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BWM.2/Circ.13/Rev.1
26 April 2012

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 for information gathering and conduct of work of the GESAMP-BWWG is 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 carried out a thorough review of the Methodology and prepared a revised version for approval by the GESAMP, and consideration and endorsement by MEPC.

5 The MEPC, at its sixty-third session (March 2012), endorsed the revised Methodology for information gathering and conduct of work of the GESAMP-BWWG, as set out in the annex, and agreed to re-issue BWM.2/Circ.13 by means of BWM.2/Circ.13/Rev.1.

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

6 MEPC 63 further agreed that the revised Methodology should be applied to all submissions for Basic Approval of ballast water management systems to MEPC 65 and subsequent sessions and to the submissions for Final Approval of those systems.

7 Member Governments are invited to bring this circular to the attention of all parties concerned and, in particular, manufacturers of ballast water management systems which make use of Active Substances.

8 This circular supersedes Circular BWM.2/Circ.13.

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ANNEX

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

(Updated version September 2011)
Endorsed at MEPC 63 on 2 March 2012

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), as revised (adopted by resolution MEPC.169(57)).

1.1 TERMS AND DEFINITIONS

For the purpose of this document, 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 **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.

.4 **Active Substances** (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.

.5 **Relevant Chemicals** (RC) means transformation or reaction products that are 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.

.6 **Other Chemicals** (OC) means any other substances, other than the Active Substance(s) or Relevant Chemicals, potentially associated with the system either intentionally or resulting from the treatment of ballast water.

.7 **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.

.8 **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 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.

.9 **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 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.

.10 **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.

1.2 ABBREVIATIONS USED IN THE TEXT

ABBREVIATIONS

<	less than
≦	less than or equal to
>	greater than
≧	greater than or equal to
µg	microgram
AS	Active Substance
ASF	interspecies allometric straining factor
ASTM	American Society for Testing of 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
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	Procedure for approval of ballast water management systems that make use of Active Substances (G9), 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

ABBREVIATIONS

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	liter
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
MAMPEC	Marine Antifoulant Model for PEC calculation
MAMPEC-BW	Marine Antifoulant 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	milliliter
m.p.	melting point
ng	nanogram
NOAEC	no observed adverse effect concentration
NOEC	No Effect Concentration
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
NTP	national toxicological programme
OC	other chemical
OECD	Organization for Economic Co-operation and Development
Organization	the International Maritime Organization
OSF	other interspecies straining factor

ABBREVIATIONS

PBT	Persistence, Bioaccumulation and Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
POC	Particulate organic carbon
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
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

2.1.1 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) through 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

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).

2.3 SUBMISSION OF AN APPLICATION FOR APPROVAL

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 (see 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 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 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 12 hours. Applicants may wish to designate a technical representative to provide clarifications on request during the Group's meeting.

2.3.13 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.

2.3.14 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.

2.3.15 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.

2.3.16 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 document and subject to a new registration fee.

2.3.17 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

2.4.1 The confidential information in the submitted documents should clearly be 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 for 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

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

2.8.1 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 new Methodology.

3 APPLICATION DATA-SET

3.1 GENERAL

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 LC_{50} 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 (G9: 4.1)

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.

3.2.2 Active Substance

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 (G9: 2.1.4)

Where the process might produce by-products when reacting with ballast water, the applicant should provide the following information for those products 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:

.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.

3.3 DATA ON EFFECTS ON AQUATIC PLANTS, INVERTEBRATES AND FISH, AND OTHER BIOTA, INCLUDING SENSITIVE AND REPRESENTATIVE ORGANISMS (G9: 4.2.1.1)

3.3.1 General

3.3.1.1 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 $L(E)C_{50}$ from freshwater or saltwater representatives of three taxa (algae, crustacea 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), USEPA 850.1035 (Mysid shrimp acute toxicity test), and Mysid shrimp acute toxicity test (USEPA 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 Treated ballast water (G9: 5.2.3).

3.3.3 Chronic aquatic toxicity

3.3.3.1 Long-term NOECs or EC10 from three freshwater or saltwater species (normally algae and/or crustacea and/or fish), representing three trophic levels by internationally standardized tests, e.g. OECD guidelines 210, 215, or 212 (fish), and OECD guideline 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).

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 treated ballast water (fish, invertebrate, plant) (G9: 5.2.3).

3.3.3.4 For the chronic aquatic toxicity testing using treated ballast water (paragraph 3.1.4), based on the experience gained in the evaluation process of BWMS, it has been shown that, where BWMS using electrolysis and/or ozonation are concerned, there is no need to evaluate the results of chronic ecotoxicity testing using treated and effectively neutralized 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 variegates,* including a minimum of two tests with marine species.

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;

.3 Relevant Chemicals; and

.4 treated ballast water.

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 (G9: 4.2.1.2)

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 other 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 its 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 its components;

.2 Active Substances; and

.3 Relevant Chemicals.

3.4.9 Toxicokinetics

3.4.9.1 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 physic-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 (G9: 4.2.1.3)

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 it is recommended to evaluate the fate of Active Substances and Relevant Chemicals in fresh water (PSU < 3) and in marine water (PSU > 30) each at low temperatures (5°C) and higher temperatures (> 25°C).

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 any other components of Preparations; 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 document 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 any components of Preparations; 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 document;

.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 any other components of Preparations; and

.3 Relevant Chemicals.

3.5.5 Bioavailability/biomagnification/bioconcentration

3.3.5.1 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 per cent of the whole body weight. BCF should be normalized to 5 per cent fat;

.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.

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

.1 Active Substances;

.2 Any components of a Preparation; 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 its components;

.2 Active Substances;

.3 Relevant Chemicals; and

.4 treated 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 its 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 its 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 (G9: 4.2.1.4)

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:

.1 Active Substances.

3.6.3 Boiling point

Data on the boiling point should be provided for:

.1 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 treated 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 its components;

.2 Active Substances;

.3 Relevant Chemicals; and

.4 treated ballast water.

3.6.9 Corrosivity to the materials or equipment of normal ship construction

3.6.9.1 Data on the corrosivity to uncoated low carbon steel and other metals (e.g. stainless steel, Cu alloys and Ni alloys) and non-metals (e.g. gasket and seal materials) as may be found in a ship's seawater piping, fittings and structures which will be exposed to the Active Substance, Relevant Chemicals or Disinfection By-products should be provided.

3.6.9.2 Substrates should include low carbon steel and other metals (e.g. stainless steel, Cu alloys and Ni alloys) and non-metals (e.g. gasket and seal materials) as may be found in a ship's seawater piping, fittings and structures which will be exposed to the Active Substance, Relevant Chemicals or Disinfection By-products.

3.6.9.3 In case passive materials are exposed to the Active Substances, Relevant Chemicals or Disinfection By-products, these should be examined for localized corrosion resistance by immersion with specimen configurations as defined in ASTM G78 Standard Guide for Crevice Corrosion Testing of Iron-Base and Nickel-Base Stainless Alloys in Seawater and Other Chloride-Containing Aqueous Environments. As an additional evaluation, short-term laboratory tests should be conducted in accordance with ASTM G61 - 86(2003) e1 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion Susceptibility of Iron-, Nickel-, or Cobalt-based Alloys.

3.6.9.4 Testing of coated substrates should be conducted using ISO 2812-2:2007 Paints and varnishes – Determination of resistance to liquids – Part 2: Water immersion method as guidance.

3.6.9.5 Testing should be conducted with controls (untreated) and treated effluents under continuous exposure. The treated effluent testing should, as a minimum, comprise continuous testing using full-strength natural seawater with the test fluid being replaced with newly treated fluid at the maximum treatment concentration at least once every fourteen (14) days throughout the term of the testing program. ASTM G31 – 72 (2004) Standard Practice for Laboratory Immersion Corrosion Testing of Metals can be used as a guide for such testing. If appropriate, testing should also include testing in fresh or brackish seawater.

3.6.9.6 Test duration should not be less than six (6) months.

3.6.9.7 Subsequent evaluation of uncoated materials should include an evaluation of the corrosion rate, by weight loss, and the depth and density of localized corrosion (i.e. pitting or crevice attack). These evaluations may be made with the assistance of ISO 11463 Corrosion of Metals and Alloys – Evaluation of Pitting Corrosion and ASTM G 46 Guide for Examination and Evaluation of Pitting Corrosion.

