Governance of Complex Socio-Environmental Risks: The Case of Hazardous Chemicals in the Baltic Sea

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Abstract Complex socio-environmental risks challenge society. In response to scientific uncertainty and socio-political controversies, environmental governance, precaution, and the ecosystem approach to management are held forward as complements to governmental risk-based sector-restricted regulation. We analyze this development for hazardous substances in the Baltic Sea. Based on interviews and policy analysis, we study informal governance and, in particular, four central EU and international policies, and investigate how present governance relates to risks and objectives at hand. While showing emergence of broader governance approaches, we conclude that central objectives will not likely be met. Furthermore, we question the quest for broad environmental governance and emphasize the value of command and control regulation, if it implements precaution. These findings contribute to the theorizing on environmental (risk) governance. Finally, we provide some ideas that could help development and implementation of risk policies for hazardous chemicals in the Baltic Sea as well as other complex risks.

Keywords Ecosystem approach · HELCOM · Marine Strategy Framework Directive · Precaution · REACH · Water Framework Directive

INTRODUCTION

Society has for long been confronted with the grand challenge to cope with a number of complex socio-environmental risks characterized by both scientific uncertainty and socio-political controversy (see e.g., Karlsson 2005; Renn 2008). This is true not least for the marine environment and for the situation in the Baltic Sea, which is one of the most polluted large marine ecosystems in the world

(HELCOM 2010). In spite of substantial management efforts, chemicals in the Baltic Sea still cause severe environmental and human health risks (SEPA 2005). The levels of some substances are so high that agencies recommend women in fertile age to be very restrictive in their consumption of fatty fish species such as herring and salmon (SNFA 2008). With exception of such pockets of knowledge, basic ecotoxicological and toxicological data are missing for the vast majority of substances (Allanou et al. 1999) and neither the number of chemicals in use,¹ nor their numerous sources and fate in the environment, influencing exposure situations, are sufficiently known. Even less is probably known about the properties of the Baltic Sea ecosystem, which due to natural circumstances and long-term human pressure has a low, although scientifically not well understood, systems resilience, which has been manifested in regime shifts in some sub-basins (Österblom et al. 2010). These scientific uncertainties, in combination with the existing arrays of complex political and other social arrangements, give room for stakeholders to compete over interpreting either data, or the lack of them, in order to influence risk governance in a multilevel context (see Eriksson et al. 2010). In total, this socio-environmental complexity contributes to the failure to reach environmental objectives for hazardous chemicals (HELCOM 2010).

In response to this and similar dilemmas, a new understanding has gradually emerged in both science and policy, which underlines environmental governance, precautionary policies and the ecosystem approach to management as essential complements to traditional governmental command and control, risk-based regulation, and sector-

¹ The REACH regulation pre-registration included, very surprisingly, over 146,000 substances.

restricted measures (de Sadeleer 2007; Joas et al. 2008; Adger and Jordan 2009; ESF, ICES, EFARO 2010). This development will be empirically described and analyzed in this article, with a focus on complex socio-environmental risks associated with hazardous substances in the Baltic Sea. We aim to investigate how far this transition of policies and systems has gone, in what ways present governance relates to the complex risks at hand, and if central environmental objectives seem likely to eventually be fulfilled. In particular, we center the analysis on the transition from government to governance, from risk to precaution and from sector-policies to ecosystem approaches, and what this means for risk assessment and risk management, which traditionally have defined much of chemicals management (Karlsson 2005). In doing so, we add both empirical information and theoretical insights, and we discuss ideas on how to improve governance in relation to contemporary environmental objectives.

A number of previous studies in the field have focused on international or EU-based sector-based policies and law on chemicals (Selin and VanDeveer 2004; Hansson and Rudén 2010; Karlsson 2010) or inland and marine waters (Borja et al. 2010; De Santo 2010; Ekelund Entson and Gipperth 2010), but few of these link the policy domains together. Furthermore, a set of related studies depart from various conceptual approaches and discuss, for example, application of the ecosystem approach to management (Murawski 2007; McLeod and Leslie 2009; ESF, ICES, EFARO 2010), implementation of the precautionary principle (de Sadeleer 2007) and environmental governance and governance of complex adaptive systems (Joas et al. 2008; Duit and Galaz 2008), but few have studied the interactions between these concepts and the environmental situation in practice, in particular in the area of chemicals management. In this article, we expand on previous studies and connect both sector-policies and conceptual approaches with the specificities of the complex risks related to hazardous chemicals, thereby also responding to research challenges presented in earlier studies (Selin and VanDeveer 2004; ESF, ICES, EFARO 2010; HELCOM 2010). We concentrate our analysis on international and EU policies, as well as on informal governance, related to risk assessment and risk management of hazardous substances in general, and we leave out national policies as well as policies on point-sources and distinct substance categories such as pesticides and pharmaceuticals. The empirical sources for the study consist of regulatory, policy, risk-related and other documents, complemented by 22 semi-structured in-depth interviews with stakeholders in February–October 2010. All respondents dealt with chemical assessment or management and worked within EU or Russia, in academies, agencies, political forums, industry,

media or civil society. The interviews centered on obstacles and opportunities for assessment and management of chemicals in the Baltic Sea region with special emphasis on issues related to governance, precaution, and the ecosystem approach to management.

