

## ANNEX 4

**METHODOLOGY FOR INFORMATION GATHERING AND THE  
CONDUCT OF WORK OF GESAMP-BWWG  
(Updated 23 May 2008)**

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## 1 INTRODUCTION

This document contains the Methodology for information gathering and the conduct of work of the GESAMP-BWWG when undertaking technical evaluations in accordance with the “Procedure for the 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 paper, 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** 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** means a substance or organism, including a virus or a fungus that has a general or specific action on or against harmful aquatic organisms and pathogens.
- .5 **Other components** of a preparation means any other substances in a preparation, other than the Active Substance(s) or Relevant Chemicals, produced during the treatment of ballast water.
- .6 **Relevant Chemicals** 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.
- .7 **Basic Approval** 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** means the approval of a ballast water management system using an Active Substance or Preparation to comply with the Convention and includes a review of the Type Approval tests in accordance with 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. The risk evaluation at Final Approval should take qualitatively into account cumulative effects that may occur due to the nature of shipping and port operations. The uncertainties involved in the application for approval should be considered during the Final Approval process, and advice on how these uncertainties can be dealt with should be provided as appropriate.
- .9 **GESAMP–Ballast Water Working Group (GESAMP-BWWG)** 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 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.

GESAMP is the IMO/FAO/UNESCO-IOC/WMO//IAEA/UN/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 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
b.p.	boiling point
Bw	body weight
BWMS	ballast water management system
°C	degree Celsius (Centigrade)
CAS	Chemical Abstract Service
Cc	cubic centimetre
D	day(s)
DOC	dissolved organic carbon

EC <sub>50</sub>	effect concentration, 50% (median effective concentration)
G	gram
GHS	Globally Harmonized System
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.
h	hour
IARC	International Agency for Research on Cancer
IC <sub>50</sub>	inhibition concentration, 50%
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
Kg	kilogram
Koc	organic carbon-water partition coefficient
L	litre
LC <sub>50</sub>	lethal concentration, 50%
LD <sub>50</sub>	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LDLO	lowest lethal dose
LOEL	lowest observed effect level
Log P	logarithm of the octanol/water partition coefficient
MEPC	Marine Environment Protection Committee
m.p.	melting point
Mg	milligram
ml	millilitre
Ng	nanogram
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
OECD Organization	Organization for Economic Co-operation and Development the International Maritime Organization
POC	particulate organic carbon
Pow	Octanol/water partition coefficient
TLV	threshold limit value
US EPA	United States Environmental Protection Agency
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 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 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 which makes use of, or generates, Active Substances, Relevant Chemicals or free radicals during the treatment process to eliminate organisms 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 Basic Approval**

2.3.1 The manufacturer of the ballast water management system should evaluate the Active Substance(s) or Preparation(s) and the potential discharge of treated ballast water in accordance with the approval criteria specified below (G9: 8.1.2.1). Upon completion, the manufacturer should prepare an application dossier for the ballast water management system that makes use of Active Substances and submit it to the maritime Administration of a Member of the Organization. An application should only be made once the ballast water management system, Active Substance or Preparation has been sufficiently designed, progressed and tested to provide the full data necessary for a Basic Approval (G9: 8.1.2.2).

2.3.2 The Administration should evaluate the application dossier and confirm that it is satisfactory and complete before submitting it to IMO. Administrations should check the quality and completeness of any Basic or Final Approval submission, against the latest version of the Methodology for information gathering and the conduct work of the Technical Group agreed by the Organization, prior to its submission to the MEPC (G9: 3.6).

2.3.3 Applications for Basic Approval of the ballast water management system, associated with Active Substances, 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.

2.3.4 Application contents:

- .1 a complete application dossier including all documents identified in this paragraph (one paper version), including full study reports and full copies of literature. The complete application dossier should contain a contents list indicating the location of the information in the application. The order in which the information is presented, including overall structure such as how information is presented for the Active Substance, preparation, ballast water, risk assessment, assessment report, should follow this format, including its numbering, which is based on Procedure (G9);
- .2 a non-confidential summary document, which would be circulated as an MEPC document to provide an overview of the application (electronic version);
- .3 a summary of the key data should be provided in a tabular format (electronic version);
- .4 the assessment report (electronic version); and
- .5 dossiers already used for registration of chemicals can be used to satisfy the data provisions of Procedure (G9) (G9: 4.2.5).

## **2.4 Confidentiality and data protection**

The confidential information of the submitted documents should clearly be identified. All information related to safety and environmental protection, including physical/chemical properties, environmental fate and toxicity, should be treated as non-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;



- .5.1 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 physical and chemical data concerning the Active Substance, the preparation and its components and Relevant Chemicals;
- .7 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;
- .8 a summary of the results of the tests conducted on the treated ballast water pursuant to section 5.2 of Procedure (G9);
- .9 recommended methods and precautions against dangers resulting from handling, storage, transport and fire;
- .10 any means of rendering the Active Substance or preparation harmless;
- .11 Safety Data Sheets;
- .12 methods of chemical analysis;
- .13 methods of disposal of the product and of its packaging;
- .14 procedures to be followed and measures to be taken in the case of spillage or leakage;
- .15 First Aid and medical advice to be given in the case of injury to persons;
- .16 all results of the Persistence, Bioaccumulation and Toxic (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 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) should be provided.

