breach, termination or invalidity thereof. Where these parties wish to seek such an amicable settlement through conciliation, the conciliation shall take place in accordance with the UNCITRAL Conciliation Rules then pertaining, or according to such other procedure as may be agreed between the parties. Any dispute, controversy or claim, which is not settled amicably, shall be referred to arbitration in accordance with the UNCITRAL Arbitration Rules then pertaining. The place of the arbitration will be London, England.
4. **Privileges and immunities:** Nothing in or relating to the process established for reviewing Active Substances used for the management of ballast water or this Letter of Agreement shall be deemed a waiver, express or implied, of any of the privileges and immunities of the International Maritime Organization, including its officers, experts or subsidiary organizations or of the privileges and immunities to which the Administration is entitled under international law.

Members of the GESAMP-Ballast Water Working Group, when performing functions in connection with the terms of reference of the Group, shall be considered to be experts of the Organization pursuant to Annex XII of the Convention on Privileges and Immunities of the Specialized Agencies of the United Nations.

Authorized signature on behalf of the maritime Administration:

Typed/Printed name:

Title/Position/Organization/Country:

Date of signature:

Name and address
for fees invoicing:

Email address:

APPENDIX 2

TIMETABLE FOR ACTIVITIES RELATED TO THE GESAMP-BWWG MEETINGS

Timeline	Activity
28 weeks before the MEPC	Deadline for submission of application dossiers and related documents to be reviewed by the GESAMP-BWWG
(8 weeks)	Preparation of the meeting, including circulation of any relevant information provided by other delegations
20 weeks before the MEPC	GESAMP-BWWG meeting
(1 week)	Editing and completion of the draft report of the meeting
(3 weeks)	Review and approval of the report by the GESAMP including response/clarification by the working group
(1 week)	Administrations confirm that no confidential data are contained in the report
(1 week)	Produce the final report addressing the comments by the GESAMP
13 weeks before the MEPC	Submission of the report of the meeting of the GESAMP-BWWG in accordance with the 13-week deadline (bulk documents) for the MEPC

APPENDIX 3

MODEL DOCUMENT FOR THE ANNEX ON NON-CONFIDENTIAL DOSSIER OF AN APPLICATION FOR BASIC APPROVAL AND/OR FINAL APPROVAL OF A BALLAST WATER MANAGEMENT SYSTEM (BWMS)

1 INTRODUCTION

This section should include:

- .1 a brief history of any previous applications; and
- .2 the results of any previous evaluations with references to any pertinent documents;

2 DESCRIPTION OF THE SYSTEM

2.1 This section should include:

- .1 a list of all the relevant parts of the BWMS, e.g. filtration, treatment (e.g. U.V. or electrolysis or chemicals), neutralization and any feedback controls;
- .2 a schematic representation of the system showing the component parts; and
- .3 a general description of how the BWMS works and how all the component parts are integrated.

2.2 The operation of the BWMS is preferably highly automated. A compact description of the control system should be provided.

3 CHEMICALS ASSOCIATED WITH THE SYSTEM

3.1 Chemical reactions associated with the system

This section should describe the anticipated chemical reactions associated with the particular system involved and residual chemicals expected to be discharged to the sea.

3.2 Identification of chemicals associated with the ballast water management system

3.2.1 This section should include all Active Substances (AS), Relevant Chemicals (RC) and any Other Chemicals (OC) potentially associated with the system either intentionally or as by-products resulting from the treatment.

Table: Composition / Chemicals associated with the BWMS

Chemical	Concentration (µg/L)	AS, RC or OC
A		
B		
C		
D		

3.2.2 A summary of all chemicals analysed in the treated ballast water, in all three salinities should be presented in a table, as shown below, including those not actually detected. Where a chemical could not be detected, a less than value ($< x \mu\text{g/L}$) should be associated with it to indicate the detection limits of the analysis.

3.2.3 For each chemical measured above the detection limits of the system (and above the control levels of untreated ballast water), a separate data sheet (as shown at the end of this appendix) should be included in the application where the chemical has not been evaluated by the GESAMP-BWWG and listed in appendix 6 to this Methodology (see paragraph 5.3). The appropriate detection limits to be used in conjunction with the chemicals listed in appendix 6 are listed in appendix 7.

Table: Chemical analysis of treated ballast water in different salinities as reported by the applicant

Chemical	Detection limit ($\mu\text{g/L}$)	Fresh water ($\mu\text{g/L}$)	Brackish water ($\mu\text{g/L}$)	Seawater ($\mu\text{g/L}$)
A				
B				
C				
D				

3.2.4 If the applicant disagrees with these data chosen by the GESAMP-BWWG, the applicant should provide reasons for disagreeing and support replacement data for consideration based on a scientific paper or test result.

3.2.5 For the further risk assessment for human health and the environment, the Group selects only the substances that have been detected in a concentration above the detection limit from the table listing all of the potential by-products produced in ballast water. These substances should be considered the Relevant Chemicals for the BWMS. If the detection limit for a substance is determined to be unreasonably high, the substance will be included in the further risk assessment with a value corresponding to the detection limit. It may be suitable to use two worst-case concentrations, one for occupational risk assessment (in a ballast water tank) and the other for environmental and general public risk assessment (in the discharged ballast water).

Table: Selected Relevant Chemicals and maximum concentrations for further risk assessment

Chemical	Maximum concentration (ballast tank) ($\mu\text{g/L}$)	Maximum concentration (discharged ballast water) ($\mu\text{g/L}$)
A		
B		
C		

4 RESPONSE TO THE GESAMP-BWWG REQUESTS (BASIC APPROVAL) OR CONSIDERATION OF CONCERNS EXPRESSED BY THE GROUP DURING ITS PREVIOUS REVIEW (FINAL APPROVAL)

This section should include a copy of each concern raised by the GESAMP-BWWG with an appropriate response from the applicant (valid in case an earlier submission was denied Basic Approval (BA) or Final approval (FA), or in case of a Final Approval submission following a Basic Approval).

5 HAZARD PROFILE DATA AND EXPOSURE OF CHEMICALS ASSOCIATED WITH THE BWMS

5.1 This section should contain a summary of the hazards to mammals and the environment associated with each chemical associated with or generated by the BWMS (the format of the summary is outlined in the section regarding a separate data sheet at the end of this appendix). Where possible, references should be added.

5.2 The hazards identified will be used to perform a risk assessment of the BWMS on the environment, the ships' crews and the general public.

5.3 For the forty-one chemicals most commonly associated with treated ballast water indicated in appendix 6, no additional properties on physico-chemistry, ecotoxicology and toxicology have to be submitted, as these substances have been already assessed by the GESAMP-BWWG. Data for these substances can be found in the online GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water (<https://gis.imo.org/>).

5.4 The reason for this approach is to:

- .1 provide a consistent set of data for all applications;
- .2 assist applicants in collating the data associated with their BWMS; and
- .3 streamline the work of the GESAMP-BWWG in assessing applications.

5.5 The following endpoints should be recorded:

- .1 The proposed PNEC based on the available ecotoxicological data, including the final assessment factor to establish the PNEC. This value will be used in the environmental risk assessment.
- .2 The proposed DNEL and/or DMEL based on the available toxicological data, including the final assessment factor to establish the DNEL and / DMEL to be used in the human risk assessment.

5.5.1 Predicted No Effect Concentrations (PNEC)

Table: PNEC values of Chemicals associated with the BWMS and included in the GESAMP-BWWG Database

Chemicals	Harbour	Near ship
	PNEC (µg/L)	PNEC (µg/L)
A		
B		
C		

Table: PNEC values of Chemicals associated with the BWMS, not included in the GESAMP-BWWG Database

Chemicals	Harbour			Near ship		
	AF	PNEC (µg/L)	Rule No.	AF	PNEC (µg/L)	Rule No.
A						
B						
C						

5.5.2 Derived No Effect Levels (DNEL) and/or Derived Minimum Effect Level (DMEL)

Based on the appropriate toxicological studies on carcinogenicity, mutagenicity and reproductive toxicity (Procedure (G9), paragraph 5.3.12), each chemical should be scored on these three items, using 'yes' if the substance showed the hazard under consideration and 'no' if the substance did not show the hazard under consideration as shown below:

Table: CMR properties for selected Chemicals

Chemical	Carcinogenic (Yes/no)	Mutagenic (Yes/no)	Reprotoxicity (Yes/no)	CMR (Yes/no)
A	Yes/No	Yes/No	Yes/No	Yes/No
B	Yes/No	Yes/No	Yes/No	Yes/No
C	Yes/No	Yes/No	Yes/No	Yes/No

Table: DNELs and DMELs to be used in the risk assessment for humans

Chemical	DNEL (mg/kg bw/d) Crew	DNEL (µg/kg bw/d) General public	DMEL (µg/kg bw/d)
A			
B			
C			

5.6 Exposure assessment

5.6.1 In order to perform a risk assessment related to both the environment and those people who may be exposed to any chemicals associated with the BWMS, it is necessary to estimate the concentration of such chemicals in:

- .1 the air space in the ship's ballast water tank;
- .2 the atmosphere surrounding the ship;
- .3 leakages and spills when operating the system; and
- .4 in the harbour water and surrounding area.

5.6.2 It is recognized that there are various computer models which can be used to fulfil this requirement and that such models can produce differing results depending on a range of input parameters which can be used. So, in order to provide some standardization and a mechanism for comparing the various systems, it is recommended that applicants use the model of paragraph 5.6.3 associated with the standard inputs described in appendix 5 resulting in a Predicted Environmental Concentration (PEC) for the Active Substance, all Relevant Chemicals and relevant disinfection by-products.

5.6.3 Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) should be calculated using the MAMPEC-BW 3.1 model or latest available version with the appropriate environment definition and emission input. The results of these calculations should be used to estimate the risk to the general public and the environment. See the guidance in appendix 4 for the risk assessment for humans and appendix 5 for the risk assessment for the aquatic ecosystem.

