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

Draft GESAMP Reports and Studies publication

Submitted by the Chair of WG 34

1 Attached at annex is a draft publication for the GESAMP Reports and Studies series, as requested by GESAMP at its 43rd session in 2016.

Action requested of GESAMP

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

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1. Background to GESAMP WG34 risk assessment approach

1.1 Ballast water and alien invasive species (AIS)

Ballast water

Ballast is defined as any solid or liquid that is brought on board a vessel to increase the draft, change the trim, and regulate the stability or to maintain stress loads within acceptable limits. Prior to the 1880s, ships used solid ballast materials such as rocks and sand, which had to be manually shoveled into cargo holds, and similarly discharged when cargo was to be loaded on board. If not properly secured, solid ballast was prone to shifting in heavy seas causing instability.

With the introduction of steel-hulled vessels and pumping technology, water became the ballast of choice. Water can be easily pumped in and out of ballast tanks, requires little manpower, and as long as tanks are kept full, poses little to no stability problems (Transport of Canada website).

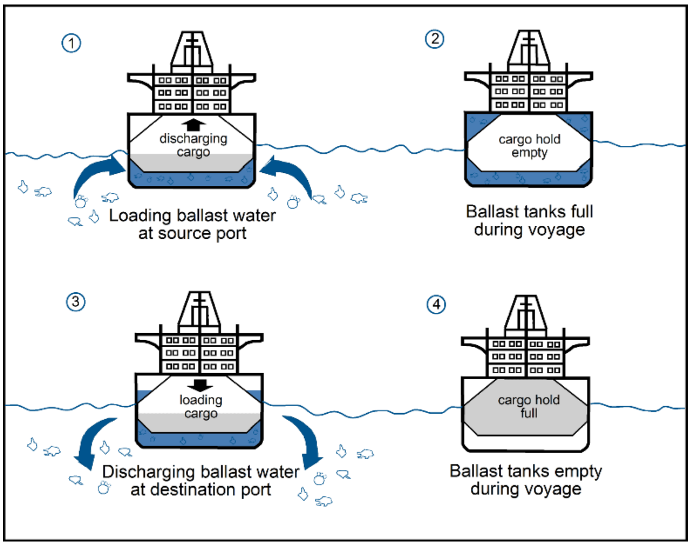

Figure 1. Loading and discharging ballast water (© GloBallast)

Invasive species (definition)

An invasive species is defined as a non-indigenous species that has been transported from its normal environment via the ballast tank on board a ship and has been introduced outside its normal distribution into a recipient ecosystem where it may become abundant (Lawrence and Cordell 2010). To become invasive the non-indigenous species has to survive introduction into the new ecosystem, establish itself and become dominant. This process of becoming invasive is influenced by a number of factors such as the number of introduced individuals with invasive potential and the frequency of introduction events, together referred to as propagule pressure (Lawrence and Cordell 2010).

Where and when did the problem with invasive species start?

The Convention was motivated by many well-known examples of invasions of 'harmful aquatic organisms', such as those caused by the zebra mussel *Dreissena polymorpha* establishing itself throughout the Great Lakes and many of the water-ways of North America and the invasion of the Black and Caspian Seas by the predatory comb-jellyfish *Mnemiopsis leidyii*. The zebra mussel is a freshwater bivalve that is native to the Black Sea region of Eurasia (Ontario's Invading Species Awareness Program, 2017).

Both of these invasions in the 1980 and 90's caused lasting changes to the ecology of large water bodies, the former leading to wide-scale retrofitting of cooling systems to reduce fouling and the latter to a massive decline in fisheries (GESAMP 1997); both ultimately had severe economic consequences.

Figure 1. Close-up of a typical shell of a zebra mussel and a comb-jellyfish

Another example of an invasive species is the Chinese mitten crab (Figure 2). This species has been spread rapidly from Asia (China and Korea) to North America and Europe, raising concerns that it competes with local species, and its burrowing nature damages embankments and clogs drainage systems (BBC News, 2006).

Figure 2. Chinese mitten crab

The first time the crab was brought to Europe was most likely by commercial vessels. Ships must fill their ballast water tanks and during one of these filling events, it could have been the spawning time for the mitten crab. Since the larvae are free floating and 1.7mm to 5mm in size, it would have been easy for them to be swept into the ballast water tank. Once the ship reached Europe and emptied its tank, the crab larvae was released. Over time, this repetition would allow for a prominent mitten crab population in Europe (Panning, 1938). The crab has spread and can be found in Continental Europe, Southern France, United States of America (the San Francisco Bay), and the United Kingdom. A 15-year period in Germany when the crabs were gradually entering Europe is known as the "establishment phase" (Herborg, *et al*, 2003).

What does the current situation look like?

Increased global trade, travel and transport of goods across borders, seas and oceans, has brought benefits to mankind. It has, however, also facilitated the spread of invasive species with increasing negative impacts, because these species often do not have natural enemies in the area that they invade. The problem has increased with the introduction of steel hulls, allowing ships to use water instead of solid materials as ballast, and in particular over the last few decades as trade and traffic volumes have expanded. The effects of the introduction of non-indigenous species have, in many areas of the world, been devastating. Quantitative data show the rate of bio-invasions increasing continuously and significantly.[J1]

[J2]

Figure 3. – Shipping intensity around the globe. (ref?)

How big is the problem?

Harmful aquatic organisms and pathogens present a major threat to marine ecosystems and shipping has been identified as a significant pathway for introducing species to new environments. Such species are found in nearly all major taxonomic groups of organisms. Even though it is only a small percentage of species that are moved across the globe, and become invasive, these may have extensive impacts. In some cases these effects can be devastating [example?[J3]]. The spread of invasive species has been recognized as a great threat to the ecological and the economic wellbeing of the planet. These species are causing enormous damage to biodiversity. Since 19XX[J4], the problem has been on the agenda of IMO in its Marine Environmental Protection Committee.

1.2 The Ballast Water Management Convention (BWMC)

A global problem calls for a global solution

The Convention aims to prevent, minimize and ultimately eliminate risks to the environment, human health, property and resources arising from the transfer of harmful aquatic organisms and pathogens, by establishing standards and procedures for the management and control of ships' ballast water and sediments. To complement the Convention the IMO and Member

States adopted over 15 sets of guidelines and other documents contained in MEPC resolutions and circulars.

Under the Convention, ships to which the Convention's provisions apply will be required to manage their ballast water and sediments to a certain standard, according to a ship-specific ballast water management plan (BWMP). Ships will also have to carry a ballast water record book (BWRB) and an International Ballast Water Management Certificate (IBWMC). The ballast water management standards will be phased in over a period of time. Initially, ships subject to the Convention's ballast water requirements are required to exchange ballast water mid-ocean. This is called the D-1 standard and is described in detail in Section D to the Convention and is also indicated as the exchange standard. In due course these ships are required to meet a performance standard that limits the number of organisms in discharged ballast water. After some time, to be determined by the parties, the D-1 standard will be phased out and completely replaced by the D-2 standard. The D-2 standard is also nominated as the performance standard. How ships should be able to confirm to the D-2 standard is described in detail in Guidelines (G8), as revised in 2016. It was envisaged that to achieve the performance standard disinfection method would be considered the most effective and would provide the necessary, sufficient efficacy. For the evaluation of the side effects of the treatment a Technical Group (see below) was established. The treatment should not have any risks to the environment, human health, property and resources. The IMO document Procedure (G9) describes in detail how the Technical Group should evaluate the Ballast Water Management Systems (BWMS), sent to the MEPC Secretariat of IMO for decision making.

Parties to the Convention are given the option to take additional measures, which are subject to criteria set out in the Convention and relevant guidelines for the uniform implementation of the Convention.

The Convention consists of articles and annexes which include legal requirements, technical standards and regulations for the control and management of ships' ballast water and sediments. There are various resolutions and circulars developed by the Organization relating to the Convention.

1.3 Procedure (G9) including general description

The IMO-document that deals wit

1.4 Working Group 34 – GESAMP-BWWG

1.4.1 Terms of reference

IMO requested GESAMP to assist the Ballast Water Convention by assessing the risks of Ballast Water Management Systems (BWMS) to the marine environment, to human health, including the ships' crew, and to the safety of the ship. In response, GESAMP set up the Ballast Water Working Group (BWWG) in 2006 for this purpose, comprised of a multidisciplinary team of experts in the fields of chemical risk assessment, ecotoxicology, occupational hygiene and toxicology as well as ships architecture and engineering.

