DELIVERABLE 5.1.
STANDARD OPERATING PROCEDURE FOR THE IMPLEMENTATION OF A RISK-BASED ASSESSMENT

rages
risk-based approaches to good environmental status

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BACKGROUND TO THE RISK-BASED APPROACH

The Marine Strategy Framework Directive

The Marine Strategy Framework Directive (MSFD) (EC, 2008a) aims **to achieve or maintain the Good Environmental Status (GES)** of the marine environment by 2020. It is an environmental initiative of unprecedented scope and scale, covering all four of Europe's regional seas (North East Atlantic, Mediterranean, Baltic and Black Seas).

The MSFD follows an ecosystem-based approach to the management of human activities **to ensure that the collective pressure of such activities is kept within levels compatible with the achievement or maintenance of GES**. For that purpose, Member States (MS) must develop and implement a marine strategy for their marine waters (article 5), and review and update it every six years (article 17), through a series of 5 steps (Figure 1).

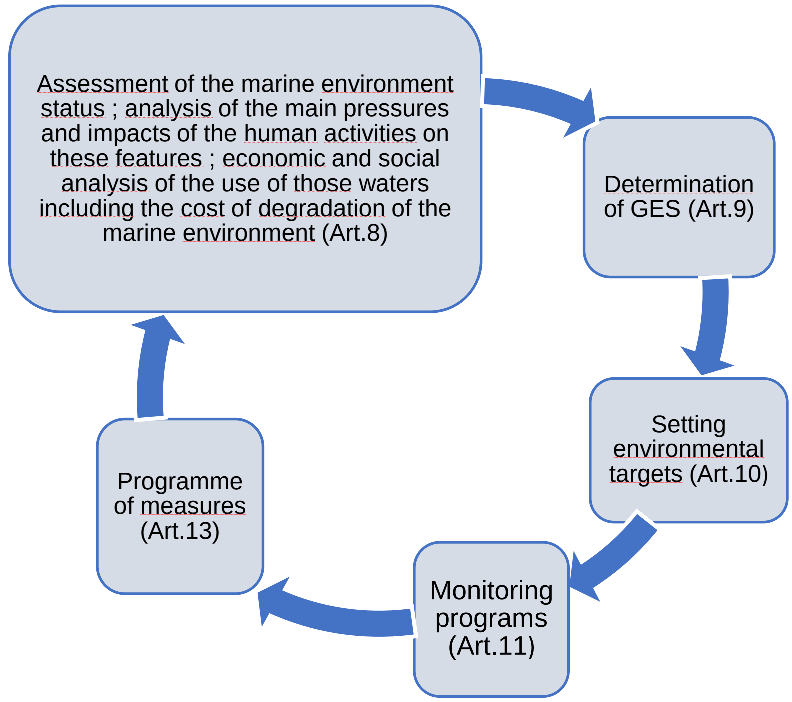

Figure 1. Five steps of the MSFD process

To consider the different features and characteristics of their marine waters, of the main impacts and pressures of the human activities that apply on those, MS must assess **11 descriptors** (Figure 2). These descriptors are either **state-related** (D1, D3, D4, D6, D7) or **pressure-related** (D2, D5, D6, D8, D9, D10 and D11), and therefore consider the relationship between the environmental status of the components of the marine ecosystem and the level of the pressures applied. However, although each step of the implementation of the MSFD is to be built on a regional and sub-regional scale, the lessons learned (DGRM, 2021) so far from the first cycle (2012-2017) and the second cycle (2018-2024) show that in many cases the lack of data and of robust GES definitions result in disparities between MS. Therefore, to ensure improved implementation and

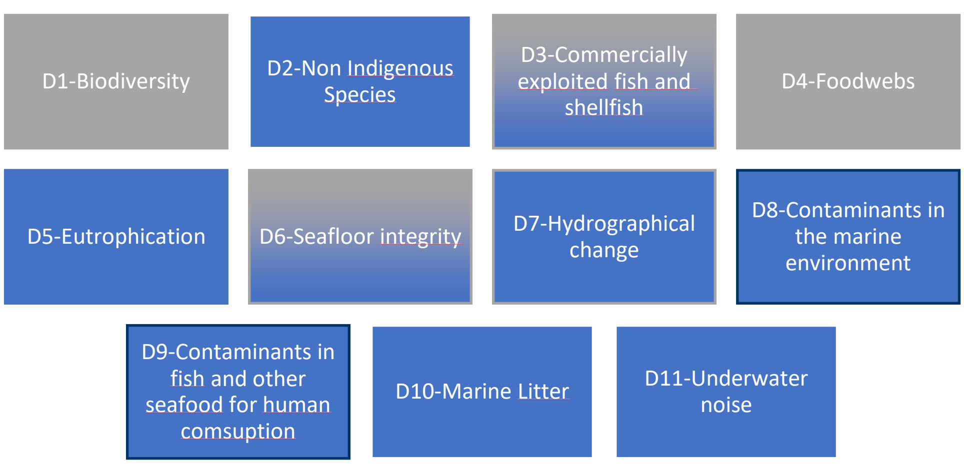

Figure 2. MSFD descriptors to be considered for the marine environment assessment *(pressure-related descriptors are in blue and state-related descriptors are in GREY)*

comparability between MS for the following MSFD cycles and to improve the link between the measures taken and the environmental status of the marine waters (pressure-state relationship), the European Commission (EC) highlighted the need **to focus on the anthropogenic pressures posing the greatest risk to the marine environment.** Focusing on the pressures and identifying the key impacts and the biodiversity components that are most threatened allows better determination of the pressure-state relationships.

Against this background of recommendations to improve the implementation of the MSFD and considering the breadth of scope of MSFD and extent of marine waters, as well as the prevailing insufficiency of data and knowledge on marine ecosystems across MS and sub(regions), adopting a common framework to assess risk in the marine environment may be the way forward (e.g., van Hoof *et* al., 2020). Furthermore, assessing risks will improve the adequacy of Monitoring Programmes (MoP) and Programmes of Measures (PMo) and therefore the likelihood of achieving or maintaining GES.