**Table: PEC from MAMPEC modelling results from the GESAMP-BWWG
Model Harbour for the harbour and near ship scenario**

Chemical	PEC (µg/L)	
	Maximum	Near ship
A		
B		
C		

5.6.4 Concentration of Chemicals associated with the BWMS in the atmosphere

An inventory should be made of the ways humans (crew, port State control and the general public) may be exposed to Relevant Chemicals due to the ballasting and deballasting processes. Guidance to the potential exposure routes is given in appendix 4, together with calculation tools, to estimate the worst-case exposure concentration. These resulting concentrations should be used in the risk assessment for humans and reported here.

Table: Resulting concentrations to be used in the risk assessment for humans

Chemical	Crew		General public	
	Concentration in tank (µg/L)	Concentration in air (mg/m ³)	Concentration MAMPEC (µg/L)	Concentration in air (mg/m ³)
A				
B				
C				

6 LABORATORY TOXICITY TEST WITH TREATED WATER (FOR BASIC APPROVAL) OR WET TESTS (FOR FINAL APPROVAL)

This section should include:

- .1 a description of the tests carried out; and
- .2 a table of the results, e.g. as shown below:

Test	Test organism	Salinity (PSU)	Endpoints (%)		References / Guidelines
			NOEC±	L(E)C ₅₀	
	Algae				
	Crustacean				
	Fish				

7 RISKS TO SHIP SAFETY

This section covers damage to the structure of the ship which might be caused by various effects including:

- .1 increased corrosion;
- .2 fire and explosion; and
- .3 storage and handling of chemicals.

8 RISKS TO THE CREW

Risks to the crew may be assumed to be associated with:

- .1 delivery, loading, mixing or adding chemicals to the BWMS;
- .2 ballast water sampling;
- .3 periodic cleaning of ballast tanks;
- .4 ballast tank inspections; and
- .5 normal work on deck.

These situations are covered in the guidance in appendix 4.

8.1 Delivery, loading, mixing or adding chemicals to the BWMS

8.1.1 Dilution of concentrated chemical products is often referred to as mixing and loading. On smaller vessels this process may be performed manually. Exposure through inhalation is considered unlikely for non-volatile or water-based chemical formulations. Potential dermal exposure of the hands can be estimated by several available models. It is recommended to use the UK Predictive Operator Exposure Model (POEM) for this estimation. This approach is described in appendix 4.

8.1.2 The result from the calculations may be presented as shown in the table below:

Table: Crew, scenario: loading and filling, scenario 1

Chemical	Chemical concentration	Exposure without gloves	DNEL	RCR Tier 1
	%w/w	mg/kg bw/d	mg/kg bw/d	-
A				
B				
C				

8.1.3 In the Tier 2 calculation it is assumed that the exposure can be reduced by the use of gloves.

8.2 Ballast water sampling/Periodic cleaning of ballast tanks/Ballast tank inspections/Normal work on deck

8.2.1 When considering various work operations, it should be assumed that the exposure routes of concern for the crew and/or port State workers will be inhalation and dermal. In this respect, it is assumed that the crew will be exposed by inhalation to the highest concentration of each chemical in the atmosphere above the treated ballast water at equilibrium and by dermal uptake to the highest concentration of each chemical in the treated ballast water. These approaches are described in appendix 4.

Table: Crew/port State control, scenarios 2 to 5, Tier 1 DNEL approach

Chemical	Scenario (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
A					
B					
C					

8.2.2 Taking into account that the DNEL is calculated for chronic exposure, while exposure through these occupational scenarios are assumed to occur only over a limited period of time, Tier 2 calculations may be performed using correction factors which are calculated from the exposure frequencies for the various scenarios multiplied by the exposure duration (20 years) and divided by the averaging time (exposure duration) for non-carcinogenic effects (7,300 days). This approach is described in paragraph 2.1.3.6 in appendix 4.

Table: Crew/Port State control, scenarios 2-5, Tier 2 DNEL approach

Chemical	Scenario (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	Corrected exposure (mg/kg bw/d)	DNEL (mg/kg bw/d)	RCR
	Dermal	Inhalation				
A						
B						
C						

8.2.3 Indicative risk levels available from internationally recognized bodies may be used to calculate the indicative RCR regarding potential cancer risk in the DMEL approach. Furthermore, the group RCR approach may be applied to the calculation. The group RCR approach is to be applied for substances with a DMEL value, and is described in paragraph 8.4.3 in appendix 4.

Table: Crew/Port State control, scenarios 2-5: – Tier 1 DMEL approach

Chemical	Scenario (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation			
A					
B					
C					
Sum					

8.2.4 Taking into account that the DMEL is calculated for daily exposure over a lifetime (70 years), while exposure through these occupational scenarios are assumed to occur only over a limited period of time, Tier 2 calculations may be performed using correction factors which are calculated from the exposure frequencies for the various scenarios multiplied by the exposure duration (20 years) and divided by the life expectancy (25,550 days).

Table: Crew/Port State control, scenarios 2-5: – Tier 2 DMEL approach

Chemical	Scenario (mg/kg bw/d)		Aggregated exposure (mg/kg bw/d)	Corrected exposure (mg/kg bw/d)	DMEL (mg/kg bw/d)	RCR
	Dermal	Inhalation				
A						
B						
C						
Sum						

9 RISKS TO THE GENERAL PUBLIC

9.1 Risks to the general public are most likely to occur as a result of:

- .1 swimming in seawater contaminated with treated ballast water where exposure may be via ingestion (accidental swallowing), inhalation and dermal contact; and

- .2 consumption of seafood which has been exposed to Relevant Chemicals in the treated ballast water.

9.2 The risk to the general public from the oral, dermal and inhalatory exposure of chemical by-products may be calculated according to the guidance in appendix 4.

Table: General public scenario: swimming and consumption of seafood

Chemical	Scenario 10.1.1 and 10.1.2 (µg/kg bw/d)				Aggregated exposure (µg/kg bw/d)	DNEL (µg/kg bw/d)	RCR
	Swimming			Consumption of seafood			
	Oral	Dermal	Inhalation	Oral			
A							
B							
C							

9.3 An indicative risk level may be used to calculate an indicative RCR regarding potential cancer risk. These values can be used to estimate a risk dose based on the probability of increased cancer incidence over a lifetime (10^{-6}) and may be regarded as a DMEL for the general public.

Table: General public scenario: swimming and consumption of seafood – Tier 1 DMEL approach

Chemical	Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	Indicative RCR
A			
B			
C			
Sum			

9.4 If an elevated risk to the general public is identified in the Tier 1 calculation, a Tier 2 calculation may be performed by taking into consideration the assumption that the general public activities take place in areas more remote to the actual harbour. In this case additional dilution of chemicals is to be expected (see paragraph 2.2.5.2 in appendix 4).

Table: General public scenario: swimming and consumption of seafood – Tier 2 DMEL approach

Chemical	Aggregated exposure (µg/kg bw/d)	DMEL (µg/kg bw/d)	Indicative RCR
A			
B			
C			
Sum			

10 RISKS TO THE ENVIRONMENT

10.1 Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T)

Based on the half-life, BCF or Log K_{ow} and the chronic NOEC values for each chemical (Procedure (G9), paragraph 6.4), the PBT properties of each chemical should be reflected in a table with the justification in parentheses as shown below:

Chemical	Persistence (P) (Yes/No)	Bioaccumulation (B) (Yes/No)	Toxicity (T) (Yes/No)	PBT (Yes/No)
A	Yes/No	Yes/No	Yes/No	Yes/No
B	Yes/No	Yes/No	Yes/No	Yes/No
C	Yes/No	Yes/No	Yes/No	Yes/No

10.2 Calculation of PEC/PNEC ratios

10.2.1 The ratio of PEC/PNEC is a measure of the risk that each chemical is deemed to present to the environment.

10.2.2 For each chemical the estimation of the PEC/PNEC ratio should be summarized as shown in the table below:

Table: PEC/PNEC ratios

Chemical	Harbour			Near ship		
	PEC	PNEC	PEC/ PNEC	PEC	PNEC	PEC/ PNEC
	(µg/L)	(µg/L)	(-)	(µg/L)	(µg/L)	(-)
A						
B						
C						

10.3 Determination of retention time

The retention time of Active Substances should be determined in accordance with the results of chapter 6 and of the assessment above.

11 ADDITIONAL HEADINGS

11.1 As part of the report to be made by the Group during its evaluations, the following parts also appear:

11.1.1 CONCLUSIONS AND RECOMMENDATIONS

11.1.1.1 Risks to ship safety

11.1.1.2 Risks to the crew and the general public

11.1.1.3 Risks to the environment

11.1.1.4 Recommendation

SEPARATE DATA SHEET FOR CHEMICALS NOT LISTED IN APPENDIX 6

DATA ON EACH COMPONENT OF THE PREPARATION AND BY-PRODUCT PRODUCED IN BALLAST WATER

Chemical Name

Where the applicant considers that it is not necessary to complete the data form for a given chemical, a full justification should be given (e.g. the $\frac{1}{2}$ -life of the chemical is only a few seconds and so will have disappeared by the time the ballast water is discharged into the sea).

1 EFFECTS ON AQUATIC ORGANISMS

1.1 Acute aquatic toxicity data

Organism	Species	duration*-LC ₅₀ (mg/L)	Reference/comments/justification for missing data
Fish			
Crustacea			
Algae			

* The duration is given in hours (h) or days (d), e.g. 96h-LC₅₀ or 7d-NOEC.

1.2 Chronic aquatic toxicity data

Organism	Species	duration*-LC ₅₀ (mg/L) or duration*-NOEC (mg/L)	Reference/comments/justification for missing data
Fish			
Crustacea			
Algae			

* The duration is given in hours (h) or days (d), e.g. 96h-LC₅₀ or 7d-NOEC.

