Risk Assessment in Ballast Water Management

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Abstract The risk assessment (RA) developed according to the BWM Convention is the most recently agreed global RA for bioinvasions. It was developed to enable a selective ballast water management (BWM) approach according to the BWM Convention and the G7 Guidelines. It describes three different BWM RA methods, "environmental matching", "species' biogeographical" and "species-specific" RA. The environmental matching RA between the areas of ballast water origin and discharge considers non-biological parameters as surrogates for the species survival potential in the new environment. The species' biogeographical RA identifies species with overlapping distribution in the donor and recipient ports and biogeographic regions which is taken as direct indications of the similarity of the environmental conditions and hence species survival in the new environment. The species-specific RA is focused on life history information and physiological tolerances to identify a species' physiological limits estimating its potential to survive or complete its life cycle in the new environment and considers target species. There are two fundamentally different RA approaches under the BWM Convention, the selective and the blanket approach. A blanket approach means that all ships intending to discharge ballast water in a port are required to conduct BWM. The selective approach means that appropriate BWM measures are required depending on different risk levels posed by the intended ballast water discharge. In one instance ships may be exempted from BWM requirements provided that the risk level of a ballast water discharge is acceptable. In another instance, if the risk is identified as (very) high,

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ships may be required to take additional measures based on the G13 Guidelines. The risk level is a RA result and input data reliability is of key importance. The chapter provides detailed step-by-step RA models for exemptions and for selective BWM measures, ready to be used by administrations.

Keywords Risk assessment • Selective ballast water management • Exemptions • Environmental matching method • Species specific method • Biogeographical method • Target species

Risk Assessment in Ballast Water Management

Risk Assessment and Its Key Principles

Risk is variously defined as the probability that an undesired event occurs in combination with the level of impact this event causes, frequently referred to as the consequence. Risk assessment (RA) is the process by which undesired events (hazards) are identified and the frequency and consequences of such undesired events are parameterized, typically including an expression of all uncertainties in the assessment process (e.g., Hewitt and Hayes 2002).

The RA may be defined by the following key principles (IMO 2007):

- **Effectiveness** – RA accurately measures the risks to the necessary extent to achieve an appropriate level of protection.
- **Transparency** – Reasoning and evidence supports the RA recommended action and uncertainty areas (as well as their possible consequences to those recommendations), are documented clearly and made available to decision-makers.
- **Consistency** – RA achieves a uniform high performance level, using a common process and methodology.
- **Comprehensiveness** – The full range of possibly affected values, including economic, environmental, social and cultural, will be considered when assessing risks and in the decision making process.
- **Risk Management** – Although risk scenarios exist, zero risk is not achievable, and therefore a risk should be managed by determining its acceptable level in each instance.
- **Precautionary** – RA incorporates a level of precaution when making assumptions and recommendations. This is to account for uncertainty, unreliability, and inadequacy of data. The absence of, or uncertainty regarding any data should therefore be considered as an indicator of potential risk.
- **Science based** – RA is to be based on the best available information that has been collected and analysed by scientific methods. Minimum data quality standards permitting a RA may be agreed.
- **Continuous improvement** – Any risk model should be reviewed and updated periodically to account for an improved understanding.

Risk Assessment of Harmful Species Introductions

Most RAs of marine biological invasions used in the past by different regulatory institutions are based on, or reflect the *Office Internationale des Epizooties* (OIE) framework (Hewitt and Hayes 2002). Here bioinvasions are understood as the culmination of a chain of events (see chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts"). A RA process to determine invasiveness requires an assessment of each event to attribute the degree of probability of successfully proceeding through that stage. The final RA of a 'successful' invasion is the result of the degree of probability attributed to each separately evaluated event. The OIE framework is efficient and simple to use for bioinvasions. Its efficiency may be improved further through the inclusion of quantitative RA fundamental principles. The quantitative RA includes five steps: (1) – hazard identification, (2) – frequency assessment, (3) – consequence assessment, (4) – risk estimation, and (5) – uncertainty analysis (e.g., Hayes 2000). The quantitative RA approach was developed for the application in complex industrial systems, but its constituent techniques and principles may also be adopted successfully within complex ecological systems.

An alternative approach bases the bioinvasion RA on environmental matching between the points of origin and destination (i.e., ballast water donor and recipient regions). One example of such an approach is that of the Queensland Ports Corporation, Australia which is based on a comparison of 40 environmental parameters (Hilliard and Raaymakers 1997). Other approaches have also addressed the issue of including environmental conditions including: a RA considering 34 parameters (GloBallast 2003), a German study based on climatic conditions and salinity (Gollasch 1996), a U.S. study considering salinity comparison alone (Carlton 1985), and a Slovenian study considered salinity as the only environmental parameter next to other species specific considerations (David 2007). In addition, an environmental match related RA was prepared for the Nordic Council of Ministers (Gollasch and Leppäkoski 1999) which was further developed for HELCOM (Leppäkoski and Gollasch 2006; Gollasch and Leppäkoski 2007).

Another approach is to consider target species, which was earlier adopted by the U.S. and Australia. This approach is based on a selection of species whose invasiveness in the examined area is likely and was confirmed in other areas. These RA activities resulted in two lists: 'America's Least Wanted' and the Australian 'Target Species List'.

These RA approaches may be supplemented by other elements. GloBallast's RA, further to the environmental matching method, includes some target species and additional risk quantifiers, such as voyage length and ballast tank size (GloBallast 2003). DNV's EMBLA also includes numerous parameters (Behrens et al. 2002; Endresen et al. 2004). Environmental matching combined with vessel voyage lengths and a target species list was also used in the Baltic to assess the risk of non-indigenous species introductions (Gollasch and Leppäkoski 1999, 2007). The Slovenian RA included ballast water sampling to confirm the presence of non-indigenous or other potentially harmful organisms in the ballast water which originated from the same biogeographic region (i.e., compatible environments) (David 2007). More recently a RA approach also in line with the IMO requirements was developed for the North and Baltic Seas (David and Gollasch 2010; David et al. 2013).

RA approaches can be differentiated in terms of data expressions, which can be qualitative, semi-quantitative, or quantitative (Norton et al. 1995). The qualitative approach aims to express the number of organisms or other parameters and uses descriptive values instead of figures (e.g., the quantity of organisms at origin: many, medium, few, the environmental match regarding salinity, e.g., high, medium, low). The quantitative approach is based on the quantification of all data in the RA system. Requirements on data intensity and the system complexity increase from the qualitative to the quantitative approaches. Different initiatives and approaches which were all developed prior the G7 Guidelines were adopted, and are presented in Table 1. Thereafter, to our knowledge, only one BWM related RA approach was yet prepared worldwide which strictly follows the G7 Guidelines and the precautionary approach (David et al. 2013). In Europe new approaches are currently being developed for the HELCOM/OSPAR area as regional activities, for the Baltic, North and western Mediterranean Seas during the VECTORS project,[1] and for the Adriatic Sea during the BALMAS project.[2]

Risk Assessment Process

The first RA steps are the introduction vector identification, followed by a hazard assessment relative to this vector and identified species. The RA approach should be selected depending on the objectives to be achieved and the data and resources availability. All these factors determine also the selection of the RA end-point.

Identification of the Vector of Transfer

More than a decade ago, 13 anthropogenic non-indigenous species transfer vectors were identified, addressing unintentional and intentional introductions (Gollasch and Leppäkoski 1999; Hewitt and Hayes 2002, see Table 2). In another summary more than 50 recognised vectors were listed (Minchin et al. 2005, 2009, see also chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts").

[1] Vectors of Change in Oceans and Seas Marine Life, Impact on Economic Sectors (VECTORS), http://www.marine-vectors.eu/

[2] Ballast Water Management System for Adriatic Sea Protection (BALMAS), http://www.balmas.eu/

Table 1 RA initiatives worldwide prior to the adoption of the G7 Guidelines

RA initiative	Goals	RA approach	Data expression approach	End-point
Australia (AQIS 1994)	Estimate costs of toxic dinoflagellate introductions in Australian waters	Species based tolerance, volume of ballast discharged and bloom dynamics	Quantitative	Estimate economic impact of toxic dinoflagellates on aquaculture, tourism, etc. (hazard assessment)
Germany (Gollasch 1996)	Risk identification for species invasions in German coastal waters	Environmental matching between donor and recipient localities	Qualitative	Species establishment potential assessment
Australian DSS[a] (Hayes and Hewitt 1998, 2000)	Identify low risk routes, vessels and tanks	Models four steps in the bio-invasion process: donor port infection, vessel infection, journey survival and survival in the recipient port	Quantitative	Target species life cycle completion in recipient port
Nordic countries (Gollasch and Leppäkoski 1999)	Risk identification for species invasions in Nordic ports and coastal waters	Environmental matching between donor and recipient localities	Qualitative	Species establishment potential assessment
DNV – EMBLA (Behrens et al. 2002, Endresen et al. 2004)	Identify low risk routes, vessels and tanks	Bioinvasion model based upon: donor port infection, vessel infection, journey survival and survival in recipient port	Quantitative	Target species life cycle completion in recipient port
GloBallast RA (e.g., Awad et al. 2004)	Enhance awareness and recommendations on BWM strategies	Environmental matching between donor and recipient localities, weighted by target species presence in the donor location and inoculation factors	Semi-quantitative	Identify and rank high and low risk ports
Slovenia 1 (David 2007)	Risk identification for species invasions in the Slovenian Sea, enhance awareness and recommend BWM strategies	Environmental matching between donor and recipient localities and identification of potentially harmful species in ballast water	Quantitative and qualitative	Identify and rank high and low risk donor ports