Scope of Work

The application of Risk-Based Approaches (RBA) to the MSFD implementation can potentially take many forms, it can be applied at the relatively small spatial scales of individual Marine Reporting Units (MRU), or MS Exclusive Economic Zones (EEZs) or it can be used at subregional/regional scales to support harmonisation and regional assessment. RBA may be applied to specific aspects of the MSFD assessment, for example to individual descriptors and criteria where:

- there is uncertainty regarding the relationships between specific environmental pressures, state changes and their impacts;
- where quantitative data are insufficient;
- RBA may also be used strategically as an overall basis for prioritising descriptors, exploring options and designing strategies and broader policies to achieve GES (amongst other policy objectives).

Any approach to assessing the environmental status and the environmental Impacts of human Activities and Pressures can be conceptualised as an analysis of risk. Under MSFD, the DAPSI(W)RM (Elliott et al., 2017) conceptual frame has been widely adopted as the principal conceptual basis for understanding and communicating the interconnections between human society and its effect on the marine environment. Understanding the links in the Driver Activity Pressure State Impact (as Welfare) Response (as Measures) causal chain (also called the DAPSI(W)R(M) enables us to understand how our Activities cause changes in environmental State, to assess how environmental conditions differ from the standards aspired to by the MSFD, and to identify management measures. However, our understanding of these links between Activities, Pressures and State changes is not well advanced in some cases. This has hampered the assessment of GES, and as a result the targets for some descriptors are not fully established. Under such circumstances an assessment is required but the empirical science may not yet be there to fully support quantitative assessment linking the elements of the causal chains from Activity to Impact. Our understanding of the causal links between the Descriptors and Criteria of GES is mixed. In the context of MSFD implementation, the provision for RBA developed in response to the situation in many MS where the vast scale of the marine territories and limited resource for complete coverage by MoP results in major uncertainties with regard to the state of the environment. In such cases RBA can allow for systematic consideration of GES status for all descriptors even with the existence of data gaps and high uncertainty.

Given the broad scope for potential implementation, this Standard Operating Procedure (SOP) sets out to describe and illustrate the major steps of a RBA as it can be applied to individual descriptors and criteria, in particular descriptors and criteria where in the first cycle of implementation the analysis of environmental status was considered insufficient often due to a perceived lack of relevant data. Thus, the method described is designed as a mechanism whereby MS can provide a rational basis for decision making, to meet the requirements of the MSFD, in the absence of complete information. The document is based around the steps of the International Organization for Standardization (ISO) risk management standards (ISO, 2009; ISO, 2018) and incorporates experiences from application of RBA in the frame of the RAGES project. Section 1 describes the SOP setting out the steps of the RBA and relates them to the Articles of the MSFD as well as the elements of the DAPSI(W)R(M) conceptual frame (Elliott et al., 2017). Finally, the potential for RBA to promote a more strategic impact/risk assessment cycle to overall MSFD implementation is introduced and discussed.

ISO Risk Management Process and MSFD

The main steps of the ISO risk management process are illustrated in Figure 3 together with the identification of relevant documents and articles of the MSFD which may contribute to each step. The associated elements of the DAPSI(W)R(M) causal chain are also illustrated. The ISO risk management process has five main steps, and these can be related to specific articles of the MSFD implementation and its supporting documentation (e.g., Commission Decision (EU) 2017/848 on criteria and methodological standards on GES) (EC, 2017). The context for the risk-based analysis (Step 1) is established by the requirements of the directive, the new provisions for the inclusion of RBA and the suite of descriptors and criteria provided in the EC Decision 2017/848 (EC< 2017). Elements of the initial assessment of pressure activities and ecosystem state (Article 8 a,b,c) as well as the previous assessment of GES along with the Commission's assessment of MS performances can provide inputs for Step 2. Step 3, the Risk analysis, enables the assessment of GES (article 9) through generic RBA. Having established the relative levels of risk for particular pressures and ecosystem components, the economic and social analysis (article 8c) can further inform the evaluation of risk (Step 4). The targets and specific measures selected by MS to achieve or maintain GES are incorporated into the risk treatment (Step 5).

Communication and Consultation

For the implementation of the MSFD, communication and consultation for the development of RBA should occur at two levels. At the national scale (MS) the MSFD as a framework directive brings together competencies and expertise from many different areas and may involve inputs from several different government agencies, departments or academic institutions as well as other stakeholders. Communication and consultation with such groups at the national scale can ensure that the full capacity of the MS can be brought to bear on MSFD implementation in the national context. At the international, sub-regional and regional levels, the major stakeholders are DG Environment as well as the national Competent Authorities (CA) and relevant regional seas conventions. Each of these stakeholders may contribute useful information on emerging best practices and developments in risk-based assessment which may aid MSFD competent authorities in the development of appropriate risk-based assessment methodologies at regional and national scales. The RBA should take into account existing best practices and ongoing activities within the European and regional contexts to ensure that the approaches are coherent with ongoing and planned future initiatives.

