

Risk analysis, the precautionary approach and stakeholder participation in decision making in the context of emerging risks from invasive alien species

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Abstract The recent development of “risk analysis” will be described focusing on stakeholder participation in decision making on addressing emerging risks, such as biodiversity loss or ecological destruction of habitat by invasive alien species. First, we discuss how such a type of “risk” is perceived and identified among the stakeholders involved in “risk analysis” which consists of "hazard identification", "risk assessment" and "risk management". The interdisciplinary nature of “risk” is a substantial factor in understanding why risk is differently perceived and managed by stakeholders involved at local, regional and global scales. Secondly, it will be discussed why the precautionary approach is one of the most fundamental approaches to decision making on this issue, in view of the scientific uncertainty and the complexity resulting from socio-cultural dynamics in our post-industrial society. Finally, the case of the “Ballast Water Convention” will be presented as an example of applying the precautionary approach as part of good risk governance in the case of invasive alien species.

Keywords: ballast water; risk analysis; risk governance, stakeholder participation; biosecurity; precautionary approach to invasive alien species

INTRODUCTION

Because of the drastic increase in both scale and variety of global trade, tourism and transport across national or regional boundaries, we have faced an increased risk to humans and to the environment due to biological invasion of alien species into the terrestrial, freshwater, and marine ecosystems since the 1990's. Traded commodities have provided pathways and vectors for intentional as well as unintentional introductions of alien species. Maritime transport has been one of the biggest means of global transfer of marine organisms, either inside the vessels, or attached to them. A large volume of ballast water results in the transportation and discharge of a large number of marine organisms at locations where they are alien. Toxic algae, such as dinoflagellates that used to be dominant in one specific coastal zone, have suddenly occurred in other coastal zones, primarily due to the large volume of ballast water being transported across the oceans (GloBallast, 2000). Biological invasions have become relevant in many contexts of biology, ecology, marine and environmental sciences as well as environmental policy sciences, and concerns include risk to human health, loss of biological diversity, habitat impacts, and other socio-economical damage.

This paper focuses on “risk analysis”. We need to examine inter-disciplinary aspects of the hazards

created by invasive alien species, including the difficulty of predicting effects of invasion, leading to high scientific uncertainty, and the added complexity due to different values among stakeholders involved. Risk analysis is considered as one of principal approaches to deal with scientific assessment and decision making in the context of uncertainty and complexity. For example, some of the recent international agreements or conventions such as the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement, 1994) or the International Plant Protection Convention (IPPC, 1997) state the need for measures taken to be based on scientific assessment of risks to human, animal, or plant health. Risk analysis is expected to underpin decisions or negotiations either at bilateral or multilateral level.

In the first part of this paper, we will discuss how modern risk analysis has been developed as an interdisciplinary approach to deal with complex and uncertain processes in the management of emerging risks in our post-industrial society. The second part will discuss the “precautionary approach or precautionary principle” as a fundamental approach in decision making, relating to invasive species, due to the high scientific uncertainty that originates from the limitations of scientific knowledge on invasiveness and to complexity of risk events in both natural and

social systems. Finally, we will illustrate the need for the interdisciplinary concept of “risk analysis” and the precautionary approach in decision making locally as well as globally, using the case of the “Ballast Water Convention”

RISK ANALYSIS FOR THE EMERGING RISKS FROM INVASIVE ALIEN SPECIES

Interdisciplinary nature of risk analysis

It has been argued that many of the emerging biological hazards affecting biodiversity loss or resulting in the global expansion of new infectious diseases to humans, animals and plants, have been technologically and socio-culturally induced, because they are deeply associated with our modern ways of production and consumption in the post-industrial society. Moreover, these risks are often latent, invisible, or inter-generational and inter-specific and can usually be characterised as “of low frequency but with catastrophic consequence”. Hence, these risks are often understood as “virtual-reality” in terms of the difference between the possibility and the reality (Renn and Klinke 2001)

To deal with those types of emerging risks, the modern concept of “risk” has evolved from the conventional view of “risk” as “expected value of the probability of a hazardous event occurring multiplied by the magnitude of the consequence of the hazard” into an ontological or sociological concept of “risk” that allows us to take into consideration a wide range of socio-cultural characters of emerging risks from biological hazards. Among such attempts to define the interdisciplinary concept of risk we take one of the simplest ones. That is:

“The potential for the realisation of unwanted, adverse consequences to human life, health, property, or the environment”.

This simple definition (http://www.sra.org/resource_glossary.php/) originated from the extended discussions on defining an interdisciplinary concept of risk at the SRA (Society for Risk Analysis: a professional and academic association founded in 1982 with major memberships in the USA, Europe and Japan). In this context, when we specify “a potential” in the framework of risk analysis, it should be noted that a certain degree of value judgement on “adverse or unwanted” has been included. To address this issue of “value” inherent either explicitly or implicitly in any concepts of risk, Kaplan and Garrick of the SRA proposed the expression in terms of a “risk triplet” (Kaplan and Garrick 1981). The risk triplet consists of scenario S, likelihood P, and

possible consequence D in relation to the following three basic questions of risk analysis:

- 1) What is the nature of the event that can happen?
- 2) How likely is it?
- 3) What are the consequences?

$$\text{Risk} = R\{< S_i, P_i, D_i>\}$$

S_i: a set of scenarios concerning the nature of the possible events

P_i: a set of likelihoods concerning the frequency, probability or ambiguity,

D_i: a set of consequences concerning the unwanted possible damages to humans, animals, plants, or the environment.