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. If submissions are lacking relevant information, it may not be possible for the GESAMP-BWWG to conduct a thorough 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 the submission of all available end-point data for Active Substances and Relevant Chemicals is necessary to enable a thorough review.

2.5.4 A list of test substances (for example, trade names) specified in study reports and literature data and an explanation of how the tested substances relate to the current application should be provided.

## **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 or of its proposed uses and taking into account all proposed risk management measures, need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification should be submitted, which would help the GESAMP BWWG's evaluation of the application dossier.

## **2.7 Additional data**

2.7.1 If, in the course of the review by the GESAMP-BWWG, it becomes evident that additional data are found to be necessary in order to finalize the evaluation, the Group may request that such data are submitted.

2.7.2 It may be useful for a technical representative of the applicant to be available to the GESAMP-BWWG for an hour or so to answer questions regarding the system.

## **3.0 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.

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.

3.1.4 For treated ballast water, the Administration should provide both acute and chronic toxicity data (G9: 5.2.2). The discharge toxicity tests should include chronic test methods performed as part of the land-based type approval process with test species (fish, invertebrate, algae) that address the sensitive life stage (G9: 5.2.4). The results should include acute LC50 values and

chronic NOECs (G9: 5.2.5). Therefore, 100% 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 also 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); and
  - .5 an indication of whether the component is an Active Substance (AS) or a stabilizer or inhibitor or solvent, etc.

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

- .1 the Trade name (where relevant);
- .2 the chemical (IUPAC) name;
- .3 the CAS number;
- .4 the UN number and proper shipping name (where relevant);
- .5 the Molar 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 Molar mass;
- .4 the empirical formula;
- .5 the structural formula; and
- .6 the classification in accordance with the GHS system.

**3.2.4 Other Chemicals:** Where the process might produce by-products not deemed to be Relevant Chemicals by the applicant, a justification for such a conclusion should be provided.

**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 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 existing toxicological knowledge for each end point listed.

**3.3.2 Acute aquatic toxicity**

3.3.2.1 Short-term L(E)Cx from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) representing three trophic levels (e.g., OECD guidelines 201 (Algae, Growth Inhibition Test), 202 (Daphnia sp. Acute Immobilization Test), 203 (Fish, Acute Toxicity Test), Mysid shrimp acute toxicity test (USEPA 850.1035) should be accepted. To reduce further any remaining uncertainty, Administrations should, preferably, also submit data for two additional marine taxonomic groups (e.g., echinoderms, molluscs).

3.3.2.2 In the case of whole effluent testing, US EPA or equivalent, short-term methods for estimating the acute toxicity of substances and discharge provide acceptable alternatives.

3.3.2.3 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 ECx from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels (e.g., Fish: OECD 210, 215, or 212; Daphnia: OECD 211). To reduce further any remaining uncertainty, Administrations should preferably also submit two long-term NOECs from additional marine taxonomic groups (e.g., echinoderms, molluscs).

3.3.3.2 In case of whole effluent testing, US EPA short-term methods 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).

### **3.3.4 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 spec.* (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 *Bioavailability/biomagnification/bioconcentration***

3.3.6.1 If  $\log Pow > 3$ , testing of the bioaccumulation potential should be considered taking into account the following points:

- .1 One bioconcentration factor (BCF) determined in a bioconcentration study (at two dosing levels) with fish (e.g., OECD 305) or bivalves. The BCF should be based on uptake/elimination kinetics ( $k_1/k_2$ ). The half-life for elimination should be reported. Fat content in marine fish typically ranges between 0.5 and 15% of the whole body weight. BCF should be normalized to 6% 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 bio-availability since it is considered that the bio-availability 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 bio-availability in the toxicity testing is to be reconsidered.

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

- .1 Active Substances;
- .2 Any components of a preparation; and
- .3 Relevant Chemicals.

### **3.3.7 *Food web/population effects***

3.3.7.1 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.

3.3.7.2 An assessment of secondary poisoning is redundant if for the substance of concern absence of bioaccumulation potential can be demonstrated (BCF  $< 500$  L/kg wet weight for the whole organism at 6% fat). If not, testing should include:

- .1 one long-term NOECs 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).

3.3.7.3 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 unnecessary 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 experience 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 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 tested by inhalation.

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 The tests should provide information on the degree and nature of skin, eye and associated mucous membrane irritation, especially with regard to the reversibility of responses. The tests should provide sufficient information to assess the potential to cause skin sensitization reactions. Animal testing should, whenever possible, be minimized. Tests should be performed with the Active Substance(s) or Preparation(s).