The role of this technical group (GESAMP-BWWG) is to review the proposals submitted for approval of ballast water management systems (BWMS) that make use of Active Substances. The experts working for GESAMP-BWWG act independently in their individual capacity and are bound by a Statement of Acceptance that ensures that proprietary data is treated as confidential. The Terms of Reference for the GESAMP-BWWG as developed by the Marine Environment Protection Committee of IMO are attached as annex 1 to this document.

It is important to note that the GESAMP-BWWG only evaluates the safety of BWMS; it is not responsible for assessing their efficacy or effectiveness in treating ballast water. On behalf of the manufacturer, administrations submit applications regarding a given BWMS to the Marine Environment Protection Committee (MEPC) of IMO. These submissions once accepted for evaluation are processed by IMO on a first-come first-served, fee-paying basis and sent on to GESAMP-BWWG. The submissions are first checked for completeness and their content summarized in a standard format by the IMO consultant and then evaluated by GESAMP-BWWG for Basic Approval according the IMO “Procedure for approval of ballast water management systems that make use of Active Substances” (G9) and following the GESAMP-BWWG Methodology, as published by IMO. As part of Basic Approval, GESAMP-BWWG makes a series of recommendations which the manufacturer is advised to take care of prior to re-submitting for Final Approval which is handled in a similar manner. GESAMP-BWWG, through MEPC, may make additional recommendations to the Administration in question with a bearing of the Type Approval. Once approval through the first two steps has been achieved by a given BWMS, the submitting administration is then responsible for issuing a Type Approval for commercial scale installation on board ships.

The reports containing the findings and recommendations of GESAMP-BWWG are peer reviewed by its parent body GESAMP and once approved, the recommendations are communicated to IMO for consideration by MEPC. Once endorsed by MEPC, the Type Approval process can begin.

2 Ballast Water Management Systems

Different Ballast Water Management Systems (BWMS)

A wide variety of BWMS using chemical, physico-chemical and physical technologies have been developed over the years and this is reflected at all stages of the evaluation and approval process. It is already clear that the front runner technology is *in situ* electrolysis where seawater is used to produce chlorine and its oxidizing derivatives (TRO). Such systems pass a rigorous environmental and human health risk assessment but the question of disinfection by-products could make them less attractive in the long run from an environmental point of view than some of the other candidates entering the market.

These processes are combined with filtration or other means of separation and are followed by a neutralization step before discharge.

Other treatment methods include ozonation, adding biocides or removal of organisms through flocculation.

Up to date 58 BWMS that make use of Active Substances have received Basic Approval from IMO (July 2017). The different treatment technologies are presented in the table below.

Table 1: BWMS that make use of Active Substances and that have received Basic Approval

Technology	Number of BWMS	Comment
Electrolysis *in situ* with or without filtration	28	13 BWMS use filtration and one system use several filters in a filtration unit
Chemical addition (biocides) with or without filtration	11	2 BWMS use filtration
UV with or without filtration	5	BWMS that use UV light need not to be reviewed by GESAMP-BWWG (decision at MEPC 59, MEPC 59/22)
Ozonation	3	
Other – either a combination of treatment steps or some other method	11	UV light is used as one of the treatment steps in 6 systems, electrolysis is

		used in 3 systems and ozone is used in 3 systems

The most frequently used technique is *in situ* electrolysis (28 systems) using seawater to produce the Active Substance (AS) total residual oxidant (TRO). In these BWMS the electrolysis unit generating the AS is either mounted directly in the main ballast water pipeline hence a full flow system, or uses a side stream of ballast water to produce a concentrated stream of AS, which is then reinjected into the ballast water pipeline.

Some BWMS (3 systems) use ozone as the only treatment step. Other BWMS use ozone in combination with electrolysis or UV (3 systems).

The second most frequent method is the addition of chemical (biocide) (11 systems). In most cases the chemical is quickly converted to the AS sodium hypochlorite by dissolving in water (for example 4 systems are using NaDCC (sodium dichloroisocyanurate)) or sodium hypochlorite, or calcium hypochlorite, are used as Active Substance. In one BWMS a combination of a triarylmethane dye and quaternary ammonium compound is being used as the AS.

Another method is UV either as the only treatment step or in combination with other techniques. At MEPC 59 it was decided that BWMS that only make use of UV light do not have to go through the approval process by GESAMP-BWWG (MEPC 59/22). UV is being used in combination with filtration and sedimentation, plasma, electrolysis or TRO in 4 systems.
Other BWMS uses methods to reduce the oxygen concentrations thereby creating hypoxic conditions, mechanical means (flocculation) to remove suspended organic matter or hydroxyl radicals ($^{\cdot}$OH).

For more detailed information regarding the approved ballast water treatment technologies please click here.

The test water
GESAMP-BWWG have investigated the possibility of using a model that could predict the formation of DBPs using different oxidants (sixth stock-taking workshop, July 2014). The aims were the following:

.1 to develop and validate kinetic models to predict the behavior of different oxidants in saline waters;

.2 to investigate, in conjunction with these models, the formation of DBPs in saline waters; and

.3 to identify a minimal test programme for the kinetic modelling of DBP formation in saline waters.

Prof. Urs von Gunten was invited to the sixth stock-taking workshop and presented his project "Formation of disinfection by-products during the oxidative disinfection of seawater". The conclusion however was that the model needed to be further developed before it could be used by GESAMP-BWWG. The results from the further development of the model have since been published (Shah, 2015).

Conclusion from eighth stock-taking workshop, February 2017:
The 2016 Guidelines (G8) include new provisions for test water augmentation, emphasizing the critical importance of dissolved organic carbon (DOC) and stipulating that "relevant properties of the augmented water (such as the oxidant demand/TRO decay and UV absorption in the range of 200 to 280 nm, the production of disinfection by-products and the particle size distribution of suspended solids) are equivalent, on a mg/L basis, to that of natural

water" (2016 Guidelines (G8), paragraph 2.4.21). Since the same test water that is used for land-based testing taking into account Guidelines (G8) is frequently also used for the identification of Relevant Chemicals and toxicity testing under Procedure (G9), MEPC 70 requested the Group to "review what kind of precursors are involved in the process of disinfection by-product (DBP) production and total residual oxidant (TRO) consumption and are considered important during Procedure (G9) assessments, in order to ensure compatibility between Guidelines (G8) and Procedure (G9)" (MEPC 70/18, paragraph 4.19.3).

GESAMP-BWWG is not in a position at the moment to recommend a specific additive for DOC adjustment of test waters, however GESAMP-BWWG is of the opinion that the same type of additive should be used for all testing to be performed with the same BWMS under Procedure (G9), in order to make the test results consistent and comparable.

Literature studies published in the last 40 years have established a clear relationship between the DBP formation potential of an organic substance and its aromaticity. A suitable measure of aromaticity can be provided by the specific UV absorbance (SUVA) at 254 nm, which has been shown to correlate well with DBP formation both in fresh and marine waters. However, too little data is available with regard to typical SUVA values of natural marine waters to make a quantitative recommendation for appropriate SUVA values of augmented test waters. GESAMP-BWWG expects to collect more experience regarding this issue in the future based on the new provisions for test water augmentation under the 2016 Guidelines (G8) and requests further applicants to provide the results of measuring Specific UV Absorbance (SUVA) at 254 nm in any future application for Basic and/or Final Approval.

Chemicals (Active Substances, Relevant Chemicals and Other chemicals)

The working definition of 'Active Substances' indicates those chemicals which ensure disinfection, while 'Relevant Chemicals' are usually auxiliary substances or Preparations added to ballast water or produced in the course of disinfection as by-products. There is often an overlap between the two due to complex speciation and chemical equilibrium in water. In practice, all systems are considered by GESAMP-BWWG to potentially produce Active Substances and/or Relevant Chemicals – until proven otherwise.

Information about chemicals that has to be submitted with any application for BA and/or FA

Any submission for BA or FA evaluation should contain information about the anticipated chemical reactions associated with the particular system involved and residual chemicals expected to be discharged to the sea. The description 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 according to Table 2.