1.3 Information on endocrine disruption

Organism	Species	Information	Reference/comments/justification for missing data
Fish			
Crustacea			
Algae			

1.4 Sediment toxicity

Organism	Species	Information	Reference/comments/justification for missing data
Fish			
Crustacea			
Algae			

1.5 Bioavailability/biomagnification/bioconcentration

Parameter	Value	Reference/comments/justification for missing data
Log P _{ow}		
BCF		

1.6 Food web/population effects

1.6.1 A description of potential food web and population effects should be provided supported by a full justification.

2 MAMMALIAN TOXICITY**2.1 Acute toxicity**

Endpoint	Value	Species	Reference/comments/justification for missing data
Oral LD ₅₀ (mg/L)			
Dermal LD ₅₀ (mg/kg bw)			
Inhalation 4h-LC ₅₀ (mg/L)			

2.2 Corrosion/irritation

Exposure route	Species	Method	Results (including scores where available)	Reference/comments/justification for missing data
Skin				
Eye				

2.3 Sensitization

Exposure route	Species	Method (e.g. Buehler, M&K)	Results (Sensitizer Y/N)	Reference/comments/justification for missing data
Skin				
Inhalation				

2.4 Repeated-dose toxicity

Parameter	Value/Comments
Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/comments/justification for missing data	

2.5 Development and reproductive toxicity

Parameter	Value/Comments
Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/comments/justification for missing data	

2.6 Carcinogenicity

Parameter	Value/Comments
Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/comments/justification for missing data	

2.7 Mutagenicity

Endpoint	Method	Dose range	Results	Reference/comments/justification for missing data
Bacterial gene mutation				
Mammalian cytogenicity				
Mammalian gene mutation				

2.8 Carcinogenicity/mutagenicity/reproductive toxicity (CMR)

Endpoint	Results	Reference/comments/justification for missing data
Carcinogenicity		
Mutagenicity		
Reproductive toxicity		

3 ENVIRONMENTAL FATE AND EFFECT UNDER AEROBIC AND ANAEROBIC CONDITIONS

3.1 Modes of degradation (biotic and abiotic)

Process	Seawater or fresh water	Test duration	Results	Breakdown products	Reference/comments/justification for missing data
Hydrolysis at pH 5					
Hydrolysis at pH 7					
Hydrolysis at pH 9					
Biodegradation					
DT ₅₀					

3.2 Partition coefficients

Parameter	Method	Results	Reference/comments/justification for missing data
Log P _{ow}			
K _{oc}			

3.3 Persistence and identification of main metabolites

Process	Method	Results	Reference/comments/justification for missing data
Persistence (d)			

3.4 Reaction with organic matter

3.5 Potential physical effects on wildlife and benthic habitats

3.6 Potential Residues in seafood

3.7 Any known interactive effects

4 PHYSICAL AND CHEMICAL PROPERTIES FOR THE ACTIVE SUBSTANCES, PREPARATIONS AND TREATED BALLAST WATER, IF APPLICABLE

Property*	Value	Reference/comments/justification for missing data
Melting point (°C)		
Boiling point (°C)		
Flammability (flashpoint for liquids; °C)		
Density (20°C; kg/m ³)		
Vapour pressure (Pa at 20°C)		
Relative vapour density (expressed as a ratio by that of air as 1.293 kg/m ³ at 0°C and 10 ⁵ Pa)		
Water solubility (mg/L, temp; effect of pH)		
pH in solution (under the intended concentration for AS)		

Property*	Value	Reference/comments/ justification for missing data
Dissociation constant (pK _a)		
Oxidation-reduction potential (V)		
Corrosivity to material or equipment (for Active Substance see paragraph 3.6.9)		
Reactivity to container material (only for Active Substance, which needs storage on board)		
Auto-ignition temperature, also flash point if applicable (°C)		
Explosive properties (narrative)		
Oxidizing properties (narrative)		
Surface tension (N/m)		
Viscosity (Pa·s), Kinetic viscosity (m ² /s) is also accepted		
Thermal stability and identity of breakdown products (narrative)		
Other physical or chemical properties (narrative)		

* If units are indicated for the property, then these should be considered the preferred unit.

5 OTHER INFORMATION

5.1 Analytical methods for measuring the concentration at environmentally relevant concentrations

Method	Comments
Applicability	
Sensitivity	
Reference/comments/justification for missing data	

5.2 Material Safety Data Sheet provided (Yes/No)

5.3 GHS classification

5.4 Risk characterization

Persistent (y/n)	Bioaccumulative (y/n)	Toxic (y/n)	Reference/comments/justification for missing data

APPENDIX 4

HUMAN RISK ASSESSMENT OF BALLAST WATER CHEMICALS

1 INTRODUCTION

1.1 In risk characterization for human health, the procedure is to compare the exposure levels to which the target groups are exposed or likely to be exposed with those levels at which no toxic effects from the chemicals are expected to occur. There are normally four stages when carrying out a quantitative risk assessment:

- .1 **Hazard identification** – what are the substances of concern and what are their effects?
- .2 **Dose (concentration) – response (effect) relation** – what is the relationship between the dose and the severity or the frequency of the effect?
- .3 **Exposure assessment** – what is the intensity, and the duration or frequency of exposure to an agent.
- .4 **Risk characterization** – how to quantify the risk from the above data.

1.2 It is proposed to apply a tiered approach when assessing the risk of the chemicals associated with the BWMS.

1.3 In the first Tier, the level of exposure to the substance below which no adverse effects are expected to occur should be derived for the relevant systemic effects. This level of exposure above, which humans should not be exposed to, is designated as the Derived No Effect Level (DNEL). Risks are regarded to be controlled when the estimated exposure levels do not exceed the predicted no effect levels (DNEL).

1.4 A DNEL is a derived level of exposure because it is normally calculated on the basis of available dose descriptors from animal studies such as No Observed Adverse Effect Levels (NOAELs) or benchmark doses (BMDs).

1.5 The DNEL can be considered as an "overall" No-Effect-Level for a given exposure (route, duration, frequency), accounting for uncertainties/variability in these data and the human population exposed by using appropriate Assessment Factors (AFs).

1.6 If an unacceptable level of risk is identified for any of the scenarios in the first Tier, a refinement of the exposure assessment and/or the assessment factors might be performed in the second Tier giving special attention to route-specific contributions and protection measures.

1.7 In order to determine the risks of chemicals associated with the treatment of ballast water, it is necessary to determine several parameters:

- .1 concentration of each chemical in the ballast water tank (and in the air phase above the water);
- .2 concentration of chemicals after discharging in the sea;

- .3 concentration of chemicals which may be transferred from the aquatic environment into the atmosphere; and
- .4 potential uptake of chemicals by humans through the various routes of exposure.

1.8 For the worker exposure situation in the ballast water tank (while performing sampling or cleaning), it is important to estimate the air concentrations in the ballast tank. The concentration of each chemical in the atmosphere above the water may be calculated using the Henry's Law Constant.

1.9 For the exposure situation regarding the general public (whilst swimming in the sea or consuming seafood), the calculated concentration of each chemical in the discharged treated ballast water needs to be used. These can be determined using environmental models and the MAMPEC-BW model version 3.0.1 or latest available version written for this purpose is the one preferred. It is normal practice to use the highest values obtained from this model which is the concentration anticipated in the harbour area.

1.10 It is important to note that the methodologies described in this document generally apply to DNELs of chemicals with a systemic and threshold related property, and do not apply to chemicals producing local effects, such as irritation. However, in some cases it is considered appropriate to derive a DNEL for a local effect when a reliable NOAEL is available. For chemicals with a non-threshold effect (i.e. cancer), a DMEL should be used.

1.11 No account has been taken of the naturally occurring background levels of contaminants in seawater, which, it is recognized, will be different in different parts of the world.

1.12 The approach described in this documentation takes into account the EU REACH guidance described in ECHA Guidance on information requirements and chemical safety assessment.

2 HUMAN EXPOSURE ASSESSMENT

2.1 Occupational

2.1.1 The exposure assessment is carried out through an evaluation of different exposure scenarios. An exposure scenario is the set of information and/or assumptions that describes how the contact between the worker and the substance takes place. It is based on the most important characteristics of the substance in view of occupational exposure, e.g. the physico-chemical properties, pattern of use, processes, tasks and controls. An exposure scenario will therefore describe a specific use of the treatment product with a set of specific parameters. Exposure estimates are intended to be used as a screening tool. The following situations have been identified as likely exposure scenarios for workers:

Table 1. Summary of occupational exposure scenarios

Operations involving the crew and/or port state workers			
Operation	Exposure	Frequency/duration/quantity	Approach described in:
Delivery, loading, mixing or adding chemicals to the BWMS	Potential dermal exposure and inhalation from leakages and spills.	Solids, dermal: on a case-by-case basis Liquids, dermal: 0.05-0.1 mL/container handled	2.1.2

Operations involving the crew and/or port state workers			
Operation	Exposure	Frequency/duration/quantity	Approach described in:
		Gases/vapours/dusts, inhalation: on a case-by-case basis	
Ballast water sampling at the sampling facility	Inhalation of air released	2 hours/day for 5 days/week; 45 weeks/year	2.1.3.1
	Dermal exposure to primarily hands	2 hours/day for 5 days/week; 45 weeks/year	2.1.3.4
Periodic cleaning of ballast tanks	Inhalation of air in the ballast water tank	8 hours/day for 5 days/week; 1 event/year	2.1.4.1
	Dermal exposure to the whole body	8 hours/day for 5 days/week; 1 event/year	2.1.4.3
Ballast tank inspections	Inhalation of air in the ballast water tank	3 hours/day for 1 day/month	2.1.5
Normal operations carried out by the crew on BWMS			
Normal work on deck unrelated to any of the above	Inhalation of air released from vents	1 hour/day for 6 months/year	2.1.6

Note: Whilst the above situations have been identified as typical exposure scenarios, it is recognized that there will be other situations when exposure of workers may be greater or less and due consideration should be given to such situations.