3.4.3.2 Testing of Active Substances or Preparation should include 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). These tests need not be carried out on a strong acid or base (pH below 2 or above 11.5). Where the Active Substance or Preparation has shown to have potentially corrosive properties, or is a severe skin irritant, an eye irritation test should not be carried out. Results from *in vitro* test methods, which are close to validation by recognized organizations, may be submitted.

3.4.3.3 The recommended test 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 the Local Lymph Node Assay (LLNA). However, scientific justification should be given when either of the two latter mentioned is used. The test is not needed if the Active Substance or Preparation is already classified in an internationally recognized system or otherwise known as a sensitizer.

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 A 90-day sub-chronic toxicity study in two species, one rodent and another 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 Substance; and
- .3 Relevant Chemicals.

#### **3.4.5 *Chronic toxicity***

3.4.5.1 There is a need for a chronic toxicity study of a minimum duration of 12 months in two species – one rodent and another 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 Testing should include:

- .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 Study).

3.4.6.2 However, these key data can be modified (either reduced or accelerated or extended) and influenced by factors such as structural relationships with a known reproductive toxicant, the results of other toxicity studies (including toxicokinetics), concerns for endocrine disruption and anticipated use, and human exposure patterns. 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 studies should be performed with one rodent and one other mammalian species. The carcinogenicity testing of an Active Substance or preparation may not be needed where justification demonstrates that these tests are not necessary. Carcinogenicity studies may be combined with the chronic toxicity studies.

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 Genotoxicity data should be available for Active Substances or preparations from 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 testing with bone marrow assay for chromosomal damage or a micronucleus test is necessary. If this test is negative it should be evaluated whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow.

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

- .1 Preparations including any of its components; and
- .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 417) should be presented, if available, to allow better understanding of toxic effects and a reduction of animal testing. The potential for dermal absorption should be evaluated preferably *in vitro* or by physico-chemical data to reduce the need for any specific dermal toxicity testing.

### **3.5 Data on environmental fate and effect under aerobic and anaerobic conditions (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 partition coefficients solids-water partition coefficient (K<sub>d</sub>) and/or organic carbon normalized distribution coefficient (K<sub>oc</sub>) 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; and
- .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).

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 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 (see above);
- .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 *Bioaccumulation, partition coefficient, octanol/water partition coefficient***

3.5.3.1 Testing should include:

- .1 data 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 freshwater 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.

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

- .1 Active Substances;
- .2 any other components of preparations; and
- .3 Relevant Chemicals.

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

3.5.4.1 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.

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

- .1 Active Substances;
- .2 any components of preparations; and
- .3 Relevant Chemicals.

### **3.5.5 *Reaction with organic matter***

3.5.5.1 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.

3.5.5.2 Radical producing chemicals are capable of forming halogenated (chlorinated, brominated) hydrocarbons that may be of concern to environmental 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.

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

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

### **3.5.6 *Potential physical effects on wildlife and benthic habitats***

3.5.6.1 Data requirements consist of physical-chemical properties also required later. Further guidance can be found in the MEPC-approved hazard evaluation procedure published as GESAMP Reports and Studies No.64.

3.5.6.2 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.

### **3.5.7 *Potential residues in seafood***

3.5.7.1 As appropriate, data should be submitted to assess the risk that residues of the Active Substance end up 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.

3.5.7.2 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.

### **3.5.8 *Any known interactive effects***

3.5.8.1 Any knowledge (or absence of this knowledge) on interactive effects of the Relevant Chemicals 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.

3.5.8.2 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 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 Preparations including any of its components; and
- .2 Active substances.

**3.6.3 *Boiling point:*** Data on the boiling point should be provided for:

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

**3.6.4 *Flammability (flash point):*** Data on the flash point should be provided for:

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

- .3 Relevant Chemicals.

**3.6.5 Density (relative density):** Data on the density should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 Treated ballast water.

**3.6.6 Vapour pressure, vapour density:** Data on the vapour pressure and vapour density should be provided for:

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

**3.6.7 Water solubility/dissociation constant:** Data on the water solubility and dissociation constants should be provided for:

- .1 Preparations including any of its components;
- .2 Active Substances; and
- .3 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:** Data on the corrosivity to materials of construction should be provided for:

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

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

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

**3.6.11 Explosive properties:** Data on the explosive properties should be provided for:

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

**3.6.12 Oxidizing properties:** Data on the oxidizing properties should be provided for:

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

**3.6.13 Surface tension:** Data on the surface tension should be provided for:

- .1 Preparations; and
- .2 Active Substances.

**3.6.14 Viscosity:** Data on the viscosity should be provided for:

- .1 Preparations; and
- .2 Active Substances.

**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 Preparations including any of its components; and
- .2 Active Substances.