(continued)

Table 1 (continued)

RA initiative	Goals	RA approach	Data expression approach	End-point
Canada 1 (MacIsaac et al. 2002)	Estimate risk associated with NOBOB[b] vessels entering the Great Lakes	Species based tolerance, and taxa concentrations for NOBOB vessels	Quantitative	Journey survival of target species
Finland (Pienimäki and Leppäkoski 2004; Leppäkoski et al. 2005; Paavola et al. 2005)	Create baseline knowledge on the risks associated with NIS and shipping	Environmental matching between donor and recipient localities	Qualitative	Vector and establishment potential assessment
Slovenia 2 (David 2007)	Vessel-to-vessel (tank) assessment for BWM measures supported by DSS	Environmental matching between donor and recipient localities (bioregions) and species specific (inside bioregion)	Quantitative and qualitative	Identify and rank high and low risk donor ports and identify high risk species
EMBLA (for Croatia) (Dragsund 2005)	Recommend ballast water management plan for Croatia	Locality based and species tolerances	Qualitative	Hazard assessment
Canada 2 (MacIsaac et al. 2004)	Review and develop a ballast water RA framework	Target species (gravity model, i.e., rates and patterns of colonization)	Quantitative	Colonization prediction of target species

Enhanced after David (2007)
[a]*DSS* decision support system
[b]*NOBOB* no ballast on board

Table 2 Anthropogenic introduction vectors of aquatic organisms

Anthropogenic vectors	
Vessels	Accidental with vessel fouling (including boring into wooden hulls)
	Accidental with ballast water
	Accidental with solid ballast (e.g., rocks, sand)
	Accidental with anchor chains and in chain lockers
Fisheries	Deliberate translocations of fish and shellfish to establish or support aquaculture
	Accidental with deliberate translocations of fish and shellfish (e.g., epi- and endobionts as well as parasites and disease agents)
	Accidental with discharge of material from fish and shellfish processing plants
	Accidental with seaweed packing material for bait and fishery products
Plant introductions	Deliberate translocation of plant species (e.g., for erosion control)
	Accidental with deliberate plant translocations
Biocontrol	Deliberate translocation for biocontrol
	Accidental translocation with deliberate biocontrol release
Canals	Range expansion through man-made canals
Individual release	Deliberate and accidental release by individuals (e.g., from aquaria)
	Equipment used for recreation (e.g., diving bags, boats)
Scientific release	Deliberate and accidental release as a result of research activities

Enhanced after Hewitt and Hayes (2002). With kind permission of Springer Science+Business Media

In different world regions the importance of species introduction vectors varies. Nevertheless, in all regions considered the most important three vectors are (possibly in different order): ballast water, hull fouling, and aquaculture, so that shipping is considered to be the worldwide principal pathway by which species are spread (see chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts"). The vector identification for each species is extremely challenging as several species may be related to more than one vector. Vectors overlap which makes many of them indistinctive (Minchin 2007), as shown in Fig. 1.

All these overlapping vectors and multiple possibilities often create uncertainties regarding the vector identification and assignment. However, this information is very critical for vector management purposes. Different levels of certainty can be assigned to each vector (e.g., in the non-indigenous species database of the DAISIE[3] project three levels of certainty (i.e., direct evidence, likely, unspecified) are available for each transfer vector). This database is currently being updated and expanded during the EU-funded VECTORS project and it is expected that the new database, named AquaNIS,[4] will become publicly available in 2015. A vector identification is important to make vector management efficient, i.e., to regulate the most important species introduction vector first.

[3] Delivering Alien Invasive Species Inventories for Europe (DAISIE).

[4] http://www.corpi.ku.lt/databases/index.php/aquanis. last accessed December 2013.

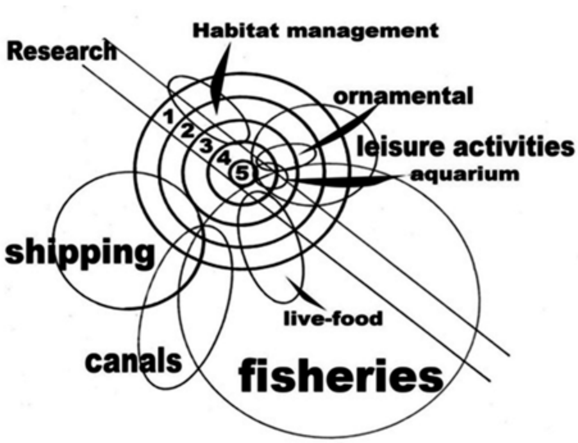

Fig. 1 Overlap of different species introduction vectors (Minchin 2007) (Reprinted from Minchin (2007), copyright 2007, with permission from Elsevier)

Identification of Hazards

Hazards may be defined as a situation to result in harm under certain circumstances, or, alternatively, as the likeliness of substances or activities to generate risk (Hewitt and Hayes 2002). In ecotoxicology a hazard is frequently considered merely as a function of the properties of a substance. However, a broader understanding would be more appropriate to include the fundamental properties of a substance as well as the circumstances. The implication inherent to the introductions of harmful aquatic organisms and pathogens (HAOP) RA is the assessment of the probability of the establishment of a species. This also depends on its potential invasiveness (i.e., its fundamental properties) and the recipient environment (i.e., circumstances).

The introduction of an organism and its possible invasiveness can be divided into several phases, or a chain of events (see above and chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts"): organism presence in the donor region, vector infection, transport survival, survival of the discharge process to the recipient environment, survival in the new environment, establishment in the new environment, and possibly spread and harm (invasiveness) in the new environment. The uncertainty relative to each step increases upon each following step, i.e., from the initial presence in the donor environment to the invasiveness in the recipient environment. In cases where the degree of uncertainty is high, quantitative methods for the definition of probability are inappropriate. Therefore, not all phases of the species invasion chain of events have to be quantified, but instead a combination of the empirical approach (based upon acceptable criteria) and the documented invasion history and adverse influences can be adopted.

IMO Risk Assessment Methods

The RA developed in the framework of the BWM Convention is the most recently agreed global RA framework for bioinvasions. It was developed to provide guidance how to implement a selective BWM approach according to the BWM

Convention and the G7 Guidelines. It describes three different BWM RA methods, "environmental matching", "species' biogeographical" and "species-specific" RA.

The environmental matching RA between the areas of ballast water origin and discharge considers non-biological parameters such as salinity and temperature as surrogates for the species survival potential in the new environment. The species' biogeographical RA seeks to identify species with overlapping distribution in the donor and recipient ports and biogeographic regions. These overlaps are taken as direct indications of the similarity of the environmental conditions and hence species survival in the new environment. The species-specific RA is focused on information on life history and physiological tolerances to identify a species' physiological limits and estimates its potential to survive or complete its life cycle in the new environment (IMO 2007).

Environmental Matching Related Risk Identification

The vector-related risk identification can be based on two fundamental elements:

- the likelihood of organism transfer (i.e., the quantity and origin of the discharged ballast water and abundance of propagules therein),
- the likelihood of organism survival in the recipient environment (match of selected environmental parameters of donor and recipient regions).

Different marine regions are typically defined as biogeographic regions, but all existing biogeographical schemes were developed for different purposes and not for biological invasions RA, e.g., Briggs (1974) and Springer (1982), IUCN bioregion system (Kelleher et al. 1995), Ekman (1953), Longhurst (1998) provinces, Spalding et al. 2007 and Briggs and Bowen (2012). IMO suggested to use the Large Marine Ecosystems (LME) approach (see Fig. 2) because at the time of drafting the G7 Guidelines this was considered the best available information, but local and regional adaptations may be necessary.

In the G7 Guidelines environmental matching was determined to assess the likelihood that species found in the ballast water donor region are able to survive in the recipient port. However, some uncertainty remains, namely the uncertainty to define the environmental conditions, which are predictive of the species to establish and cause harm in a new location. Another key point is the determination whether the risk of ballast water discharge is sufficiently low to be exempted from BWM requirements. Environmental matching RA is of limited use in cases where the differences between a donor region and a recipient port are small. In these cases, such as shipping within one biogeographic region, high similarity between donor and recipient areas is likely and indicates a high likelihood of successful species establishment. However, there are exemptions from this rule, e.g., areas with different water salinities in the same bioregion, which may be caused due to, e.g., run-offs of major rivers.

