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Applying risk-based approaches to implementation of the Marine Strategy Framework Directive in the North-East Atlantic: Learning lessons and moving forward

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ABSTRACT

Risk-based Approaches (RBA) are increasingly playing an explicit and important role in a number of environmental regulations across Europe and globally. In this paper, we summarise a generic RBA developed for the Marine Strategy Framework Directive (MSFD) and its application to two descriptors of Good Environmental Status (GES) for marine waters, Non-Indigenous Species and Underwater Energy and Noise (Descriptors 2 and 11). We provide an overview of the findings and outcomes emerging from the application, which focus on identifying common advantages as well as common challenges encountered in the application of the RBA. Recommendations are then made, aimed at identifying potential solutions to the common problems, particularly in relation to data and expert-judgement approaches. Further recommendations address the development of governance structures to facilitate the uptake of risk-based approaches at the level of the MSFD common implementation strategy. Finally, some general and specific recommendations are made to effectively embed RBA and enhance regional cooperation for future implementation of the MSFD.

1. Introduction: the case for a risk-based approach

The European Union's Marine Strategy Framework Directive (MSFD) [12] aims to achieve or maintain the Good Environmental Status (GES) of the marine environment. The directive operates on a six-year cycle mandating that European Member States (MSs) first perform an initial assessment of the state of their marine waters, establish targets and respective indicators, establish monitoring programmes, identify programmes of measures (marine strategies) and subsequently implement these measures. The directive specifies 11 descriptors of Good Environmental Status (GES) which bring together obligations under previously existing legislation (e.g., the Water Framework Directive and Habitats Directive and the Common Fisheries Policy) as well as introducing a suite of relatively new environmental considerations (non-indigenous species, hydrographic changes, marine litter, energy and noise). The types of information required to assess these descriptors are further set out in a series of criteria [14]. The MSFD is an environmental initiative of unprecedented scope and scale, covering all five of Europe's regional seas (North-East Atlantic (NEA), the North Sea, Mediterranean, Baltic and Black Seas) and covering human pressures from fisheries, non-indigenous species, eutrophication, underwater energy and noise, marine litter and contaminants in seafood and in the marine environment as well as requiring assessment of the state of the environment including benthic and pelagic biodiversity as well as food web structure, seafloor integrity and hydrographic conditions. In addition, the directive requires that these assessments be made not only within national maritime territories, but also on the scale of regional seas. Regional assessment for the MSFD requires international

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collaboration. The directive also advocates for the use of the Ecosystem Based Approach which is considered synonymous with Ecosystem Based Management (EBM) [15]. Ideally such an approach can enable the balancing of human activities with conservation actions by explicit consideration of ecosystem services and quantification of negative environmental externalities [30].

From the commission's assessment of the first cycle of implementation of the MSFD, it is clear that this ambitious scope and scale have proved a major challenge for MSs, [18,11]. In particular, the geographic differences between EU MS's maritime territories result in varying levels of difficulty in implementation. While some MSs (particularly those in the North Atlantic) have vast maritime territories where there are relatively few pressures and where the scale of the territories precludes full coverage of intensive sampling, other MS have relatively small maritime territories where pressures may be more intense, but sampling and assessment are more manageable. The size of EU MS's territorial waters ranges from approximately 200 km^2 in Slovenia to 1.7million km^2 in Portugal. In addition, in some locations where formal measurement, monitoring and management structures have been in place for over a century (e.g., the North Sea) there is a strong legacy of institutional capacity and regional cooperation, while other MS's management structures have come into existence far more recently. Moreover, while the directive mandates regional cooperation, the institutional structures to carry out this regional and subregional cooperation are not formally defined, leading to institutional ambiguity [40]; van Tatenhove., 2013). In practice MSs have largely relied for the regional component of MSFD implementation on the structure of the Regional Seas Conventions. In recognition of the challenge posed to different MSs by the implementation of the MSFD over varying spatial scales and under different conditions of legacy and capacity, the provision for a RBA [14] was incorporated to "enable MSs to focus their efforts on the main anthropogenic pressures affecting their waters". RBAs may also serve to facilitate improved coherence, harmonization and indeed cooperation in the implementation across MSs at the regional scale, by providing a robust method that can be applied consistently. A review of the MSFD is scheduled for 2023, providing an opportunity to develop more efficient and effective implementation. This review comes in the context not only of the difficulties experienced in the initial cycles of MSFD implementation but also of emerging European environmental policy initiatives. The Green Deal [17] provides for an increased focus on environmental protection for sequestration of Carbon as well as the rapid development of offshore renewable energies while the EU Biodiversity Strategy [19] aims to achieve 30% protected area coverage in European marine waters by 2030. Effective delivery of these emerging objectives will require improved ability to efficiently and effectively manage marine environments.

Under MSFD, the DAPSI(W)RM **D**river **A**ctivity **P**ressure **S**tate **I**mpact (as **W**elfare) **R**esponse (as **M**easures) [9] 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. The DAPSI(W)R(M) and its predecessors, for example the DPSWR (Cooper et al., 2013) are themselves based on an understanding of the links in the. This causal chain enables us to understand how our Activities and their resulting Pressures cause environmental State changes, how these changes affect human Welfare (in terms of Ecosystem Services), how environmental conditions differ from the standards aspired to by the MSFD and finally how to identify management Measures to improve environmental status.