Table 2. – Composition / Chemicals associated with the BWMS

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

A summary of all chemicals analyzed in the treated ballast water, in all three salinities should be presented in a table, as shown above, including those not actually detected. Where a chemical could not be detected, a less than value (< x µg/L) should be associated with it to indicate the detection limits of the analysis.

Contaminated source water

Over the years GESAMP-BWWG have encountered situations where the source water used to conduct the mandatory tests has been contaminated. The result of such a situation being that the PEC/PNEC ratio for the control water itself may exceed 1, that is, discharge could lead to a potentially hazardous situation for the organisms in the receiving waters. As a consequence it may not be safe for crew and Port State Control officers who handle the ballast water while performing the tasks described in the human health part of this report. For the sake of being able to conduct the evaluation according to the Methodology the GESAMP-BWWG has repeatedly recommended applicants to make sure that the source water used for tests is of good quality (MEPC 64/23). In a real life situation where ballast water is retrieved from a heavily polluted harbour the handling of the ballast water may pose a risk to humans.

Information gathered by GESAMP-BWWG regarding chemicals associated with BWMS and the development of the Database

At its first Workshop in 2009 GESAMP-BWWG identified a list of more than 70 by-products which have been formed during the treatment by various ballast water management systems. An Excel file was created that listed all of the chemicals reported in any submission dossier regardless of whether present in the source water from the start, or formed during treatment. Based on this, the Workshop identified, as a first step, 18 by-products believed to pose a potential risk to the environment as well as to humans being exposed, as the remaining chemicals were usually under their detection limits. Hazard profiles (toxicological, ecotoxicological and physico-chemical properties) were developed for these 18 chemicals with support from the GESAMP-EHS Working Group and were approved at the Third Stocktaking Workshop. The information from the hazard profiles were used to populate the first version of a database which was based on Microsoft Access.

At the Fourth Stocktaking Workshop it was decided to increase the number of substances in the Database. The Workshop agreed on the physico-chemical properties of an additional 25 chemicals. The number of chemicals is now 41, and data for these substances can be found in the online GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water (https://gisis.imo.org/).

Formation of DBPs

Oxidizing chemicals affects the organisms that are present in the water, and will also have an oxidizing effect on the organic matter and halogens that are naturally present in the environmental waters.

Due to the high concentration of halogen ions, including bromide and iodide, the amount of DBPs formed during sea water treatment with oxidative agents may be much higher than in fresh water. Different inorganic and organic compounds containing bromine and iodine in the molecule could be expected in higher concentrations.

Electrolysis in seawater

Figure 4: Mechanisms of electrolysis in seawater

Anode :	$2Cl^-$	→	$Cl_2 + 2e^-$
Cathode :	$2H_2O + 2e^-$	→	$H_2 + 2OH^-$
Solution :	$Cl_2 + 2NaOH$	→	$NaClO + NaCl + H_2O$
	$NaClO + H_2O$	→	$HClO + Na^+ + OH^-$
	$HClO$	⇔	$H^+ + ClO^-$

Electrolysis using seawater generate oxidants, such as bromine (hypobromous acid and hypobromite, $HOBr/OBr^-$) and chlorine (hypochlorous acid and hypochlorite, $HOCl/OCl^-$), which are active in inactivating marine organisms. For simplicity these oxidants are generally referred to as total residual oxidants (TRO) (Perrins, *et al*. 2006).

Hypochlorous acid is generated by electrolysis. Chlorine and water react to form hypochlorous acid (HOCl) and hydrochloric acid (HCl). The HOCl dissociates into hypochlorite ion (OCl^-) and hydrogen ion (H^+):

$$\mathbf{Cl_2 + H_2O \Leftrightarrow HOCl + HCl}$$
$$\mathbf{HOCl \Leftrightarrow H^+ + OCl^-}$$

Hypochlorous acid is a weak acid (pKa of about 7.5), and dissociates into hydrogen and hypochlorite ions. The dissociation is incomplete between pH 6.5 and pH 8.5. Both HOCl and OCl^- species are present to some extent. Below pH 6.5, no dissociation of HOCl occurs, while above pH 8.5, complete dissociation to OCl^- occurs. As the germicidal effect of HOCl is much higher than that of OCl^-, chlorination at a lower pH is preferred. The OCl^- and HOCl species are commonly referred to as free active chlorine (FAC), which is extremely reactive with cell the components of numerous microorganisms.

In nature bromine is present as bromide salts or organic bromine substances. These substances are produced by several marine organisms. Bromine is mostly in soluble salts in seawater, salt lakes and brine. Chlorine can oxidize bromide to form hypobromous acid:

$$\mathbf{Cl_2 + H_2O \Leftrightarrow HClO + H^+ + Cl^-}$$
$$\mathbf{HOCl + Br^- \Leftrightarrow HOBr + Cl^-}$$

Hypobromous acid (HOBr) is an effective biocide. The rate of the production of hypobromous acid and hypobromite ions is determined by the pH value of the water. When the pH value is between 6.5 and 9 both hypobromous acid and hypobromite ions can be found in water.

Chlorine gas oxidizes bromide to bromine. When chlorinated water is added to a watery solution containing bromides, the solution turns brown due to the formation of bromine.

$$\mathbf{2Br- + Cl_2 \Leftrightarrow 2Cl- + Br_2}$$

DBP formation during BWMS testing

The most commonly employed chemical is chlorine, which generates trihalomethanes, halogenated acetic acids and bromate in larger quantities than reported from other water treatment areas (reference to cooling water in power plants). Levels differ considerably among systems, but are always highest in brackish water. An increase in DBPs being formed is also observed with increased oxidant doses. For other parameters, such as natural organic matter or contact time, no clear correlation can be derived. Brominated species predominate, in particular bromoform and dibromoacetic acid. Ozonation, which is less frequently utilized, produces similar DBPs, but in lower concentrations.

DBPs in drinking water

Over the last 40 years, the formation of DBPs in drinking water and waste water has been investigated, beginning with the discovery of trihalomethane formation in the 1970s (Shah, 2015).

More than 500 DBPs have been reported in the literature for chemical drinking water disinfection (Richardson, 1998). The reported DBPs belong among others to the groups of the trihalomethanes (e.g. trichloromethane, tribromomethane), haloacetic acids (e.g. dichloro- and trichloroacetic acid), haloacetonitriles (e.g. bromoacetonitrile and chloroacetonitrile), haloketones, haloaldehydes, and haloamides (e.g. Caughran, *et al*., 1999; Weinberg, *et al*., 2002; Richardson, *et al*., 2007).

Mixture toxicity

The great variety in the DBPs formed results in different toxicity levels of treated ballast water. Because of the multiple mixtures of produced chemicals the predictability of the resulting toxicity and the possible pathways of decomposition of the compounds in the water is not easy. Therefore, whole effluent tests are required in toxicity testing by Procedure (G9).

Neutralization of AS

Treatment with reducing agents (for example sodium thiosulfate), is commonly applied to get rid of excess oxidant.

$$4NaClO + Na_2S_2O_3 + 2\ NaOH \rightarrow 4\ NaCl + 2\ Na_2SO_4 + H_2O$$

Neutralization of DBPs

Active carbon treatment of disinfected water prior to discharge effectively reduces DBP levels The experience in approving and testing BWMS in the last years' shows a further inconvenience of the DBPs. Beside their toxicity and their persistence, DBPs are not be inactivated by the use of sulfur reductants. Even after removal of the oxidizing agents, the DBPs remain in the discharged water after the neutralization step and may cause a more or less strong residual toxicity of the ballast water.

Mitigation measures

Measures are needed to protect the sensitive ecosystems from the invasion of non-indigenous species and from the harm by the used chemicals and their DBPs. Such mitigation measures are e.g. an elongation of the holding time of the water in ballast tanks or the deactivation of the active substances. A very common and efficient method is to combine different methods of ballast water treatment. Currently, a typical BWTS consists of a pre-treatment unit, like an effective filter system, followed by a disinfection unit and finally by an inactivation step if necessary.

2 GESAMP-BWWG risk assessment: a tiered approach

Introduction

For the risk assessment for human health and the environment, the GESAMP-BWWG selects the substances that have been detected in a concentration above the detection limit from the full chemical analysis for all three salinities (refer to table 3). These substances should be considered the Relevant Chemicals (RCs) for the BWMS.