In addition to comparing the environmental conditions of biogeographic regions, this comparison should further be undertaken between the donor and recipient ports, i.e., in much smaller scale. Similarity of key environmental conditions between the

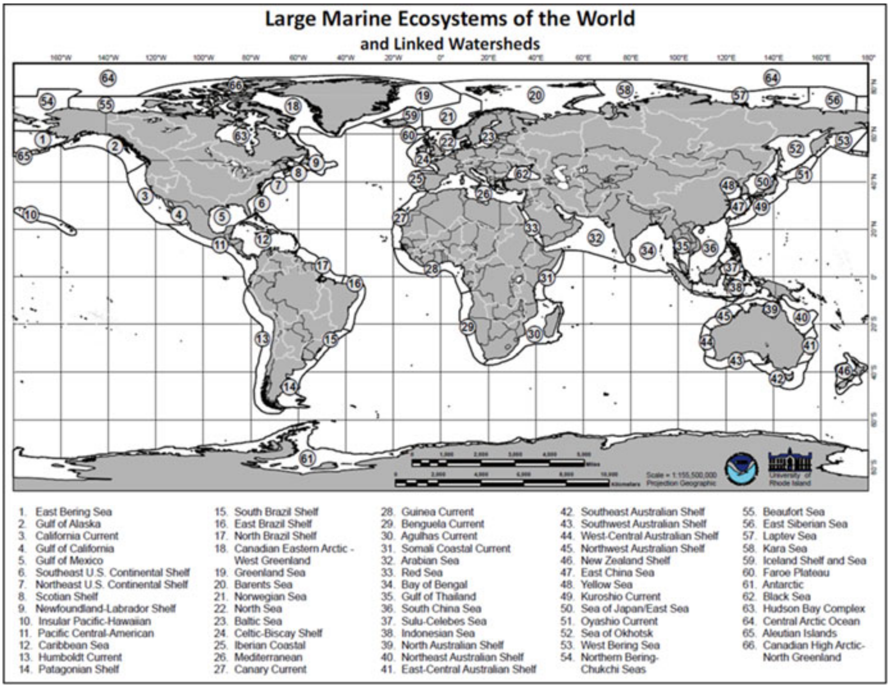

Fig. 2 Map of large marine ecosystems (Source NOAA, http://www.lme.noaa.gov/, last accessed in November 2013)

two ports to be assessed is a strong indication that species of the donor port will survive when released in the recipient port water.

The data needed to enable a RA using the environmental matching approach to determine the degree of environmental similarity between the donor and recipient environments (IMO 2007) include:

- the origin of the ballast water to be discharged in the recipient port,
- the biogeographic region of donor and recipient ports, and
- the average and range of environmental conditions, also considering seasonal differences, in particular salinity and temperature.

The analysis of the environmental similarity may be followed by an evaluation of species known to occur in the donor region, which tolerate extreme environmental differences. If such species are found, a species-specific approach should be used for RA associated with these species (IMO 2007). Such species include:

- species which migrate between fresh and marine environments to complete their life-cycle (anadromous species, such as salmon spend most of their life in the sea and return to fresh water to spawn, whereas the catadromous species, e.g., the Chinese mitten crab, do the opposite);
- species with a wide tolerance of temperature (eurythermal species) or salinity (euryhaline species).

Species' Biogeographical Risk Assessment

The species' biogeographical RA compares the distribution of non-indigenous, cryptogenic, and harmful native species presently occurring in the donor and recipient ports and biogeographic regions. Should species occurrences overlap in the donor and recipient ports and regions this is a direct indication of environmental similarity to enable a shared fauna and flora. The biogeographical approach may also be used to identify high risk species (see also the species-specific approach). As an example, harmful species in the ballast water donor biogeographic region which are known to have successfully invaded other (similar) biogeographic regions, but are not (yet) found in the recipient biogeographic region of the RA, could be considered as high risk species for the ballast water recipient region. As a general rule, the higher the number of biogeographic regions in which such species have invaded, the greater is the potential that those species would also be able to become established in the recipient port or biogeographic region. Another general risk indicator is given in case where the donor biogeographic region is a major source of species to other areas.

The data requirements (IMO 2007) to enable a species biogeographical approach RA include:

1. species invasion records in the donor and recipient biogeographic regions and ports;
2. records of native or non-indigenous species in the donor biogeographic region which may be transferred with ballast water and which have already invaded other biogeographic regions and the number and characteristics of these invaded biogeographic regions;
3. records of native species in the ballast water donor region which have the potential to affect human health or to cause substantial negative ecological or economic impacts after introduction to the ballast water recipient region.

The species' biogeographical RA may also be used to identify potential target species (see below) in the donor region(s). Criteria to identify such species include native species with a wide biogeographical or habitat distribution or species which are known as invaders in other biogeographic regions, which are similar to that of the ballast water recipient port.

Species-Specific Risk Identification

The identification of species-related risk focuses on the evaluation of the potential invasiveness of each selected species considering also the harm that it could cause in the new environment. Today we lack data and have insufficient knowledge concerning the invasiveness of organisms with some key questions remaining unanswered, e.g., What predicts invasiveness in a new environment? How does the degree of species tolerance regarding environmental conditions, food availability, reproduction behaviour and capabilities influence invasion success? How can we anticipate the harm that could be caused?

In many environments (or biogeographical regions) the knowledge on the taxonomy of indigenous organisms is deficient, while the identification of organisms originating from other parts of the world is even more demanding. Consequently, numerous organisms may remain unidentified.

For a target list of unwanted organisms, fundamental selection criteria must be defined. Based upon the IMO definition in the G7 Guidelines, at least all following factors need to be considered (IMO 2007) when identifying target species:

– evidence of prior introduction, i.e., thereby the species shows its capability to become introduced outside its native range;
– potential impact on environment, economy, human health, property or resources;
– strength and type of ecological interactions, i.e., severeness of its impact;
– current distribution within the biogeographic region and in other biogeographic regions; and
– relationship with ballast water as a vector, i.e., when the species was already found in a ballast tank or if the life cycle of the species include a larval phase which makes a ballast water transport likely.

Numerous attempts were undertaken to identify typical characteristics of an 'ideal' invasive species. It was discussed that species with high environmental tolerances and those with high reproduction rates may have a higher invasion potential (Safriel and Ritte 1980, 1983; Kareiva 1999; Hewitt 2003).

The objective of this approach is to consider species life history information and physiological tolerances to characterise physiological limits of a certain species which leads to its survival potential or potential to complete its life cycle in the recipient environment. In other words, the individual species characteristics need to be compared with the environmental conditions in the recipient port, which results in a determination of the likelihood of transfer and species survival.

A target species is not needed in all circumstances but may be useful to focus a surveillance action or may be necessary for legislative compliance. The species of concern (target species) need to be selected for a specific port, country, or biogeographical region. As a first step to generate a target species list, all species being potentially harmful and invasive (including cryptogenic and harmful native species) present in the donor port(s) should be listed and, secondly, target species are to be selected based on pre-defined criteria (see above).

A problem is subjectivity with the target species selection. It may occur that the assessment whether or not a species should become a target species will result with a degree of uncertainty associated with the approach. It is possible that species identified as harmful in some environments may not be harmful in others and vice versa.

In addition to the data referred above, the following information is needed to enable a RA using the species-specific approach (based on G7 Guidelines, IMO 2007):

– biogeographic region of donor and recipient port(s); the presence of all non-indigenous species (including cryptogenic species) and native species in the

donor port(s), port region and biogeographic region, not present in the recipient port, to allow identification of target species;
- the presence of all target species in the recipient port(s), port region, and biogeographic region;
- the difference between target species in the donor and recipient ports, port region, and biogeographic region;
- life history information on the target species and physiological tolerances, in particular salinity and temperature, of each life stage; and
- habitat type required by the target species and availability of habitat type in the recipient port.

Even when a target species has been reported, although its establishment status and abundance may be unknown, from the donor and recipient ports, its continued introduction into the recipient port(s) may increase the probability that it will become established and to cause negative impacts. This is especially the case when the target species occurs in higher abundance in the donor port compared to the recipient port.

As a starting point, a simple assessment may be conducted to evaluate whether a target species is present in the donor port, but not in the recipient port, and if it can be transported via ballast water. In a more comprehensive approach the following points may need to be evaluated (IMO 2007):

- Uptake – probability of viable stages entering the vessel's ballast water tanks during ballast water uptake operations;
- Transfer – probability of survival during the voyage;
- Discharge – probability of viable stages entering the recipient port through ballast water discharge on arrival; and
- Population establishment – probability of the species establishing a self-sustaining population in the recipient port.

An even more detailed scenario would be to determine the likelihood of a target species to survive each of the stages listed above. However, the required data may only be available in rare cases, especially when considering that all life stages of the target species need to be assessed also including seasonal variations in the target species presence in the donor port with seasonal conditions in the recipient port to meet the species abiotic tolerances (e.g., temperature and salinity). Consequently, the overall RA of unmanaged ballast water discharges should be determined based on the evaluation of all target species surviving all these stages.

To groundtruth the chosen species-specific RA approach, data may be gathered for already introduced species in the recipient port. This is to check whether or not the RA approach selected would have predicted this species to be able to survive in the ballast water recipient port. A failure to predict existing invaders correctly may indicate that the model under-predicts the risk, noting that species may have arrived by various vectors.

Risk Assessment End-Point

The risk of ballast water and sediment discharges may be defined as the likelihood of an undesired event to occur as a consequence of ballast discharge from a ship. The interpretation of this definition entirely depends on the assessment end-point. The end-point can be defined either as the discharge probability of potentially harmful organisms via ballast water, or their establishment in the new environment, or their invasiveness in and impact on the new environment.

When the identified end-point is the probability of impact,[5] a risk would need to be accurately defined through all RA stages from the bottom up (i.e., starting with the introduction and establishment probability of new organisms). The RA process was defined by the G7 Guidelines as "a logical process for objectively assigning the likelihood and consequences of specific events, such as the entry, establishment, or spread of harmful aquatic organisms and pathogens".[6]

The scenarios presented below describe the dependence of RA on the identified end-point under the assumption that the RA end-point is:

1. the discharge of HAOP via ballast water from a ship;
2. the establishment of HAOP in a novel environment;
3. the impact (invasiveness) of HAOP in a novel environment.