The relationship between the conventional concept of risk (P_i x D_i) and this interdisciplinary one R {< S_i, P_i, D_i>} is illustrated in Fig. 1 (Ikeda 2004). In addition to the scientific knowledge of P_i and D_i, scenario S_i can put questions and conditions on ontological and socio-cultural factors in relation to our anthropocentric activities in the complex and uncertain worlds. For example, in cases of risk analysis for invasive alien species, the scenarios will try to identify what are the most critical endpoints to be assessed in terms of possible impacts to human, animals or plants, to achieve better risk management. As generic indices of endpoints, we could, for instance, take the number of species endangered, declining population of native species, loss of habitats or landscapes, disease outbreaks in human and non-human environments, economic loss of agricultural or fishery products and so on, depending on our concerns in relation to the biohazard under consideration.

Once we have identified the adequate endpoints to be assessed, the next step is to specify the

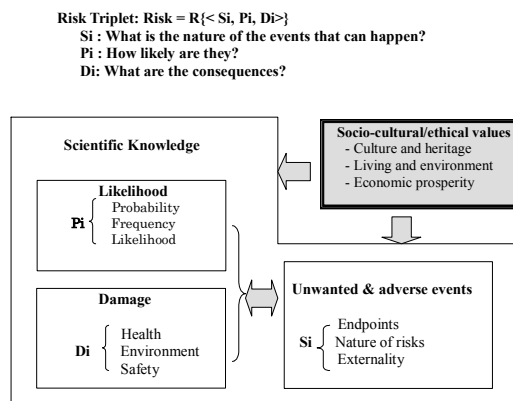


Figure 1 Triplet expression of risk in terms of interdisciplinary concept

particular types of risks that are associated with the endpoints, both in terms of likelihood and of damage. Then we also need to explore possible “external impacts” which might be accidentally or intentionally brought about, by posing the following questions:

- 1) Are the impacts or damages within our management limit or are they out of our control?
- 2) What scale or degree of irreversibility could these impacts have?
- 3) Are there likely indirect impacts on other genotypes or species, beyond the biological and ecological boundaries?
- 4) Do these impacts pose a moral or ethical problem with regards to nature or global ecosystems?

These are typical questions to arrive at scenarios (S_i) that should be clarified in the stage of problem formulation, when we begin the scientific or objective evaluation of P_i and D_i . It is the role of “risk analysis” to provide answers to these questions either in qualitative or quantitative ways in relation to the risk triplet $R = \{< S_i, P_i, D_i>\}$. Hence, the framework of risk analysis consists of identifying the possible biohazards, assessing the likelihoods associated with

vectors and pathways, the extent of exposure to the endpoints, and their responses to the exposures.

Risk analysis framework for ecological and biological hazards

An example of “risk analysis” in the biological or ecological context is the “ecological risk assessment” (US EPA 1998) that was based on the classical framework of risk analysis proposed by US National Research Council (US NRC 1983). The NRC framework that was intended primarily for regulating hazardous chemicals to protect human health and protect against environmental degradation consists of the following three processes (see the upper part of Fig. 2 as modified for ecological risk analysis):

- 1) *Research Processes* (or problem formulation) on the possible risk events in laboratories, fields, communities, mostly based on both natural and social sciences.
- 2) *Risk Assessment* which provides an objective and integrated judgment in terms of scientific evaluations on hazards identification,