STEP 1: ESTABLISHING THE CONTEXT

External context

The EC Decision 2017/848 (EC, 2017) aims to facilitate the assessment and determination of GES in MS marine waters as well as ensure consistency across the Union in the implementation of the MSFD. To meet these objectives, the Decision distinguishes primary and secondary criteria, stating that "*the primary criteria for Good Environmental Status should be used to ensure consistency across the Union*". MS are afforded flexibility in their application of secondary criteria. As such the primary criteria represent the basis for the harmonised regional application of the MSFD. The introduction of the RBA was intended to enable MS "*to focus their efforts on the main anthropogenic pressures affecting their waters"*. The Commission Reports (Article 20) on MS implementation of MSFD provide vital context for the development of RBA. These assessments indicate the adequacy of MS performance as well as regional performance on the various aspects and descriptors of MSFD. The adequacy of MS implementation and of regional cooperation as assessed by the Commission provides the external context for the RBA. Where the Commission assessments indicate areas of inadequacy or partial adequacy, RBA may be useful to improve the adequacy of the assessment. While implementation of the MSFD is a MS competency falling to an individual CA, the directive also mandates regional cooperation (Article 6). Because MSFD MoP and PoM apply to individual MS marine waters and are generally not "joined-up" between MS, the RBA can form a useful common basis for regional assessment. The periodic review (Article 23) of the MSFD also provides important external context; while MS currently aim to maintain or achieve GES under the current directive RBA may enable them to anticipate likely future obligations including consideration of changing climate.

Internal context

The national priorities for applying RBA should be informed by the Commission assessment reports (article 20) which highlight the strengths and weaknesses of MS performance in MSFD implementation. For individual MS assessing descriptors and criteria where assessments in previous cycles of implementation were considered partially adequate or inadequate can guide the selection of descriptors and criteria to which an RBA might most usefully be applied. The varying scale of MS EEZs along with varying national capacities and differing national research and monitoring infrastructures result in the situation where data availability and levels of detail of information are highly variable between descriptors and criteria. For each MS the existing MoP and type of relevant data and information available can also inform the areas of MSFD where RBA is most appropriate. The internal context of MSFD within each MS also depends on the institutional arrangement for delivery of MSFD in that MS. Different government departments and agencies with responsibility for different aspects of delivery each have a role to play and should be involved as appropriate in the RBA.

Establishing the risk management process

Designation of a project management team**:** Although the structures are not currently in place to facilitate the creation of a Project Management Team (PMT) at a subregional or regional scale, CAs in the region should follow best management practices when considering risk management. If a PMT were to be set up in the future, members should come from diverse institutions involved in the overall delivery of MSFD and have a range of expertise. Sufficient expertise in all MSFD descriptors as well as regional knowledge should be covered to create a collective regional and technical competence. Some key roles could also be defined within the PMT, for example a Project Manager (PM) to oversee the process and a scientific coordinator to liaise with research community, address knowledge gaps and provide a long-term perspective to improve the RBA under next MSFD cycles. Research funding agencies and CAs should also communicate to prepare future research according to knowledge and scientific data gaps identified during the RBA exercise.

Best management practices**:** The PMT should apply best expert management practices in order to ensure a productive working environment and constructive discussions between experts of different fields. A common understanding of the scope of the RBA, aims and concept and should be agreed and established at an initial stage. Financial implications of establishing a working group should be considered at the outset.

Expert network identification: Further to this core team responsible for the overall scientific RBA and progress of the project, a network of specialized scientific experts should be created. These experts will work at different stages throughout the RBA, but importantly, their input is critical when "expert judgement" is used in the risk assessment. As a general indication, experts in the following fields should be considered for inclusion in the "expert group" (EG):

- Risk assessment and decision support in environmental public policy,
- All types of pressures and each type or group of receptors related to the region (in other terms, relevant MSFD Descriptors and all pressures and ecosystem components involved)
- Marine Ecosystem approaches and modelling
- Economics and Social sciences
- Experts responsible for delivering the MSFD reports of the different descriptors

Defining the risk criteria

Having established the external and internal context as well as the necessary participants in the risk management process, the specific criteria for the assessment of risk must be determined. Defining the risk criteria involves several individual choices. While the Commission Decision (EU) 2017/848 (European Commission, 2017) clearly defines the criteria elements that should be assessed, in some cases the indicators used to assess these criteria are at the discretion of MS. For example, in many cases the Commission Decision (EU) 2017/848 mandates that pressures are not at levels causing adverse effects. In defining the risk criteria, these adverse effects must be defined in terms of their **consequences** for individual ecosystem components such as species or habitats. At this stage the way in which the probabilities or **likelihood** of adverse effects are to be estimated should also be established.

Defining the risk criteria will involve identifying and prioritizing relevant datasets and information sources and choosing a methodology to combine data sets for the application in the risk assessment phase. For example, the step may involve choosing whether to use qualitative (e.g. low, medium, high) semi quantitative (suitable proxies) or quantitative data relating to activities (e.g. data on the distribution and frequency of activities) and pressures (e.g. measured or modelled data on distribution and extent of particular pressure levels) and state (e.g. measured or modelled data on the distribution of particular species or habitats) including the choices of proxies or modelled data sets. Where possible, these should be such that they enable comparison and harmonisation of results on a regional scale. The choices made when defining risk criteria will affect the remainder of the risk management process and thus require thorough consideration of multiple factors, including the spatial and temporal availability and reliability and expense of detailed data and information. When choosing the risk criteria their suitability to assess the likelihood and consequence of adverse environmental effects (see STEP 3) should be carefully considered in terms of reliability and confidence.