In scenario 1 the presence of HAOP in the discharged ballast water is understood as an undesired event. In scenario 2 an undesired event is defined as the establishment of a species, which means that the discharge of HAOP per se is not recorded as an undesired event in cases where they remain unestablished. In scenario 3 the undesired event is the impact while the discharge and establishment of a HAOP are not recorded as undesired events.

After the discharge of HAOP in a new environment many of the discharged individuals may not survive. Moreover, should they survive and establish themselves in the new environment, harm is not necessarily generated. However, considering the stochastic and complex array of factors which science is still unable to predict, one of the key points is that it is extremely difficult or practically impossible to conduct highly reliable assessments as to whether a new species introduced to a novel environment will cause harm or not. There are also cases of established of HAOP which have not caused harm for years but then, under certain circumstances, suddenly turned invasive. This lack of knowledge reveals that the conservativeness of the approach descends from the first to the third scenario presented above as does the degree of certainty of the identification of an event.

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[5] i.e., various aspects of risk to human health, the natural environment, or the economy/resources.

[6] G7 guidelines, paragraph 5.1.

The decision as to the identification of the RA end-point is made by the risk assessor[7] and depends on the assessor's objectives, values, and abilities (Cothern 1996; Kirchsteiger et al. 1998). The perception of values can be highly diverse (Cothern 1996; Kirchsteiger et al. 1998; Souvorov 1999), e.g., the preservation of the native biological diversity in an environment will bear extraordinary value to a biologist whereas it might have a comparatively lower value to other stakeholders. A reverse relation would probably be observed when economic effects are considered (e.g., effects on fisheries and aquaculture). Therefore, we conclude that the perception of the degree of risk (within a broader circle of stakeholders in a state and usually in direct correlation to the country's level of development) exerts a significant influence on the acceptability degree of each risk.

Risk Assessment Errors

RA includes potential errors which can occur at any assessment step. The errors can be divided into two groups (Hayes 2000):

- Type I errors – to cause overestimates of the real risk situation;
- Type II errors – to cause underestimates of the real risk situation.

RA provides the basis for the implementation of preventive measures. Therefore, it can be assumed that a Type I error will result in higher protection from negative impacts yet concurrently laying the additional burden of preventive measures on the shipping industry. In contrast, a Type II error will result in a potentially lower degree of protection from negative impacts with consequently a lighter burden on the shipping industry.

The RA aims certainly to reflect the real situation as accurately as possible and implement appropriate measures in relation to the obtained results. However, given that the ballast water issue has not been extensively researched yet in this regard, the likelihood of error is high. In these cases the precautionary approach should be adopted, with primary emphasis laid on the avoidance of Type II errors through the entire RA and BWM process. In some cases Type II errors simply cannot be prevented (e.g., sampling on-board ships, data collection with ballast water reporting forms) and all possible measures aiming towards the error reduction have to be taken while the presence of the error has to be clearly recorded to allow for correct RA data interpretation also for the consideration of the error during the next step and the adoption of measures (Kirchsteiger et al. 1998; Hayes 2000).

[7] Given that the objective of RA is the prevention of undesired events via state regulation, the 'assessor' is to be understood as a state.

Application of Risk Assessment Under the Ballast Water Management Convention

There are two fundamentally different RA approaches under the BWM Convention, the selective and the blanket approach. The selective approach means that appropriate BWM measures are required depending on different risk levels posed by the intended ballast water discharge. This is further also depending on the BWM feasibility under certain circumstances. In one instance ships may be exempted from BWM requirements provided that the risk level of a ballast water discharge is acceptable based on the G7 Guidelines. In another instance, if the risk is identified as (very) high, ships may be required to take additional measures based on *Guidelines for Additional Measures Regarding Ballast Water Management Including Emergency Situations* (G13 Guidelines). The level of risk is a result of a RA. A blanket approach means that all ships intending to discharge ballast water in a port are required by the port State to conduct BWM.

Risk Assessment for Granting Exemptions from Ballast Water Management Requirements

Exemptions from BWM requirements may be given when a RA, prepared according to the G7 Guidelines, results in an acceptable low risk. This is specific for a ship, or different ships, sailing only between specified ports or locations. The exemptions may be granted for up to 5 years, but may also be withdrawn when the risk situation becomes unacceptable during this period (IMO 2007; David and Gollasch 2010). The RA developed under the BWM Convention is the newest and the only globally agreed RA framework for BWM purposes. This RA presented here was developed to enable a selective BWM approach (David 2007).

The need for a commonly agreed RA approach/model is outlined in section 6.5 Evaluation and decision-making of the G7 Guidelines. Paragraph 6.5.1 requires that port States considering to grant exemptions shall for both the evaluation and consultation processes especially consider Regulation A-4.3 which states that any exemption shall not negatively impact upon the environment, human health, property or resources of adjacent or other states. Any state potentially or adversely affected shall be consulted.

Furthermore, as stated in paragraph 7.4 of the procedures for granting exemptions, a RA model needs to be prepared, which is to be made available to exemptions applicants. It is also stipulated that if any Party (i.e., a country signatory to the BWM Convention) has decided that the shipowner or operator who applies for the exemption should conduct a RA, this Party should provide to that shipowner or operator all relevant information, including application requirements, the RA model to be used, the target species that should be considered and the required data reporting and collection standards. In turn, the shipowner or operator should make available all relevant information to this Party to enable a decision if an exemption can be granted (or not).

The RA itself could be conducted by any Party, or a Party may ask the applicant to prepare it. In both cases the Party which receives the application needs to have a common RA model available. Further this Party has to receive all necessary data and arrangements to conduct a RA with the aim to grant (or not) an exemption from BWM requirements. This is essentially needed as Parties are responsible to ensure that any action or decision taken may not cause harm to neighbouring or other states (see above). This process is globally applicable (Fig. 3).

Risk Assessment Framework

Data Reliability

The most critical point is to have reliable input data for the RA process as the decision taken by the Party has cost and legal consequences. However, there are known uncertainties, unpredictable stochastic events, as well as a lack of knowledge and

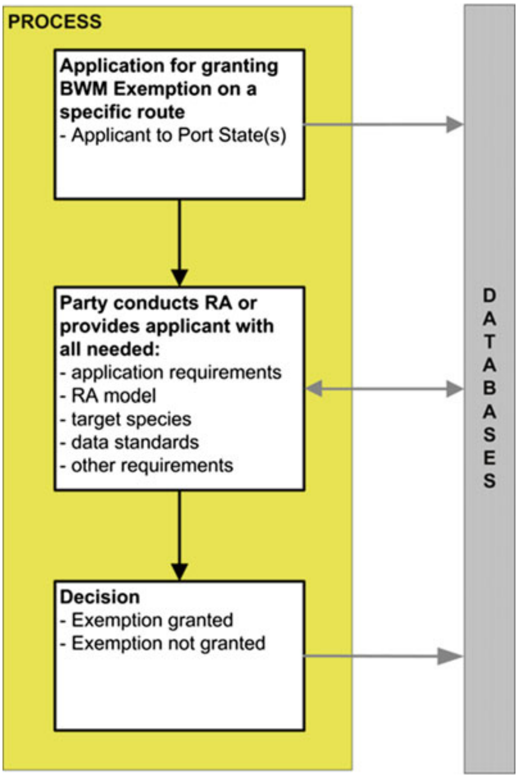

Fig. 3 General process and parties involved in the application for BWM exemptions (David et al. 2013) (Reprinted from David et al. (2013), copyright 2013, with permission from Elsevier)

data to characterise the introductions of harmful species via ballast water. Therefore, to keep the selective RA based BWM approach effective as much as possible, the precautionary principle[8] applies as a fundamental principle[9] in this RA process (EU Commission 2000; IMO 2007).

For the needs of environmental matching RA reliable environmental data need to be provided. For the needs of species-specific and species' biogeographical RA reliable biological data is needed. Critical issues identified regarding knowledge and data needs for RA include:

– the lack of data on harmful aquatic organisms and pathogens (HAOP) presence and abundance in ports (i.e., donor environment/port);
– the lack of knowledge regarding the survival of species during the voyage; and
– the lack of knowledge on their possible behaviour in the new environment.

Due to the poor general knowledge already mentioned, the weighting of importance of even a single parameter is difficult or may be impossible. Therefore we consider the risk parameters as of equal importance.

There have been relatively few comprehensive port baseline surveys conducted worldwide which have focused on collecting data regarding the presence of harmful species in ports and surrounding environments. In total, >100 port baseline surveys were conducted in more than 20 countries (Campbell et al. 2007; WGBOSV 2013; WGITMO 2013) which cover only ca. 1 % of the more than 9,400 ports in the world (Lloyd's Register 2007). Additionally, many of these studies are now out of date, with few continuous surveillance regimes in place (Hewitt et al. 2004a; Campbell et al. 2007). Consequently, the knowledge on cryptogenic and non-indigenous species as well as harmful native species in ports is limited, but essential for a comprehensive RA.