**3.6.16 Reactivity towards container material:** Data on the reactivity towards container materials should be provided for:

- .1 Preparations including any of its components;
- .2 Active substances;
- .3 Relevant Chemicals; and
- .4 Treated ballast water.

**3.6.17 pH:** Data on the pH should be provided for:

- .1 Preparations; and
- .2 Treated ballast water.

**3.6.18 Salinity:** Data on the salinity should be provided for:

- .1 Treated ballast water.

**3.6.19 TOC, DOC, % particulate matter:** Data on the TOC, DOC and % of particulate matter should be provided for:

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

## **4 USE OF THE ACTIVE SUBSTANCE OR THE PREPARATION**

### **4.1 The manner of application**

4.1.1 The proposal should include the manner of application of the Active Substance or the preparation for the ballast water management (BWM), including required dosage and retention time (G9: 4.2.6).

4.1.2 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, including quantity to be added to ballast water and maximum 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 release in the marine environment;
- .6 procedures of waste management of the Active Substance;
- .7 the possibility of reuse or recycling;
- .8 the possibility of neutralization;
- .9 conditions for controlled discharge; and
- .10 the amount of substance on board ship.

4.1.3 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.

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

## **5 MATERIAL SAFETY DATA SHEETS (G9: 4.2.7)**

5.1 With respect to the classification of hazards, a detailed technical guidance document has been prepared for the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to aid in interpreting data for classifying substances as dangerous. Reference is also made to the MEPC-approved hazard evaluation procedure published as GESAMP Reports and Studies No.64 under the title “The Revised GESAMP Hazard Evaluation Procedure for Chemical Substances Carried by Ships”, which reflects the GHS for marine environmental protection aspects. The Administration is referred to this document for a more detailed guidance on hazard identification.

5.2 The Classification under GHS and the (Material) Safety Data Sheet ((M)SDS) should be given for all components of a Preparation (G9: 6.3.2). Where a component is not classified as hazardous under GHS, this should also be clearly stated.

5.3 The same information should also be given for Relevant Chemicals and other by-products produced by the system unless a clear justification is provided e.g., the half-life of the by-product is so short that the hazards cannot be determined. Key data for these should be summarized in the Key Data Summary Table.

## **6 RISK CHARACTERIZATION**

### **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 Pow.

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?**

See Procedure (G9): Table 1.

Criterion	PBT criteria
Persistence	Half-life: > 60 days in marine water, or > 40 days in fresh water,* or > 180 days in marine sediments, or > 120 days in freshwater sediments
Bioaccumulation	Experimentally determined BCF > 2,000, or if no experimentally BCF has been determined, Log Pow $\geq$ 3
Toxicity	Chronic NOEC < 0.01 mg/L

\* For the purpose of marine environmental risk assessment half-life data in fresh water and freshwater sediment can be overruled by data obtained under marine conditions.

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

## **6.2 Evaluation of the treated ballast water (G9: 5.2)**

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 Basic Approval**

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

6.2.1.2 A system using 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).

### **6.2.2 Final Approval**

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

6.2.2.2 In accordance with regulation D-3.2, a ballast water management system using an Active Substance or Preparation to comply with the Convention (that received Basic Approval) must be approved by the Organization.

### **6.2.3 Determination of holding time**

6.2.3.1 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 variables (e.g., temperature, pH, salinity and sediment loading).

## **6.3 Risk characterization and analysis**

### **6.3.1 Reaction with organic matter (see G9: 4.2.1.3; this document: 3.5.5)**

6.3.1.1 The reaction with organic matter of Active Substances and Preparations including any of its components should be addressed qualitatively and quantitatively, so as to identify Relevant Chemicals that may be of concern to the environment.

### **6.3.2 Characterization of degradation route and rate (G9: 5.3.5)**

6.3.2.1 The route and rate of abiotic and biotic degradation of the Active Substances and Preparations, including any of its components, under aerobic and anaerobic conditions (see 3.5.2 above) should be assessed, resulting in the characterization of the Active Substances, Preparations including any of its components and Relevant Chemicals in terms of degradation rates under specified conditions (e.g., pH, redox, temperature).

### **6.3.3 Prediction of discharge and environmental concentrations**

6.3.3.1 Based on the information on fate and behaviour of Active Substances, Preparations including any of its components and Relevant Chemicals, the discharge concentrations at selected time intervals should be predicted (G9: 5.3.8).

6.3.3.2 Environmental concentrations after discharge of treated ballast water under controlled conditions during development and type approval tests should be estimated (e.g., by a suitable model simulating the test conditions) and provided in the application dossier for Basic Approval. Concentrations of treated ballast water, Active Substances, Relevant Chemicals and other components of Preparations, as appropriate, should be estimated.

6.3.3.3 Environmental concentrations, under suitable emission scenarios to be 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.