2.1.2 Delivery, loading, mixing or adding chemicals to the BWMS

2.1.2.1 There is potential for exposure to chemical substances during transfer of concentrated formulations in containers or within closed systems. It is considered that the risks are dealt with through the use of appropriate chemical protective clothing, in particular gloves. The applicant should provide details of the intended methods to be used to transfer Active Substances, Preparations or Other Chemicals, e.g. neutralizers, to the on-board storage and propose the appropriate personal protective equipment to prevent exposure.

2.1.2.2 Dilution of concentrated chemical products is often referred to as mixing and loading. On smaller vessels this process may be performed manually. Exposure through inhalation is considered unlikely for non-volatile or water-based chemical formulations. Potential dermal exposure of the hands can be estimated by several available models. It is recommended to use the UK Predictive Operator Exposure Model (POEM) for this estimation. In this model, the daily level of exposure during the handling of containers depends on the properties of the container (capacity and diameter of the opening) and the number of containers handled per day. Containers with narrow openings (< 45 mm) are not considered for this scenario.

Principal equation:

$$Dose = (1 - f_{RMM}) \cdot \frac{C \cdot N \cdot E \cdot f_{derm} \cdot f_{pen}}{BW}$$

Dose	=	skin exposure (mg/kg bw/d)
f_{RMM}	=	risk mitigation factor (Tier 1 = 0, Tier 2 = 0.95)
C	=	concentration of Active Substance (mg/L)
N	=	number of containers handled, to be determined according to the total volume needed for the specific BWMS (d ⁻¹)
E	=	contamination per container handled (Tier 1 = 0.1 mL, Tier 2 = 0.05 mL)

f_{derm}	=	dermal absorption factor (default = 1)
f_{pen}	=	penetration factor (default = 1)
BW	=	body weight (default = 60 kg)

The Tier 1 assessment is based on the handling of containers with an opening diameter of 45 mm and a volume of 10 L. For this case, UK POEM predicts a hand exposure of 0.1 mL fluid per container handled. The number of containers handled depends on the total volume of liquid that needs to be transferred. The Tier 2 assessment is based on the handling of containers with an opening diameter of 63 mm and a volume of 20 L. For this case, UK POEM predicts a hand contamination of 0.05 mL for each container. The total volume handled should be the same as in Tier 1, i.e. the number of containers handled is half of that in Tier 1. The exposure estimation can be further refined by the use of substance-specific values for the dermal absorption factor or the penetration factor, if available. Exposure can be reduced by the use of gloves. According to UK POEM, suitable gloves will reduce exposure to 5% of the original value. This value is used as a default for Tier 2.

2.1.2.3 On larger vessels, transfer of chemicals will more likely occur through closed transfer systems. These systems do not necessarily result in reduced levels of operation exposure. The connection and removal of adaptors may result in similar levels of exposure as those from open pouring operations. Therefore, calculation of exposure by the above equation is recommended also for these systems.

2.1.2.4 Measures to safeguard installations against unintended release of chemicals should be discussed under "Risks to the safety of the ship" (see chapter 7.1 of the Methodology).

2.1.3 Ballast water sampling

2.1.3.1 There is a potential risk for inhalation of chemicals that have evaporated into the air phase while performing the task of taking samples of the ballast water from the sampling facility. The worst concentration of chemicals in the air may theoretically be calculated using the Henry's Law Constant in the equation presented below:

$$C_{\text{air}} = \frac{H}{R \cdot T} \cdot C_{\text{water}}$$

where:

C_{air}	=	concentration in air (mg/m ³)
H	=	Henry's Law Constant (Pa m ³ /mole)
R	=	gas constant (8.314 Pa m ³ /mole K)
T	=	absolute temperature (K)
C_{water}	=	measured concentration in ballast water (µg/L)

2.1.3.2 If the applicant proposes that the sampling facility be placed in the engine room, a dilution factor of 100 may be introduced to estimate the concentration in the air surrounding test facilities. This is based on the assumption that any air released from the sampling facilities will be diluted by the surrounding air

2.1.3.3 Once a concentration of a volatile component has been estimated, a simple Tier 1 exposure assessment can be performed.

$$Dose_{\text{Tier1}} = \frac{C_{\text{air}} \times ET \times IR}{BW}$$

where:

Dose _{Tier1}	=	inhaled dose (mg/kg bw/d)
C _{air}	=	concentration of volatile component in air (mg/m ³)
ET	=	exposure time (2 h/d)
IR	=	inhalation rate (default = 1.25 m ³ /h)
BW	=	body weight (default = 60 kg)

2.1.3.4 There is also a potential risk for dermal uptake of chemicals from the ballast water while taking samples from the sampling facility. The dermal uptake may be calculated using the equation below:

$$U_{sd} = \frac{A_{hands} \cdot TH_{dermal} \cdot C_{water} \cdot BIO_{derm}}{BW}$$

where:

U _{sd}	=	dermal uptake (mg/kg bw/d)
A _{hands}	=	surface area of two hands (0.084 m ²)
TH _{dermal}	=	thickness of the product area on the skin (0.0001 m)
C _{water}	=	concentration of chemical in treated ballast (µg/L)
BIO _{derm}	=	dermal bioavailability (default = 1)
BW	=	body weight (default = 60 kg)

2.1.3.5 The aggregated uptake, that is the sum of the inhaled dose and the dermal dose, is then compared with the DNEL to assess whether the risk is acceptable or not.

2.1.3.6 If the Tier 1 risk assessment indicates an unacceptable risk, a Tier 2 exposure assessment can be performed by averaging the short-term daily exposure over an extended period of time, in accordance with a methodology developed by the U.S. EPA⁴. For this purpose, employment duration of 20 years is assumed.

$$Dose_{Tier2} = (1 - f_{RMM}) \frac{C_{air} \times IR \times ET \times EF \times ED}{BW \times AT}$$

where:

Dose _{Tier2}	=	inhaled dose (mg/kg bw/d)
f _{RMM}	=	risk mitigation factor
C _{air}	=	concentration of volatile component in air (mg/m ³)
IR	=	inhalation rate (default = 1.25 m ³ /h)
ET	=	exposure time (2 h/d)
EF	=	exposure frequency (225 d/y)
ED	=	exposure duration (20 y)
BW	=	body weight (default = 60 kg)
AT	=	averaging time (7,300 d (= exposure duration) for non-carcinogenic effects; 25,550 d (= life expectancy) for carcinogenic effects)

The dermal exposure is modified in an analogous manner.

2.1.3.7 For further refinement, the effect of risk mitigation measures may be taken into account using a system-specific risk mitigation factor.

⁴ U.S. Environmental Protection Agency, 2002. Supplemental guidance for developing soil screening levels for superfund sites.

2.1.4 Periodic cleaning of ballast water tanks

2.1.4.1 In this scenario a worker works in the emptied ballast tank, where he may be exposed to volatile components arising from treatment of the ballast water that have remained in the tank atmosphere after discharge of the treated ballast water. The concentration of chemicals in the air phase may be calculated in the same manner as in 2.1.3.1. A dilution factor of 10 is introduced based on the assumption that the ballast tank was previously filled to 90% capacity and so the air from the headspace will be diluted as the ballast water is discharged and fresh air is drawn in.

2.1.4.2 Once a concentration of a volatile component has been estimated, the Tier 1 exposure assessment can be performed as described in 2.1.3.3, using an exposure time of 8 hours/day (see Table 1).

2.1.4.3 The dermal uptake of chemicals from the sediment and sludge in the ballast tank may be calculated in the same manner as in 2.1.3.4 taking into account possible exposure to more parts of the body apart from the hands.

2.1.4.4 For risk assessment, the aggregated exposure is calculated according to 2.1.3.5.

2.1.4.5 If necessary, a Tier 2 exposure assessment can be performed as described in 2.1.3.6, using an exposure frequency of 5 days/year (see Table 1).

2.1.4.6 For this scenario effects of risk mitigation measures may be taken into account as described in the following. The data underlying the UK POEM model suggest that for higher levels of challenge, it is reasonable to assume that impermeable protective coveralls provide 90% protection against aqueous challenge. Protective gloves, for this type of work, are considered to always have the potential to get wet inside and the high-end default value is used as a measure of hand exposure even for the Tier 2 assessment (exposure occurs owing to water entering via the cuff). For boots, a lower default value may be selected to represent the worker wearing appropriate impermeable boots.

2.1.5 Ballast tank inspections

2.1.5.1 In this scenario a crew member or a port state inspector enters the emptied ballast tank and may be exposed to volatile components arising from treatment of the ballast water. The concentration of chemicals in the air phase may be calculated in the same manner as in 2.1.3.1, using a dilution factor of 10 to account for the dilution by fresh air drawn into the emptied ballast tank.

2.1.5.2 Once a concentration of a volatile component has been estimated, the Tier 1 exposure assessment can be performed as described in 2.1.3.3. Exposure time in this scenario is 3 hours/day (see Table 1).

2.1.5.3 No dermal exposure is assumed for this scenario, and the calculated inhaled dose can be directly used for risk assessment.

2.1.5.4 If necessary, a Tier 2 exposure assessment can be performed as described in 2.1.3.6, using an exposure frequency of 12 days/year (see Table 1).

2.1.5.5 For further refinement, the effect of system-specific risk mitigation measures may be taken into account.

2.1.6 Crew carrying out normal work on deck unrelated to any of the above

2.1.6.1 Exposure in this scenario is through inhalation of air released from the air vents on deck. The concentration of chemicals in the atmosphere surrounding the air vents may be calculated as detailed in 2.1.3.1 and 2.1.3.3, taking into account a dilution factor of 100 for the dilution by the surrounding atmosphere.

2.1.6.2 Once a concentration of a volatile component has been estimated, the Tier 1 exposure assessment can be performed as described in 2.1.3.3. Exposure time in this scenario is 1 hour/day (see Table 1).