3.6.9.8 Subsequent evaluation of coated materials and coating properties of both controls and samples exposed to treatment conditions should include:

.1 coatings adhesion according to ISO 4624 Paints and Varnishes – Pull-Off Test for Adhesion;

.2 degree of blistering according to ISO 4628-2 Paints and Varnishes – Evaluation of Degradation of Coatings – Designation of Quantity and Size of Defects and of Intensity of Uniform Changes in Appearance – Part 2: Assessment of Degree of Blistering;

.3 degree of rusting according to ISO 4628-3 Paints and Varnishes – Evaluation of Degradation of Coatings – Designation of Quantity and Size of Defects and of Intensity of Uniform Changes in Appearance – Part 3: Assessment of Degree of Rusting;

.4 degree of cracking according to ISO 4628-4 Paints and Varnishes – Evaluation of Degradation of Coatings – Designation of Quantity and Size of Defects and of Intensity of Uniform Changes in Appearance Part 4: Assessment of Degree of Cracking;

.5 degree of flaking according to ISO 4628-5 Paints and Varnishes – Evaluation of Degradation of Coatings – Designation of Quantity and Size of Defects and of Intensity of Uniform Changes in Appearance – Part 5: Assessment of Degree of Flaking; and

.6 degree of delamination around a scribe according to ISO 4628-8 Paints and Varnishes – Evaluation of Degradation of Coatings – Designation of Quantity and Size of Defects and of Intensity of Uniform Changes in Appearance – Part 8: Assessment of Degree of Delamination and Corrosion around a Scribe.

3.6.9.9 This testing should be provided for:

.1 treated ballast water.

3.6.9.10 Testing should also be conducted on low carbon steel coated in compliance with the PSPC – (resolution MSC.215(82)) to determine the effect on such coatings.

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:

.1 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

Data on the pH should be provided for:

.1 uptake water, treated water and discharge water.

3.6.18 Salinity

Data on the salinity should be provided for:

.1 uptake water, treated water and discharge water.

3.6.19 TOC, DOC, percentage of particulate matter

Data on the TOC, DOC and percentage of particulate matter should be provided for:

.1 uptake water, treated water and discharge water.

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 treated ballast water.

3.7 ANALYTICAL METHODS AT ENVIRONMENTALLY RELEVANT CONCENTRATIONS (G9: 4.2.1.5)

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 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

4.1.1 The proposal for Basic Approval and Final Approval should include maximum dosage and maximum allowable discharge concentrations of Active Substances.

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 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 emergency measures in case of an accident;

.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 possibility of reuse or recycling;

.8 the possibility of neutralization;

.9 conditions for controlled discharge;

.10 minimum retention time of treated water on board before discharge; and

.11 the amount of substance on board ship.

4.1.4 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.

4.1.5 The risk management measures proposed should be evaluated in respect to the hazards to ship, personnel and the environment.

5 RISK CHARACTERIZATION – HUMAN HEALTH

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.

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:

$$DNEL = N(L)OAEL/AF$$

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 Where data are of an unsatisfactory quality, 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, reproductive toxic and endocrine disruptive properties. If the screening results give rise to concerns, this should give rise to a further effect 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 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. In these cases, a Derived Minimal Effect Level (DMEL) or equivalent endpoint, should be determined.

5.14 Cancer risk levels of 10^{-5} and 10^{-6} are normally seen as indicative, tolerable risk levels when setting DMELs for workers and the general population, respectively. 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 6.1 of this document).

5.16 The procedure followed 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 (G9: 5.1)

6.1.1 Persistence (G9: 5.1.1.1)

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 document.

6.1.2 Bioaccumulation (G9: 5.1.1.2)

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 document.

6.1.3 Toxicity tests (G9: 5.1.2.3)

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 document.

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 Preparation meet all three criteria for PBT?

Table 1: 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 fresh water sediments
Bioaccumulation	Experimentally determined BCF > 2,000, or if no experimental BCF has been determined, Log P_{ow}≥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 fresh water 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 TREATED BALLAST WATER (G9: 5.2)

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 document.

6.2.1.3 The number of replicates both for each test concentration and control should be three or more for the all three species, described in sections 3.3.2 and 3.3.3 of this document.

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

6.2.1.5 For the acute and chronic 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 for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) must not exceed 35 per cent (OECD 201).

.3 The coefficient of variation of average specific growth rates in the replicates during the whole test period must not exceed 7% (ISO10253) or 10 per cent (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 strongly recommended 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. Any limitations as to environmental acceptability should be clearly indicated in the submission.

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 From a pragmatic standpoint, the following information would provide adequate safeguards for the environment and may replace the requirement of the submission of chronic toxicity data on the full-scale WET tests:

.1 acute toxicity testing using algae (or plants), invertebrates and fish; or

.2 chemical analysis demonstrating that there are no significant increases in the concentrations of chemical by-products during at least a five-day tank holding time or a holding time in accordance with the sampling scheme under the Guidelines (G8); or

.3 both chemical analysis and acute aquatic toxicity testing; immediately after treatment and after 24 or 48 hours.

6.2.3.3 Recently gained experience on the data availability of a full chemical analysis of the treated and/or neutralized ballast water in combination with the acute toxicity testing of the WET test would reveal, based on expert judgment, that unacceptable effects on the receiving aquatic environment are not to be expected. In this way, expensive chronic ecotoxicity testing may be avoided with sufficient safety on the potential effects on aquatic organisms.

6.2.4 Comparison of effect assessment with discharge toxicity

6.2.4.1 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 holding time

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 half-life, decay and dosage rates, system parameters and toxicity should be used to determine the amount of time needed to hold the treated ballast water before discharge (G9: 5.2.7). An indication of the uncertainty of the holding time should be given, taking into account different variables (e.g. temperature, pH, salinity and sediment loading).

6.3 RISK CHARACTERIZATION AND ANALYSIS

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 sea 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):

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

where:

C_{max} = the maximum concentration due to near sea 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 Active Substance is considered.

6.3.2 Effects assessment

6.3.2.1 The effect assessment of the Active Substances, Preparations including any of its 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. crustacea), 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 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 (e.g. OECD) (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 sea) 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 2, 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 2: Assignment of Assessment Factors (AF) used for deriving PNEC values

Data-set	Assessment Factor		Rule number
	PNEC general	PNEC near sea	
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 document for information on suitable chronic testing.

.4 For the determination of the assessment factor for the NOEC values in Table 2 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 refer to the GESAMP-BWWG database containing the 18 substances as indicated in appendix 6 to this Methodology and indicates the relevant Assessment Factors as used for these 18 substances.

6.3.3.2 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.

6.3.3.3 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.

6.3.3.4 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.

6.3.3.5 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.

6.3.4 Comparison of effect assessment with discharge toxicity

6.3.4.1 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

7.1.1 The potential risk to the safety of the ship and crew 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/crew may include, *inter alia*:

.1 increased corrosion;

.2 fire and explosion;

.3 storage and handling of the substances;

.4 contact with, or inhalation of, process products; and

.5 noise.

7.2 RISKS TO HUMAN HEALTH

7.2.1 General

7.2.1.1 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 document. The population groups deemed to be at risk and so to be examined should include crew, passengers and all personnel, including the public, in ports. Potential health risks connected to

the exposure of consumers via seafood or persons at the coast (e.g. beach) after discharge should be evaluated. Special attention should be given to service and repair of the system by technicians and accidental situations on board (e.g. specific personal protection equipment). 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

7.2.2.1 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 document).

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, using the guidance contained in appendix 4 of this document (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 component, including connecting piping, a description of such exposures needs to be provided, e.g. chemical storage, chemical application, processing of treated ballast water, ballast tank operations, including associated piping, as well as discharge operations and maintenance. The risk assessment should also include the risk reduction measures envisaged for all of the above-defined unit operations, i.e. stating clear Personal Protective Equipment (PPE) requirements for each step in the process.

7.2.3.3 Equipment failure and accident situations should be considered separately from conditions of normal operation.

7.2.3.4 In cases where an exposure/DNEL or exposure/DMEL ratio is not less than 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

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 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 not less than 1, then, to demonstrate that there is no unacceptable risk, the applicant should provide scientific justification, which may include potential risk mitigation measures.