#### **6.3.4 *Assessment of potential for bioaccumulation***

6.3.4.1 For Active Substances, Preparations including any of its components and Relevant Chemicals, the potential for bioaccumulation should be assessed in marine or freshwater organisms (fish or bivalves) if the logarithm octanol/water partition coefficient ( $\log P_{ow}$ ) is  $>3$  (G9: 5.3.7).

#### **6.3.5 *Effects assessment***

6.3.5.1 The effect assessment of the Active Substances, Preparations including any of its components and Relevant Chemicals is initially based on a dataset of acute and/or chronic ecotoxicity data for aquatic organisms, being primary producers (algae or sea grasses), consumers (crustaceans), predators (fish), (G9: 5.3.9).

6.3.5.2 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 6% fat) (G9: 5.3.10).

6.3.5.3 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).

6.3.5.4 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).

#### **6.3.6 *Effects on aquatic organisms***

6.3.6.1 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 exposure may be useful. PNEC values are normally derived from short-term and/or long-term 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 be guiding 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.

6.3.6.2 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.

6.3.6.3 When aquatic toxicity data are available only for freshwater species but a PNEC for the marine environment (PNEC saltwater) is needed, this may be derived by applying a higher assessment factor than for the derivation of a PNEC fresh water to reflect the greater uncertainty in protecting sensitive species in saltwater environments. Where data are available for additional taxonomic groups, for example, rotifers, echinoderms or molluscs, the uncertainties in the extrapolation are reduced and the magnitude of the assessment factor applied to a dataset can be lowered.

6.3.6.4 For naturally occurring Active Substances not meeting PBT-Criteria and being rapidly degradable, the PNEC could be set along the background concentration in the environmental compartment under consideration.

Table 2 – Effect assessment for deriving PNECs for fresh water and saltwater

Data-set	Assessment Factor	
	PNEC <sub>long</sub>	PNEC <sub>short</sub>
Freshwater assessment		
Lowest short-term L(E)C <sub>50</sub> from freshwater species representing three trophic levels	1000	10-100
Lowest chronic NOEC from three freshwater or saltwater species representing three trophic levels	10	
Saltwater assessment		
Lowest short-term L(E)C <sub>50</sub> from marine species representing three trophic levels	1000	10-100
Lowest chronic NOEC from three freshwater or saltwater species representing three trophic levels	100	
Lowest chronic NOEC from three saltwater species representing three trophic level	100	
Lowest chronic NOEC from three freshwater or saltwater species representing three trophic levels + at least two chronic NOECs from additional marine taxonomic groups	10	

### 6.3.7 *Effects on sediment*

6.3.7.1 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. Most of the existing whole sediment tests measure acute toxicity and only a few measure long-term, sublethal endpoints. Only the latter tests are considered applicable to risk assessment because of the long-term exposure of benthic organisms to sediment-bound substances that occur under field conditions. Due to the generally long-term exposure of benthic organisms to sediment-bound substances, long-term tests with sub-lethal endpoints like reproduction, growth, emergence, sediment avoidance and

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burrowing activity are regarded as most relevant. It is recommended to use pooled marine and freshwater sediment toxicity data for effect assessment for the sediment compartment. However, when sufficient data for ecologically relevant saltwater species are available, lower assessment factors can be applied. Since there are no chronic marine sediment test methods that are internationally accepted, the results from any tests should always be evaluated with caution.

Table 3 – Effect assessment for deriving PNECs for sediment

Data-set	Assessment factor
Freshwater assessment	
Three chronic sediment tests with species representing different living and feeding conditions	10
Saltwater assessment	
Three chronic sediment tests with species representing different living and feeding conditions	50
Lowest chronic NOEC from three freshwater or saltwater species representing different living and feeding conditions including at least two chronic NOECs from marine species	10

### 6.3.8 Comparison of effect assessment with discharge toxicity

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

## 7 RISK ASSESSMENT

### 7.1 Risk to safety of ship

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 risk 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 The human health risk assessment should follow generally accepted guidelines including acute 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. 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 regulations based on the SOLAS Convention as well as specific measures proposed by the manufacturer and of the ballast water management system that should then be assessed by the Administration concerned.

### **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 endocrine disruptive properties. If the screening results give rise to concerns, this should give rise to a further effect assessment (G9: 5.3.12).

### **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 2 of this document (G9: 6.3.3).

7.2.3.2 There are normally four stages when carrying 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 either 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?

7.2.3.3 The identification of “unit operations” in the whole BWM process of each system is important to the understanding human exposures. The term “unit operation” is used in chemical process engineering to describe a basic step in a process. A chemical or other manufacturing/treatment process may have many unit operations. Occupational hygienists depend on knowledge of such unit operations to be able to determine exposure to chemicals involved in each step of a process. A similar approach is proposed with regard to BWMS evaluations.

7.2.3.4 The risk assessment should include a description of the ballast water treatment process associated with their 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. 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 requirements for each step in the process.

