

**GESAMP**

Joint Group of Experts on the
Scientific Aspects of Marine
Environmental Protection

METHODOLOGY FOR THE EVALUATION OF BALLAST WATER MANAGEMENT SYSTEMS USING ACTIVE SUBSTANCES

GESAMP WORKING GROUP 34



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GESAMP WORKING GROUP 34

Published by the
INTERNATIONAL MARITIME ORGANIZATION
4 Albert Embankment, London SE1 7SR
www.imo.org

Printed by CPI Colour

ISSN: 1020-4873

Cover photo: Ship discharging ballast water in port

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ISSN 1020-4873 (GESAMP Reports & Studies Series)

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For bibliographic purposes this document should be cited as:

GESAMP (IMO/FAO/UNESCO-IOC/UNIDO/WMO/IAEA/UN/UN Environment/UNDP/ISA Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection), 2019. Methodology for the evaluation of ballast water management systems using Active Substances. Rep. Stud. GESAMP No. 101, 110 p.

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ACKNOWLEDGEMENTS

The report was subject to rigorous peer review prior to publication, including the established internal review process by Members of GESAMP.

The review process greatly improved the content and presentation of the final report. However, any factual errors or misrepresentation of information remain the responsibility of the principal editors.

The following experts (in alphabetical order) in their fields have over the years participated in the Stocktaking Workshops and have assisted the GESAMP-BWWG to elaborate on the Methodology on which this report is based:

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EXECUTIVE SUMMARY

Over 90% of the world's global trade is carried by sea, with trading patterns being more intense between the more populous and developed nations. Over the years, ships have become larger and faster, with greater ballast capacities. Modern ports with more efficient cargo handling methods have developed and expanded. This has resulted in shorter vessel turn-around times and consequently, the potential for more shipping movements at each port. Developing world markets have also created shipping routes into areas previously not used to high volumes of shipping.

Ships are unintentionally acting as vectors for invasive aquatic species (IAS). An IAS is a non-indigenous aquatic organism that has been transported from its normal environment and has been introduced outside its normal distribution into a recipient ecosystem where it may become abundant. Ballast water is a significant pathway for the transfer of IAS. In marine and coastal environments, IAS represent one of the four greatest threats to the world's oceans along with:

- Marine pollution
- Over-exploitation of living marine resources
- Physical alteration or destruction of marine habitats.

IAS can have serious effects on:

- The local ecology through habitat reduction and loss of native species
- Human health, by spreading of harmful toxic blooms
- Economic effects: Corrosion and weakening of coastal structures, fouling of water inlets to water extraction facilities and a general overall reduction in local economy net worth resulting from the closure of marine related businesses.

Following requests to take action, IMO in 1997 adopted resolution A.868(20), *Guidelines for the control and management of ships' ballast water to minimize the transfer of harmful aquatic organisms and pathogens*. In 2004, IMO adopted the *International Convention for the Control and Management of Ships' Ballast Water and Sediments* (Ballast Water Management (BWM) Convention). IMO subsequently requested GESAMP to assist in implementing the BWM 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 or WG 34 of GESAMP) is to review proposals submitted for approval of ballast water management systems that make use of Active Substances. The underlying principle of the work of the GESAMP-BWWG is that treatment should not have any risks to the environment,

human health, property, and/or resources.

Over the years, the GESAMP-BWWG has evaluated a wide variety of ballast water management systems using chemical, physico-chemical and physical technologies. The most common technique is *in situ* electrolysis, where seawater is used to produce chlorine and its oxidizing derivatives, termed total residual oxidants (TRO). These processes are combined with filtration or other means of separation and are normally followed by a neutralization step before discharge. Other treatment methods include ozonation, belonging to TRO producing methods, adding biocides or removal of organisms through flocculation.

At the time of publication, more than 60 BWMS that make use of Active Substances and/or Preparations have received Basic Approval from IMO. In parallel to the work consisting of evaluating BWMS, the GESAMP-BWWG has developed its Methodology, which is based on the IMO document *Procedure for approval of ballast water management systems that make use of Active Substances* (G9). Procedure (G9) describes in detail how the GESAMP-BWWG should evaluate ballast water management systems. The risk assessment approach is described in this report.

The BWM Convention entered into force on 8 September 2017, requiring shipowners to comply with either the D-1 (ballast water exchange) or D-2 (ballast water discharge) standards until such time as it is required that they comply only with the D-2 standard, as set out in regulation B-3 of the Convention. New build ships must comply with the D-2 standard if constructed (keel-laid) on or after 8 September 2017. For existing ships, shipowners are required to comply with the D-2 standard at the time of the first or second International Oil Pollution Prevention (IOPP) renewal survey. All ships will need to comply with the D-2 standard by 8 September 2024. In practice, the vast majority of ships choose to comply with the D-2 standard by installing a BWMS.

The main intention of this report is to present the way of evaluation of BWMS as it has evolved during the last ten years. This methodology is based on internationally accepted methods of risk assessment as they are practised in several countries and regions worldwide. Methods and assumptions come from the World Health Organization (WHO), the Organization for Economic Co-operation and Development (OECD), the European Union, mainly the European Chemicals Agency (ECHA) for the evaluation of chemicals and biocides, the US Environmental Protection Agency (EPA), and are used in decision support systems in these organizations. The GESAMP-BWWG is accountable for its interpretation of these methods. Another aim of this publication is to present this risk assessment approach to the scientific community in order to evoke criticism and therefore improve the methodology. The evaluation of BWMS deserves a scientifically justifiable way to approve systems, thereby fulfilling the aim of protecting the environment, human health, property and resources.

1 INTRODUCTION

1.1 The Ballast Water Working Group

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 aquatic species (IAS) globally with increasing negative impacts. These species often do not have natural enemies in the area that they invade. The problem increased with the introduction of steel hulls in the 1830s, allowing ships to use water instead of solid materials as ballast.

According to a statement of Mr. Dandu Pughuic (Figure 1), former Senior Deputy Director of the International Maritime Organization (IMO), and former Chief Technical Adviser, the issue of invasive aquatic species was raised at IMO by Australia and Canada in particular with scientific evidence of invasion of new species in their water in the 1980s.

In Australian waters alone some 62 exotic species were recorded in the 1980s with no Australian state or territory untouched. The proliferation of zebra mussels (*Dreissena polymorpha*) in Canada's Great Lakes is often seen as the wakeup call when it comes to the problem with invasive aquatic species. The zebra mussel is a species native to the Black, Caspian and Azov Seas that had a dramatic impact on Great Lakes fisheries and caused havoc to water utilities with huge financial consequence. Following requests to take action, IMO, in 1997, adopted resolution A.868(20), *Guidelines for the control and management of ships' ballast water to minimize the transfer of harmful aquatic organisms and pathogens*. In 2004, IMO adopted the *International Convention for the Control and Management of Ships' Ballast Water and Sediments* (Ballast Water Management (BWM) Convention).



Figure 1 Dandu Pughuic (photo H. Lofthouse)

IMO requested GESAMP to assist in implementing the Ballast Water Management Convention by assessing the risks of ballast water management systems (BWMS) to the marine environment, 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 ship construction and engineering.



Figure 2 The GESAMP-BWWG during its meeting at IMO (2017)

The role of this technical group (GESAMP-BWWG, i.e. WG 34 of GESAMP, Figure 2) is to review proposals submitted for approval of ballast water management systems that make use of Active Substances.

1.1.1 Terms of Reference for the GESAMP-BWWG

The experts working for the 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 I to this document, including the membership and the consultants. 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, national Administrations (governments) submit applications regarding a given BWMS to the Marine Environment Protection Committee (MEPC) at IMO. The submission contains a non-confidential summary and a confidential dossier. The non-confidential part is available for all Administrations attending MEPC, while the confidential part, which may contain confidential business information (CBI), is only submitted to the IMO Secretariat and made available for the experts in the GESAMP-BWWG. These submissions, once accepted for evaluation, are processed by IMO on a first-come, first-served, fee-paying basis and sent to the GESAMP-BWWG for assessment. The submissions are first checked for completeness and their content summarized in a standard format by the IMO consultant and then evaluated by the GESAMP-BWWG for Basic Approval according to the IMO's *Procedure for approval of ballast water management systems that make use of Active Substances* (G9) and following the GESAMP-BWWG Methodology, the IMO technical circular BWM.2/Circ.13 and its revisions. As part of Basic Approval, the GESAMP-BWWG makes a series of recommendations which the manufacturer is advised to address prior to re-submitting for Final Approval which is then handled in a similar manner.

The GESAMP-BWWG, through MEPC, may make additional recommendations to the Administration in question with a bearing on 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 the 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 may be initiated.

1.2 The Marine Environment

Approximately 70% of the earth's surface is covered by oceans, and more than 80% of the ocean's surface overlies water depths greater than 200 m, making open-ocean, deep-sea environments the largest of all marine environments (example in Figure 3) (Free dictionary, 2019).



Figure 3 *The marine environment (photo L. Dock)*

Different marine environments are identified by their physical-geological setting including estuaries, coastal marine and nearshore zones, and open-ocean, deep-sea regions. (Marine ecology, 2018a).



Figure 4 *Coral reef (File: The Coral Reef at the Andaman Islands.jpg, Wikipedia Commons)*

An ecosystem is a system that includes biotic factors (living organisms) and abiotic factors (physical factors) functioning together as a unit. Different marine ecosystems include mangrove forests, coastal salt marshes, submersed seagrasses and seaweeds, and tropical coral reefs (Figure 4).

One form of interaction in the ecosystem is the food chain, where energy and matter move through organisms and the environment. A fish with parasites represents an ecosystem on a microscale. A coral reef in which the fish live could be regarded as a meso-ecosystem and considered to represent the larger scale (macro) (Marine Ecology, 2018b).

1.2.1 Trophic Levels

The organisms present in the ecosystem may be divided into different trophic levels, where the different levels indicate the organism's place in the food chain. The lowest level in the food chain, or pyramid, represents the producers, whereas the higher levels represent the consumers (Figure 5).

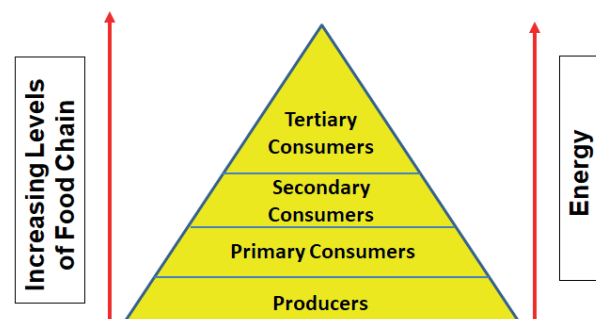


Figure 5 *The trophic levels*

In general, each trophic level relates to the one below it by absorbing some of the energy it consumes, and thereby rests on the next lower trophic level. The food chain in the form of a pyramid illustrates the amount of energy moving from one trophic level to the next.

1.2.2 Biodiversity

The European Commission defined biodiversity as follows: Biological diversity, or biodiversity, describes the variety of life on earth, and this diversity operates at various scales, from genes, species to entire ecosystems. Biodiversity, therefore, refers to all life-forms and their behaviours, the environments or habitats in which they live, and the complex system of relationships between organisms, such as food webs and competition for resources. A rich ecosystem has many available habitat niches, and many different organisms, which fill those niches. Such a system containing a wide variety of life-forms generally is more resilient to environmental change than one with either a more restricted range of species or where the species present have a narrower range of lifestyles. As conditions change, some organisms are less able to survive and reproduce, but others readily take their place. Similarly, species which have a high genetic variability within populations are more resistant to environmental stress than those with a more restricted range of genetic combinations (European Commission, 2019a)

Although the ocean covers approximately 70% of the earth's surface, and occupies a much larger volume than the terrestrial environment, the biomass on land, at ≈ 470 Gt C (gigatons of carbon), is about two orders of magnitude higher than the ≈ 6 Gt C of marine biomass (Bar-On *et al.*, 2018). Even though there is a large difference in the biomass content of the terrestrial and marine environments, the primary productivity of the two environments is roughly equal (Field, *et al.*, 1998). For plants, it can be shown that most biomass is concentrated in terrestrial environments (plants have only a small fraction of marine biomass, <1 Gt C, in the form of green algae and seagrass). For animals, most biomass is concentrated in the marine environ-

ment, and for bacteria and archaea, most biomass is concentrated in deep subsurface environments. It should, however, be noted that these estimates should be interpreted with caution due to the large uncertainty associated with some of the estimates, mostly those of total terrestrial protists, marine fungi, and contributions from deep subsurface environments.

One of the most important functions of marine ecosystems is the production of photosynthetic biomass from sunlight and nutrients (primary productivity), which represents the basic food source for most life in the sea, and ultimately for humans as well. Approximately half of the worldwide primary productivity is achieved by microscopic phytoplankton, which reproduces and grows in the sea. Another function performed by

ecosystems is the creation of habitats, or structures, in coastal ecosystems. For example, macro-algae, seagrass and corals form large undersea forests, meadows or reefs that provide habitats for many other species such as molluscs, crustaceans and fish. Kelp forests and seagrass meadows in the Baltic Sea are vital habitats for the fry and juvenile fish that grow up there before swimming into the open sea as adults. Gastropods and small crustaceans likewise feed on microalgae growing on the kelp or seagrass. They thereby ensure that the structure-forming plants are not smothered and are allowed to grow – that is their contribution to the ecosystem. The molluscs and crustaceans that feed on microalgae are the basic food source for larger predatory crustaceans and fish.

2 BALLAST WATER AND INVASIVE AQUATIC SPECIES

2.1 Ballast Water and Tanks

2.1.1 *Ballast Water*

Ballast is defined as any solid or liquid that is brought on board a ship to keep it safe in three fundamental areas:

- It is used to control the centre of gravity of the ship and so ensures that it can maintain positive stability characteristics and survive the perils of high winds and heavy seas.
- Ballast is taken on board during a non-cargo carrying voyage to lower the ship in the water, to adjust the ship's trim or attitude in order to make her more sea kindly and also to keep the propeller and rudder immersed sufficiently enough to allow the ship to be maneuvered safely during the voyage.
- It can also be used when ships are loading or discharging cargo or are only carrying partial loads to balance the forces of weight and buoyancy along the length of the ship and thus ensure that hull stress limits are not exceeded.

Prior to the 1830s, ships used solid ballast materials such as rocks and sand. This material had to be physically manhandled into cargo holds, and similarly unloaded when cargo was to be taken on board. With the introduction of steel-hulled vessels, water taken from the harbour became the ballast of choice due to its ready availability and ease of handling. Modern ships are designed with dedicated ballast tanks and pumping systems to allow for the flexibility of ballast water distribution around the vessel as well as to quickly load and discharge the water.

2.1.2 *Ballast Tanks*

Ballast tanks come in a wide variety of shapes and sizes subject to vessel size and type (Figure 6). They can be small and confined, carrying a few hundred tonnes in smaller coastal vessels or can be vast cathedral-like structures allowing large vessels such as tankers and bulk carriers to have an overall ballast capacity in excess of 150,000 tons.



Figure 6 Cross-section of bulk carrier showing cargo space (center) and ballast water tanks (gCaptain, 2019)

Tank design is dependent on ship type and size, but what they all have in common is a complex network of structural members. The internal construction (Figures 7 and 8) must ensure that the tank is of sufficient strength to form an essential part of the ship's

structural integrity and also to safely carry the weight of the ballast water pumped into it. Because of this, ballast tanks can consist of a labyrinth of cavities and chambers fitted with openings and channels designed to allow water to enter all areas of the tank during

ballasting operations and similarly, to allow the water to drain back to the pump suction point in the tank during de-ballasting.

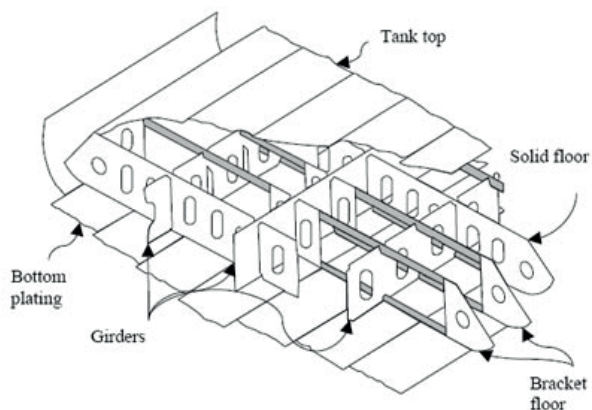


Figure 7 Typical double bottom ballast tank construction (Transport Canada, 2019)



Figure 8 Tank internal structures create many compartments and chambers linked by openings and drain channels (D. Smith)

The environment inside the ballast water tanks is harsh: dark, often hypoxic or anoxic, and may be exposed to changes in both temperature and salinity during a voyage when ballast water is changed in the tank (Figure 9). Vegetative cells of phytoplankton will die during the voyage or ballast water discharge, however, some species or resting stages can tolerate the changing and harsh conditions and will survive (Hallegraeff and Bolch, 1992; Yoshida, et al., 1996; Olenin, et al., 2000).

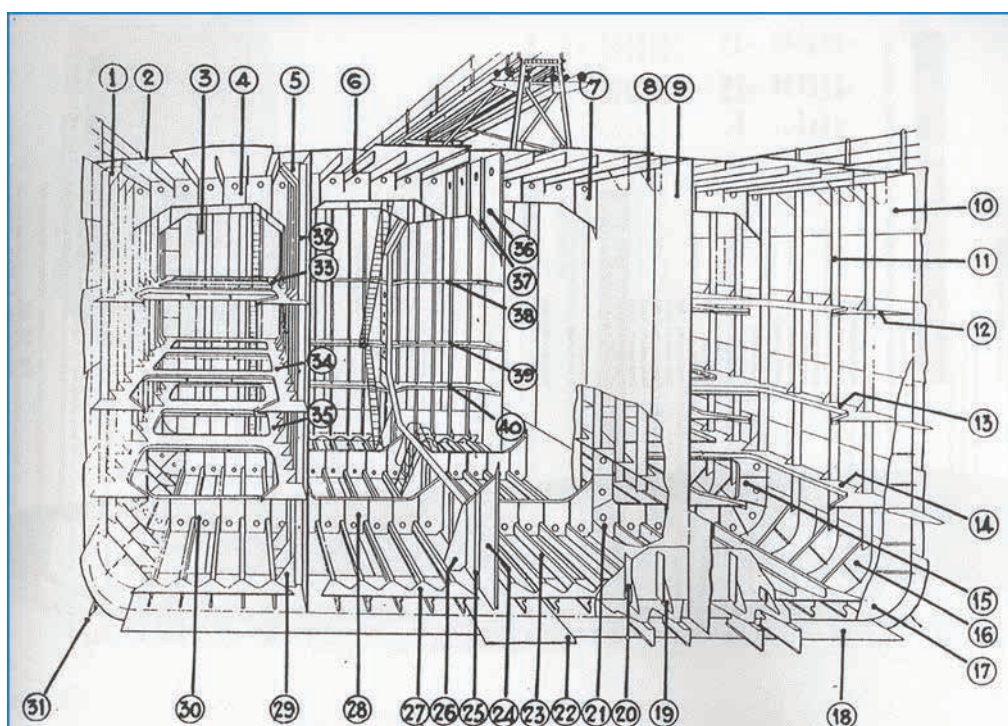


Figure 9 The environment inside the ballast tank is full of pockets for stowaways (J. Linders)

Ballast water within a tank can be a rich broth of aquatic life. In addition to those aquatic species existing within the water column in a ballast tank, most of the unicellular ballast water organisms accumulate in the sediments in the tank bottom (Hülsmann and Galil, 2002). It has been estimated that bottom sediments in a single ballast tank contain more than 300 million harmful cysts, which may later germinate into vegetative cells (Hallegraeff and Bolch, 1992). Most of these sediment-associated cysts are not discharged into the environment, because the sediments lie confined to bottoms usually away from the ballast water outlets

(Hamer, et al., 2001; Rigby, 2001). However, even a single living phytoplankton cell or cyst can theoretically be the initiatory seed for an algal population in a new environment.

Ballast water exchange in the open sea is partially efficient in removing the organisms from the ballast water by flushing the tanks out and replacing the ballast taken up by a ship in ports or coastal regions with oceanic water containing lesser amounts of marine aquatic life. (Hallegraeff and Bolch, 1992; Rigby, 2001).

Given the complex nature of ballast tank structures and the existence of numerous chambers within, each tank has the potential for bottom sediment accumulation during ballast water carriage and this hidden environment can provide favourable conditions for species to survive and be effectively carried as stowaways on board a vessel (Figure 10).



Figure 10 Sediment inside a ballast tank (D. Smith)

2.1.3 Ballast Water – the Issue

It is true to say that there is a natural migration of certain types of marine species which occurs globally, and we can see some changes in these patterns due to climate change. However, ships acting as a vector, when loading ballast water at one location and subsequently carrying local species from that region and discharging them into a receiving port's local environment, exacerbate the non-natural movement of species globally (Figure 11).

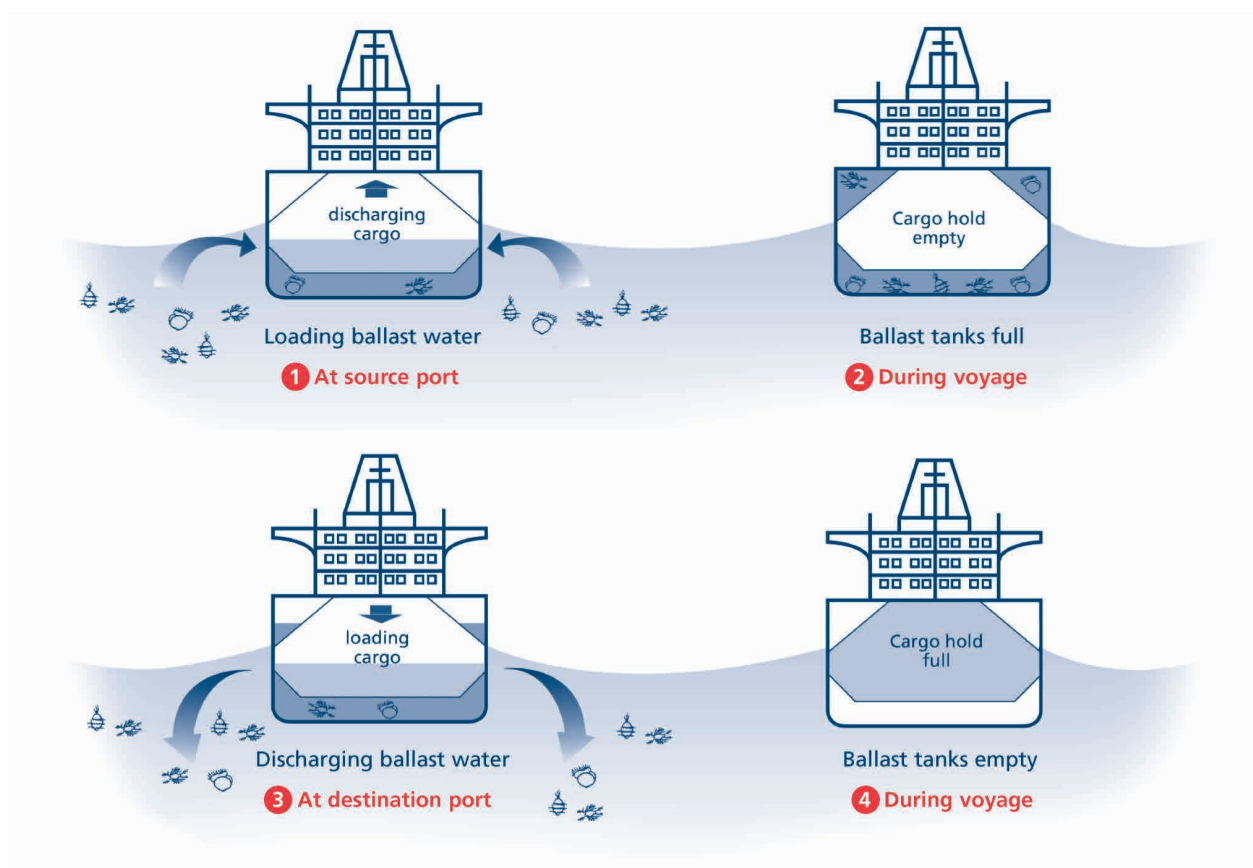


Figure 11 Ship ballast operations provide a transport medium for aquatic species (GloBallast, 2017)

2.2 Ballast Water – Ships as Global Pathways

Over 90% of the world's global trade is carried by sea; trading patterns are naturally more intense between the more populous and developed nations. The global map (Figure 12) illustrates the network of principal

trade routes followed by commercial shipping and thus indicates the more likely areas where potential invasive species pathways connect such as between Europe and the Americas.

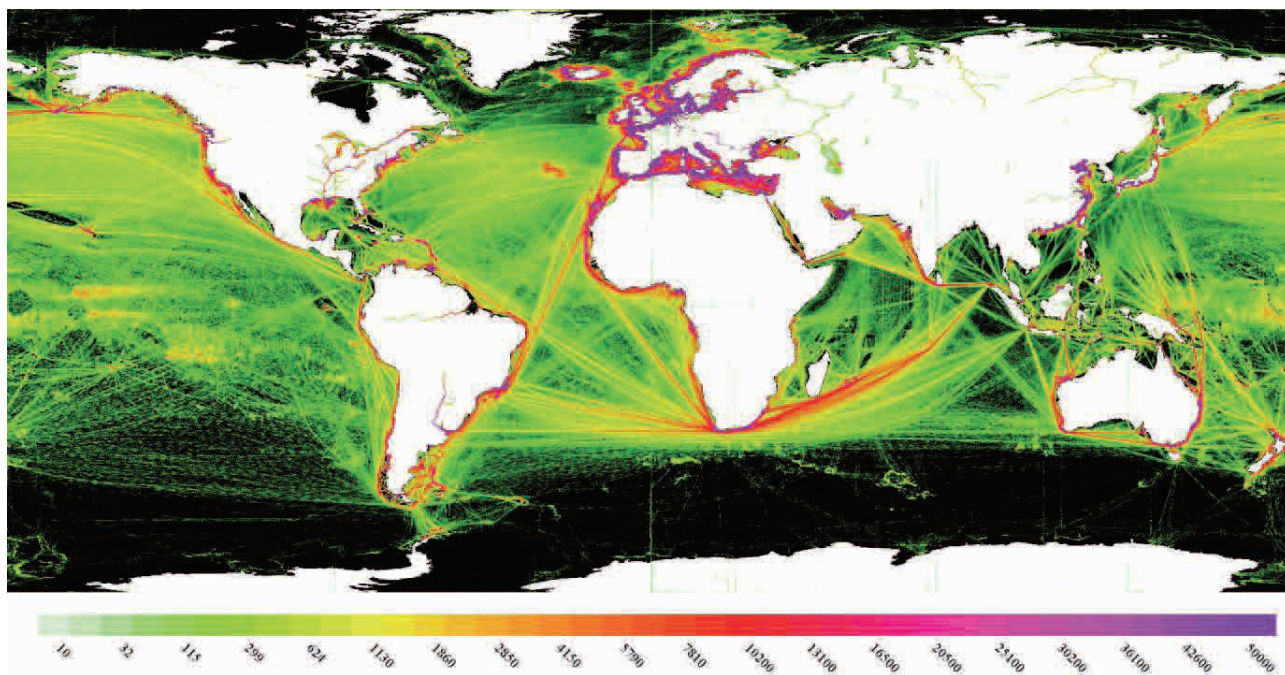


Figure 12 Maritime shipping routes and strategic locations (IMO, 2015)

Over the years, ships have become larger and faster, with greater ballast capacities. Modern ports with more efficient cargo handling methods have developed and expanded. This has resulted in shorter vessel turn-around times, and consequently the potential for more shipping movements at each port. Developing world markets have also created shipping routes into areas previously not used to high volumes of shipping and thus introducing a higher risk of IAS transfers. As a consequence of these changes, global ballast water carriage by shipping has now been estimated by the World Wildlife Fund to be in the region of 10 billion tons per annum and is indeed set to rise year-on-year (WWF, 2019). To put the issue into perspective, this represents almost a ton of ballast for every person on the planet or the equivalent of Niagara Falls flowing for around 50 days.

2.3 Ballast Water – the Problem

When aquatic species from a particular global area are delivered by a ship into a new environment, most will perish due to osmotic shock, temperature differentials or lack of suitable habitat and nutrients. When, however, the receiving environmental conditions are favourable, some species may flourish and, when this occurs, these marine hitch hikers can become permanent residents to the detriment of indigenous species and

the local habitat. In marine and coastal environments, such invasive arrivals represent one of the four greatest threats to the world's oceans along with:

- Marine pollution
- Over-exploitation of living marine resources
- Physical alteration or destruction of marine habitats.

They can have serious effects on:

- The local ecology through habitat reduction and loss of native species
- Human health, by spread of harmful toxic blooms
- Economic effects: Corrosion and weakening of coastal structures, fouling of water inlets to water extraction facilities and a general overall reduction in local economy net worth resulting from the closure of marine related businesses.

2.3.1 The problem is increasing

There is an increasing rate of introduction of invasive species associated with ships' ballast water (Figure 13). Studies have shown that it is rising exponentially due to the deployment of larger and faster ships and port expansions into new locations as humans seek out new sources of raw materials.

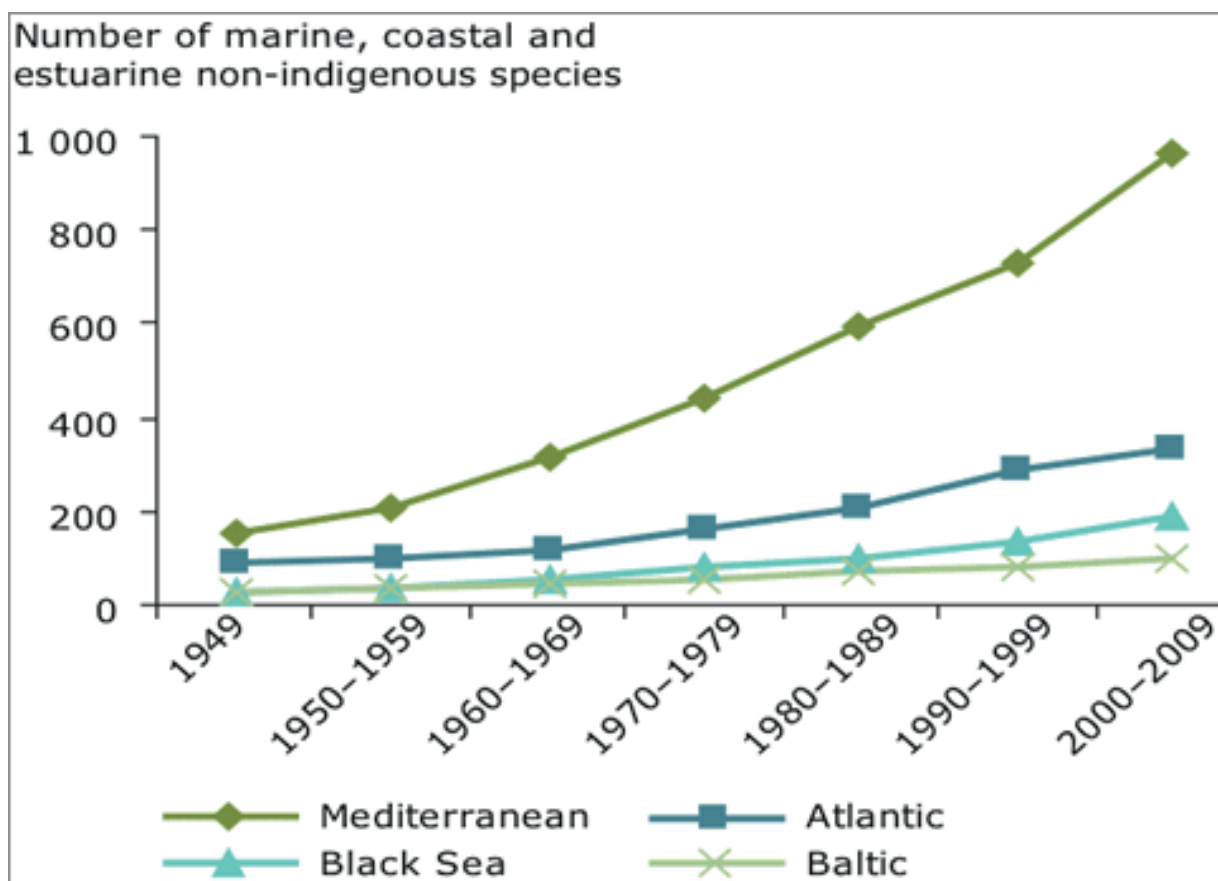


Figure 13 Increasing number of non-indigenous species in European coastal regions (European Commission, 2019b)

Australia now has over 250 known introduced marine species. Most have little impact but some, including several crabs, mussels, sea stars and seaweeds, have become aggressive pests in some regions (Australian Government, 2019).