8 ASSESSMENT REPORT (G9: 4.3)

8.1 The Assessment Report referred to in section 4.3 of Procedure (G9) should be presented by the concerned Administration and should at least provide:

.1 an overview of the data and endpoints on which the risk characterization according to section 6 of Procedure (G9) is based, including a description of the quality of test reports;

.2 an assessment of risks to the safety of ships, human health (crew and general public), the environment and resources in accordance with section 6 of Procedure (G9);

.3 if any monitoring has been conducted, a summary of the results of that monitoring, including information on the analytical methodology used, ship movements and a general description of the area monitored;

.4 a summary of the available data on environmental exposure and any estimates of environmental concentrations developed through the application of mathematical models, using all available environmental fate parameters, preferably those that were determined experimentally, along with an identification or description of the modeling methodology;

.5 an evaluation of the association between the ballast water management system making use of Active Substances or Preparations containing one or more Active Substances to comply with the Convention in question, the related adverse effects and the environmental concentrations, either observed or expected, based on the risk assessment and the effluent testing;

.6 a qualitative statement of the level of uncertainty in the evaluation referred to under the preceding paragraph; and

.7 a detailed description of risk management possibilities, e.g. for neutralization of the Active Substance in case of emergency or if PEC/PNEC at discharge >1. These management measures are an integral part of the ballast water management system.

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 the Guidelines (G8), paragraph 2.3, 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), then 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 toxicity testing should be done on two types of water at two appropriate time intervals after treatment (preferably immediately after treatment and after a 24 or 48-hour interval), and organisms normally found in the selected types of water should be used in the toxicity testing. Dependent upon recommendations made at Basic Approval, in many cases only acute toxicity testing will be needed for Final Approval;

.6 all information related to Total Residual Oxidants (TROs), Total Residual Chlorine (TRC) and the chemicals included in such groupings, including their concentrations, should be provided to the GESAMP-BWWG for Final Approval when requested as part of its evaluation for Basic Approval;

.7 in addition to the basic data-set needed for the treated ballast water and the individual chemicals produced by the system – as identified in the Methodology for Basic Approval – a generated meaningful PEC/PNEC ratio would be required for Final Approval; and

.8 the application for Final Approval should address the concerns identified during the consideration for Basic Approval.

* * *

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

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) 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. 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.

   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: _____

_____

_____

* * *

APPENDIX 2

TIMETABLE FOR ACTIVITIES RELATED TO THE GESAMP-BWWG MEETINGS

Timeline	Activity
28 weeks before 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 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 MEPC	Submission of the report of the meeting of the GESAMP-BWWG in accordance with the 13-week deadline (bulk documents) for 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)

ANNEX

1 INTRODUCTION

1.1 This section should include:

.1 a brief history of any previous applications;

.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.

3 CHEMICALS ASSOCIATED WITH THE SYSTEM

3.1 Chemical reactions associated with the system

3.1.1 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.

3.2.2 A summary of all chemicals analysed for in the treated ballast water 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 mg/L) should be associated with it to indicate the detection limits of the analysis.

Chemical analysis of treated ballast water

Chemical	Concentration in treated ballast water (µg/L)	Type
A	20*	AS
B	5*	RC
C	<0.1*	OC
D	<0.5*	OC

* The values indicated are examples.

3.3 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 in appendix 1 to this document) should be included in the application where the chemical has not been evaluated by the GESAMP-EHS or the GESAMP-BWWG and listed in appendix 6 to this document.

3.4 Unless the applicant disagrees with these data in which case the applicant should provide reasons for disagreeing and supported replacement data for consideration.

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

4 CONSIDERATION OF CONCERNS EXPRESSED BY THE GROUP DURING ITS PREVIOUS REVIEW

4.1 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 an FA submission following a BA approval).

5 HAZARD PROFILE DATA 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. Such a summary should be shown in appendix 1 to this document. Where possible, references have been 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 In order to assist applicants in providing these summary data, the GESAMP Evaluation of Hazardous Substances Working Group (EHS) and the GESAMP-Ballast Water Working Group (BWWG) have evaluated some of the chemicals commonly associated with Ballast Water Management Systems (BWMS). This means that for the substances indicated in appendix 6 no additional properties on physico-chemistry, ecotoxicology and toxicology have to be submitted, unless the applicant has other, scientifically more relevant data available.

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.

6 WHOLE EFFLUENT TESTING (WET) – (LABORATORY TEST FOR BASIC APPROVAL AND LAND-BASED TEST OR ON-BOARD TEST FOR FINAL APPROVAL)

6.1 This section should include:

.1 a brief description of the tests carried out; and

.2 a table of the results, e.g. as shown below:

	Species	Example results			Comments
		NOEC*	LOEC*	EC_{50}*	
Algae		50%	75%	83%	
Crustacea		> 100%	> 100%	> 100%	
Fish		> 100%	> 100%	> 100%	
Amphipod		> 100%	> 100%	> 100%	

* The values indicated are examples.

6.2 If the applicant decides not to perform chronic studies the results of the identification of disinfection by-products should be included together with the detection limit for these compounds.

7 ESTIMATION OF THE CONCENTRATION OF CHEMICALS IN THE ENVIRONMENT

7.1 Background

7.1.1 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 dipping, leakages and spills when operating the system; and

.4 the sea in the vicinity of the discharged ballast water, which is particularly important where recreational activities might take place, e.g. swimming.

7.1.2 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 following models

associated with the standard inputs described in appendix 5 resulting in a Predicted Environmental Concentration for the Active Substance, all Relevant Chemicals and relevant disinfection by-products.

7.2 Calculation of the Predicted Environmental Concentration (PEC)

7.2.1 The Predicted Environmental Concentration (PEC) should be calculated using the MAMPEC-BW 3.0 model or later available version with the appropriate environment definition and emission input. The results of these calculations should be used to estimate the risk to crew, port state control, 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.

7.3 Estimation of concentration of chemicals in the atmosphere

7.3.1 An inventory should be made of the ways humans (crew, port state control and the general public may be exposed to Relevant Chemicals and disinfection by-products due to the ballasting and de-ballasting 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.

8 RISKS TO THE SAFETY OF THE SHIP

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

.1 explosion;

.2 fire; and

.3 corrosion.

9 RISKS TO THE SAFETY OF THE CREW

9.1 Risks to the safety of the crew may be assumed to be associated with:

.1 tank cleaning;

.2 tank inspection;

.3 tank ballast water sampling; and

.4 exposure on board from vapours of treated ballast water or from any chemical stored on board as part of the ballast water treatment.

These situations are covered in the guidance in appendix 4.

9.2 Tank cleaning operations

9.2.1 When considering tank cleaning operations, it should be assumed that the exposure routes of concern for the crew will be inhalation and dermal exposure. 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.

9.2.2 Overall, a table should be produced for each chemical by-product as shown below:

Chemical	**[ ] air mg/m^3**	**Exposure (mg/m^3)**	**DNEL$_{inh}$ (mg/m^3)**	**[ ] liquid (mg/L)**	**Exposure (mg/L)**	**DNEL$_{der}$ (mg/kg bw)**	**Total RCR (aggregated exposure/critical DNEL*)**

Legend: [ ] refers to the concentration in the appropriate compartment.

* The lowest DNEL value should be considered in terms of risk assessment decision-making.

10 RISKS TO THE SAFETY OF THE GENERAL PUBLIC

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

.1 inhalation of the atmosphere containing chemical by-products which have evaporated (partitioned) from the treated ballast water;

.2 ingestion of seafood which has been exposed to chemical by-products in the treated ballast water; and

.3 bathing in seawater contaminated with treated ballast water when exposure may be via ingestion (accidental swallowing), inhalation and dermal contact.

10.2 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.

10.3 The PEC$_{air}$, based on Henry's law constant, and the PEC$_{water}$ calculated using the MAMPEC system should be compared respectively to the DNEL$_{air}$, DNEL$_{water}$ and DNEL$_{oral}$ No Observable Adverse Effect Level (NOAEL) and reflected in a table as shown below:

Chemical	**PEC$_{air}$**	**DNEL$_{inh}$**	**RCR= PEC /DNEL$_{inh}$**	**PEC$_{water}$**	**DNEL$_{der}$**	**DNEL$_{oral}$**	**RCR=PEC/ DNEL**	**Total RCR**
A								
B								
C								

* The lowest DNEL value should be considered in terms of risk assessment decision-making.

10.4 The RCR approach is preferred over the MOS approach.

10.5 The oral exposure of the general public due to the consumption of seafood can be found in appendix 4, section 2.2.4 and is triggered by the K_{ow} as the BCF value is often not available.