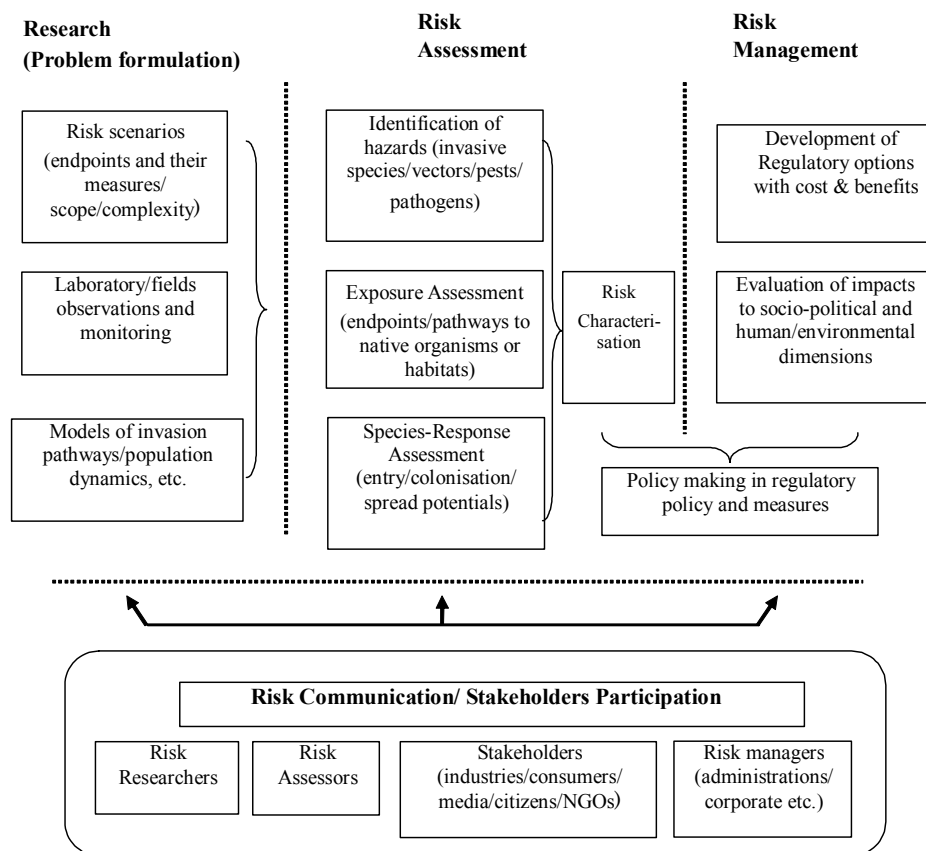


Figure 2 An example of a Risk analysis framework for ecological and biological hazards (Modified from the classical framework by NRC 1983)

dose-response, and exposure assessment as a form of risk characterisation,

- 3) *Risk Management* which is a subjective decision making process of selecting regulatory measures among alternative options, in conjunction with the outputs of scientific risk assessment and other socio-economic and cultural conditions.

One of the most important features of the NRC framework is to have made a clear conceptual or functional separation between “risk assessment” and “risk management”. The explicit representation of the risk scenarios sits at the interface of the two processes for making better assessment and regulatory decisions, while dealing with high scientific uncertainty and complexity of values among researchers, assessors, managers and stakeholders. However, after several controversial cases failed to gain public acceptability or credibility, the critical role of *risk communication* and stakeholder involvement in risk analysis has been widely acknowledged as the fourth process in the risk analysis framework (shown in the lower part of Fig. 2).

Risk analysis for biological or ecological hazards could follow the same processes by modifying some of the elements in the general risk assessment procedures to be more focussed on biological invasion. For example “possible hazards or stressors” could be replaced by “invasive species” or “vectors”, their “exposure to the ecological endpoints” by “pathways” to native indigenous species/ecosystems, and “dose-responses” by “species-responses” (as displayed in the upper part of Fig. 2). In addition, because it provides for participation of stakeholders throughout the entire cycle of risk analysis, the process of risk communication has been advocated, in particular, for cases where there is high scientific uncertainty and where the issue of values of stakeholders is complicated. Risk communication creates a social platform to share different risk perceptions, associated with the human dimension of invasive alien species (US NRC 1996).

Following the ecological risk assessment framework (US EPA 1998), several frameworks have been proposed for assessing risks, targeting invasive species associated with traded commodities or with transport, such as in the case of ships’ ballast water. A typical framework is the “Generic Non-indigenous Aquatic Organisms Risk Analysis Review Process (abbreviation: Review Process)” developed by the U.S. Aquatic Nuisance Species Task Force. The Review Process consists of three major steps (Orr 2003):

1. *Initiation (problem formulation) step*: seeking the data for invasive species in terms of their possible origins, pathways and past and present mitigation actions. This allows the development of risk

scenarios.

2. *Risk assessment step*: preparing a list of alien organisms of concern with their pathways, and then, conducting a species-based “organism risk assessment” in terms of probability of species establishment and consequences of the establishment (e.g. economic impacts). ,
3. *Risk management step*: developing mitigation measures and procedures primarily based on the output from the risk characterisation.

One of the interesting features of the Review Process is that it uses a simple and flexible set of codes indicating the degree of uncertainty that the risk assessors encountered, from a level of high certainty up to a level of high uncertainty. Uncertainty can originate from assessment methodology, assessor’s bias or errors, or biological/ecological unknowns. The assessment also includes codes indicating the types of references used, e.g. literature, extrapolation from related species, etc. (Orr 2003). In their model, the “organism risk assessment” is expressed by the following forms of P and D in the risk triplet Risk = R {< S_i, P_i, D_i>}:

P: Probability of establishment:

$$P = (X_a) \cdot (X_b) \cdot (X_c) \cdot (X_d)$$

(X_a) = probability of being associated with possible pathways.

(X_b) = probability of entry potential surviving in transit.

(X_c) = probability of maintaining population in the habitat.

(X_d) = probability of spreading beyond the habitat area

D: Consequences of establishment:

$$D = Y_a + Y_b + Y_c$$

Y_a : Economic impact

Y_b: Environmental and ecological impact

Y_c: Socio-cultural impact (human-dimensional influence) (source: Orr 2003)

As far as a specific risk assessment framework for ballast water is concerned, a variety of models have been proposed, mostly qualitative, but some quantitative. For example, the Norwegian Maritime Directorate developed an integrated assessment model called EMBLA (Environmental Ballast Water Management Assessment). The model has three components: 1) Initial and detailed hazard screening, 2) Hazard Analysis, and 3) Impact/Consequence Assessment. It has basically the same structure as the US Review Process, but it is oriented more to practical operations to reduce invasion risks of alien species. It aims to combine realistic policy measures

Degree to which stakeholders are affected / interested	Low	Issue: Design & Operation Approach: Risk-based Applied Sciences & Engineering 1	Issue: Diagnosis & Inference Approach: Precaution-based Surveillance and Warning Diagnostic Science 3
	High	Issue: Deliberation & Stakes Approach: Participation-based Consensual and Policy Sciences 2	Issue: Values and Ethics Approach: Discursion-based Meta-Assessment Procedures (Inter-/cross- disciplines) 4
		Low	High

Degree of uncertainty

Figure 3 Classification of “nature of risk”

and risk assessment in order to prevent the transfer of harmful aquatic organisms (Norwegian Maritime Directorate 2005). The Australian Quarantine and Inspection Service (AQIS) developed a risk assessment model for ballast water, based on event-tree analysis, where probabilities are assigned in a series of possible events (Hayes 2003):

$$\text{Risk of "ballast water"} = p(a) p(b) p(c) p(d)$$

where

p(a) :contamination of donor port with the invasive species,

p(b) :infection of vessel with the species,

p(c): survival of the species during transport, and

p(d): survival of the species in recipient port.