Table 3: Chemical analysis of treated ballast water in different salinities as reported by the applicant

Chemical	**Detection limit** (µg/L)	**Fresh water** (µg/L)	**Brackish water** (µg/L	**Seawater** (µg/L)
A				
B				
C				
D				

If the Active Substances (AS) are not consumed during the treatment process they may be included in the risk assessment together with the Relevant Chemicals (RC). If the detection limit for a substance is determined to be unreasonably high, the substance will be included in the further risk assessment with a value corresponding to the detection limit. It may be suitable to use two worst-case concentrations, one for occupational risk assessment (in a ballast water tank) and the other for environmental and general public risk assessment (in the discharged ballast water) as shown in Table 4.

Table 4: Selected (Active Substances and) Relevant Chemicals and maximum concentrations for further risk assessment

Chemical	**Maximum concentration (ballast tank) (µg/L)**	**Maximum concentration (discharged ballast water) (µg/L)**
A		
B		
C		

2.1 Environmental risk assessment

[Text to come]

Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) should be calculated using the MAMPEC-BW 3.0 model or latest available version with the appropriate environment definition and emission input. The results of these calculations should be used to estimate the risk to the general public and the environment (see Table 5).

Table 5: PEC from MAMPEC modelling results from the GESAMP-BWWG Model Harbour for the harbour and near ship scenario

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

Predicted No Effect Concentrations (PNEC)

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 according to the Tables 6. and 7.

Table 6: PNEC values of Chemicals associated with the BWMS and included in the GESAMP-BWWG Database

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

Table 7: PNEC values of Chemicals associated with the BWMS, not included in the GESAMP-BWWG Database

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

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

This section should include:

.1 a description of the tests carried out; and

.2 a table of the results, e.g. as shown in Table 8.

Table 8. – WET test reporting

Test	Test organism	Salinity (PSU)	Endpoints (%)		References / Guidelines
			NOEC*	L(E)C$_{50}$	
	Algae				
	Crustacean				
	Fish				

Assessment of Persistence (P), Bioaccumulation (B) and Toxicity (T)
Based on the half-life, BCF or Log K_{ow} and the chronic NOEC values for each chemical (Procedure (G9), paragraph 6.4) (refer to table 9), the PBT properties of each chemical should be assessed.

Table 9 – Criteria for identification of PBT Substances

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

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

See also Table 1 in Procedure (G9).

The PBT properties of each chemical should be reflected in a table with the justification in parentheses according to table 10.

Table 10 – Reporting of PBT properties

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

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

For each chemical the estimation of the PEC/PNEC ratio should be summarized as shown in the table 11.

Table 11 – PEC/PNEC ratios

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

2.2 Human health risk assessment

Introduction

The Methodology, including the approach used in the human health risk assessment, has been developed over the years at the GESAMP-BWWG stocktaking workshops (MEPC 59/2/13, MEPC 60/2/13, MEPC 62/2/14, MEPC 65/2/8, MEPC 66/2/6, MEPC 68/2/8 and MEPC 69/4/3).

From the start none of the human exposure scenarios existed, and only one scenario, representing a worst case situation (drinking 2 liters of water per day), was being used (MEPC 56/2/2, Annex 9). In the first revision of the Methodology (BMW.2/Circ.13/Rev.1) the human exposure scenarios developed at the first stock-taking workshop in 2009 were implemented.

The risk assessment approach consists of five different steps; exposure identification (identification of relevant tasks that will lead to exposure), exposure assessment (estimation of dose/concentration of substances during exposure and duration of exposure), hazard identification (identification of the intrinsic toxicological properties of Active Substances, Preparations and Relevant Chemicals), dose-response assessment (toxicological endpoints associated with exposure to substances), and risk characterization. Figure 5 illustrates the risk assessment approach.

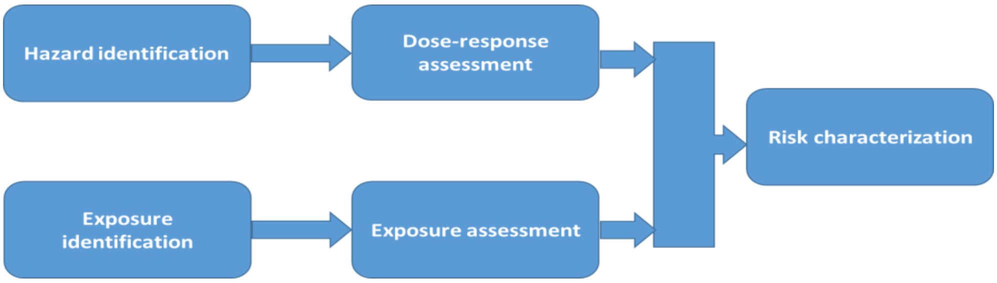

Figure 5. Risk assessment approach

2.2.1 Human Exposure Scenarios (HES)

Exposure identification

How and where do humans get exposed to ballast water?

Humans may get exposed to ballast water and the chemicals contained therein either directly on board the ship while taking samples from the water in the tank, cleaning the ballast water tanks or inspecting the tanks.

Exposure may also occur indirectly as is the case for the general public who may swim in the water where the ballast water has been discharged, or who eat seafood that has been caught in the vicinity of harbour where the ballast water was discharged.

Exposure assessment

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 the operations associated with the potential exposure. The intention behind the assessment is to identify the operations that may pose a risk to the crew and/or Port State control officers. There are a number of operations when an exposure to ballast water can take place. These operations have been identified throughout the GESAMP-BWWG evaluations and have been thoroughly discussed at the second STW when an invited expert, Dr. Andrew Phillips, was assisting the Group to further elaborate the human exposure scenarios.

2.2.2 Operations involving the crew and/or port state control officers

The human exposure scenarios that have been identified and established at the stocktaking workshops are described in table 12.

Table 12. Summary of occupational exposure scenarios

Operations involving the crew and/or port state control officers		
Operation	**Exposure**	**Frequency/duration/quantity**
Delivery, loading, mixing or adding chemicals to the BWMS	Potential dermal exposure and inhalation from leakages and spills.	*Solids, dermal: scenario to be developed* Liquids, dermal: 0.05-0.1 mL/container handled *Gases/vapors/dusts, inhalation: scenario to be developed*
Ballast water sampling at the sampling facility	Inhalation of air released	2 hours/day for 5 days/week; 45 weeks/year
	Dermal exposure to primarily hands	
Periodic cleaning of ballast tanks	Inhalation of air in the ballast water tank	8 hours/day for 5 days/week; 1 event/year
	Dermal exposure to the whole body	
Ballast tank inspections	Inhalation of air in the ballast water tank	3 hours/day for 1 day/month
Normal operations carried out by the crew on BWMS		
Normal work on deck unrelated to any of the above	Inhalation of air released from vents	1 hour/day for 6 months/year

A number of assumptions are being used in the human exposure scenarios. The assumptions being used in the crew/PSC scenarios are all listed in table 13. In all scenarios, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of males is assumed, but the body weight of women (60 kg) is applied. The surface area of the exposed skin for hands (fronts and backs) for males is 0.084 m^2 and the whole body surface area for men is 1.94 m^2 (ECHA, 2016).

Table 13. Summary of physiological parameters in human exposure scenarios for crew/Port State officers

Parameter	Value	Reference
Body weight	60 kg	ECHA (R.15)
Hands (2), surface area	0.084 m^2	ECHA (R.15)
Whole body, surface area	1.94 m^2	US EPA (2011)
Inhalation rate (light activity for workers)	1.25 m^3/h	ECHA (R.8)
Temperature	293 K	GESAMP-BWWG assumption
Dilution factor, ballast tank entry	10	GESAMP-BWWG assumption
Dilution factor, sampling facility	100	GESAMP-BWWG assumption

Dilution factor, work on deck	100	GESAMP-BWWG assumption

Delivery, loading, mixing or adding chemicals to the BWMS

There is potential for exposure to chemicals in concentrated solutions or as solids, either as granules or in powder form, during the delivery, loading, mixing or adding of chemicals to the BWMS. Dilution of concentrated chemicals is often referred to as mixing and loading. On smaller vessels this process may be performed manually. Exposure through inhalation is considered unlikely for non-volatile or water-based chemical formulations. Potential dermal exposure of the hands can be estimated by several available models.