11 RISKS TO THE ENVIRONMENT

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

11.1.1 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 by-product	Persistence (P) (Yes/No)	Bioaccumulation (B) (Yes/No)	Toxicity (T) (Yes/No)
A	Yes/No (½-life*=……)	Yes/No (Log K_{ow} or BCF= ….)	Yes/No (Chronic NOEC= …)
B	Yes/No (½-life*=……)	Yes/No (Log K_{ow} or BCF= ….)	Yes/No (Chronic NOEC= …)
C	Yes/No (½-life*=……)	Yes/No (Log K_{ow} or BCF= ….)	Yes/No (Chronic NOEC= …)

* ½-life or DT_{50}

11.2 Calculation of PEC/PNEC ratios

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

11.2.2 For each chemical [deemed to be hazardous], the estimation of the PEC/PNEC ratio should be summarized as shown in the table below:

Chemical	Environment	PEC (µg/L)	Toxicity (µg/L)	Assessment Factor	PNEC (µg/L)	PEC/PNEC (-)
A	Harbour					
	Near sea					
B	Harbour					
	Near sea					

* * *

APPENDIX TO APPLICANT'S SUBMISSION FOR DATA ON CHEMICALS
NOT INCLUDED IN APPENDIX 6

NOTE 1: The information as intended in this appendix should be submitted for an application for Basic Approval. Repetition for Final Approval is not needed.

NOTE 2: If the Active Substance, Relevant Chemicals or disinfection by-products are the same as the chemicals mentioned in appendix 6, then the submission of these data is not required. For chemicals not mentioned in that appendix, information on all data is obligatory.

KEY DATA SUMMARY FORM FOR THE GESAMP-BWWG TECHNICAL EVALUATION OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES TO COMPLY WITH THE CONVENTION

(For each piece of data selected for the Summary Form, the range of data that this has been chosen from should be included as an appendix, e.g. if the Summary Form includes an Acute Oral LD_{50} for a rat, the appendix should include the complete list of values identified in the literature from which this value was chosen as a proposal to the BWWG.)

1 CHEMICAL IDENTIFICATION

Trade name of Preparation			
Composition of Preparation			
Component Chemical Name	**CAS Number**	**Concentration (%)**	**AS, RC or Other***

* Indicate whether the chemical is believed to be one of the following, giving justification for each proposal:

AS = Active Substance
RC = Relevant Chemical
OC = Any other chemical, e.g. solvent

List of ALL potential by-products produced in ballast water			
Chemical Name	**CAS Number**	**Concentration (%)**	**(Bio)degradation rate or half-life**

Notes: 1 A separate index for the Active Substance(s) and all by-products should be created unless a scientific explanation is provided to justify not including them.

2 A chemical analysis should also be provided to show the concentration of possible by-products produced in the treated ballast water. Such analyses should be carried out to a level of detection commensurate with the level of naturally occurring chemical in seawater and/or the level that could be justified as not being hazardous to human health or the environment, where appropriate.

3 A clear description of, or reference to, the chemical analysis should be provided along with the length of time, after treatment, that the analysis was carried out. It is recommended that there should be:

.1 one analysis carried out following the shortest possible time that the treated ballast water would be permitted to be discharged; and

.2 one analysis carried out five (5) days later.

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 ½-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).

2 EFFECTS ON AQUATIC ORGANISMS

2.1 Acute aquatic toxicity data

	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-LC_{50} or 7d-NOEC).

2.2 Chronic aquatic toxicity data

	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-LC_{50} or 7d-NOEC).

2.3 Information on endocrine disruption

	Species	Information	Reference/Comments/Justification for missing data
Fish			
Crustacea			
Algae			

2.4 Sediment toxicity

	Species	Information	Reference/Comments/Justification for missing data
Fish			
Crustacea			
Algae			

2.5 Bioavailability/biomagnification/bioconcentration

	Reference/Comments/Justification for missing data
Log P_{ow}	
BCF	

2.6 Food web/population effects

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

3 MAMMALIAN TOXICITY

3.1 Acute toxicity

	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)			

3.2 Corrosion/irritation

	Species	Method	Results (including scores where available)	Reference/Comments/Justification for missing data
Skin				
Eye				

3.3 Sensitization

	Species	Method (e.g. Buehler, M&K)	Results (Sensitizer Y/N)	Reference/Comments/Justification for missing data
Skin				
Inhalation				

3.4 Repeated-dose toxicity

Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/Comments/ Justification for missing data	

3.5 Development and reproductive toxicity

Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/Comments/ Justification for missing data	

3.6 Carcinogenicity

Exposure route	
Exposure duration	
Exposure dose	
Species	
Method	
Results	
NOAEL	
NOEL	
Reference/Comments/ Justification for missing data	

3.7 Mutagenicity

	Method	Dose range	Results	Reference/Comments/ Justification for missing data
Bacterial gene mutation				
Mammalian cytogenicity				
Mammalian gene mutation				

3.8 Carcinogenicity/mutagenicity/reproductive toxicity (CMR)

	Results	Reference/Comments/ Justification for missing data
Carcinogenicity		
Mutagenicity		
Reproductive toxicity		

4 ENVIRONMENTAL FATE AND EFFECT UNDER AEROBIC AND ANAEROBIC CONDITIONS

4.1 Modes of degradation (biotic and abiotic)

	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					
DT50		NR			

4.2 Partition coefficients

	Method	Results	Reference/Comments/Justification for missing data
Log P_{ow}			
K_{oc}			

4.3 Persistence and identification of main metabolites

	Method	Results	Reference/Comments/Justification for missing data
Persistence (d)			

4.4 Reaction with organic matter

4.5 Potential physical effects on wildlife and benthic habitats

4.6 Potential Residues in seafood

4.7 Any known interactive effects

5 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 (20°C; Pa)		
Vapour density (air = 1)		
Water solubility (temp; effect of pH; mg/L)		
pH in solution		
Dissociation constant (pK_a)		
Oxidation-reduction potential		
Corrosivity to material or equipment		
Reactivity to container material		
Auto-ignition temperature (°C)		
Explosive properties		
Oxidizing properties		
Surface tension		
Viscosity		
Thermal stability and identity of breakdown products		
Other physical or chemical properties		

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

6 OTHER INFORMATION

6.1 Analytical methods for measuring the concentration at environmentally relevant concentrations

Method	
Applicability	
Sensitivity	
Reference/Comments/Justification for missing data	

6.2 Material Safety Data Sheet provided (Yes/No)

6.3 GHS classification …….

6.4 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 with 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 It is assumed that the applicant will measure the concentration of each chemical in the treated ballast water under GLP conditions and that the appropriate QA statement will be provided.

1.9 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.

1.10 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 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.

1.11 It is important to note that the methodologies described in this document generally applies 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.

1.12 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.

1.13 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:

Operations involving the crew and/or port state workers			
Operation	**Exposure**	**Frequency/duration/quantity**	**Paragraph**
Delivery, loading, mixing or adding chemicals to the BWMS	Potential dermal and inhalation for leakage and spills. For closed or automated systems the exposure is assumed to be minimal*	Solids:100mg/container handled Liquids: 0.1mL/container handled	2.1.2
Ballast water sampling	Inhalation of air in the tank headspace	2 hours/day for; 5 days/week (acute exposure) 45 weeks/year (chronic exposure)	2.1.3
	Dermal exposure to primarily hands	2 hours/day for; 5 days/week (acute exposure) 45 weeks/year (chronic exposure)	2.1.3
Periodic cleaning of ballast tanks	Inhalation of air in the ballast water tank	8 hours/day for; 5 days/week; 1 event/year (acute/short term exposure)	2.1.4
	Dermal exposure to the whole body	8 hours/day for; 5 days/week; 1 event/year (acute/ short term exposure)	2.1.4
Ballast tank inspections	Inhalation of air in the ballast water tank	3 hours/day for 1 day/month (acute exposure)	2.1.5
Normal operations carried out by the crew on BWMS			
Carrying out ballast water treatment activities	Case by case		2.1.6
Maintenance work on the BWMS	Case by case		2.1.7
Normal work on deck unrelated to any of the above	Inhalation of air released from vents	1 hour/day for 6 months (short-term exposure)	2.1.8

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.

* The applicant needs to describe the PPE and methods of work designed to minimize exposure.

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

2.1.2.1 Although 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 and gloves. Some substances and formulations will be of greater concern than others if they are released from the holding tanks, containers or transfer pipe work. The applicant should provide details of the intended methods to be used to package and then transfer active chemical substances from delivery vehicles to the on board storage. The applicant should give details of methods of work and propose the appropriate standard of personal protective equipment to deal with exposure arising from any loss of containment or through contact with contaminated plant and equipment.