2.1.6.3 No dermal exposure is assumed for this scenario, and the calculated inhaled dose can be directly used for risk assessment.

2.1.6.4 If necessary, a Tier 2 exposure assessment can be performed as described in 2.1.3.6, using an exposure frequency of 180 days/year (see Table 1).

2.1.6.5 For further refinement, the effect of system-specific risk mitigation measures may be taken into account.

2.2 General public

2.2.1 Indirect exposure of humans via the environment where treated ballast water is discharged may occur by consumption of seafood and swimming in the harbour area in the Tier 1 risk assessment. The Tier 2 risk approach is described in paragraph 2.2.5.2.

2.2.2 The following situations have been identified as likely exposure scenarios for the general public:

Table 2: Summary of exposure scenarios for the general public

Situations in which the general public might be exposed to treated ballast water containing chemical by-products			
Situation	Exposure	Duration/quantity	Approach described in:
Recreational activities in the sea	Inhalation of chemicals partitioning into the air above the sea	5 events of 0.5 hours/day for 14 days of the year	2.2.3.1
	Dermal exposure to chemicals whilst swimming in the sea	5 events/day for 14 days of the year	2.2.3.2
	Swallowing of seawater contaminated with treated ballast water	5 events of 0.5 hours/day for 14 days of the year	2.2.3.3
Eating seafood exposed to treated ballast water	Oral consumption	Once or twice/day equivalent to 0.188 kg/	2.2.4
Aggregated exposure (through swimming and consumption of seafood)			2.2.5

Note: Whilst the above situations have been identified as typical worst-case exposure scenarios, it is recognized that there will be other situations when exposure of the general public may be greater or less and due consideration should be given to such situations.

In addition, the consumer exposure (general public) is normally assessed as chronic/lifetime risk in order to protect the most vulnerable population groups taking also into account that they would not use protective equipment when exposed to chemicals.

2.2.3 Recreational activities (swimming) in the sea

2.2.3.1 Inhalation of chemicals partitioning into the air above the sea

2.2.3.1.1 Exposure in this scenario is through inhalation of air above the sea while swimming. The concentration of chemicals in the air may be calculated while using the Henry's Law Constant as already described in 2.1.3.1. However, in this case the concentration in the water is the PEC harbour value as calculated by MAMPEC, and taking into account a dilution factor of 100 (due to wind, turbulence and insufficient time for the chemical to reach equilibrium).

2.2.3.1.2 The inhaled dose may be estimated using the equation below, while taking into account various assumptions (number of swims, etc.):

$$U_{si} = \frac{C_{air} \cdot IR \cdot n \cdot D \cdot BIO_{inh}}{BW}$$

where:

U_{si}	=	inhalation intake of chemical during swimming (mg/kg bw/d)
C_{air}	=	concentration in air (mg/m ³)
IR	=	inhalation rate – light activity assumed (1.25 m ³ /h)
n	=	number of swims per day (5/d)
D	=	duration of each swim (0.5 h)
BIO_{inh}	=	fraction of chemical absorbed through the lungs (1)
BW	=	body weight (default = 60 kg)

2.2.3.2 Dermal exposure to chemicals whilst swimming in the sea

Exposure in this scenario is via dermal uptake of chemicals when swimming, while using the following equation:

$$U_{sd} = \frac{C_w \cdot TH_{dermal} \cdot n_{swim} \cdot A_{skin} \cdot BIO_{dermal}}{BW}$$

where:

U_{sd}	=	dermal uptake per day during swimming (mg/kg bw/d)
C_w	=	concentration in the water, i.e. PEC _{MAMPEC} (µg/L)
TH_{dermal}	=	thickness of the product layer on the skin (0.0001 m)
n_{swim}	=	number of events (5/d)
A_{skin}	=	surface area of whole body being exposed to water (1.94 m ²)
BIO_{dermal}	=	bioavailability for dermal intake (default= 1)
BW	=	body weight (kg)

2.2.3.3 Oral uptake of seawater contaminated with treated ballast water

The oral uptake via swimming is calculated according to the following:

$$U_{so} = \frac{C_w \cdot IR_{swim} \cdot n_{swim} \cdot Dur_{swim} \cdot BIO_{oral}}{BW}$$

where:

U_{so}	= amount of chemical swallowed ($\mu\text{g/kg bw/d}$)
C_w	= concentration in the water, i.e. PEC_{MAMPEC} ($\mu\text{g/L}$)
IR_{swim}	= ingestion rate of water while swimming (0.025 L/h)
n_{swim}	= number of swims per day ($5/\text{d}$)
Dur_{swim}	= duration of each swim (0.5 h)
BIO_{oral}	= bioavailability for oral intake (default = 1)
BW	= body weight (default = 60 kg)

2.2.3.4 Tier 2 swimming

If the Tier 1 risk assessment indicates an unacceptable risk, the exposure estimation for this scenario can be refined in a Tier 2 assessment, which is based on the concentrations of substances in the surrounding water instead of the harbour (as calculated with MAMPEC).

2.2.4 Consumption of seafood exposed to treated ballast water

2.2.4.1 The concentration of chemicals in the seafood that is being consumed is calculated in this way:

$$C_{fish} = BCF \cdot PEC_{mampec}$$

where:

C_{fish}	= concentration in fish ($\mu\text{g/kg}$)
BCF	= bioconcentration factor (L/kg)
PEC_{mampec}	= concentration of chemical in water derived from MAMPEC ($\mu\text{g/L}$)

2.2.4.2 The calculation of concentrations in seafood has to be carried out for all Active Substances and Relevant Chemicals. The cut-off value for the bioconcentration factor as described for the environmental risk assessment (paragraph 3.3.6.2 of the Methodology) is not applicable in the risk assessment for human health.

2.2.4.3 While taking into account the assumption that people in the area only eat fish that is being caught locally (worst-case scenario), the daily intake may be calculated in the following way:

$$U_{fish} = \frac{QFC \cdot C_{fish} \cdot BIO_{oral}}{BW}$$

where:

U_{fish}	= uptake of chemical from eating fish ($\mu\text{g/kg bw/d}$)
QFC	= quantity of fish consumed/day (= 0.188 kg/d (FAO, Japan))
C_{fish}	= concentration of chemical in fish ($\mu\text{g/kg}$)
BIO_{oral}	= bioavailability for oral intake (default = 1)
BW	= body weight (default = 60 kg)

2.2.5 Aggregated exposure (through swimming and consumption of seafood)

2.2.5.1 The total exposure to the general public whilst swimming in the sea and eating fish is the sum of the amount of chemical absorbed through eating fish plus the oral intake, dermal absorption and inhalation absorption whilst swimming.

2.2.5.2 If an elevated risk to the general public is identified in Tier 1, a Tier 2 calculation may be performed by taking into consideration the assumption that the general public activities take place in areas more remote to the actual harbour. For these calculations the standard output from MAMPEC regarding the concentrations in the surrounding water may be used.

2.2.6 Concluding remarks

2.2.6.1 It should be noted that whilst the above situations have been identified as typical worst-case exposure scenarios, it is recognized that there will be other situations when exposure of the general public may be greater or less. Due consideration should be given to such situations.

2.2.6.2 In addition, the consumer exposure (general public) is normally assessed as chronic/lifetime risk in order to protect the most vulnerable population groups taking also into account that they would not use protective equipment when exposed to chemicals.

3 CALCULATION OF DERIVED NO-EFFECT LEVELS (DNELS)

3.1 The next step of the risk assessment process includes the definition of toxicologically significant endpoints for comparison with the calculated aggregated exposure doses. These endpoints, for example No Observed Adverse Effect Levels (NOAELs), Lowest Observed Adverse Effect Levels (LOAELs) or Benchmark Doses (BMDs) from experimental animal studies, are then further transformed to Derived No-effect Levels (DNELs) or Derived Minimal Effect Levels (DMELs) for the characterization of toxicological risks to humans.

3.2 The DNEL can be considered as an 'overall' No-Effect-Level for a given exposure (route, duration, frequency). Uncertainties/variability in these data and the human population exposed are taken into account by using appropriate Assessment Factors (AFs) according to this equation:

$$DNEL = \frac{Dose_{descriptor}}{Assessment\ Factor}$$

4 DNELS FOR THE WORKER POPULATION

4.1 For the exposure at the workplace, the following DNELs may be calculated:

- .1 DNEL, short-term exposure (mg/kg bw): the dose descriptor might be an LD₅₀ from an oral or dermal study or an LC₅₀ from an inhalation study.
- .2 DNEL, long-term exposure (mg/kg bw/d): the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic oral or dermal study or a NOAEC or LOAEC from an inhalation study.

4.2 It is also possible to derive DNELs for local effects. This is relevant for instance for corrosive/irritant substances that can produce immediate severe effects at the first site of contact (skin, eyes and/or respiratory tract).

5 DNELS FOR THE GENERAL PUBLIC

5.1 The exposure of the general public is normally assessed as chronic/lifetime risk in order to protect the most vulnerable population groups, taking also into account that they would not use protective equipment when exposed to chemicals.

5.2 Therefore, for the exposure of the general public via swimming or consumption of seafood, only one DNEL is calculated:

- .1 DNEL, general public: (mg/kg bw/d): the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic oral or dermal study or a NOAEC or LOAEC from an inhalation study.

6 DNEL CALCULATION FROM MAMMALIAN TOXICOLOGY ENDPOINTS

6.1 The DNEL may be calculated in accordance with the following equation:

$$DNEL = \frac{Dose_{descriptor} \cdot CF_{dr}}{ASF \cdot OSF \cdot ISF \cdot ESF \cdot SF_{dur} \cdot CF_{abs}}$$

where:

Dose _{descriptor}	=	see 6.3
CF _{dr}	=	experimental dosing regime, see 6.4
ASF	=	interspecies allometric factor, see 6.5
OSF	=	other interspecies scaling factor, see 6.6
ISF	=	intraspecies scaling factor, see 6.7
ESF	=	observed effect scaling factors, see 6.8
SF _{dur}	=	duration scaling factors, see 6.9
CF _{abs}	=	differential absorption factors, see 6.10

6.2 It should be noted that the DNEL is only appropriate for chemicals which cause a threshold systemic effect and is not appropriate for such effects as carcinogenicity for which a **Derived Minimal Effect Level (DMEL)** should be determined (see 7).