Following this introduction, the second section provides an empirical overview of the development from conventional risk policies to present governance elements, and describes four central policies in more detail. Against this background, the subsequent two sections analyze how risk assessment and risk management, respectively, cope with the complex risk situation. The final section discusses the relevance of the policy development in relation to the risks and objectives at hand, and concludes with a set of proposals for possible improvements of chemical risk governance in the Baltic Sea.

FROM POLLUTION CONTROL TO RISK GOVERNANCE

Some elements of environmental policy go centuries back in history (Karlsson 2006) but the basic building blocks of contemporary environmental law in Europe were mainly laid in the 1960s. By then, particularly point sources like industries were in focus and various preventive measures were stipulated on basis of a “polluter-oriented perspective.” When implementing and applying this perspective, the technological options and the economic situation of the polluter were commonly weighed against environmental objectives, ending up in compromises. The previous Swedish Environmental Protection Act (1969) is illustrative. It permitted, for example, establishment of new industries if these selected environmentally justified locations and used the best available technologies, as codified in long-term licenses, but only as far as the requirements were not unreasonably costly (Article 4, 5). For the Baltic Sea, this allowed for continued but, compared to the pre-legislation period, decreased water pollution by heavy metals, chlorinated organic substances, and other pollutants. Also within the EU, water and air pollutants were regulated by statutes requiring licensing and emission limits (Krämer 2006). This polluter-oriented perspective based on prevention still constitutes a core in much environmental law, and has dominated chemicals policy since the 1960s, including directives on substance classification and labeling, restrictions, and chemicals in products, which all have placed the chemicals and polluters in focus, rather than the environment (see Karlsson 2005).

In contrast, policies can alternatively focus on the environmental dimension, for example, on pollution con-

centrations that human health can tolerate without unacceptable effects. Early examples of this “environment-oriented perspective” are given by the set of EU environmental quality standards that emerged in the 1970s, specifying limit values for pollutants in various environmental compartments, but these were often sector-based. In the 1980s, a number of “daughter directives” were connected to the water pollution directive (EEC 1976), which in total came to regulate both levels of emissions and environmental concentrations for a larger number of hazardous substances even though the implementation often turned out problematic (see e.g., Krämer 2006).

In parallel with the gradual emergence of environment-oriented legislation, and in response to the broadening of the sources for hazardous chemicals from basically production to production and consumption (Fig. 1), both the theory and practice of environmental policy has developed from the focus on government-based structures to the much broader governance approach, a trend clearly visible in the Baltic region (Joas et al. 2008). The concept of governance has been described differently by various scholars, with empirical and theoretical, as well as normative perspectives (see e.g., Young 1994; Kooiman 2003; Pierre and Peters 2005; Adger and Jordan 2009), but a common core can be identified in the transfer of national authority, upward to the international institutions, sideways to non-governmental actors, and downwards to local actors (Kern and Löffelsend 2008). For the Baltic Sea environment, which is influenced by activities in several sectors on all levels in a 14-country large catchment area, multi-level and transnational governance is not only an empirical reality, but has also been considered desirable from a normative point of view (Joas et al. 2008). It has been argued that governance studies need to investigate the problem-solving capacity of various governance systems confronted with challenges posed by “complex adaptive systems” (Duit and Galaz 2008), a concept substantially broader, but still sharing a common core with the notion of “complex socio-environmental risks” used in this article.

The broad view taken in the theorizing on governance is also visible in the normative concept of “ecosystem approach to management” (EAM), which nowadays is widely advocated in both science and policy (Murawski 2007; Backer et al. 2009; Curtin and Prellezo 2010; Österblom et al. 2010), and which is incorporated in the Convention on Biodiversity (UN 1992) and defined for the marine environment (HELCOM and OSPAR 2003) as:

“the comprehensive integrated management of human activities based on the best available scientific knowledge about the ecosystem and its dynamics, in order to identify and take action on influences which are critical to the health of marine ecosystems,

thereby achieving sustainable use of ecosystem goods and services and maintenance of ecosystem integrity. The application of the precautionary principle is equally a central part of the ecosystem approach.”

According to this holistic perspective—which is based on the recognition of the complexities in natural systems (e.g., uncertain thresholds and cascade effects) and social systems (e.g., sector divisions and transboundary contexts)—all relevant and interlinked systems and parameters should be considered, across all relevant scales, sectors, and disciplines over time. One implication relevant for chemicals in the marine environment would thus be to consider various sources and mixtures of different chemicals in relation to the ecosystem characteristics and in relation to the multi-level governance context.