For some descriptors there are well-established procedures for monitoring, assessment and setting thresholds within the context of EU law. For example, the assessment of Descriptor 5 - Eutrophication is informed by the implementation of the Water Framework Directive (WFD; [16] for areas specified by that directive and MS have long experience with its assessment and monitoring since its inception in 2000. Similarly, for Descriptor 3 - Commercial Fish and Shellfish there are long established procedures and processes for the assessment of commercial fish stocks and the Descriptor is supported by a wealth of research as a result of the implementation of the Common Fisheries Policy. However, for other descriptors the causal links between Pressures, environmental State change and adverse effects are less well understood. For example, Descriptors 10 (Marine Litter) (see [20] and 11 (Underwater Energy and Noise) (see [41] are relatively novel and have not been the subject of the same volume of research and standardized assessment procedures as those that already have a long-established legislative basis. This has hampered the assessment of GES [18] and as a result for some descriptors the targets are not fully established. Under such circumstances, while an assessment is required under the directive the empirical science may not yet be there to fully support quantitative assessment linking the elements of the causal chains from Activity to Impact. In the context of the MSFD, the provision for RBA [14] has developed because in many MSs the vast scale of the marine territories and limited resources for Monitoring Programmes to cover all descriptors over the entire management areas result in major uncertainties with regard to the state of the environment. In such cases RBA can allow for systematic consideration of GES for all descriptors even where there are data gaps and high uncertainty. However, since the provision for a RBA is relatively recent there are not many examples of precedents for MSs to follow in implementation for MSFD.

Any approach to assessing the environmental status and the environmental Impacts of human Activities and Pressures can be conceptualised as an analysis of risk. Several RBAs have been developed to enable EU MSFD implementation following the DAPSI(W)R(M) or similar conceptual frameworks (e.g [27,35]). Many of these causal chain analyses have used expert judgment approaches to identify the full suite of environmental pressures and state changes that occur from human activities within a particular ecosystem, attempting to compare the levels of risk between systems (e.g., [4,37]). However, the complexity of the outputs along with the reliance on expert judgement approaches (without a fully documented process) result in the case where the outputs are rarely (if ever) sufficiently robust to support real-world policy decisions and few (if any) have been applied in real world to MSFD implementation. Another approach to RBA has focused on standardization [7]. The authors developed a simple schema for each MSFD descriptor relating the human activities to pressures and measures using the bow-tie approach. While this last study illustrates the conceptual basis by which this particular form of RBA might apply to MSFD, it assumes that the empirical data are available to populate the elements of the causal chain. In reality, the incorporation of the RBA into MSFD was designed to enable MSs to make rational, process-based decisions, where there are high levels of uncertainty regarding pressures, states and their interactions (due to geographical scales or lack of empirical data). Kenny et al. [25] described a pragmatic approach to RBA to assess cumulative impacts on benthic habitats (MSFD Descriptor 6), using empirical and modelled data to assess exposure and expert judgement to assess sensitivity.

This work was the result of a collaboration across four North-East Atlantic EU Member States with large maritime territories (Ireland, France Spain and Portugal). National competent authorities responsible for implementation of the Directive sought to develop and demonstrate a standard approach to apply a RBA in MSFD implementation with a specific focus on descriptors and regions where assessments are required, yet empirical data are lacking. These authorities were the Department of Housing, Local Government and Heritage (DHLGH) in Ireland, Direç ão-Geral de Recursos Naturais, Segurança e Serviços Marítimos (DGRM) in Portugal, Minstière de la Transition Écologique et Solidaire (MTES) in France and Dirección General de Sostenibilidad de la Costa y del Mar- Subdirección General para la Protección del Mar (DGSCM-SGPM) in Spain.

This paper first briefly describes a generic RBA developed as part of the RAGES project. Common steps are outlined in the parallel application of the approach to two different MSFD pressure descriptors (Descriptor 2, Non-indigenous species, and Descriptor 11, Energy and

Noise). Finally, common advantages and challenges in the application are identified and some general conclusions are drawn regarding further application of the RBA and its role in the future development of the MSFD.

2. Workflow and methodology

The overall workflow for development of the operational methodology is illustrated in Fig. 1. The first task involved a review of literature including overall risk management frameworks as well as examples of proposed methods for application of RBA to various descriptors of the MSFD, including harmonization of the ecosystem management framework mentioned above (DAPSI(W)R(M), see [9] with the Risk Assessment standards created by the ISO and the articles of the MSFD (RAGES, 2020). Box 1 illustrates the standardized risk process harmonizing the articles of the MSFD with the steps of the ISO-Risk management process and the elements of the DAPSI(W)R(M). This risk-based methodology sets out a series of steps, which can act as a standard basis for the application of the RBA under MSFD, both nationally and regionally. It was drawn up in collaboration with MSFD competent authorities responsible for the MSFD implementation at national level, and while the MSFD does place specific obligations to assess Ecosystem Services (the W in DAPSI(W)R(M), the risk analysis phases focused on environmental (rather than Welfare) Impacts.

The aim of developing the approach was to set out a standard methodology and a common framework for RBA to enable MSs to reach their obligations under MSFD and the European Commission to fairly assess MSFD implementation efforts across MSs while recognizing that the levels of data and information vary across MSs and descriptors.