It is, however, obvious that some of the most difficult issues involved in “risk analysis of the biological hazards” have not been fully addressed yet. In particular, it is essential to produce a reasonable set of interdisciplinary risk scenarios S_i so that they can work as a bridge between scientific assessment and subjective policy measures in order to achieve the management goals. The task is therefore to develop possible risk scenarios S_i that focus on the specific nature of risks from biological invasion, while dealing with high uncertainty and complexity. The risk scenarios must be able to be used under the current regulatory institutions, monitoring or surveillance systems and resources limitation and must be able to address differences in risk perceptions and in social or ethical values among stakeholders in terms of biodiversity or biosecurity. In addition, local, national and global perspectives need to be accommodated as appropriate.

RISK ISSUES AND MANAGEMENT APPROACHES TO DEAL WITH UNCERTAINTY AND COMPLEXITY

We can classify the above described “nature of the risk” into the following four areas by dividing two axes into “high” and “low” respectively (Fig. 3). One axis is used to indicate the degree of uncertainty of our knowledge (a scientific evaluation axis) and the other axis to indicate the degree to which stakeholders are affected or interested in the risk events (a socio- economic/cultural/ethical evaluation axis) (Ikeda 2000).

Area 1: This is an area where scientific knowledge about risk events is fairly certain and there are few value-based stakeholder issues. An evaluation of the results of the scientific assessment is possibly using objective indices or standards. Here, we can rather logically take regulatory measures for risk reduction based on the objective risk assessment. In this area, the most important management issue is the objectiveness of risk information so as to ensure accountability for the regulatory decisions and choice of options to reduce the risks up to some acceptable levels. The management strategy is a “risk-based” regulatory approach under the existing legislative framework including setting an acceptable level of risks, monitoring and surveillance for invasive species, etc.

Area 2: This is an area where scientific knowledge about risk events is fairly certain, but there are rather significant issues among the stakeholders influencing their evaluation of the outcomes of the risk assessment. In this area, a “participation-based”

consensus-building approach to risk management is required as a major management strategy. Here, it becomes critical to ensure not only the reliability but also the transparency of the procedure of risk assessment. This requires not only that there is stakeholder participation at all levels of the regulatory decision making, but also that some democratic institutional arrangements are in place to ensure such stakeholder collaboration.

Area 3: This is an area where the level of uncertainty in scientific knowledge is fairly high, but there are few value-based issues among the stakeholders when evaluating the results of the risk assessment, in spite of uncertainty. Examples are infectious diseases or epidemics. Here, it is inevitable that the risk assessment includes a high degree of qualitative scenario or subjective scores under high uncertainty. In this area, the main management strategy is to effectively promote “precaution-based” diagnosis and presumption under high uncertainty. Hence, it would be desirable to allocate significant resources, not only to monitoring or surveillance systems for early warning, but also to the development of risk communication for sharing the risk information with the experts and public.

Area 4: This is an area where uncertainty in scientific knowledge is high and there are significant issues among stakeholders, resulting in potential conflict when evaluating the assessment and/or in relation to the setting of acceptable levels of risk. Since existing approaches based on scientific and objective indices or standards can not be used in this area, it is necessary to develop a “discursion-based” meta-science which evaluates both scientific and socio-cultural factors (human dimension of invasive species problems) including anthropological, ethical and value judgment issues. At the same time, as is in “Area 3”, we need to create a social platform of “risk communication” to allow discussion of the different risk perceptions among the stakeholders.

In Areas 1 and 2, we can make scientific assessments of possible events either qualitatively or quantitatively, with low uncertainty – for example, the probability of traffic accidents or odds ratio of excess deaths by SO₂ air pollution above some regulatory SO₂ standard. In such cases, the important management issues are 1) how to properly choose risk scenarios and how to decide on monitoring and regulating the related indices or measures for the risks on the endpoints, and 2) how to ensure stakeholder participation in the decision making and consensus building processes. Some of the specific risk management for invasive alien species in the quarantine systems under the SPS agreement falls in these domains, where we have

reasonably good scientific data, allowing objective assessment.

However, since most of the emerging risks from invasive species are likely to be in situations of high uncertainty in our scientific knowledge, risk management issues relating to protecting native biodiversity/ecosystems from impacts by new genetically modified species or by alien, potentially, invasive species fall into the Areas 3 or 4. Whether the case will be in Area 3 or in Area 4 depends on the of socio-cultural issues among the interested stakeholder groups who have risk perceptions deeply rooted in their ontological or anthropological perspectives beyond the conventional science paradigms. Here, we need an approach of stakeholder participation in decision making that centres around a “precautionary framework or principle” with the support of a discursive “risk communication” among stakeholders, as is displayed in the lower part of Fig. 2 (Renn and Klinke 2001). We use “risk governance” as a specific type of risk management strategy in which interdependence or intercommunication among the stakeholders involving governmental or non-governmental actors is essential in the pursuit of collective decision making aimed at attaining policy goals.