2.4 Invasive Aquatic Species

An invasive aquatic species (IAS) is defined as a non-indigenous aquatic organism that has been transported from its normal environment and has been introduced outside its normal distribution into a recipient ecosys-

tem where it may become abundant. 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. This is referred to as propagule pressure (Lawrence, *et al.*, 2010). Ballast water is recognized as a significant vector for the transfer of IAS in marine and coastal environments.

IMO has made a list of ten of the most unwanted IAS (GloBallast, 2017), as shown in Table 1 and Figure 14.

Table 1 IMO's list of the ten most unwanted IAS (GloBallast, 2017)

1	<i>Vibrio cholera</i>	bacterium
2	<i>Cercopagis pengoi</i>	water flea (cladoceran)
3	<i>Eiocheir sinensis</i>	mitten crab
4	Toxic algae	over 5000 species of marine phytoplankton
5	<i>Neogobious melanostomus</i>	round goby (fish)
6	<i>Dreissena polymorpha</i>	zebra mussel
7	<i>Mnemiopsis leidyi</i>	North American comb jelly
8	<i>Asterias amurensis</i>	North Pacific sea star
9	<i>Carcinus maenas</i>	European green crab
10	<i>Undaria pinnatifida</i>	Asian kelp



Figure 14 Illustration from Awareness material, GloBallast (2017)

2.5 Organisms in Ballast Water Tanks

As ballast water is sourced from different ports or at sea, it may contain a large number of different organisms. In addition, these organisms may represent different life stages such as eggs, cysts, spores, larvae and adults. There may be over at least 4,000 known and unknown different species present in a single tank (Ruiz, *et al.*, 2000; Veldhuis, *et al.*, 2010).

An investigation by Gollasch, *et al.* (2000) confirmed the general rule that abundance and species diversity of plankton decreases with the length of the confinement of the organisms in the tanks. This rule had been established by the observation that an inverse relationship existed between the occurrence of planktonic organisms and the age of the ballast water (Carlton, 1985; Williams, *et al.*, 1988). The rule proved only to be valid for plankton and not for benthic organisms, which are able to live in ballast water tanks for long periods. The benthic amphipod, *Corophium acherusicum*, found after 116 days of confinement, is an example of such a

long survival (Gollasch, 1996). The conclusion made by Gollasch, *et al.* (2000) was that at least semi-planktonic organisms, such as harpacticoid copepods, are able to thrive and reproduce in ballast water tanks. A ballast water tank can thus function as an incubator during the cruise for some species.

2.6 Organisms in Discharge Water

The Ballast Water Performance Standard (Regulation D-2 of the Ballast Water Management Convention, Figure 15) defines the number of viable¹ organisms that are allowed to be present in ballast water when it is being discharged.

¹ New definition in the 2016 Guidelines (G8) (IMO, 2016) and BWMS Code:

The IMO regulations further define viable as:

"Viable organisms means organisms that have the ability to successfully generate new individuals in order to reproduce the species." (Paragraph 3.19)

The Ballast Water Performance Standard (D-2):

Regulation D-2 of the Ballast Water Management Convention stipulates that ships meeting the requirements of the Convention shall discharge:

- less than 10 viable organisms per cubic metre greater than or equal to 50 micrometres in minimum dimension
- less than 10 viable organisms per millilitre less than 50 micrometres in minimum dimension and greater than or equal to 10 micrometres in minimum dimension
- less than the following concentrations of indicator microbes, as a human health standard:
 - Toxigenic *Vibrio cholerae* (O1 and O139) with less than 1 colony-forming unit (cfu) per 100 millilitres or less than 1 cfu per 1 gram (wet weight) of zooplankton samples
 - *Escherichia coli* less than 250 cfu per 100 millilitres
 - *Intestinal Enterococci* less than 100 cfu per 100 millilitres.

Figure 15 Definition of the D-2 Standard in the BWM Convention

To comply with the D-2 standard, most ships have installed or will install a BWMS. Many BWMS use Active Substances to render potentially present organisms in ballast water harmless. During the evaluation process of the GESAMP-BWWG, the Maximum Allowable Discharge Concentration (MADC) has to be determined for every Active Substance (AS). The discharge of the Active Substances should be limited to the MADDC. By the application of Active Substances, as a side effect, disinfection by-products (DBP) are formed that also should be harmless at discharge for the environment, human health, property and resources. This means that the concentrations of these DBPs should present no unacceptable effects to the receiving aquatic environment.

2.7 History and Examples

The relocation of organisms across geographical boundaries occurs naturally by various means. Since humans began exploring the globe, however, the rate of new species being introduced into regions has greatly increased. In some cases, humans have dispersed species on purpose; for instance, many plants were transported from Europe to North America for agricultural and ornamental purposes. Others were transported accidentally by ship, train, airplane and even on the shoes of hikers. Some species may be introduced and not be able to survive in their new habitat. Others may find optimal conditions for growing, reproducing, and adapting to the new environment, and their populations soar. For instance, lack of predators may contribute to their rapid population increases.

One of the first suggested examples of an invasive species, a diatom, introduced by humans (presumably carried by ballast water) is *Odontella sinensis*, originating from Asia and the Pacific. It was originally described in China (Greville, 1866) but came to Europe in 1889 (Boalch, 1987). It was then further noted in the North Sea in 1903 and in British waters in 1906. It rapidly spread to become widely distributed throughout European waters in less than 10 years (Ostenfeld, 1908; Boalch and Harbour, 1977; Boalch, 1987; Christensen, *et al.*, 1985). Recent studies, however (Gomez, 2010), suggest that this particular species may in fact be neither introduced nor non-native in the European Seas and may simply have gone unnoticed before 1903 due to scarce sample coverage and unfavourable conditions prior to this period.

2.7.1 Zebra Mussel (*Dreissena polymorpha*)

There are many well-known examples of invasions of invasive aquatic species, such as that of the zebra mussel *Dreissena polymorpha* (Figure 16) throughout the Great Lakes in the 1980s and 1990s, which caused lasting changes to the ecology of many of the waterways of North America (Bowmer and Linders, 2010).



Figure 16 Close-up of typical shells of zebra mussels (USGS, 2018)

The zebra mussel is a freshwater bivalve that is native to the Black, Caspian and Azov Seas region of Eurasia (Ontario, 2017).

2.7.2 North American Comb Jelly (*Mnemiopsis leidyi*)

The comb jelly (*Mnemiopsis leidyi*) (Figure 17), is endemic to temperate to subtropical estuaries along the North and South American Atlantic coast, and consumes large amounts of plankton, including eggs and larvae of fish. It was first recorded in the Black Sea in 1982, where it became well established, occurring in massive numbers. It also spread rapidly to the Azov, Marmara and Eastern Mediterranean, and towards the end of 1999 was recorded in the Caspian Sea, where its biomass eventually exceeded levels ever recorded in the Black Sea. The invasion of this species led to a massive decline in fisheries that had severe economic consequences. It also led to wide-scale retrofitting of cooling systems to reduce fouling (GESAMP, 1997).



Figure 17 Close-up of a comb jelly (File: *Mnemiopsis leidyi.jpg*, Wikipedia Commons)

This species has caused a population collapse of planktivorous fish species that were already suffering from overfishing in the Caspian Sea, the Sea of Azov and the Black Sea. Since the comb jelly keeps consuming the plankton and the fish larvae it also prevents

the recovery of the impacted fish populations (Ivanov, *et al.*, 2000; Shiganova, 2002; Shiganova, *et al.*, 2001). According to most of the scientists who studied the feeding of *Mnemiopsis*, it is capable of feeding (or, at least, of ingesting and killing) any organisms available to be captured by its oral lobes – holo-planktonic organisms, planktonic larvae of benthic animals (meroplankton), and fish eggs and larvae (Nelson, 1925; Main, 1928; Tzikhon-Lukanina, *et al.*, 1993). Similar to the majority of lobate ctenophores, *M. leidyi* is capable of excessive feeding; even if its gastrovascular atrium is full, it continues hunting and vomits large amounts of undigested food in mucous clots (Harbison, *et al.*, 1978).

More recently, the accidental introduction into the Black Sea of another comb jelly – *Beroe ovata* (Figure 18) – which is a predator of *Mnemiopsis*, has resulted in a major decline of *Mnemiopsis* there, and a substantial recovery of the ecosystem (Shiganova, *et al.*, 2011).

Almost exclusively, the ctenophores of the *Lobata* order are zooplankton-feeding predators; occasionally phytoplankton and detritus were encountered in their gastrovascular cavities (Reeve and Walter, 1978).



Figure 18 *Beroe ovata* (File: *Beroe ovata.jpg*, Wikipedia)

2.7.3 Mitten Crab (*Eriocheir sinensis*)

Another example of an invasive species is the Chinese mitten crab (Figure 19). This species has 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 19 Mitten crab (File: *EriocheirSinensis1.jpg*, Wikipedia Commons)

The first time the crab was brought to Europe was most likely by commercial vessels. During one of the filling events of ballast tanks, it could have been the spawning time for the mitten crab. Since the larvae are free floating and 1.7 mm to 5 mm 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 were released. Over time, 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, the United States of America (San Francisco Bay), and the United Kingdom. During the very early phase of establishment of the species in northern Europe, crab populations were usually characterized by low numbers and small spatial extent prior to the rapid exponential phase of invasion (Herborg, *et al.*, 2003). This establishment phase lasted 15 years in Germany (Herborg, *et al.*, 2003) and 22 years in the United Kingdom (Herborg, *et al.*, 2005).

3 BALLAST WATER MANAGEMENT SYSTEMS

3.1 The Ballast Water Management Convention (BWM Convention)

The Ballast Water Management Convention (IMO, 2004) 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 have adopted over 15 sets of technical guidelines and numerous other documents contained in MEPC reso-

lutions and circulars. 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 also various resolutions and circulars developed by the Organization relating to the Convention. These documents can all be found on IMODOCS (<https://docs.imo.org>).

The BWM Convention entered into force on 8 September 2017, requiring shipowners to comply with either D-1 (ballast water exchange) or D-2 (ballast water discharge) standards until such time as it is required

that they comply only with the D-2 standard. New build ships must comply with the D-2 standard if constructed (keel-laid) on or after 8 September 2017. For existing ships, shipowners are required to comply with the D-2 standard at the time of the first or second International Oil Pollution Prevention (IOPP) renewal survey. Under the Convention, ships to which the Convention's provisions apply will be required to manage their ballast water and sediments to the D-1 or D-2 standards, 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).

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, regulation D-1, to the Convention and is referred to as the exchange standard. This is an interim standard, and each ship must comply with the D-2 standard at the time of the first or second IOPP renewal survey. All ships will need to meet the D-2 standard by 8 September 2024. The D-2 standard is a discharge or performance standard that limits the number of viable organisms in discharged ballast water (Figure 15). How ships must comply with the D-2 standard is not dictated by the BWM Convention. In practice, however, the vast majority of ships choose to install a BWMS. BWMS used to comply with the Convention must be approved by Administrations, taking into account IMO's *Guidelines for approval of ballast water management systems* (G8). The Guidelines (G8) were revised in 2016 (2016 Guidelines (G8)), and subsequently made mandatory as the Code for Approval of Ballast Water Management Systems (BWMS Code), which will enter into force in October 2019.

For the evaluation of the side effects of ballast water management systems using Active Substances, a Technical Group (the GESAMP-BWWG) was established. The treatment should not have any risks to the environment, human health, property or resources. Procedure (G9) describes in detail how the GESAMP-BWWG should evaluate the Ballast Water Management Systems (BWMS). The reports of the BWWG are subsequently sent to the MEPC Secretariat of IMO for decision making at MEPC.

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 as a result of their complex speciation and chemical equilibrium in water. In practice, all systems are considered by the GESAMP-BWWG to potentially produce Active Substances and/or Relevant Chemicals until proven otherwise.

3.2 Procedure (G9) – General Description

Regulation D-3.2 of the BWM Convention stipulates that 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) (MEPC, 2006). Resolution MEPC.169(57) (MEPC, 2008) revoked the initial Procedure and provided a revised version of it. (Figure 20).

From Procedure (G9):

1.1 This procedure describes the approval and withdrawal of approval of ballast water management systems that make use of Active Substances to comply with the Convention and their manner of application as set out in regulation D-3 of the International Convention for the Control and Management of Ships' Ballast Water and Sediments. The Convention requires that at withdrawal of approval, the use of the relevant Active Substance or Substances shall be prohibited within one year after the date of such withdrawal.

1.2 To comply with the Convention, ballast water management systems that make use of Active Substances or Preparations containing one or more Active Substances shall be approved by the Organization, based on a procedure developed by the Organization.

1.3 The objective of this procedure is to determine the acceptability of Active Substances and Preparations containing one or more Active Substances and their application in ballast water management systems concerning ship safety, human health and the aquatic environment. This procedure is provided as a safeguard for the sustainable use of Active Substances and Preparations.

1.4 This procedure is not intended for the evaluation of the efficacy of Active Substances. The efficacy of ballast water management systems that make use of Active Substances should be evaluated in accordance with the Guidelines for approval of ballast water management systems (G8).

1.5 The goal of the procedure is to ensure proper application of the provisions contained in the Convention and the safeguards required by it. As such the procedure is to be updated as the state of knowledge and technology may require. New versions of the procedure will be circulated by the Organization following their approval.

Figure 20 Excerpt from Procedure (G9)

3.2.1 Summary of Procedure (G9) Requirements

For BWMS that make use of Active Substances, the application dossier that must be submitted should consist of the following information:

- full description of the system
- tests results
- study reports
- references
- copies of the literature referenced
- any other relevant information.

Furthermore, the chemical identity of Active Substances, Preparations, and any other Relevant Chemicals, including those that may be formed during or after application of the BWMS, should be provided.

The description of chemicals should include a dataset including the following:

- physical and chemical properties
- mammalian toxicity
- environmental fate
- environmental effects.

Following production of this information, an effect assessment should be presented that includes screening for the following properties:

- PBT (persistence, bioaccumulation and toxicity)
- CMR (carcinogenicity, mutagenicity and reproductive toxicity).

For the Basic Approval evaluation, the requirements are more general, such that theoretical studies, literature data and laboratory-scale testing will fulfil the data and information requirements. In effect, the applicant does not have to perform laboratory tests, as a reference to results used in risk assessment evaluation by internationally recognized organizations is considered sufficient. For Basic Approval, the GESAMP-BWWG reviews the comprehensive proposal, along with any additional data submitted, as well as other relevant information available to the Group, and reports back to the Organization.

For Final Approval, more detailed tests and assessments are required, that are based on land-based testing of the BWMS at full scale. The application dossier should include tests performed using the treated ballast water discharge. This type of test is part of the land-based type approval process (under the 2016 Guidelines (G8), IMO, 2016 and the BWMS Code) and specifically addresses any concerns identified and recommendations made during the consideration for Basic Approval. The Final Approval dossier should also confirm the evaluation carried out during Basic Approval of the risks to the ship and the crew including consideration of the storage, handling and application of the chemicals being used.

3.2.2 Quality Assurance and Quality Control Procedures

The testing body should implement a quality control programme during testing in accordance with the recognized international standards that are acceptable to the Administration. In summary, the quality control programme should consist of the following:

- .1 Quality Management Plan (QMP) that addresses the quality management structure and policies of the testing body
- .2 Quality Assurance Project Plan (QAPP) which is a project-specific technical document pertaining to the BWMS being tested, the test facility, and other testing implementation details.

3.2.3 Technical Requirements

For chemicals that are commonly associated with treated ballast water, data are gathered in the *GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water*. The database is available through the Global Integrated Shipping Information System (GISIS) (<https://gisis.imo.org/>). For these chemicals, no other data need to be submitted by the applicant. For other chemicals, not included in the database (Active Substances, components of a Preparation and Relevant Chemicals), data need to be submitted with the application dossier. The applicant is required not to be limited to the list of chemicals available in GISIS but has to actively search for other potential chemicals present.

The data required includes:

Effects on aquatic organisms:

- acute aquatic toxicity data
- chronic aquatic toxicity data
- information on endocrine disruption
- sediment toxicity
- bioavailability/biomagnification/bioconcentration
- food web/population effects.

Mammalian toxicity:

- acute toxicity
- corrosion/irritation
- sensitization
- repeated-dose toxicity
- development and reproductive toxicity
- carcinogenicity
- mutagenicity
- results from the carcinogenicity/mutagenicity/reproductive toxicity (CMR) screening.

Environmental fate and effect under aerobic and anaerobic conditions:

- modes of degradation (biotic and abiotic)
- partition coefficients
- persistence and identification of main metabolites
- reaction with organic matter
- potential physical effects on wildlife and benthic habitats
- potential residues in seafood
- any known interactive effects.

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

- melting point
- boiling point
- flammability (flash point)
- relative vapour density
- water solubility
- pH in solution
- dissociation constant
- oxidation-reduction potential
- corrosivity to material or equipment
- reactivity to container material (only for Active Substance, which needs storage on board)
- auto-ignition temperature
- explosive properties
- oxidizing properties
- surface tension
- viscosity
- thermal stability and identity of breakdown products
- other physical or chemical properties.

Following the screening for PBT properties, the environmental risk assessment is performed using the known (measured) concentration of chemicals present in the discharge ballast water to estimate the exposure to the environment by using MAMPEC Ballast Water (version 3.1.0.3, Annex III) (van Hattum, *et al.*, 2002). MAMPEC-BW is a mathematical model to predict environmental concentrations of chemicals in the aquatic environment. The calculated concentrations from MAMPEC-BW are referred to as the predicted environmental concentrations (PEC). The ratio between the resulting PEC and the corresponding predicted no-effect concentration (PNEC) is then calculated, and where the result is below 1, the assumption is that no unacceptable risk will result from exposure to that chemical. Further details of MAMPEC BW are presented in Annex III.

In the human risk assessment, the exposure derived from the human exposure scenarios (HES) is compared with the level above which humans should not

be exposed, the derived no-effect level (DNEL) and/or the derived minimal effect level (DMEL). The risk characterization ratio (RCR) is calculated dividing the resulting aggregated exposure (for the relevant pathways/routes) for single chemicals by the DNEL or DMEL under the assumption that where the result is below 1, no unacceptable risk will result from the exposure to that chemical. Furthermore, group RCRs are calculated for chemicals that are identified as non-threshold carcinogens.

3.3 Evaluation of BWMS: the Early Days

During its first meetings, the GESAMP-BWWG would often receive submissions that were very difficult to evaluate since important information was missing in the dossiers, and furthermore, the systems themselves were of a conceptual nature. In the report from the second meeting (MEPC, 2006, "Action requested by the Committee", paragraph 4.7) the GESAMP-BWWG invited MEPC to "agree that the Group should not be requested to evaluate conceptual systems that do not include details of how the system would be working in practice."

In October 2008, MEPC 58 (MEPC, 2008b), agreed to the GESAMP-BWWG's proposal to take stock of the experience achieved during the first seven meetings and to discuss the lessons learned and general aspects related to the evaluation process, including further refinement of the Methodology, without the pressure of having to review specific submissions. Subsequently two Stocktaking Workshops took place in 2009 and the first steps towards the development of the GESAMP Database of chemicals most commonly associated with treated ballast water were taken. Further development of the Human Exposure Scenarios (HES) was also discussed. Dr. Bert van Hattum (University of Amsterdam and Deltares, The Netherlands) was invited to discuss the further development of the MAMPEC-BW model to include a worst-case scenario of a ballast water discharge by establishing a set of parameters regarding the model ballast water discharge harbour and an agreed by-products emission scenario.

3.4 Historical Background of Methods for Treating Ballast Water

Many of the methods for treating ballast water have their origin in technologies developed for the purification of drinking water and for wastewater treatment. Water purification is the process of removing undesirable chemicals, biological contaminants, suspended solids and gases from water. Most water is disinfected for human consumption (drinking water), but water purification may also be designed for a variety of other purposes, including fulfilling the requirements of industrial applications. The methods used include physical processes such as filtration (slow sand filters or activated carbon filter), sedimentation, and distillation; biological processes (digestion and biodegradation); chemical processes (flocculation and (electro-)chlorination, and the use of electromagnetic radiation such as ultraviolet light).

Water treatment originally focused on improving the aesthetic qualities of drinking water. Methods to improve the taste and odour of drinking water were recorded as early as 4000 BCE. Ancient Sanskrit and Greek writings recommended water treatment methods such as filtering through charcoal, exposing to sunlight, boiling, and straining. Visible cloudiness (later termed turbidity) was the driving force behind the earliest water treatments, as many source waters contained particles that had an objectionable taste and appearance. During the mid to late 1800s, scientists gained a greater understanding of the sources and effects of drinking water contaminants, especially those that were not visible to the naked eye. In 1855, epidemiologist Dr. John Snow proved that cholera was a waterborne disease by linking an outbreak of illness in London to a public well that was contaminated by sewage. The outbreak seemed less severe in areas where sand filters had been installed. John Snow applied chlorine to purify the water, and this paved the way for water disinfection. In the late 1880s, Louis Pasteur demonstrated the “germ theory” of disease, which explained how microscopic organisms (microbes) could transmit disease through media like water (US EPA, 2000).

3.5 Treatment Steps in Ballast Water

The technologies used in various BWMS can be categorized into three types based on their primary mechanism: mechanical, physical and chemical. Many BWMS use a combination of two or more technologies, e.g., filtration combined with UV, filtration combined with chemical injection or *in situ* electrolysis (or electrochlorination).

3.5.1 Mechanical Treatment

One of the most common of the mechanical treatments is filtration, however other types of mechanical treatment are also possible such as cyclonic separation and electro-mechanical separation. Filtration is generally done at intake. Screen and disk filters can be used to reduce sediment and organisms. Mesh sizes of these filters vary and the smaller the mesh size the more will be filtered out prior to intake. Filters with a mesh size of 50 µm or less are commonly applied in BWMS to contribute to achieving the standard described in regulation D-2. In other words, the filter mainly has effect on organisms >50 µm. Most filters are self-cleaning with back flushing cycles. Waste water from the back flush is discharged directly overboard. Together with the resistance of the filter this self-cleaning procedure will form pressure drops and reduce the flow rate. Cyclonic separation uses centrifugal forces to separate solid particles from water. However, this is only possible with particles having a specific gravity higher than that of water. Electro-mechanical separation works with a flocculent injection that attaches to the sediment and organisms. Solid particles are then removed by filtration and magnetic separation.

3.5.2 Physical Treatment

Physical treatment can be done, for example, by ultra-violet irradiation (UV), de-oxygenation, cavitation and ultrasound. UV is used to eliminate or damage organ-

isms (phytoplankton, zooplankton, human pathogens and bacteria) to such extent that they are not able to reproduce (non-viable). The effectiveness is dependent on the turbidity and the UV transmittance in water. Most ballast water management systems that use UV irradiation combine it with prior mechanical treatment. Often UV treatment may be performed at intake and/or discharge of ballast water. For further details see Section 3.6.6.

Removing dissolved oxygen in the ballast water is called de-oxygenation and affects aerobic organisms (i.e. organisms that require oxygen). Oxygen is replaced by inert gases (often nitrogen). De-oxygenation may prevent corrosion, however it is important to use inert gas, which does not react chemically, to avoid any oxidative or hydrolytic effects. De-oxygenation may require a longer tank holding time, which should be considered for ships employed on short voyages.

Some systems use cavitation as a treatment step. Cavitation is the rapid formation and collapse of vapour bubbles within a liquid. Cavitation occurs mainly when the static pressure becomes smaller than the liquid's vapour pressure. The cavitation method can be used in order to damage membranes of organisms, ensuring that they are not able to reproduce when discharged into the environment. Care should be taken to protect against the possible effects of hydrodynamic forces and ultrasonic oscillations on materials and the environment, including humans. This treatment can be applied on long and short voyages and is often combined with another physical treatment method.

3.5.3 Chemical Treatment (Active Substances and Relevant Chemicals)

Ballast water can be chemically treated by the use of chemicals (Active Substances) or Preparations, or by the production of Active Substances on board. Commonly used Active Substances are sodium hypochlorite, ozone and hydrogen peroxide. Sodium hypochlorite can be generated on board by using an electrolytic cell and having enough salinity in the ballast water. The chemical treatment systems are dealt with in Section 3.6.

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 as a result of their complex speciation and chemical equilibrium in water. In practice, all systems are considered by the GESAMP-BWWG to potentially produce Active Substances and/or Relevant Chemicals until proven otherwise.

3.6 Ballast Water Management Systems using Active Substances

A wide variety of BWMS using chemical, physico-chemical and physical technologies have been developed over the years. The most common technique is *in situ* electrolysis where seawater is used to produce chlorine and its oxidizing derivatives, termed total residual oxidants (TRO). These processes are combined with filtration or other means of separation and

are normally followed by a neutralization step before discharge. Other treatment methods include ozonation, adding biocides or removal of organisms through flocculation.

At the time of publication, more than 60 BWMS that make use of Active Substances and/or Preparations have received Basic Approval from MEPC and more than 40 have received Final Approval. The different treatment technologies are presented in Table 2.

Table 2 BWMS that make use of Active Substances and have received Basic Approval

Technology	Number of BWMS	Comment
Electrolysis <i>in situ</i> with or without filtration	29	20 BWMS use filtration and one system uses several filters in a filtration unit
Chemical addition (biocides) with or without filtration	13	10 BWMS use filtration
UV with or without filtration	7	BWMS that use UV light need not to be reviewed by the GESAMP-BWWG (decision at MEPC 59, MEPC, 2009c)
Ozonation	6	In one BWMS, ozone is used in combination with UV
Other – either a combination of chemical treatment steps or some other method	8	UV light is used as one of the treatment steps in three systems, electrolysis is used in three systems

3.6.1 *In Situ Electrolysis (or Electrochlorination)*

As already mentioned, the most frequently used technique is *in situ* electrolysis (29 systems) where sea-water is used to produce the Active Substance TRO. In these BWMS the electrolysis unit generating the Active Substance 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 Active Substance, which is then reinjected into the ballast water pipeline. If ships have to operate in fresh water and have an *in situ* electrolysis system on board, then these ships have to use a separate brine

tank available as well to provide the source water for the BWMS.

Reaction Mechanisms

Electrolysis

Electrolysis using seawater generates oxidants, such as hypobromous acid and hypobromite (HOBr/BrO^-), and hypochlorous acid and hypochlorite (HOCl/ClO^-), which are strong oxidants of organic matter including aquatic organisms.

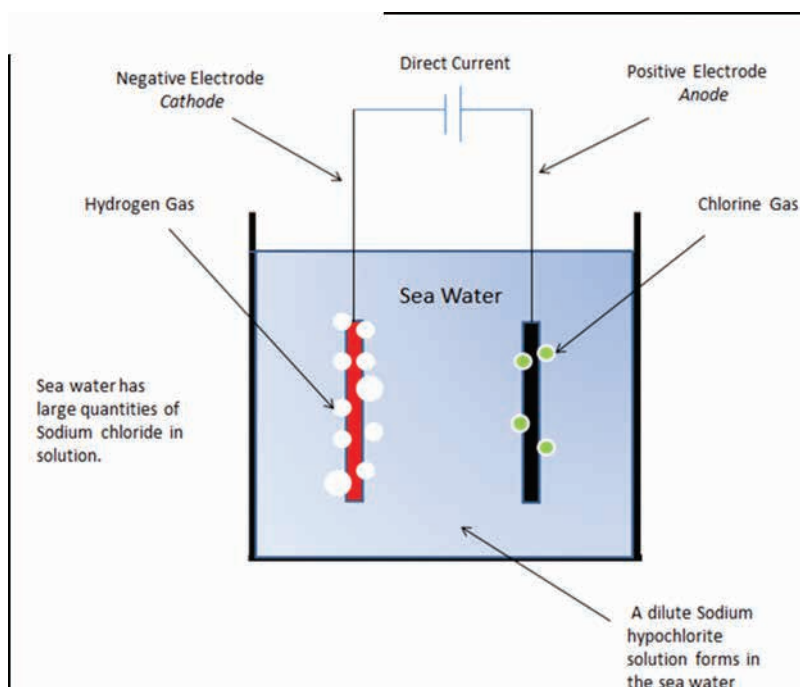


Figure 21 Hydrogen gas (H_2) production during electrolysis (D. Smith)

When an electrolyte such as seawater has a direct current passed through it via two electrodes, chemical reactions occur where hydrogen and chlorine gas are formed; much of the chlorine gas dissolves in the water.

Figure 21 represents the chemical activity using a single anode and cathode; a BWMS electrolysis system will incorporate numerous large surface area electrodes and apply large direct currents across them to effectively scale up the chemical reaction many thousands of times to produce significant volumes of hydro-

gen and chlorine gas, the latter of which will dissolve into the solution to form sodium hypochlorite (NaClO).

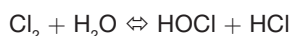
For simplicity the transient oxidants mentioned above, and a large number of their derivatives are generally referred to as total residual oxidants (TRO) (Perrins, et al., 2006). (Figure 22).

Anode:	2Cl^-	\Rightarrow	$\text{Cl}_2 + 2 \text{e}^-$
Cathode:	$2 \text{Na}^+ + 2 \text{e}^- + 2 \text{H}_2\text{O}$	\Rightarrow	$2 \text{NaOH} + \text{H}_2$
In solution:	$\text{Cl}_2 + 2 \text{NaOH}$	\Rightarrow	$\text{NaClO} + \text{NaCl} + \text{H}_2\text{O}$
	$\text{NaClO} + \text{H}_2\text{O}$	\Rightarrow	$\text{HClO} + \text{Na}^+ + \text{OH}^-$
	HClO	\Leftrightarrow	$\text{H}^+ + \text{ClO}^-$

Figure 22 Mechanisms of electrolysis in seawater

Chlorine gas

Chlorine gas (Cl_2) and water react to form hypochlorous acid (HOCl) and hydrochloric acid (HCl). The HOCl dissociates into hypochlorite ion (ClO^-) and hydrogen ion (H^+):



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 ClO^- species are present to some extent. Below pH 6.5, no dissociation of HOCl occurs, while above pH = 8.5, complete dissociation to ClO^- occurs (Figure 23). As the germicidal effect of HOCl is much higher than that of ClO^- , chlorination at a lower pH is preferred. The ClO^- and HOCl species are commonly referred to as free active chlorine (FAC), which is extremely reactive with the cell components of numerous microorganisms.