The second task involved application of the proposed risk management process to descriptors 2 and 11. This task involved identification and collation of relevant datasets and development of approaches to use these data to apply risk analysis to the criteria selected for each descriptor through a process of trial and error. This process is detailed in a series of reports for D2 [3,1,2,23] and for D11 [41,42,43]. In this task the first 3 steps (establishing the context, risk identification and risk analysis) of the RBA were attempted. The Risk Evaluation and Risk Treatment are national competencies for individual MSs and are beyond the scope of a research project. Finally, the common experiences, both positive and negative in applying the RBA were identified and these were used to develop a series of recommendations for further efforts to embed RBAs formally into the MSFD common implementation strategy.

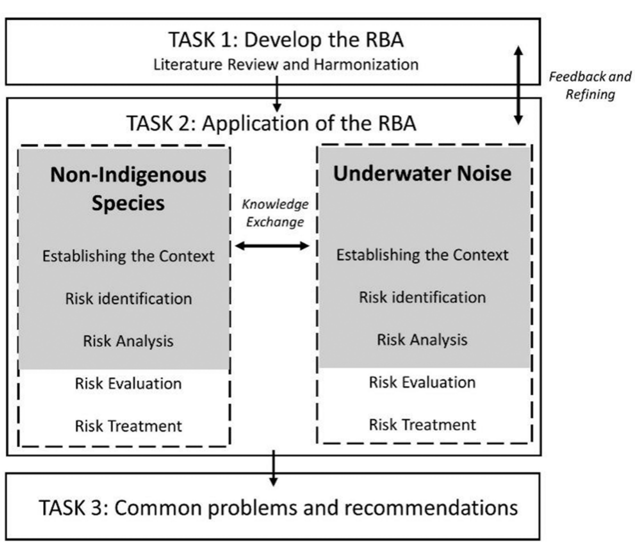


Fig. 1. Workflow for the design and application of the RBA. Grey areas indicate the part of the Risk Management process that was applied in parallel to the two descriptors as part of the project.

The following section describes how the standardized process developed was ultimately applied to each of the relevant data sources for each of the two Descriptors.

3. Applying the risk-based approach for MSFD descriptors 2 and 11

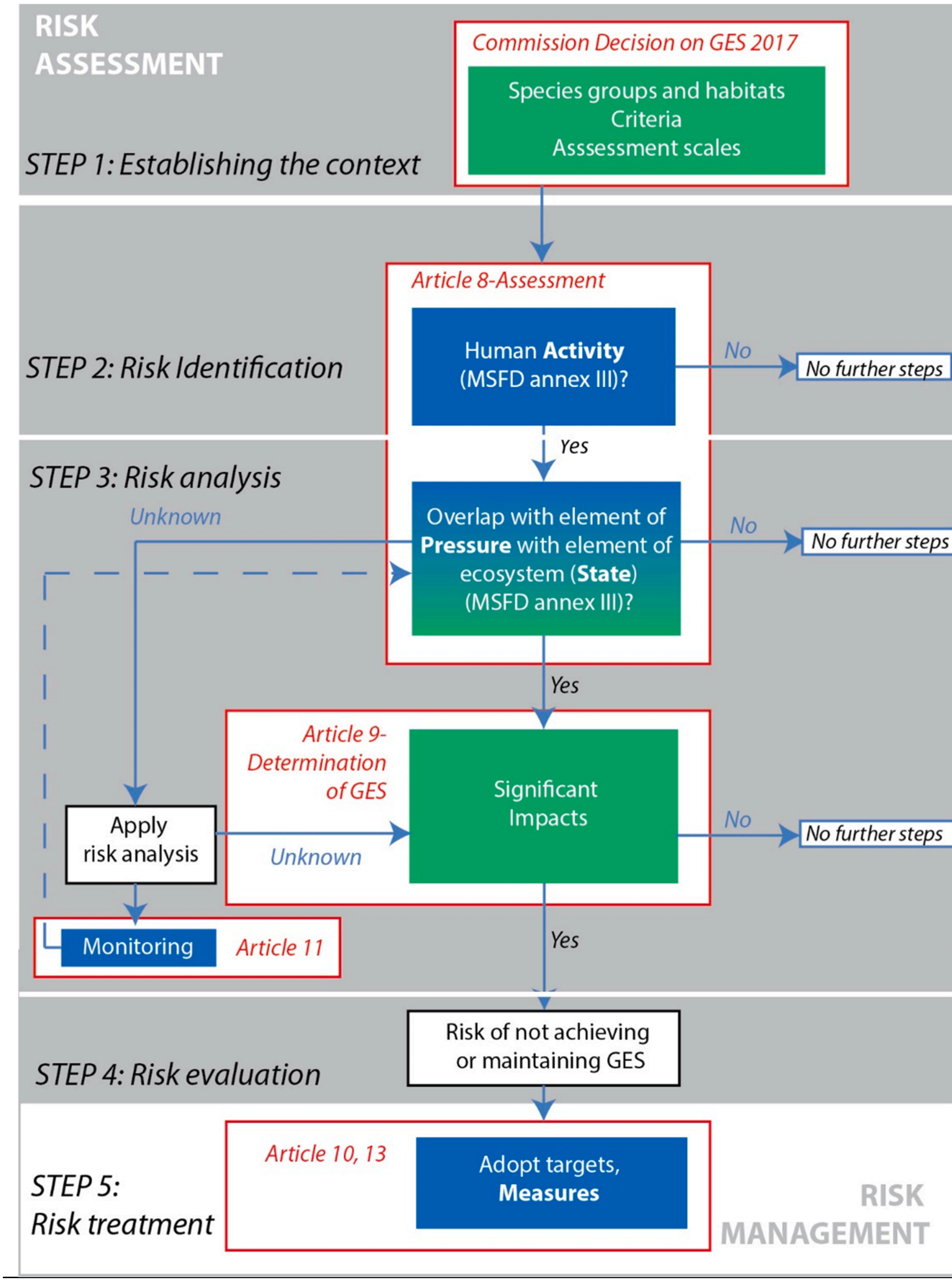
The first three steps of the RBA process were applied to the assessment of two descriptors, at subregional (for D2) and regional scales (for D11), these were: D2 Non-indigenous species with a focus on criterion D2C1 (number of newly introduced NIS), and D11 Underwater Energy and Noise, with a focus on criterion D11C2 (continuous noise); for both of these criteria, MS are obliged to establish the threshold values through regional or subregional cooperation (see Table 1 for further details). These two pressure descriptors were selected because for both, there is significant uncertainty regarding the connections along the DAPSI(W)R(M) causal chain while the nature of the pressures in each case is very different in terms of their spatial scale and environmental effects (e.g. [8,38]). While the spatial scale examined does not change the drivers, it does greatly affect the type and quantity of pressure data available. For both descriptors during the first cycle of the MSFD, aspects of implementation in the North-East Atlantic were found to be inadequate or partially adequate [18]. As a result, these descriptors provided both a challenge and an opportunity to apply and test a robust, coherent, and defensible RBA under circumstances of limited data and spanning broad geographic areas.