6.3 Dose descriptor

If the dose descriptor is a NOAEC or LOAEC from an inhalation study, expressed e.g. as mg/m³, the internal exposure, expressed as mg/kg bw/d, can be calculated using the standard respiratory volume (sRV) of the test species:

$$NOAEL = \frac{NOAEC}{sRV_{animal}}$$

For the rat the sRV is 1.15 m³/kg bw/d

For the mouse the sRV is 1.03 m³/kg bw/d

6.4 Experimental dosing regime (CF_{dr})

This factor is needed to correct the dose value when the dosing regime in an experimental animal study differs from the exposure pattern anticipated for the human population under consideration.

For example:

- .1 Starting NOAEL/NOAEC adjusted for treatment schedule (if dosing 5 days/week then a factor of 5/7 is applied)

6.5 Interspecies Allometric Scaling Factor (ASF)

6.5.1 Allometric scaling extrapolates doses according to an overall assumption that equitoxic doses (expressed in mg/kg/d) are related to, though not directly proportional to, the body weight of the animals concerned.

6.5.2 The following Allometric Scaling Factors are recommended for use in determining DNELs:

Species	Body Weight (kg)	ASF
Rat	0.25	4
Mouse	0.03	7
Hamster	0.11	5
Guinea pig	0.80	3
Rabbit	2.00	2.4
Monkey	4.00	2
Dog	18.00	1.4

6.6 Other Interspecies Scaling Factor (OSF)

If no substance-specific data are available, the standard procedure for threshold effects would be, as a default, to correct for differences in metabolic rate (allometric scaling) and to apply an additional factor of 2.5 for other interspecies differences, i.e. toxicokinetic differences not related to metabolic rate (small part) and toxicodynamic differences (larger part). In case substance-specific information shows specific susceptibility differences between species, which are not related to differences in basal metabolic rate, the default additional factor of 2.5 for "remaining differences" should be modified to reflect the additional information available.

6.7 Intraspecies scaling factor for the general population (ISF_{gp}) and workers (ISF_w)

Humans differ in sensitivity to exposure to toxic substances owing to a multitude of biological factors such as genetic polymorphism, affecting e.g. toxicokinetics/metabolism, age, gender, health and nutritional status. These differences, as the result of genetic and/or environmental influences, are greater in humans than in the more uniform inbred experimental animal population. Therefore, "intraspecies" in this context refers only to humans, which are divided into the following groups:

- .1 **workers**, which are considered to be reasonably fit and of working age. As a result, the variation in the effect of a chemical on this group is considered to be relatively small, hence:

the scaling factor for **workers** (ISF_w) = 5

- .2 **the general population**, which are considered to include children, the elderly as well as the unfit and unwell. As a result, the variation in the effect of a chemical on this group is considered to be greater than that of workers, hence:

the scaling factor for the **general population** (ISF_{gp}) = 10

6.8 Observed effect scaling factors (ESF)

6.8.1 For the dose-response relationship, consideration should be given to the uncertainties in the dose descriptor (NOAEL, benchmark dose) as the surrogate for the true no-adverse-effect-level (NAEL), as well as to the extrapolation of the LOAEL to the NAEL (in cases where only a LOAEL is available or where a LOAEL is considered a more appropriate starting point).

6.8.2 The size of an assessment factor should take into account the dose spacing in the experiment (in recent study designs generally spacing of 2-4 fold), the shape and slope of the dose-response curve, and the extent and severity of the effect seen at the LOAEL.

6.8.3 When the starting point for the DNEL calculation is a LOAEL, it is suggested to use an assessment factor of 3. However, the benchmark dose (BMD) approach is, when possible, preferred over the LOAEL-NAEL extrapolation.

6.9 Duration scaling factors (SF_{dur})

In order to end up with the most conservative DNEL for repeated dose toxicity, chronic exposure is the 'worst case'. Thus, if an adequate chronic toxicity study is available, this is the preferred starting point and no assessment factor for duration extrapolation is needed. If only a sub-acute or sub-chronic toxicity study is available, the following default assessment factors are to be applied, as a standard procedure:

Duration	Scaling Factor (SF_{dur})
Sub-chronic to chronic	2
Sub-acute to chronic	6
Sub-acute to sub-chronic	3

"sub-acute" usually refers to a 28 day study
 "sub-chronic" usually refers to a 90 day study
 "chronic" usually refers to a 1.2-2 year study (for rodents)

6.10 Differential Absorption Factors (CF_{abs})

6.10.1 It is recognized that route-to-route extrapolation is associated with a high degree of uncertainty and should be conducted with caution relying on expert judgement.

6.10.2 For simplicity 100% absorption for the oral and the inhalation route for animals and humans is assumed. On the assumption that, in general, dermal absorption will not be higher than oral absorption, no default factor (i.e. factor 1) should be introduced when performing oral-to-dermal extrapolation.

7 CALCULATION OF DMELS – NON-THRESHOLD CARCINOGENS

7.1 Background

According to Procedure (G9), paragraph 5.3.12, the effect assessment of the Active Substances, Preparations and Relevant Chemicals should include a screening on carcinogenic, mutagenic and endocrine disruptive properties. If the screening results give rise to concerns, this should give rise to a further assessment.

7.2 The Linearized approach and the Large Assessment Factor approach

7.2.1 Carcinogens can have a threshold or non-threshold mode of action. When it comes to the threshold carcinogens these can be assessed by using a DNEL approach, however, in the case of the non-threshold carcinogens (i.e. with mutagenic potential) a different approach to risk assessment is recommended.

7.2.2 As a general rule, exposure in the workplace must be avoided or minimized as far as technically feasible. In addition, a risk for the general public from secondary exposure to a non-threshold carcinogenic substance is also unacceptable. However, calculation of an exposure level corresponding to a defined low risk is possible based on a semi-quantitative approach, i.e. a derived minimal effect level (DMEL). In contrast to a DNEL, a DMEL does not represent a safe level of exposure. It is a risk-related reference value that should be used to better target risk management measures.

7.2.3 At the present status of knowledge there are two methodologies which can be applied for deriving a DMEL. The "**Linearized**" approach essentially results in DMEL values representing a lifetime cancer risk considered to be of very low concern and the "**Large Assessment Factor**" approach similarly results in DMEL values representing a low concern from a public health point of view. If data allow, more sophisticated methodologies for deriving a DMEL may be applied. The choice of such alternative methodologies should be justified.

7.2.4 Cancer risk levels between 10^{-4} to 10^{-6} are normally seen as indicative tolerable risk levels when setting DMELs. Where these values are available from internationally recognized bodies, they can be used to set DMELs for risk assessment purposes.

8 RISK CHARACTERIZATION

8.1 General approach

The Risk Characterization Ratios (RCR) compares the exposure levels to various DNELs or DMELs. The RCR is calculated according to the following formula:

$$RCR = \frac{Exposure}{DNEL} \qquad RCR = \frac{Exposure}{DMEL}$$

8.2 Occupational health risks

8.2.1 While considering ballast water sampling and tank cleaning operations, it should be assumed that the exposure routes of concern for Port State control officers and the crew will be inhalation and dermal exposure. The assumption being that the exposure will include inhalation to the highest concentration of each chemical in the atmosphere above the treated ballast water at equilibrium and the dermal uptake to the highest concentration of each chemical in the treated ballast water.

8.2.2 In the other two scenarios, ballast tank inspection and normal work on deck, only inhalation is taken into consideration.

8.3 Health risks for the general public

In the two scenarios applicable for general public, swimming in seawater contaminated with treated ballast water and ingestion of seafood which has been exposed to treated ballast water are taken into consideration.

8.4 Conclusion

8.4.1 If the $RCR < 1$, the exposure is deemed to be safe.

8.4.2 However, risks are regarded not to be controlled when the estimated exposure levels exceed the DNEL and/or the DMEL, that is, if the $RCR > 1$.

8.4.3 If the treated ballast water contains two or more chemicals with the same toxicological effect, these should be evaluated as an "assessment group". The RCR for an assessment group is calculated by addition of all RCRs of the individual components:

$$RCR_{group} = RCR_A + RCR_B + RCR_C + \dots$$

For the group RCR the same conclusions apply as described above.

8.4.4 Based on past experiences with human health risk assessment of BWMS, the only 'assessment group' that has been identified so far is non-threshold carcinogens.

8.4.5 If an unacceptable level of risk is identified for any of the scenarios in the first Tier, the second Tier is applied. If still an unacceptable risk is identified further refinement of the exposure assessment and/or the assessment factors might be performed giving special attention to route-specific contributions and additional RMM.

APPENDIX 5

MAMPEC-BW 3.1 INFORMATION

1 GENERAL

1.1 The model Marine Antifoulant Model for PEC calculation for Ballast Water (MAMPEC-BW 3.1) or latest available version may be downloaded from the website of Deltares in the Netherlands. The website is:

<https://download.deltares.nl/en/download/mampec/>

1.2 Click on the link using also the <Ctrl>-button. You will be directed to the download page of Deltares in the Netherlands. Deltares is an independent institution for applied research in the area of water and subsoil. For the ballast water application only portable versions are available. This means that the user is able to run the model without having "Administrator" rights on his computer.

1.3 At the Deltares website click on "Portable version MAMPEC 3.1.0.3 BW". Go to the right hand side of the screen and enter your name and e-mail address. You will receive a link to download a zip-file with the model.

1.4 Look in the directory where you downloaded the zip-file, click on the zip-file and unpack the programme. If you follow the default settings of the programme you will find the model with its executables in the directory specified in the set-up conversation. You may change the standard settings to your own choices.