PRECAUTIONARY APPROACH TO EMERGING RISKS, UNDER HIGH UNCERTAINTY AND COMPLEXITY

The term “precautionary approach” first appeared in the ministerial declaration of the second International Conference on the Protection of the North Sea, in London (1987), reflecting increased environmental concern about the marine and coastal pollution problems, such as oil spill accidents and the associated massive death of marine mammals in the 1980's. A typical example is the Convention for the Protection of the Marine Environment of the North East Atlantic (OSPAR Convention, 1992) which introduced a “precautionary regulation on any substances” discharged into the sea in spite of the limitations in scientific knowledge (and monitoring data) to anticipate potential threats (catastrophic events). This strict form of precautionary measure was, in fact, supported by most of the coastal countries who began to shift their regulatory approach from the traditional ones to the precautionary one (Horiguchi, 2000). Since then, the precautionary approach or precautionary principle (as it is called in some other environmental policy areas) has become one of the basic concepts to address the emerging environmental risks in the fields of marine pollution.

Because of the history of this concept, there is

variation in the formulation of the precautionary approach or precautionary principle depending on the aims of the conventions or agreements. In addition, a number of different terms are used, such as “precautionary framework”, “precautionary approach” or “precautionary principle”. Here, we use “precautionary approach” which the international organisations of WHO and FAO are currently using as a term in the context of the problems of public health, food safety and animal or plant sanitary issues. The different versions of the concept, for instance, appeared in: 1) The declaration from the ministerial meeting of the North Sea marine pollution protection in 1990; 2) Rio Agenda 21 of the United Nations Environment Programme 1992; 3) Wingspread Declaration in 1998, and 4) EU Guidelines, 2000, and so on. The common features of the above examples can be formulated in terms of “*threat*”, “*uncertain*”, “*action*”, and “*mandatory*” (Sandin 1999) as follows:

If there is (1) a *threat*, which is (2) *uncertain*, then (3) some kind of *action* is (4) *mandatory*.

The former two terms are associated with the evaluation of the scientific knowledge about the nature of the risk event. The latter two terms are related with decision making about the management strategy or regulatory measures. Here we have again two substantial dimensions of uncertainty in scientific knowledge and complexity relating to socio-cultural issues. In more elaborated words, we could state that:

- If there exists a serious or irreversible *threat* (potentially dangerous) to human health and the environment, and also
- the causal association between the hazards and the endpoints is *uncertain* (not fully scientifically established),
- then, *action* (preventative or regulatory measures) is *mandatory* (with the status of the action subject to some conditions, e.g. balancing “cost-effectiveness” or “costs and benefits”, depending on institutional or resource constraints).

In addition to the above conditions, the Wingspread Declaration 1998, which is one of the strongest assertions, added another condition, about the burden of proof being on the developers (promoters of the development). However, as far as the precautionary regulation or management issues are concerned, many problems remain ambiguous and require further discussion. These are, for example, 1) the degree of threat or irreversibility where precautionary measures should be taken without full scientific validation of

the link between biological invasion and consequences, 2) the content of precautionary measures, and 3) the cost burden for malpractices, including the problem on what degree of the burden of proof should be required, etc. O’Riordan (1999) has elaborated six core elements of the precautionary approach which are relevant to the discussion of stakeholder participation in decision making in the context of biohazard risks from invasive alien species:

- 1) Action before scientific justification
- 2) Proportionality of response (cost effectiveness)
- 3) Ecological margin to allow for human ignorance
- 4) Shift of the onus of proof onto polluters
- 5) Concern for future generations
- 6) Ecological debts incurred by developed countries in the past

Among these elements, a couple of policy elements, such as “proportionality of response”, “shift of the onus of proof onto polluters” and “ecological debt”, are closely related to the issues of balancing costs and benefits of preventive actions or balancing ecological effectiveness and ethics of policy measures under high scientific uncertainty and complexity of stakeholder issues. The first of these elements is concerned primarily with the adequacy of precautionary actions in terms of the cost-effectiveness or opportunity cost during the whole management process. As for the second of these elements, for example, the ballast convention imposed responsibility to the administrators of the ship with some exceptional conditions of granting discharge of ballast water when ships operate only between specified ports. In general, it considers that a proof of safety is required beforehand and potentially affected states shall be consulted aiming at solving the concerns. The latter element of “ecological debts” is related to the sensitivity or vulnerability of global marine ecosystems and the responsibility of developed countries in terms of dumping industrial pollutants and over-utilisation of resources.

In the following section, we will discuss how these core elements of the precautionary approach are taken into considerations in the draft convention of ballast water as a major institutional vehicle towards decision making to address the emerging risks of biohazards from invasive marine organisms, incorporating the precautionary approach and stakeholder participation.