It is recommended to use the UK Predictive Operator Exposure Model (POEM,1992) for this scenario. The model is based on a review of the data available on the exposure of pesticide spray operators (in the UK). The review, on which the model is based on, has indicated that the exposure of the operators depends on several factors. These included the following: the volume of external contamination, the extent to which this external contamination penetrated clothing to reach the skin and the dermal absorption factor. These various independent factors were assumed, with the exception of dermal absorption, to be of a sufficient generic nature to be suitable for extrapolation purposes. Two major work activities were differentiated: mixing/loading and application of products. According to this model, the daily level of exposure during the handling of containers depends on the properties of the container (capacity and diameter of the opening), and the number of containers handled per day.
The tier 1 assessment (equation 1) is based on the handling of containers with an opening diameter of 45 mm and a volume of 10 L. For this case, UK POEM predicts a hand exposure of 0.1 mL fluid per container handled. The number of containers handled depends on the total volume of liquid that needs to be transferred.

Principal equation, Tier 1:

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

Dose = skin exposure (mg/kg bw/d)
f_{RMM} = risk mitigation factor (Tier 1 = 0)
C = concentration of Active Substance (mg/L)
N = number of containers handled, to be determined according to the total volume needed for the specific BWMS (d^{-1})
E = contamination per container handled (Tier 1 = 0.1 mL)
f_{derm} = dermal absorption factor (default = 1)
f_{pen} = penetration factor (default = 1)
BW = body weight (default = 60 kg)

The resulting internal dose from the skin exposure is presented as shown in table 14.

Table 14: Crew, scenario: loading and filling, scenario 1

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

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

Tier 2

Taking personal protective equipment into consideration

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

Principal equation, Tier 2:

$$Dose_{Tier2} = (1 - f_{RMM}) \cdot \frac{C \cdot N \cdot E \cdot f_{derm} \cdot f_{pen}}{BW} \quad \text{(Equation 2)}$$

$Dose_{Tier2}$ = skin exposure (mg/kg bw/d)
f_{RMM} = risk mitigation factor (tier 2 = 0.95)
C = concentration of Active Substance (mg/L)
N = number of containers handled, to be determined according to the total volume needed for the specific BWMS (d^{-1})
E = contamination per container handled (tier 2 = 0.05 mL)
f_{derm} = dermal absorption factor (default = 1)
f_{pen} = penetration factor (default = 1)
BW = body weight (kg)

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

Ballast water sampling

There are occasions when there is a need for taking a sample of the ballast water by Port State Control officers (PSC). This occurs during the checking of compliance with the D-2 standard of the BWC. While taking the sample, there is a potential risk for inhalation of chemicals that have evaporated into the air phase from the sampling facility. The worst concentration of chemicals in the air may theoretically be calculated using the Henry’s law constant in the equation presented below (equation 3). Henry’s law constant (H) is one of the most important factors in determining the environmental fate of chemicals. This physical law states that the mass of gas dissolved by a given volume of solvent is proportional to the pressure of the gas with which it is in equilibrium. The relative constant quantifies the partitioning of chemicals between the aqueous phase and the gas phase such as rivers, lakes and seas with respect to the atmosphere (gas phase). While making use of the concentration in the water phase, the concentration in the air phase is calculated according:

$$C_{air} = \frac{H}{R \cdot T} \cdot C_{water} \quad \text{(Equation 3)}$$

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) (default = 293 K)
C_{water} = measured concentration in ballast water (µg/L)

If the applicant proposes that the sampling facility be placed in the engine room, a dilution factor of 100 (GESAMP-BWWG expert assumption) may be introduced to estimate the concentration in the air surrounding test facilities. This is based on the assumption that any air released from the sampling facilities will be diluted by the surrounding air. Once a concentration of the volatile substance has been estimated while using equation 3, a simple tier 1 exposure assessment (equation 4) can be performed to calculate the inhaled dose resulting from the scenario.

$$Dose_{Tier1} = \frac{C_{air} \cdot ET \cdot IR}{BW} \qquad \text{(Equation 4)}$$

$Dose_{Tier1}$ = inhaled dose (mg/kg bw/d)
C_{air} = concentration of volatile substance in air (mg/m^3)
ET = exposure time (2 h/d)
IR = inhalation rate (default = 1.25 m^3/h)
BW = body weight (kg)

There is also a potential risk for dermal uptake of chemicals from the ballast water while taking samples from the sampling facility. In this scenario it is assumed that both hands are being exposed to the ballast water. The equation used for dermal uptake is the dermal scenario A (ECHA, 2016). In the dermal scenario A, a substance is contained in a mixture. This option is said to be applicable when, for example, hands are dipped into a solution containing the substance under evaluation, or splashes occur. In the tier 1 assessment it is assumed that all the substance contained in a contact layer of 0.01 cm thickness (default value) will be available to form the dermal load on the skin surface. It is to be noted that this tier 1 assumption may not be valid for continuous immersion of body parts. The dermal uptake may be calculated using the equation below while making the worst case assumption that the whole dermal load is being absorbed through the skin:

$$Dose_{Tier1} = \frac{A_{hands} \cdot TH_{dermal} \cdot \mathrm{C}_{\mathrm{water}} \cdot BIO_{derm}}{BW} \qquad \text{(Equation 5)}$$

$Dose_{Tier1}$ = dermal uptake (mg/kg bw/d)
A_{hands} = surface area of two hands (0.084 m^2)
TH_{dermal} = thickness of the chemical layer on the skin (0.0001 m)
C_{water} = concentration of chemical in treated ballast (µg/L)
Bio_{derm} = dermal bioavailability (default = 1)
BW = body weight (kg)

The aggregated uptake, that is the sum of the inhaled dose (equation 4) and the dermal dose (equation 5), is then compared with the DNEL to assess whether the risk from the ballast water sampling scenario is acceptable or not.

Tier 2

Taking exposure time into consideration

If the tier 1 risk assessment indicates an unacceptable risk, a tier 2 exposure assessment can be performed by averaging the short-term daily exposure over an extended period of time, in accordance with a methodology developed by the U.S. EPA (U.S. EPA, 2009). The basic principle behind this methodology is that an adjustment of duration to a continuous exposure scenario is regularly applied as a default procedure to studies with repeated exposures but not to single-exposure inhalation toxicity studies in animals (USEPA, 1994). The first step in the recommended process of estimating an exposure concentration (EC) for use in calculating a risk characterization ratio (note that in the US EPA methodology the term ‘hazard quotient’ is used) involves assessing the duration of the exposure scenario at a site. Risk assessment according to this methodology includes to decide whether the exposure in question is acute, sub-chronic or chronic. In the case at hand the exposure is regarded as chronic since the crew are assumed to be exposed throughout their employment period. The exposure duration for each 'receptor' (person being exposed) is being evaluated, as well as the period over which the exposure is averaged (i.e., the averaging time (AT)) to arrive at a time-weighted exposure concentration (EC).

$$EC = \frac{C_{air} \cdot ET \cdot EF \cdot ED}{AT} \qquad \text{(Equation 6)}$$

EC = exposure concentration (mg/m^3)
C_{air} = concentration of volatile component in air (mg/m^3)
ET = exposure time (h/d)
EF = exposure frequency (d/y)
ED = exposure duration (y)
AT = averaging time (7,300 d (= exposure duration) for non-carcinogenic effects;
25,550 d (= life expectancy) for carcinogenic effects)

The GESAMP-BWWG has further modified the 'averaging time approach' for calculation of the inhaled dose, while making an assumption that the whole fraction being inhaled is bioavailable, that is being absorbed through the lungs, as well as regarding the duration of the exposure (ED). For this purpose an employment duration of 20 years is assumed (GESAMP-BWWG expert assumption). The exposure time (ET) and exposure frequency (EF) for the scenario (2 h/d and 225 d/y) has been described in table 12.

$$Dose_{Tier2} = (1 - f_{RMM}) \frac{C_{air} \cdot IR \cdot ET \cdot EF \cdot ED}{BW \cdot AT} \qquad \text{(Equation 7)}$$

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

The dermal exposure resulting from this scenario (equation 5) is modified in an analogous manner. For further refinement, the effect of risk mitigation measures may be taken into account using a system-specific risk mitigation factor, that is, risk mitigation provided by the use of respiratory protection and/or gloves.