7.2.3.5 Maintenance, equipment failure and accident situations should be considered separately from conditions of normal operation.

### **7.3 Risks to the aquatic environment**

7.3.1 The potential risks to the aquatic environment during experimental development and type approval testing should be assessed.

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 estimates ratios between predicted concentrations of the Active Substance, components of preparations or Relevant Chemicals, as appropriate, and the respective PNEC values are below 1, no further assessment of direct toxic effects to the aquatic environment is necessary.

7.3.3 In other cases, the dilution necessary to ensure that the PNEC values are not exceeded should be calculated by an appropriate model for relevant controlled use and discharge scenarios.

7.3.4 The potential risks to the aquatic environment resulting from full-scale deployment on board ships and discharge of treated ballast water under representative conditions should be assessed. An Emission Scenario Document (ESD) should be provided by the applicant as part of the Risk Assessment procedure for ballast water management systems. The ESD should be based on the worst case discharge scenario and should be regarded as the first stage of a stepped approach to the development of a full ESD, when more data on potential discharges and technologies becomes available (G9: 6.4.4).

## **8 ASSESSMENT REPORT (G9: 4.3)**

8.1 The Assessment report referred to in section 4.3 of Procedure (G9) 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, crew (human health), the environment and resources (e.g., fisheries) 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 modelling 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 given first;
- .2 the Member of the Organization, submitting an application should conduct the Type Approval tests in accordance with 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);
- .3 it is to be noted that from the Guidelines (G8) 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 of Type Approval testing, as an Administration can regulate discharges from its own ships in its own

jurisdiction. Basic Approval would still be required, and the specific technology could not be used in vessels in another jurisdiction without Basic Approval (G9: 8.2.2);

- .4 it should be noted that once a system has received Final Approval under Procedure, 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 seawater at two appropriate time intervals after treatment (preferably immediately after treatment and after a 24 or 48 hours interval), and organisms normally found in the selected types of seawater should be used in the toxicity testing;
- .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 reflect the concerns identified during consideration of Basic Approval. This would mean that in some cases only acute toxicity testing would be needed for Final Approval and in some cases chronic toxicity might be needed whilst in others both acute and chronic data might be required.

\* \* \*

## APPENDIX 1

### KEY DATA SUMMARY FORM FOR 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<sub>50</sub> 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

<b>Trade Name of Preparation</b>			
<b>Composition of Preparation</b>			
<b>Component Chemical Name</b>	<b>CAS Number</b>	<b>Concentration (%)</b>	<b>AS, RC or Other*</b>

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

**AS** = Active Substance  
**RC** = Relevant Chemical  
**Other** = Any other Chemical e.g., solvent

<b>List of ALL potential by-products produced in ballast water</b>			
<b>Chemical Name</b>	<b>CAS Number</b>	<b>Concentration (%)</b>	<b>(bio)degradation rate or half-life</b>

- 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 [5] five days later.

**Data on each component of the  
 preparation and by-product produced in ballast water**

<b>Chemical</b>	<b>Name</b>
.....	

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	LC <sub>50</sub> (mg/l/duration)	Reference/Comments/Justification for missing data
<b>Fish</b>			
<b>Crustacea</b>			
<b>Algae</b>			

**2.2 Chronic Aquatic Toxicity Data**

	Species	LC <sub>50</sub> (mg/l/duration) or NOEC(mg/l /duration)	Reference/Comments/Justification for missing data
<b>Fish</b>			
<b>Crustacea</b>			
<b>Algae</b>			

**2.3 Information on Endocrine Disruption**

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

**2.4 Sediment Toxicity**

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

**2.5 Bioavailability/Biomagnification/Bioconcentration**

Log Pow	Reference/Comments/Justification for missing data
<b>BCF</b>	

## 2.6 Food Web/Population Effects

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

## 3 MAMMALIAN TOXICITY

### 3.1 Acute mammalian Toxicity

	Value	Species	Reference/Comments/Justification for missing data
Oral LD <sub>50</sub> (mg/l)			
Dermal LD <sub>50</sub> (mg/l)			
Inhalation LC <sub>50</sub> (mg/l/4 h)			

### 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

<b>Exposure Route</b>	
<b>Exposure Duration</b>	
<b>Exposure dose</b>	
<b>Species</b>	
<b>Method</b>	
<b>Results</b>	
<b>NOAEL</b>	
<b>NOEL</b>	
<b>Reference/Comments/ Justification for missing data</b>	

### 3.6 Carcinogenicity/Mutagenicity/Reprotoxicity

	<b>Species</b>	<b>Method Details</b>	<b>Results</b>	<b>Reference/Comments/ Justification for missing data</b>
<b>Carcinogenicity</b>				
<b>Mutagenicity</b>				
<b>Reprotoxicity</b>				