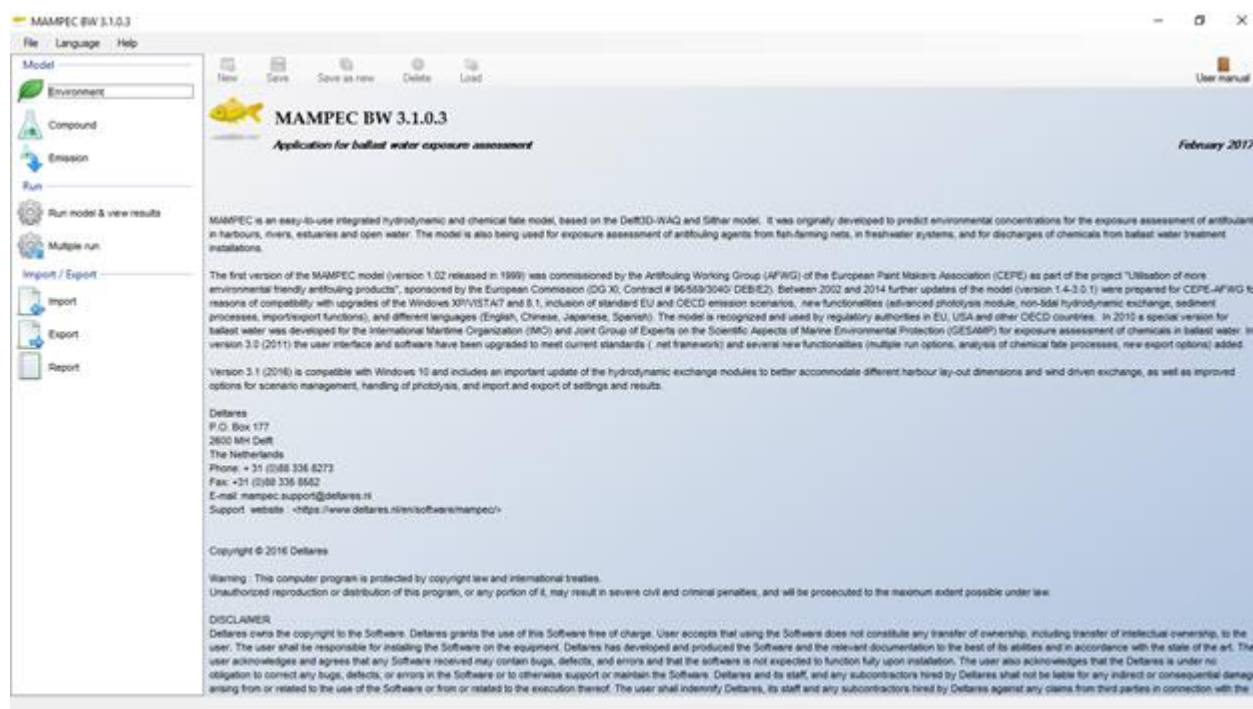
1.5 Go to the specified directory and click on the executable "mampec.exe" and the main entrance screen will be shown.

2 CALCULATION OF THE PREDICTED ENVIRONMENTAL CONCENTRATION (PEC)

2.1 This calculation procedure is important for carrying out a risk assessment to the environment.

2.2 In order to provide a standard approach, it is recommended that the MAMPEC-BW 3.1.0.3 or latest available version is used to determine the PEC for each chemical identified.

2.3 When this model is used for calculation of the predicted concentration (PEC) in the harbour, several data have to be selected from the main menu of the programme. The entrance screen of MAMPEC-BW 3.1.0.3 looks as follows:

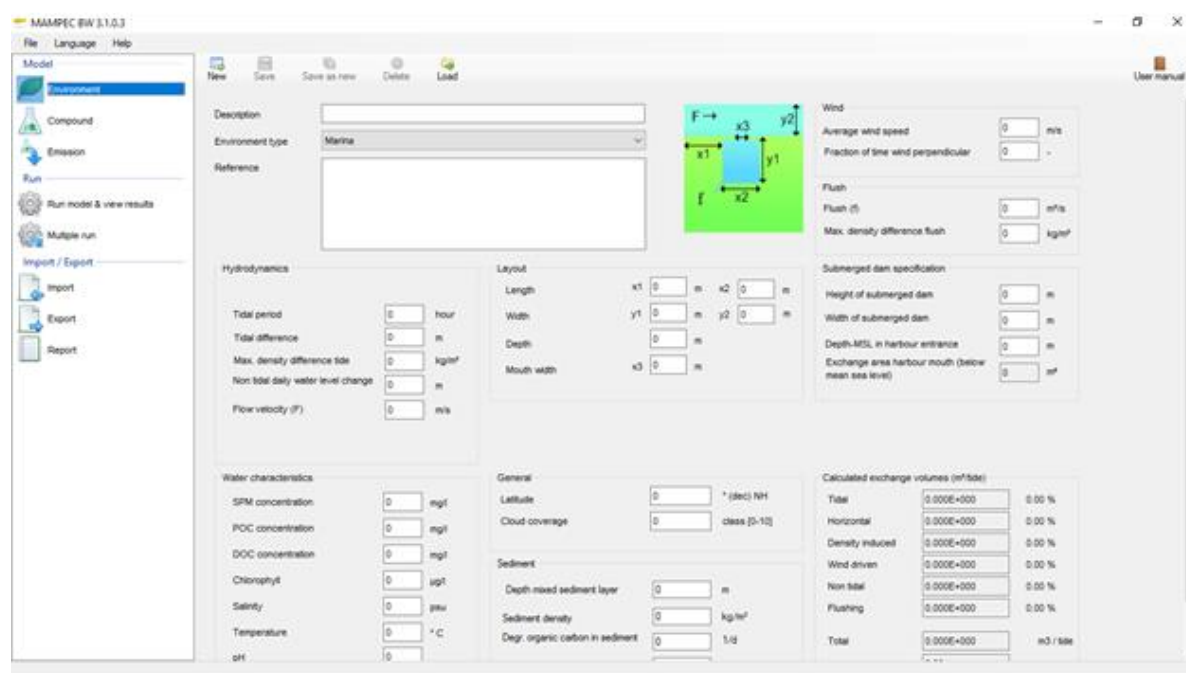


NOTE: in the upper right corner of the screen a user manual is always available.

2.4 To run the MAMPEC model three inputs are needed:

- .1 the Environment (first item under "model" at the left hand side of the screen);
- .2 the Compound (second item); and
- .3 the Emission (third item).

2.5 Click on "Environment" and the following screen appears:



2.6 To load the GESAMP-BWWG Standard Harbour click on "Load" and the next screen appears:

Label	Description
GESAMP-BWWG Model Harbour	
OECD-EU Commercial harbour	
OECD-EU Shipping Lane	

2.7 In the "Description" box you may enter a name of the project, then click "GESAMP-BWWG Model Harbour" and successively on "Load". You will be taken back to the "Environment" screen but now the screen is loaded with the GESAMP-BWWG Model Harbour's specific data. It is recommended not to change the default values if the results will have to be used for a submission to IMO with respect to an approval in accordance with Procedure (G9).

2.8 To load the data for a compound click on "Compound", on which the "Compound" screen appears, as follows:

2.9 Click on "Load" and a list of all the GESAMP-BWWG compounds commonly associated with ballast water (41 compounds) will appear as follows:

Load

Description

	Label	Description
	Label	(41)
		1,1,1-trichloroethane
		1,1,2-Trichloroethane
		1,1-dibromoethane
		1,1-Dichloroethane
		1,2-Dibromo-3-chloropropane
		1,2-dichloroethane
		1,2-Dichloropropane
		2,4,6-Tribromophenol
		Acetaldehyde
		Bromate ion
		Bromochloroacetic acid
		Bromochloroacetonitrile
		Bromoform
		Chloral hydrate
		Chloroform
		Chloropicrin
		Dalapon
		Dibromoacetic acid
		Dibromoacetonitrile
		Dibromochloroacetic acid

Delete

Save labels

Load

Cancel

2.10 For example, by clicking "Bromoform" and "Load" the data for bromoform can be shown in the "Compound" screen, like:

MAMPEC BW 3.1.0.3

File Language Help

New Save Save as new Delete Load

Model
Environment
GESAMP-BWWG Model Harb.
Compound
Emission
Run
Run model & view results
Multiple run
Import / Export
Import
Export
Report

Compound description: Bromoform
Compound name: Bromoform
Molecular mass: 252.73 (g/mol)
Saturated vapour pressure at 20 °C: 660 (Pa)
Solubility at 20 °C: 3190 (g/m³)

CAS number: 75-29-2
EINECS number:
Reference: GESAMP-BWWG, STN3 4-8 April, 2011. R from TOXNET-HSCB.

Metal Organic

Depth and time-averaged degradation rates

	Water (l/kg)		Sediment/SPM	
	Rate Constant (day ⁻¹)	Half-life (day)	Rate Constant (day ⁻¹)	Half-life (day)
Hydrolysis and other abiotic (20 °C)	0.00E+000	Infinity	0.00E+000	Infinity
Photolysis (20 °C)	0.00E+000	Infinity	0.00E+000	Infinity
Biodegradation (aerobic and anaerobic) (20 °C)	0.00E+000	Infinity	0.00E+000	Infinity

☐ Use advanced photolytic degradation [Advanced photolytic degradation](#)

Parameters describing partitioning

Octanol-water partition coefficient K_{ow}: 2.40E+000 (10 log K_{ow})
Partition coefficient K_{oc}: 1.90E+001 (10 log K_{oc} (log OC))
Henry's constant at 20 °C: 6.41E+001 (Pa·m³/mol)

Estimate missing values

Melting temperature: 8 °C
Acid dissociation constant pK_a: 14 (-)

2.11 In the middle of the "Compound" screen biodegradation data may be shown for several of the 41 substances. It is advisable to start the calculation with all rate constants set to 0 (zero) as this is considered the worst-case situation. If the worst-case situation does not lead to the conclusion of potentially unacceptable effects, entering available degradation data with the accompanying calculation may solve the problem of exceeding a PEC/PNEC ratio of 1. This may be done by entering a rate constant or a half-life in the appropriate boxes.