Introductions of new harmful aquatic species occur almost on a monthly basis, which has been proven by different studies around the world (e.g., Carlton 1985; Williams et al. 1988; Macdonald and Davidson 1997; Gollasch et al. 2000, 2002; Olenin et al. 2000; Carlton 2001; Hewitt et al. 2004b; David et al. 2007; Flagella et al. 2007). In ICES member countries a new species introduction forming a new population beyond its natural range occurs about every 9 weeks (Minchin et al. 2005). This includes the secondary spread of earlier introduced species in neighbouring areas (Minchin et al. 2005) (see chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts"). For instance, during the ballast water sampling study conducted in the Port of Koper (Slovenia), ballast water originating from ports in the same region (i.e., Mediterranean Sea, and mostly the Adriatic Sea) contained non-indigenous species that were not yet recorded in the Port of Koper area (David et al. 2007). This also leads to the conclusion that results from a port baseline survey by itself cannot last forever, but should be followed by a monitoring program to document possible new arrivals of harmful

[8] Communication from the Commission on the Precautionary Principle, Brussels, 02.02.2000.

[9] In the EU should be implemented when RA concerns environmental and human health protection and in the lack of robust scientific evidence (EU Commission 2000).

species. Further, the full comprehensive port baseline study may further need to be repeated to ensure most up-to-date information for RA (e.g., Hewitt and Martin 2001). In conclusion, biological data on a ballast water donor port can only be considered as reliable if a baseline survey for HAOP has been conducted and a regular monitoring program for HAOP is in place. The lowest frequency of surveys per time need to be decided depending on the target species group, e.g., harmful algae, indicator species for pathogens. Another way to determine the required frequency for sampling is proposed by Hewitt and Martin 2001, i.e., with a repeated survey one could then calculate the rate of arrival/establishment function which would then inform about a suitable re-survey frequency based on the acceptable level of protection/risk.

During the developing HELCOM/OSPAR RA port survey sampling data are regarded valid for granting an exemption for applicants for a period of in maximum 5 years. This means that the port survey data from the sampling in year one can also be taken up to 5 years later as a basis for granting an exemption, i.e., no new port baseline surveys are required (HELCOM/OSPAR 2013). We feel that a 5 year period is rather long considering that approximately two new primary introductions of non-indigenous species were found in this region per year over the last decade. In consequence, should this species introduction trend continue, this approach may overlook up to ten non-indigenous species thereby accepting the risk that such species are transported, which could have been avoided.

It should further be noted that introduced and cryptogenic species are registered only occasionally in continuous biological monitoring programs in Europe. The dominating first records of such species were made in projects and individual studies not part of regular monitoring programs. In some sampling studies the working standards are unclear, i.e., the data reliability is uncertain. In Europe only very few regular monitoring programs specifically target aquatic non-indigenous and cryptogenic species (e.g., in Estonia and Germany (WGITMO 2013)). However, reliable data are a crucial component for a proper RA (Lodge et al. 2006; David 2007). Further, introduced and cryptogenic species are also seldom targeted in port area monitoring programs in most European countries. In less than 10 European ports out of the more than 1,200 ports of all 22 coastal Member states[10] preliminary port baseline surveys were conducted to document the presence and abundance of non-indigenous and cryptogenic species. These port studies should be considered as preliminary because not all habitats were surveyed. Other continents are more advanced as, e.g., in North America, Australia and New Zealand the share of surveyed ports is much higher compared to Europe (Campbell et al. 2007).

Introductions of harmful species may occur every day also between ports within the same bioregion by secondary introductions and natural spread (e.g., Olenin et al. 2000; David et al. 2007; McCollin et al. 2008; Darling et al. 2012). As a result a one-time port baseline survey alone cannot be sufficient as a long-term basis for RA, but should be followed by a regular monitoring program for new (harmful) species (e.g., Hewitt and Martin 2001) and this should be done by experts in this field

[10] European Sea Ports Organisation (ESPO), http://www.espo.be/, last accessed November 2013.

to ensure reliable data quality. This is to avoid that exemptions are wrongly ongoing in cases of new species arrivals. We recommend that such monitoring (surveys) needs to be established regularly (e.g., every 6 or 12 months) to deliver reliable and current information.

Applying the precautionary principle, in cases where reliable data are lacking, no RA-based exemption can be granted. This is especially important where a RA relates to environmental and human health protection (EU Commission 2000; IMO 2007).

Risk Assessment Methods Applied

Environmental Matching Method

The environmental matching RA method uses environmental parameters as surrogates for species. Of the two most frequently used RA parameters, water temperature and salinity, the salinity variability is the only parameter common to all past RAs. Furthermore, the more variables a RA includes, the lesser transparent becomes the decision process. We believe that water salinity is the most "straight forward" concept, hence the RA presented here uses salinity as the only meaningful environmental parameter. Water temperature was also considered as a RA quantifying factor in the environmental match approach. However, we believe this is of lesser reliability to identify low risk scenarios because we assume that organisms are more flexible regarding temperature tolerances compared to salinity in temperate and polar regions. One reason for this assumption is the greater temperature difference compared to salinity difference over the annual seasons which the species need to tolerate. In the tropics this may be different as the temperature may be more similar throughout the year and here the rainy seasons may result in a stronger organism tolerance towards salinity. However, also the use of salinity shows its weakness. In cases when two ports may have totally different salinity ranges the RA result will be low risk. However, species salinity tolerance may cover both environments so that a high risk should have been the result (Hewitt and Hayes 2002; Hayes and Sliwa 2003). As a compromise, this RA uses salinity as the only environmental parameter. The difference between the ballast water donor and recipient ports as freshwater and marine ports respectively is the suggested acceptable salinity difference offering acceptable precaution levels to trigger a low risk result because the number of species being able to tolerate such a large salinity difference is comparably low (but not zero!).

In a two-step approach we considered that the minimum salinity difference to assume a low risk for a successful species transfer. A low risk was assumed when ballast water is moved between freshwater (<0.5 psu) and fully marine conditions (>30 psu). However, such conditions are rarely applicable in coastal shipping, but may occur in areas with larger estuaries, run-off of major rivers, when a port is situated on a river more inland etc. To cope with that situation other possibilities were considered. What could be acceptable, but at the price of a slightly higher risk, is when ballast water is transported between freshwater ports and higher saline brackish ports with salinities >18 psu. In these cases a species-specific method would be required in addition to the environmental match taking into account the species salinity tolerance ranges, especially considering species which have a known salinity tolerance higher than <0.5 psu and >18 psu.

The salinity limit of 18 psu is based upon the work of Remane (1934) and Remane and Schlieper (1958). They compared the diversity of freshwater, brackish and marine species along salinity gradients and showed that for many groups of species the minimum species diversity was found in low salinity conditions. A borderline used in their studies is at approximately 18 psu. It is interesting to note that the Venice salinity system (Venice System 1959) draws the line between polyhaline and mesohaline also at this psu level and it is found that this relates to a change in species diversity (den Hartog 1964). Paavola et al. (2005) more recently found the same trend for native and non-indigenous species. In European brackish seas, most non-indigenous species are well adapted to salinities with the lowest native species diversity. Also the non-indigenous species diversity maximum is frequently observed in the salinity ranges where the native species diversity reached a minimum. Bleich (2006) compared the macrozoobenthos diversity at different Baltic Sea sampling stations with different salinities. He found that the species diversity changed by more than 80 % at ca. 18 psu and concluded that this may be a salinity-related distribution limit. We therefore assume that the 18 psu salinity limit chosen is well enough justified.

Species-Specific Method

The identification of species-related risk takes into account the potential invasiveness of each selected species and the potential harm that it could cause in a new environment. The selection of target species was based on the IMO definition in the G7 Guidelines using the following criteria: (a) evidence of a prior introduction; i.e., where a species has become introduced outside its native range; (b) potential impact on the environment, economy, human health, property or resources; (c) strength and type of ecological interactions, i.e., severeness of its impact; (d) current distribution within the biogeographic region and in other biogeographic regions; and (e) relationship with ballast water as a vector, i.e., it has been shown to be carried in ballast water or it has a life-history stage that might be carried in ballast water.

The target species selection process should consider all harmful native, non-indigenous and potentially harmful cryptogenic species present within the donor and recipient ports and their surrounding areas. For a species-specific RA, an assessment results in an unacceptable risk if it identifies at least one target species that satisfies all following criteria: the target species is (a) likely to cause an unacceptable level of harm; (b) present in the donor port, but not in the recipient port; (c) likely to be transferred to the recipient port with ballast water; and (d) likely to survive in the recipient port.

Further, should both the ballast water donor and recipient regions have the identical target species, but these occur in very different abundances, each species case needs to be examined separately to qualify the level of risk. This is because a target species may occur at a low level of abundance in a recipient port not with a fully self-sustaining population, but further releases from a donor port, where abundance of this species is higher, may lead to a self-sustaining population in the recipient port. As a result it is unacceptable to transfer unmanaged ballast water in cases a target species occurs in much higher abundance in any of the donor ports compared with a recipient port.

In addition to human-assisted movements, aquatic native and non-indigenous biota have the potential to spread naturally from a donor to a recipient port without being moved by a vector. The ability to spread naturally is species-specific, and in the RA this is acceptable only in situations where all target species of concern could easily spread naturally from a donor to a recipient port.

A coastal state may introduce a control or eradication program for the most unwanted species already introduced into their waters; this has RA implications. A control or eradication program would only be undertaken to manage high impact species. Should these species be potentially carried in ballast water, then their inoculation in a recipient area would not be acceptable. Therefore any such control or eradication program conducted in the donor port indicates a high risk.

Combined Environmental Matching and Species-Specific Method

In this RA we considered that it may be still acceptable that ballast water is moved between freshwater ports and brackish ports with salinities >18 psu, in which case a species-specific method would additionally be required. This would especially consider the species with known higher salinity tolerances than <0.5 psu and >18 psu. The presence of one such species in only one of the donor ports considered results in the situation that a low risk cannot be assumed.