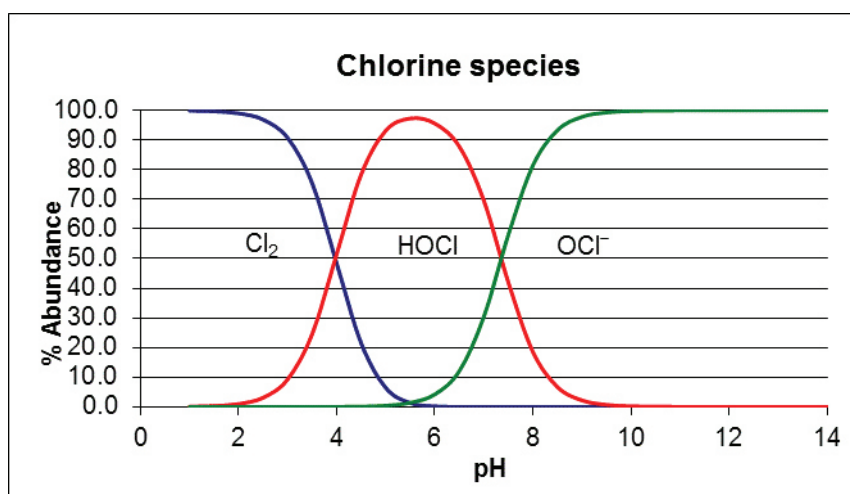


Figure 23 Distribution of chlorine species at different pH values

In nature, bromine is present as bromide salts or organic bromine substances. Bromine occurs mostly in soluble salts in seawater, salt lakes and brine. Chlorine can oxidize bromide to form hypobromous acid:



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

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



Other TRO disinfectants

In this group we combine all Active Substances that can be distinguished under the term TRO (Total Residual Oxidants). These contain peracetic acid, hydrogen peroxide (H_2O_2), ozone (O_3), hydroxyl-radicals ($\bullet\text{OH}$), chlorine dioxide (ClO_2) and sodium dichloroisocyanurate (NaDCC). We consider it unnecessary to go into more detail on the reaction mechanisms here as the number of systems that make use of these disinfectants is limited except ozone (see Section 3.6.2).

Other BWMS use methods to reduce dissolved oxygen concentrations, thereby creating hypoxic conditions, mechanical means (flocculation) to remove suspended organic matter. In some BWMS a combination of different treatment methods is used, for example ozone in combination with electrolysis or UV (3 systems). UV is used in combination with filtration and sedimentation, plasma, electrolysis or TRO in 4 systems.

More detailed information regarding the approved ballast water treatment technologies can be found at the link to approved systems below:

<http://www.imo.org/en/OurWork/Environment/BallastWaterManagement/Pages/BWMTechnologies.aspx>

3.6.2 Ozonation

Ozone is an unstable gas, consisting of three oxygen atoms, which readily degrade back to oxygen gas (O_2). During this transition a free oxygen atom, or free radical, is formed. The free oxygen radical is highly reactive and short-lived, and under normal conditions it only survives for milliseconds. Due to its high oxidation potential, ozone oxidizes cell components of the cell wall. This is a consequence of cell wall penetration. Once ozone has entered the cell, it oxidizes all essential

components (enzymes, proteins, DNA, RNA). When the cellular membrane is damaged during this process, the cell will fall apart. This is called lysis (Rojas-Valencia, 2011).

Some BWMS (4 systems) use ozone as the only treatment step. Figure 24 shows an overview of possible interactions. Being a powerful oxidant, ozone can oxidize the bromide in seawater into bromate. The concentration of bromide is a major factor in the formation of bromate (Cefas, 2010). Bromate is also formed during electrolysis of seawater. A recent study (Jung, 2014) that compared the formation of bromate, and chlorate, by ozonation, electrolysis and a combined process of both treatments, found that the combined process generated higher levels of bromate and chlorate than any of the individual processes. Bromate is formed by the stepwise oxidation by ozone of bromide to hypobromite and then to bromate (von Gunten and Hoigné, 1992):



A parallel reaction between hypobromite and ozone consumes ozone:

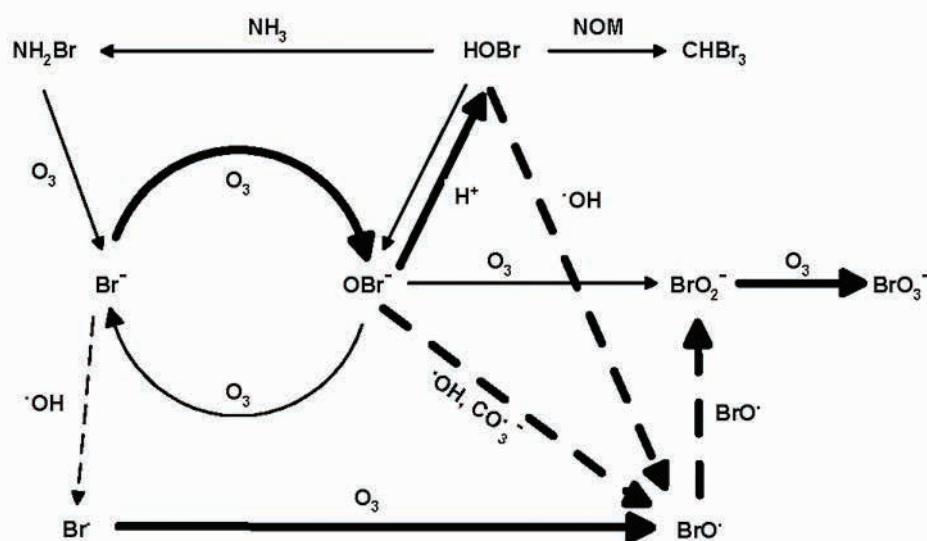
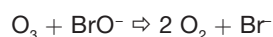


Figure 24 Reaction pathways for decomposition of ozone in seawater (from von Gunten and Hoigné, 1994)

3.6.3 Addition of Chemical Biocide

The second most frequent method (11 systems) is the addition of another biocide. In most cases the chemical is quickly converted to the Active Substance sodium hypochlorite by dissolving in water. NaDCC (sodium dichloroisocyanurate) is used in four BWMS, while other BWMS use sodium hypochlorite or calcium hypochlorite as Active Substance. Disinfection by-products (DBPs) are formed in the same way as with BWMS using electrolysis since the Active Substance is the same (hypochlorite ion, ClO^-).

In another BWMS a combination of a triarylmethane dye and a quaternary ammonium compound has been used as the Active Substance.

3.6.4 UV Light

UV light can be used either as the only treatment step, or in combination with other techniques. The main mode of action of UV irradiation is to damage the genetic material (DNA and RNA) of the organisms, thus making them unable to reproduce. UV affects all organisms but has the highest impact on organisms in the 0-50 μm range, mainly algae, due to the size-

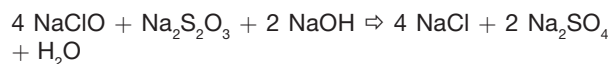
related penetration depth, that is, the organism must be fairly small to allow for a sufficient amount of excitation energy to be able to penetrate the cell membrane of the organism (and to reach the genetic material). Irradiation with UV light is highly effective and has been used for decades to reduce or eliminate various micro-organisms. Related research indicates that when organisms are exposed to UV in the range of 200 ~ 300 nm, the UV can be absorbed by DNA, RNA, and proteins. The inactivation mechanism involves absorption of ultraviolet light by DNA or RNA pyrimidine-based thymine or cytosine in DNA and uracil or cytosine in RNA causing a photochemical reaction in which a chemical dimer is formed between the two bases. The dimer inhibits the formation of new DNA or RNA chains in the process of cell replication mitosis, thus resulting in the affected micro-organism's inactivation of the ability to reproduce (Bolton and Linden, 2003).

MEPC 59 decided that BWMS that only make use of UV light do not have to go through the approval process in accordance with Procedure (G9).

3.6.5 Neutralization of Active Substance

Most BWMS are equipped with a neutralization step to ensure compliance with the maximum allowable discharge concentration (MADC) of the Active Substance. Treatment with reducing agents (for example sodium thiosulfate or sodium bisulfite) is commonly applied to quench (get rid of) excess oxidant. In this way, the residual Active Substance in the discharge water would not lead to unacceptable effects on the environment, human health, ship safety and resources, in addition

the production of DBPs is stopped. For sodium thiosulfate the reaction equation is as follows:



3.6.6 Formation of Disinfection By-Products (DBPs)

The TRO produced during the electrolysis reactions affect the organisms that are present in the water, and have also an oxidizing effect on the organic matter and halogens naturally present in the receiving waters.

Due to the high concentrations of halogen ions, including bromide and iodide, the amount of DBPs formed during seawater treatment with oxidative agents may be much higher than in fresh water. The formation of DBPs is described in more detail in Section 3.11.

3.7 Maximum Allowable Discharge Concentration

During the evaluation process of the GESAMP-BWWG, the Maximum Allowable Discharge Concentration (MADC) must be determined for every Active Substance (AS). The Active Substance performs the disinfection of the ballast water and, of course, should itself at discharge not lead to unacceptable effects on the environment, human health, ship safety and resources. For the different Active Substances evaluated, the GESAMP-BWWG has determined the MADC, as shown in Table 3.

Table 3 Oxidants used in BWMS and their MADC

Active Substance	MADC (mg/L)
chlorine dioxide	0.1
hydrogen oxide radical	not applicable ¹
hydrogen peroxide	0.5
hydrogen peroxide / peracetic acid	0.5 / 0.3
hypochlorous acid	0.1
ozone	0.1
polyaluminium chloride / polyamide sodium acrylate	not defined ²
sodium dichloroisocyanurate	0.1

¹ OH• has only a lifetime of milliseconds

² this is a more physical than chemical process (i.e. coagulation)

The Active Substances chlorine dioxide, hypochlorous acid, ozone and sodium dichloroisocyanurate, are measured and monitored as Total Residual Oxidants (TRO) and are expressed as mg Cl₂/L.

3.8 Monitoring – Practical Implications

A key feature in BWMS is the monitoring of TRO formed by the BWMS. The concentration of Active Substance in the discharged water should be measured quickly and reliably to ensure that it maintains under the MADC.

At the fourth Stocktaking Workshop (MEPC, 2013b), the GESAMP-BWWG considered in detail the main methods that had been used by applicants to measure TRO (i.e. colorimetry by DPD, amperometry, and oxidation reduction potential). The Workshop concluded that measuring and defining specific Active Substances in seawater is very difficult, especially if the Active Substance is an oxidant, and noted that data from online monitoring should be compared with calibrated data from a test laboratory.

3.9 Recommending a Preferred Method for Measuring TRO

At the fifth Stocktaking Workshop (MEPC, 2014), the GESAMP-BWWG concluded that the use of the N,N-diethyl-p-phenylenediamine (DPD) colorimetric method should be the preferred method, as it is commercially available for on-board use. Furthermore, unlike other methods, non-linearity and interferences can be anticipated and mitigated and there is limited interference caused by neutralizers used in the ballast water management process. The Workshop, however, agreed that further discussion would be needed to further underpin the preferred measuring method for TRO.

The Workshop agreed that reliable TRO monitoring is one of the important points to control the Active Substance in ballast water as approved by MEPC with regard to maximum dose and maximum allowable discharge concentration. The practical application of TRO sensor(s) in BWMS is recommended to minimize possible interference from various factors on TRO monitoring. The Workshop recommended that the submitted information on TRO monitoring should include the installation and control scheme (engineering aspects) and the physical/chemical factors (including salinity and water temperature) that affect the accurate reading of TRO in automated in-line monitoring.

3.10 Environmental Acceptability of the Use of Active Substances in BWMS

The Correspondence Group involved in the revision of Guidelines (G8) raised concerns about the environmental acceptability of the use of Active Substances, particularly under extreme conditions (e.g., cold water) as all chemical reaction rates are temperature-dependent. The concerns were related to the maximum allowable discharge concentration, which may not be guaranteed under these extreme conditions as the reaction rate between the Active Substance and the neutralizer will slow down due to these conditions.

As a response to these concerns, the GESAMP-BWWG agreed at the seventh Stocktaking Workshop (MEPC, 2016a) that applicants should be urged at Basic Approval to perform a simulation of the discharge immediately after treatment (when a maximum dose of the neutralizer will be needed). The raw monitored data listed below should be provided in the application:

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

Furthermore, the GESAMP-BWWG agreed that three functions in the neutralization process are crucial for an appropriate control scheme aimed at maintaining the MADC effectively in the full-scale BWMS at all times:

- .1 an initial overdose of neutralizer against stoichiometric demands calculated from an accurate monitoring of TRO concentration prior to the neutralization process

- .2 an additional overdose of neutralizer above the one referred to in .1, to be used under extreme conditions
- .3 a proper shutdown of ballast water discharge if the MADC is exceeded.

It should be noted that the main reasons why the GESAMP-BWWG has decided not to recommend MEPC to grant Basic or Final Approval have been associated with imprecise control of the maximum allowable dose and the MADC (lack of data regarding proper function of neutralization or neutralization step not sufficiently developed, control of dose of neutralizer uncertain to allow proper control of MADC, etc.).

3.11 Disinfection By-Products

As mentioned in Section 3.6, several BWMS use oxidants to disinfect the ballast water at uptake. The disinfection by-products, DBPs, are formed when these oxidants come into contact with organic matter, including organisms, and halogen ions present in the ballast water.

3.11.1 Experience from Drinking Water Disinfection

Despite much research on disinfection by-products in drinking water over the last several years, they have only been known since the early 1970s. Rook (1974) reported the identification of the first DBPs (trihalomethanes, THMs) that are formed when hypochlorous acid and hypobromous acid react with naturally occurring organic matter water. Rook's discovery of THMs in drinking water led to research on other chemicals formed when chlorine is added to water, and to the health effects of these chemicals.

More than 600 DBPs have been identified in chlorinated tap water (Richardson, 2002). The reported DBPs belong to the groups of the trihalomethanes (e.g., tribromomethane, trichloromethane), haloacetic acids (e.g., dichloro- and trichloroacetic acid), haloacetonitriles (e.g., bromoacetonitrile and chloroacetonitrile), haloketones, haloaldehydes, and haloamides (e.g., Weinberg, *et al.*, 2002; Richardson, *et al.*, 2007).

Trihalomethanes (THMs)

THMs are halogen-substituted single-carbon compounds with the general formula CHX_3 , where X represents a halogen, which may be fluorine, chlorine, bromine, or iodine, or combinations thereof.

The THMs most commonly present in ballast water are:

- Tribromomethane (bromoform) (CHBr_3)
- Trichloromethane (chloroform) (CHCl_3)
- Dichlorobromomethane (CHBrCl_2) (BDCM)
- Dibromochloromethane (CHBr_2Cl) (DBCM).

All four THMs are volatile; volatility decreases in the order $\text{CHCl}_3 > \text{CHBrCl}_2 > \text{CHBr}_2\text{Cl} > \text{CHBr}_3$. Solubility decreases in the same order from 8 g/L for chloroform to 3 g/L for tribromomethane (Pickup, 2010 in ECHA, 2017a). The substance that is usually found in the highest concentrations in BWMS using oxidants is tribromomethane.

Haloacetic acids (HAA)

Haloacetic acids are carboxylic acids in which a halogen atom takes the place of a hydrogen atom in acetic acid.

The HAAs most commonly present in ballast water are:

- Monochloroacetic acid ($C_2H_3ClO_2$) (MCAA)
- Dichloroacetic acid ($C_2H_2Cl_2O_2$) (DCAA)
- Trichloroacetic acid ($C_2HCl_3O_2$) (TCAA)
- Monobromoacetic acid ($C_2H_3BrO_2$) (MBAA)
- Dibromoacetic acid ($C_2H_2Br_2O_2$) (DBAA)
- Tribromoacetic acid ($C_2HBr_3O_2$) (TBAA)
- Bromochloroacetic acid ($C_2H_2BrClO_2$) (BCAA)
- Dichlorobromoacetic acid ($C_2HBrCl_2O_2$) (BDCAA)
- Dibromochloroacetic acid ($C_2HBr_2ClO_2$) (DBCAA).

Haloacetic acids are relatively polar, non-volatile, water-soluble species. Solubility in water at normal temperatures is of the order of 1000 g/L for TCAA increasing to 6000 g/L for MCAA; DCAA is a miscible liquid. Octanol/water partition coefficients range from 1.33 for TCAA down to 0.22 for MCAA (Pickup, 2010 in ECHA, 2017a).

Haloacetonitriles (HAN)

Haloacetonitriles are compounds in which a methyl group (CH_3) is attached to a CN group where one or more of the hydrogen atoms are substituted by halogens (chlorine, bromine, fluorine and/or iodine).

The HANs most commonly present in ballast water are:

- Bromochloroacetonitrile ($C_2HBrClN$)
- Dibromoacetonitrile (C_2HBr_2N)
- Dichloroacetonitrile (C_2HCl_2N)
- Monobromoacetonitrile (C_2H_2BrN)
- Monochloroacetonitrile (C_2H_2ClN)
- Trichloroacetonitrile (C_2Cl_3N).

Haloacetonitriles are relatively volatile, the mono-derivatives being most volatile and other bromo-derivatives less volatile. In chlorinated drinking water, haloacetonitrile levels are typically an order of magnitude lower than THM levels, and below 5% of total halogenated by-products. The haloacetonitriles are relatively susceptible to hydrolysis, via haloacetamides to form haloacetic acids, the rate of hydrolysis rising with increasing pH and number of halogen atoms in the molecule (Pickup, 2010 in ECHA, 2017a).

Other compounds that may be formed are the haloaldehydes, whose carbon chain molecules contain the $C=O$ (carbonyl) functional group at the end of a carbon chain (aldehydes), with one or more hydrogen atoms substituted by halogens (chlorine, bromine, fluorine, and/or iodine). Often occurring in ballast water is chloral hydrate ($C_2H_3Cl_3O_2$).

The most commonly known representative of this

group is chloral hydrate (trichloroacetaldehyde), other chloro- and bromo-substituted acetaldehydes are also reported (Richardson *et al.*, 2003; 2010). Laboratory data show halogenated aldehydes can be produced by chlorinating humic and fulvic acids (Pickup, 2010 in ECHA, 2017a). Trihaloacetaldehydes hydrolyze to the corresponding THMs. Reported half-lives for haloacetaldehydes in water are 2 to 6 days at neutral pH and ambient temperatures, stability decreases as pH and temperature increases (Pickup, 2010 in ECHA 2017a).

Halogenated amines may also be formed as the result of the reaction of hypochlorous acid with ammonia. Often occurring in ballast water is monochloramine (NH_2Cl).

3.11.2 Factors that May Impact the Formation of Disinfection By-Products

Natural organic matter

Natural organic matter (NOM) is a broad term for the complex mixture of thousands of organic compounds found in water and results from natural processes in the environment, including decomposition of decaying plant and animal matter. The total quantity and chemical characteristics of NOM varies with seasonal changes in temperature and precipitation.

The dissolved part of NOM, dissolved organic matter (DOM, commonly measured as DOC), can typically be divided into aromatic and non-aromatic chemical constituents. The relative amounts of aromatic and non-aromatic constituents in natural waters vary significantly, but the aromatic type of NOM often dominates. Aromatic compounds such as humic and fulvic acids can:

- react with total residual oxidants (TRO) and produce disinfectant by-products (DBPs)
- absorb UV.

The non-aromatic constituents such as polysaccharides and fatty acids do not exhibit these properties.

Additives for DOC adjustment

With the purpose of verifying the biological efficacy of a BWMS under extreme conditions, additives such as total suspended solids (TSS), particulate organic carbon (POC) and dissolved organic carbon (DOC) may be added to test water by testing facilities (Table 4). Although it is outside of the mandate for the GESAMP-BWWG to evaluate the biological efficacy of the BWMS, the testing according to Procedure (G9) and the 2016 Guidelines (G8)/BWMS Code is being performed at the same time. Therefore, any application for Basic and/or Final Approval must contain all details of DOC, POC, TSS, organisms and augmentation material applied.

Table 4 Augmentation requirements at different salinities (IMO, 2016)

Parameter	Salinity		
	Marine water (28 – 36 PSU)	Brackish water (10 – 20 PSU)	Fresh water (< 1 PSU)
Dissolved Organic Carbon (DOC)	> 1 mg/L	> 5 mg/L	> 5 mg/L
Particulate Organic Carbon (POC)	> 1 mg/L	> 5 mg/L	> 5 mg/L
Total Suspended Solids (TSS)	> 1 mg/L	> 50 mg/L	> 50 mg/L

The 2016 Guidelines (G8)/BWMS Code includes 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” (IMO, 2016, paragraph 2.4.21). Some of the additives commonly used for augmentation of POC content are presented in Table 5.

Table 5 Substances commonly used as POC additives

POC additives
Starch
Metamucil®
Corn starch
Micromate®-micronized humate

Specification of the additive for DOC adjustment

The test water used for land-based testing, while taking into account the 2016 Guidelines (G8)/BWMS Code, is frequently used for the identification of Relevant Chemicals (for definition see 3.5.3) and toxicity testing under Procedure (G9) to avoid duplication of testing. In this regard it is important to ensure compatibility between the 2016 Guidelines (G8)/BWMS Code and Procedure (G9). MEPC 70 requested the GESAMP-BWWG to review the kind of precursors involved in the process of disinfection by-product (DBP) production and total residual oxidant (TRO) consumption (MEPC, 2016b, paragraph 4.19.3). The aim was for the GESAMP-BWWG to be able to come up with a recommendation regarding a specific additive for DOC adjustment (Table 6).

Table 6 Substances commonly used as DOC additives

DOC additives
Iced tea
Methylcellulose
Sodium citrate
Sucrose
Glucose
Lignin
Lignin sulfonate
Sodium acetate

From the viewpoint of Procedure (G9), the use of additives may have an effect on the degradation rate of the Active Substance and on Relevant Chemical production during the storage period. This is confirmed both by information from testing facilities and by the evaluation of several proposals for approval of BWMS by the GESAMP-BWWG. Differences in the concentrations of Relevant Chemicals between Basic and Final Approval have been found to result from changing additives used for increasing the DOC content. The GESAMP-BWWG discussed the matter of being able to recommend a specific additive for DOC adjustment of test waters at its eighth Stocktaking Workshop (MEPC, 2017) in February 2017, but concluded that it is not in such a position at the moment.

Literature studies published in the last 30 to 40 years have established a clear relationship between the DBP formation potential of an organic substance and its aromaticity (Edzwald, *et al.*, 1985; Reckhow, *et al.*, 1990; Fabbricino, *et al.*, 2005; Shah, *et al.*, 2015). 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. The GESAMP-BWWG is, however, also aware of research where SUVA did not correlate as well with DBP formation potential (Weishaar, *et al.*, 2003). The GESAMP-BWWG further recognized that 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.

As a conclusion, the GESAMP-BWWG stated that, while being unable to recommend any specific additive for DOC adjustment at the moment, it 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)/BWMS Code, and will request 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. Furthermore, the 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), to make the test results consistent and comparable.

The impact of time on DBP formation

The period for a test cycle in the Guidelines (G8) was five days in the first version. For practical reasons this length of time was also adopted in the first version of the Methodology for chemical identification. The formation of DBPs increase with increasing contact time of the treated water and the oxidant (Gallard and von Gunten, 2002). Figure 25 shows one exemplary data set from testing of a chlorine-based BWMS, measured over a total period of ten days. It is shown that the maximum concentration of DBPs is not reached immediately, but that a rather fast increase in the initial phase of disinfection is followed by a phase that can be interpreted either as a very much reduced increase, or a plateau, or perhaps also a slow decline of DBP concentrations (Werschkun, 2012).

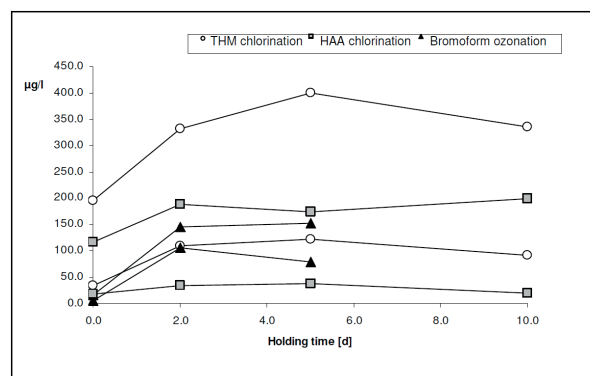


Figure 25 Impact of holding time on DBP formation (Werschkun, 2012)

At its sixth Stocktaking Workshop (MEPC, 2015) the Group took a preliminary look at chemical data provided by applicants in the past years and found that the data indicated that the concentrations of several analysed Relevant Chemicals (for definition see 2.3.3) were still increasing with time in the tests done with treated ballast water; that is, the highest concentrations of RCs were in many cases found on day 5, at the end of the storage period (Table 7).

A series of 10 chemical data sets were compared and relative concentrations (expressed as percentage of day 0 values) were calculated. Mean values for all compounds and all sampling periods are reported in Table 7. In most cases, concentrations are higher at days 1, 2 and 5 than at day 0 (which is set to 100%). The results indicate that secondary oxidants persist in treated ballast water for hours and days, and are still producing some organic Relevant Chemicals such as bromoacetonitrile, dichlorobromomethane and tribromoacetic acid. The data presented also shows that the increase is particularly clear for tribromomethane.

Table 7 Relative concentrations (%) of main Relevant Chemicals in treated ballast waters with time compared to day 0. Mean values are obtained from 10 chemical data sets provided by various applicants in non-confidential applications. 'N' signifies the number of values

Chemical name	Day 0 (%)	Day 1 (%)	N	Day 2 (%)	N	Day 5 (%)	N
Bromate ion	100	254	7	119	4	131	9
Bromoacetonitrile	100	333	4	114	2	336	6
Bromochloroacetic acid	100	349	6	163	5	180	8
Bromochloroacetonitrile	100	219	3		0	148	3
Bromodichloroacetic acid	100	66	1		0	11	1
Bromodichloroacetonitrile	100	283	1		0	1	1
Chlorate ion	100	102	3	98	3	100	3
Chlorodibromoacetic acid	100	141	1		0	148	1
Dibromoacetic acid	100	305	7	291	4	332	9
Dibromoacetonitrile	100	90	5	124	2	91	7
Dibromochloroacetic acid	100	156	5	127	4	108	7
Dibromochloromethane	100	197	8	701	5	408	10
Dichloroacetic acid	100	158	3	180	2	201	4
Dichloroacetonitrile	100	2	2		0	2	2
Dichlorobromoacetic acid	100	93	3	183	4	258	5

Chemical name	Day 0 (%)	Day 1 (%)	N	Day 2 (%)	N	Day 5 (%)	N
Dichlorobromomethane	100	130	6	1567	4	470	8
Tribromoacetic acid	100	289	6	285	4	373	8
Tribromoacetonitrile	100	173	2		0	269	2
Tribromomethane	100	268	8	250	5	388	10
Trichloro(nitro)methane	100		0	839	1	462	1
Trichloroacetic acid	100	115	5	166	3	138	7
Trichloromethane	100	69	3	827	3	439	4

The **bold** values show the maximum mean value from different samples after tank holding time (one, two and five days).

The GESAMP-BWWG nevertheless came to the conclusion that the concentrations of Relevant Chemicals formed after a prolonged period in the ballast tank (i.e. > 10 days under ambient temperature) were more strongly linked to the size of the dose of Active Substance and the nature of the specific DOC than time. The conclusion being that, at the present moment, no scientific justification based on kinetics supports either a shorter or a longer storage period than 5 days. The GESAMP-BWWG did, in other words, not find any reason to deviate from the existing requirement for a storage period of 5 days, however since the period for a test cycle in the 2016 Guidelines (G8)/BWMS Code was changed to be variable, to fit the geographical location of the test facility, an additional paragraph had to be added to take into account the need for sufficient volumes of test water to be made available for the test sample for day 5, in accordance with the requirements of Procedure (G9) and the Methodology.

The impact of temperature on DBP formation

With respect to temperature, there are no specific requirements either in the 2016 Guidelines (G8)/BWMS Code or Procedure (G9). As the volume of the tank for 2016 Guidelines (G8)/BWMS Code testing at Final Approval should be more than 200 m³, temperature control on test water at Final Approval is impractical. Therefore, the GESAMP-BWWG has accepted raw concentrations of Relevant Chemicals without any adjustment with regards to temperature, which may vary in the range from 4 – 30 °C. Several applicants have submitted data on the concentrations of Relevant Chemicals under varied conditions both concerning tank holding time and temperature. The data indicate that the variation of Relevant Chemical concentrations due to temperature is unclear, and rather depend on the various physicochemical properties of the Relevant Chemicals.

Neutralization process and DBP formation

Active carbon treatment of disinfected water prior to discharge effectively reduces DBP levels. DBPs are, however, not inactivated by the use of sulphur reductants. Even after removal of the oxidizing agents, the DBPs remain in the discharged water after the neutralization step.

Evaporable DBPs may decrease in the mixing process with air bubbles, even if they hardly react with the neutralizer. Furthermore, the GESAMP-BWWG has observed that several Relevant Chemicals in the µg/L order of concentration may react partially with the neutralizer, provided that it had been over-dosed significantly against stoichiometric demands of Active Substance in the mg/L order.

3.12 Information Gathered by the GESAMP-BWWG Regarding Chemicals Associated with BWMS and the Development of the Database

At its first Stocktaking Workshop in 2009 (MEPC, 2009a), the GESAMP-BWWG identified a list of more than 70 disinfection by-products which had been assessed in the applications of various ballast water management systems. An Excel spreadsheet 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 list, the Workshop identified, as a first step, 18 chemicals believed to pose a potential risk to the environment as well as to exposed humans. The remaining chemicals reported were usually present 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 (MEPC, 2011). 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 (MEPC, 2013b), 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. Recently, a few chemicals were added (chlorate ion, isocyanuric acid and sodium sulfite) while some substances have been deleted (sodium bromate and potassium bromate have been replaced by bromate ion). The current number of chemicals is 44 (Table 8), and data for these substances can be found in the online *GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water* (<https://gis.imo.org/>). The revised GESAMP-BWWG Database was presented at MEPC 70 in November 2016, and in the report of the meeting applicants and Administrations were encouraged to make use of the online version of the GESAMP-BWWG Database.