2.12 In addition to the GESAMP-BWWG Harbour Environment shown above and the compound, the standard GESAMP-BWWG emission data need to be included as part of the GESAMP-BWWG Standard model in the same way as described already by clicking on "Emission" and successively on "Load". The following screens appear after each other:

and

Label	Description
Label (2)	
	Default Emission GESAMP BWWG Model Harbour
	GESAMP BWWG 3 mg/L

2.13 By clicking on "Default Emission GESAMP Model Harbour" and on "Load" take you back to the emission screen, where you can complete your input by entering the concentration of the substance under consideration found in ballast water at the appropriate box. Successively clicking on "Calculate" gives the final emission in g/d. NOTE, that the concentration of the substance should be entered in mg/L (not $\mu\text{g/L}$).

MAMPEC BW 3.1.0.3

File Language Help

Model

- Environment
 - GESAMP-BWBG Model Harb...
- Compound
 - Bromofom
- Emission
 - Default Emission GESAMP BW...
- Run
 - Run model & view results
 - Multiple run
- Import / Export
 - Import
 - Export
 - Report

New Save Save as new Delete Load

Description: Default Emission GESAMP BW Model Harbour Total emission: 300000 g/d

Reference: GESAMP-BWBG, STW3 4-6 April, 2011

Calculate emission

Ballast water discharge: 100000 m³/day

Concentration: 3 mg/L

Calculate

2.14 All necessary input for MAMPEC has now been defined and the model can now be run by clicking on "Run model and view results". The following screen will appear:

MAMPEC BW 3.1.0.3

File Language Help

Model

- Environment
 - GESAMP-BWBG Model Harb...
- Compound
 - Bromofom
- Emission
 - Default Emission GESAMP BW...
- Run
 - Run model & view results
 - Multiple run
- Import / Export
 - Import
 - Export
 - Report

New Save Save as new Delete Load

Run name: [] Generate name

Environment: GESAMP-BWBG Model Harbour Change

Compound: Bromofom Change

Emission: Default Emission GESAMP BW Model Harb... Change

Load: 300000 g/d

Background concentrations

ug/l (total conc. whole area): 0 0 0

ug/l (dissolved water conc. whole area): 0 0 0

Run date: []

Run model

2.15 In this screen some additional identifiers can be added, like a project name. A date will automatically be added (This box is grey and cannot be changed). It is not recommended to add information on background concentrations. Successively press "Run model" at the right hand side of the screen. The following screen appears:

MAMPEC BW 3.1.0.3

File Language Help

Model

Environment
GESAMP-BWWG Model Harb...

Compound
Bromofom

Emission
Default Emission GESAMP BW...

Run
Run model & view results
Test run bromofom

Import / Export
Import
Export
Report

New Save Save as new Delete Load

Run name: Test run bromofom Generate name

Environment: GESAMP-BWWG Model Harbour Change

Compound: Bromofom Change

Emission: Default Emission GESAMP BWWG Model Har Change

Load: 300000 g/t

Background concentrations

Background conc. ☐ Add constant to simulation results ☐ Add initial sediment concentration

ug/l (total conc. whole area) 0 0 0

ug/l (dissolved water conc. whole area) 0 0

Run date: 2017-03-02 7:10 Run model

Predicted concentrations at steady state Analysis of fate and fluxes at steady state PEC profile surroundings

Harbour

	Total conc.	Freely dissolved	DOC-bound	Suspended matter	Sediment after 1 Year	Sediment after 2 Years	Sediment after 5 Years	Sediment
Maximum concentration	3.68E+001 ug/l	3.68E+001 ug/l	1.67E+005 ug/l	1.69E+003 ug/g dw	9.81E+006 ug/g dw	1.90E+004 ug/g dw	4.34E+004 ug/g dw	7.49E+004
95 % concentration	3.68E+001 ug/l	3.68E+001 ug/l	1.67E+005 ug/l	1.69E+003 ug/g dw	9.81E+006 ug/g dw	1.90E+004 ug/g dw	4.34E+004 ug/g dw	7.49E+004
Average concentration	1.79E+001 ug/l	1.79E+001 ug/l	8.19E+006 ug/l	7.79E+004 ug/g dw	4.79E+006 ug/g dw	9.29E+005 ug/g dw	2.12E+004 ug/g dw	3.69E+004
Median concentration	1.67E+001 ug/l	1.67E+001 ug/l	7.79E+006 ug/l	7.37E+004 ug/g dw	4.66E+006 ug/g dw	8.84E+005 ug/g dw	2.02E+004 ug/g dw	3.43E+004
Minimum concentration	1.66E+000 ug/l	1.66E+000 ug/l	7.70E+007 ug/l	7.29E+006 ug/g dw	4.51E+006 ug/g dw	8.74E+006 ug/g dw	1.99E+005 ug/g dw	3.44E+005

Surroundings

	Total conc.	Freely dissolved	DOC-bound	Suspended matter	Sediment after 1 Year	Sediment after 2 Years	Sediment after 5 Years	Sediment
Maximum concentration	3.26E+001 ug/l	3.26E+001 ug/l	1.62E+007 ug/l	1.44E+006 ug/g dw	8.92E+007 ug/g dw	1.73E+006 ug/g dw	3.94E+006 ug/g dw	8.81E+006
95 % concentration	3.07E+001 ug/l	3.07E+001 ug/l	1.44E+007 ug/l	1.36E+006 ug/g dw	8.41E+007 ug/g dw	1.63E+006 ug/g dw	3.72E+006 ug/g dw	8.42E+006
Average concentration	8.67E+002 ug/l	8.67E+002 ug/l	4.01E+008 ug/l	3.80E+006 ug/g dw	2.36E+007 ug/g dw	4.66E+007 ug/g dw	1.04E+006 ug/g dw	1.79E+006
Median concentration	1.62E+002 ug/l	1.62E+002 ug/l	7.12E+009 ug/l	6.74E+007 ug/g dw	4.17E+008 ug/g dw	8.08E+006 ug/g dw	1.84E+007 ug/g dw	3.19E+007
Minimum concentration	0.00E+000 ug/l	0.00E+000 ug/l	0.00E+000 ug/l	0.00E+000 ug/g dw	0.00E+000 ug/g dw	0.00E+000 ug/g dw	0.00E+000 ug/g dw	0.00E+000

☐ Using hydrodynamics v2.6
☒ Using hydrodynamics v3.1

2.16 The predicted concentrations at steady state in the harbour and the surroundings can now easily be identified.

2.17 At the left hand side some input/output facilities are given, like the generation of a report for publication.

2.18 The results of carrying out this procedure for each of the chemicals associated with the BWMS will be a series of PEC values, which should be included in a table with the Predicted No Effect Concentration (PNEC) and the appropriate assessment factor (AF). As a first assessment, the maximum value from the MAMPEC-BW 3.1.0.3 or latest available version calculations should be used. If this comparison results in PEC/PNEC ratios above 1, the 95%-ile may be used. If the PEC/PNEC ratio is still above 1, additional mitigation measures or a scientific reasoning may be proposed for discussion in the GESAMP-BWWG.

2.19 In addition to the mitigation measure mentioned in paragraph 2.11 above (taking into account the degradation of the substance), it can be useful to use the concentrations in the surroundings as a higher Tier evaluation.

2.20 The resulting table should be reported in the main document of the submission.

3 CALCULATION OF THE PEC IN THE VICINITY OF THE SHIP (PEC_{NEAR SHIP})

3.1 The MAMPEC-BW, latest available version, will calculate the stationary concentration in the harbour after discharge of ballast water. To account for local effects, near the ship at discharge, the local concentration at near ship is estimated using the formulae suggested in Zipperle et al., 2011 (Zipperle, A., Gils J. van, Heise S., Hattum B. van, Guidance for a harmonized Emission Scenario Document (ESD) on Ballast Water discharge, 2011):

$$C_{\max} = \frac{C_{BW} + (S - 1) \cdot C_{\text{mean}}}{S}$$

where:

$C_{\max}$	=	the maximum concentration due to near ship exposure (µg/L) = PEC _{near ship}
C_{BW}	=	the concentration found in the discharged ballast water (µg/L)
S	=	dilution factor based on sensitivity analysis with a higher Tier model, default value = 5
C_{mean}	=	the mean concentration as output from MAMPEC-BW = called average in the MAMPEC results calculated.

3.2 The concentration calculated with this formula will be compared to acute toxicity data for the Active Substances and Relevant Chemicals to evaluate the short-term effects on aquatic organisms according to the ratio:

$$\text{PEC}_{\text{near ship}} / \text{PNEC}_{\text{near ship}}$$

APPENDIX 6

DATABASE OF CHEMICALS MOST COMMONLY ASSOCIATED WITH TREATED BALLAST WATER

The GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water is provided as a GISIS module (<https://gisis.imo.org/>).

For the chemicals in the GESAMP-BWWG Database, the GESAMP-BWWG holds sufficient information from the literature on physico-chemical, ecotoxicological and toxicological properties, and no additional supporting information needs to be submitted by applicants. It is recommended that applicants make use of the Database when preparing their application dossiers.

APPENDIX 7

APPROPRIATE DETECTION LIMITS FOR DIFFERENT RELEVANT CHEMICALS

1 The information previously included in this annex on appropriate detection limits for different chemicals associated with treated ballast water was moved to the IMO website.

2 A link to the document containing the table of suggested detection limits, which will be continuously updated as those detection limits may be revised, can be found at: <https://www.imo.org/en/OurWork/Environment/Pages/BWMTechologies.aspx>.