The underlining of the precautionary principle in the definition above is central and there are clear linkages between the two concepts (Trouwborst 2009). Precaution has been implemented in policies since long, but only emerged as an explicitly stated “approach” (somewhat weaker) or “principle” (somewhat stricter) in the 1980s, for example in agreements on the protection of the North Sea (Karlsson 2006). On the international level, the precautionary principle is included in various versions of several environmental treaties, and it constitutes customary law on at least a regional basis (de Sadeleer 2007), whereas on the EU level it is a clear part of the treaty since the 1990s, as well as of much secondary law on for example risk management measures (Karlsson 2005). Even though the interpretations of the principle varies (Di Salvo and Raymond 2010) much of the criticism toward the principle has been shown non-valid (Sandin et al. 2002) and elements of the principle have clearly been implemented in practice and applied by courts (de Sadeleer 2007). Karlsson (2006, 2010) has suggested that the principle in the field of chemicals policy, could guide classification, prevention and decision-making.

In the following sub-sections, we describe the most central policies on chemical risks in the Baltic Sea region—namely the Helsinki Convention, as well as the REACH regulation, the Water Framework Directive (WFD) and the Marine Strategy Framework Directive (MSFD) of the EU²—and we provide examples of informal governance on chemicals. We will characterize and compare these approaches in relation to the trends described above, before we in subsequent sections analyse their meaning, or not, for risk assessment and risk management.

² The EU Baltic Sea Strategy is not included since we consider its additional value as limited.

Fig. 1 **a** The traditionally sources for hazardous chemicals (Photo: Mattias Barthel/Azote) are increasingly complemented with **b** ordinary consumer products (Photo: Tom Hermansson Snickars/Azote) causing challenges for governance

The Helsinki Convention and the Baltic Sea Action Plan

The 1974 Convention on the Protection of the Marine Environment of the Baltic Sea Area, the Helsinki Convention was the first international agreement for control of principally all sources of Baltic Sea pollution, and since then it has imposed specific obligations on the contracting parties to counteract hazardous substances (Selin and VanDeveer 2004). In the 1990s, the convention was revised (Helsinki Convention 1992) with the aim to extend, strengthen, and modernize the previous agreement by introducing more technical and specific provisions and through further actions in the field of pollution prevention and control, including chemical pollution. This time, the precautionary principle (Article 3) was included, but even though not explicitly included in the previous version, the concept was referred to in a 1988 ministerial meeting and already under the 1974 version of the convention, precautionary measures were taken, such as banning or recommending phasing-out substances not scientifically proven to cause damage (Pyhälä et al. 2007).

The implementation of the convention is carried out by a governing body, the Helsinki Commission (HELCOM), which among other tasks is charged with developing non-binding “Recommendations” for the parties of the convention. Since the beginning of the 1980s some 200 recommendations have been adopted, the first ones focusing on airborne and waterborne dispersal of DDT with derivatives and PCBs. Recommendations from 1985 and 1988 aimed to reduce emissions and discharges of mercury, cadmium, and lead. In the 1980s, 47 substances were identified to be reduced to 50% by 1995, but this proved difficult for many of them (Selin and VanDeveer 2004). In 1998, a central recommendation on hazardous substances was issued, stipulating the continuous reduction of discharges, emissions and losses of hazardous substances into the environment toward the target of their cessation by 2020, in order to reach background values for naturally occurring substances and close to zero concentrations for man-made substances (HELCOM 1998). 280 chemicals were listed as potential substances of concern to be considered by HELCOM, and 42 were then prioritized for

action, including pesticides, metals and other industrial substances, e.g., nonylphenol.

The most recent concrete outgrowth from the convention is the Baltic Sea Action Plan (BSAP, see Table 1), which explicitly underlines the need for applying an ecosystem-based approach (HELCOM 2007) and which to some extent is based on the ideas behind the MSFD. In the hazardous substances segment of the plan, four “ecological objectives” are set out, namely concentrations of hazardous substances close to natural levels, all fish safe to eat, healthy wildlife and radioactivity at pre-Chernobyl level. The BSAP prioritizes 11 of the 42 mentioned substances and sets ecosystem-based targets for these.

EU Chemicals Policy and the REACH Regulation

New chemicals were for a long time allowed to enter society without much control. When EU took stock of the situation in 1981 and registered 100 106 “existing” substances, a system for prioritized risk assessment was set up, but it covered no more than 141 substances and due to a strong burden of proof placed in the public domain, the process was never finalized for all substances (Karlsson 2010). By the end of the 1990s, EU politicians considered that policies needed development and after a contested debate, the present main piece of chemicals law, the REACH regulation, entered into force in 2007 (EC 2006).