THE EXAMPLES OF BALLAST WATER AND RISK GOVERNANCE

Risk management scenarios in the context of the IMO ballast water convention

Ballast water, which is freshwater or seawater loaded at a cargo discharging port, is necessary for a ship's safe operations to maintain stability. When it is discharged at a cargo loading port, organisms in the ballast water create a set of potential risks not only to native marine species, but also to economic values and human health, e.g. through harmful algae blooms, infectious diseases, etc. Once an alien species has established within a new ecosystem it is usually impossible to eliminate and restore the ecosystem back to the original. The volume of ballast water transported worldwide is estimated at about 10 billion tons per year. It is estimated that Japan, exports 300 million tons and imports 1.7 million tons of ballast water per year (Kikuchi, 2001). In addition, there is a risk that biological invasions will become more prevalent due to global climate change.

The first official report of damage caused by ballast water was by the WHO in 1973, on a cholera epidemic in Latin America. Although the WHO concluded that ballast water accounted for the 1991 epidemic in Peru (WHO 1999), some experts insisted that there were many other possible vectors of *Vibrio cholerae*, and thus, ballast water should not be blamed on its own. (Seas, *et al.* 2000). During the 1980s, a global scale of toxic phytoplankton blooms in most of the coastal zone of marginal seas strongly suggested a possible role for ballast water in the global transportation of invasive alien species (Carlton 1985). Nevertheless, scientific or biological mechanisms of the release of ballast water in the establishment of invasive alien species have not been well understood (Ruiz, *et al.* 2000). For example, in the case of the paralytic shellfish poisoning on the coast of Tasmania islands in 1986, either Japan or Spain was suspected as the origin of ballast water that acted as a vector for the toxic plankton sampled from the ballast tank of a log bulk carrier. However, toxicological research could not verify that species in the ballast water were definitely the sources of the shell fish epidemics (Oshima, 1992).

Because of the global and trans-boundary nature of invasion by marine alien species, individual countries and shipping societies have addressed concerns in relation to ballast water by preparing their own guidelines based on precautionary measures. Countries with significant concern about potential impacts of marine invasive alien species on their native marine resources and ecosystems worked towards the establishment of a global legal framework beyond territorial waters. Eventually, in

2004, the International Maritime Organisation (IMO) adopted the convention on the management of ships' ballast water at a diplomatic conference in February 2004. Ratification is anticipated by 2009 (GloBallast 2003).

According to the draft convention adopted by IMO in 2000, one of the most important issues of risk governance is how to introduce mandatory regulations to minimise the transfer of harmful aquatic organisms and pathogens from original habitats to other places while increasing the level of participation from port- and flag-states and non-governmental bodies, and other countries who are concerned about marine invasive alien species. Such mandatory regulations requiring a "precautionary approach" include measures to lessen the chance of taking on board harmful organisms along with ballast water, prevention of loading and discharging ballast water in shallow water, procedures for the exchange of ballast water at sea and for discharge to reception facilities at port-states.

As expected under regime theory, developed in the field of policy and political sciences (Young and Osherenko, 1993), the development process of the ballast water regime can be divided into the following three stages according to the degree of scientific knowledge and values and participation of the actors and stakeholders concerned - based on both scientific reports of ballast water prepared by the joint GEF/IMO/UNDP project (Gollasch 1997, IMO 1998, GloBallast 2002, 2003, 2004) and our interviews to the port regulatory authorities in Japan (Hijikata and Ikeda 2003):

- 1) guideline formation (before the adoption of the IMO guidelines in 1991),
- 2) guideline development and review (from 1992 to 1997),
- 3) convention formation (from 1998 to 2004).

In this section, we will examine how the framework of "risk analysis" relates to regime analysis of the ballast water convention. Then, based on examination of the development process of the draft ballast water convention, we also discuss what this show us about interdisciplinary or human dimensional factors that we need to incorporate in the framework of risk analysis for emerging risks from invasive alien species. In order to examine the core governance issues relating to the ballast convention, we need to specify key stakeholders and actors as well as the specific factors and issues of importance to stakeholders that participated in the regime formulation.

Actors in the ballast water convention

1) *Port states (the US, Canada, Australia, Germany, Brazil, etc.):*

They are the primary actors that insisted on imposing mandatory regulations. However, within those countries the issues of concern are not completely the same, for example, in the US and Canada the concern focused on economic costs incurred to control invasive species; in Brazil and Chile there was an interest in reducing the risks to human health and aquaculture contamination (e.g. concerns caused by pathogens such as *Vibrio cholera*), and in Australia and New Zealand there was a concern about degradation of tourism resources, as well as concern about red tides and shellfish poisoning.

2) *Flag states (Panama, Liberia, Greece, etc.):*

Since the number of flag-of-convenience ships is increasing, control of the flag states in regards to compliancy with international regulations has become “loosened”. In addition, since flag states are often port states at the same time (such as Panama or Japan), there may be conflicting interests. As for Japan, it has insisted that regulations should not hamper trade.

3) *Associations of ship owners (International Association of Independent Tanker Owners (INTERTANKO), The International Chamber of Shipping (ICS):*

While they are observers at the Marine Environment Protection Committee (MEPC), at the Ballast Water Working Group (BWWG) and Correspondence Group, they directly contributed to the formation of the regime by stating opinions and submitting comments. They provided voluntary guidelines. They stressed not only the need for affordable treatment techniques, but also the intention to participate in the preparation of IMO’s guidance, when the Convention was adopted.

4) *Environmental NGOs (e.g. The World Conservation Union (IUCN), Friends of the Earth International (FOEI):*

They mainly focus on conservation of biodiversity and have made a continued effort with campaigns to improve the awareness of marine invasive species

problems.