Box : Sensitivity Analysis to identify the most relevant receptor species

The consequence of the noise pressure for each population was quantified by adding up a list of scaled (from 0-4) criteria, so that a higher total value indicated more severe consequences of noise disturbance. The criteria used were:

1. **Conservation status.** This was based on the IUCN Red List classification, but also took into account regional directives (e.g., the EU Habitats Directive Annex II/IV) and local population assessments. **CR/EN=4, DD/VU=3, NT=2, LC=0, Under EU protection=3, Locally threatened=4**
2. **Critical/important habitats affected.** These included areas such as foraging hotspots, breeding/nursing grounds, and migration corridors, as well as areas that encompassed all or most of a species' known range. **None=0, ~one third of breeding grounds=3, More than half the feeding grounds=4**
3. **Sensitive life stage affected.** This took into account that impacts on reproduction and survival of juveniles to reproductive age will negatively affect a population's ability to recover from disturbance, thus lowering its resilience. **None=0, Neonates/Pregnant females=4**
4. **Type and severity of sensitivity to acoustic disturbance.** This criteria weighted impact by the **probability** of occurrence and the **severity** of the outcome, i.e., how commonly is that effect observed and how damaging are the consequences. . Both severity and probability are given a score between 0 and 1. Due to data deficiencies, these scores were given as 0, 0.25, 0.5, 0.75, 1 which reduced the possibility of false accuracy. The two values were then multiplied to give the overall sensitivity for that species between 0 and 1.. The following table illustrates this:

Type of impact	**Probability**	**Severity**	**Sensitivity (Prob*Severity)**
Physical (auditory)	0-1	0-1	0-1
Physical (non-auditory)	0-1	0-1	0-1
Perceptual	0-1	0-1	0-1
Behavioural	0-1	0-1	0-1
Overall sensitivity	**0-4**		

Box 1. Sensitivity analysis to identify the most relevant receptor cetacean species for Descriptor 11: Energy including Underwater Noise (Verling et al., 2021)

Analytical choices should also be made regarding how levels of risk are to be established i.e., how the likelihood and consequence of and adverse effects are to be combined. Where possible the acceptable levels of risk should also be determined. In the case where thresholds have already been established at the community scale defining acceptable levels of risk is simplified, for other descriptors and criteria no such thresholds have been established, and acceptable levels of risk must be determined based on the internal and external context.

STEP 2: RISK IDENTIFICATION

While the Commission Decision (EC) 2017/848 (EC, 2017) lays down criteria and methodological standards on GES, the Annex III of the directive broadly defines the ecosystem elements, anthropogenic pressures and human activities which must be considered; in any given case specific risks must be identified. When considering an individual pressure, we must also consider a receptor or ecosystem component on which that pressure will act. The broad scope (data sources, ecosystem components) of the enquiry is established in Step 1. The risk identification stage enables the further focusing of the problem in order to proceed to the risk analysis. In many cases the ecosystem components identified in Article 8a, b and Article 9 assessments from previous implementation cycles can make a useful starting point for the risk identification step. For example, for pressure-related descriptors a shortlist of vulnerable ecosystem components may be established through a prioritization exercise-Box 1 provides an example of a simple expert judgment procedure for D11 (underwater noise) which was used to prioritize cetacean species for further analysis about susceptibility to continuous underwater noise (see Verling et al. 2021). The exact type of process used to identify risks will vary according to the characteristics of a descriptor and the ecosystem component to be assessed. For example, the index above was used to generate a shortlist of cetacean from a long list of species know to be present in a particular area. Bartilotti et al. (2021) took a similar approach to prioritise non-indigenous species for further risk analysis. Based on an extensive literature review (by compiling data from peer-reviewed scientific papers, online databases, technical-scientific reports, as well as academic thesis, scientific reports of the Working Group on Introductions and Transfers of Marine Organisms (WGITMO) of ICES (International Council for the Exploration of the Sea) as well as other data obtained from relevant research projects) a full list of 454 species non indigenous species was obtained for the Bay of Biscay and Iberian coast and Macaronesian sub-regions. A Horizon Scanning exercise considering the likelihood of introduction, establishment and spread as well as potential adverse impacts of non-indigenous species was used to rank the species resulting in a priority subset of non-Indigenous species for more detailed analysis (see also Hollatz et al., 2021).

Developing such procedures for the ranking of risk priorities amongst a range of ecosystem components requires the development of a (semi-quantitative) scoring system. The methods for aggregation of scores and the weighing of the scoring components affect the outcome of the ranking process. Therefore, it is essential at this stage to ensure that the weighting criteria and aggregation procedures are appropriate.

STEP 3: RISK ANALYSIS

Key Concepts

The MSFD and the Commission Decision (EU) 2017/848 (EC, 2017) set out multiple objectives for GES. Broadly speaking, these all pertain to the adverse effects (State changes) on the environment caused by human Activities and their resulting Pressures (either individual or cumulative).

For an adverse effect on the marine environment to occur, there must be an exposure, the **likelihood** of an interaction between a component of the ecosystem whose condition may be used to assess the state of the ecosystem (or receptor) and an environmental Pressure (or stressor). Assessment of the adverse effect (**consequence**) on the marine environment requires knowledge on the Activities which cause the pressures, the Pressures themselves and ecosystem (State) components (information collected under MSFD Article 8b and 8a respectively). Risk is the effect of uncertainty on objectives and may be defined as the product of **likelihood** and **consequence**.

Therefore, the analysis of risk in the assessment of Environmental Status (Article 9) for an individual MSFD descriptor or criterion has two major steps: an assessment of **likelihood** and an assessment of **consequence** and these are described in more detail below.

Likelihood Analysis

The first step in a generic risk analysis involves the assessment of likelihood. The nature of this assessment will depend on the types of pressures and receptors to be analysed. In an ideal case, where for example there is real-time monitoring of a specific pressure the pressure levels at a given location can be determined (as in the wind farm example below, there is a 100% chance of a known pressure in a known location). In other cases where pressure monitoring data are not present (such as the underwater noise example) information on pressures may not be available. Depending on the nature of the Activity/Pressure relationship, maps of human activity may be useful proxies for pressure maps. In other cases, various modelling approaches may be used to assess the likelihood of a pressure in a particular location. The complexity of such modelling approaches can vary widely. For example, simple box models to highly complex mechanistic models may be used to calculate with more certainty the distribution of pressures. In order to establish whether a particular pressure may affect a particular ecosystem component, information regarding the distribution of the ecosystem component must also be considered. Just as with pressure, the level of monitoring of a particular ecosystem component determines our confidence in the estimates of distribution and/or abundance of a particular component, and modelled distribution and abundance data may be appropriate proxies for field measurements. Whatever the source of pressure and receptor data, by spatially and temporally overlaying the pressure and distribution maps of relevant components of the environmental state it is possible to identify the **likelihood of an exposure** where adverse effects may occur.