Species' Biogeographical Method

The study focus was laid on species movements within the same biogeographical region. The species' biogeographical method is considered here through the target species selected (see section "Species-specific method").

Shipping Vector Factors

Species Survival of the Voyage

Prerequisites for a species to be successfully transported from a donor to a recipient port with ballast water include that it first needs to enter the vessel during the ballasting process, survive the physical stress during ballasting, survive the likely unfavourable conditions inside the tank during a voyage, become discharged from the vessel and to survive the deballasting process. This “chain of events” needs to coincide with opportunities in the recipient area that they find suitable environmental conditions and food sources so that they can survive and reproduce. The latter requirements are termed ‘invasion windows’. The survival of species during vessel voyages has been studied earlier. It was assumed that longer containment inside ballast tanks negatively affects species survival.

In contrast it was found that species survive several months in ballast tanks. Resting stages may even be viable for many years (e.g., Hallegraeff and Bolch 1992; Gollasch et al. 2000; Olenin et al. 2000; David et al. 2007; McCollin et al. 2008). Further, a RA model as the chain of events was prepared (Hayes 2000; Bailey et al. 2011). However, the high diversity of potential species in transit with their stochastic behaviors, e.g., some species have even been found to reproduce in ballast tanks (Gollasch et al. 2000), it can be assumed that some species will survive a vessel voyage (see chapter “The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts”) so that survival en-route is considered as not robust or reliable enough to be used as a risk quantifying factor.

Noting the above and applying the precautionary principle, this RA model assumes that all species present in a ballast water donor port which can theoretically be transported with ballast water will become discharged alive in a recipient port. However, it is impossible to predict at which point in time this might happen. This means that, *a priori*, ballast water discharges from a donor port with a harmful species is an undesirable (unacceptable) event.

Quantity and Frequency of Ballast Water Discharges

Other shipping factors such as the quantity and frequency of ballast water discharges also relate to the risk level (Bailey et al. 2011; Chan et al. 2013). We assume that the higher the number of introduced organisms is and also the higher the introduction frequency is, the greater is the expected probability of a successful species introduction. However, this is species-specific and certainly depends on many conditions in each new environment where the species is introduced (Briski et al. 2012).

We found that the total number of ballast water discharge events and their temporal distribution in the recipient environment are insufficiently studied regarding their possible risk level impact and influence, and were therefore not considered in this RA model. Ruiz et al. (2013) concluded recently that there was no relationship between the quantity and frequency of ballast water discharges of foreign vessels with the number of introduced ballast water mediated species in 16 large bays in the United States. Furthermore, to our knowledge there is not even a single study to quantify the minimum number of organisms (propagule pressure) which would need to be discharged with ballast water to enable a species establishment with a self-sustaining population which may subsequently become invasive in a new environment.

In conclusion we consider that even small quantities of harmful organisms present in discharged ballast water may result in a successful transfer of a species which in turn may have negative consequences. As a result the RA described here does not consider the ballast water volume discharged in a recipient port and neither the discharge frequency as a risk level indication.

Definition of Potential Impacts

Studies have proven that organisms even after entering a new environment may not survive, reproduce or cause harm. However, other species introductions resulted in drastic negative impacts on various stakeholders (see chapter "The Transfer of Harmful Aquatic Organisms and Pathogens with Ballast Water and Their Impacts" for examples). In many cases it was shown that the process of introduction and species adaptation to the new environment, before they cause harm, may last for years. If a newly arrived species is not being studied in depth case by case (i.e., for each recipient environment) it is very difficult, if not almost impossible, to predict the species behaviour in the new environment(s) with an acceptable reliability. Hence, a prediction of these stochastic events seems impractical and almost impossible.

As a result, the precautionary approach for the RA decision process considers all aquatic non-indigenous organisms as harmful, and assumes that all harmful species present in the ballast water donor port, if discharged, will cause harm in the recipient environment. In conclusion this means that the discharge of ballast water from a donor port that contains harmful species is already an undesirable event.

The Main Risk Assessment Model Premises

As outlined above, the RA model in the decision making process considers different premises, which are based on best available scientific knowledge covering the expertise from different fields (e.g., invasion biology, maritime transport, BWM, RA, regulatory affairs, environment and human health protection, etc.). In summary, the premises on which this RA model (see Fig. 4) is based are:

- The input environmental (i.e., salinity) and biological data for the RA must be reliable.
- Biological data may be considered as reliable if a port baseline survey for HAOP has been conducted, and a regular monitoring program for HAOP is in place.
- If salinity based RA results in acceptable low risk, no biological data is needed.
- If a species is present in the ballast water donor port it will be discharged alive with ballast water in the recipient port.
- The voyage length, quantity of ballast water discharged and the frequency of discharges as RA factors are difficult to be defined to a reliable level to change the RA result.

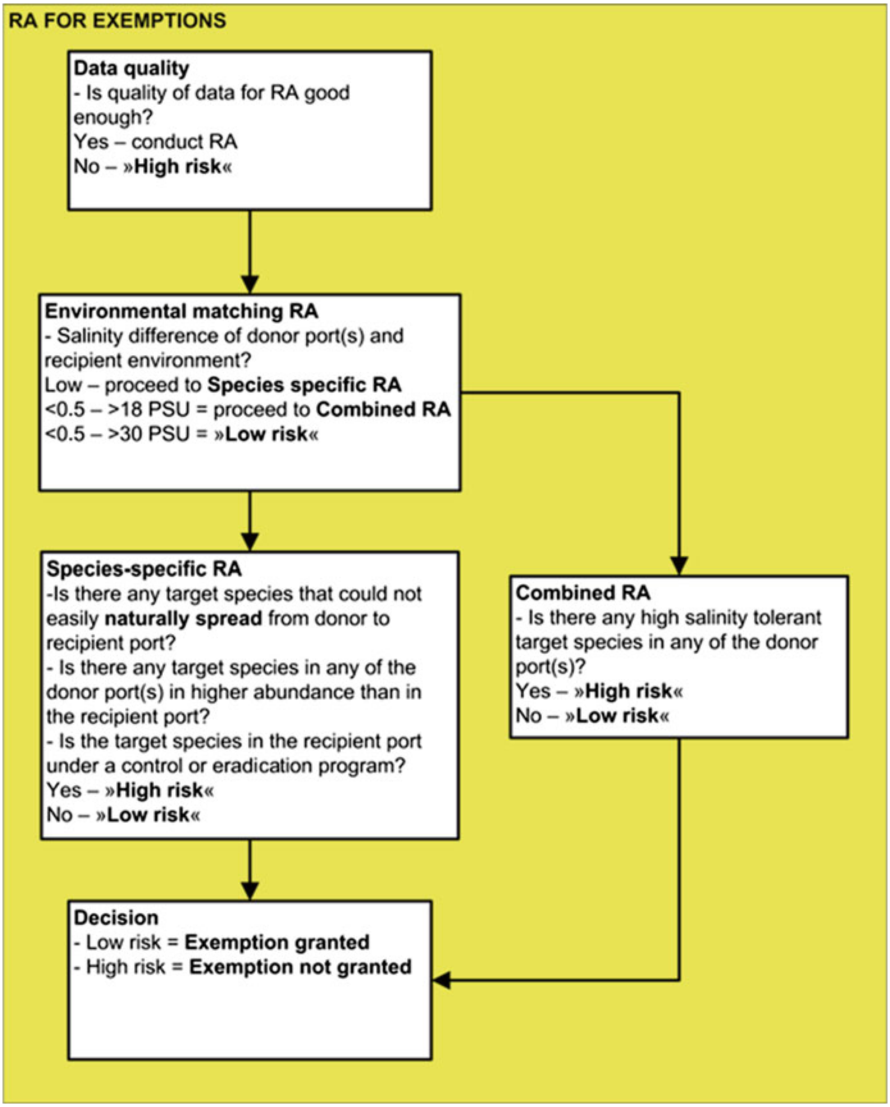

Fig. 4 Basic principles for the RA for exemptions

- Salinity is the only enough reliable parameter for the environmental matching RA.
- RA would result in acceptable low risk only if the donor and recipient ports are located one in freshwater (<0.5 psu) and the other in fully marine conditions (>30 psu).
- If the donor and recipient ports are located one in freshwater (<0.5 psu) and the other in polyhaline conditions (>18 psu), than a combined approach with species-specific RA is needed to consider high salinity tolerant species.

- If the salinity difference between donor and recipient ports is less than between freshwater (<0.5 psu) and polyhaline conditions (>18 psu), than a species-specific RA is needed.
- Species-specific RA should consider non-indigenous, cryptogenic and harmful native species to identify target species, and human pathogens.
- The presence of any human pathogens in the donor port means unacceptable risk.
- The presence of any target species in the donor port not yet present in the recipient port, and which could not easily spread to the recipient port naturally, means an unacceptable risk.
- The presence of any target species in the donor port and its occurrence in lower abundance in the recipient port, and which could not easily spread to the recipient port naturally, means an unacceptable risk.
- The presence of any target species in the donor port also present in the recipient port, which could not easily spread to the recipient port naturally, but is under a control or eradication program in the recipient port, means unacceptable risk.