REACH focuses on common industrial chemicals and is binding throughout the EU. A number of stipulations on registration, evaluation, authorization, and restriction of substances, and in some cases for substances in products, enter into force stepwise until 2018 (Table 2). The precautionary principle is one of the explicit fundamentals for the regulation (Article 1), but the ecosystem approach is not mentioned at all. The provisions on compulsory data registration prioritize substances produced or imported in higher volumes (above 1,000 ton per producer and importer and year), whereas low volume substances will be phased-in much later or—in cases below 1 ton per importer or producer and year—not at all (Title II). Registered data may then serve as a basis for substance evaluation (Title VI) and are to be shared among companies (Title III–V).

Table 1 Timeline for key events under the Baltic Sea Action Plan

Event	Year	Comments
The BSAP is adopted	2007	Ministerial meeting in Krakow 15/11/07
National implementation programs	2010	Also including the other segments of the BSAP
Ministerial evaluation of programs	2013	Too early to comment on
Zero emission target hazardous substances	2020	This follows previous decisions under the convention
Good environmental status	2021	As defined during the implementation

Table 2 Timeline for the development and implementation of the EU REACH regulation

Event	Year	Comment
White paper. Strategy for a future chemicals policy	2001	The basic ideas presented by the Commission
The regulation enters into force	June 2007	Including parts of evaluation and authorization
Pre-registration	Nov 2008	Pre-registration allowed for the deadlines below
Registration of high volumes and toxic substances	Dec 2010	Carcinogenic, mutagenic and reproductive toxic
Registration of medium volumes	June 2013	Data demands lower than for high volumes
Registration of lower volumes	June 2018	Thousands of substances would not still be included

Table 3 Timeline for development and implementation of the EU Water Framework Directive

Event	Year	Comment
Council conclusions, Commission communication	1995–1996	Request and principles for EU water policy
The directive enters into force	2000	The implementation rests with Member States
Set-up of river basin districts and authorities	2003	Member States responsible
Final river basin management plans	2009	Done in most Member States
Programs of measures operational	2012	Too early to evaluate
Good surface water chemical status	2015	As defined during the implementation

Under the authorization title (VIII), the European Chemicals Agency (ECHA) has placed 38 “substances of very high concern” (SVHC) on the “candidate list”, out of which seven have been recommended, but not finally decided, to go through the authorization process (ECHA 2010). SVHCs are, in short, those considered being toxic (i.e., carcinogenic, mutagenic and toxic to reproduction); persistent, bioaccumulative, and toxic (PBTs); very persistent and very bioaccumulative (vPvBs), or substances giving rise to equivalent levels of concern (Article 57). The authorization process is complicated and involves a weighing exercise in which various risks, as well as socio-economic aspects and substitution options may, depending on the case at hand, be considered. Finally, REACH also has a title on restrictions (VIII), which may be issued according to about the same standards as in previous law.

The EU Water Framework Directive

After many years of disparate regulation of water issues in the EU, often focusing on separate water environments but without reaching agreed targets (Krämer 2006), the Water Framework Directive (WFD) was developed, which step-by-step will incorporate much of previous EU water legislation (EC 2000; see Table 3). The directive ultimately aims at eliminating priority hazardous substances and achieving near background concentrations for naturally occurring substances (Recital 27) and has the purpose to prevent further deterioration as well as enhancement of the water status (Article 1). For marine areas, Article 2 explicitly refers to international agreements and set out to

achieve close to zero concentrations for man-made substances. A key concept in the directive is “good status” of various water bodies from chemical, ecological, and quantitative perspectives (Article 1, 4). The directive grasps over whole river basins, viewed as integrated systems, and assigns responsibility to Member States to assess the water status (Article 5, 8), take measures for simultaneously achieving necessary emission reductions and quality improvements (Article 4, 10, 11, 16), including adopting River basin management plans (Article 13), and to set up river basin district agencies (Article 3).

On chemical substances, the WFD (Article 16) and the related Priority Substances Directive (EC 2008a) set environmental quality standards for 33 priority substances or groups of substances, of which 13 are considered “priority hazardous substances” (e.g., PBT and vPvBs) aimed to be phased out. The latter directive also lists eight other pollutants subject to review. The priority substances were identified, and the target concentrations calculated, on basis of the scientific risk assessment procedure laid down in the technical guidance documents for chemicals,³ but Member States can define separate values, also for other specific substances, if motivated. The quality targets should be complied with by 2015 at the latest, with allowance for prolonged implementation periods under specific circumstances. The precautionary principle is mentioned twice in the WFD, both in general (Recital 11) and as a concept to

³ These Technical Guidance Documents supported chemicals risk assessment before REACH entered into force and has since been replaced with new guidelines.

take into account in the science-based assessment and identification of hazardous substances (Recital 44). The ecosystem approach to management is not explicitly mentioned in the directive, but its general meaning permeates the provisions (Petersen et al. 2009).