No quantitative exposure assessment is expected for enclosed and automated systems.

2.1.2.2 Dilution of concentrated chemical products is often referred to as mixing and loading. This process may take place on smaller vessels and simple models are available to help predict potential exposure to the skin – exposure through inhalation is considered unlikely for non-volatile or water-based chemical formulations chemicals. Several models are used to estimate hand exposure arising from handling containers of concentrated product.

Tier 1:

For a Tier 1 assessment, UK POEM predicts as a worst case a hand exposure of 0.1 ml of concentrated fluid per 10 L container handled. In the worst case, the container has a 45 mm opening.

Studies indicate a wider necked container (63 mm) delivers lower levels of hand contamination at 0.05 ml for each container handled and this applies to 10 and 20 L containers. Solids produce 100 mg of contamination for each 10 kg pack handled.

Principal equation:

$$Dose_{Tier1} = \frac{C_{form} \cdot N_{Tier1} \cdot E_{hand,Tier1} \cdot \rho \cdot f_{derm}}{V_{form} \cdot BW}$$

where:

Specific values for Tier 1 calculation:

$Dose_{TierI}$	=	skin exposure (mg/kg bw/d)
C_{form}	=	concentration of Active Substance (%w/w)
N_{Tier1}	=	number of containers handled (10)
$E_{Hand,Tier1}$	=	contamination to concentrated formulation during 1 event (0.1 mL)
ρ	=	density (1 g/mL)
f_{derm}	=	dermal absorption factor (1)
V_{form}	=	volume of Preparation handled (L)
BW	=	body weight (default = 60 kg)

Tier 2:

UK POEM suggests suitable gloves will reduce exposure by about 95%.

$$Dose_{Tier2} = \frac{C_{form} \cdot N_{Tier2} \cdot E_{hand,Tier2} \cdot \rho \cdot f_{derm} \cdot f_{pen}}{V_{form} \cdot BW}$$

where:

Specific values for Tier 2 calculation:

$Dose_{Tier2}$	=	skin exposure (mg/kg bw/d)
C_{form}	=	concentration of Active Substance (%w/w)
N_{Tier2}	=	number of containers handled (5)
$E_{Hand,Tier2}$	=	contamination to concentrated formulation during 1 event (0.05 mL)
ρ	=	density (1 g/mL)
f_{derm}	=	dermal absorption factor (1)
f_{pen}	=	penetration factor (1)
V_{form}	=	volume of Preparation handled (L)
BW	=	body weight (default = 60 kg)

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 in the tank. The concentration of chemicals in the air may be calculated while using the Henry's Law Constant in the equation presented below:

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

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 A dilution factor of 10 is introduced on the assumption that the ballast water tank will be filled to 90 per cent capacity and so the air in the headspace will be diluted by, at least, a factor of 10 as the ballast water is discharged and fresh air is drawn in. It is understood that, even small movements of the vessel (pitching and rolling) will cause the air in the headspace to be pumped out of the vents, by sloshing, so diluting the theoretical concentration of chemical still further.

2.1.3.3 Once a concentration of a volatile component has been estimated, a simple Tier 1 exposure assessment can be performed. Default inhalation rate is taken as 1.25 m^3/h.

$$Dose_{Tier1} = \frac{C_{vol} \cdot T_{\exp} \cdot I_{rate}}{BW}$$

where:

$Dose_{Tier1}$	=	inhaled dose (mg/kg bw/d)
C_{vol}	=	concentration of volatile component (mg/m^3)
T_{exp}	=	exposure duration (2 h/d)
I_{rate}	=	inhalation rate (default = 1.25 m^3/h)
BW	=	bodyweight (default = 60 kg)

2.1.3.4 The inhaled dose ($Dose_{Tier1}$) is then compared with the $DNEL_{inh}$ to assess whether the risk is acceptable or not.

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

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

where:

U_{sd}	=	dermal uptake (mg/kg/d)
A_{hands}	=	surface area of one hand (0.084 m^2)
TH_{dermal}	=	thickness of the product area on the skin (0.0001 m)
PEC_{mampec}	=	concentration of chemical in treated ballast (mg/m^3)
BIO_{derm}	=	dermal bioavailability (1)
BW	=	bodyweight (default = 60 kg)

Reference: ECHA R15, 2010 example R.15-2, page14.

2.1.3.6 The dermal uptake (U_{sd}) is then compared with the $DNEL_{der}$ to assess whether the risk is acceptable or not.

2.1.3.7 An adequate model designed for the assessing of dermal exposure is the US EPA film thickness model. It is assumed a hand retains about 5 ml of fluid and all of the Active Substance in this volume of water is available for absorption through the skin. A default 100% dermal absorption is applied but a simple Tier 2 calculation could insert a reduced verified value.

2.1.3.8 The exposure time in this scenario is either regarded as acute exposure (2 hours/day for; 5 days/week) or chronic exposure (45 weeks/year).

2.1.4 **Periodic cleaning of ballast water tanks**

2.1.4.1 In this scenario a worker may be exposed to volatile components arising from treatment of the ballast water. Enough information will need to be available to assess the likely airborne concentrations of gaseous and volatile components partitioning between water and the airspace.

2.1.4.2 The concentration of chemicals in the air phase may be calculated in the same manner as in 2.1.3.1.

2.1.4.3 Once a concentration of a volatile component has been estimated, the simple Tier 1 exposure assessment can be performed as already mentioned in 2.1.3.3.

2.1.4.4 The dermal uptake of chemicals from the sediment and sludge in the ballast tank may be calculated in the same manner as in 2.1.3.5 taking into account possible exposure to more parts of the body apart from the hands.

2.1.4.5 If it is thought necessary, the assessor may introduce refinement based on protection afforded by use of appropriate impermeable personal protective clothing. 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 due to water entering via the cuff). For boots a lower default value may be selected to represent the worker wearing appropriate impermeable boots.

2.1.4.6 The exposure time in this scenario is 8 hours/day for; 5 days/week. The event occurs once per year (acute/short term exposure).

2.1.5 **Ballast tank inspections**

2.1.5.1 In this scenario an inspector is exposed to volatile components arising from treatment of the ballast water. Enough information will need to be available to assess the likely airborne concentrations of gaseous and volatile components partitioning between water and the airspace.

2.1.5.2 The concentration of chemicals in the air phase may be calculated in the same manner as in 2.1.3.1.

2.1.5.3 Once a concentration of a volatile component has been estimated, the simple Tier 1 exposure assessment can be performed as already mentioned in 2.1.3.3.

2.1.5.4 Exposure time in this scenario is 3 hours. Thus, total exposure is from inhalation of 3.75 m^3 of air.

2.1.6 **Crew carrying out ballast water treatment activities**

2.1.6.1 Exposure during normal operating conditions is deemed to be minimal. However, emergency situations will have to be assessed including possible system leakages. Only qualitative exposure assessment is necessary where the applicant has to describe process controls, methods of work and PPE designed to minimize exposure during both normal operation and emergency situations.

2.1.7 **Crew carrying out maintenance work on the BWMS**

2.1.7.1 Exposure during maintenance work is to be described. Only qualitative exposure assessment is required.

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

2.1.8.1 Exposure in this scenario is through inhalation of air released from the air vents on deck. An additional dilution factor of 10 may be taken into account in this scenario.

2.1.8.2 Exposure time in this scenario is 1 hour/day for 6 months (short-term exposure). Thus, total exposure is from inhalation of 1.25 m^3 of air.

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 surrounding area.

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

Situations in which the general public might be exposed to treated ballast water containing chemical by-products			
Situation	**Exposure**	**Duration/quantity**	**Approach**
Recreational activities in the sea	Inhalation of chemicals partitioning into the air above the sea	5 hours/day for 14 days of the year	2.2.3.1
	Dermal exposure to chemicals whilst swimming in the sea	5 hours/day for 14 days of the year	2.2.3.2
	Swallowing of seawater contaminated with treated ballast water	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/day	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 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 while using the equation below, while taking into account various assumptions (number of swims etc.):

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

where:

U_{si}	=	inhalatory intake of chemical during swimming (mg/kg/d)
C_{air}	=	concentration in air (mg/m^3)
RespR	=	respiration 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**

2.2.3.2.1 Exposure in this scenario is via dermal uptake of chemicals when swimming, while using the following equation which is the so-called Dermal A model from TGD:

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

where:

U_{sd}	=	dermal uptake per day during swimming (mg/kg/d)
PEC_{mampec}	=	concentration of chemical in water derived from MAMPEC (mg/m^3)
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)

Reference: Guidance on information requirements and chemical safety assessment, Chapter R15: Consumer exposure estimation, May 2008 (version 1.1).