Periodic cleaning of ballast water tanks

In this scenario, which is regarded to be the scenario involving the highest degree of exposure, a worker is cleaning the emptied ballast tank, where he may be exposed to volatile components arising from the treated ballast water that have remained in the tank atmosphere after discharge of the treated ballast water, as well as to the sediment and sludge remaining in the tank. The concentration of chemicals in the air phase may be calculated in the same manner as described above (equation 3). A dilution factor of 10 (GESAMP-BWWG expert assumption) is introduced based on the assumption that the ballast tank was previously filled to 90 percent capacity, and so the air from the headspace will be diluted as the ballast water is discharged and fresh air is drawn in.

Once a concentration of a volatile substance has been estimated (equation 3), the tier 1 exposure assessment can be performed as described above (equation 4), using an exposure time of 8 h/d (see table 12). The dermal uptake of chemicals from the sediment and sludge in the ballast tank, which will involve manual handling, may be calculated in the same manner as in the previous scenario (equation 5) while taking into account possible exposure to the whole body, that is, 1.94 m^2. For further risk assessment, the aggregated uptake from inhalation and dermal exposure is calculated.

Tier 2

If necessary, a tier 2 exposure assessment can be performed as described in equation 7, using an ET of 8 h/d and an EF of 5 d/y (see table 12). The dermal exposure is modified in an analogous manner. For this scenario effects of risk mitigation measures may be taken into account as described in the following. The data underlying the UK POEM model suggest that for higher levels of challenge, it is reasonable to assume that impermeable protective coveralls provide 90% protection against aqueous challenge. Protective gloves, for this type of work, are considered to always have the potential to get wet inside and the high-end default value is used as a measure of hand exposure even for the tier 2 assessment (exposure occurs owing to water entering via the cuff). For boots, a lower default value may be selected to represent the worker wearing appropriate impermeable boots.

Ballast tank inspections

In this scenario a crew member or a Port State Control inspector enters the emptied ballast tank and may be exposed to volatile components arising from treatment of the ballast water. The concentration of chemicals in the air phase may be calculated in the same manner as described above (equation 3), using a dilution factor of 10 (GESAMP-BWWG expert assumption) to account for the dilution by fresh air drawn into the emptied ballast tank. Once a concentration of a volatile component has been estimated (equation 3), the tier 1 exposure assessment can be performed as described in equation 4. Exposure time in this scenario is 3 h/d (see table 12). No dermal exposure is assumed for this scenario, and the calculated inhaled dose can be directly used for further risk assessment.

Tier 2

If necessary, a tier 2 exposure assessment can be performed as described in equation 6, using an ET of 3 h/d and an EF of 12 d/y (see table 12). For further refinement, the effect of system-specific risk mitigation measures (respiratory protection) may be taken into account.

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

Exposure in this scenario is through inhalation of air released from the air vents on deck. The concentration of chemicals in the atmosphere surrounding the air vents may be calculated as detailed above (equation 3), taking into account a dilution factor of 100 (GESAMP-BWWG expert assumption) for the dilution by the surrounding atmosphere. Once a concentration of a volatile component has been estimated, the tier 1 exposure assessment can be performed (equation 4). Exposure time in this scenario is 1 h/d (see table 12). No dermal exposure is assumed for this scenario, and the calculated inhaled dose can be directly used for further risk assessment. If necessary, a tier 2 exposure assessment can be performed as described in equation 6, using an ET of 1 h/d and an EF of 180 d/y (see table 12). For further refinement, the effect of system-specific risk mitigation measures may be taken into account.

The aggregated internal dose resulting from exposure according to scenarios 2 to 5 in table 15 (Ballast water sampling/Periodic cleaning of ballast tanks/Ballast tank inspections/Normal work on deck) above may be presented as in the table shown below.

Table 15 Crew/port State control, scenarios 2 to 5, Tier 1 DNEL approach

Chemical	Scenario (mg/kg bw/d)			RCR

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

Tier 2

Taking into account that the DNEL is calculated for chronic exposure, while exposure through these occupational scenarios are assumed to occur only over a limited period of time, Tier 2 calculations may be performed using correction factors which are calculated from the exposure frequencies for the various scenarios multiplied by the exposure duration (20 years) and divided by the averaging time (exposure duration) for non-carcinogenic effects (7,300 days). This approach is described in the section about ballast water sampling above (*Tier 2, Taking time into consideration*). See Table 16.

Table 16: Crew/Port State control, scenarios 2–5, Tier 2 DNEL approach

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

DMEL approach

Indicative risk levels available from internationally recognized bodies may be used to calculate the indicative RCR regarding potential cancer risk in the DMEL approach. Furthermore, the group RCR approach may be applied to the calculation. The group RCR approach is to be applied for substances with a DMEL value, and is described in the section on risk characterization. See also Table 17.

Table 17: Crew/Port State control, scenarios 2-5: – Tier 1 DMEL approach

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

Taking into account that the DMEL is calculated for daily exposure over a lifetime (70 years), while exposure through these occupational scenarios are assumed to occur only over a limited period of time, Tier 2 calculations may be performed using correction factors which are calculated from the exposure frequencies for the various scenarios multiplied by the exposure duration (20 years) and divided by the life expectancy (25,550 days). See Table 18.

Table 18: Crew/Port State control, scenarios 2-5: – Tier 2 DMEL approach

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

C						
Sum						

2.2.3 Situations in which the general public might be exposed to treated ballast water containing chemical by-products

Indirect exposure of humans via the environment where treated ballast water is discharged may occur by consumption of seafood and swimming in the harbour or the surrounding area. As a general principle, consumer exposure is normally assessed as being chronic and thus taking place throughout the whole lifetime in order to protect the most vulnerable population groups.

The following situations have been identified as likely exposure scenarios for the general public, and have been regarded as worst case exposures as shown in Table 19.

Table 19: Summary of exposure scenarios for the general public

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

A number of assumptions are being used in the human exposure scenarios for general public. The assumptions being used are all listed in table 4. In all scenarios, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of males is assumed, but the body weight of women (60 kg) is applied. The surface area of the exposed skin for hands (fronts and backs) for males is 0.084 m^2 and the whole body surface area for men is 1.94 m^2 (ECHA, 2016). One parameter, ingestion rate of water while swimming, is taken from the Swimodel (EPA, 2003).

Table 20. Summary of physiological parameters in human exposure scenarios for general public

Parameter	**Value**	**Reference**
Body weight	60 kg	ECHA (R.15)
Whole body, surface area	1.94 m^2	US EPA (1997)
Inhalation rate (light activity)	1.25 m^3/h	ECHA (R.8)
Ingestion rate of water while swimming	0.025 L/h	EPA (Swimodel, 2003)
Quantity of fish consumed	0.188 kg/d	FAO, 2009
Temperature	293 K	GESAMP-BWWG assumption
Dilution factor, swimming	100	EUSES

Recreational activities (swimming) in the sea

Inhalation of chemicals partitioning into the air above the sea

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 equation 3. However in this case the concentration in the water is the predicted environmental concentration (PEC) harbour value as calculated by MAMPEC, and taking into account a dilution factor of 100 (due to wind, turbulence and insufficient time for the chemical to reach equilibrium) (EUSES). The inhaled dose may be estimated using the equation below, while taking into account various assumptions (number of swims, etc.):

$$Dose_{Inh} = \frac{C_{air} \cdot IR \cdot n \cdot D \cdot Bio_{inh}}{BW} \qquad \text{(Equation 8)}$$

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

Dermal exposure to chemicals while swimming in the sea

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

$$Dose_{Der} = \frac{C_{water} \cdot TH_{dermal} \cdot n \cdot A_{skin} \cdot Bio_{dermal}}{BW} \qquad \text{(Equation 9)}$$

$Dose_{Der}$ = dermal uptake per day during swimming (mg/kg bw/d)
C_{water} = concentration in the water, i.e. PEC_{MAMPEC} (µg/L)
TH_{dermal} = thickness of the product layer on the skin (0.0001 m)
n = number of swims per day (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)

Swallowing of water contaminated with treated ballast water

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

$$Dose_{Oral} = \frac{C_{water} \cdot IR_{swim} \cdot n \cdot Dur_{swim} \cdot Bio_{oral}}{BW} \qquad \text{(Equation 10)}$$

$Dose_{Oral}$ = amount of chemical swallowed (µg/kg bw/d)
C_{water} = concentration in the water, i.e. PEC_{MAMPEC} (µg/L)
IR_{swim} = ingestion rate of water while swimming (0.025 L/h)
n = number of swims per day (5/d)
Dur_{swim} = duration of each swim (0.5 h)
Bio_{oral} = bioavailability for oral intake (default = 1)
BW = body weight (kg)

Eating seafood exposed to treated ballast water

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

$$C_{fish} = BCF \cdot C_{water} \qquad \text{(Equation 10)}$$

C_{fish} = concentration in fish (µg/kg)
BCF = bioconcentration factor (L/kg)

C_{water} = concentration in the water, i.e. PEC_{MAMPEC} (µg/L)

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

$$Dose_{fish} = \frac{QFC \cdot C_{fish} \cdot Bio_{oral}}{BW} \qquad \text{(Equation 11)}$$

$Dose_{fish}$ = uptake of chemical from eating fish (µg/kg bw/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 (kg)

Aggregated exposure (through swimming and consumption of seafood)

The total exposure to the general public whilst swimming in the sea and eating fish is the sum of the amount of chemical absorbed through eating fish plus the oral intake, dermal absorption and inhalation absorption whilst swimming may be summarized as in table 21.