Consequence Analysis

Once areas of exposure have been identified, the second step in a generic risk analysis is the consequence analysis. In order to assess risk, it is necessary to establish the environmental consequences (adverse effects of a particular pressure). In terms of the MSFD, where threshold values for particular descriptors or criterion are already established, the consideration of consequence may be relatively simple. For example, if a particular fish stock is found to be fished at levels above Maximum Sustainable Yield (MSY), it is not in GES. Similarly, for Descriptors 8 and 9 (Contaminants) there are established dose-response relationships between the levels of pressure and the environmental and human impacts, and the consequence of a particular level of exposure can be numerically constrained. For other descriptors since quantitative thresholds have not yet been established, or the relationship between pressure and state is not well understood (e.g., the consequence for cetaceans exposed to continuous noise); there is uncertainty regarding the relationship between the pressure and its effect on the ecosystem component. Where these quantitative relationships between pressure and state are unknown, the consequence can be assessed using expert judgement approaches, based on the sensitivity of particular ecosystem components to particular Pressures. For example, Verling et al. (submitted) developed a simple questionnaire to assess the sensitivity of different cetacean species to continuous noise levels, resulting in a sensitivity index. Similarly, Bartilotti et al. (2021) combined an extensive literature review with an expert judgement approach (where information was not sufficient) to assess the socio-economic and environmental impacts or consequence of non-indigenous species based on literature review. Similar expert judgement-based approaches have been employed to the assessment of cumulative effects of multiple pressure on benthic biota (Kenny et al., 2017; Tyler-Walters et al., 2018)

Although conceptually valid at a general level, this approach of using likelihood and consequence cannot always be transformed into a mapping of risk. In some situations, the link between pressures and consequences is more complex and highly non-linear. In that case, superposition of likelihood and mapping levels of risk in a static way may be inappropriate, and other methods are used (specific models for birds collision for instance, population dynamic modelling, eco-systemic modelling, Bow-Tie methods for non-linear, uncertain and complex risk problems). Thus, while the general steps of the SOP are valid for any RBA the tools used to populate, in particular, the risk analysis steps of the process (Step 3) are many and varied.

Confidence Assessment

Uncertainty is inherent to risk assessment, and in order to ensure that a risk-based assessment can support decisions it is critical to incorporate an assessment of confidence in the risk analysis. Confidence analysis provides an assessment of the degree of certainty on the background data knowledge (concerning likelihood and consequence). As with the assessments of likelihood and consequence themselves, this may be estimated, qualitatively or quantitatively, depending on the type of data available.

STEP 4: RISK EVALUATION

The aim of risk evaluation is to arrive at a measure of **relative risk**, which can in turn inform GES assessments and enable prioritization of Measures. Following the ISO process and building on work carried out in the MISTIC SEAS II project (MISTIC SEAS II, 2019), the likelihood and consequence information can be considered together as follows:

RISK = CONSEQUENCE X LIKELIHOOD

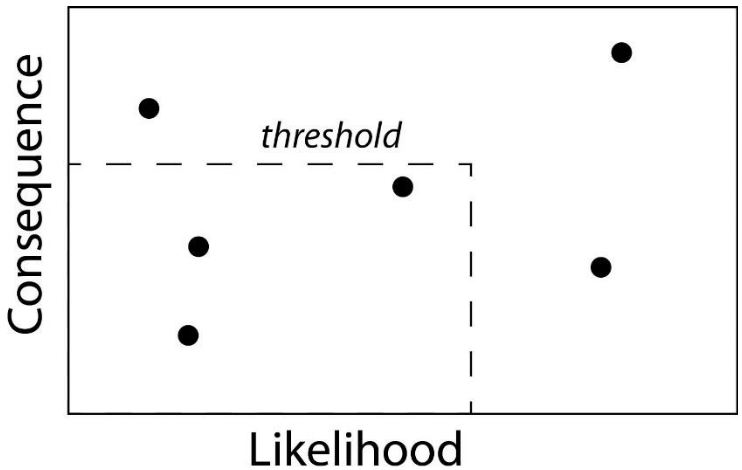

Figure 3: Generic plot of consequence and likelihood, the black dots show individual ecosystem components and the dashed line shows a hypothetical threshold.

Once both likelihood and consequence have been estimated for each ecosystem component and marine reporting unit, these can be plotted against each other to assist in risk evaluation. A generic example of the resulting plot is illustrated in Figure 3. Depending on the earlier analytical choices and data availability the likelihood and consequence scores may be qualitative, semi-quantitative or quantitative. The evaluation of risk therefore depends on the type of data used in the Risk Analysis step. Where qualitative expert judgement approaches have been employed, the likelihood and consequence plot can be generated based for example on a scoring system associated with this expert judgement.

STEP 5: RISK TREATMENT

The Risk Treatment step - as defined within the ISO standard (ISO 31000, 2018) – essentially determines the action recommended for areas or situations deemed to be "at risk". Where risks are deemed to exceed the threshold levels and confidence in the assessment is sufficiently high, the treatment of risk may come in the form of measures. Such measures may be directed at specific Activities through input and output controls, at Pressures or at ecosystems. In some cases (for example D3, commercial fisheries) the consequences can be ultimately connected back to economic consequences and their evaluation can be used to assess the costs and benefits of a particular measure.