The Marine Strategy Framework Directive

EU has traditionally not focused its water policy on marine issues, with exception of some attention to coastal waters covered by the water pollution legislation described above. Recently, however, a general maritime policy with an environmental dimension has emerged, the latter foremost in form of the Marine Strategy Framework Directive (MSFD), which aims to achieve or maintain “good environmental status in the marine environment by the year 2020”, with allowance for a number of exemptions (EC 2008b, Article 1). The directive explicitly specifies the ecosystem approach to management (e.g., Article 1) as a basis for action, as well as the precautionary principle (Recitals 27, 44). Member States are responsible for defining “good status” on basis of criteria and methodology from the Commission, and for developing more precise and regionally adapted targets, operative indicators and monitoring programs for quality descriptors, including chemical pollution. The Baltic Sea is one of the marine regions that are specified in the directive (Article 4), and the directive underlines the need for working across borders, including linking activities to regional sea conventions (Article 5, 6), in our case the Helsinki Convention, thereby stretching the EU collaboration to Russia as well.

For each region, the Member States shall cooperate closely on developing marine strategies (Article 5), first in a preparatory stage with assessment and determination of targets and indicators in 2012, and a monitoring program in 2014, followed by a program of measures in 2015–2016, at the latest (see Table 4). The criteria for definition of good status was presented by the EU Commission in October 2010 and concerns, for the two dimensions particularly related to chemicals, references to limit values expressed in EU law, with options to modify these under special circumstances (in particular the health related parameters are more EU-universal than parameters for other dimensions of

good environmental quality, such as biological aspects which naturally varies more in the sea regions within the EU).

Informal Governance

Today, environmental management is based on much more than governmental intervention. This has been true not least in the Baltic Sea, where various types of governance initiatives increasingly have been taken the last two decades. Kern and Löffelsend (2008), for instance, have identified two types of governance beyond nation states, the EU and international regimes, namely “transnational policy networks” with various stakeholders involved, e.g., Baltic 21 by the Council of the Baltic States, and “transnational networks,” such as the Union of the Baltic Cities. Looking closer at these, however, chemicals management has hardly been in focus, and if so only related to particular issues, such as management of point sources or waste. Informal governance on chemicals is to a larger extent target for activities in companies and civil society. One example from the business sector is retailers selling textiles, who claim to work proactively to voluntarily phase out substances on, e.g., the REACH candidate list, which might end up in the Baltic Sea (Boström et al. 2010). Among environmental organizations, associations are promoting stricter policies and voluntary measures, the latter not least associated with testing of substances in various consumer products, such as nonylphenol (see e.g., SSNC 2007), with the aim to spur further measures, for example substitution in line with the so-called SIN-list of the International Chemicals Secretariat, developed in collaboration with some companies (ChemSec 2008). However, in spite of substantial efforts and results in single cases, these efforts have limited scope and are mostly effective when it comes to products close to final consumers. Consequently, informal governance of chemical risks has quite limited influence.

Comparing the Governance Approaches

Against this background, we can now start to compare the four policies (Table 5). It is obvious that the objectives and

Table 4 Timeline for development and implementation of the EU Marine Strategy Framework Directive

Event	Year	Comments
The directive enters into force	2008	Individual or groups of Member States responsible.
Criteria, methodology for good environmental status	2010	Commission decision September 1, 2010.
Determination of good environmental status	2012	Depends on contextual interpretation of the criteria.
Program of measures operative	2016	Too early to evaluate.
Good environmental status achieved	2020	As defined during the implementation.

Table 5 Comparison I of the four policies and informal governance

	Helsinki Convention	REACH	WFD	MSFD	Informal governance
Objective	For chemicals, close to zero levels for man-made substances	Balance between environment and market	Good ecological and chemicals status 2015	Good environmental status 2020	Varies depending on context
Chemical scope	Few substances	Many thousands of substances	Few substances	Few substances	Very few substances
Environmental scope	Covers the sea and most of the catchment area	Covers chemicals irrespective of setting	Stretches 12 nautical miles for chemicals	The entire marine environment	Depends on the situation
Orientation	Environment	Polluter	Environment	Environment	Both polluter and environment
Responsible actors	Convention parties, including Russia	EU, but also Member States	EU Member States	EU Member States	Nongovernmental actors, networks
Formal character	Voluntary	Directly binding	Member States operationalize	Member States operationalize	Voluntary

the chemical and environmental scope of the four policies differ substantially. The Helsinki Convention, the WFD, and the MSFD are all clearly environment-oriented, which REACH is not, and they have very high ambitions in terms of environmental quality. Furthermore, the EU policies are clearly more prescriptive and binding than the convention, in particular the REACH regulation, and they have also become more wide-reaching after the EU enlargement. Concerning Russia though, the Helsinki Convention is one of the few applicable agreements with regional relevance, which also offers a platform for broad state collaboration.