In **Step 1 Establishing the context** the Directive itself and the Commission Decision on criteria and methodological Standards [14], as well as the revised annex III of the Directive [13], provided considerable context for the analysis, in terms of analytical elements, guidance on Activities and Pressures and ecosystem elements. Beyond these legal documents, several other considerations were also necessary at this stage, and these required important analytical choices in terms of data sources, methods to combine and analyse the data and to estimate levels of confidence. Given the different types of descriptors to be considered in each application, the details of the approaches necessarily varied between the two applications, while the broad steps of the analysis remained the same. In both applications, the ISO framework provided a useful structure to break down the assessment of risk to GES. However, the generic nature of ISO risk steps meant that in both cases considerable care and attention was required to establish exactly how each element of the analysis could be aligned with the generic steps.

In the **Risk Identification step (2)** data was a primary consideration. For D2 - Non-Indigenous Species, considerable effort was required to compile and harmonise quite a large amount of data from a range of sources, including peer reviewed literature, online databases, technical reports and academic theses [3]. Similarly, for D11, since there is no harmonized regional database on cetacean sensitivity to noise, it was necessary to first develop a priority index of species. To develop a priority index of cetacean species and their sensitivity to noise, an expert judgement-based approach had to be developed, the method needed to be tested, validated and applied and researchers with relevant expertise. A number of researchers were contacted and some were willing to participate. Further details are published elsewhere [42].

At the **risk analysis stage (Step 3)** both applications took a broadly similar approach by assessing the **likelihood** of a pressure-receptor interaction. Assessing the likelihood of an environmental Impact required an assessment of exposure of an ecosystem component to a pressure. This was obtained by identifying areas of exposure, where pressures and ecosystem components overlapped (Fig. 2). The spatial distribution of pressures was assessed through the compilation of relevant GIS data sets. The spatial data on Activities relevant to the two descriptors considered came from a range of sources (e.g., a dataset on shipping density freely downloadable from the EMODnet portal and maps of aquaculture activities). For continuous underwater noise, at the regional scale shipping density data were employed (as a pressure proxy

Box 1
Steps of the RAGES RBA and their alignment with elements of the MSFD.



Step 1: establishing the context involved the consideration of which aspects of the Directive, descriptors and criteria were to be considered, at which scales and using which data sources, proxies and the choice of an analytical approach (which risk-based methodologies were to be used).**Step 2: risk identification** involved the assessment of potential pressures and choice of ecosystem elements which were to be assessed. In the case of D2, a compilation of data on NIS in the subregions was conducted and for D11, an initial screening process was carried out.**Step 3: risk analysis** involved the analysis of **likelihood** through analysis of exposure of areas or ecosystem elements to pressures. These were carried out by overlapping maps of ecosystem components and pressures (or their proxies) using Geographic Information Systems. Step 3 also involved an analysis of **consequence**, which was conducted for D11 through expert judgement approaches. **Step 4: Risk evaluation** involved the comparison of different likelihood and consequences of risk to ecosystem elements in different marine reporting units to identify which elements in which areas were most at risk.**Step 5**: Finally, **risk treatment** involved the choice of measures under article 13 of the Directive.

in the absence of pressure maps for noise at this scale) and at the finer scale modelled data for the spatial distribution of underwater noise were used to assess likelihood of adverse effects. There was considerable debate on the choice and reliability of proxy datasets for noise pressures. While modelled datasets of pressures were considered preferable, detailed analysis also revealed that there was agreement between proxies and modelled datasets in the busiest areas (See [36] for further analysis), although the noise extended beyond those areas.

For D11, an assessment of **consequence** was conducted via an expert judgement approach that ranked the sensitivity of cetacean species to continuous underwater noise, based on conservation status, habitats and life stage affected and the severity and sensitivity of a species to acoustic disturbance (physical, perceptual and behavioural). As in the risk-identification step, this process and scoring system had to be designed

Table 1
The criteria elements and criteria for Descriptors 2 and 11 (from [14]).