For a species-specific RA, an assessment is deemed **unacceptable risk** if it identifies at least one **target species** that meets all of the following:

- likely to cause unacceptable harm;
- present in the donor port or biogeographic region, but not in the recipient port;
- likely to be transferred to the recipient port through ballast water; and
- likely to survive in the recipient port.

The Risk Assessment Model for Granting Exemptions

In the first step the data reliability is checked to ascertain that this is at the required level. If the data are not reliable the process ends with an unacceptable risk. If the data quality is adequate, then the model proceeds to the environmental matching RA with verification of the water salinity in the donor and recipient ports. If the salinity is of an acceptable difference, i.e., between freshwater (<0.5 psu) and fully marine conditions (>30 psu), the process ends with an acceptable risk result. If this condition is not met, than the model proceeds to verify if the salinity difference is between freshwater (<0.5 psu) and euryhaline conditions (>18 psu). If this condition is met then the model proceeds with a species-specific approach, but considering human pathogens and only high salinity tolerant target species. While if none of the environmental (miss)-matching conditions are met, then the process proceeds with a complete species-specific approach, i.e., considering all target species and human pathogens. The model in the next steps checks if species could spread naturally to the recipient port, if these are already present in the recipient port and in which abundance, and if these are under any control or eradication program. The RA result depends on answers to all these questions.

Human pathogens were here defined as microbes or microorganisms (virus, bacterium, prion, or fungus) that cause a disease in humans. It should be noted that many human pathogens are difficult to identify in water. Therefore IMO suggested to use "indicator microbes" such as *Escherichia coli* and Enterococci and to limit their acceptable numbers in ballast water discharges. Although these indicator microbes themselves are usually harmless, natural mutations may result in human diseases, as recently shown by a strain of bacteria known as enterohaemorrhagic *E. coli* (EHEC), a natural mutation of *E. coli* (Carter et al. 2012). Further, the presence of elevated numbers of human faecal bacteria like *E. coli* and Enterococci in water indicates an improper wastewater treatment system and the water may consequently also include other more problematic species, such as disease agents. IMO further includes the toxic strains of *Vibrio cholerae*, the agent of the Cholera disease, in this standard (D-2 standard).

In the context of this model less abundant target species in the recipient port means a considerable difference in species abundance, e.g., if in the donor port a species occurs with 100 ind/m^2 and in the recipient port with 10 organisms, the recipient port clearly inhabits a less abundant target species population. However, should the target species occur in the donor port with 2,000 ind/m^2 and in the recipient port with 1,500 ind/m^2 this can be considered as a comparable abundance. These numbers should give an indication only, but need to be reconsidered as per the species concerned.

The BWM RA model in the form of a flow chart is presented in Fig. 5.

Risk Assessment for Selective Ballast Water Management Measures

Risk Assessment Framework – Background, Principles, Assumptions and End-Point

The precautionary principle[11] is applied as a fundamental principle (EU Commission 2000) in this RA process which considers all aquatic non-indigenous organisms as being harmful, and assumes that all HAOP, if present in the ballast water donor port, if discharged, will cause harm in the recipient environment. This sets the RA end-point "at discharge" and means that already the discharge of ballast water from a donor port with HAOP is an undesirable event (see above).

The quantity of discharged ballast water is also one of the factors possibly related to the risk level. However, RA here does not relate the risk level to the quantity of discharged ballast water as also a small quantity of harmful organisms present in the discharged ballast water may result in critical consequences in the recipient environment.

[11] Communication from the Commission on the Precautionary Principle, Brussels, 02.02.2000.

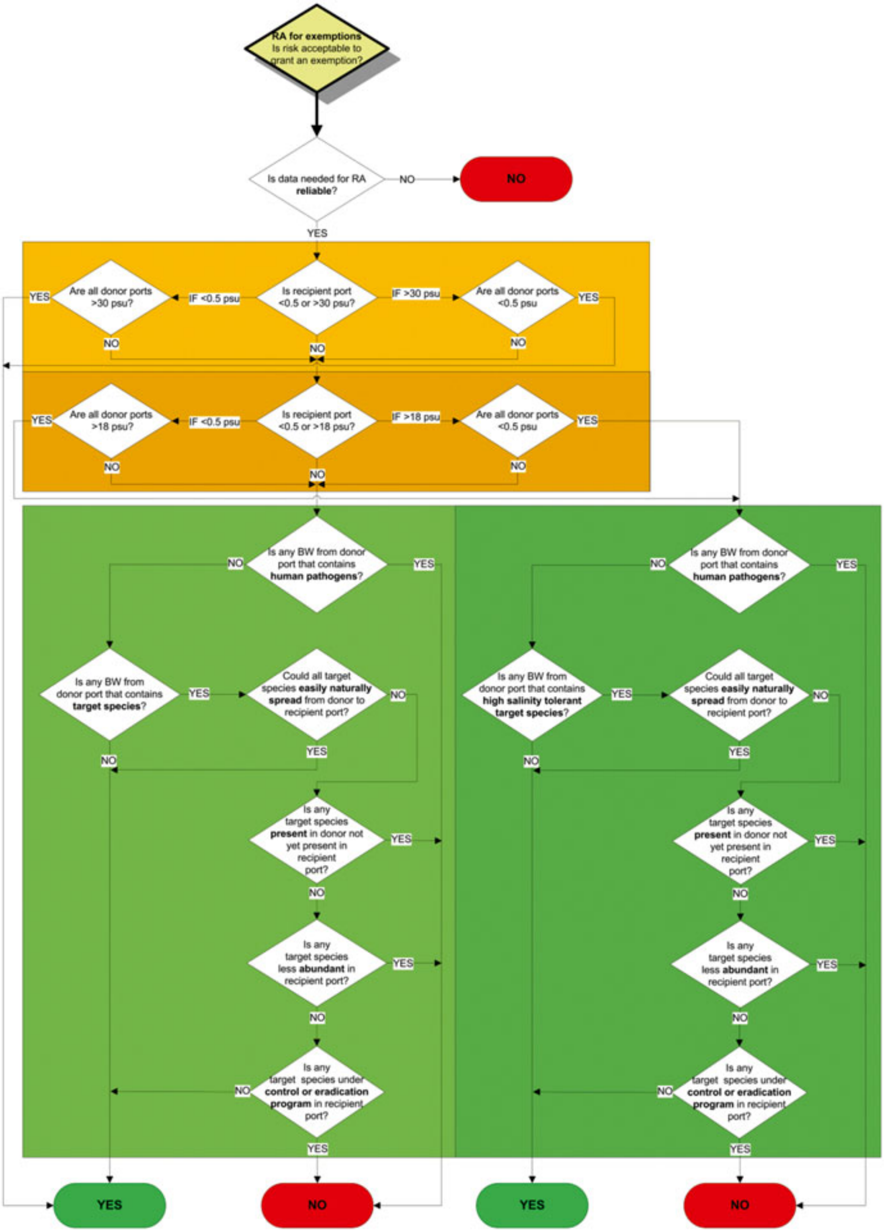

Fig. 5 The RA model for granting exemptions from BWM requirements. The *orange* box area is the environmental matching RA process, in the *green* box area is the species-specific RA process, in the shaded dark orange and green area is the combined RA approach. Reprinted from David et al. (2013), copyright 2013, with permission from Elsevier (This figure can be downloaded from http://extras.springer.com/)

The level of risk is assigned based on the different approaches as described above: environmental matching, species specific and considering biogeographical approach with target species.

In line with the G7 Guidelines on RA (IMO 2007), the Large Marine Ecosystems (LME)[12] approach was chosen as units for regions. For the RA and according to the LME philosophy this means that ports inside each LME have higher biological similarity and environmental compatibility. In cases when the ballast water donor port is in a different region (LME) from the recipient port, this means that species living in that region are by default considered non-indigenous to the recipient environment. However, there also may be an overlap of species between bioregions as, e.g., the Baltic and North Seas have many species in common, but are two separate LMEs. The more distant the LMEs are located, the more different seems the species assemblage.

The number of different risk rankings is directly related or actually dependent on BWM needs, i.e., how many different BWM responses are needed. This RA has a four level approach that was chosen as appropriate and detailed enough for BWM responses with different needs. Nevertheless, this can be easily adapted to more or fewer levels if there are different needs.

The selected risk levels are:

- low risk,
- intermediate risk,
- high risk, and
- extreme risk,

each of them resulting from a different ballast water source situation, and in the following steps triggering different BWM requirements.

The environmental matching RA is based on salinity. The input environmental (i.e., salinity) and biological data for the RA must be reliable. Biological data may be considered as reliable if a port baseline survey for HAOP has been conducted, and a regular monitoring program for HAOP is in place. If salinity based RA results in acceptable low risk, no biological data is needed.

The species specific RA is included with the questions on the presence of different species in the donor port that are associated with different levels of risk posed. The presence of HAOP in the donor port triggers different levels of risk, depending on their presence and abundance in the recipient port and whether they were included in a control program.

The logic behind this is:

- if a HAOP is not yet present in the recipient port, its introduction poses a high risk;
- if a HAOP is present also in the recipient port and was not included in any control program, the perception of it's harmfulness from the recipient port State is

[12] http://woodsmoke.edc.uri.edu/Portal/

uncritical, and hence the level of risk is lower than intermediate, but still not acceptable for unmanaged ballast water discharges, however,
– if a HAOP is present also in the recipient port and was included in a control program, this means that it was perceived and selected by the port State as critical. Therefore, the level of associated risk is extreme.