As described, and as being clear among most of our respondents, policies have developed toward ecosystem-based precautionary governance, and we will now examine in more detail how to cope with the huge burden of the past, and address the questions on how to increase knowledge and improve data and, in the subsequent section, how to manage uncertainty.

CHALLENGES FOR RISK ASSESSMENT: IMPROVING KNOWLEDGE

The combination of huge data gaps and limited resources makes it important to conduct risk assessments as efficient as possible. Consequently, strategies are commonly developed for prioritizing among assessment approaches and substances. However, the high scientific uncertainty linked to chemical risks makes these prioritized choices extra difficult and often contested.

Depending on context, risk assessments can be performed with different aims, for numerous types, sources and risks of chemicals and for various objects of protection (Jones and Gilek 2004). Assessments can be proactive, i.e., be performed before exposure based primarily on laboratory testing and modeling, or reactive, i.e., be performed

after contamination has occurred, based also on monitoring of concentrations and effects in the contaminated environment. A further division can be made between assessments that focus on single-substances and those that are site or ecosystem-specific, i.e., assessments of chemical risks (often mixtures) at a particular site or in a specific ecosystem. The scope and aims of risk assessments influence the suitability of methods and data requirements, and should therefore be based on thorough problem formulation, planning, and scoping in dialog with stakeholders (Abt et al. 2010).

Turning to the Baltic Sea, the complexities of both ecosystems and chemicals make site-specific assessments most relevant, since they allow consideration of relevant site and ecosystem-specific features. This reasoning is in line with the ecosystem approach to management (McLeod and Leslie 2009) as well as the assessment approach intended under HELCOM, WFD, and MSFD. In practice, however, many site-specific assessments have been shown to focus on chemical concentration data rather than on monitoring biological and ecological effects, developing site-specific effects thresholds to compare measured concentrations with, or assessments of mixture toxicity (Jones et al. 2006). HELCOM strives to address these problems, but lacks data and suffers from methodological problems. For example, an integrative assessment tool (CHASE) is used for various priority chemicals to yield classifications of environmental status based on comparisons between measured environmental concentrations and established threshold levels (HELCOM 2010; see Fig. 2). This focus on environmental concentrations of priority substances is quite bleak compared to the state-of-art in risk assessment of contaminated sites, which includes a “triad approach” that integrates three lines of evidence, namely chemical analysis of concentrations, ecotoxicological data, and field assessments of biological and ecological effects, the latter

Fig. 2 Integrated classification of hazardous substances in 144 assessment units in the Baltic Sea. High and good status indicate “areas not disturbed by hazardous substances”. *Large dots* represent units of the open basins, whereas *small dots* represent coastal units. (From HELCOM 2010)

being a field approach which might capture mixture effects (Jensen and Mesman 2006). In addition, concern has been raised that all available data, for example concentration data from monitoring, are not used when assessing hazardous properties (Rudén and Gilek 2010).

Under the WFD, the focus for chemicals is placed on monitoring concentrations of priority chemicals in water and sediments, and then comparing these with defined quality standards, meaning that site and ecosystem-specific effect thresholds are generally not considered in this context either. Since prioritization criteria and procedures according to some of our respondents differ from the HELCOM processes, there is a lack of harmonized methodology, obstructing a rapid assessment and exchange of results between regulatory frameworks. Even in cases where methodological guidelines have been issued, problems may remain if these guidelines are voluntary and

implementation varies, as one respondent claimed, not “everyone follows...exactly” and therefore, that depending on preparation of “the sample, fat content, and the quality of... laboratory... you can end up with totally different results”. The MSFD, on the other hand, requires a process in which Member States first are requested to determine what can be considered as a good environmental status and then establish targets, indicators, monitoring, and action plans. Although the final outcomes of this process are not yet known, the procedure seems to allow consideration of ecosystem-specific sensitivity and many of our respondents considered the MSFD to have a potential to improve Baltic Sea management of chemicals, and more fully than before incorporate the EAM.

However, looking at HELCOM as well as WFD and MSFD, the number of substances dealt with equals less than one percent of those circulating in society. The

Table 6 Comparison II of the four policies analyzed

	Helsinki Convention	REACH	WFD	MSFD
Implements EAM	Yes	No	Partly, in theory	Yes, in theory
Implements precaution	In some cases	Partly	Partly	Partly
Implementation progress	Relatively successful	Varies between provisions, slow on authorization	Not in line with objectives	Remains to be seen
May objectives be reached?	Probably not	In some parts	Probably not	Most likely not

majority of chemical risks therefore commonly fall outside the scope of site-specific assessments with the exception of a limited amount of biological effects monitoring and screening activities (HELCOM 2010). Here, the main legal framework within EU is the REACH regulation but its registration provisions only focus on single substances and mostly on generic environmental compartments such as air and water and soil. Similarly, the evaluation and authorization requirements overlook effects of exposure to chemicals mixtures (Kortenkamp et al. 2009) as well as ecosystem-specific risks, no matter if the approach is proactive (i.e., considers also new substances) or reactive (considers only existing substances). Our respondents generally viewed this as problematic, for example: “A substance by substance approach might not be the best way to deal with the problem, as one chemical might not do that much damage for the ecosystem as the mix of chemicals.”