Table 8 The chemicals in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water

Chemical name	CAS-number
Acetaldehyde	75-07-0
Bromate ion	15541-45-4
Bromochloroacetic acid	5589-96-8
Bromochloroacetonitrile	83463-62-1
Chloral hydrate	302-17-0
Chlorate ion	14866-68-3
Chloropicrin	76-06-2
Dalapon	75-99-0
1,2-dibromo-3-chloropropane	96-12-8
Dibromoacetic acid	631-64-1
Dibromoacetonitrile	3252-43-5
Dibromochloroacetic acid	5278-95-5
Dibromochloromethane	124-48-1
1,1-dichloroethane	75-34-3
1,1-dibromoethane	557-91-5
Dibromomethane	74-95-3
Dichloroacetic acid	79-43-6
Dichloroacetonitrile	3018-12-0
Dichlorobromoacetic acid	71133-14-7
Dichlorobromomethane	75-27-4
1,2-dichloroethane	107-06-2
Dichloromethane	75-09-2
1,2-dichloropropane	78-87-5
Formaldehyde	50-00-0
Isocyanuric acid	108-80-5
Monobromoacetic acid	79-08-3
Monobromoacetonitrile	590-17-0
Monochloroacetic acid	79-11-8
Monochloroacetonitrile	107-14-2
Monochloroamine	10599-90-3
Sodium sulfite	7757-83-7
Sodium hypochlorite	7681-52-9
Sodium thiosulphate	7772-98-7
Tetrachloromethane	56-23-5
Tribromoacetic acid	75-96-7
Tribromomethane	75-25-2
2,4,6-tribromophenol	118-79-6
Trichloroacetic acid	76-03-9
Trichloroacetonitrile	545-06-2
Trichloroethene	79-01-6
1,1,1-trichloroethane	71-55-6
1,1,2-trichloroethane	79-00-5
Trichloromethane	67-66-3
Trichloropropane	96-18-4

3.13 A Possible Kinetic Model to Predict Formation of DBPs

The GESAMP-BWWG has investigated the possibility of using a model that could predict the formation of DBPs using different oxidants (MEPC, 2015). The aims were the following:

- to develop and validate kinetic models to predict the behaviour of different oxidants in seawater
- to investigate, in conjunction with these models, the formation of DBPs in seawater
- to identify a minimal test programme for the kinetic modelling of DBP formation in seawaters.

Prof. Urs von Gunten (ETH Zürich) was invited to the sixth Stocktaking Workshop (MEPC, 2015) 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 the GESAMP-BWWG. The results from the further development of the model have since been published (Shah, *et al.*, 2015).

3.14 Contaminated Source Water

Over the years, the GESAMP-BWWG has encountered situations where the source water used to conduct the required tests had been contaminated. The result of such a situation is that the PEC/PNEC ratio for the control water itself may exceed 1, that is, discharge of non-treated ballast water could lead to a potentially hazardous situation for 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 acceptable quality (MEPC 64/23) according to the quality plan.

Experiences gained and lessons learned

At the seventh Stocktaking Workshop, the GESAMP-BWWG concluded that a change in the concentration of DBPs between Basic and Final Approval has appeared to be the result of changes made in the additives to increase the DOC content between testing at BA and FA. This observation is confirmed both by information from testing facilities and by the Group's own experience.

The GESAMP-BWWG has investigated the impact of different additives (DOC) on the DBP production with the aim of being able to recommend a suitable DOC source for testing of ballast water.

The conclusion at the eighth Stocktaking Workshop was that the 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)/BWMS Code and will request 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.

The GESAMP-BWWG has also investigated the importance of time on the formation of DBPs with the purpose of finding justification for keeping the current time points for the characterization of concentrations of chemicals. The conclusion was that there is no reason to propose either a longer or shorter storage period since the concentrations would rather be linked to the dose of Active Substance and the specific source of DOC used.

4 THE GESAMP-BWWG RISK ASSESSMENT: A TIERED APPROACH

The general risk assessment process is depicted in Figure 26. There are 2 important routes distinguished: the upper route gives the hazard identification based on toxicological information, while in the lower route the exposure assessment is indicated. The exposure is based on the dose of the substance under consid-

eration and its physico-chemical characteristics. The ratio of exposure and hazard defines the risk assessment quotient: PEC/PNEC for the environment and PEC/DNEL or PEC/DMEL for the human health assessment. Each step may be refined to represent more realistic situations: the tiered approach.

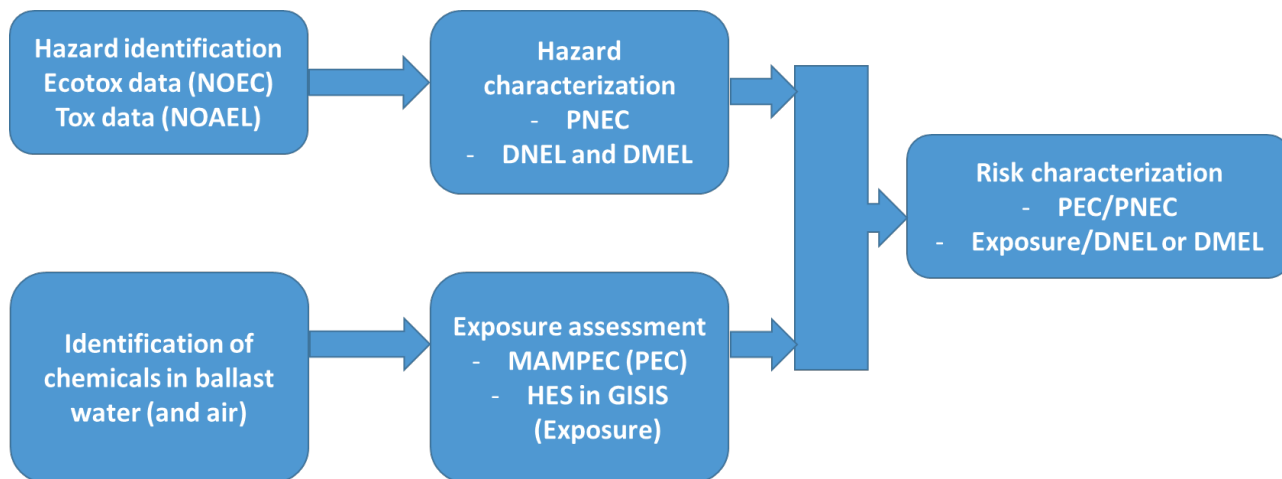


Figure 26 Steps in the risk assessment approach

4.1 Identification of Chemicals Associated with each BWMS

For each BWMS the following information is provided by the applicant; and an example is shown in Table 9:

- Chemical identity of Active Substances
- Chemical identity of Preparations
- Any other Relevant Chemicals including those that may be formed during or after application of the BWMS.

Table 9 Different types of chemicals associated with BWMS

Type of chemical	Example
Active Substance (AS)	Ozone
	Sodium dichloroisocyanurate (NaDCC)
Relevant chemicals (RC)	Trihalomethanes (tribromomethane)
	Trihaloacetic acids (tribromoacetic acid)
Other chemical (OC)	Sodium thiosulfate

For the chemicals associated with the BWMS, the applicant performs a chemical analysis using three different salinities. According to the 2016 Guidelines (G8)/BWMS Code, the salinities of the test water should be in the following ranges: < 1 PSU (fresh water), 10 – 20 PSU (brackish water) and 28 – 36 PSU (marine water).

For the risk assessment on human health and the environment, the applicant has selected the substances that have been detected in a concentration above the detection limit from the full chemical analysis for all three salinities (Table 10). These substances are considered the Relevant Chemicals (RCs) for the BWMS.

Table 10 Chemical analysis of treated ballast water in different salinities

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

The GESAMP-BWWG uses two worst-case concentrations of chemicals, 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 11.

Table 11 Selected (Active Substances and) Relevant Chemicals and maximum concentrations for further risk assessment

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

The GESAMP-BWWG selects the maximum concentrations that have been identified for each chemical, as these concentrations represent the worst-case scenario, and use these when it performs its own risk assessment for environmental and human health. 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). The GESAMP-BWWG requests the applicant to try to achieve as low as possible detection limits.

4.2 Data Requirements for Hazard Identification

For all chemicals identified (Active Substance(s), Relevant Chemicals and Other Chemical(s)) that are associated with each BWMS the applicant provides a dataset containing information on the general endpoints (Table 12) and the more detailed information contained in Annex II, Table II.3. However, if the chemicals are already part of the Database mentioned in Section 3.12, no additional information needs to be provided.

The description of chemicals includes a dataset including the following:

- Physical and chemical properties
- Mammalian toxicity
- Environmental fate
- Environmental effects.

Table 12 General endpoints for identified chemicals (appendix 3, Methodology)

Toxicological endpoint	Description
Acute ecotoxicity	At least 3 species from different trophic levels
Chronic ecotoxicity	At least 3 species from different trophic levels
Acute toxicity	Systemic effect (the effect occurs in the body after the chemical 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

4.2.1 Screening with Regard to PBT and CMR Properties

Following production of this information, an effect assessment should be presented that includes screening for the following properties:

- Persistency, bioaccumulation and toxicity (PBT)
- Carcinogenicity, mutagenicity and reproductive toxicity (CMR).

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

Persistence (P)

Persistence (P) deals with the degradation of a substance. Substances that rapidly degrade are quickly removed from the environment. While effects of such substances can occur, particularly in the event of a spillage or accident, they are localized and of short duration.

The degradation of a substance is important to take into consideration since substances that are degraded slowly linger in the environment for a long time. The degradation of a substance often takes place stepwise and may happen either through the action of microorganisms (biodegradation), chemically (hydrolysis) or due to impact of sun light (photolysis). In the absence of rapid degradation in the environment, a substance in the water has the potential to persist. One way to find out whether a substance is biodegradable or not, is to measure its "Biological Oxygen Demand" (BOD), that is the biological consumption of oxygen via degradation. BOD may be measured through the means of different OECD tests (such as Test Guidance 301C (OECD, 1992) and Test Guidance 302C (OECD, 2009). Another way to find out the inherent ability to become biodegraded is to measure the difference between the BOD over 5 days and the Chemical Oxygen Demand (COD). In this test the difference between the consumption of oxygen when the substance is degraded by microorganisms

versus the consumption of oxygen when the substance is oxidized is measured. A BOD(5 days)/COD ratio ≥ 0.5 is considered as indicative of rapid degradation. Thus, a substance which passes this screening test is considered likely to biodegrade 'rapidly' in the aquatic environment, and is thus unlikely to be persistent.

Bioaccumulation (B)

A simple way to measure whether a substance has a tendency to bioaccumulate, that is, accumulate in living organisms or not, is to measure the solubility of a substance in an organic fluid versus its solubility in water. Generally, the tendency to bioaccumulate increases as the solubility in fat increases. A simple test may be performed where the substance is blended with a mixture of water and n-octanol. The concentration of the substance in alcohol versus water is then measured when the two phases of alcohol and water have separated and are at equilibrium. The ratio between the two concentrations is referred to as the partition coefficient K_{ow} (or P_{ow}). This ratio is a measure for the difference in solubility of the compound in the two phases (alcohol and water). Bioaccumulation may also be measured as the bioconcentration factor (BCF) which is determined experimentally. The bioconcentration factor shows the ability of the substance to accumulate in an aquatic organism and is depicted as the ratio of the concentration of the substance in the organism and the concentration of the substance in the surrounding water.

Toxicity (T)

Acute aquatic toxicity

Acute aquatic toxicity is the ability of a substance to cause harm to aquatic organisms from short-term exposure. A substance is considered to be acutely toxic if by its direct action it kills 50% or more of the exposed population of test organisms in a relatively short period of time, such as 48 – 96-h (typically 48-h for crustaceans, 72-h for algae and 96-h for fish). Three different species representing three different trophic levels are used as surrogates for all aquatic organisms (see Section 4.6.1).

Chronic aquatic toxicity

Chronic aquatic toxicity is the ability of a substance to cause harm to aquatic organisms after long-term exposure. A substance is considered to be chronically toxic if the no-observed-effect-concentration (NOEC) over the duration of the chronic toxicity test is less than 0.01 mg/L (Table 13). The test duration for a chronic test is typically 4 days for algae, 14 days for crustaceans and 28 days for fish.

PBT evaluation

Based on the half-life, BCF or Log K_{ow} and the chronic NOEC values for each chemical (Procedure (G9), paragraph 6.4) (Table 13), the PBT properties of each chemical are assessed.

Table 13 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, $\text{Log } P_{ow} \geq 3$
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 are reflected in a table with the justification in parentheses according to Table 14.

Table 14 Reporting of PBT properties of selected Chemicals

Chemical name	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

It should be noted that the resulting PBT-score only results in a 'yes' if all three categories score a 'yes'. In other words, the chemical is considered to be a "PBT substance" if all three criteria is fulfilled. As a consequence of a substance being PBT, the BWMS producing such a chemical cannot be approved.

4.2.3 Assessment of Carcinogenicity (C), Mutagenicity (M) and Reproductive Toxicity (R)

As part of the hazard identification, a screening on carcinogenicity, mutagenicity, and reproductive toxicity is carried out. Each chemical is 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 in Table 15.

Table 15 Reporting of CMR properties for selected Chemicals

Chemical name	Carcinogenic (Yes/No)	Mutagenic (Yes/No)	Reproductive Toxicity (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

It should be noted that if an item scores a 'yes' on one of these items, the resulting CMR-score is also a 'yes'. If the screening results indicate concerns, this should

give rise to a further effect assessment. For chemicals that are non-threshold carcinogens a DMEL should be established as described below (Section 4.3.2).

4.3 Hazard Characterization – Establishing the Guidance Levels for the Chemicals

Based on the information presented in the dataset a hazard characterization is performed with the aim of establishing guidance levels above which no adverse effects to the aquatic organisms or humans is expected. For aquatic organisms this value is called the PNEC and for humans it is called the derived no effect level (DNEL) or in the case of non-threshold carcinogens (DMEL).

4.3.1 Predicted No Effect Concentrations (PNEC)

For the assessment of effects to the aquatic environment, appropriate PNEC values have to be derived. A PNEC is typically derived at a level that, when not exceeded, protects the aquatic ecosystem against toxic effects of long-term exposures. However, for situations where only short-term exposures are expected, an additional PNEC for short-term (or near-ship) exposure are useful.

PNEC values are normally derived from preferably chronic and/or acute aquatic toxicity results for relevant aquatic species by dividing the lowest available effect concentration by an appropriate assessment factor intended to provide a margin of safety. For the aquatic effect assessment, the assessment factors given in Table 16 provide guidance although these may be altered on a case-by-case basis based on expert judgement. In cases where a comprehensive data-set is available, the PNEC may be derived with a mathematical model of the sensitivity distribution among species. It should be noted that, for acute studies with especially algae and daphnids, it is not always possible to determine whether or not the organism is already dead. Therefore, the distinction L (lethal) or E (effect) is used in the result of the test. So, L(E)C₅₀ means the 50% lethal or effect concentration.

Table 16 Assignment of Assessment Factors (AF) used for deriving PNEC values

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

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

The proposed PNECs based on the available ecotoxicological data, including the final assessment factors to establish the PNEC, are reported in the submission for Active Substances and for all Relevant Chemicals found in a concentration above the detection limit (Table 17). The PNEC values will be used in the environmental risk assessment for the calculation of the PEC/PNEC ratios. In the case where the substances

are among the 44 chemicals in the *GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water* only the PNEC values are reported. The currently used PEC_{harbour} and $PNEC_{\text{nearship}}$ for the DBPs considered are listed in Annex V. Due to potentially new data received in the future, these PNECs may change, and the GESAMP-BWWG database should be checked for up-to-date values.

Table 17 PNEC values of Chemicals associated with the BWMS and included in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water

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

For substances that are not among the 44 chemicals in the GESAMP-BWWG Database, the PNEC values and

the corresponding Assessment Factor used from Table 16 have to be reported (Table 18).

Table 18 PNEC values of Chemicals associated with the BWMS, not included in the GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water

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

4.3.2 Derived No-Effect level (DNEL) and Derived Minimal-Effect Level (DMEL)

For assessment of effects on humans, appropriate derived no-effect levels (DNELs) should be established, and derived minimal-effect levels (DMELs) should be determined or selected. In assessing an acceptable level of a particular substance, the procedure usually follows moving from available toxicological data giving a no-observed-adverse-effect level (NOAEL) or a lowest-observed-adverse-effect level (LOAEL) to deriving an exposure limit above which humans should not be exposed (DNEL). Assessment factors (AFs) have to be taken into account to allow for extrapolation from experimental data to real human exposure situations.

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. The currently used DNELs for the DBPs considered are listed in Annex V. Due to potentially new data received in the future, these DNELs may change, and the GESAMP-BWWG database should be checked for up-to-date values.

However, in the case of non-threshold carcinogens a DMEL should be determined. Cancer risk levels of 10^{-4} to 10^{-6} from internationally recognized bodies, corresponding to a risk for cancer in 1 per 10,000 or 1,000,000 exposed individuals, are normally seen as indicative tolerable risk levels, for example when setting guideline values for drinking water quality (WHO, 2001). In the GESAMP-BWWG risk assessment the figure 10^{-5} , that is, a risk for cancer in 1 per 100,000 exposed individuals, is applied for the selection of DMELs. The currently used DMELs for the DBPs considered are listed in Annex V. Due to potentially new data received in the future, these DMELs may change as well, and the GESAMP-BWWG database should be checked for up-to-date values.

The proposed DNELs and DMELs are reported by the applicant in the submission for Active Substances and for all Relevant Chemicals found in a concentration above the detection limit (Table 19). The DNEL/DMEL values will be used in the human risk assessment for the calculation of the Risk Characterization Ratios (RCRs). In the case where the substances are among the 44 chemicals in the GESAMP-BWWG Database the existing DNEL/DMEL values are reported. For additional substances, the applicant derives a DNEL or DMEL value, that will be approved by the GESAMP-BWWG.

Table 19 DNELs and DMELs to be used in the risk assessment for humans

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

4.4 Exposure assessment

4.4.1 MAMPEC-BW Model for PEC Calculation for Ballast Water

The highest concentrations of chemicals present in

the discharge ballast water are used to estimate the exposure to the environment by using MAMPEC-BW. The calculated concentrations from MAMPEC-BW are PECs. Two scenarios are being used in the GESAMP-BWWG risk assessment; the harbour and the near ship scenario (Table 20).

Table 20 PEC from MAMPEC-BW modelling results from the GESAMP-BWWG Model Harbour for the harbour and near ship scenario

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

MAMPEC-BW is a model to predict environmental concentrations of chemicals in the aquatic environment. MAMPEC was originally developed to predict environmental concentrations (PECs) for the exposure assessment of antifoulants in harbours, rivers, estuaries and open water. MAMPEC is a steady-state, 2D-integrated hydrodynamic and chemical fate model (van Hattum, *et al.*, 2002, 2016).

The MAMPEC-BW model was adapted for exposure assessment of chemicals discharged from ballast water treatment systems and has the same features as MAMPEC. Before 2011 MAMPEC was used on a voluntary basis by a number of applicants (summarized in Zipperle, *et al.*, 2011). On the request of the GESAMP-BWWG and IMO, a special standardized version of MAMPEC-BW for ballast water was created (MAMPEC-BW v3.0) in 2011, with a dedicated environment, a compound and an emission scenario.

Currently the model is part of the evaluation methodology for Basic and Final Approval by the Marine Environmental Protection Committee (MEPC) of IMO, based on the recommendations of the GESAMP-BWWG. See Annex III for a detailed description.

The environmental screen of MAMPEC-BW, latest version, for ballast water includes a default GESAMP-BWWG Model Harbour, with specifications and dimensions decided by the GESAMP-BWWG during the third Stocktaking Workshop (MEPC, 2011). This is one of the mandatory environmental scenarios that applicants need to use.

The GESAMP-BWWG Model harbour

The GESAMP-BWWG Model harbour was derived from the OECD-EU Commercial Harbour, but with a lower hydrodynamic exchange (32% per tidal cycle), due to a lower mouth width of the harbour (1000 m compared to 2500 m in the OECD-EU Commercial Harbour) and a slightly increased pH (from 7.5 to 8.0). It is assumed to represent an average-sized European harbour. The total area of the harbour is about 25% of the Port of Rotterdam. The dimensions were discussed during the stocktaking meetings of the GESAMP-BWWG during Stocktaking Workshops one and two in 2009 (MEPC, 2009a and MEPC, 2010a) and the third Stocktaking Workshop in 2011 (MEPC, 2011).

Data for the 44 chemicals in the GESAMP-BWWG Database included in MAMPEC-BW

MAMPEC-BW includes 44 chemicals in the online *GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water* (<https://gis.imo.org/>). For a number of chemicals, data on biodegradation, hydrolysis, and photolysis rates have been added to the system. However, in the Tier 1 risk assessment made by the GESAMP-BWWG a worst-case assumption of no degradation is implemented.

The original 18 chemicals, with an additional 25 chemicals added in version 3.0.1, are included as default entries in the database and cannot be changed by the user. However, copies of the compounds can be edited and saved under a different user-defined name. The update with the latest chemicals has not (yet) been included in MAMPEC's internal database. MAMPEC-BW features an emission screen, allowing specification of the ballast water discharge rate (in m³/d) and the concentration of the target compound (in mg/L). The

input to MAMPEC-BW is the actual emission rate of the substance in the GESAMP-BWWG model harbour. For further details, including download instructions and operation manual, see Annex III.

4.4.2 Human Exposure Scenarios (HES)

Ships' crew members and/or port State control officers represent the type of humans who 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.

The highest concentrations of chemicals present in the ballast water in the tanks are used to estimate the exposure to humans. The concentration in the ballast water is used directly to estimate the dermal exposure (uptake via skin), and the concentration in the air (head space of ballast water tanks) may be calculated by making use of the Henry's law constant (HLC). These two concentrations are then used to estimate the exposure in the human exposure scenarios (HES).

Operations involving the crew and/or port State control officers

The human exposure scenarios that have been identified and established at the GESAMP-BWWG Stocktaking Workshops are described in Table 21.

Table 21 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 <i>Gases/vapours/dusts, inhalation: scenario to be developed</i>
Ballast water sampling at the sampling facility	Inhalation of air released	2 hours/day for 5 days/week;
	Dermal exposure to primarily hands	45 weeks/year
Periodic cleaning of ballast tanks (Figure 26)	Inhalation of air in the ballast water tank	8 hours/day for 5 days/week;
	Dermal exposure to the whole body	1 event/year
Ballast tank inspections (Figure 25)	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

The equations for the estimation of exposure in all scenarios are described in more detail in Annex II of this report. Furthermore, all scenarios are implemented in the *GESAMP-BWWG Database of chemicals most commonly associated with treated ballast water* (<https://gis.imo.org/>). The Database calculates the exposure as the resulting body burden (mg/kg bw/d) from the aggregated exposure through inhalation and dermal contact (ECHA, 2017b) as applicable in each scenario. Some examples are shown in the Figures 27 and 28.



Figure 27 Sampling on board, inspecting a double bottom tank (D. Smith)



Figure 28 Crew cleaning ballast water tanks (D. Smith)

Exposure scenarios involving the general public

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)

a harbour where the ballast water was discharged. 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 22. The aggregated exposure approach (ECHA, 2017b) is applied in this case as well.

Table 22 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)		

For the human exposure scenarios associated with exposure of the general public, the PEC values from MAMPEC-BW (harbour scenario and/or surrounding area) are used. 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, 2009a; MEPC, 2010a; MEPC, 2011; MEPC, 2013b; MEPC, 2014; MEPC, 2015; MEPC, 2016a; and MEPC, 2017). Also for the general public, further details are given in Annex II.

4.5 Risk Characterization

4.5.1 PEC/PNEC

The ratio between the resulting PEC for the harbour and for the area close to the ship from the MAMPEC-BW calculation, and the corresponding predicted no-effect concentration (PNEC), is calculated, and where the result is below 1, the assumption is that no unacceptable risk will result from exposure to that chemical. For each chemical associated with the BWMS, the estimation of the PEC/PNEC ratio is summarized as shown in Table 23.

Table 23 PEC/PNEC ratios

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

At the Basic Approval evaluation stage, the PEC/PNEC evaluation prevails over the laboratory ecotoxicity tests. However, the GESAMP-BWWG generally accepts that the PEC/PNEC ratios for some chemicals exceed 1. The applicant is nevertheless encouraged to address this point in any future application for Final Approval. At the Final Approval evaluation stage the results of the WET tests are regarded to be of higher importance, such that in the case where results from the WET tests only show slight toxic effects, PEC/PNEC ratios above 1 may be acceptable. See further Section 4.6.4.

4.5.2 Exposure/DNEL or DMEL

The risk characterization ratio (RCR) is calculated while dividing the resulting exposure from the human exposure scenarios with the DNEL and/or DMEL with the assumption that where the result is below 1, no unacceptable risk will result from the exposure to that chemical.

4.5.3 Dose Addition Approach

Since the development of the first list of unit operations in 2008, the GESAMP-BWWG has continued to elaborate the details of the human risk assessment process. The latest development has been the introduction of the dose-addition approach, which is aimed at addressing mixture toxicity.

Treated ballast water frequently contains mixtures of several potentially carcinogenic DBPs. One possible way to deal with this situation is to adopt an established international risk assessment approach (known as “grouping” or “dose addition”; Kortenkamp, *et al.*, 2009) that 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 one “assessment group”. The RCR for an assessment group is calculated by the addition of all RCRs of the individual components:

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

For the group RCR the same conclusions apply as described above, that is if the RCR < 1, the exposure is deemed to represent no unacceptable risk. The GESAMP-BWWG has discussed the possibility of applying the dose-addition approach to substances classified as mutagens and reproductive toxicants. However, no firm decision has been reached to date. The approach in the human exposure risk assessment is further described in Annex II of this report.

4.6 Ballast Water Testing

4.6.1 Aquatic Organisms from Three Trophic Levels

The environmental risk assessment aims at making sure that the discharge water from the BWMS does not cause harm to aquatic organisms. Since it is impossible to test the response to discharged ballast water of all types of aquatic organisms, species representing three different trophic levels (see Section 1.2.1) and taxa, namely algae, crustaceans and fish, are used for toxicity assessment (see Section 4.6.3). The Methodology defines the preferred species to allow for a comparison between different BWMS.

4.6.2 WET Tests

The most important part of the material that the applicants submits to the GESAMP-BWWG is the results from the whole effluent test (WET) as part of the Final Approval submission. In general terms, risk assessment deals with one substance at a time when in reality, aquatic organisms are exposed to a mixture of substances. The advantage of toxicity testing on the ballast water discharge (the whole effluent test) is that it integrates and addresses the potential aquatic toxicity of the Active Substance, any Preparations, including any of its components (e.g., decomposed chemicals like isocyanuric acid), and Relevant Chemicals formed during and after application of the BWMS (such as DBPs from electrolysis systems).

4.6.3 Laboratory Toxicity Test with Treated Water (for Basic Approval) or WET Tests (for Final Approval)

Algae are generally considered to be the most sensitive species in ecotoxicity tests with treated ballast water. The GESAMP-BWWG recognized that adverse effects of treated water on algal growth are frequently reported in proposals submitted for Basic Approval and/or Final Approval.

For Basic Approval, ecotoxicity testing is performed in the laboratory using a sample prepared by simulation of the BWMS. It is required that the residual toxicity of treated ballast water is assessed in marine, brackish and fresh water to provide certainty as to acceptability when the treated water is discharged, because discharge of ballast water may occur in all three salinities. Therefore, risk assessment in three salinities is needed. Any limitations as to environmental acceptability should be clearly indicated in the submission. Water that has been assayed for Relevant Chemicals (RC) is used for ecotoxicity testing at Basic Approval. At Final

Approval the WET tests are performed with samples of ballast water treated with the BWMS from the land-based test setup.

Acute aquatic toxicity

Short-term L(E)C₅₀ tests are performed using freshwater or marine representatives of three taxa (algae, crustacea and fish), representing three trophic levels, and internationally standardized toxicity tests (e.g., algae, Growth Inhibition Test (OECD, 2011), *Daphnia* sp., Acute Immobilization Test (OECD, 2004), fish, Acute Toxicity Test (OECD, 1992a), and algae, Growth Inhibition Test (ISO, 2016e), *Daphnia*, Inhibition of Mobility (ISO, 2012b), fish, acute lethal toxicity (ISO 1996a or 1996b), and mysid shrimp acute toxicity test (Guideline 850.1350 (US EPA, 1996)). To reduce uncertainty, applicants should, preferably, also submit data for two additional marine taxa (e.g., echinoderms, molluscs).

Acute aquatic toxicity data should be provided for:

- Preparations including any of its components
- Active Substances
- Relevant Chemicals
- Discharged ballast water.

For algal toxicity testing, it is recommended that:

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

Chronic aquatic toxicity

Long-term NOECs or EC₁₀ from three freshwater or marine species representing three trophic levels (normally algae and/or Crustacea and/or fish), using internationally standardized tests (e.g., algae (OECD, 2011), *Daphnia* (OECD, 2012), fish (OECD, 2013, 1998, 2000), algae (ISO 2016e), rotifer (ISO, 2008), and fish (ISO, 1994) are generally acceptable). To reduce remaining uncertainty, applicants should preferably also submit two long-term NOECs from additional marine taxa (e.g., echinoderms, molluscs).

⁴ Recent taxonomic reviews have resulted in new identification of *Skeletonema costatum* in *Skeletonema* sp. (refer to ISO, 2016e).

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

Such chronic aquatic toxicity data should be provided for:

- Preparations including any of their components
- Active Substances
- Relevant Chemicals
- Discharged ballast water (fish, invertebrate, plant).

For the chronic aquatic toxicity testing using discharged ballast water, based on the experience gained in the evaluation process of BWMS, it has been shown that, where the BWMS uses an Active Substance that can be characterized as TRO, there is no need to evaluate the results of chronic ecotoxicity testing using

discharged ballast water. This is because the levels of Relevant Chemicals, such as THMs and HAAs, have been found to remain in similar concentration ranges that lead to PEC/PNEC ratios < 1 . It is also recognized that with these types of BWMS, Relevant Chemicals other than the range of well-known chlorinated and brominated low molecular weight substances are not produced. Therefore, it is considered appropriate that such BWMS could fully be evaluated at Basic Approval without the results of chronic ecotoxicity testing. Also, from a pragmatic standpoint, the submission of WET tests on growth inhibition using algae (plants) and acute toxicity for invertebrates and fish would provide adequate safeguards for the environment.

In the submission for Basic and Final Approval the results from the ecotoxicity tests/WET tests are reported as shown below.

- A description of the tests carried out
- A table of the results, e.g., as shown in Table 24.

Table 24 Ecotoxicity test/ WET test reporting

Test	Test organism	Salinity (PSU)	Endpoints (%)			References / Guidelines
			NOEC ¹	L(E)C ₁₀ ¹	L(E)C ₅₀ ¹	
Growth inhibition	Alga 1					
	Alga 2 ²					
Acute	Crustacean			NA		
	Fish			NA		
Chronic ³	Crustacean				NA	
	Fish				NA	

¹ Determine all parameters according to the type of test

² The second algae test organisms is needed only for marine water

³ The chronic tests may be omitted according to the Methodology

Validity criteria

During evaluation of ecotoxicity tests/WET tests with discharged ballast water, both applicants and the GESAMP-BWWG have recognized that the most sensitive test organisms are algae. Therefore it is very important that the algal growth inhibition tests fulfil the validity criteria to allow for appropriate evaluation of the ecotoxicity of the discharge ballast water. At the fourth Stocktaking Workshop (MEPC, 2013b), the GESAMP-BWWG agreed that algal growth inhibition tests need to

meet the validation criteria to allow for appropriate evaluation of the ecotoxicity of treated ballast water. The validity criteria for algal toxicity growth tests, including calculation of mean coefficient of variation (mCV), as outlined in Guideline OECD Test Guidance 201 (calculation of mean coefficient of variation (mCV) section-by-section), were subsequently added to the Methodology (BWM.2/ Circ.13/ Rev.3, Paragraph 6.2.1.4). If applicants use another guideline than OECD201 (OECD, 2011), e.g., ISO10253 (ISO, 2016e), often the quality criteria are missing or wrongly calculated.