If a port State has selected target species which it does not want to become discharged in its jurisdictional waters, then these by default trigger the extreme risk should these species occur in the donor port or region. Target species are selected based on selection criteria (see section "Species-specific method"). The species' biogeographical method is considered through the target species selection.

When considering human pathogens, these are certainly one of the most unwanted species, and therefore have also been selected to trigger the same level of extreme risk. In the case of toxic algae, the approach is split in two levels. In many cases, these are present in ports as resting stages in sediments and may not cause blooms. However, these can be loaded on board ships with ballast water. This may occur when sediments are stirred-up in the water column so that some resting stages of toxic algae may also be present in the ballast water, and therefore have been selected as posing a high risk. In case these algae are in the bloom state, these will certainly be loaded on board the vessel within the ballast water in millions and possibly form resting stages in the ballast tank to survive the voyage. Hence, they represent a serious threat to the ballast water recipient environment and have also been selected to trigger extreme risk. After a vessel has loaded ballast in an algal bloom state, it may be expected that water and/or sediments inside a ballast tank will have a great potential to contain harmful algae, which may last for a longer time, i.e., also multiple ballasting operations in their next ports of call may not remove those organisms completely. Therefore, the cleaning of tanks and notifications issued by port State authorities to vessels in case of harmful algal blooms is critical.

Risk Assessment Model for Selective Ballast Water Management Measures

The discharge of ballast water will be deemed as posing a **low risk** in conditions when:

– the ballast water is moved between ports with freshwater (<0.5 psu) and fully marine conditions (>30 psu), independent of whether the donor and recipient ports are in the same region; or
– the ballast water is from a donor port that does not contain HAOP and is from the same region as the recipient port.

The discharge of ballast water will be deemed as posing an **intermediate risk** in conditions when:

– the ballast water is from a donor port that contains HAO that are already present in the recipient port and also occur in a similar abundance, where these are not under any control program.

The ballast water will be deemed as posing a **high risk** in conditions when:

– there is no reliable data about environmental (i.e., salinity) or biological conditions in the donor port; or
– the ballast water is from a donor port that contains HAO (i.e., non-indigenous species and toxic algae (not in the blooming state), which are not present in the recipient port).

The RA will result in an **extreme risk** in conditions when:

– the ballast water is from a donor port that contains target species, especially when those occur in much higher abundance as in the recipient port;
– the ballast water is from a donor port that contains toxic algae that are in a bloom state;
– the ballast water is from a donor port that contains human pathogens; or
– the ballast water is from a donor port that contains HAO that are already present in the recipient port, where these are under any control program in the donor port.

The BWRA model to assess the level of risk posed by ballast water to the recipient port is shown in Fig. 6. According to each level of risk identified different BWM measures may be applied (see chapter "Ballast Water Management Decision Support System").

Implementation of Selective Ballast Water Management Based on Risk Assessment

The advantages of the blanket approach include low data and skill requirements and it is simple for port State implementation. However, the main disadvantages are that more burden is placed on ship crews with "unnecessary" BWM requirements (in case of low risk), which will result in more costs for the shipping industry. Depending on the BWM method used also more pressures may be placed on the environment (e.g., in case chemical treatment of ballast water is required which may result in residual toxic components in discharged ballast water or in the addition of neutralization agents before ballast water discharge).

The selective approach places less "unnecessary" BWM burden on vessels, but it requires more extensive data gathering for port States as well as more data and reporting requirements for vessels. It may require higher skills and knowledge for port State personnel; however with an appropriate decision support system (DSS) this can be overcome.

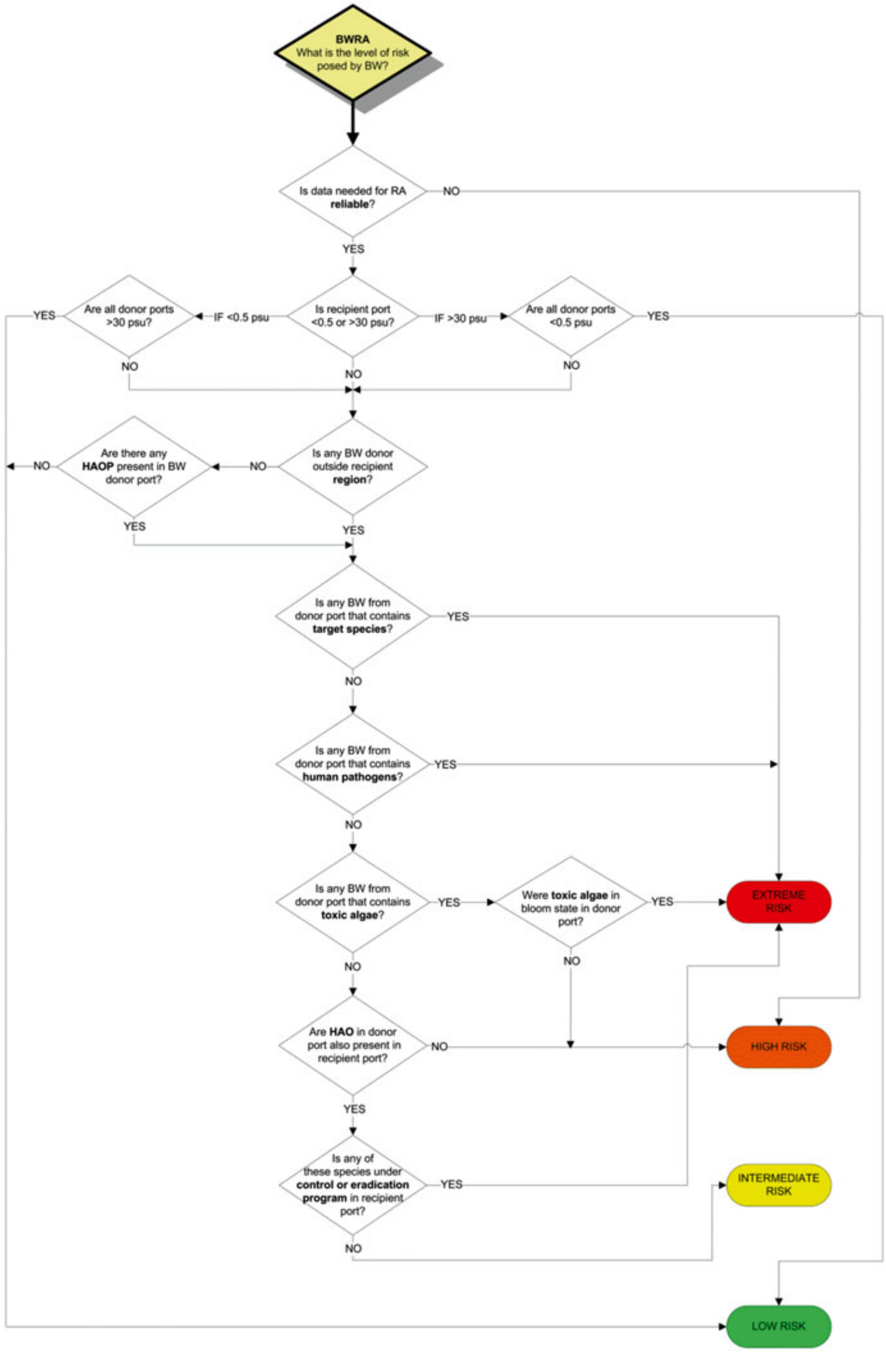

Fig. 6 RA model resulting in four different risk levels (Enhanced after David 2007) (This figure can be downloaded from http://extras.springer.com/)

With too many limiting factors for vessels discharging ballast water in a port, the blanket approach becomes ineffective. Further to the feasibility, a decision on the appropriate (blanket or selective) approach can be taken considering their advantages and disadvantages which we summarize here:

The advantages of the blanket approach include:

– low data requirements for the port State;
– low skill requirements for the port State personnel to come to a RA result; and
– simple implementation for the port State.

The disadvantages of the blanket approach include:

– all vessels conduct BWM, even those that do not carry harmful organisms and pathogens;[13]
– more burden on vessels crew by requiring "unnecessary" BWM measures;
– more costs with BWM; and
– depending on the BWM method used also some additional environment pollution or pressures.[14]

The advantages of the selective approach include:

– less "unnecessary" BWM burden for vessels;
– lower costs for the shipping industry; and
– less unnecessary environment pollution or pressures.[15]

The disadvantages of the selective approach include:

– more extensive data requirements[16] for port State;
– more data and reporting requirements for vessels;
– more complex BWM approach requiring the use of a RA system;
– more complex BWM system requiring DSS;
– higher skill and knowledge requirements for port State personnel; and
– in cases of a lack of data or false data, the risk may be underestimated and consequently "high risk" ballast water may be discharged.

As stated above, the implementation of the BWM Convention under the blanket approach is clearly simpler. However, there are many factors arising from unique situations/conditions worldwide that may limit the possibility of its implementation, which, at the same time, favours the selective approach. On the other side, the selective approach is without doubt more demanding, which would appear to limit its application. Hence, appropriateness should be studied and decisions taken on a case by case – port by port basis.

[13] Source ports may be in the same region and not infected by harmful organisms and/or pathogens.

[14] e.g., more oil consumption and gas emissions for creating more power supply necessary for ballast water treatment or exchange, chemicals (active substances) used for treatment.

[15] e.g., more oil consumption and gas emissions for creating more power supply necessary for ballast water treatment or exchange, chemicals (active substances) used for treatment.

[16] i.e., quantitative and especially qualitative.

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