## 4 ENVIRONMENTAL FATE AND EFFECT UNDER AEROBIC AND ANAEROBIC CONDITIONS

### 4.1 Modes of degradation (biotic and abiotic)

	<b>Sea water or Fresh Water</b>	<b>Test Duration</b>	<b>Results</b>	<b>Break-down products</b>	<b>Reference/Comments/ Justification for missing data</b>
<b>Hydrolysis at pH 5</b>					
<b>Hydrolysis at pH 7</b>					
<b>Hydrolysis at pH 9</b>					
<b>Biodegradation</b>					
<b>1/2-Life</b>		NR			

### 4.2 Partition Coefficients

	<b>Method</b>	<b>Results</b>	<b>Reference/Comments/Justification for missing data</b>
<b>Log Pow</b>			
<b>Koc</b>			

#### 4.3 Persistence and Identification of Main Metabolites

	Method	Results	Reference/Comments/Justification for missing data
Persistence			

#### 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 (flash point for liquids; °C)		
Density (20°C; kg/m <sup>3</sup> )		
Vapour pressure (20°C; Pa)		
Vapour density (air = 1)		
Water solubility (temp; effect of pH; mg/l)		
pH in solution		
Dissociation constant (pKa)		
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		

**6 OTHER INFORMATION**

**6.1 Analytical Methods for Measuring the Concentration at environmentally Relevant Concentrations**

<b>Method</b>	
<b>Applicability</b>	
<b>Sensitivity</b>	
<b>Reference/Comments/Justification for missing data</b>	

**6.2 Material Safety Data Sheet provided (Yes/No) .....**

**6.3 GHS Classification .....**

**6.4 Risk Characterization**

<b>Persistent (y/n)</b>	<b>Bioaccumulative (y/n)</b>	<b>Toxic (y/n)</b>	<b>Reference/Comments/Justification for missing data</b>

\* \* \*



## APPENDIX 2

### HUMAN EXPOSURE ASSESSMENT

#### 1 INTRODUCTION

1.1 In risk assessment for human health, the normal procedure is to compare the exposure levels to which the population is exposed or likely to be exposed with those levels at which no toxic effects are expected to occur.

1.2 There are normally four stages when carrying 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 either 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.

1.3 The greatest part of information about the potential human toxic effects of chemical substances is obtained from studies on animals.

1.4 In assessing an acceptable level of a particular substance, the procedure usually follows moving from an experiment database of animal 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 deriving exposure limit at a lower exposure value, to allow for the uncertainties in the data. Comparison of this exposure limit with a measured or estimated exposure level is then used to judge whether the situation is satisfactory or whether risk management measures are required.

#### 2 THE MARGIN OF SAFETY (MOS) OR MARGIN OF EXPOSURE (MOE) APPROACH

2.1 In this procedure the ratio of NOAEL determined in the animal studies and expressed in mg/kg/day is compared with the level to which a human may be exposed:

$$\text{MOS or MOE} = \frac{\text{NOAEL mg/kg/d}}{\text{Exposure mg/kg/d}}$$

2.2 Assuming that the exposure of a human population to a substance in drinking water is 1 mg/L, for 60 kg woman consuming on average 2 L of water/day, then:

$$\text{Exposure} = \frac{1 \text{ mg/L} \times 2 \text{ L/day}}{60 \text{ kg}} = 0.03 \text{ mg/kg/day}$$

2.3 The next step in the MOS approach is to derive and apply a so-called “reference MOS” (MOSref). The MOSref is an overall assessment factor (AF) addressing differences between animal experimental data and real human exposure situation, taking into account variability and uncertainty. Normally, the value for each AF is based on substance-specific information or, if missing, on default values. It is common in Human Risk Assessment to use an MOSref of 100 (10 for interspecies variability – between animals and humans – and 10 for intraspecies variability – among humans).

2.4 Example: taking into account the exposure value referred in 2.2. (0.03mg/kg/day) and, for instances, a NOAEL for developmental toxicity of 100 mg/kg/day, the MOS will be  $100/0.03$ , i.e. 3333, a reassuring large value comparing to MOSref (100). However, if this value was much lower or lower than MOSref, it would indicate an inadequate MOS value over the NOAEL and an unacceptable human risk towards this adverse effect.

2.5 The selection of the critical NOAEL for RA will depend on the **extent, duration and route of human exposure** and the selection of the most **critical adverse effect**.

### 3 EXPOSURE ASSESSMENT

3.1 The aim of assessing human exposure is to obtain a realistic estimate of total human exposure, expressed in terms of dose per unit weight, e.g., mg/kg.

3.2 In principle, the exposure of a human population could be assessed by representative monitoring data and/or model calculations based on available information on substances with analogous uses and exposure patterns or properties.

3.3 The predictions of exposure levels should describe a reasonable worst case situation, covering normal use patterns and where general public or workers may be exposed to the same substance. It is important to assess the **reliability** and the **representativeness** of the exposure measurements.

3.4 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.