POTENTIAL APPLICATION OF THE RISK-BASED APPROACH

The task of RAGES was to explore and develop robust risk-based solutions to assist CAs when implementing MSFD under conditions of limited data and/or extensive marine areas. This RBA represents a repeatable and transparent method that CAs can follow to assess the risk of impacts to ecosystem elements for implementation of the Directive even when full quantitative information and empirical data regarding the pathways between Activities, Pressures and Impacts are lacking. The focus of our analysis was on developing practical solutions to problems of uncertainty in the interactions between activities pressures and the assessment of environmental state. While RBA can be applied in many ways to the implement MSFD; holistic RBA such as Environmental Impact Risk Assessment can provide an overarching strategic risk-based framework for implementation and RBA can be applied to assess the effectiveness of controls and measures. For example, Cormier et al. (2017) used hypothetical examples to illustrate how the "Bow-Tie" methodology could be applied to each of the MSFD descriptors. The method illustrated here and in RAGES Deliverable 2.3 (RAGES, 2021) was designed to meet the practical challenges faced by some MS for some descriptors. The application focussed on meeting the immediate requirements for the implementation of the directive in descriptors where uncertainty along the causal chain from Activity to Impact, combined with limited empirical data, constrained ability of MS to make quantitative assessment of GES.

Consider for example, the case of offshore wind farm construction (Activity), where one Pressure may be the complete removal of the benthic substrate. In this case there is 100% **likelihood** that a known area of substrate will be removed, which is relevant to descriptor 6 (seafloor integrity) and descriptor 1 (biodiversity). The environmental **consequence** of this activity and pressure depends on the habitats and associated communities present on the substrate that will be removed. If the substrate contains ecologically significant habitats (e.g., those designated under the habitats directive) there may be significant consequence for environmental status and this consequence can be relatively easily expressed on an areal basis. In this example there is known likelihood (100%) of a known impact or consequence (removal of a specific area of habitat type) and a RBA is not necessary to determine this.

In other cases, however, where quantitative information relating the elements of the causal chain from Activities to Impacts are lacking, this is where the RBA described above might most usefully be applied. For example, maritime transport (and other maritime activities) introduce the pressure of continuous underwater noise to the marine environment (D11C2), and this may have adverse effects on cetacean populations since they are dependent on sound for communication and for hunting. While we understand that there is causal chain between the noise produced by a vessel's engine and the underwater soundscape, there is uncertainty about the exact sound pressure level emitted by an individual vessel (the link between the activity and pressure, which varies depending on vessel size, construction, and operation) and thus uncertainty around the **likelihood** of an impact. In addition, the presence of multiple vessels and the propagation of noise underwater means that the soundscape in an individual location is the complex product of multiple activities and environmental parameters. In this case there is a great degree of uncertainty as to the nature of the pressure. Furthermore, since the effect of the pressure on the receptor is also related to the relative position in space and time, and there is limited information on the ecological consequences of the pressures to particular receptor species, the **consequence** of a disturbed soundscape on the survival, behaviour fitness on individual species of cetacean populations is subject to a high degree of uncertainty. Qualitative or semi-quantitative approaches to assessing likelihood and consequence may be appropriate in the absence of more robust quantitative evidence.

Even within the limited scope of the RAGES project, differing levels of information and data between MS led to differences in the risk-based analytical approaches that were feasible, for example, the existence of modelled noise datasets in different geographic regions. These differences are also reflected in strengths and weaknesses identified by the Commission in different elements of implementation for different MS. Therefore, it is impossible to provide a complete picture of the exact circumstance under which the approach described above may be most useful. Nevertheless, given the common obligations under the MSFD and the common history of development of EU environmental legislation it is possible to draw some general guidelines on the descriptors and criteria, to which the approach described above may be most applicable.

In addition to distinguishing between pressure and state-related criteria, Commission Decision (EU) 2017/848 distinguishes between primary criteria (those which must be assessed) and secondary criteria, those used "*to complement a primary criterion or when, for a particular criterion, the marine environment is at risk of not achieving or not maintaining good environmental status*". As such the primary criteria represent the basis for the harmonised regional application of the MSFD and in total there are 10 primary criteria for State-related descriptors, and 17 primary criteria for Pressure-related descriptors. Most of the criteria for the primary state-related descriptors (D1C2, D1C3, D1C6, D6C4, D6C5, D4C1 and D4C2)[*] refer to "anthropogenic pressures" rather than individual pressure-state interactions. As such, rather than

*The 3 criteria for state-related descriptors which do not require consideration of cumulative effects are D1C1, which requires the measurement of incidental by-catch in commercial fisheries (which has associated established prodcedures. D1C4 and D1C5 which relate to the distribution and extent of species and habitats respectively, these criteria do not consider the interaction between pressure and state and have implications for monitoring rather than the application of the risk-based approaches described here.

the single pressure-state interaction methodologies applied here, these require assessment of cumulative pressures on ecosystems. While risk-based “linkage framework” approaches to the assessment of multiple interacting activities pressures and state changes, relevant to these primary state-related descriptors with multiple interacting pressures have also been developed (Knights et al., 2013; Borgwardt et al., 2019), they have not yet been commonly applied in implementation of MSFD. As such the RBA described above which considers the links between exposure to individual pressures and their consequences in terms of GES is best suited to the analysis of pressure-based descriptors.