Experience gained and lessons learned

In cases where the selection, and/or preparation, of test water is questionable, the ecotoxicity data are unreliable. In such cases only preliminary conclusions may be made with regard to the environmental acceptability of a BWMS since the ecotoxicity of the test water may not represent the actual case that will take place in the discharged ballast water.

Validity criteria for algal ecotoxicity testing are often not met. The tests commonly classified as not Valid are related to the criteria required for the control culture of the algae:

- a greater than 16-fold growth rate
- a mean coefficient of variation (mCV) for section-by-section growth rate lower than 35 per cent (if the test duration is 3 days).

Both criteria are crucial to ensure that the growth of the test species in the control is maintained in a constant exponential growth phase throughout the exposure period, and not in a lag-phase. If the growth of the control is partially in a lag-phase, it is not appropriate to determine relevant parameters by using a usual computerized statistical method. In principle, the non-valid test should be re-performed, or a close examination of the growth curves should be carried out.

4.6.4 Hierarchy of the Environmental Risk Assessment

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

Table 25 gives an overview of the different data available at Basic Approval and Final Approval in relation to their risk assessment possibilities.

Table 25 Overview of data availability and risk assessment possibilities

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

¹ MDL = maximum detection limit

As indicated in Table 25, there are only differences between Basic Approval and Final Approval with respect to the results of the effluent testing and the conclusion. The laboratory ecotoxicity tests at Basic Approval are considered indicative for potential effects but are not yet final and decisive. The WET tests at Final Approval are intended to be final and to give decisive information on the hazards of the discharge. If the discharge shows no effects in the WET tests, the discharge should be considered safe. Therefore, the preferred method of risk assessment changes between Basic Approval and Final Approval. The risk assessment based only on the PNEC determined and literature data is not considered sufficient for a final decision, at least not for Final Approval. For Basic Approval, such an assessment result gives an indication where to search for improvements in the system leading to a lower PEC/PNEC ratio. To estimate the risk of near ship exposure, a dilution factor of 5 is used (see Annex III). The GESAMP-BWWG decided that this factor of 5 also can be used to mitigate risks at the interpretation of the WET test results at Final Approval.

4.7 Human Health Risk Assessment

4.7.1 Evaluation of BWMS: the Early Days

At the start, only one “scenario”, representing a worst-case situation (drinking 2 litres of water per day), was described (MEPC, 2006), Annex 9). At its fourth meeting (MEPC, 2008a), the GESAMP-BWWG invited the Committee to “endorse the Group’s proposal to introduce a questionnaire to facilitate the description of the BWMS as a set of unit operations and system components describing the individual potential of each system component/operation for human exposure and identifying the respective Risk Management Measures. Such a questionnaire should be introduced as part of the further development of a Human Exposure Scenario to

assist manufacturers in preparing their applications for approval of BWMS”.

Further developments of the Human Exposure Scenario (HES) were also discussed and the first list of unit operations, that is tasks involving crew and/or port State control officers, with descriptions of anticipated exposure was assembled. In the first revision of the Methodology (BMW.2/Circ.13/Rev.1) the human exposure scenarios developed at the first Stocktaking Workshop in 2009 were implemented.

4.7.2 Measured Concentrations of Tribromomethane and Chlorine Gas in the Ballast Tank

Tribromomethane

Tribromomethane is the Relevant Chemical that has repeatedly been reported at the highest concentrations in treated ballast water from electrolysis systems. Adverse effects to humans linked to the exposure of tribromomethane are well known, since in the past tribromomethane was used as intermediate in chemical synthesis, as a sedative, and as a cough suppressant (ATSDR, 2019). These effects include irritation to eyes, nose and throat, increased tear flow and also narcotic effects like dizziness and headache (NIOSH, 1994). Tribromomethane is classified as irritating to eyes and skin, and as toxic if inhaled (European Commission, 2008). It is also classified as harmful if swallowed.

The GESAMP-BWWG is aware of incidents where the inhalation of vapours from ballast tanks, presumably containing tribromomethane, have affected sampling teams thereby causing headache, nausea, dizziness; the effects have been strong enough to cause individuals to leave the engine room (David, Hanayama, Wiley, 2018). The physical effects are reported to clear after returning to the deck.

Table 26 Health effects caused by inhalation of tribromomethane (NIOSH, 1994)

Concentration	Effect
1.3 mg/m ³	Odour threshold
6,000 mg/m ³	Generally fatal over 30 minutes
10,000 mg/m ³	Immediately dangerous to life or health concentration (IDLH)
5 mg/m ³	OSHA PEL

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit

According to the risk assessment approach of the GESAMP-BWWG, the usual tribromomethane concentration produced in the natural seawater is around 200-700 µg/L, however, with additives for augmentation required in 2016 Guidelines (G8)/BWMS Code, the concentration may reach to 3,000 µg/L. These worst-case concentrations may be converted to the corresponding concentration in air using the Henry’s Law constant (see equation 6 in annex II). Consequently, a water concentration of 2250 µg/L corresponds to an air concentration in the ballast tank, which equals the permissible occupational exposure level defined by OSHA (Figure 26).

On one occasion (MEPC, 2010c), an applicant measured the concentration of tribromomethane in the air in ballast tanks immediately following operation of the system. The reported concentration was under the detection limit of 0.019 µg/m³. There have, however, been no reported measurements of tribromomethane in the ballast tank, for example, while taking samples directly from the tank. Nevertheless, the opinion of the GESAMP-BWWG is that it would be in these situations that the highest concentrations are likely to occur.

Chlorine gas

There is a risk of formation of chlorine gas in BWMS that make use of for instance sodium hypochlorite as a bulk chemical, or sodium dichloroisocyanurate (NaDCC) as a Preparation. However, in the case of sodium hypochlorite as a bulk chemical, the formation of chlorine gas depends on the pH of the stock solution (see Figure 23), and the risk only applies if the pH is below 4. In the actual case, the pH of sodium hypochlorite as a preparation is around 12, such that there is no risk of chlorine gas formation.

Applicants have repeatedly measured the concentrations of chlorine gas, together with hydrogen gas, during land-based testing but on most occasions no concentrations above detection level (0.2 ppm) are reported (for example MEPC, 2010a; MEPC, 2010c; MEPC, 2010d). According to the GHS classification system, gases are measured in ppmV (GHS 2017). Chlorine gas is classified as irritating to eyes, skin and the respiratory tract, and as toxic if inhaled (European Commission, 2008).

At shipboard testing with a BWMS making use of *in situ* electrolysis, one applicant measured chlorine gas concentrations in the air at four different locations at five different time points (MEPC, 2008a). The highest concentration was detected in the ballast tank immediately following treatment (0.9 ppm). After 1 hour the concentration dropped to 0.5 ppm, and after 2 hours to 0.3 ppm. In all other locations (surrounding the BWMS, upper regions of the vessel and alongside the vessel), chlorine gas was not detected. The short-term (15 minutes) OSHA permissible exposure limit (PEL) for chlorine gas is 0.5 ppm (Table 27).

To mitigate the effects of chlorine gas exposure (irritation of the upper and lower respiratory tract) one of the applicants described the following procedure:

“In the event that ship’s crew need to enter the ballast tank just after de-ballasting, it is recommended that crew enter at least one hour after the opening of the ballast tank’s maintenance hatch. If chlorine gas is detected, the air in the ballast tank must be exchanged with fresh air by a gas-free fan. Just prior to entering the ballast tank, it is recommended that residual chlorine gas be checked using a portable chlorine gas detector”. (MEPC, 2013a).

Table 27 Health effects caused by inhalation of chlorine gas (modified from White, C.W. and Martin, J.G., 2010)

Concentration	Effect
0.02 – 0.05 ppm	Odour threshold
1 – 3 ppm	Mild irritation of the eyes, nose and throat
3 – 5 ppm	Moderate irritation of eyes and respiratory tract, headache
5 – 15 ppm	Severe irritation of eyes, nose and respiratory tract
> 30 ppm	Immediate chest pain, shortness of breath, nausea and vomiting
40 – 60 ppm	Toxic pneumonitis and/or acute pulmonary oedema, possibly causing suffocation and death
> 400 ppm	Generally fatal over 30 minutes
0.5 ppm	ACGIH, NIOSH PEL

ACGIH = Association Advancing Occupational and Environmental Health

NIOSH = The National Institute for Occupational Safety and Health

PEL = Permissible Exposure Limit.

In a recent submission, where the applicant made use of NaDCC as the Preparation (MEPC, 2019), an evaluation regarding chlorine gas generated during and after the chemical dissolving process was performed, and that the conclusion of the study was that a maximum concentration of chlorine gas of 5 ppm in the ventila-

tion duct at the downwind of the fan would not last for more than 1.5 minutes. The Group consequentially recommended that a ventilation system that removes the chlorine gas to a suitably safe location, and that has a comparable performance as the ventilation system from the study, is fitted on the ship.

5 RISKS TO SHIP SAFETY

5.1 Introduction

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:

- increased corrosion
- fire and explosion
- storage and handling of the substances.

In the successive sections of this Chapter, for each of these potential risks some important considerations are presented. How to deal with these potential risks on board the ship is presented in Section 5.4 of this Chapter also with regard to the BWMS's operations manual.

5.2 Increased Corrosion

For a ship owner, the carrying of ballast water is a necessity of modern ship operation but it has no direct money-generating function such as the condition of cargo holds and propulsion machinery which allow the vessel to offer a clean and reliable cargo-carrying service. As a consequence, over the years ship operators tended to ignore the internal condition of these ballast tanks. The overall result of this neglect was an alarming number of ship casualties in the 1990s directly related to loss of integral hull strength as a result of severe corrosion and steel wastage in ballast tanks (Figure 29). Some of these events, such as the loss of the tankers Erika and Prestige, resulted in severe pollution events (Figure 30).



Figure 29 Corrosion of steel in a ballast tank (D. Smith)



Figure 30 The tanker ERIKA – lost as a result of steel corrosion (BBC News, 1999)

In order to address this unacceptable situation, the IMO adopted resolution MSC.215(82) (IMO, 2006) which is the “Performance Standard for Protective Coatings for Dedicated Seawater Ballast Tanks in all Types of Ships and Double-Side Skin Spaces of Bulk Carriers”. This is commonly known as the IMO PSPC (Figure 31). This standard took effect in 2008 and provides detailed technical requirements for the testing and approval of protective coatings designed for ballast tank application.

The overall aim of the PSPC is that ballast tank coatings should be of a tested and approved type and also properly applied in a suitably controlled manner so that they have a minimum lifespan in excess of 15 years. The standard also prescribes the frequency and protocol of regular inspections and also stresses the need to repair the ballast tank coating as necessary to maintain the continued effectiveness of the coating as a corrosion inhibitor.

IMO Resolution MSC.215(82) (adopted 8 December 2006)

Performance standard for protective
coatings for dedicated sea water ballast
tanks in all types of ships and double
skin spaces of bulk carriers



Figure 31 Resolution MSC.215(82) (IMO, 2006)

A BWMS that makes use of an Active Substance (such as hypochlorite electrolysis, chlorine dioxide, sodium hypochlorite, peracetic acid or ozone) may have a direct effect on epoxy tank coatings. Depending on the dose and degradation rate of the Active Substance, there could be a consequential detrimental impact on the ballast tank coating resulting in loss of coating effectiveness and thus allowing increased corrosion rates within tanks. In the case of a BWMS with

a TRO dose ≥ 10 mg/L, expressed as mg Cl_2 /L, the compatibility with coating systems is to be validated by testing. Testing should be conducted in accordance with the NACE TM0112-2012 Standard Test Method (NACE, 2012) with two series of test panels and the coating should be applied in accordance with Table 1 of the IMO PSPC performance standards. One set of panels should be exposed to treated ballast water. Other test conditions are described in Table 28 below:

Table 28 Test conditions corrosion

Parameter	Quantification	Reference/Remark
The size of each test panel	200 mm x 400 mm x 3 mm	NACE standard TM0112-2012
Depth of immersion	250 \pm 10 mm	NACE standard TM0112-2012
Water temperature in tanks for exposure	35 \pm 2 °C	NACE standard TM0112-2012
The total test duration	182 days	NACE standard TM0112-2012
Ballast water	Natural seawater (> 32 PSU)	Preferred by GESAMP/BWWG but artificial seawater 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 can take place in the laboratory, but it is recommended to make use of the full-scale BWMS water which is to be used for efficacy testing. After the required exposure duration, several corrosion-relevant measurements should be scored against the PSPC criteria and reported.

5.2.1 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 as listed below 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 (NACE, 2012) 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:

- 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, paragraph 3.1 (ISO, 2016a)
- ISO 4628-2: Blistering: "Fail" if any blisters occur (ISO, 2016b)
- ISO 4628-3: Rusting: "Fail" if any rusting occurs (ISO, 2016c)
- ISO 4628-4: Cracking: "Fail" if any cracking occurs (ISO, 2016d)

- 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, paragraph 3.1 (ISO, 2012a)
- 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, paragraph 3.1 (ISO, 2003).

Experiences gained and lessons learned

Revised guidelines for corrosion testing were introduced in the latest revision of the Methodology (4th revision).

The first set of guidelines for corrosion testing was presented by the GESAMP-BWWG at its eighth meeting (MEPC, 2009b).

Over the years the GESAMP-BWWG has encountered a number of different situations when it comes to corrosion testing:

- *No data submitted*
- *Insufficient testing (not following guidelines)*
- *Insufficient testing (visual examination)*
- *Insufficient testing (limited number of test coupons)*
- *Insufficient testing (no uncoated test samples included)*
- *Long-term testing had not yet commenced.*

Where such shortfalls have been noted, applicants have been requested to revisit this important part of the Methodology and re-submit appropriate data.

5.3 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 are included in the submission. In addition to the normal mitigation barriers that applicants will outline, such as electrical installation safety and the provision of general emergency procedures, the GESAMP-BWWG has identified the particular potential for fire and explosion resulting from the use of a BWMS employing electro-chlorination techniques using sea water as the feed stock and which gives rise to the generation of highly explosive and unstable hydrogen gas as a by-product of the production of Active Substances such as sodium hypochlorite.

5.3.1 Hydrogen Gas Generation

Hydrogen (H₂) is formed as a by-product of seawater electrolysis in a cathodic reaction as explained in Section 3.6.1. Due to the explosive properties of hydrogen gas, an accumulation above the lower explosion limit (LEL; 4% by concentration) in the ballast tanks or other areas in and around the generation location on board a ship could create an unsafe situation.

The hydrogen gas (H₂) may be removed from the ballast water stream through the use of dedicated separators. The separated gas is subsequently reduced to less than 1% of atmospheric concentration by air dilution.

This is usually achieved by methods such as cyclonic division, with the resultant gas being passed to a blower system to dilute it with air which is then subsequently vented to atmosphere at a safe location on board the ship. A four-fold safety factor of the explosion limit is recognized to be sufficient. A hydrogen gas detector with alarm should be provided in the space where the electrolyzer is installed; this will shut down the system in the case of any hydrogen gas accumulation.

At its seventh Stocktaking Workshop (MEPC, 2016a), the GESAMP-BWWG discussed the fact that, as the evaluations under Procedure (G9) are carried out based on land-based test results, there are certain areas at that point in the type approval process where the applicant may not have been able to fully develop information on ship-specific installation and operational use issues.

The GESAMP-BWWG noted that H₂ production rates of individual BWMS are not required from applicants. This is because H₂ production by electrolytic systems can be adequately predicted based on TRO and ballast water flow rates (Annex IV).

The conclusion of the eighth Stocktaking Workshop was that the GESAMP-BWWG should recommend future applicants to submit some form of quantified mass balance calculation at key locations, such as gas venting outlets from gas separators, to allow suitable monitoring and management of the produced H₂ during the operation of the BWMS.

Experiences gained and lessons learned

The GESAMP-BWWG has previously not been assessing the capacity of gas separators that have been incorporated in BWMS that use electrolysis. However, after having looked into the matter in more detail during the seventh and eighth Stocktaking Workshops, the GESAMP-BWWG has decided to change its approach in this regard.

To be able to determine whether the produced H₂ during the operation of the BWMS is suitably monitored and managed, and that appropriate gas separators with sufficient capacity are being used, the GESAMP-BWWG will in the future recommend applicants to submit some form of quantified mass balance at key locations, such as gas venting outlets from gas separators.

5.4 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 the Methodology. The hazards associated with the possible creation of atmospheric particulates should also be included. Generally, it is considered that risks of crew members and port State control (PSC) officers from dermal and inhalation exposure to leakages and spills are dealt with by wearing adequate protective personal equipment (PPE) and/or respiratory protective equipment (RPE). This protective equipment is meant to be used by trained professionals and is designed to protect against local toxic effects from chemical substances, e.g., with corrosive or irritant properties. The GESAMP-BWWG evaluates all submissions while taking into consideration all potentially hazardous substances and always recommend that the safe storage and handling of Active Substances and neutralizers (sometimes in powder form), along with the method for making up the Active Substance and neutralizer solutions, be detailed in the instruction manual for the system. The GESAMP-BWWG also on a general basis recommends that the ballast water treatment neutralization process be made fully automatic and that the control systems for the procedure are carefully considered.

5.5 Risk Management – Mitigation and Control

The operations manual provided for the BWMS includes suitable and sufficient information regarding the safe operation of the system under normal use as well as risk management measures including mitigation and control. 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 by the GESAMP-BWWG. The identified risk management measures should be incorporated within the procedures given in the Operations Manual submitted. When it comes to determining the hazards and consequential risks associated with a particular BWMS, there are several methods available to effectively carrying out a quantitative risk assessment. Applicants have used in some cases, Hazard and Operational Studies (HAZOP) (Galante, *et al.*, 2014) and Failure Modes and Effect Analysis (FMEA) (Carson, 2012). The GESAMP-BWWG has welcomed these as they may highlight specific risks which the Group can consider as part of the overall assessment of a particular BWMS. Both HAZOP and FMEA determine specific hazards within individual components of the system and attempt to quantify both the level of risk prior to and after the application of appropriate risk management measures (RMM). In determining and applying RMMs, the applicant should use the strategy shown in Figure 32 to ensure that the risk reduction technique in effect had been taken into account as the most effective way to deal with the identified risk.

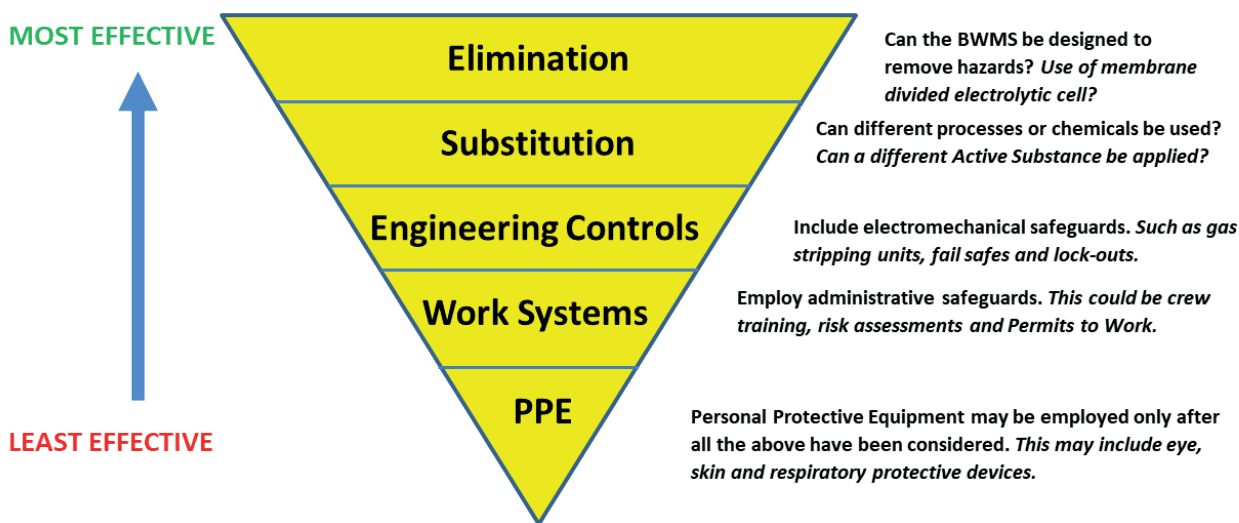


Figure 32 Hierarchy of Risk Control

Using the above general principle, and the documentation provided by the applicant, the Group considered the risk reduction techniques that the applicant had chosen for the BWMS. However, there were occasions where the Group identified the potential for improved or additional RMMs and made recommendations to the applicant accordingly.

It should be noted that the use of Personal Protective Equipment (PPE) is considered to be a last resort when it comes to human exposure to potentially harmful substances and that the Group will examine each application in detail to determine that no other controls can

be reasonably employed. When PPE are employed, the operation manual must include specific information to unequivocally identify the adequate equipment to be used and the assigned protection factor, as applicable. At the seventh Stocktaking Workshop (MEPC, 2016a), the Group decided to systematically collect data from submitted application dossiers in relation to RMMs for human exposure, with the aim of developing a harmonized approach to report RMMs and their efficiency in a systematic and transparent manner.

6 CONCLUSIONS AND FUTURE CHALLENGES

6.1 Current Status

To date, more than 60 BWMS that make use of Active Substances and/or Preparations have received Basic Approval from IMO, representing various technologies such as electrolysis, chemical addition (biocides) and ozonation. In addition, more than 40 BWMS have also received Final Approval. The main technique to treat ballast water using Active Substances is the electro-chlorination/electrolysis method that produces the Active Substance *in situ* on board of the ship. The reason is probably that the source water, water containing chloride, is abundantly available when sailing the world's oceans. When sailing in fresh waters (e.g., the Great Lakes in the USA and Canada) special arrangements have to be installed, like a special tank filled with water of sufficient salinity. The GESAMP-BWWG has developed a specific procedure for BWMS with Final Approval that did not receive a recommendation for use in fresh water to allow the applicants to further improve their BWMS to also work under fresh water conditions. To date, one BWMS has received an extension to its Final Approval to include use in fresh water.

The Methodology is well developed, although the GESAMP-BWWG is of the opinion that some details may need further development. Especially on the topic of the formation of DBP, much scientific information is missing and could be improved by additional research (see also Section 6.4). Furthermore, during several Stocktaking Workshops, the GESAMP-BWWG has discussed the possibility to request additional information on the CMR characteristics of the whole effluent. It remains to be seen if and how future Stocktaking Workshops can be held in view of the decreasing tendency of the amount of applications submitted.

6.2 Future Developments

There is an increasing rate of introduction of invasive species associated with ships' ballast water. Studies have shown that it is rising exponentially due to the deployment of larger and faster ships and also due to port expansions into new locations as man seeks out new sources of raw materials.

The BWM Convention entered into force on 8 September 2017, requiring shipowners to comply with either D-1 (ballast water exchange) or D-2 (ballast water discharge) standards until such time as it is required that they have to comply only with the D-2 standard. New build ships must comply with the D-2 standard if constructed (keel-laid) on or after 8 September 2017. For existing ships, shipowners are required to comply with the D-2 standard at the time of the first or second International Oil Pollution Prevention Certificate (IOPPC) renewal survey. All ships will need to comply with the D-2 standard by 8 September 2024. Through the work of the GESAMP-BWWG, a number of IMO-approved BWMS are available on the market to allow shipowners to comply with the requirements of the BWM Convention.

6.3 Sediment

Given the complex nature of ballast tank structures and the existence of numerous chambers within, each tank has the potential for bottom sediment accumulation during ballast water carriage and this hidden environment can provide favourable conditions for species to survive and be effectively carried as stowaways on board a vessel. From the perspective of the GESAMP-BWWG, sediment in the ballast water tank does not seem problematic as all Active Substances, Relevant Chemicals and Other Chemicals do not have a sufficiently high sorptive capacity based on the K_{ow} to expect accumulation in the sediment. If the ballast water is entering the ballast tank with such a high velocity that resuspension of the sediment occurs, the Active Substance may have sufficient activity to also affect the organisms adhering to the sediment particles. However, if the level in the ballast tanks is only increasing slowly without causing any turbulence, the resting stages of organisms may survive. In any case, this seems more a matter of efficacy than related to the chemicals introduced by the BWMS and may have to be addressed separately (for instance by the Global TestNet).

6.4 Endocrine Disruptive Properties

In the GESAMP-BWWG Methodology (IMO, 2017), one of the data requirements is that an applicant should submit information in their dossiers for BA and FA whether there could be an endocrine disrupting chemical. Endocrine disruptors are chemicals that may interfere with the body's endocrine system and produce adverse developmental, reproductive, neurological, and immune effects in both humans and wildlife. A wide range of substances, both natural and man-made, are thought to cause endocrine disruption, including pharmaceuticals (NIH, 2019). Although the animal's body's endocrine system is not specifically mentioned, the GESAMP-BWWG is of the opinion that the same effect may occur there. However, up to now no information has been received in the submitted dossiers that any of the chemicals associated with ballast water treatment (AS, RC or OC) may have endocrine disrupting properties. Therefore, a problem in this field has not yet arisen but may, of course, not be excluded for the future.

6.5 Same Type of Organic Carbon Additive for Testing should be Established

The GESAMP-BWWG is of the opinion that the same type of organic carbon additive should be used for all testing to be performed with the same BWMS under Procedure (G9), to make the test results consistent and comparable. Up to now, it has not been possible to determine a causal relation between the dosage in the BWMS, the additives used to fulfil the requirements of the 2016 Guidelines (G8) /BWMS Code and the formation of DBPs in the system. The GESAMP-BWWG has requested the test facilities, working together under the umbrella of the Global TestNet, to investigate a

potential relation in the systems they have tested. A test facility has the strategy to apply the same additives each time they test a new system. This may be helpful in the interpretation of the test results of each test facility. First of all, a statistical relation should be identified before a more scientific relation can be determined. The results of this research may influence the further development of the evaluation methodology applied by the GESAMP-BWWG.

6.6 Methodological Aspects

The Methodology used by the GESAMP-BWWG to evaluate the submissions for Basic and Final Approval may still need to be updated as continuously information becomes available that should be taken into

account to achieve a robust and sufficiently worst-case situation for the risk assessment of DBPs (David, *et al.*, 2018). Especially, the GESAMP-BWWG Model Harbour needs to be investigated more closely in this respect.

The mechanism of how the concentration of DBPs may be affected by different means is still to a large extent unknown. For instance, evaporable DBPs may decrease in the mixing process with air bubbles, even if they hardly react with the neutralizer. Furthermore, the GESAMP-BWWG has observed that several RCs in the “µg/L” order may react partially with the neutralizer, provided that it had been over-dosed significantly against stoichiometric demands of Active Substance in “mg/L” order. More research will be needed to further illuminate the fate of the DBPs.

GLOSSARY OF TERMS AND DEFINITIONS USED BY THE GESAMP-BWWG

Active Substance (AS) means a substance or organism, including a virus or a fungus that has a general or specific action (chemical or biological) on or against harmful aquatic organisms and pathogens.

Acute (eco) toxicity is the ability of a substance to cause adverse effects within a short period following exposure.

Administration means the government of the state under whose authority the ship is operating.

Aggregated exposure means the combined exposure to a single chemical through all relevant routes (e.g., oral, dermal, inhalation).

Ballast water means water with its suspended matter taken on board a ship to control trim, list, draught, stability or stresses of the ship.

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.

Ballast Water Management Convention (the BWM Convention) means the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004.

Ballast water management system (BWMS) means any system which processes ballast water such that it meets or exceeds the ballast water performance standard in the Convention. The BWMS includes ballast water treatment equipment, all associated control equipment, monitoring equipment and sampling facilities.

Ballast water tank is any tank, hold or space used for the carriage of ballast water.

Basic Approval (BA) means the preliminary approval of Active Substances and the ballast water management system that uses them in order to comply with the Ballast Water Management Convention. Basic Approval should confirm that the available information does not indicate possible unacceptable adverse effects or a potential for unreasonable risk to environment, human health, property or resources. This should include consideration of potential risks associated with the Active Substance during full-scale deployment on commercial ships when possible.

Bioaccumulation (B) is the progressive increase in the amount of a substance in an organism or tissue which occurs because the rate of intake exceeds the organism's ability to remove the substance.

BWMS Code means the Code for approval of ballast water management systems. Regulation D-3 of the BWM Convention requires that ballast water management systems used to comply with the Convention must be approved by the Administration taking into account the Guidelines for approval of ballast water management systems (G8). The Guidelines (G8) were revised in 2016 (2016 Guidelines (G8)) and converted into the mandatory Code for approval of ballast water management systems (BWMS Code).

Chronic (eco) toxicity is the capacity for a substance to produce adverse effects following longer term exposure or to produce effects which persist.

Degradation is the process by which a substance is broken down to simpler structures through biodegradation or abiotic mechanisms.

DPD method is the colorimetric analytical method based on use of the reagent DPD (N, N-diethyl-p-phenylenediamine) where oxidants such as chlorine react with DPD causing a deep-purple colour to form with an intensity proportional to the oxidant concentration. The oxidant concentration (mg/L) in the test water is then determined as the absorbance of light in a colorimetric flow cell.

Exposure is the concentration or amount of a substance that reaches the target organism, usually expressed in numerical terms of concentration, duration and frequency.

Final Approval (FA) means the approval of a ballast water management system using an Active Substance or Preparation to comply with the Convention and includes an evaluation of the whole effluent toxicity (WET) tests performed as part of the land-based type approval process in accordance with the Guidelines for approval of ballast water management systems (G8). The review does not include the re-evaluation of efficacy testing results conducted by Administrations under the Guidelines (G8). The Final Approval should confirm that previous evaluations of risks to ship, crew and the environment including storage, handling and application of Active Substances or Preparations remain valid and the concerns expressed during the Basic Approval process have been addressed, and that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval.

GESAMP is the IMO/FAO/UNESCO-IOC/WMO/IAEA/UN/UNDP/UNEP/UNIDO Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, an advisory and multi-disciplinary body consisting of specialized experts nominated by the sponsoring agencies. Experts working for the GESAMP act independently in their individual capacity.

GESAMP-Ballast Water Working Group (GESAMP-BWWG), also being referred to as the Group, means the Technical Group consisting of independent experts acting in their individual capacity that review the proposals for approval of ballast water management systems that make use of Active Substances submitted by the Administration and report, through the GESAMP, to MEPC. When reviewing the proposals, the Group should take account of any other relevant data as well as other relevant information submitted to it, or the Group is aware of, because of its members' expertise.

Hazard is the set of inherent properties of a substance which gives potential for adverse effects, and depending on the level of exposure.

Lower Explosive Limit (LEL) is the lowest concentration (percentage) of a gas or a vapour in air capable of producing a flash of fire in presence of an ignition source (arc, flame, heat).

IOPP Survey and Certificate is issued to each new ship after an appointed surveyor has inspected it and found it to be in compliance with the MARPOL convention. The IOPP certificate gives details of all oily water separation and filtering equipment and also the associated monitoring equipment required under the convention.