Table 21: General public scenario: swimming and consumption of seafood

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

An indicative risk level may be used to calculate an indicative RCR regarding potential cancer risk. These values can be used to estimate a risk dose based on the probability of increased cancer incidence over a lifetime (10^{-6}) and may be regarded as a DMEL for the general public. See Table 22.

Table 22: General public scenario: swimming and consumption of seafood – Tier 1 DMEL approach

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

Tier 2

If an elevated risk to the general public is identified in Tier 1, a Tier 2 calculation may be performed by taking into consideration the assumption that the general public activities take place in areas more remote to the actual harbour. For these calculations the standard output from MAMPEC regarding the concentrations in the surrounding water may be used. See Table 23.

Table 23: General public scenario: swimming and consumption of seafood – Tier 2 DMEL approach

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

Concluding remarks

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. In addition, the consumer exposure (general public) is normally assessed as chronic/lifetime risk in order to protect the most vulnerable population groups.

CALCULATION OF DERIVED NO-EFFECT LEVELS (DNELS)

Derived no effect level (DNEL)

A derived no effect level is the level above which humans should not be exposed. The derivation of DNELs involves the following steps:

- *Hazard identification*
- *Hazard characterization*
  - *Definition of dose descriptor*
  - *Definition of assessment factors*

Hazard identification

The term *hazard* refers to an intrinsic, or inherent, property of a chemical that is able to cause adverse effects to health or environment as a result of exposure. The inherent property may be of a chemical or a physical nature. A substance may for instance have an adverse effect on the uptake of enough oxygen for the body to function properly. On the other hand, if the substance has the shape of a small particle, it may be transported through breathing to the lower parts of the lungs and block the oxygen uptake. In toxicology, which is the science dealing with the safety of chemicals, different chemicals can be divided into different categories depending on their effect (refer to table 1).

Table 24. Summary of toxicological endpoints

Toxicological endpoint	Description
Acute toxicity	Systemic effect (the effect occurs in the body after the chemicals is taken up)
Corrosion/irritation	Local effect (the effect occurs where exposure happens)
Sensitization	Effect that involves the immune system (allergy)
Repeated dose toxicity	Systemic effect that occurs in the body in one or several target organs after repeated exposure
Development and reproductive toxicity	Effect on the growing fetus and/or the parents ability to have children
Carcinogenicity	Chemical that causes cancer in an individual
Mutagenicity	Chemical that causes mutation in cells (somatic cells or germ cells) which may lead to cancer and/or reproductive toxicity

Information about chemicals that has to be submitted with any application for BA and/or FA

With any application for either BA or FA evaluation the applicant have to submit toxicological information about the chemicals associated with or generated by the BWMS for all endpoints mentioned in table 1. However, for the forty one chemicals most commonly associated with treated ballast water indicated in appendix 6 of the Methodology, no additional properties on toxicology have to be submitted, as these substances have been already assessed by the GESAMP BWWG. Data for these substances can be found in the online GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water (https://gisis.imo.org/).

The early days

The DNEL approach, as described below, was developed at the third stocktaking workshop in April 2011, and was subsequently implemented into the Methodology in its first revised version (April 2012). Before the DNEL model came into use GESAMP-BWWG made use of the margin of safety (MOS) approach (MEPC 56/2/2, Annex 9). The safety factor that was used at that time was a MOSref of 100. The GESAMP-BWWG also made use of the guidance values for drinking water from the WHO Guidelines for Drinking water quality (WHO, 2003) (see for example MEPC 56/2/2).

Hazard characterization

Dose descriptor

If the dose descriptor is a NOAEC or LOAEC from an inhalation study, expressed e.g. as mg/m^3, the internal exposure, expressed as mg/kg bw/d, can be calculated using the standard respiratory volume (sRV) of the test species in question (table 25):

$$NOAEL = \frac{NOAEC}{sRV_{animal}} \quad \text{(Equation 14)}$$

NOAEL = No observed adverse effect level (mg/kg bw/d)
NOAEC = No observed adverse effect concentration (mg/m^3)
sRV_{animal} = Standard respiratory volume (m^3/kg bw/d)

Table 25. Standard respiratory volumes (modified from ECHA, 2008)

Species	**Standard respiratory volume (m^3/kg bw/d)**
Rat	1.15
Mouse	1.03

How to derive a DNEL?

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

$$DNEL = \frac{Dose_{descr}}{AF} \qquad \text{(Equation 12)}$$

DNEL = Derived no effect level (mg/kg bw/d)
$Dose_{desc}$ = Dose descriptor (NOAEL/NOAEC or LOAEL/LOAEC (mg/kg bw/d or mg/m^3))
AF = Assessment factors

The overall assessment factor (AF) consists of a number of individual assessment factors that are further described in the equation below:

$$DNEL = \frac{Dose_{descr} \cdot CF_{dr}}{ASF \cdot OSF \cdot ISF \cdot ESF \cdot SF_{dur} \cdot CF_{abs}} \quad \text{(Equation 13)}$$

$Dose_{desc}$ = Dose descriptor (NOAEL/NOAEC or LOAEL/LOAEC (mg/kg bw/d or mg/m^3))
CF_{dr} = experimental dosing regime
ASF = interspecies allometric factor
OSF = other interspecies scaling factor
ISF = intraspecies scaling factor
ESF = observed effect scaling factors
SF_{dur} = duration scaling factors
CF_{abs} = differential absorption factors

Assessment factors (AF)

The assessment factors (refer to table 26) are introduced for taking into account interspecies and intraspecies variability, data quality and other uncertainties.

Table 26. Default assessment factors (modified from ECHA, 2008)

Assessment factor accounting for differences in		**Default value systemic effect**
Interspecies (ASF)	Correction for differences in metabolic rate per body weight	$AS^{1,2}$
(OSF)	Remaining differences	2.5
Intraspecies (ISF)	Worker	5
	General public	10^3
Exposure duration (SF_{dur})	Subacute to subchronic	3
	Subchronic to chronic	2
	Subacute to chronic	6

[1] AS = factor for allometric scaling
[2] Caution should be taken when the starting point is an inhalation or a diet study
[3] Not always covering for young children

Experimental dosing regimen (CF_{dr})

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

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

Interspecies Allometric Scaling Factor (ASF)

Allometric scaling extrapolates doses according to an overall assumption that equitoxic doses (when expressed in mg/kg bw/day) scale with body weight to the power of 0.75. This results in different default allometric scaling factors for the different animal species when compared with humans. The following allometric scaling factors (ASF) are recommended for use in determining DNELs (table 27).

Table 27. Allometric scaling factors for different species as compared to humans[1]
(modified from ECHA, 2008)

Species	**Body weight (kg)**	**AS factor[2]**
Rat	0.250	4
Mouse	0.03	7
Rabbit	2.00	2.4
Dog	18.00	1.4

[1] Assuming the human body weight is 70 kg

[2] Not applicable when setting an inhalation DNEL based on an inhalation animal study

Other Interspecies Scaling Factor (OSF)

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

Intraspecies scaling factor (ISF)

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

Observed effect scaling factors (ESF)

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

Exposure duration scaling factors (SF_{dur})

In order to end up with the most conservative DNEL for repeated dose toxicity, chronic exposure is the 'worst case'. Thus, if an adequate chronic toxicity study is available, this is the preferred starting point and no assessment factor for duration extrapolation is needed. If only a sub-acute or sub-chronic toxicity study is available, the following default assessment factors are to be applied, as a standard procedure according to Table 28.