Descriptor	Criteria elements	Criteria management objectives	Methodological Standards
2	Newly-introduced non-indigenous species.	**D2C1** — Primary: The number of non-indigenous species which are newly introduced via human activity into the wild, per assessment period (6 years), measured from the reference year as reported for the initial assessment under Article 8(1) of Directive 2008/56/EC, is minimised and where possible reduced to zero.	*Scale of assessment*: Scale should be defined from local to regional scales, e.g., Marine Reporting Units (MRUs), subdivisions of the region or subregion, divided where needed by national boundaries. *Use of criteria:* The extent to which good environmental status has been achieved shall be expressed for each area assessed as follows: — the number of non-indigenous species newly introduced via human activity, in the 6-year assessment period and a list of those species.
11	Anthropogenic continuous low-frequency sound in water	**D11C2** — Primary: The spatial distribution, temporal extent and levels of anthropogenic continuous low-frequency sound do not exceed levels that adversely affect populations of marine animals.	*Scale of assessment:* Region, subregion or subdivisions. *Use of criteria:* The extent to which good environmental status has been achieved shall be expressed for each area assessed as follows: for D11C2, the annual average of the sound level, or other suitable temporal metric agreed at regional or subregional level, per unit area and its spatial distribution within the assessment area, and the extent (%, km2) of the assessment area over which the threshold values set have been achieved. The use of criteria D11C1 and D11C2 in the assessment of good environmental status for Descriptor 11 shall be agreed at Union level. The outcomes of these criteria shall also contribute to assessments under Descriptor 1.

and tested with the use of expert judgement. Although a true consequence analysis was not appropriate for D2, two methods were examined to deliver a ranked list of NIS identifying those that should be prioritized for risk assessment, including a Horizon Scanning (HS) approach [33] and an alternative approach, ELECTRE III [28,5]. Both methods considered a range of factors related to the ecology, life-history and adverse impacts of NIS present in the sub-regions Bay of Biscay and Iberian coast, and Macaronesia. A scoring system was then developed (see [2]) to enable ranking and crucially, the scoring process was supported by the large dataset assembled on the NIS in the area. Both this and the scoring system developed for D11 (see [41]) allowed for regional approaches to assessment of consequence of pressures and were found to be practicable and broadly acceptable by the experts involved in the development, testing and application. Therefore, they represent a useful first step towards the harmonized implementation of RBA, at least within the scope of regional cooperation in the NEA.

4. Common problems encountered in RBA application

Based on the application of the common risk methodology a number of problems common to both descriptors were identified. These difficulties are related to three main areas: data availability, use of expert judgement and evidence base.

4.1. Data considerations

4.1.1. Pressure data

As described above, human activity data (shipping density and aquaculture production locations) were used in the absence of true pressure maps in both applications to indicate the spatial distribution of activities and by proxy their resulting pressures. In contrast to the broadscale shipping density data, maps of aquaculture activity (used to support application of the methodology to D2) were not freely available at the regional scale, and were acquired from different sources (e,g, data regarding the aquaculture facilities acquired from reports and government information for Portugal, but retrieved from EMODnet services for France). The mapping of Sound Pressure Levels (SPL) through analysis of ship locations is an area of active research, and even the most up-to-date and reliable maps of SPL are currently limited in their spatial coverage (e.g. Farcas et al., 2020). The generation of these SPL maps relies on certain assumptions about the SPL emanating from different ship types (as well as on a highly complex suite of environmental and physical variables). Ship traffic moves all the time, but generally follows distinct geographic patterns (largely established both through shipping routes and fishing practices). For practical applications, the level of detail and the frequency of assessment of SPL needs to be carefully considered. Harmonizing the shipping type used in the freely available shipping density data set (employed in our analysis) with the shipping categories commonly employed in SPL modelling [44,24] could provide a standard basis for the regular modelling of noise at the appropriate temporal and spatial scales for application to MSFD. Similarly, when considering the pressure of NIS, the vessel traffic activity information may provide a useful proxy for pressure but a more detailed definition of ship types, shipping routes and ballast water management information (see for example the work of the National Ballast Information Clearinghouse in the USA: https://nbic.si.edu/) could enable further consideration of likely volumes of ballast water discharge in specific locations and the risk associated with those discharges.

4.1.2. Species and Receptor data

For Descriptor 2, despite dedicated project funding, and an emerging EU-scale initiative to harmonise NIS Data for MSFD D2 (https://easin.jrc.ec.europa.eu/easin), the compilation of the complete subregional species list was a major undertaking. Data reported by individual MS in the first cycle of the MSFD implementation were accessible but did not contain all the relevant information for the RBA (e.g., information about the pathways of introduction of NIS). As a result, accessing such information required consultation of several sources as well as voluntary cooperation of researchers from universities and research institutions responsible for D2 reports outside the project. Compilation of cetacean distribution data for Descriptor 11 ran into similar problems. Compilation of the initial cetacean density datasets required re-digitization of published data from reports from across MS. In addition, the compilation of cetacean data required the harmonization of datasets collected at vastly different spatial scales and relied on exploitation of professional networks and willingness to exchange data as professional courtesy.