5) *Governmental scientific institutes (Smithsonian Environmental Research Centre (SERC), EU Concerted Action, Centre for Research on Introduced Marine Pests (CRIMP), etc.):*

The experts have formed an international network among institutes through sharing information or cooperating on research projects, such as SERC with research institutes in Australia, Germany, Israel, Italy, The Netherlands and New Zealand (Gollasch, 1997). The researchers contributed indirectly by giving policy advice or participating as delegates. Ecological experts claimed that only 100% treatment/sterilisation could be effective to avoid the establishment of unwanted species.

Development of a regime: relation between general factors and specific issues in the ballast water regime

The relationship between general factors in the development of a regime and specific issues in the case of the ballast water regime are mapped out in Fig. 4, based on the regime model of Young and Osherenko (1993).. Such general factors are, for examples, “scientific convergence”, “veil of uncertainty”, “salient solutions”, “exogenous shock and crisis”, “participation”, “value”, “equality”, “compliance mechanisms” and “integrative bargaining” and they are shown in relation to the ballast water specific issues (Fig. 4) .

Our analysis shows that the first stage of the development of the ballast water regime strongly experienced “exogenous shock” due to the damage caused by invasive alien species and pathogens. Then, “scientific convergence” emerged, that is, a common belief in a causal relationship between ballast water and the damage. However, the belief still lacked full scientific proof at this stage, so that the “veil of uncertainty” still functioned. This factor motivated various actors to protect their interests and aim for development of a regime incorporating and dealing with uncertainty. The existence of a “salient solution” (such as ballast water exchange in the open sea), based on a common understanding of marine ecosystems, persuaded policy makers to support a pro-active approach.

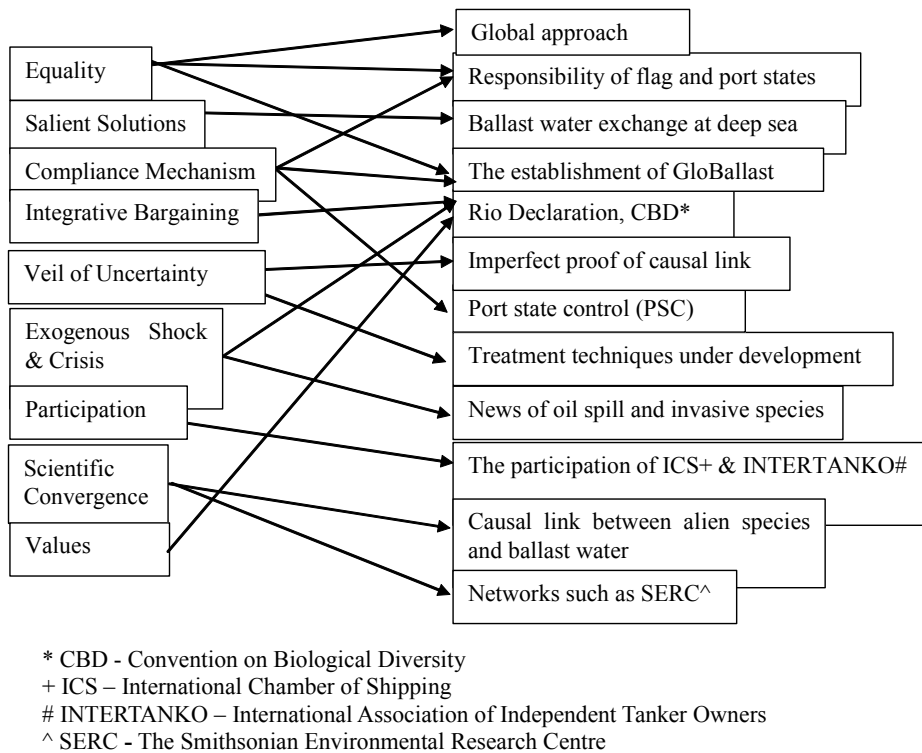


Figure 4 Development of a regime: relationship between general factors and specific issues in the ballast water regime development (Source: Hijikata and Ikeda 2003).

At the second stage, a change in “values” caused by the adoption of the Rio Declaration and the Convention on Biological Diversity (CBD) in 1992 was a very important factor that enabled integrative bargaining among actors and stakeholders in the next stage. The values held by the actors worked toward the integration of the conservation of biodiversity into considerations at a global level, although it was not fully integrated in considerations at a local level. In addition, “participation” of the ship owners association in the development of the regime was important. The International Chamber of Shipping (ICS) and the International Association of Independent Tanker Owners (INTERTANKO) actively participated in the development of the regime and presented the viewpoint of ship operators.

Finally, in the stage of the regime formation, the “equality” factor contributed, as in response to the increase in different voluntary regulations by individual states and ports, some actors - especially ship owners - began to ask for an international, global, convention. “integrative bargaining” was achieved by the change in values at this stage so that actors benefited from the formation of the convention to conserve biodiversity, which was the common value. “compliance mechanisms” that could be guaranteed primarily through port state control (PSC) promoted the formation of legally binding international rules in the third stage. Preceding success in PSC (port state control) increased the confidence in effective compliance.