<u>Pressure-related descriptors</u>

In theory, the RBA is applicable to any of the eleven MSFD descriptors, but some of these already have well-developed targets and indicators that are supported by scientific research over many years and therefore it may not be necessary to use a RBA. For certain primary pressure criteria, relationships between Activities, Pressures and State changes are easily understood and already well constrained, this is particularly true where there is relatively long history of management under existing legislation. For example, Descriptor 8 (Contaminants) and Descriptor 9 (Contaminants in Seafood) perhaps best illustrate the classic causal chain where the links between Activities and Pressures and the resulting environmental Impacts are well understood. The causes and consequences of contamination, adverse human and environmental effects are well established and reflected in European Law (European Commission, 2008b). Essentially the risk analysis component has already been conducted and the resulting thresholds for acceptable levels have already been formalised, such that the burden for Member States under MSFD is one of compliance rather than of risk analysis. A similar situation exists for Descriptor 3 (commercial fish and shellfish). The economic importance of sustainable fish stocks, and the potential for overfishing has been the subject of scientific enquiry for almost two centuries (Jones et al., 2016) and the development of fisheries science is such that the technical capacity and expertise have been developed to quantitively link the levels of fishing pressure (and mortality) to the environmental state (in terms of spawning stock biomass) and species age and size distribution. In this case, the adverse environmental consequences (collapse of fish stocks) as well as their human (economic) consequences are clear and well understood. As with the contaminants descriptors there are established methods, as well as scientific and institutional processes to assess the levels of risk. The challenge for MS is one of compliance rather than evidence gathering and specific RBA have been developed in cases where uncertainty prevails (e.g. Dankel et al, 2020). For Descriptor 5 (Eutrophication), MS’s experiences with implementation of the Water Framework Directive (WFD) (EC, 2000) as well as with the OSPAR convention have meant that the problem of eutrophication is well defined and that the thresholds for the Pressures (Nutrient concentrations, criterion D5C1) causing “undesirable disturbances” to the environmental State (criteria: D5C2, Chlorophyll, and D5C3, Oxygen) are already well established in terms of quantitative limits for different coastal regions around Europe (e.g. Lefebvre et al., 2020). Under the WFD, in cases where monitoring data are scarce, RBA have been used to identify and prioritise areas where measures may be most effectively targeted (le Moal et al, 2019). The introduction of MSFD has led to a geographical extension of obligations under WFD rather than a requirement to develop new scientific competences expertise and capacity.

Table 2 highlights the Primary Pressure Criteria and shows which of these might lend themselves best to a Risk-based Approach.

Table 2: List of primary MSFD pressure Criteria and their applicability to the RAGES RBA

No	Criteria	Description	Suitability of RBA	Examples of Existing Approaches
2	D2C1	The number of non-indigenous species which are newly introduced via human activity into the wild, per assessment period.	Yes-tested as part of RAGES project	
3	D3C1	Fishing mortality rate of populations of commercially-exploited species is at or below levels which can produce MSY.	Not required, well-developed knowledge, thresholds, processes	• Target fishing mortality have been established in many cases • (MSY established for commercial species
	D3C2	The Spawning Stock Biomass of populations of commercially-exploited species are above biomass levels capable of producing MSY	Not required, well-developed knowledge, thresholds, processes	• Thresholds have been established in many cases • Spawning Stock Biomass (SSB) has been established for commercial species
	D3C3	The age and size distribution of individuals in the populations of commercially-exploited species is indicative of a healthy population. This shall include a high proportion of old/large individuals and limited adverse effects of exploitation on genetic diversity	Uncertain, well-developed knowledge, thresholds and processes though there is a lack of data for some species	• Indicators have been created for size and age population structure
5	D5C1	Nutrient concentrations are not at levels that indicate adverse eutrophication effects.	Not required, well-developed knowledge, thresholds, processes	• Environmental Quality Standards have been specified in WFD • Concentration of nutrients in can be assessed
	D5C2	Chlorophyll a concentrations are not at levels that indicate adverse effects of nutrient enrichment.	Not required, well-developed knowledge, thresholds, processes	• Thresholds have been established • Chlorophyll concentration can be assessed • Environmental Quality Standards specified in WFD
	D5C5	The concentration of dissolved oxygen is not reduced, due to nutrient enrichment, to levels that indicate adverse effects on benthic habitats or other eutrophication effects.	Not required, well-developed knowledge, thresholds, processes	• Concentration of dissolved oxygen can be assessed • Environmental Quality Standards have been specified in WFD
6*	D6C1	Spatial extent and distribution of physical loss (permanent change) of the natural seabed	May be applicable	• Development of indicators still underway in many cases
	D6C2	Spatial extent and distribution of physical disturbance pressures on the seabed.	May be applicable	• Development of indicators still underway in many cases
	D6C3	Spatial extent of each habitat type which is adversely affected, through change in its biotic and abiotic structure and its functions by physical disturbance.	May be applicable	• Development of indicators still underway in many cases
8	D8C1	Within coastal and territorial waters, the concentrations of contaminants do not exceed the following threshold values	Uncertain, well-developed knowledge, thresholds and processes, however there may be RBA applications for a selection of species at regional or national level	• Thresholds for contaminants have been established • Concentration of contaminants in marine compartments can be assessed
	D8C3	The spatial extent and duration of significant acute pollution events are minimised.	May be applicable	
9	D9C1	The level of contaminants in edible tissues (muscle, liver, roe, flesh or other soft parts, as appropriate) of seafood (including fish, crustaceans, molluscs, echinoderms, seaweed and other marine plants) caught or harvested in the wild (excluding fin-fish from mariculture) does not exceed:	Not required, well-developed knowledge, thresholds, processes	• Compliance of contaminant concentrations in fish and shellfish destined for human consumption with regulatory limits set in regulation (EC) 1881/2006 • Concentrations of contaminants in fish and shellfish destined for human consumption can be established
10	D10C1	The composition, amount and spatial distribution of litter on the coastline, in the surface layer of the water column, and on the seabed, are at levels that do not cause harm to the coastal and marine environment.	May be applicable	• The need to understand the consequence fully has been bypassed in favour of proposing a percentile-based threshold at an EU level
	D10C2	The composition, amount and spatial distribution of micro-litter on the coastline, in the surface layer of the water column, and in seabed sediment, are at levels that do not cause harm to the coastal and marine environment.	May be applicable	
11	D11C1	The spatial distribution, temporal extent, and levels of anthropogenic impulsive sound sources do not exceed levels that adversely affect populations of marine animals.	Yes-tested as part of RAGES project	Impulsive Noise Indicator under development within OSPAR and EC Technical groups
	D11C2	The spatial distribution, temporal extent and levels of anthropogenic continuous low-frequency sound do not exceed levels that adversely affect populations of marine animals.	Yes-tested as part of RAGES project	Continuous Noise Indicator under development within OSPAR and EC Technical groups

* These are primary criteria for the overall assessment of Descriptor 6, together with that for benthic habitats (under Descriptor 1)

Within the scope of the RAGES project there has also been considerable progress on adapting the RBA for consideration of Descriptor 6 (Seafloor Integrity) and the following section provides an overview of this work. D6 is comprised of five primary criteria, Criteria D6C1, D6C2 and D6C3 relate only to the pressures 'physical loss' and 'physical disturbance' and their impacts, whilst criteria D6C4 and D6C5 address the overall assessment of Descriptor 6, together with that for benthic habitats under Descriptor 1.