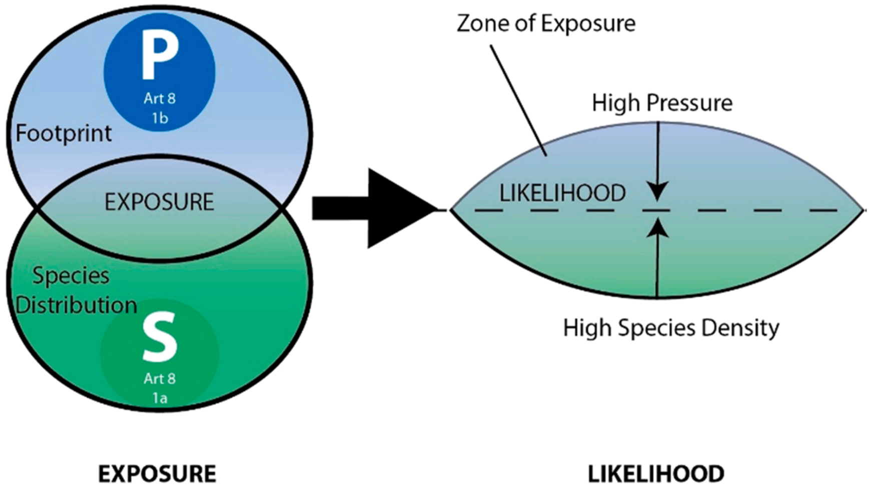


Fig. 2. Schematic illustration of the relationship between exposure and likelihood. Exposure implies an overlap between Pressure (P) and State (S). The likelihood of an environmental impact on a particular ecosystem element depends on the intensity of the pressure and the density of the ecosystem element under consideration.

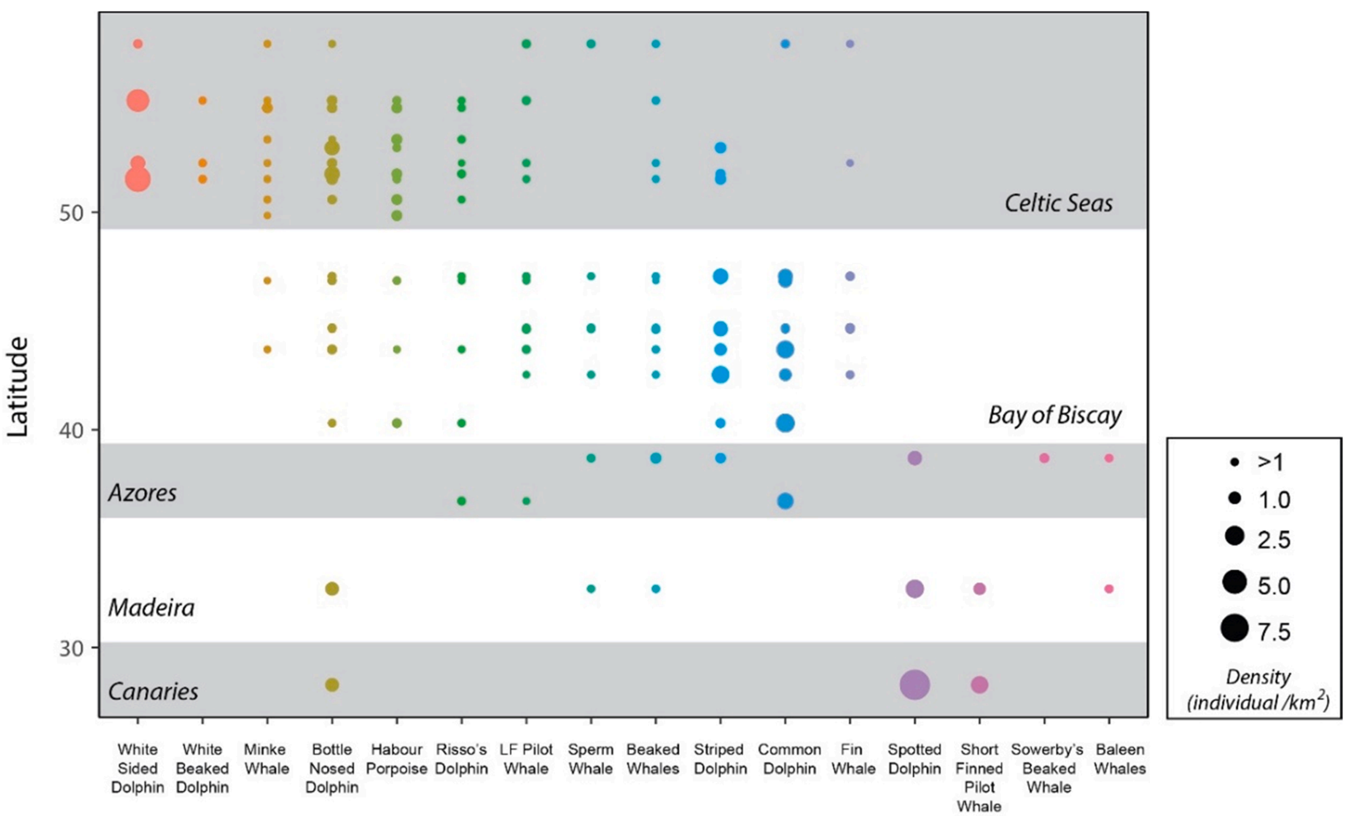


Fig. 3. Cetacean density data for the Celtic Seas, Bay of Biscay and Macaronesia, taken from [22,32] and Saaverdra et al., 2018), represented by the latitude at which species densities were reported.