2.2.3.3 **Swallowing of seawater contaminated with treated ballast water**

2.2.3.3.1 The oral uptake via swimming is calculated from 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 (µg/kg/d)
C_w	=	concentration in the water i.e. PEC (µg/L)
IR_{swim}	=	ingestion rate of water while swimming (0.025 L/h)
n_{swim}	=	number of swims per day (5)
Dur_{swim}	=	duration of each swim (0.5 h)
BIO_{oral}	=	bioavailability for oral intake (default = 1)
BW	=	body weight (default = 60 kg)

2.2.4 **Eating 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 (µg/kg)
BCF	=	bioconcentration factor (L/kg)
PEC_{mampec}	=	concentration of chemical in water derived from MAMPEC (µg/L)

2.2.4.2 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 (µg/kg/d)
QFC	=	quantity of fish consumed/day (= 0.188 kg/d (FAO, Japan))
C_{fish}	=	concentration of chemical in fish (µg/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 from 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.

Swimming (inhalation)	:	µg/kg/d
Swimming (dermal)	:	µg/kg/d
Swimming (oral)	:	µg/kg/d
Eating fish	:	µg/kg/d
Total	:	µg/kg/d

Note: Make sure all values are in the same units.

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.

2.2.7 **Assumptions**

2.2.7.1 The following assumptions have been used in this report.

.1	IR (Ingestion rate of water while swimming):		0.025 L/h
.2	n (number of events (swims)):		5/d
.3	length of event (swim):		0.5 h
.4	BW (Average body weight):		60 kg
.5	Human (general public) respiration rate – basal activity:		20 m^3/d (0.83 m^3/h) (sRV_{hum})
.6	Human (worker) respiration rate – light activity:		30 m^3/d (1.25 m^3/h) (wRV_{hum})
.7	A_{skin} (Surface area of whole body):		1.94 m^2
.8	A_{hands} (Surface area of front and back of hands):		0.084 m^2
.9	Amount of fish eaten (60 kg man):		0.188 kg/d (FAO, Japan)
.10	Thickness of chemical on the skin (m):		0.0001 m (default value) ECHA
.11	Standard Respiratory Volume of a rat (sRV)	:	0.2 L/min/250g Rat
		:	0.8 L/min/kg
		:	0.8 x 60 x 24/1000m^3/kg/24h
		:	1.15 m^3/kg/d

3 CALCULATION OF DNELS

3.1 Definition of toxicologically significant endpoints

3.1.1 The next step of the risk assessment process includes the definition of toxicologically significant endpoints for comparison with the calculated exposure doses. These endpoints, being for example NOAELs or LOAELs, are then further derived into DNELs (see 1.3 to 1.5) or DMELs (see 5.7).

3.1.2 As already mentioned in the introduction of this report, a DNEL is a derived level of exposure normally calculated on the basis of available dose descriptors from animal studies such as No Observed Adverse Effect Levels (NOAELs) or benchmark doses (BMDs).

3.1.3 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) according to this equation:

$$DNEL = \frac{Dose_{descriptor}}{Assessmentfactors}$$

3.1.4 In estimating the DNEL for humans, various assessment factors and Correction Factors are employed in order to reflect:

.1 **Exposure duration (**SF_{dur})

The difference in exposure duration (e.g. 28 d, 13 w, 2 y) between experimental data and the assumed lifetime exposure for humans.

.2 **Observed effect (**ESF)

The experimentally observed effect in animals, e.g. NOAEL, NOEL, LOAEL, which is to be used as the starting point in the risk assessment process.

.3 **Exposure route (**CF_{abs})

The route of exposure in the animal study, which gives rise to the observed effect, is to be used to calculate the DNEL of the appropriate route of human exposure being considered. In practice, the rates of absorption of chemicals into the body via the lungs, the skin and through the intestinal tract are not known. As a result, certain default assumption values are used to correct for such different absorption rates.

.4 **Interspecies differences (**ASF and OSF)

Differences between the test species and humans.

.5 **Intraspecies differences (**ISF)

There are anticipated differences between groups of humans. Workers are assumed to be healthy adults whereas the general population includes children, oldies and the unhealthy. Hence, there is greater variability accounted for between people in the general public as compared to workers.

.6 **Experimental dosing regime (**CF_{dr})

This is needed to correct the dose value when the dosing regime is 5 days/week.

3.1.5 Once the relevant assessment factors have been established, a **Derived No Effect Level (DNEL)** may be calculated.

3.1.6 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)** or equivalent endpoint, should be determined (see 5.7).

3.2 Selection of scaling factors

3.2.1 Interspecies Allometric Scaling Factor (ASF)

3.2.1.1 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.

3.2.1.2 The following Allometric Scaling Factors are recommended for use in determining DNELs (Table R8-3 in the reference below):

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

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health, December 2010.

3.2.2 Other Interspecies Scaling Factor (OSF)

3.2.2.1 This factor is based on perceived toxicokinetic and toxicodynamic differences between species. There appears to be differences of opinion between the experts in the field, some saying that this factor should be applied unless there is evidence to demonstrate that it is not appropriate whilst others believe the reverse logic is to be preferred.

3.2.2.2 The OSF is set to 2.5, but can be modified when substance specific information shows susceptibility differences between species, which are not related to differences in basal metabolic rate.

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health (Chapter R-8, R.8.4.3.1, and table R.8-6), December 2010.

3.2.3 Intraspecies scaling factor for the general population (ISF_{gp}) and workers (ISF_{w})

3.2.3.1 Humans differ in sensitivity to toxic insult due to a multitude of biological factors such as genetic polymorphism affecting, e.g. toxicokinetics/metabolism, age, gender health and nutritional status. These differences can be the result of genetic and/or environmental influences and are greater in humans than in the more inbred experimental animal population. As a result for these purposes, 'intraspecies' 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:

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

.2 **the general population**, which are considered to include, children, old people 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:

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

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health (table R.8-6), December 2010.

3.2.4 Observed Effect Scaling Factors (ESF)

3.2.4.1 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).

3.2.4.2 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.

3.2.4.3 When the starting point for the DNEL calculation is a LOAEL, it is suggested to use an assessment factor between 3 (as minimum/majority of cases) and 10 (as maximum/exceptional cases). However, the benchmark dose (BMD) approach is, when possible, preferred over the LOAEL-NAEL extrapolation.

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health (*Dose-response relationship*, page 29), December 2010.

3.2.5 Duration scaling factors (SFdur)

3.2.5.1 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 (90 d) to chronic	2
Sub-acute (28 d) to chronic	6
Sub-acute (28 d) to sub-chronic	3

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health (table R.8-5),December 2010.

3.2.6 Dosing Regime Correction Factor (CF_{dr})

3.2.6.1 To correct for dosing regimens, which are often performed for five days/week over the duration of the trial, the resultant endpoint (for instance NOEL/NOEC) is corrected by a factor of 5/7.

3.2.7 Differential Absorption Factors (CF_{abs})

3.2.7.1 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.

3.2.7.2 Whilst recognizing that it would be most useful to know the differential absorption rates of each chemical in question through the exposure routes, in the absence of such information default values have been applied which assume that 100% of chemical is absorbed through the intestines, the skin and the lungs.

4 DNELS FOR THE WORKER POPULATION

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

.1 DNEL, short-term, dermal exposure: (mg/kg), in this case the dose descriptor might be a LD_{50} from a dermal study.

.2 DNEL, short-term, inhalation: (mg/m^3), in this case the dose descriptor might be a LC_{50} from an inhalation study.

.3 DNEL, long-term, dermal exposure: (mg/kg/d), in this case the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic dermal study.

.4 DNEL, long-term, inhalation: (mg/kg/d), in this case the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic inhalation study.

4.2 It is also possible to derive DNELs for local effects. This is the case for instance for chlorine, which is a corrosive gas that can produce immediate severe effects at the first site of contact (skin, eyes and/or respiratory tract). The NOAEL (1.5 mg/m^3) that may be used for risk characterization is based on human studies.