Descriptor 6: Seafloor Integrity

The RAGES Project undertook some more detailed work on Descriptor 6: Seafloor integrity, for which there are five primary criteria, three of which are primary pressure criteria for assessment:

- the spatial extent and distribution of physical loss (D6C1)
- disturbance of the seabed (D6C2) and
- spatial extent of the habitat types adversely affected by physical disturbance (D6.C3)

Criteria D6C4 and D6C5 address the overall assessment of Descriptor 6, together with that for benthic habitats under Descriptor 1 (see footnote on page 57 of the Commission Decision 2017/848 and methodological standards for D6C4 and D6C5, page 70). In addition, the outcomes of D6C1 can be used to assess D6C4 and D7C1 and the outcomes of D6C3 can be used to assess D6C5.

In the case of seafloor integrity, D6C1 and D6C2 require relatively simple information relating Activities to Pressures in order to map the extent (C1) and distribution (C2) of loss and disturbance of seafloor. However, assessing the adverse effects to habitats (D6C3) caused by physical disturbance requires further information relating the Pressure to the environmental State change (environmental Impact). This requires knowledge of the ecological components making up the habitat type and their tolerance to disturbance and in many cases empirical evidence for these tolerances is lacking.

Considerable work has been conducted on the assessment of pressures under the auspices of ICES, including workshops on the physical loss (ICES, 2019) and physical disturbance (ICES, 2018). The approach to seafloor integrity outlined by ICES is described here and the steps of the analysis are aligned with the ISO risk-based framework.

Risk Identification-ICES have identified the major Activities associated with seabed loss and disturbance as a) fisheries, (b) aggregate extraction of minerals, (c) dredging and depositing of materials, (d) shipping and anchoring and (e) physical restructuring (Coastal defence). Table 1 illustrates these activities and the main types of seabed disturbance associated with them.

Table 1. Activities associated with different types of seabed loss and disturbance as defined by ICES

Pressure	Pressure subtype	Main human activities
Disturbance/ Loss (Unsealed)	Abrasion	Fishing with mobile bottom-contacting gears
	Removal	Aggregate extraction (removal of sediment for use elsewhere) and dredging (removal of sediment to clear/maintain area)
Disturbance	Deposition	Dredge disposal and fishing with mobile bottom-contacting gears
Loss (sealed)	Sealing	Placement of permanent structures during a variety of activities (e.g. oil and gas extraction, renewable energy harbors and coastal defense, tourism/recreation, pipelines and cables, wrecks, artificial reefs)

Risk Analysis (Exposure): Exposure of benthic habitats to abrasion pressures (D6C1, D6C2) can be conducted by overlaying maps of individual pressures (identified above) with habitat maps for the region. For the North East Atlantic the spatial extent of abrasion pressures from fishing is already well constrained. Regional data on bottom fishing intensity has been collated through OSPAR (OSPAR 2017) for much of the MSFD region and the process for the compilation and analysis of the data has already been standardised, with the Swept Area Ratio (the number of times a particular area experiences abrasion in a year) being the unit of pressure. For the other relevant pressures, disturbance or removal is associated with activities that occur on more discrete spatial scales. For example, removal of seabed substrate (sediment) is mainly controlled by aggregate extraction (suction-trailer dredger) and this is generally confined to licensed areas with known extents. In such cases the information from EMS and AIS, depending on the country, are used to deduce the footprint of the aggregate extraction. Permitted extraction areas should be delivered as polygon layers, enabling subtraction of the areas of extraction. A similar situation exists for physical loss, where Activities such as renewable energy development are spatially constrained, and areas to be lost can be accurately mapped.

For the criteria D6C1 and D6C2, which require maps of the spatial extent and distribution of disturbance, simple overlays of pressure and habitat type can provide accurate assessments of Pressures (the likelihood of a disturbance). However, the assessment of adverse effects (D6C3) and the relationship between Pressure and environmental State change requires additional information to assess the consequences (State changes) caused by the mapped Pressures.

Risk Analysis (Consequence): Linking pressure and impact involves the assessment of sensitivity of the benthic components to disturbance in order to assess the consequence of the exposure (mapped by D6C1 and D6C2). Detailed Population Dynamics (PD) models have been used to assess the impact of abrasion and applied successfully in the North Sea. However, the empirical data on the composition and the of benthic fauna in many areas including the Bay of Biscay and Celtic Seas are not currently sufficient to parameterise the PD model for application in these areas and since the Activities and Pressures have already affected these areas, the collection of empirical "baseline" data is problematic. In developing a RBA, alternative expert judgement approaches can be a useful alternative to empirical modelling at the regional scale. Several authors (Kenny et al., 2017; Tyler-Walters et al., 2018) have used expert judgement approaches in this context. Regional harmonisation of D6C3, will require an agreed approach to the assessment of sensitivity at the regional scale whether this involves the collection of further empirical data through monitoring or through the development of a broadly applicable, and regionally agreed sensitivity assessment based on expert judgement. As mentioned above, for D6C4 and D6C5 the additional burden of considering multiple pressures simultaneously remains a challenge.

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