Fig. 3 (created by combining cetacean density data from [22,32] and [34] shows the varied distribution of cetacean species across the North-East Atlantic, with some species (such as the Bottlenose Dolphin and the Sperm Whale) occurring across several sub-regions. This highlights why GES should be considered at a number of spatial scales and assessment of GES would be facilitated by a more harmonised approach to data collection, storage and access.

4.2. Use of expert judgement

The selection of criteria elements and the analysis of likelihood and consequence relied on the development and application of ranking schemes and the application of expert judgement. These tools are essential to the RBA in the absence of quantitative data. While ranking schemes for each of the two descriptors were developed, tested and accepted by expert groups within their disciplines (NIS and Cetacean biology respectively) sufficient expert time and effort was not available within the scope of the project to rank all species, either for NIS or for cetacean sensitivity. For example, the methodology developed for D2 was only applied to a subset (188) of the total species compiled (454), as well as for D11, where sufficient time and expertise was available to assess the sensitivity of just 8 of the total 16 species with reported abundance and density estimates in the study area.

4.3. Evidence base

Certain descriptors of the MSFD bring with them more uncertainty than others, therefore the evidence base to support fully quantitative approaches to the analysis of some activity-pressure-state causal chains is not fully developed. Many of the questions raised by the practical implementation of the MSFD result in uncertainty, and indeed arise from it and the RBA used in the examples above has been designed in response to such conditions. Other approaches have been developed previously to facilitate EU nature policy implementation (e.g [27,35,37]. Cormier et al. [7] for example, advocates for the use of bow-tie approaches for the assessment of risk analysis and presents hypothetical models for the application of such approaches. To date these have seen limited practical application in the implementation of the MSFD. In our two applications (regardless of individual MS national resources and capacity for the implementation of the MSFD) there are still a number of fundamental gaps in the evidence-base for management for Descriptors 2 and 11 that can only be filled by dedicated and ongoing research.

4.3.1. Non-indigenous species

Regarding the evidence of the adverse impacts of NIS in the sub-regions examined in the North-East Atlantic the major source of uncertainty is the lack of information on the distribution, abundance, population status, biology, ecology, and introduction pathways of NIS within MS territories.

For NIS, it has long been acknowledged that the exact ecological conditions which may enable a particular species to become established and/or invasive in a particular location are complex and difficult to predict, particularly in the marine environment (see [6]. This results in a limited predictive capacity to identify which new NIS will arrive and establish, or their behaviour and adverse impacts once they do. In fact, our ability to define and predict the types of impacts that may occur represents a major uncertainty [31] along the causal chain from Pressure to Impact. Therefore, even the use of complex mechanistic models to identify which species may be transferred and to where has limited ability to enable appropriate management actions. Ultimately fully effective methods to understand the distribution, spread and in particular, the adverse impacts of NIS (such as out-competing native species, altering native habitats or socioeconomic impacts) will require fundamental insights into the dynamics of invasion, the physiological and environmental characteristics which enable establishment and spread, as well as an understanding of pathway dynamics.

4.3.2. Continuous noise

There are significant ongoing efforts to improve the accuracy and reliability of the mapping of underwater sound pressure levels emanating from both impulsive and continuous noise and this is in no small part due to recent attempts at implementation of the MSFD. Research has resulted in the rapid emergence of improved regional and local sound pressure level maps (e.g. Farcas et al., 2020) as well as the development of useful models focusing on the Population Consequences of Disturbance (PCoD) for cetaceans (e.g. [26]. However, the link between underwater sounds and changes in environmental state in terms of individual and population level responses of cetaceans to sound sources still entails much uncertainty. Much research effort over many decades has focused on the impact of noise on cetacean species, with potential impacts including behavioural changes and displacement resulting from processes such as acoustic masking and hearing loss [29, 10]. However, despite these long-standing research efforts, it has proven very difficult to draw robust statistical conclusions between noise and cetacean behavior and physiology [21]. Without quantitative empirical evidence of noise impacts, RBAs are the only operational approach to assessing GES for descriptor 11 of the MSFD that enables us to harness the expertise held by a range of experts across Europe.

There are inherent difficulties in surveying mobile animals over the large regions in the North-East Atlantic specified under the directive. The North-East Atlantic region addressed under this study included the Celtic Seas, the Bay of Biscay and Iberian Coast, and the Macaronesia sub-regions. As a result, despite repeat, state-of-the-art monitoring of cetacean distribution and density at the sub-regional scale (e.g., [22, 32]) confidence in the distribution and abundance for cetacean species is variable and low in many cases. For example, in extensive aerial surveys of the Irish continental shelf in the summer of 2016, Rogan et al. [32] estimated an abundance of 5664 Common Dolphins with a coefficient of variance (CV) of 85% while in the same period an abundance of 95 Fin Whales was estimated with a CV of 73%. This variability results in a situation where even if the science of underwater noise modelling continues to advance and the pressures of underwater noise are mapped with great accuracy and precision over large spatial scales, there remains a mismatch between the large (and inevitable) uncertainty in the abundance and density of the impacted species. As a consequence of uncertain Pressure- State change relationships between underwater noise and impact on behaviour and ecology of cetaceans, as well as the uncertain abundance and distribution of cetaceans, the development of increasingly accurate and precise underwater noise models may add little to our understanding of environmental status of cetaceans. This means that expert judgement and RBAs are likely to continue to be vital in assessing underwater noise (D11) until such time as the evidence base improves.