5 DNELS AND DMELS 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 For the secondary exposure to the general public via swimming or consumption of seafood, the following DNELs may be calculated:

.1 DNEL, oral, general public: (mg/kg/d), in this case the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic oral study.

.2 DNEL, dermal, general public: (mg/kg/d), in this case the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic dermal study.

.3 DNEL, inhalation, general public: (mg/kg/d), in this case the dose descriptor might be a NOAEL or LOAEL from a sub-acute, sub-chronic or chronic inhalation study.

.4 For chemicals with a non-threshold effect a DMEL needs to be established for the general public.

.5 A cancer risk level of 10^{-6} is normally seen as indicative tolerable risk levels when setting DMELs for the general population. Where these values are available from internationally recognized bodies they can be used to set DMELs for risk assessment purposes.

6 Oral DNEL ($DNEL_{oral}$) FROM ORAL MAMMAL TOXIC ENDPOINTS

6.1 The Oral DNEL may be estimated in accordance with the following calculation:

$$DNEL_{oral} = \frac{NOAEL_{rat} \cdot CF_{dr}}{ASF \cdot OSF \cdot ISF \cdot ESF \cdot SF_{dur} \cdot CF_{abs}}$$

7 DERMAL DNEL FROM ORAL OR DERMAL MAMMAL TOXIC ENDPOINTS

7.1 Based on the assumption that the dermal absorption is the same as the oral absorption, and in the absence of a repeated dermal dose study:

Dermal DNEL = Oral DNEL

8 INHALATION DNEL FROM THE MAMMALIAN ORAL NOAEL

8.1 In order to calculate the Inhalation DNEL from mammalian repeated dose studies, the following two options, described in this section, are considered.

8.1.1 In the calculations documented in this section, the following physiological assumptions are made:

.1 The Standard Respiratory Volume of a rat (sRV_{rat})
= 0.8 L/min/kg;
= 1.15 m^3/kg/d

.2 The Standard 24 h Respiratory Volume for a human (sRV_{hum})
= 20 m^3/60kg
Note: sRV_{human} assumes only basic activity

.3 The Worker 24 h Respiratory Volume for a human ($wSRV_{hum}$)
= 30 m^3/60kg
Note: wRV_{human} assumes light activity

8.1.2 Corrected rat inhalation NOAEL

8.1.2.1 The steps taken to calculate the corrected rat inhalation NOAEL from a rat oral NOAEL are:

.1 In order for the rat to inhale the same quantity of chemical/day as its Oral NOAEL, the concentration in the atmosphere would be as express by the following equation:

$$24\text{ h NOAEL}_{Rat\text{-}Inh} = \text{NOAEL}_{Rat\text{-}Oral} / sRV_{rat}$$

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterization of dose [concentration]-response for human health (table example R.8-1), May 2008.

9 DNEL FROM THE CORRECTED RAT INHALATION NOAEL

9.1 Having established the corrected inhalation NOAEL for animals it is necessary to:

.1 correct this value for the general population which is assumed to be exposed for 24 h/day whilst they are engaged in basic activity; and

.2 apply all of the appropriate Assessment Factors, with the exception of the Allometric Scaling Factor, in order to derive the DNEL. In this particular example (rat oral NOAEL to human inhalation DNEL), the following Assessment Factors are relevant:

ASF	=	4	Not appropriate in this case
OSF	=	2.5	Remaining interspecies differences
ISF_{gp}	=	10	Human Intraspecies differences between the general population
ISF_{w}	=	5	Human Intraspecies differences between workers
ESF	=	1	Rat NOAEL as a starting point
SF_{dur}	=	2	Sub-chronic to Chronic exposure

9.2 To apply such relevant factors, the Inhalation DNEL may be calculated according to the following formulae:

.1 **Workers engaged in light activity exposed for 8 h per day:**

.1 The corrected human 8 h inhalation, light activity NOAEL is calculated according to the following formula:

$$NOAEL_{hum-inh-8h-la} = NOAEL_{rat-inh} \cdot \frac{24}{Exposure\ time} \cdot \frac{sRV_{hum}}{wRV_{hum}}$$

Note: The unit of the $NOAEL_{hum\text{-}inh\text{-}8h\text{-}la}$ is mg/m^3.

.2 From this the human 8 h inhalation light activity DNEL can be determined by the application of the appropriate Assessment Factors referred to in paragraph 4.3.2 as shown by the following formula:

$$corNOAEL_{inh-8h-la} = \frac{CorNOAEL_{hum-inh-8h-la}}{OSF \cdot ISF \cdot ESF \cdot SF_{dur}}$$

.2 **For the general population engaged in basal activity, exposed for 24 h per day:**

.1 The corrected human 24 h inhalation, basal activity NOAEL is calculated according to the following formula:

$$corNOAEL_{hum-inh-24h-ba} = corNOAEL_{rat-inh} \cdot \frac{24}{Exposure\ time} \cdot \frac{sRV_{hum}}{sRV_{hum}}$$

where: $corNOAEL_{hum\text{-}inh\text{-}24h\text{-}ba}$ = the corrected human (hum) inhalation (inh) NOAEL assuming 24 h/d exposure and basal activity (ba).

Note: The unit of the $corNOAEL_{hum\text{-}inh\text{-}24h\text{-}ba}$ is mg/m^3.

.2 As shown by the above calculations, it is not necessary to apply correction factors for the exposure time or the level of activity as these are both 1.

.3 From this the human 24 h inhalation basal activity DNEL can be determined by the application of the appropriate Assessment Factors referred to in paragraph 5.3.2 as shown by the following formula:

$$DNEL_{inh-24h-ba} = \frac{CorNOAEL_{hum-inh-24h-ba}}{OSF \cdot ISF \cdot ESF \cdot SF_{dur}}$$

.3 **For the general population engaged in light activity, exposed for 2.5 h/d while swimming:**

.1 The corrected human 2.5 h inhalation, light activity NOAEL is calculated according to the following formula:

$$corNOAEL_{hum-inh-2.5h-la} = corNOAEL \cdot \frac{24}{Exposure\ time} \cdot \frac{sRV_{hum\_ba}}{sRV_{hum\_la}}$$

Note: The unit of the $corNOAEL_{hum\text{-}inh\text{-}2.5h\text{-}la}$ is mg/m^3.

.2 From this the human 2.5 h inhalation light activity DNEL can be determined by the application of the appropriate Assessment Factors referred to in paragraph 4.3.2 as shown by the following formula:

$$DNEL_{inh-2.5h-la} = \frac{CorNOAEL_{hum-inh-2.5h-la}}{OSF \cdot ISF \cdot ESF \cdot SF_{dur}}$$

10 CALCULATION OF DMELS – HOW TO DEAL WITH NON-THRESHOLD CARCINOGENS?

10.1 Background

10.1.1 According to Procedure (G9) 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.

10.2 The Linearized approach and the Large Assessment Factor approach

10.2.1 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.

10.2.3 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, an exposure level corresponding to a low, possibly theoretical, risk is possible to be calculated based on semi-quantitative approach, i.e. a derived minimal effect level (DMEL). In fact a DMEL is a risk-related reference value that should be used to better target risk management measures.

10.2.4 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.

Reference: Guidance on information requirements and chemical safety assessment, Chapter R8: Characterisation of dose [concentration]-response for human health (R.8-5), May 2008.

10.2.5 Cancer risk levels of 10^{-5} and 10^{-6} are normally seen as indicative tolerable risk levels when setting DMELs for workers and the general population, respectively. Where these values are available from internationally recognized bodies, they can be used to set DMELs for risk assessment purposes.

11 RISK CHARACTERIZATION

11.1 General approach

11.1.1 The Risk Characterization Ratios (RCR) compares the exposure levels to various Derived No Effect Levels. The RCR is calculated according to the following formula:

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

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

11.1.3 However, risk are regarded to be controlled when the estimated exposure levels do not exceed the predicted no effect levels (DNEL), that is, if the RCR ≥1.

11.1.4 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.