Median effective/lethal concentration/dose (EC_{50} , LC_{50} , LD_{50}) is the statistically derived concentration/dose of a substance expected to produce a certain effect/kill 50% of test organisms in a given population under defined conditions.

No-observable/adverse-effect-concentration/level (NOEC, NOEL, NOAEC, NOAEL) is the highest concentration or amount of a substance that causes no observable/adverse biological effect to the target organism.

Organization means the International Maritime Organization (IMO).

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

Persistence (P) is the residence time of a substance in a defined environmental compartment such as soil, seawater, fresh water, etc.

Predicted environmental concentration (PEC) is the predicted concentration of a substance within an environmental compartment such as seawater.

Predicted no-effect concentration (PNEC) is an estimated no observable effect concentration for an aquatic species based on extrapolated experimental data.

Relevant Chemical (RC) means transformation or reaction products that are produced during and after employment of the ballast water management system in the ballast water or in the receiving environment and that may be of concern to the ship's safety, aquatic environment and/or human health.

Risk is the probability of any defined hazard occurring from exposure to a substance under specific conditions. Risk is a function of the likelihood of exposure and the likelihood to produce adverse effects.

Sampling facility is that place in the ballast water piping where the sample is taken.

Sediments means matter settled out of ballast water within a ship.

Ship means a vessel of any type whatsoever operating in the aquatic environment.

Stocktaking Workshop (STW) is the activity of the GESAMP-BWWG to take stock of the experience achieved during its meetings, and to discuss the lessons learned and the general aspects related to the evaluation process, including further refinement of the Methodology.

Toxicity (T) is the adverse effect of a substance on an organism.

Trophic level is the grouping together of functionally similar organisms based on similarities in the patterns of food production and consumption amongst the different organisms.

Type Approval is granted to a BWMS that meets a minimum set of regulatory, technical and safety requirements. Generally, Type Approval is required before a system is allowed to be sold in a particular country.

LIST OF ABBREVIATIONS AND ACRONYMS USED BY THE GESAMP-BWWG

<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
A	Ampere
AMS	Automated Manifest System
AS	Active Substance(s)
B	bioaccumulation
BWMS	ballast water management system
BWWG	Ballast Water Working Group
°C	degree Celsius (Centigrade)
CMR	carcinogenicity, mutagenicity and reproductive toxicity
CT	Contact time
CV	Coefficient of Variation
d	day(s)
DBP	disinfection by-product(s)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
DOC	dissolved organic carbon
DPD	N,N-diethyl-p-phenylenediamine
EC ₅₀	effect concentration, 50% (median effective concentration)
ECOSAR	Ecological Structure Activity Relationships Predictive Model
g	gram
Guidelines (G8)	Guidelines for approval of ballast water management systems
Procedure (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(s)
HMI	Human-Machine Interface
HPLC	High Performance Liquid Chromatography
IMO	International Maritime Organization
ISO	International Organization for Standardization
kg	kilogram
L	litre
LC ₅₀	lethal concentration, 50%
LC-MS	Liquid Chromatography Mass Spectrometry
LD ₅₀	lethal dose, 50%
LEL	lower explosive limit
MADC	maximum allowable discharge concentration
MAMPEC	Marine Antifoulant Model for PEC calculation
MAMPEC-BW	MAMPEC model with specific BW features
MEPC	Marine Environment Protection Committee
mCV	minimum Cell Volume
mg	milligram

mJ	milliJoule
mL	milliLitre
mW	milliWatt
NA	Not applicable or Not available
ND	Not detected
nm	nanometre
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OC	Other Chemical(s)
OECD	Organisation for Economic Co-operation and Development
P	Persistence
PBT	Persistence, Bioaccumulation and Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
POC	Particulate organic carbon
PPE	Personal protective equipment
PSPC	Performance Standard for Protective Coatings
PSU	Practical salinity unit
QA/QC	Quality Assurance/Quality Control
RC	Relevant Chemical(s)
RCR	Risk Characterization Ratio
T	Toxicity
TRC	Treatment rated capacity
TRO	total residual oxidant
TSS	Total suspended solids
UV/TiO ₂	ultraviolet/titanium dioxide
WET	Whole Effluent Toxicity test(s)/testing

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ANNEX I – MEMBERSHIP OF THE WORKING GROUP, TERMS OF REFERENCE

Members of GESAMP WG 34 during the years

Al-Thukair, A. (Saudi Arabia, member BWWG 35 onwards)

Behrends, B. (Germany, member BWWG 6)

Borges, T. (Portugal, member BWWG 1 onwards)

Bowmer, T. (Netherlands, chair BWWG 3 through 5)

Chatterjee, A. (India, member BWWG 15 and 16)

Dock (Kronborg), A. (Sweden, member BWWG 4 onwards)

Dragsund, E. (Norway, member BWWG 1 through 7)

Fernandes, F. (Brazil, member BWWG 31 onwards)

Gollasch, S. (Germany, member BWWG 8 through 13, 15 and 18 through 23)

Hanayama, S. (Japan, member BWWG 1 onwards)

Lemieux, E. (United States of America, member BWWG 8 and 10 through 12)

Linders, J. (Netherlands, member BWWG 1 onwards, chair BWWG 6 and 8 onwards)

Mauro, C. (Brazil, member BWWG 1)

Oyewo, E. (Nigeria, member BWWG 15 through 25)

Pedersen F. (Denmark, chair for BWWG 1 and 2, 7)

Pelletier, E. (Canada, member BWWG 24 through 30)

Rhie, K. (Republic of Korea, member BWWG 8 onwards)

Rouleau, C. (Canada, BWWG 32 onwards)

Smith, D. (United Kingdom, member BWWG 26 onwards)

Stuer-Lauridsen, F. (member BWWG 8 through 18)

Tongue, D. (United Kingdom, member BWWG 1 through 24)

Werschkun, B. (Germany, member BWWG 27 onwards)

Ziegler, G. (United States of America, member BWWG 26 onwards)

GESAMP-BWWG Consultants

Behrends, B. (Germany, BWWG 4, 5, and 7)

Cooke, M (United Kingdom, BWWG 1)

Craven, A. (United Kingdom, BWWG 8 through 10, 12 through 14 and 16 through 23)

Crayford, J. (United Kingdom, BWWG 2 and 3, 6, 8, 11 and 12)

Dock, A. (Sweden, BWWG 16 onwards)

Nauke, M. (Germany, BWWG 1)

Stuer-Lauridsen, F. (Denmark, BWWG 15)

General Terms of Reference for the Technical Group GESAMP-BWWG (WG 34)

1 Consideration of development of necessary methodologies and information requirements in accordance with the “*Procedure for approval of ballast water management systems that make use of Active Substances (G9)*” for consideration by MEPC.

2 For Basic Approval, the Group should review the comprehensive proposal submitted by the Members of the Organization, along with any additional data submitted, as well as other relevant information available to the Group and report to the Organization. In particular, the Group should undertake:

- .1 scientific evaluation of the data-set in the proposal for approval (see paragraphs 4.2, 6.1, 8.1.2.3 and 8.1.2.4 of Procedure (G9));
- .2 scientific evaluation of the assessment report contained in the proposal for approval (see paragraph 4.3.1 of Procedure (G9));
- .3 scientific evaluation of the risks to the ship and personnel to include consideration of the storage, handling and application of the Active Substance (see paragraph 6.3 of Procedure (G9));
- .4 scientific evaluation of any further information submitted (see paragraph 8.1.2.6 of Procedure (G9));
- .5 scientific review of the risk characterization and analysis contained in the proposal for approval (see paragraph 5.3 of Procedure (G9));
- .6 scientific recommendations on whether the proposal has demonstrated a potential for unreasonable risk to the environment, human health, property or resources (see paragraph 8.1.2.8 of Procedure (G9)); and
- .7 preparation of a report addressing the above-mentioned aspects for consideration by the MEPC (see paragraph 8.1.2.10 of Procedure (G9)).

3 For Final Approval, the Group should review the discharge testing (field) data and confirm that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval and that the previous evaluation of the risks to the ship and personnel including consideration of the storage, handling and application of the Active Substance remains valid. The evaluation will be reported to the MEPC (see paragraph 8.2 of Procedure (G9)).

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

ANNEX II – HUMAN RISK ASSESSMENT IN DETAIL

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1 INTRODUCTION

Here we present the various steps in the human health risk assessment in the GESAMP-BWWG Methodology. The risk assessment approach itself has been compiled over the years by the GESAMP-BWWG while taking into account the approaches being used by applicants. In the early days the work done by the toxicologists of the GESAMP-BWWG was mainly focused on gathering data for the chemicals that are associated with BWMS. As a result of this work the hazard profiles were compiled in collaboration with GESAMP WG 1, all in all eighteen hazard profiles were compiled for physical chemical properties, ecotoxicological data and toxicological data. For example, guidance levels (PNEC, DNEL and DMEL) were established. The data from the hazard profiles was subsequently transferred into an Access database. The human exposure scenarios (HES) were developed during a series of workshops while taking into consideration information from various applications. The risk characterization approach consists of parts being used in Europe (described in various ECHA guidelines) combined with other parts being used in the United States (US EPA, 2002 and 2009). Figure II.1 describes the different steps in the risk assessment.

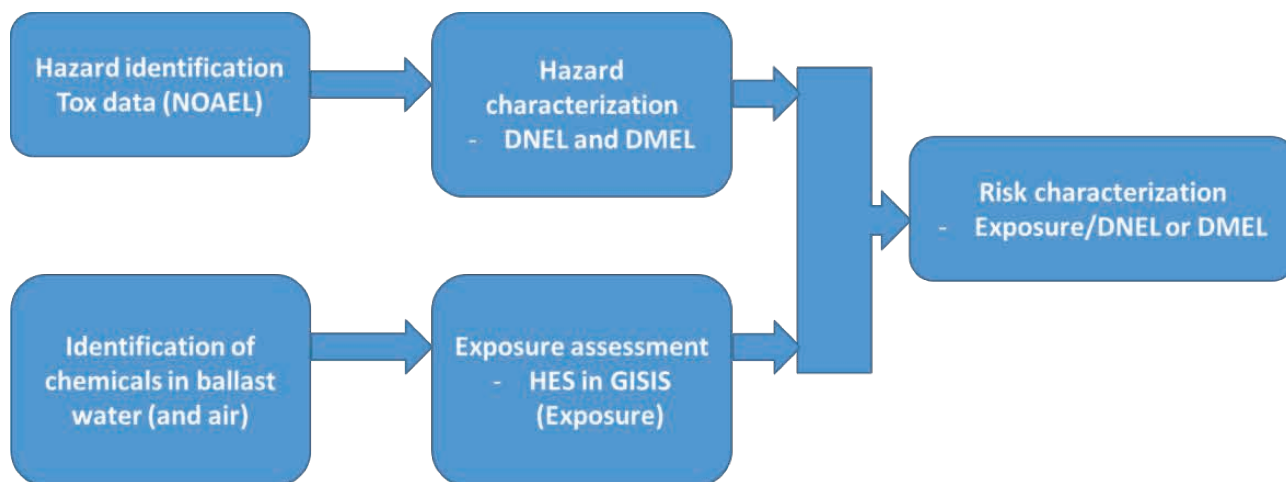


Figure II.1 Steps in the risk assessment approach

References to the various guidelines used in this annex (ECHA, US EPA, etc.) are listed in the main body of the text.

The most commonly used guidelines are:

- ECHA (2012). 'Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2.1 November 2012.
- ECHA (2016a). Guidance on Information Requirements and Chemical Safety Assessment. Part E: Risk Characterisation. Version 3.0 May 2016.
- ECHA (2016b). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.15: Consumer exposure assessment. Version 3.0 July 2016.
- ECHA (2017). Guidance on the Biocidal Products Regulation. Volume III Human Health – Assessment and Evaluation (Parts B+C). Version 4.0 December 2017.
- Kortenkamp, A.; Backhaus, T.; and Faust, M. (2009). 'State of the art report on mixture toxicity'. Final report.
- WHO (2001). Water Quality Guidelines, Standards and Health. Assessment of risk and risk management for water-related infectious disease. Fewtrell, L. and Bartram, J. (Eds)
- US EPA (1997). Exposure Factors Handbook Vol. I-III. (Update to Exposure Factors Handbook EPA/600/8-89/043 – May 1989). US Environmental Protection Agency (EPA), Office of Research and Development, EPA/600/P-95/002Fa, Washington, DC.
- US EPA (2003). User's Manual Swimmer Exposure Assessment Model (SWIMODEL) Version 3.0. US EPA, Office of Pesticide Programs, Antimicrobials Division, November 2003.
- US EPA (2002). Supplemental guidance for developing soil screening levels for superfund sites. Office of Emergency and Remedial Response U.S. Environmental Protection Agency, Washington, DC 20460. OSWER 9355.4-24.
- US EPA (2009). Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment). EPA-540-R-070-002. OSWER 9285.7-82

2 THE STEPS IN THE HUMAN HEALTH RISK ASSESSMENT

2.1 Identification of Chemicals Associated with each BWMS

The general approach of the GESAMP-BWWG on the risk assessment was already described in Chapter 3. Here more specifically the scenarios for human health (workers and general public) are presented in more detail.

2.2 Data Requirements for Hazard Identification

2.2.1 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 toxicological effect.

2.2.2 Information about Chemicals in any Application for Basic Approval and/or Final Approval

With any application for either Basic Approval or Final Approval evaluation the applicant submits physico-chemical and (eco-)toxicological information about the chemicals associated with or generated by the BWMS for all endpoints mentioned in Table II.1. However, for the forty-four chemicals most commonly associated with treated ballast water, 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://gis.imo.org/>).

Table II.1 Data requirements for identified chemicals (appendix 3, Methodology)

EFFECTS ON AQUATIC ORGANISMS			
Acute aquatic toxicity data			
Organism	Species	Duration*-LC ₅₀ (mg/L)	Reference/comments/ justification for missing data
Fish			
Crustacea			
Algae			
* The duration is given in hours (h) or days (d), e.g., 96h-LC ₅₀ or 7d-NOEC.			
Chronic aquatic toxicity data			
Organism	Species	Duration*-LC ₅₀ (mg/L) or duration*-NOEC (mg/L)	Reference/comments/ justification for missing data
Fish			
Crustacea			
Algae			
* The duration is given in hours (h) or days (d), e.g., 96h-LC ₅₀ or 7d-NOEC.			
Information on endocrine disruption			
Organism	Species	Information	Reference/comments/ justification for missing data
Fish			
Crustacea			
Algae			
Sediment toxicity			
Organism	Species	Information	Reference/comments/ justification for missing data
Fish			
Crustacea			
Algae			

Bioavailability/biomagnification/bioconcentration				
Parameter	Value		Reference/comments/justification for missing data	
Log P _{ow}				
BCF				
Food web/population effects				
A description of potential food web and population effects should be provided supported by a full justification.				
MAMMALIAN TOXICITY				
Acute toxicity				
Endpoint	Value		Species	Reference/comments/justification for missing data
Oral LD ₅₀ (mg/kg bw)				
Dermal LD ₅₀ (mg/kg bw)				
Inhalation 4h-LC ₅₀ (mg/L)				
Corrosion/irritation				
Exposure route	Species	Method	Results (including scores where available)	Reference/comments/justification for missing data
Skin				
Eye				
Sensitization				
Exposure route	Species	Method (e.g., Buehler, M&K)	Results (Sensitizer Y/N)	Reference/comments/justification for missing data
Skin				
Inhalation				
Repeated-dose toxicity				
Parameter			Value/Comments	
Exposure route				
Exposure duration				
Exposure dose				
Species				
Method				
Results				
NOAEL				
NOEL				
Reference/comments/justification for missing data				
Development and reproductive toxicity				
Parameter			Value/Comments	
Exposure route				
Exposure duration				
Exposure dose				
Species				
Method				
Results				
NOAEL				
NOEL				
Reference/comments/justification for missing data				

Carcinogenicity					
Parameter				Value/Comments	
Exposure route					
Exposure duration					
Exposure dose					
Species					
Method					
Results					
NOAEL					
NOEL					
Reference/comments/justification for missing data					
Mutagenicity					
Endpoint	Method	Dose range	Results	Reference/comments/justification for missing data	
Bacterial gene mutation					
Mammalian cytogenicity					
Mammalian gene mutation					
Carcinogenicity/mutagenicity/reproductive toxicity (CMR)					
Endpoint			Results	Reference/comments/justification for missing data	
Carcinogenicity					
Mutagenicity					
Reproductive toxicity					
ENVIRONMENTAL FATE AND EFFECT UNDER AEROBIC AND ANAEROBIC CONDITIONS					
Modes of degradation (biotic and abiotic)					
Process	Seawater or fresh water	Test duration	Results	Breakdown products	Reference/comments/justification for missing data
Hydrolysis at pH 5					
Hydrolysis at pH 7					
Hydrolysis at pH 9					
Biodegradation DT ₅₀					
Partition coefficients					
Parameter	Method	Results		Reference/comments/justification for missing data	
Log P _{ow}					
K _{oc}					
Persistence and identification of main metabolites					
Process	Method	Results	Reference/comments/justification for missing data		
Persistence (d)					

Reaction with organic matter		
Potential physical effects on wildlife and benthic habitats		
Potential Residues in seafood		
Any known interactive effects		
PHYSICAL AND CHEMICAL PROPERTIES FOR THE ACTIVE SUBSTANCES, PREPARATIONS AND TREATED BALLAST WATER, IF APPLICABLE		
Property*	Value	Reference/comments/ justification for missing data
Melting point (°C)		
Boiling point (°C)		
Flammability (flashpoint for liquids; °C)		
Density (20°C; kg/m³)		
Vapour pressure (Pa at 20°C)		
Relative vapour density (expressed as a ratio by that of air as 1.293 kg/m³ at 0°C and 105 Pa)		
Water solubility (mg/L, temp; effect of pH)		
pH in solution (under the intended concentration for AS)		
Dissociation constant (pKa)		
Oxidation-reduction potential (V)		
Corrosivity to material or equipment (for Active Substance see paragraph 3.6.9)		
Reactivity to container material (only for Active Substance, which needs storage on board)		
Auto-ignition temperature, also flash point if applicable (°C)		
Explosive properties (narrative)		
Oxidizing properties (narrative)		
Surface tension (N/m)		
Viscosity (Pa·s), Kinetic viscosity (m²/s) is also accepted		
Thermal stability and identity of breakdown products (narrative)		
Other physical or chemical properties (narrative)		
* If units are indicated for the property, then these should be considered the preferred unit.		
OTHER INFORMATION		
Analytical methods for measuring the concentration at environmentally relevant concentrations		
Method	Comments	
Applicability		
Sensitivity		
Reference/comments/justification for missing data		

2.2.3 The Early Days

The DNEL approach, as described below, was developed at the third Stocktaking Workshop in April 2011 (MEPC, 2011), and was subsequently implemented into the Methodology in its first revised version (BWM.2/Circ.13/Rev.1). Before the DNEL model came into use the GESAMP-BWWG made use of the margin of safety (MOS) approach (MEPC, 2007, Annex 9). The safety factor that was used at that time was a MOS_{ref} 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, 2007).

2.2.4 CMR Screening

As part of the hazard identification a screening on carcinogenic, mutagenic and endocrine disruptive properties based on the appropriate toxicological studies on carcinogenicity, mutagenicity and reproductive toxicity (Procedure (G9)) has to be carried out. 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 in Table II.2:

Table II.2 CMR properties for selected Chemicals

Chemical name	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

It should be noted that if an item scores a 'yes' the resulting CMR-score is also a 'yes'.

If the screening results indicate concerns, this should give rise to a further effect assessment.

For chemicals that are non-threshold carcinogens a DMEL should be established as described below.

2.3 Hazard Characterization

2.3.1 Calculation of Derived No Effect Levels (DNELs)

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

Dose descriptor

From the dataset that is to be provided for each chemical associated with a BWMS (Table II.4), the dose descriptor is chosen. If the dose descriptor is a NOAEC or LOAEC from an inhalation study, expressed e.g., as mg/m³, the internal exposure, expressed as mg/kg bw/d, can be calculated using the standard respiratory volume (sRV) of the test species in question (Table II.3):

$$\text{NOAEL} = \frac{\text{NOAEC}}{\text{sRV}_{\text{animal}}} \quad (\text{Equation 1})$$

NOAEL = No observed adverse effect level (mg/kg bw/d)

NOAEC = No observed adverse effect concentration (mg/m³)

sRV_{animal} = Standard respiratory volume (m³/kg bw/d)

Table II.3 Standard respiratory volumes (modified from ECHA, 2012)

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:

$$\text{DNEL} = \frac{\text{Dose}_{\text{desc}}}{\text{AF}} \quad (\text{Equation 2})$$

DNEL = Derived no effect level (mg/kg bw/d)

Dose_{desc} = Dose descriptor (NOAEL/NOAEC or LOAEL/LOAEC (mg/kg bw/d or mg/m³))

AF = Assessment factors

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

$$\text{DNEL} = \frac{\text{Dose}_{\text{desc}} \cdot \text{CF}_{\text{dr}}}{\text{ASF} \cdot \text{OSF} \cdot \text{ISF} \cdot \text{ESF} \cdot \text{SF}_{\text{dur}} \cdot \text{CF}_{\text{abs}}} \quad (\text{Equation 3})$$

Dose_{desc} = Dose descriptor (NOAEL/NOAEC or LOAEL/LOAEC (mg/kg bw/d or mg/m³))

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 (Table II.4) are introduced for taking into account interspecies and intraspecies variability, data quality and other uncertainties.

Table II.4 . Default assessment factors (modified from ECHA, 2012)

Assessment factor accounting for differences in		Default value systemic effect
Interspecies (ASF) (OSF)	Correction for differences in metabolic rate per body weight	AS ^{1,2}
	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, see below

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_{dur})

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/d) 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 II.5).

Table II.5 Allometric scaling factors for different species as compared to humans¹ (modified from ECHA, 2012)

Species	Body weight (kg)	AS factor ¹
Rat	0.250	4
Mouse	0.03	7
Rabbit	2.00	2.4
Dog	18.00	1.4

¹ 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 II.6.

Table II.6 Scaling factors relating to exposure duration (modified from ECHA, 2012)

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.

2.3.2 DNELs for the Worker Population (Crew/PSC Officers)

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

- 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
- 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).

2.3.3 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:

- 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.

The currently used DNELs for the DBPs considered are listed in Annex V. Due to potentially new data received in the future, these DNELs may change, and the GESAMP-BWWG database should be checked regularly to take into consideration up-to-date values.

2.3.4 Calculation of Derived Minimal Effect Levels (DMELs)

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.

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 (ECHA, 2016a) 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} (a risk for cancer in 1 per 10,000 or 1,000,000 exposed individuals) are normally seen as indicative tolerable risk levels when setting DMELs (WHO 2001, ECHA 2016a). Where these values are available from internationally recognized bodies, they can be used to set DMELs for risk assessment purposes. In the GESAMP-BWWG risk assessment the figure 10^{-5} , that is, a risk for cancer in 1 per 100,000 exposed individuals, is applied for the selection of DMELs. The currently used DMELs for the DBPs considered are listed in Annex V. Due to potentially new data received in the future, these DMELs may change, and the GESAMP-BWWG database should be checked for up-to-date values.

2.4 Exposure assessment

2.4.1 How and Where Humans Have Exposure to Ballast Water

Humans may get exposed to ballast water and the chemicals contained therein either directly on board the ship while taking samples of ballast water at the sampling facility, 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. In the GESAMP-BWWG risk assessment the aggregate exposure approach, as defined by WHO/IPCS (WHO/IPCS, 2009) is applied, that is the combined exposure applicable to each scenario is estimated. The term 'aggregate exposure' (or 'combined exposure'), as defined by the WHO/IPCS, takes into account all relevant pathways (e.g., food, water, residential uses, occupational) as well as all relevant routes (oral, dermal, inhalation). The 'aggregate risk' is the risk associated with multiple pathways/routes of exposure to a single chemical.

2.4.2 Human Exposure Scenarios

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 ships' crew members 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 (MEPC, 2010a) when an invited expert, Dr. Andrew Phillips, was assisting the Group to further elaborate the human exposure scenarios.

Operations involving the crew and/or PSC officers

The five human exposure scenarios that have been identified and established at the GESAMP-BWWG Stocktaking Workshops are described in Table II.7.

Table II.7 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/vapours/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 officer scenarios are all listed in Table II.11. In all scenarios, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of men 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 men is 0.084 m² and the whole body surface area for men is 1.94 m² (Table II.8). Furthermore it is the aggregated exposure through the relevant routes that are taken into account, as outlined above, for each scenario.

Table II.8 Summary of physiological parameters in human exposure scenarios for crew/PSC officers

Parameter	Value	Reference
Body weight	60 kg	WHO (2017)
Hands (2), surface area	0.084 m ²	ECHA (2016b)
Whole body, surface area	1.94 m ²	US EPA (1997)
Inhalation rate (light activity for workers)	1.25 m ³ /h	ECHA (2012)
Temperature	293 K	GESAMP-BWWG assumption

Parameter	Value	Reference
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, 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 4) 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:

$$\text{Dose} = (1 - f_{\text{RMM}}) \cdot \frac{C \cdot N \cdot E \cdot f_{\text{derm}} \cdot f_{\text{pen}}}{\text{BW}} \quad (\text{Equation 4})$$

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)

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 operational 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:

$$\text{Dose}_{\text{Tier2}} = (1 - f_{\text{RMM}}) \cdot \frac{C \cdot N \cdot E \cdot f_{\text{derm}} \cdot f_{\text{pen}}}{\text{BW}} \quad (\text{Equation 5})$$

$\text{Dose}_{\text{Tier2}}$	=	skin exposure (mg/kg bw/d)
f_{RMM}	=	risk mitigation factor (default 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 (default tier 2 = 0.05 mL)
f_{derm}	=	dermal absorption factor (default = 1)
f_{pen}	=	penetration factor (default = 1)
BW	=	body weight (default = 60 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 BWM Convention. 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 6). 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 accordingly:

$$C_{\text{air}} = \frac{H}{R \cdot T} \cdot C_{\text{water}} \quad (\text{Equation 6})$$

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)

The sampling facility is to be placed in the engine room, such that a dilution factor of 100 (GESAMP-BWWG expert assumption) is introduced in the scenario 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 6, a simple tier 1 exposure assessment (equation 7) can be performed to calculate the inhaled dose resulting from the scenario.

$$\text{Dose}_{\text{Tier1}} = \frac{C_{\text{air}} \cdot \text{ET} \cdot \text{IR}}{\text{BW}} \quad (\text{Equation 7})$$

$\text{Dose}_{\text{Tier1}}$	=	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 (default = 60 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, 2016b). 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:

$$\text{Dose}_{\text{Tier1}} = \frac{A_{\text{hands}} \cdot \text{TH}_{\text{dermal}} \cdot C_{\text{water}} \cdot \text{Bio}_{\text{derm}}}{\text{BW}} \quad (\text{Equation 8})$$

$\text{Dose}_{\text{Tier1}}$	=	dermal uptake (mg/kg bw/d)
A_{hands}	=	surface area of two hands (0.084 m ²)
$\text{TH}_{\text{dermal}}$	=	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 (default = 60 kg)

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 (2002, 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 (US EPA, 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 (US EPA 2002, 2009) 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).

$$EC = \frac{C_{air} \cdot ET \cdot EF \cdot ED}{AT} \quad (\text{Equation 9})$$

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 II.10.

$$\text{Dose}_{\text{Tier2}} = (1 - f_{\text{RMM}}) \frac{C_{air} \cdot IR \cdot ET \cdot EF \cdot ED}{BW \cdot AT} \quad (\text{Equation 10})$$

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 6). 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 6), the tier 1 exposure assessment can be performed as described above (equation 7), using;

- Exposure time (ET): 8 h/d.

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 8) while taking into account possible exposure to the whole body, that is, 1.94 m².

Tier 2

If necessary, a tier 2 exposure assessment can be performed as described in equation 10, using;

- Exposure time (ET): 8 h/d
- Exposure frequency (EF): 5 d/y.

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 officer 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 6), 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 6), the tier 1 exposure assessment can be performed as described in equation 7.

- Exposure time in this scenario is 3 h/d (Table II.7).

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;

- Exposure time (ET): 3 h/d
- Exposure frequency (EF): 12 d/y.

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 6), 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 7) using:

- Exposure time (ET): 1 h/d.

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:

- Exposure time (ET): 1 h/d
- Exposure frequency (EF): 180 d/y.

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

Situations in which the general public might be exposed to treated ballast water

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 II.9.

Table II.9 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 II.10. In all scenarios, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of men 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 men is 0.084 m² (ECHA, 2016b) and the whole body surface area for men is 1.94 m². One parameter, ingestion rate of water while swimming, is taken from the Swimodel (US EPA, 2003).

Table II.10 Summary of physiological parameters in human exposure scenarios for general public

Parameter	Value	Reference
Body weight	60 kg	WHO (2017)
Whole body, surface area	1.94 m ²	US EPA (1997)
Inhalation rate (light activity)	1.25 m ³ /h	ECHA (2012)
Ingestion rate of water while swimming	0.025 L/h	US EPA (Swimodel, 2003)
Quantity of fish consumed	0.180 kg/d	FAO (2003, Japan)
Temperature	293 K	GESAMP-BWWG assumption
Dilution factor, swimming	100	EUSES (EUSES, 2016)

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-BW, and taking into account a dilution factor of 100 (due to wind, turbulence and insufficient time for the chemical to reach equilibrium) (EUSES, 2016). The inhaled dose may be estimated using the equation below, while taking into account various assumptions (number of swims, etc.):

$$\text{Dose}_{\text{inh}} = \frac{C_{\text{air}} \cdot \text{IR} \cdot n \cdot D \cdot \text{Bio}_{\text{inh}}}{\text{BW}} \quad (\text{Equation 11})$$

Dose_{inh} = inhalation intake of chemical during swimming (mg/kg bw/d)

C_{air} = concentration in air (mg/m³)

IR = inhalation rate – light activity assumed (1.25 m³/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 (default = 60 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:

$$\text{Dose}_{\text{Der}} = \frac{C_{\text{water}} \cdot \text{TH}_{\text{dermal}} \cdot n \cdot A_{\text{skin}} \cdot \text{Bio}_{\text{dermal}}}{\text{BW}} \quad (\text{Equation 12})$$

Dose_{Der}	=	dermal uptake per day during swimming (mg/kg bw/d)
C_{water}	=	concentration in the water, i.e. PECMAMPEC-BW (µg/L)
$\text{TH}_{\text{dermal}}$	=	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)
$\text{Bio}_{\text{dermal}}$	=	bioavailability for dermal intake (default = 1)
BW	=	body weight (default = 60 kg)

Swallowing of water contaminated with treated ballast water

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

$$\text{Dose}_{\text{Oral}} = \frac{C_{\text{water}} \cdot \text{IR}_{\text{swim}} \cdot n \cdot \text{Dur}_{\text{swim}} \cdot \text{Bio}_{\text{oral}}}{\text{BW}} \quad (\text{Equation 13})$$

$\text{Dose}_{\text{Oral}}$	=	amount of chemical swallowed (µg/kg bw/d)
C_{water}	=	concentration in the water, i.e. PECMAMPEC-BW (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 (default = 60 kg)

Eating seafood exposed to treated ballast water

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

$$C_{\text{fish}} = \text{BCF} \cdot C_{\text{water}} \quad (\text{Equation 14})$$

C_{fish}	=	concentration in fish (µg/kg)
BCF	=	bioconcentration factor (L/kg)
C_{water}	=	concentration in the water, i.e. PECMAMPEC-BW (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:

$$\text{Dose}_{\text{fish}} = \frac{\text{QFC} \cdot C_{\text{fish}} \cdot \text{Bio}_{\text{oral}}}{\text{BW}} \quad (\text{Equation 15})$$

$\text{Dose}_{\text{fish}}$ = uptake of chemical from eating fish ($\mu\text{g/kg bw/d}$)
 QFC = quantity of fish consumed/day (= 0.180 kg/d (FAO (2003), Japan))
 C_{fish} = concentration of chemical in fish ($\mu\text{g/kg}$)
 Bio_{oral} = bioavailability for oral intake (default = 1)
 BW = body weight (default = 60 kg)

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.