3.5 The most probable scenarios for human exposure to BWMS still need to be properly identified. However, one can assume two potential groups, with some characteristics of each and expected route of exposure as follows:

- .1 **Crew** (exposed occupationally):
  - .1.1 exposure assumed during working week – 8-hour day, 5 days per week;
  - .1.2 relatively healthy part of general population; and
  - .1.3 exposure routes: normally inhalation and dermal.

- .2 **General public/Human exposure via environment** – Users of coastal amenities, beach coastlines and offshore installations and harbours:
  - .2.1 exposure intermittent – needs to be estimated;
  - .2.2 exposures may not be controlled;
  - .2.3 exposure routes: oral, inhalation and/or dermal; and
  - .2.4 includes vulnerable groups e.g., children and elderly people.

3.6 Normally occupational exposure will be an external exposure, i.e. the amount in contact with the skin, inhaled, or the concentration in the atmosphere. Where the conclusion is that this level “is of concern”, it may be necessary to determine internal exposure, i.e. the amount taken into the tissues of the body, or its bioavailability.

3.7 The predictions of the consequences of exposure have to be carried out for each exposed human population (e.g., workers, general public) and for each effect.

#### 4 OCCUPATIONAL EXPOSURE

4.1 The most common routes of exposure in the workplace are by inhalation or by absorption through intact skin. Dermal exposure may also result in local effects, such as irritation or dermatitis.

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

4.3 Of primary importance in developing the assessment of occupational exposure is a full understanding of the **processes** and **unit operations** in which exposure occurs, and of the actual **work** activities resulting in exposure. With this background knowledge, the following questions have to be answered:

- .1 what is the population of potentially exposed individuals?
- .2 what are the magnitude, frequency and duration of inhalation and dermal exposures?
- .3 what personal protective equipment and control measures are used to reduce or mitigate exposure? and
- .4 how effective are they in reducing exposure?

4.4 The overall assessment of each type of exposure should be repeated for all the various production processes and uses made for the chosen chemical, and from a knowledge of the frequency and duration of exposure the “worst case” highlighted.

4.5 If “real” data are missing for a chosen substance, as an alternative to modelling it may be possible to substitute data from another chemical with a similar pattern of exposure.

4.6 The following major factors can affect exposure potential:

- .1 **size of activity** – the greater the quantity of the substance involved or the higher the concentration in solution, the greater the potential for exposure is likely to be. Any potential hazard from 10 tons is likely to be much greater than that of 10 mg;
- .2 **physical characteristics of the activity** – particle size of a solid or volatility of a liquid are also likely to affect the exposure, as is the presence of barriers to the exposure and containment of the substance away from human contact. Procedures involving elevated temperature, particularly with substances with significant vapour pressures, may engender an enhanced inhalation exposure; and
- .3 **time of exposure** – the duration and frequency of exposure to an activity will also be a factor – the longer the time of exposure the higher the exposure potential.

4.7 The quantitative human exposure assessment results in a reasonable worst-case estimate for external exposure via the inhalation and dermal route (the main routes of concern for occupational exposure) that are taken forward to the risk characterization.

4.8 These estimates are obtained for all relevant scenarios that have been identified taking into account all relevant available information.

4.9 In the risk characterization phase 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.

## 5 CONTROL OF THE RISK

5.1 When a risk assessment results in the conclusion that the risk is too high, consideration has to be given to introducing the following controls that will lower this risk to acceptable levels:

- .1 **Prevention** that includes:
  - .1.1 elimination;
  - .1.2 substitution; and
  - .1.3 good hygiene practice.
- .2 **Physical segregation** that includes:
  - .2.1 complete enclosure with extraction;
  - .2.2 local exhaust ventilation with or without partial enclosure; and
  - .2.3 screening.

- .3 **Personal protection** that includes:
  - .3.1 respiratory protective equipment including respirators and self-contained breathing apparatus; and
  - .3.2 protective clothing (eye and head protection, gloves, shoes, etc.).

## **6 OCCUPATIONAL EXPOSURE QUESTIONS**

6.1 Questions need to be addressed by the applicant in the Application for Basic Approval of a BWMS are as follows:

- .1 What are the chemical substances/products used/generated at the workplace and what is their physical-state (gas, liquid or solid) and concentration?
- .2 Where and how the substances/products are used/generated at the workplace?
- .3 By whom the substances/products will be directly used (primary exposure)?
- .4 Description of the operator tasks, frequency and duration at each operation unit – please include the relevant tasks in the process flow chart.
- .5 What are the expected measures to reduce worker exposure (PPE, RPE)?
- .6 Who else may be exposed (secondary exposure)?

## **7 REFERENCES**

- .1 Chemical Risk Assessment – UNEP/IPCS, WHO, 1999; and
- .2 Technical Guidance Document on Risk Assessment, European Chemicals Bureau (ECB) – Part I, European Communities, 2003.

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