Table 28. – Scaling factors relating to exposure duration

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

"Sub-acute" usually refers to a 28 day study
"Sub-chronic" usually refers to a 90 day study
"Chronic" usually refers to a 1.5-2 year study (for rodents)

Differential Absorption Factors (CF_{abs})

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

DNELs for the worker population (crew/PSC)

For the exposure at the workplace, in this case on board ship, the following DNELs may be calculated:

.1 DNEL, short-term exposure (mg/kg bw): the dose descriptor might be an LD_{50} from an oral or dermal study or an LC_{50} from an inhalation study.

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

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

DNELs for the general public

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

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

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

Derived Minimal Effect Level (DMEL)

Carcinogens can have a threshold or non-threshold mode of action. When it comes to threshold carcinogens, these can be assessed by using a DNEL approach, however in the case of the non-threshold carcinogens a different approach to risk assessment is recommended. In these cases, a Derived Minimal Effect Level (DMEL) should be determined.

[According to the WHO (2000) there is indication that brominated DBPs may be more carcinogenic than their chlorinated analogs.]
[And, in addition, iodinated compounds may be more toxic than their brominated analogs (Plewa et al., 2004)]

CMR properties for selected Relevant Chemicals

Based on appropriate toxicological studies on carcinogenicity, mutagenicity and reproductive toxicity (Procedure (G9), paragraph 5.3.12), each chemical should be scored on these three items, using ‘yes’ if the substance showed the hazard under consideration and ‘no’ if the substance did not show the hazard under consideration as shown below. If the screening results give rise to concerns, this should give rise to a further assessment.

Table 29: CMR properties for selected Chemicals

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

The Linearized approach and the Large Assessment Factor approach

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. As a general rule, exposure in the workplace must be avoided or minimized as far as technically feasible. In addition, a risk for the general public from secondary exposure to a non-threshold carcinogenic substance is also unacceptable. However, calculation of an exposure level corresponding to a defined low risk is possible based on a semi-quantitative approach, i.e. a derived minimal effect level (DMEL). In contrast to a DNEL, a DMEL does not represent a safe level of exposure. It is a risk-related reference value that should be used to better target risk management measures. 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. Cancer risk levels between 10^{-4} and 10^{-6} are normally seen as indicative tolerable risk levels when setting DMELs (WHO 2001, ECHA 2016). Where these values are available from internationally recognized bodies, they can be used to set DMELs for risk assessment purposes.

RISK CHARACTERIZATION

General approach

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

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

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

If the RCR < 1, the exposure is deemed to be safe. However, risks are regarded not to be controlled when the estimated exposure levels exceed the DNEL and/or the DMEL, that is, if the RCR ≥ 1.

Occupational health risks

While considering ballast water sampling and tank cleaning operations, it should be assumed that the exposure routes of concern for Port State control officers and the crew will be inhalation and dermal exposure. The assumption being that the exposure will include inhalation to the highest concentration of each chemical in the atmosphere above the treated ballast water at equilibrium and the dermal uptake to the highest concentration of each chemical in the treated ballast water. In the other two scenarios, ballast tank inspection and normal work on deck, only inhalation is taken into consideration.

Health risks for the general public

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

Mixture toxicity (dose addition approach)

Treated ballast water frequently contains mixtures of several potentially carcinogenic disinfection by-products. One possible way to deal with this situation is to adopt an established international risk assessment approach (known as 'grouping' or 'dose addition' (Kortenkamp, 2009)), which entails a summation of the Risk Characterization Ratios (RCRs) of all substances with recognized carcinogenic potential. Thus, if the treated ballast water contains two or more chemicals with the same toxicological effect, these could be evaluated as an 'assessment group'. The RCR for an assessment group is calculated by addition of all RCRs of the individual components:

$$RCR_{group} = RCR_A + RCR_B + RCR_C + RCR_n$$

For the group RCR the same conclusions apply as described above, that is if the RCR < 1, the exposure is deemed to be safe. GESAMP-BWWG has discussed the possibility to apply the dose addition approach to substances classified as mutagens and reproductive toxicants. However, no firm decision has been reached up to date. If an unacceptable level of risk is identified for any of the scenarios in the first tier, the second tier is applied. If still an unacceptable risk is identified further refinement of the exposure assessment and/or the assessment factors might be performed giving special attention to route-specific contributions and additional RMM.

RISKS TO SHIP SAFETY

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

.1 increased corrosion;

.2 fire and explosion; and

.3 storage and handling of the substances.~~;~~

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

Increased corrosion

The introduction of Active Substances into ship operating equipment and ballast tanks may give rise to detrimental corrosion effects. In paragraphs 7.1.2.2 to 7.1.2.7 the criteria are stated for instigating a prescribed corrosion assessment along with the standard test procedure to be adopted and the resultant minimum acceptable values. The BWMS that make use of an Active Substance (such as hypochlorite electrolysis, chlorine dioxide, sodium hypochlorite, peroxyacetic acid or ozone) may have a direct effect on organic material like epoxy tank coatings. Depending on the dose and degradation rate of Active Substance there could be an impact on the coating system. For a BWMS with a TRO dose ≥ 10 mg/L, expressed as Cl_2 mg/L, the compatibility with coating systems is to be validated by the testing described in paragraphs 7.1.3.3 and 7.1.3.4. Testing should be conducted in accordance with the NACE TM0112-2012 Standard Test Method with two series of test panels and the coating should be applied in accordance with Table 1 of the *Performance standard for protective coatings for dedicated seawater ballast tanks in all types of ships and double-side skin spaces of bulk carriers* (PSPC) (resolution MSC.215(82)). One set of panels should be exposed to treated ballast water. Other test conditions are described in table 30.

Table 30: Test conditions corrosion

Parameters	Quantification	Reference~~[1]~~/Remark

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

Testing of corrosion should take place in the laboratory, but it is recommended to make use of the full-scale BWMS which is to be used for efficacy testing in accordance with the 2016 Guidelines (G8), for the preparation of treated ballast water for this purpose. However, if it is impractical to maintain the renewal frequency described in the table, ballast water may be prepared by a separate treatment using an identical BWMS. After the exposure duration, several corrosion relevant measurements as listed above should be scored against the PSPC criteria and reported.

Acceptance criteria

In order to determine whether the BWMS has influenced the coating's properties as evaluated according to ISO standards, the principles and acceptance criteria mentioned above should be employed. Paint coatings evaluation should be carried out on treated ballast water. Paint coatings for BWMS compliance testing will already be required to have PSPC approval and this additional evaluation is to employ the NACE TM0112-2012 Standard Test Method to assess any potential detrimental effects on a coating system resulting from the use of a particular BWMS. For the BWMS to be found suitable for Final Approval, it should not fail in any test evaluation of epoxy based coating systems as specified below:

.1 ISO 4624: Adhesion: "Fail" if the adhesive or cohesive values at the treated panel are below those required in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1;

.2 ISO 4628-2: Blistering: "Fail" if any blisters occur;

.3 ISO 4628-3: Rusting: "Fail" if any rusting occurs;

.4 ISO 4628-4: Cracking: "Fail" if any cracking occurs;

.5 ISO 4628-8: Delamination and corrosion around a scribe: "Fail" if the delamination at the treated panel is greater than that specified in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1; and

.6 ISO 15711: Cathodic protection - disbondment from artificial holiday (NACE TM0112-2012 Method B – Sacrificial Anode): "Fail" if the values at the treated panel are greater than those required in the table in resolution MSC.215(82), annex 1, appendix 1, paragraph 3.1.

Fire and explosion

Where ship safety may be affected by potential fire or explosion arising from the use of a BWMS, the outline procedures to prevent such occurrence and consequent mitigating emergency actions to be taken should be included in the dossier as expressed in paragraphs 4.1.3.3 and 4.1.3.4 of this Methodology.

Storage and handling
Where a BWMS has operational features requiring the loading, storage and handling of ancillary substances, the potential hazards arising from the improper handling or storage on board a ship of such substances should be addressed as required in section 4.1.3.2 of this Methodology. The hazards associated with the possible creation of atmospheric dusts should also be included.

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Annex I – Membership of the working group

Annex II – List of reports and studies