Looking closer at single-substance assessment, REACH prioritizes substances produced and imported at higher volumes, but this might be misleading since the assumption that risks are smaller when substance volumes are lower is not generally valid—risks can be high even for low volume substances. Under REACH, however, low volume substances will be phased in very late or not at all, and when substances fall outside the registration, it is unlikely that the related REACH provisions on evaluation, authorization and restriction will be applied. A related question concerns the scientific validity of data and risk assessments from industry, which ECHA questioned by stating that quite many pre-registration dossiers had been rejected since they did not provide sufficient data, possibly due to the fact that smaller enterprises might lack the necessary expertise.⁴ ECHA also stated that it “...will get around 30000 dossiers for the high volume substances” [being] “impossible to check and verify all of them. So [ECHA has] to trust industry.”

In conclusion, neither ecosystem-specific nor single-substance assessments approaches adequately cope with the complexity at hand. Uncertainties will remain for the

foreseeable future, which leads us to the question on management under uncertainty.

CHALLENGES FOR RISK MANAGEMENT: COPING WITH UNCERTAINTY

The regulation of chemicals has, as shown, traditionally been based on a reactive single-substance approach, with the burden of proof placed on society. Without scientific consensus on assessments showing unacceptable risks, it has been difficult to restrict the use of a substance—lack of data has more or less been regarded as absence of risk (Karlsson 2005). The broadening of policies to governance based on precaution and the EAM is commonly heralded, and a majority of our respondents recognized the EAM as important and relevant, but pointed at differing interpretations and a vagueness of the concept, allowing for problems from absence of “...tools for implementing...” it, to methodological challenges, that when “...you do the monitoring you have to be very specific and to choose one factor and analyze whether it is getting better or getting worse. From this point of view it is hard to look at the whole ecosystem.” We will now consider how the policies in focus implement the EAM and the precautionary principle (see Table 6).

In the case of REACH, the precautionary principle is applied in the registration section, which places a binding burden of proof on industry to provide data. As explained, one problem here is that, e.g., thousands of low volume substances are left outside of REACH. On the other hand, inherent hazardous properties, such as PBT and vPvB, are recognized and can lead to further regulatory measures, for example authorization requirements, even though the substance in question may not necessarily be harmful. It is difficult, though, to place a substance on the candidate list, or to win support for a restrictive measure, due to the traditional strong burden of proof on society in these cases, which is one reason why the authorization has not yet started (Karlsson 2010). To conclude, unless fundamental reforms are made, it will take decades or more before REACH will prevent continued release of hazardous

⁴ This was observed in a debate at the fourth Stakeholders’ Day of the European Chemicals Agency.

substances to the Baltic Sea. A critical view was also taken by most respondents, who regarded REACH as a great leap forward, but that EU chemical law is too far from implementing the ecosystem approach. Much of this is also true for the WFD and the MSFD, since these also rely on the traditional view on risk assessment, i.e., that non-proven risks do not exist, in spite of their environment-oriented character.

Furthermore, while most respondents supported that the WFD requires assessment of water status, and not only traditional quality measurement, respondents simultaneously pointed at several problems, e.g., the inappropriateness in focusing on contamination levels in water or sediments instead of in biological objects. Similarly, some scholars have shown problems within the directive as such. On the legal side, Ekelund Entson and Gipperth (2010) have shown in a study on Scandinavian countries that the directive and, in particular, transposed provisions are so vague that authorities due to the rule of law principle⁵ are blocked from effective decision-making. This applies in particular when attempting to decide on strict measures on diffuse emission sources connected with a variety of actors in non-attainment areas. One effect of this might be slow implementation, which has also been predicted in other studies (Hering et al. 2010). On the natural science side, Moss (2008) claims that the implementation, e.g., the criteria for good status, focus more or less completely on secondary environmental features, such as contaminant concentrations, of little or no significance for the fundamental ecological qualities which the directive aims to protect. We agree with this analysis and take the view that listing concentration-based quality standards of a few priority substances will never be sufficient to guarantee a toxic-free environment, less a suitable environment for human health and biodiversity.

Concerning the MSFD, it has the most ambitious set-up of the policies studied and several respondents considered the MSFD to be able to improve the management of the Baltic Sea by more fully incorporating the EAM and by strengthening the cross-Baltic political and scientific cooperation. For example, assigning responsibility to Member States for defining targets, indicators and monitoring allows for flexibility and adaptation to specific regional situations, such as the unique properties of the Baltic Sea. However, the extent of this ecosystem-basis remains to be evaluated and criticism has been forwarded that it is problematic to assign responsibility for solution-oriented strategies to Member States when problem-causing and mitigating policies, e.g., REACH, are EU-common (Salomon 2009). What is clear at this stage, however, is

that the time schedule for implementation is very tight and that a fulfillment of the objectives by 2020 may prove unrealistic (Salomon 2009).