Our analysis revealed that there are interactions

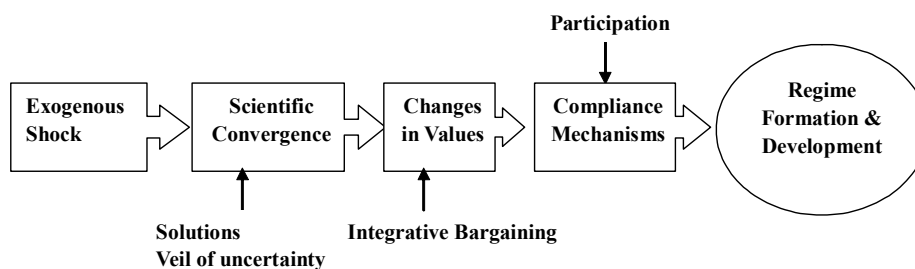


Figure 5 Critical factors and issues in the development of the ballast water regime (Source: Hijikata and Ikeda 2003).

between factors. For example, “changes in values” enable “institutional bargaining” to be an “integrative” one. Also, “scientific convergence” stimulated the emergence of “solutions” and a way to lift the “veil of uncertainty”. “Compliance mechanisms” functioned, partly because of participation of ICS and INTERTANKO. The most influential factors (keeping in mind interaction) in the development of the ballast water regime, are outlined in the flow diagram in Fig. 5.

CONCLUDING REMARKS: TOWARDS BETTER RISK GOVERNANCE

An interdisciplinary framework for “risk analysis” is presented focusing on the issue of stakeholder participation in decision making when dealing with risks from invasive alien species. Such risks include biodiversity loss and global expansion of new infectious diseases. Since these risks are likely to be latent or inter-generational and likely to be catastrophic, but with low probability, they are often thought of as “virtual-reality” in terms of the difference between the potential and the reality in our generation. To deal with such risks, an interdisciplinary concept has been developed that allows us to include a wide range of socio-cultural aspects of emerging risks from biological hazards.

The expression of inter-disciplinary concept of risk as a “risk triplet: $R \{< S_i, P_i, D_i>\}$ ” (Kaplan and Garrick 1981) asks risk assessors or risk managers to answer the following three basic questions:

- 1) S_i : risk scenario: What is the nature of the events that can happen?
- 2) P_i : probability: How likely is it?
- 3) D_i : damages: What are the consequences?

Among them, the scenario S_i shall put questions and conditions on “acceptable level of risks” and “management options for better risk governance” in relation to our anthropocentric activities in the complex and uncertain world. A clear representation of the risk scenarios can work as a catalyst at the interface between risk assessment and risk management under the condition of high scientific uncertainty and complexity of values and issues among stakeholders in our post-industrial society.

The precautionary approach is fundamental in the decision making where scientific uncertainty and complexity, both ecological and socio-cultural, need to be addressed. This was examined in the context of the development of the “Ballast Water Convention”. It seems that this convention has reflected most of core elements of the precautionary approach: first, it

takes some “mandatory preventive actions” before scientific proof: second, it attempts to shift the burden of proof ships’ administration: and third, it allows for a “proportional response” to socio-economic issues in terms of cost-effectiveness during the management process. In fact, when the precautionary approach is practiced, decision makers or risk managers have to address the fact that actions to avoid biological invasions, such as the exchange of ballast water in the open sea may produce operational safety risks for crews and ships.

Our analysis showed that there are several critical interactions between the difficult regime factors and the ballast water specific issues that influence the development of the ballast water regime. Those includes such interactions among “changes in values”, “scientific convergence”, “veil of uncertainty”, “compliance mechanism” and “integrative bargaining” as illustrated in Fig. 5 that set the stage for the remaining issues to be explored for attaining better risk governance in the context of the emerging risks from invasive alien species. That is to say:

- 1) The public, including in fishery and marine industries, NGO’s, and researchers were mobilised due to global networking and access to information and data on risks, impacts and concerns. Those networks, and the proliferation of a wide range of stakeholders, will facilitate “changes in values” and “scientific convergence” among stakeholders which will allow better risk governance.
- 2) The development of education or training programmes such as the Global Ballast Water Management Programme for developing countries initiated in 2000 by IMO (GloBallast 2000) facilitated port regulatory systems. This could also assist “changes in values” as well as increase the reliability of the regime in the legal sense.
- 3) The revised guidelines 1997 were not legally binding. Different country-based regulations created potential confusion and an incentive to develop further a variety of “compliance mechanisms” that clarified the responsibility of ship-owners and state authorities.
- 4) New investment in research to decrease the “veil of ignorance” associated with ballast water treatment can lead to effective regulatory measures.

In the East Asian Sea, it seems that we are just at the beginning stage of “scientific convergence” in the case of the ballast water regime, since experts have just started to discuss risk scenarios and issues associated with ballast water transportation into Asian

coastal waters. As indicated at the first East Asia regional workshop on ballast water, the issues are not yet studied well (GloBallast 2003). In order to reach the final stage of regime formation, there must be a “change in values” and enough capability for “integrative bargaining” to end up with better governance. This could be done by promoting the sharing of information on scientific research on harmful algae blooms and on other marine impacts through a variety of networks from the grass roots up to government agencies. Risk analysis in the context of an interdisciplinary framework is likely to contribute to lifting “the veil of ignorance” by making risk scenarios more explicit through identification of sources and pathways of biohazards, and characterisation of the risks to biodiversity and ecosystems. It could also serve as an indispensable tool for regulatory decisions and for collaboration among stakeholders, at bilateral as well as multilateral levels.

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