2.5 Risk Characterization

2.5.1 General Approach

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

$$\text{RCR} = \frac{\text{Exposure}}{\text{DNEL}} \quad (\text{Equation 16})$$

or

$$\text{RCR} = \frac{\text{Exposure}}{\text{DMEL}} \quad (\text{Equation 17})$$

In both cases, if the $\text{RCR} < 1$, the exposure will lead to no unacceptable risk. However, risks are regarded not to be controlled when the estimated exposure levels exceed the DNEL and/or the DMEL, that is, if the $\text{RCR} \geq 1$.

2.5.2 Occupational Health Risks

DNEL approach

Delivery, loading, mixing or adding chemicals to the BWMS

The resulting internal dose from the skin exposure in the tier 1 assessment (equation 4), which is based on the handling of containers according to the UK POEM model is presented as shown in Table II.11. In the tier 2 assessment personal protective equipment is taken into account (equation 5).

Table II.11 Crew, scenario: loading and filling – DNEL approach

Chemical name	Chemical concentration	Exposure with or without gloves	DNEL	RCR
	%w/w	mg/kg bw/d	mg/kg bw/d	-
A				
B				
C				

Ballast water sampling/Periodic cleaning of ballast tanks/Ballast tank inspections/Crew carrying out normal work on deck.

Tier 1

The aggregated internal dose resulting from exposure according to the other scenarios described in Section 2.4.2.1 (Ballast water sampling/Periodic cleaning of ballast tanks/Ballast tank inspections/Crew carrying out normal work on deck) may be presented as in the Table II.12 shown below.

Table II.12 Crew/ PSC officers – Tier 1 DNEL approach

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

While considering ballast water sampling and tank cleaning operations, it should be assumed that the exposure routes of concern for PSC 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.

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 Section 2.4.2 about ballast water sampling above (Tier 2, Taking time into consideration, Equation 9). (Table II.13).

Table II.13 Crew/ PSC officers – Tier 2 DNEL approach

Chemical name	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

Tier 1

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 Section 2.5.4. See also Table II.14.

Table II.14 Crew/PSC officers – Tier 1 DMEL approach

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

Tier 2

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 II.15.

Table II.15 Crew/ PSC officers – Tier 2 DMEL approach

Chemical name	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						

2.5.3 Health Risks for 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.

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 II.16.

Table II.16 General public scenario: swimming and consumption of seafood – DNEL approach

Chemical name	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 (Table II.17).

Table II.17 General public scenario: swimming and consumption of seafood – Tier 1 DMEL approach

Chemical name	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-BW regarding the concentrations in the surrounding water may be used (Table II.28).

Table II.18 General public scenario: swimming and consumption of seafood – Tier 2 DMEL approach

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

2.5.4 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, *et al.*, 2009), which entails a summation of the Risk Characterization Ratios (RCRs) of all substances with recognized carcinogenic potential. This approach had, for example, been used previously for carcinogens by the US EPA (US EPA, 1989), where it is based on the assumption that for carcinogens no dose threshold exists, and that the dose-response function is therefore essentially linear. Furthermore, since risk estimates are probabilities, cancer risks associated with different substances can, according to this approach, be added together irrespective of whether the substances cause cancer by (1) similar mechanisms, or (2) completely independent mechanisms. Under such conditions the use of simple effect summation for the estimation of a cancer risk estimate produces results similar to independent action, since the predicted cancer probabilities are very much smaller than 0.001 (Kortenkamp, *et al.*, 2009). 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 the addition of all RCRs of the individual components:

$$RCR_{\text{group}} = RCR_A + RCR_B + RCR_C + \dots + RCR_n \quad (\text{Equation 18})$$

For the group RCR the same conclusions apply as described above, that is if the $RCR < 1$, the exposure is deemed to represent no unacceptable risk. The 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.

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ANNEX III – HOW TO PERFORM MAMPEC-BW CALCULATIONS

MAMPEC-BW 3.1.0.3 MODEL

1 GENERAL

1.1 The model Marine Antifoulant Model for PEC calculation for Ballast Water (MAMPEC-BW 3.1.0.3) or latest available version may be downloaded from the website of Deltares in the Netherlands. The website is: <https://download.deltares.nl/en/download/mampec/>

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

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

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

1.5 Go to the specified directory and click on the executable “mampec.exe” and the main entrance screen will be shown. More detailed installation instructions are provided with the documentation.

2 CALCULATION OF THE PREDICTED ENVIRONMENTAL CONCENTRATION (PEC)

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

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

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

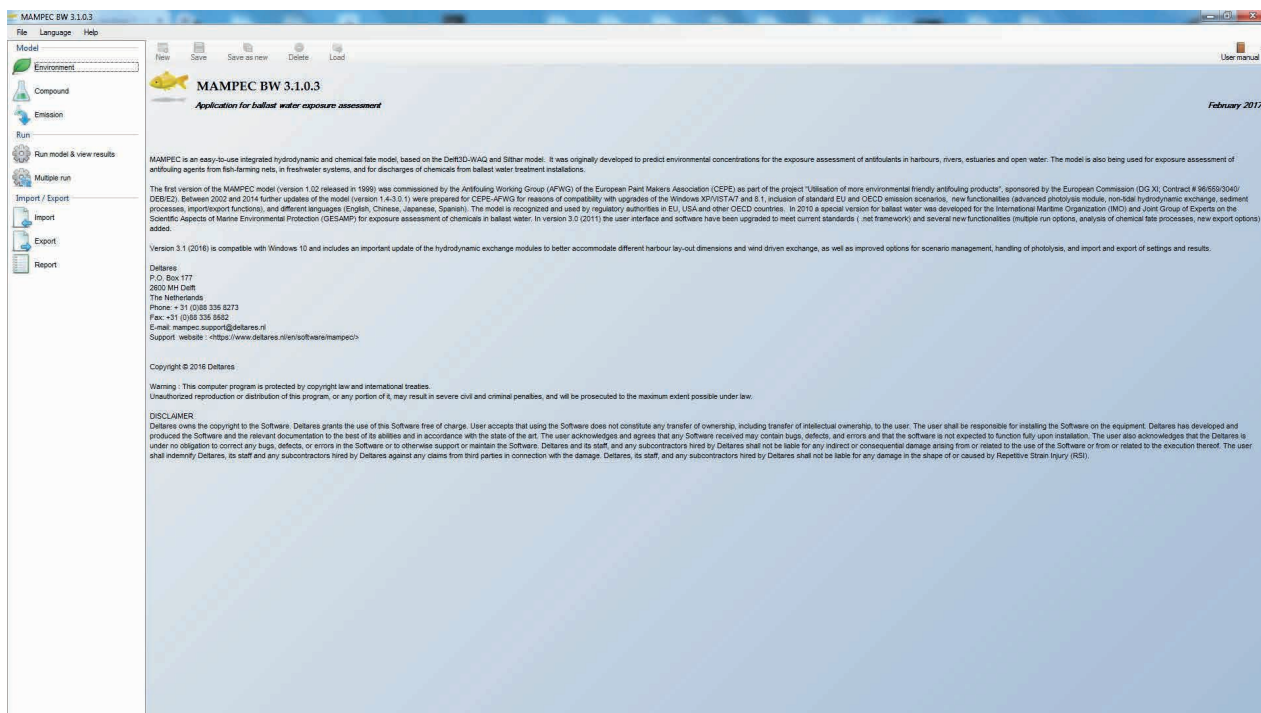


Figure III.1 Entrance screen of the MAMPEC-BW model

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

2.4 To run the MAMPEC-BW model three inputs are needed:

- The Environment (first item under “model” at the left hand side of the screen)
- The Compound (second item)
- The Emission (third item).

2.5 Click on “Environment” and the following screen appears:

Figure III.2 Input screen MAMPEC-BW

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

The screenshot shows a software window titled "Load". At the top, there is a search icon and a text box labeled "Description". Below this is a table with two columns: "Label" and "Description". The table contains three rows of data. The first row is highlighted with a blue background. To the left of the table, there is a minus sign icon and the text "Label (3)". At the bottom of the window, there are four buttons: "Delete", "Save labels", "Load", and "Cancel".

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

Figure III.3 *Input screen for the environment for MAMPEC-BW*

2.7 The “Description” box can be used as a filter for selection of environment scenarios. Select and click “GESAMP BWWG Model Harbour” and successively press the “Load” button. You will be taken back to the “Environment” screen but now the screen is loaded with the GESAMP-BWWG Model Harbour’s specific data. It is recommended not to change the default values when the results will be used for a submission to IMO with respect to an approval in accordance with Procedure (G9).

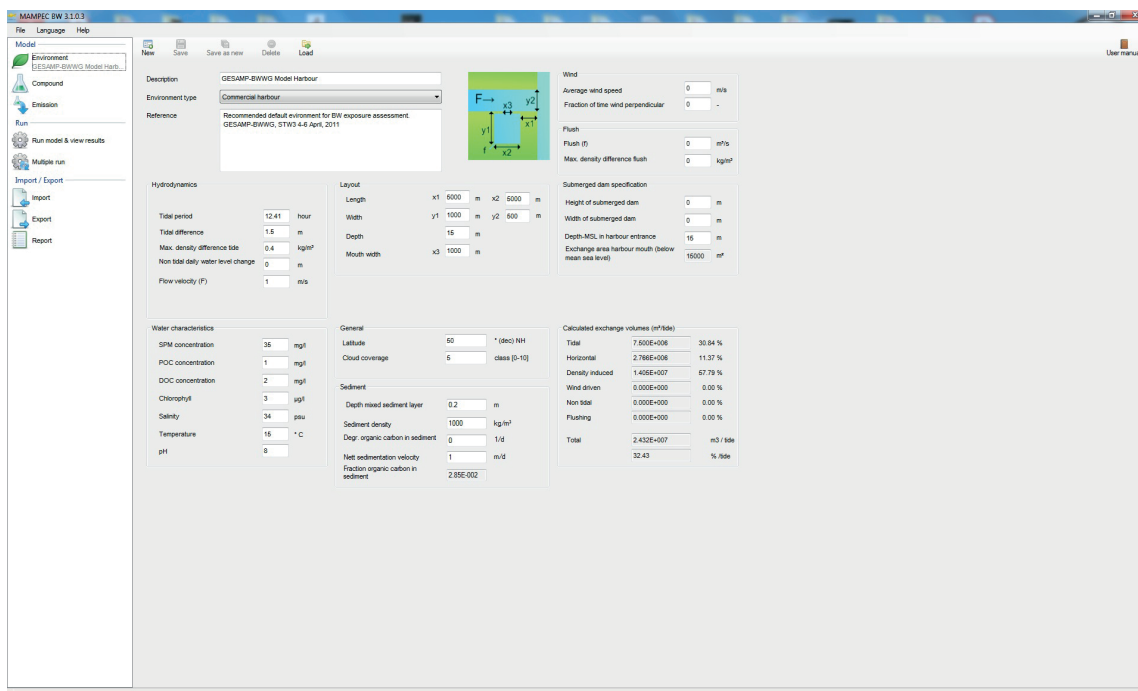


Figure III.4 Screen after loading the discharge environment for MAMPEC-BW

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

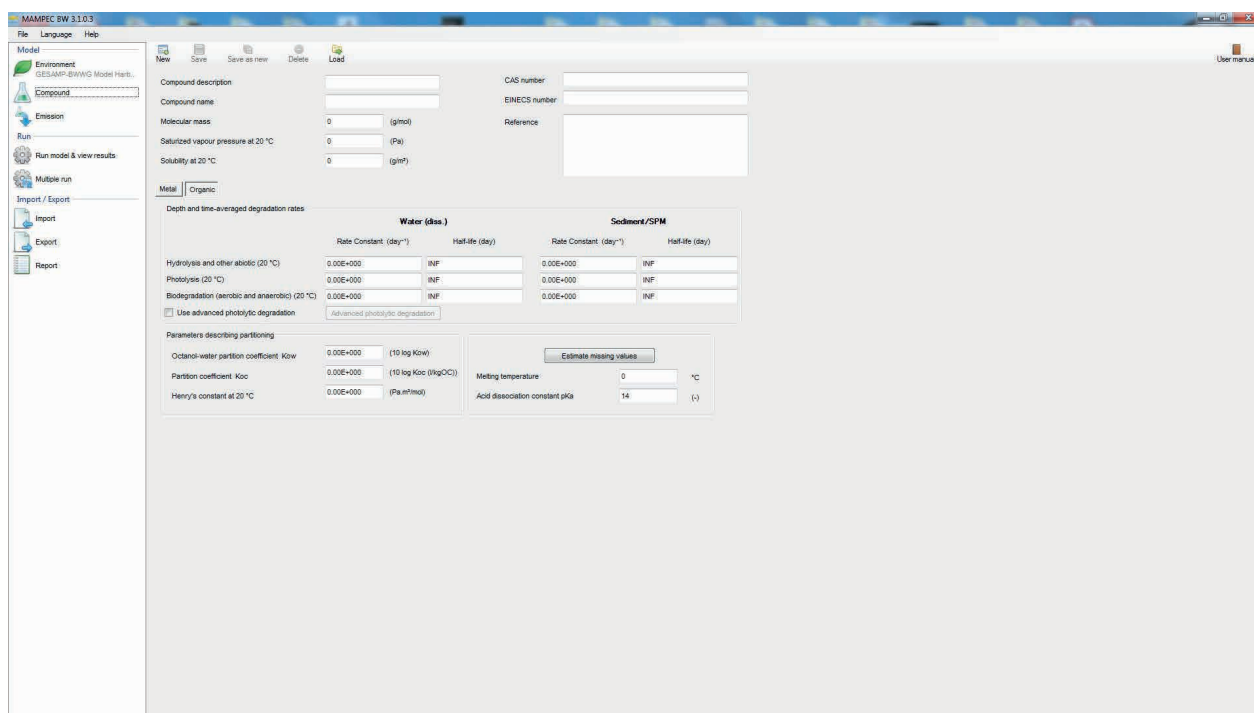


Figure III.5 Input screen for the substance in MAMPEC-BW

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

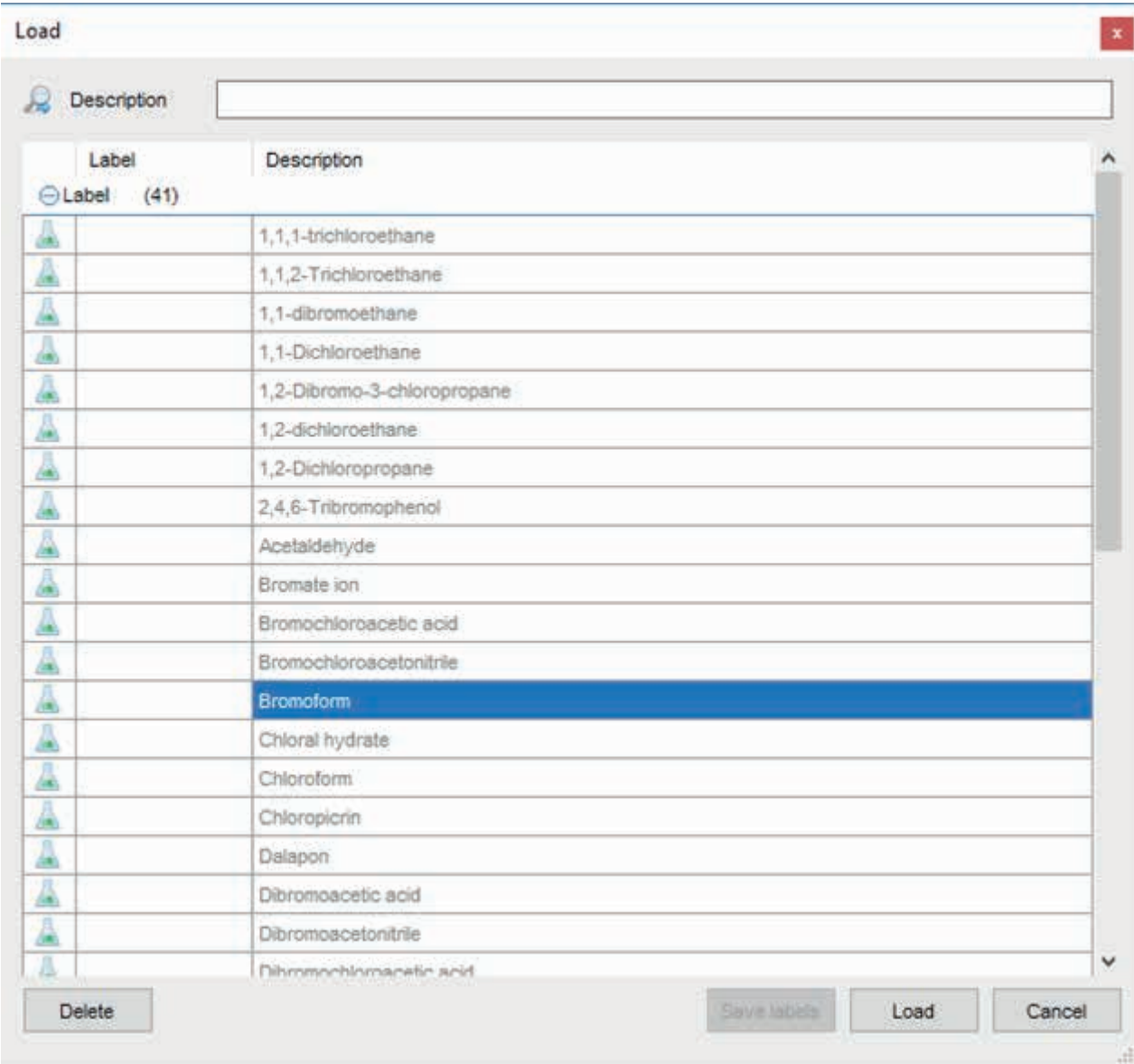


Figure III.6 Substance screen for bromoform in the MAMPEC-BW database

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

The screenshot shows the MAMPEC BW 3.10.3 software interface. The 'Compound' screen for Bromoform is active. The sidebar on the left contains icons for Environment, Compound, Emission, Run, Run model & view results, Multiple run, Import / Export, Import, Export, and Report. The main window has a menu bar (File, Language, Help) and a toolbar (New, Save, Save as new, Delete, Load). The 'Compound description' section shows 'Bromoform' for both description and name. The 'CAS number' is 75-25-2, and the 'EINECS number' is blank. The 'Reference' field contains 'GESAMP-BWVG, STW3 4-6 April, 2011, II from TOXNET-HS06'. Physical properties listed are: Molecular mass 252.73 (g/mol), Saturated vapour pressure at 20 °C 660 (Pa), and Solubility at 20 °C 3190 (g/m³). The 'Metal' field is set to 'Organic'. The 'Depth and time-averaged degradation rates' section has two tabs: 'Water (diss.)' and 'Sediment/SPM'. Under 'Water (diss.)', there are input fields for Rate Constant (day⁻¹) and Half-life (day) for Hydrolysis and other abiotic (20 °C), Photolysis (20 °C), and Biodegradation (aerobic and anaerobic) (20 °C). All these fields are currently set to 0.00E+000 or INF. There is a checkbox for 'Use advanced photolytic degradation' and a button for 'Advanced photolytic degradation'. The 'Parameters describing partitioning' section includes input fields for Octanol-water partition coefficient Kow (2.40E+000), Partition coefficient Koc (1.90E+001), and Henry's constant at 20 °C (5.41E+001). There is also a button for 'Estimate missing values' and fields for Melting temperature (8 °C) and Acid dissociation constant pKa (14).

Figure III.7 Substance screen for bromoform in the MAMPEC-BW database

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

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

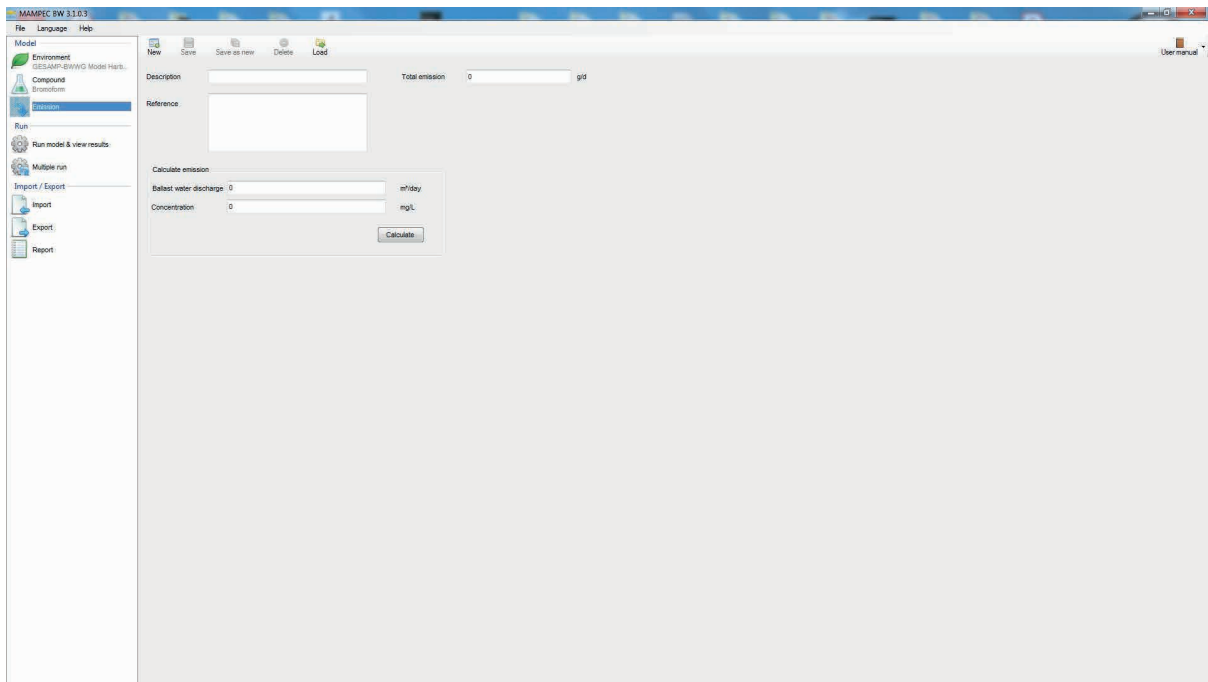


Figure III.8 Input screen for the total discharge in MAMPEC-BW

and

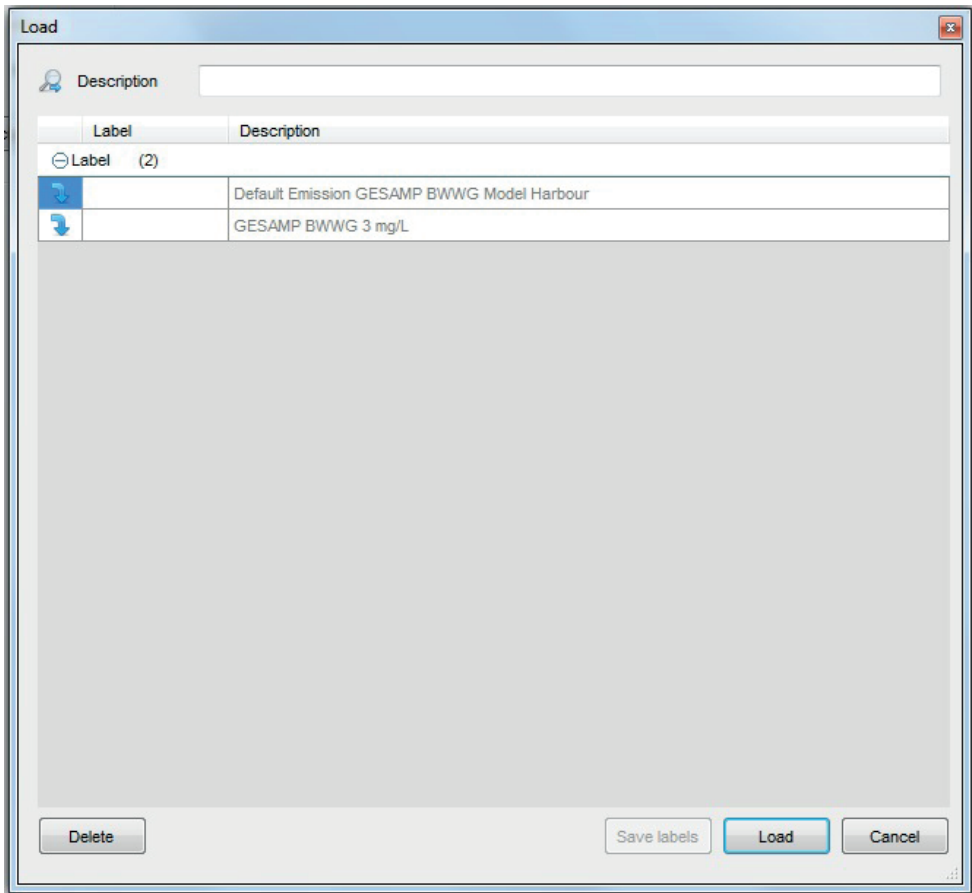


Figure III.9 Input screen for a predetermined load in MAMPEC-BW

2.13 Clicking on “Default Emission GESAMP Model Harbour” and on “Load” takes you back to the emission screen, where you can complete your input by entering the concentration of the substance under consideration found in ballast water at the appropriate box. Successively clicking on “Calculate” gives the final emission in g/d. Note that the concentration of the substance should be entered in mg/L (not µg/L).

Figure III.10 Screen to calculate the load discharged in MAMPEC-BW

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

Figure III.11 Screen to perform the calculations in MAMPEC-BW

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

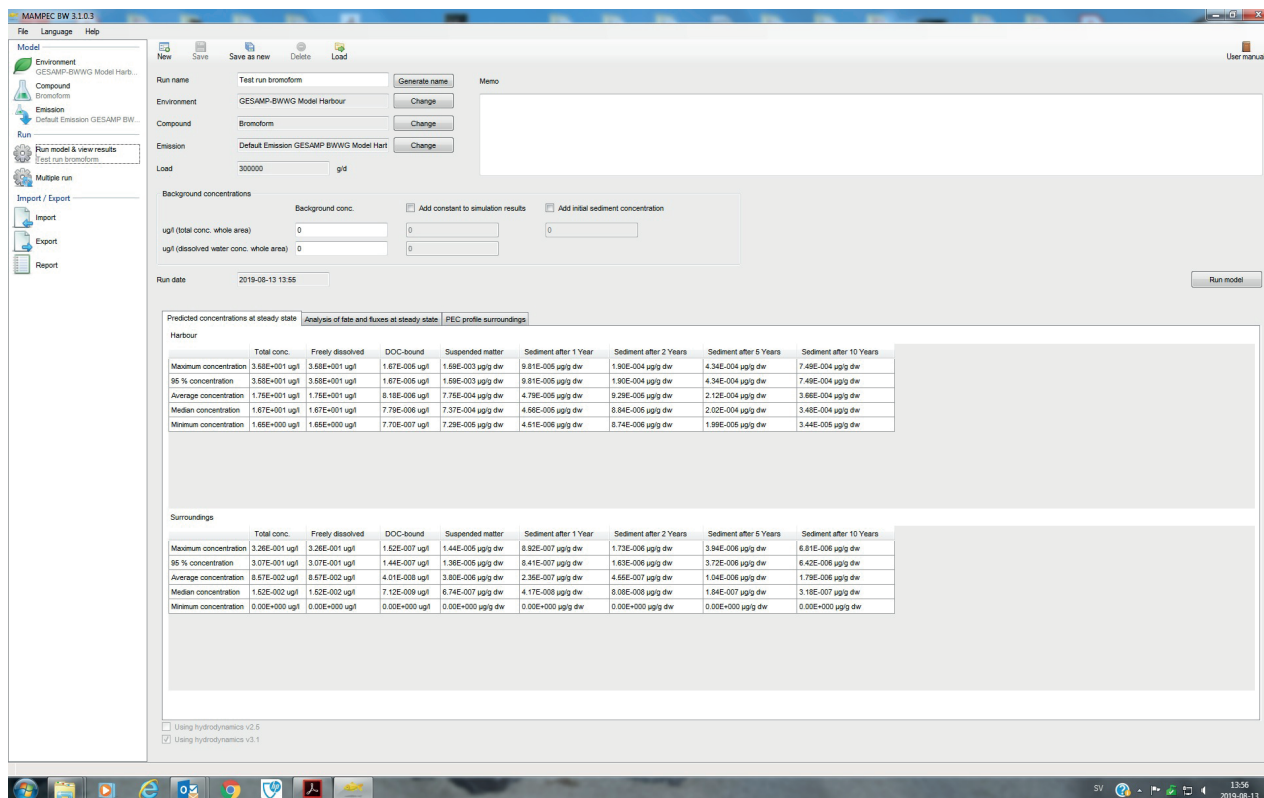


Figure III.12 Screen with calculation results from MAMPEC-BW

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

2.17 At the left hand side some input/output facilities are given, for exporting the results and the generation of a report with comprehensive model settings, input and results for publication. Detailed instructions for using these options are provided in the Manual.

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

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

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

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

3.1 The MAMPEC-BW, latest available version, will calculate the stationary annual average concentration in the harbour after discharge of ballast water. To account for local effects, near the ship at discharge, the local concentration at near ship is estimated using the formulae suggested in Zipperle *et al.*, (2011):

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

where:

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

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

$$PEC_{\text{near ship}} / PNEC_{\text{near ship}}$$

4 SOME THEORETICAL BACKGROUND REGARDING MAMPEC-BW

This section is based on the entrance screen of the model and the MAMPEC 3.0 Handbook – Technical Documentation, October 2016, and is included with the permission of Deltares.

Introduction, History and Copyright

MAMPEC is a steady-state 2D integrated hydrodynamic and chemical fate model, originally developed for the exposure assessment of antifouling substances (Van Hattum, *et al.*, 2002, 2006). The first version of the model was developed in 1999 commissioned by the Antifouling Working Group (AFWG) of the European Paint Makers Association (CEPE / CEFIC) and co-sponsored by the European Commission (DG XI). Since then updates have been released sponsored by CEPE-AFWG in 2002 (v1.4) [1], 2005 (v1.6), and 2008 (v2.5) compatible with changing requirements of common operating systems (Win9X-NT-2000-XP-VISTA-Win7) and requirements of users and competent authorities. The model and support documentation has been distributed freely via the internet (<http://www.deltares.nl/en/software/1039844/mampec/1039846>). The model is recognized and used by regulatory authorities in EU, USA and other OECD countries.