The Helsinki Convention, deviates from the EU policies since it for long has applied the precautionary principle for several substances assumed, but not proven, to be problematic. On the other hand, however, all HELCOM recommendations are voluntary and up to the parties to implement, which differs from the EU legislation, in particular REACH, which is binding throughout the union and thus can be expected to be better implemented. Nevertheless, in spite of all merits with the work under the convention, it seems impossible to achieve the objective of close to zero levels for man-made substances by 2020, if not for other reasons so at least due to the fact that many toxic substances already emitted will not be completely degraded by then.

Finally, since uncertainty will prevail for the foreseeable future, we consider it as problematic that communication of uncertainty seldom is given more than marginal emphasis in risk assessments. Several respondents expressed the same view, in particular in relation to non-experts, for example: “If you communicate uncertain results, people cannot understand them. People understand cancer, allergy, cost....” This is clearly an area in which improvements can be made, especially since several alternative methods for assessing various uncertainties already exist (e.g., Verdonck et al. 2007).

CONCLUSIONS

Returning to our objectives, we can see that the commonly claimed trend from government to governance is only partly valid for the case we have studied. It is true that broader policy approaches, even within the frames of legislation such as the MSFD, have emerged during the last decade, but REACH is a clear example of a recently enacted traditional command and control regulation. Considering the central position given to the ecosystem approach under the Helsinki Convention as well as the WFD and MSFD, it is also clear that policy-makers have strived to develop policies that better than previously relate to the complex risks at hand, starting from an environmental approach. Nevertheless, no policy in place is coping with more than a small share of the total chemical substances in the environment, and the assessment of risks is commonly conducted without proper considerations to the specific environmental situation at hand. Neither will any system in place generate the data required for decision-making under present law in a way that will enable environmental objectives to be met in time, if at all. As has been stated often, it is evidently urgent to accelerate the

⁵ This often constitution-based principle demands that any official use of power must be supported by law.

knowledge and data gathering processes in scientific, risk assessment, and monitoring activities. At the same time though, a more harmonized assessment methodology needs to be developed and implemented, not least for chemical mixtures, ecological effects as well as methods for integrating various lines of evidence. In doing so, regulators should demand mutual information flows between ecosystem-based assessments under HELCOM, WFD, and MSFD, and risk assessments of single chemicals under REACH.

Here, we must ask if there really is a need for command and control regulations, when broad governance incorporating the ecosystem approach to management is under development and implementation. Our answer is a definitive yes, for at least two reasons. First, the set-up of the Helsinki Convention and the WFD and MSFD will only lead to management of a limited number of substances, far from desirable in relation to the objectives in, e.g., the Helsinki Convention. Secondly, making full use of the EAM to, e.g., consider interactions between various chemicals and sectors in relation to the specific properties of the entire marine ecosystem, presumes data that simply do not exist at present and for the foreseeable future. Consequently, the theoretical idealism of EAM could increase uncertainty and exacerbate socio-political ambiguity, in turn slowing decision-making, in particular in a multi-level governance context. Without neglecting the value of implementing the EAM as far as possible, the huge uncertainties necessitate upstream measures where the REACH regulation at present is the only broad piece of policy in place. To be relevant in our case of huge uncertainty, however, REACH must be reformed in line with the precautionary principle. When data is missing, default values could be used, and unknown substances could be classified as the most hazardous known substance in the same group, or as the “worst-case” reasonably imaginable. Among the preventive measures, substitution of hazardous substances with better known and less hazardous suitable alternatives (including non-chemical options) could be a key tool. As for decision-making criteria as such, alternatives to conventional cost-benefit analysis could be applied, and the burden of proof should be placed on the polluter.

In summary, our empirical findings illustrate a general policy development trend in the Baltic Sea region in so far as traditional command and control regulation has been complemented with broader governance approaches, partly based on the EAM and the precautionary principle. We have also shown though, that this policy transition far from sufficiently transforms the production and use of hazardous chemicals, and that it therefore is unlikely that all environmental objectives will be fully met. There is still a need for command and control policies, but these should be based on a genuine implementation of the precautionary

principle in order to improve the management of uncertainty. These findings challenge the common normative quest for new forms of environment-oriented governance based on the EAM, and thus both contributes to ongoing discussions on the practical implementation of EAM as well as to theoretical discussions on environmental (risk) governance. In particular, we provide an analysis of the capacity of environmental risk governance to solve the problems connected with complex socio-environmental risks of high societal relevance not only in the Baltic Sea, but in fact for the entire planet.

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