* * *

APPENDIX 5

MAMPEC 3.0 INFORMATION

1 GENERAL

1.1 The model MAMPEC-BW 3.0 or latest available version may be downloaded from the website of Deltares in The Netherlands. The website is:

http://www.deltares.nl/en/software/1039844/mampec/1232321

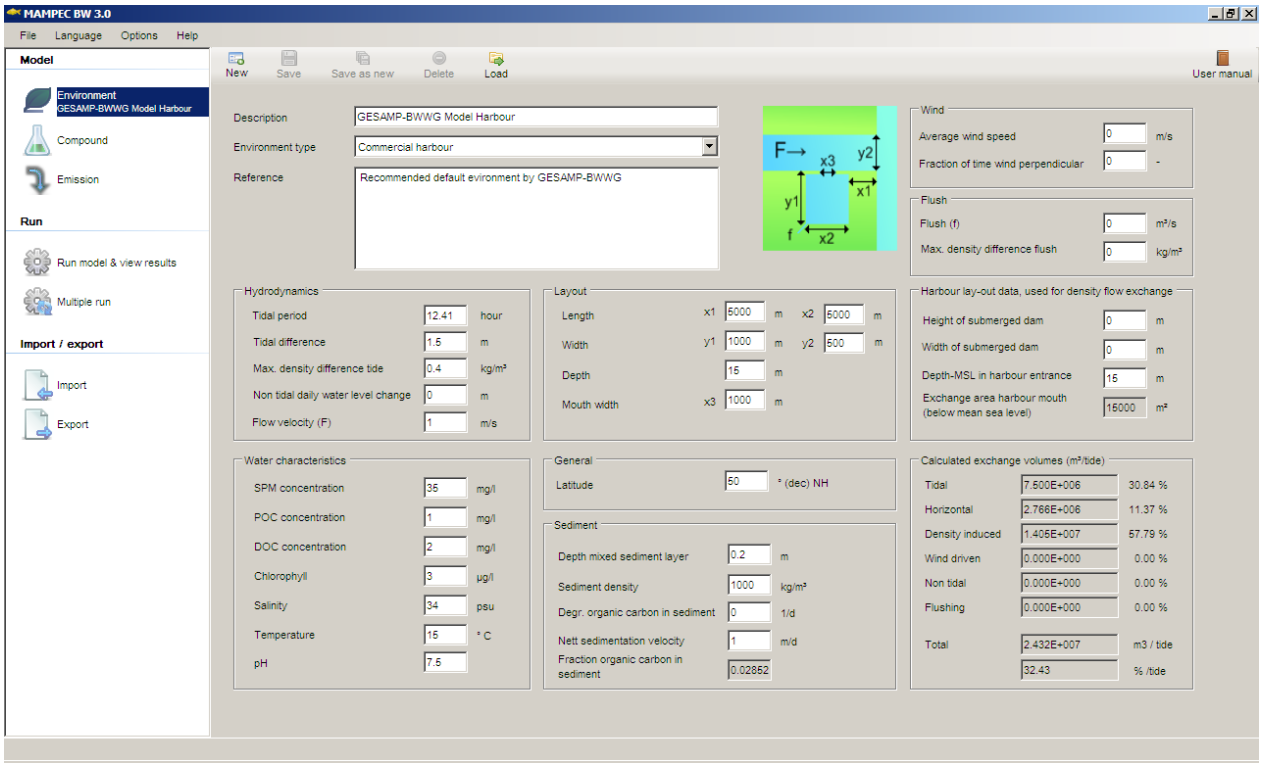
.1 Follow the installation instructions and run the model.

2 CALCULATION OF THE PREDICTED ENVIRONMENTAL CONCENTRATION (PEC)

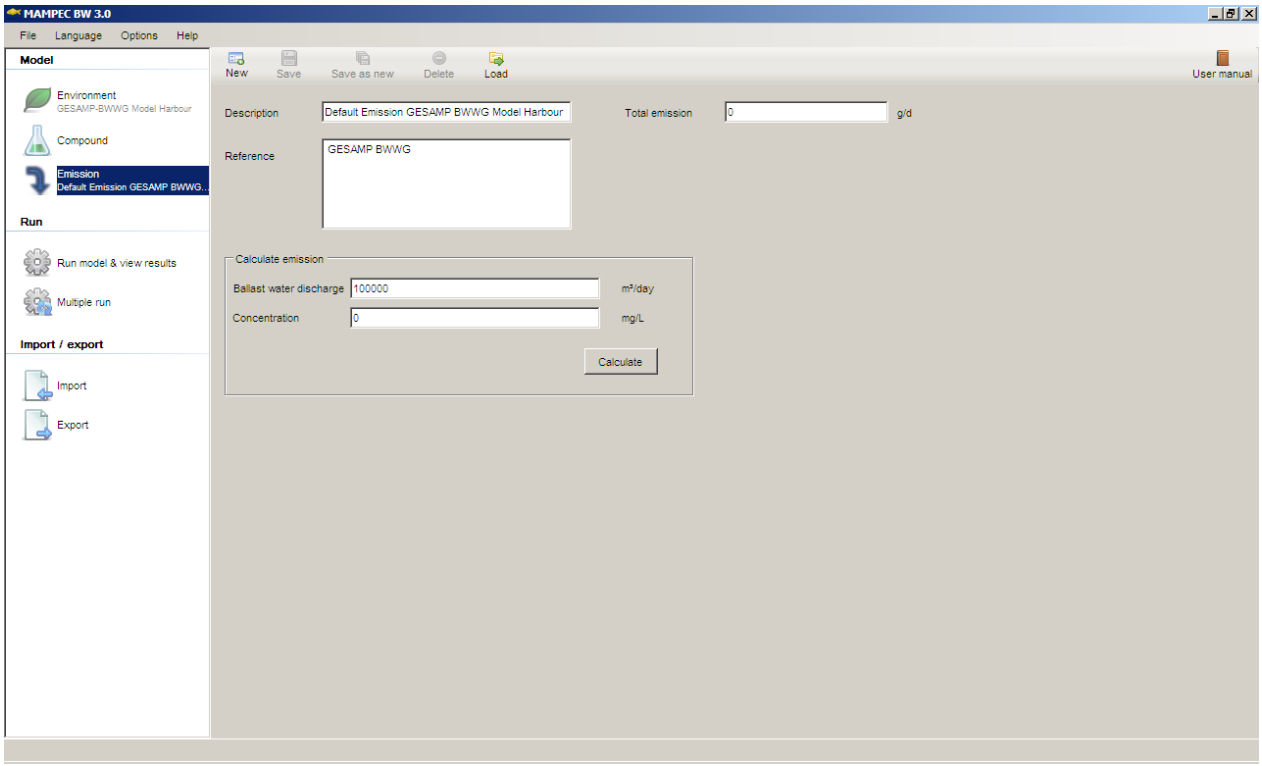
2.1 This procedure is important for carrying out a risk assessment to the environment.

2.2 In order to provide a standard approach, it is recommended that the MAMPEC-BW 3.0 or latest available version model is used to determine the PEC for each chemical identified.

2.3 When this model is used, the following the GESAMP-BWWG Harbour Environment should be selected from the options available:



2.4 In addition to the GESAMP-BWWG Harbour Environment shown above, the following standard GESAMP-BWWG emission data need to be included as part of the GESAMP-BWWG Standard model:



2.5 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 3.0 or latest available version calculations should be used. If this comparison results in PEC/PNEC ratios above 1.0, the 95%-ile may be used. If the PEC/PNEC ratio is still above 1.0, additional mitigation measures or a scientific reasoning may be proposed for discussion in the GESAMP-BWWG.

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

* * *

APPENDIX 6

LIST OF CHEMICALS, FOR WHICH THE GROUP HOLDS SUFFICIENT INFORMATION FROM THE LITERATURE ON PHYSICOCHEMICAL, ECOTOXICOLOGICAL AND TOXICOLOGICAL PROPERTIES AND NO ADDITIONAL SUPPORTING INFORMATION NEEDS TO BE SUBMITTED

No.	Substance	CAS-number
1	Bromochloroacetic acid	5589-96-8
2	Bromoform	75-25-2
3	Chloroform	67-66-3
4	Dibromoacetic acid	631-64-1
5	Dibromoacetonitrile	3252-43-5
6	Dibromochloromethane	124-48-1
7	Dichloroacetic acid	79-43-6
8	Dichlorobromomethane	75-27-4
9	Monobromoacetic acid	79-08-3
10	Monochloroacetic acid	79-11-8
11	Monochloroamine	10599-90-3
12	Potassium bromate	7758-01-2
13	Sodium bromate	7789-38-0
14	Sodium hypochlorite	7681-52-9
15	Sodium thiosulphate	7772-98-7
16	Tribromoacetic acid	75-96-7
17	Trichloroacetic acid	76-03-9
18	Trichloropropane	96-18-4