5. Conclusions

These applications of a RBA have demonstrated the clear potential for Risk-based and expert judgement approaches to contribute to the implementation of MSFD for descriptors where quantitative relations between pressure and state have not yet been established. In many cases, establishing these quantitative relationships is beyond the scope of the MSFD competent authorities and can only be addressed at the European scale (or at a Regional Sea scale, for example via Convention for the protection of the marine environment of the North-East Atlantic OSPAR, Helsinki Convention on the protection of the marine environment of the Baltic Sea area HELCOM or similar) through the relevant research funding mechanisms (e.g., Horizon Europe and the Joint Programming Initiatives). However, while the applications above demonstrate the feasibility of such approaches to assist in regional assessments, large scale implementation of such approaches for practical application will require further efforts, both in terms of establishing a common process and the streaming and rationalizing of MSFD data. Importantly, the RBA can be adapted to suit a wide range of policy scenarios and applications beyond those MSFD specific ones illustrated here. This work has shown that even in situations which are not data rich, the RBA is sufficiently flexible to be applied and the approach to each individual step can be adapted to suit the particulars of that region.

We recommend that the existing approaches and scoring systems could be used to centralise efforts of a broader group of experts in NIS and cetacean ecology and biology, in a series of workshops to finalize and agree sensitivity scores (for cetaceans) and to rank the NIS according to the Horizon Scanning approach and/or using an alternative approach. For NIS the timeframe for such initiatives could in principle be aligned with the cycle of MSFD implementation. Such an initiative would enable a common basis for assessment at the beginning of each MSFD cycle. The cetacean sensitivity index, once agreed by a sufficiently broad panel of experts, would likely require updating less frequently but should be sufficiently frequent as to ensure the sensitivity index keeps abreast of the latest scientific knowledge (and for the sake of harmonization with the MSFD, a six-year cycle might also be appropriate).

Specific steps that could improve coherency and efficiency in applying the RBA for any descriptor include using the structure already established under MSFD (under the Common Implementation Strategy) to identify the descriptors most appropriate for RBA, agree standard protocols to RBA and assembling panels of experts to apply the agreed methodologies at a European scale. While our experience relating to the compilation and assembly of data relate specifically to the geographic scope of the North-East Atlantic and to Descriptors 2 and 11, we anticipate that similar problems are likely to be present in other regions and for other descriptors.

The reporting structures of the MSFD are complicated and not centrally coordinated and as a result, the information contained within reports is scattered. While recognizing the significant time and effort of MS in the preparation of marine strategies and their associated reports as well as the efforts of the European Commission in their detailed appraisals of MS reporting (including the useful MSFD online scoreboard), compiling regional information on monitoring and measures is still a major effort. Failure to centralize such data information in a harmonised and easily accessible manner represents a significant inefficiency. Harmonised regional assessment of GES should not rely on ad-hoc data collection and exploitation of individual professional networks as was the case for this work. Free availability of relevant datasets should be ensured in compliance with MS and Commission obligations under the stipulations of the Aarhus Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters [39], for which data sharing, data archive centres and freely available environmental data are central pillars. Centralized portals providing data on species, human activities, pressures and environmental conditions (e.g., European Alien Species Information Network EASIN, Information System on Aquatic Non-Indigenous and Cryptogenic Species AquaNIS, European Marine Observation and Data Network EMODnet, the Earth Observation Component of the European Union Space Programme Copernicus, Ocean Biodiversity Information System OBIS) have an invaluable role to play in the regional harmonization of MSFD implementation. Opportunities should be found to add value and maximize the potential of existing portals and datasets for use in MSFD (e.g., for centralization of data reported in MSFD, shipping data with ship categories that can be related to marine noise and to NIS introduction pathways; harmonized regional cetacean datasets; maps of the main NIS introduction pathways, including via ballast water and hull fouling). Ultimately, until such time as the evidence base and data accessibility improves, the RBA will remain an essential tool in the implementation of the MSFD.

At a time when the risks posed by climate to marine management are ever increasing and where the EU biodiversity strategy 2030 is setting ambitious goals for marine conservation, the requirement for efficient and effective risk-based management has never been greater. At present, a lack of data of sufficient quality, temporal scope or spatial extent is the rule rather than the exception when making management decisions in the marine environment. Our efforts indicate the potential for RBAs to contribute to more efficient and effective marine management, under conditions of high uncertainty and poor data and point to a number of areas where relatively simple actions can generate a standardized basis for common implementation of RBA within individual countries and across regions.

CRediT authorship contribution statement

Emma Verling: Conceptualization, Visualisation, Writing – original draft and overall manuscript original draft, overall Methodology, Investigation, Formal analysis, Data curation. **Claudia Hollatz:** Methodology, Investigation, Formal analysis, data curation. **Cátia Bartilotti**: Writing –original draft, Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation. **Miriam Tuaty Guerra**: Writing – original draft, Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation. **Jorge Lobo-Arteaga**: Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation. **Tim O'Higgins**: Conceptualization, Visualisation, overall Methodology, Writing – review & editing, Project administration, Funding acquisition.

Data Availability

The only data presented (Fig 3) come from other existing publications, all of which have been named and identified in the text.

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