In 2010 a special version for ballast water (MAMPEC-BW) was developed for the International Maritime Organization (IMO) and Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP) for the exposure assessment of chemicals in ballast water.

In version 3.0 (2011) the user interface and software have been upgraded to meet current standards (.net framework) and several new functionalities (multiple run options, analysis of chemical fate processes, new export options) and languages (Chinese, Spanish) have been added. Various minor bug fixes were addressed in version 3.0.1 (2014). The database of the ballast water version (MAMPEC-BW v3.0.1) was completed with default properties for 41 compounds.

Version 3.1 (2016) is compatible with Windows 10 and includes new regional marina scenarios, an important update of the hydrodynamic exchange modules to better accommodate different harbour lay-out dimensions and wind driven exchange, as well as improved options for scenario management, handling of photolysis, and import and export of settings and results. This version further included all items of the 'Consolidated list of PT 21 technical agreements' – version 1.2 September 2013 – TM II 2013 (Item 1.6 of the Technical Meetings of the European Biocidal Products Directive (No. 98/8/EC) and the Biocidal Products Regulation (No 528/2012).

The model and support documentation has been distributed freely via the internet (<http://www.deltares.nl/en/software/1039844/mampec/1039846>). The model predicts concentrations of antifoulants in generalized 'typical' marine environments (open sea, shipping lane, estuary, commercial harbour, yachting marina, open harbour). For ballast water a representative model harbour has been defined. The user can specify: emission factors (e.g., leaching rates, shipping intensities, residence times, ship hull underwater surface areas), compound-related properties and processes (e.g., K_d , K_{ow} , K_{oc} , volatilization, speciation, hydrolysis, photolysis, biodegradation), and properties and hydrodynamics related to the specific environment (e.g., currents, tides, salinity, DOC, suspended matter load, port dimensions). MAMPEC includes options for advanced photolysis modelling, incorporation of wind-driven hydrodynamic exchange, and other non-tidal exchange processes important for areas without tidal action or inland freshwater environments. Included are also service-life emission and other scenarios developed by an OECD-EU working group (OECD, 2004) and adopted by EU as the standard environmental emission scenarios to be used for evaluation of the biocides under the Biocidal Products Directive (BPD, Directive 98/8/EC) and the more recent Biocidal Product Regulation (BPR, Regulation (EU) 528/2012).

The model has been validated for a number of compounds and is today recognized by regulatory authorities in EU, USA, Japan, and other OECD countries. MAMPEC has been adapted, sponsored by IMO, to include the standard environment and emission scenarios for ballast-water as recommended by GESAMP: MAMPEC-BW.

The documentation of formulations and backgrounds in MAMPEC has been described in different reports issued with new updates (e.g., Van Hattum, *et al.*, 1999, 2002, 2006; Baart, 2003; Boon, *et al.*, 2008), and with additional explanations in release notes or documents prepared for the Technical Meetings of competent European authorities for the Biocidal Products Directive.

Scientific Background

The MAMPEC model first calculates the hydrodynamics and transport mechanisms of the harbour under consideration. The processes taken into account are the total water exchange volume influenced by the tide, density currents based on differences in salinity, wind driven exchange, non-tidal exchange flow and extra flush from within the harbour. These different flows require a 3D-model and the Delft3D-FLOW has been used (Delft Hydraulics, 2005).

The general advection-dispersion equation is the basis for the calculation of transporting the substance in the area defined.

$$\frac{aC}{at} = D_x \frac{a^2C}{ax^2} - u \frac{aC}{ax} + D_y \frac{a^2C}{ay^2} - v \frac{aC}{ay} + E + S = 0$$

where

C = total concentration (g/m³)

D_x, D_y = dispersion coefficients in two directions (m²/s)

E = emissions (g/m³/s)

S = source term representing decay and retention processes (g/m³/s)

u, v = velocity components in two directions (m/s)

x, y = spatial coordinates (m).

Chemical processes modelled include volatilization, sorption, sedimentation and degradation. The degradation includes photolysis, hydrolysis and biodegradation. The output of the model is the estimated PEC in the harbour and the surroundings of the defined area as a yearly average concentration. The model has been validated with several case studies, although not particularly for ballast water. For further details see the Technical Documentation (Van Hattum *et al.*, 2016).

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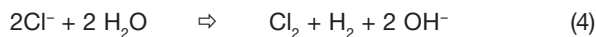
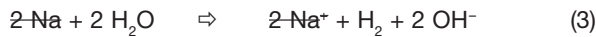
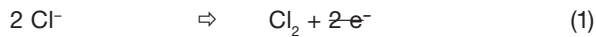
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ANNEX IV – HYDROGEN (H₂) GAS PRODUCTION AS A FUNCTION OF TRO PRODUCTION IN ELECTROCHLORINATION-BASED BWMS

Chemical reactions occurring in electrochlorination-based BWMS are:



The overall chemical reaction (equation 4) shows that the production of 1 mole of TRO, as chlorine (Cl₂), results in the production of 1 mole of H₂ gas, which has a volume of 22.414 L at a temperature of 0°C and atmospheric pressure of 101.325 kPa.

From there, it is easy to calculate the hourly or daily production rate of H₂ as a function of the target TRO concentration in water (in mg/L, as Cl₂) and ballast water flow rate (FL_{BW}, in m³/h).

$$\text{H}_2 \text{ (L/h)} = 0.316 \times \text{FL}_{\text{BW}} \times \text{TRO} \quad (5)$$

$$\text{H}_2 \text{ (m}^3\text{/d)} = 0.00758 \times \text{FL}_{\text{BW}} \times \text{TRO} \quad (6)$$

Note that H₂ production is given in litre per hour (L/h) with equation (5) and in cubic metre per day (m³/d) with equation (6).

For a quick estimation of H₂ production see Figures IV.1 and IV.2.

Figure 1

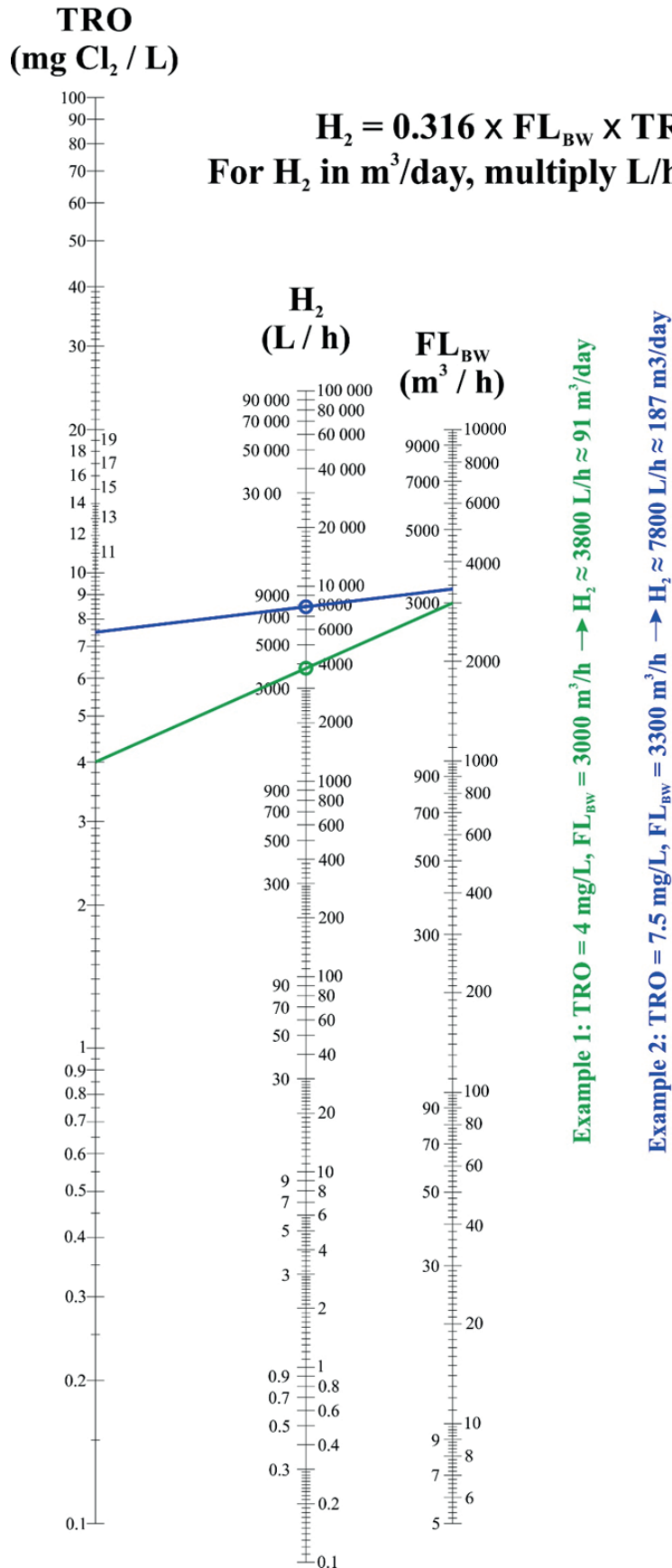


Figure IV.1 Nomogram for the calculation of hydrogen gas production (H₂, in L/h) by electrochlorination as a function of total residual oxidant target concentration (TRO, in mg Cl₂/L) and ballast water flow rate (FL_{BW}, in m³/h)

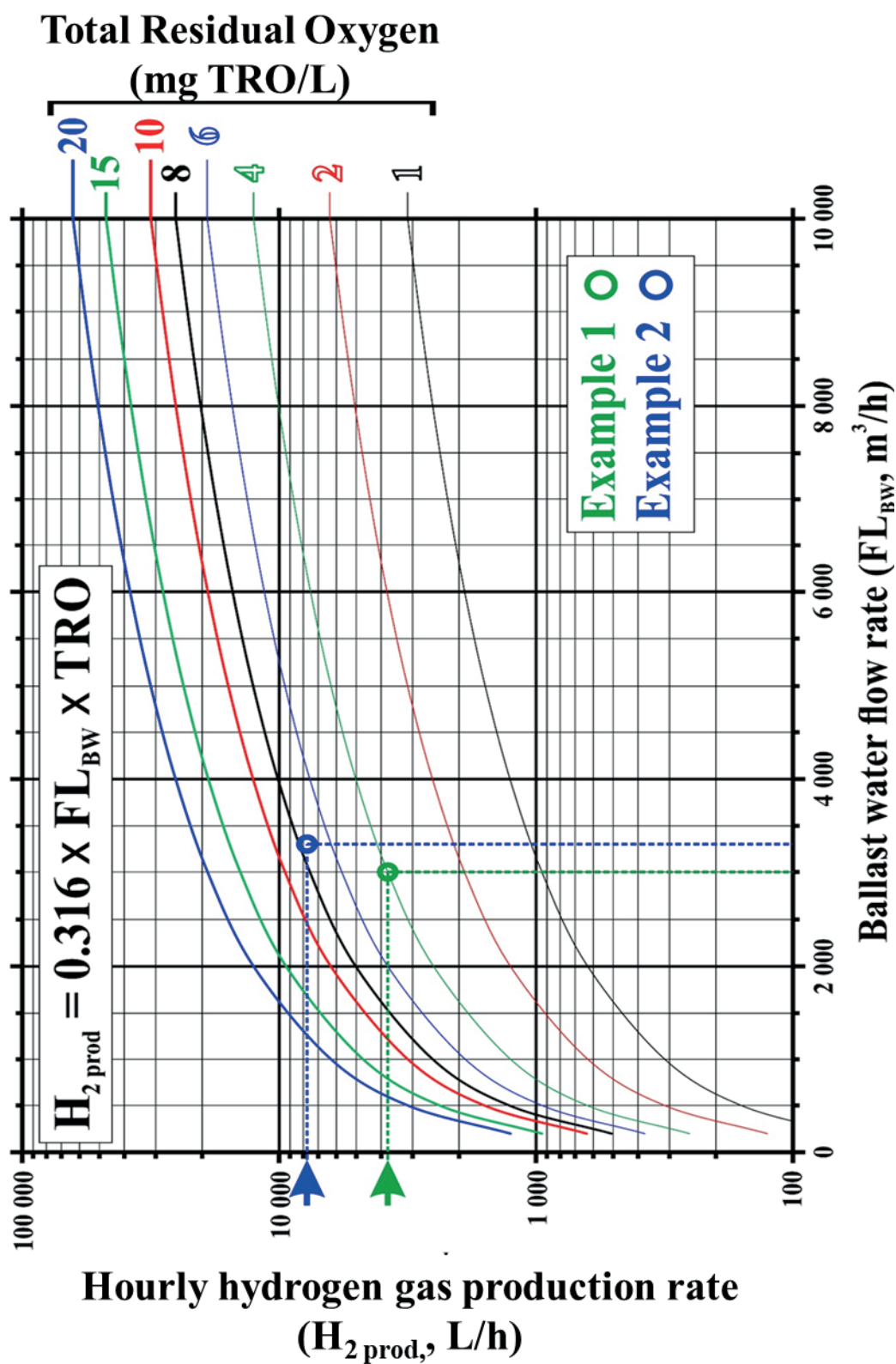


Figure IV.2 H_2 production (in L/h) by electrochlorination as a function of ballast water flow rate (FL_{BW} in m^3/h) and for TRO target concentrations of 1, 2, 4, 6, 8, 10, 15, and 20 mg Cl_2/L

ANNEX V – OVERVIEW OF MAXIMUM EXPOSURE LIMITS FOR DBPS IN GISIS

Chemical name	PNEC general (µg/L)	PNEC near ship (µg/L)	DNEL worker (mg/kg bw/d)	DNEL general public (µg/kg bw/d)	DMEL (µg/kg bw/d)
Acetaldehyde	2.2E+0	2.2E+1	4.2E-1	2.1E+2	NA
Bromate ion	1.4E+2	1.4E+3	2.2E-2	1.1E+1	1.1E-1
Bromochloroacetic acid	1.6E+1	1.6E+1	7.5E-1	3.8E+2	1.3E-1
Bromochloroacetonitrile	6.9E-1	6.9E+0	1.5E-1	7.5E+1	NA
Chloral hydrate	9.7E+1	9.7E+2	6.7E-1	3.3E+2	NA
Chlorate ion	4.8E+3	4.8E+3	1.0E-1	5.0E+1	NA
Chloropicrin	2.5E-2	2.5E-2	4.1E-3	2.0E+0	NA
Dalapon	1.1E+1	1.1E+2	1.7E-1	8.4E+1	NA
Dibromoacetic acid	6.9E+3	6.9E+3	7.2E-2	3.6E+1	1.3E-1
Dibromoacetonitrile	5.5E-2	5.5E-1	1.6E-1	8.2E+1	NA
Dibromochloroacetic acid	3.0E+2	3.0E+2	3.0E-1	1.5E+2	NA
Dibromochloromethane	6.3E+0	2.7E+2	2.1E-1	1.1E+2	1.5E+0
1,2-dibromo-3-chloropropane	1.6E+2	1.5E+2	5.0E-3	2.5E+0	3.3E-2
1,1-dibromoethane	2.4E+1	2.4E+2	1.0E+0	5.0E+2	NA
Dibromomethane	4.5E+2	4.5E+2	1.1E+0	5.5E+2	NA
Dichloroacetic acid	2.3E+1	2.3E+2	1.2E-1	6.0E+1	1.7E+0
Dichloroacetonitrile	2.4E+1	2.4E+2	5.7E-2	2.9E+1	NA
Dichlorobromoacetic acid	6.0E+1	1.0E+2	5.0E+0	2.5E+3	1.7E+0
Dichlorobromomethane	7.8E+1	7.8E+1	4.0E-2	2.0E+1	2.4E+0
1,1-dichloroethane	1.1E+1	3.4E+1	6.2E+0	3.1E+3	NA
1,2-dichloroethane	2.2E+2	3.6E+2	5.0E-1	2.5E+2	1.0E+0
Dichloromethane	1.2E+2	2.7E+2	1.2E-1	6.0E+1	NA
1,2-dichloropropane	9.6E+1	1.5E+2	8.9E-1	4.4E+2	NA
Formaldehyde	5.8E+0	3.1E+1	2.0E-1	1.0E+2	2.2E-1
Isocyanuric acid	3.2E+2	6.2E+2	3.1E+0	1.5E+3	NA
Monobromoacetic acid	1.6E+1	1.6E+1	7.0E-2	3.5E+1	NA
Monobromoacetonitrile	2.3E+1	2.3E+2	8.0E-3	4.0E+0	NA
Monochloramine	9.8E-1	6.4E+0	1.9E-1	9.5E+1	NA
Monochloroacetic acid	5.8E-1	5.8E-1	7.0E-2	3.5E+1	NA
Monochloroacetonitrile	1.6E-1	1.6E+0	8.2E-3	4.1E+0	NA
Sodium hypochlorite	2.1E-1	2.1E-1	2.8E-1	1.4E+2	NA
Sodium sulfite	2.6E+2	2.6E+2	2.9E+0	1.4E+3	NA
Sodium thiosulphate	8.1E+2	8.1E+2	1.9E+1	9.6E+3	NA
Tetrachloromethane	9.8E+0	7.6E+1	4.4E-2	2.2E+1	NA
Tribromoacetic acid	1.4E+4	2.2E+4	8.6E-1	4.3E+2	NA
Tribromomethane	9.6E+1	9.6E+1	1.8E-1	8.9E+1	7.7E+0
2,4,6-tribromophenol	2.0E+0	2.6E+0	7.1E-1	3.6E+2	NA
Trichloroacetic acid	3.0E+2	3.0E+2	8.6E-1	4.3E+2	NA
Trichloroacetonitrile	6.0E+0	6.0E+1	3.3E-3	1.7E+0	NA
1,1,1-trichloroethane	1.3E+2	1.3E+2	6.0E+0	3.0E+3	NA
1,1,2-trichloroethane	1.3E+2	1.8E+3	2.4E+0	1.2E+3	NA
Trichloroethene	3.0E+0	2.2E+2	6.7E-4	3.3E-1	2.1E-1
Trichloromethane	1.5E+2	1.5E+2	2.4E-1	1.2E+2	NA
1,2,3-Trichloropropane	4.0E-1	2.7E+1	5.7E-2	2.9E+1	2.0E-4

NA = not applicable

These currently used maximum exposure limits for the DBPs considered may change due to potentially new data received in the future. The GESAMP-BWWG database should be checked for up-to-date values.

ANNEX VI – GESAMP REPORTS AND STUDIES PUBLICATIONS

The following reports and studies have been published so far. They are available from the GESAMP website: <http://gesamp.org>

- 1 Report of the seventh session, London, 24-30 April 1975. (1975). Rep. Stud. GESAMP, (1):pag.var. Available also in French, Spanish and Russian
- 2 Review of harmful substances. (1976). Rep. Stud. GESAMP, (2):80 p.
- 3 Scientific criteria for the selection of sites for dumping of wastes into the sea. (1975). Rep. Stud. GESAMP, (3):21 p. Available also in French, Spanish and Russian
- 4 Report of the eighth session, Rome, 21-27 April 1976. (1976). Rep. Stud. GESAMP, (4):pag.var. Available also in French and Russian
- 5 Principles for developing coastal water quality criteria. (1976). Rep. Stud. GESAMP, (5):23 p.
- 6 Impact of oil on the marine environment. (1977). Rep. Stud. GESAMP, (6):250 p.
- 7 Scientific aspects of pollution arising from the exploration and exploitation of the sea-bed. (1977). Rep. Stud. GESAMP, (7):37 p.
- 8 Report of the ninth session, New York, 7-11 March 1977. (1977). Rep. Stud. GESAMP, (8):33 p. Available also in French and Russian
- 9 Report of the tenth session, Paris, 29 May - 2 June 1978. (1978). Rep. Stud. GESAMP, (9):pag.var. Available also in French, Spanish and Russian
- 10 Report of the eleventh session, Dubrovnik, 25-29 February 1980. (1980). Rep. Stud. GESAMP, (10):pag.var. Available also in French and Spanish
- 11 Marine Pollution implications of coastal area development. (1980). Rep. Stud. GESAMP, (11):114 p.
- 12 Monitoring biological variables related to marine pollution. (1980). Rep. Stud. GESAMP, (12):22 p. Available also in Russian
- 13 Interchange of pollutants between the atmosphere and the oceans. (1980). Rep. Stud. GESAMP, (13):55 p.
- 14 Report of the twelfth session, Geneva, 22-29 October 1981. (1981). Rep. Stud. GESAMP, (14):pag.var. Available also in French, Spanish and Russian
- 15 The review of the health of the oceans.(1982). Rep. Stud. GESAMP, (15):108 p.
- 16 Scientific criteria for the selection of waste disposal sites at sea. (1982). Rep. Stud. GESAMP, (16):60 p.
- 17 The evaluation of the hazards of harmful substances carried by ships. (1982). Rep. Stud. GESAMP, (17):pag.var.
- 18 Report of the thirteenth session, Geneva, 28 February - 4 March 1983. (1983). Rep. Stud. GESAMP, (18):50 p. Available also in French, Spanish and Russian
- 19 An oceanographic model for the dispersion of wastes disposed of in the deep sea. (1983). Rep. Stud. GESAMP, (19):182 p.
- 20 Marine pollution implications of ocean energy development. (1984). Rep. Stud. GESAMP, (20):44 p.
- 21 Report of the fourteenth session, Vienna, 26-30 March 1984. (1984). Rep. Stud. GESAMP, (21):42 p. Available also in French, Spanish and Russian
- 22 Review of potentially harmful substances. Cadmium, lead and tin. (1985). Rep. Stud. GESAMP, (22):114 p.
- 23 Interchange of pollutants between the atmosphere and the oceans (part II). (1985). Rep. Stud. GESAMP, (23):55 p.
- 24 Thermal discharges in the marine environment. (1984). Rep. Stud. GESAMP, (24):44 p.
- 25 Report of the fifteenth session, New York, 25-29 March 1985. (1985). Rep. Stud. GESAMP, (25):49 p. Available also in French, Spanish and Russian
- 26 Atmospheric transport of contaminants into the Mediterranean region. (1985). Rep. Stud. GESAMP, (26):53 p.
- 27 Report of the sixteenth session, London, 17-21 March 1986. (1986). Rep. Stud. GESAMP, (27):74 p. Available also in French, Spanish and Russian

- 28 Review of potentially harmful substances. Arsenic, mercury and selenium. (1986). Rep. Stud. GESAMP, (28):172 p.
- 29 Review of potentially harmful substances. Organosilicon compounds (silanes and siloxanes). (1986). Published as UNEP Reg. Seas Rep. Stud., (78):24 p.
- 30 Environmental capacity. An approach to marine pollution prevention. (1986). Rep. Stud. GESAMP, (30):49 p.
- 31 Report of the seventeenth session, Rome, 30 March - 3 April 1987. (1987). Rep. Stud. GESAMP, (31):36 p. Available also in French, Spanish and Russian
- 32 Land-sea boundary flux of contaminants: contributions from rivers. (1987). Rep. Stud. GESAMP, (32):172 p.
- 33 Report on the eighteenth session, Paris, 11-15 April 1988. (1988). Rep. Stud. GESAMP, (33):56 p. Available also in French, Spanish and Russian
- 34 Review of potentially harmful substances. Nutrients. (1990). Rep. Stud. GESAMP, (34):40 p.
- 35 The evaluation of the hazards of harmful substances carried by ships: Revision of GESAMP Reports and Studies No. 17. (1989). Rep. Stud. GESAMP, (35):pag.var.
- 36 Pollutant modification of atmospheric and oceanic processes and climate: some aspects of the problem. (1989). Rep. Stud. GESAMP, (36):35 p.
- 37 Report of the nineteenth session, Athens, 8-12 May 1989. (1989). Rep. Stud. GESAMP, (37):47 p. Available also in French, Spanish and Russian
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- 39 The state of the marine environment. (1990). Rep. Stud. GESAMP, (39):111 p. Available also in Spanish as Inf. Estud.Progr.Mar.Reg.PNUMA, (115):87 p.
- 40 Long-term consequences of low-level marine contamination: An analytical approach. (1989). Rep. Stud. GESAMP, (40):14 p.
- 41 Report of the twentieth session, Geneva, 7-11 May 1990. (1990). Rep. Stud. GESAMP, (41):32 p. Available also in French, Spanish and Russian
- 42 Review of potentially harmful substances. Choosing priority organochlorines for marine hazard assessment. (1990). Rep. Stud. GESAMP, (42):10 p.
- 43 Coastal modelling. (1991). Rep. Stud. GESAMP, (43):187 p.
- 44 Report of the twenty-first session, London, 18-22 February 1991. (1991). Rep. Stud. GESAMP, (44):53 p. Available also in French, Spanish and Russian
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- 46 Review of potentially harmful substances. Carcinogens: their significance as marine pollutants. (1991). Rep. Stud. GESAMP, (46):56 p.
- 47 Reducing environmental impacts of coastal aquaculture. (1991). Rep. Stud. GESAMP, (47):35 p.
- 48 Global changes and the air-sea exchange of chemicals. (1991). Rep. Stud. GESAMP, (48):69 p.
- 49 Report of the twenty-second session, Vienna, 9-13 February 1992. (1992). Rep. Stud. GESAMP, (49):56 p. Available also in French, Spanish and Russian
- 50 Impact of oil, individual hydrocarbons and related chemicals on the marine environment, including used lubricant oils, oil spill control agents and chemicals used offshore. (1993). Rep. Stud. GESAMP, (50):178 p.
- 51 Report of the twenty-third session, London, 19-23 April 1993. (1993). Rep. Stud. GESAMP, (51):41 p. Available also in French, Spanish and Russian
- 52 Anthropogenic influences on sediment discharge to the coastal zone and environmental consequences. (1994). Rep. Stud. GESAMP, (52):67 p.
- 53 Report of the twenty-fourth session, New York, 21-25 March 1994. (1994). Rep. Stud. GESAMP, (53):56 p. Available also in French, Spanish and Russian
- 54 Guidelines for marine environmental assessment. (1994). Rep. Stud. GESAMP, (54):28 p.
- 55 Biological indicators and their use in the measurement of the condition of the marine environment. (1995). Rep. Stud. GESAMP, (55):56 p. Available also in Russian

- 56 Report of the twenty-fifth session, Rome, 24-28 April 1995. (1995). Rep. Stud. GESAMP, (56):54 p. Available also in French, Spanish and Russian
- 57 Monitoring of ecological effects of coastal aquaculture wastes. (1996). Rep. Stud. GESAMP, (57):45 p.
- 58 The invasion of the ctenophore *Mnemiopsis leidyi* in the Black Sea. (1997). Rep. Stud. GESAMP, (58):84 p.
- 59 The sea-surface microlayer and its role in global change. (1995). Rep. Stud. GESAMP, (59):76 p.
- 60 Report of the twenty-sixth session, Paris, 25-29 March 1996. (1996). Rep. Stud. GESAMP, (60):29 p. Available also in French, Spanish and Russian
- 61 The contributions of science to integrated coastal management. (1996). Rep. Stud. GESAMP, (61):66 p.
- 62 Marine biodiversity: patterns, threats and development of a strategy for conservation. (1997). Rep. Stud. GESAMP, (62):24 p.
- 63 Report of the twenty-seventh session, Nairobi, 14-18 April 1997. (1997). Rep. Stud. GESAMP, (63):45 p. Available also in French, Spanish and Russian
- 64 The revised GESAMP hazard evaluation procedure for chemical substances carried by ships. (2002). Rep. Stud. GESAMP, (64):121 p.
- 65 Towards safe and effective use of chemicals in coastal aquaculture. (1997). Rep. Stud. GESAMP, (65):40 p.
- 66 Report of the twenty-eighth session, Geneva, 20-24 April 1998. (1998). Rep. Stud. GESAMP, (66):44 p.
- 67 Report of the twenty-ninth session, London, 23-26 August 1999. (1999). Rep. Stud. GESAMP, (67):44 p.
- 68 Planning and management for sustainable coastal aquaculture development. (2001). Rep. Stud. GESAMP, (68):90 p.
- 69 Report of the thirtieth session, Monaco, 22-26 May 2000. (2000). Rep. Stud. GESAMP, (69):52 p.
- 70 A sea of troubles. (2001). Rep. Stud. GESAMP, (70):35 p.
- 71 Protecting the oceans from land-based activities – Land-based sources and activities affecting the quality and uses of the marine, coastal and associated freshwater environment.(2001). Rep. Stud. GESAMP, (71):162p.
- 72 Report of the thirty-first session, New York, 13-17 August 2001. (2002). Rep. Stud. GESAMP, (72):41 p.
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- 74 Report of the thirty-third session, Rome, 5-9 May 2003 (2003) Rep. Stud. GESAMP, (74):36 p.
- 75 Estimations of oil entering the marine environment from sea-based activities (2007), Rep. Stud. GESAMP, (75):96 p.
- 76 Assessment and communication of risks in coastal aquaculture (2008). Rep. Stud. GESAMP, (76):198 p.
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- 80 Report of the thirty-sixth session, Geneva, 28 April - 1 May 2009 (2011), Rep. Stud. GESAMP, (80):83 p.
- 81 Report of the thirty-seventh session, Bangkok, 15 - 19 February 2010 (2010), Rep. Stud. GESAMP, (81):74 p.
- 82 Proceedings of the GESAMP International Workshop on Micro-plastic Particles as a Vector in Transporting Persistent, Bio-accumulating and Toxic Substances in the Oceans (2010). Rep. Stud. GESAMP, (82):36 p.
- 83 Establishing Equivalency in the Performance Testing and Compliance Monitoring of Emerging Alternative Ballast Water Management Systems (EABWMS). A Technical Review. Rep. Stud. GESAMP, (83):63 p, GloBallast Monographs No. 20.
- 84 The Atmospheric Input of Chemicals to the Ocean (2012). Rep. Stud. GESAMP, (84) GAW Report No. 203.
- 85 Report of the 38th Session, Monaco, 9 to 13 May 2011 (pre-publication copy), Rep. Stud. GESAMP, (85):118 p.
- 86 Report of the Working Group 37: Mercury in the Marine Environment (in prep.). Rep. Stud. GESAMP, (86).
- 87 Report of the 39th Session, New York, 15 to 20 April 2012 (pre-publication copy), Rep. Stud. GESAMP, (87):92 p.
- 88 Report of the 40th Session, Vienna, 9 to 13 September 2013, Rep. Stud. GESAMP, (88):86p.

- 89 Report of the 41st Session, Malmö, Sweden 1 to 4 September 2014, Rep. Stud. GESAMP, (89):90p.
- 90 Report of Working Group 40: Sources, fate and effects of microplastics in the marine environment: a global assessment. Rep. Stud. GESAMP (90) :96 p.
- 91 Pollution in the Open Ocean 2009-2013: A Report by a GESAMP Task Team, (2015) Rep. Stud. GESAMP (91):85 p.
- 92 Report of the forty-second session, Paris, 31 August to 3 September 2015. Rep. Stud. GESAMP, (2015):58 p.
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- 97 The magnitude and impacts of anthropogenic atmospheric nitrogen inputs to the ocean (2018). Rep. Stud. GESAMP (97):47 p.
- 98 High level review of a wide range of proposed marine geoengineering techniques (2019). Rep. Stud. GESAMP (98):143 p.
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- 101 Methodology for the evaluation of ballast water management systems using Active Substances (2019). Rep. Stud. GESAMP (101):110 p.



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ISSN 1020-4873