DEVELOPING A RISK-BASED APPROACH TO GOOD ENVIRONMENTAL STATUS

rages

risk-based approaches to good environmental status

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DEVELOPING A RISK-BASED APPROACH TO GOOD ENVIRONMENTAL STATUS

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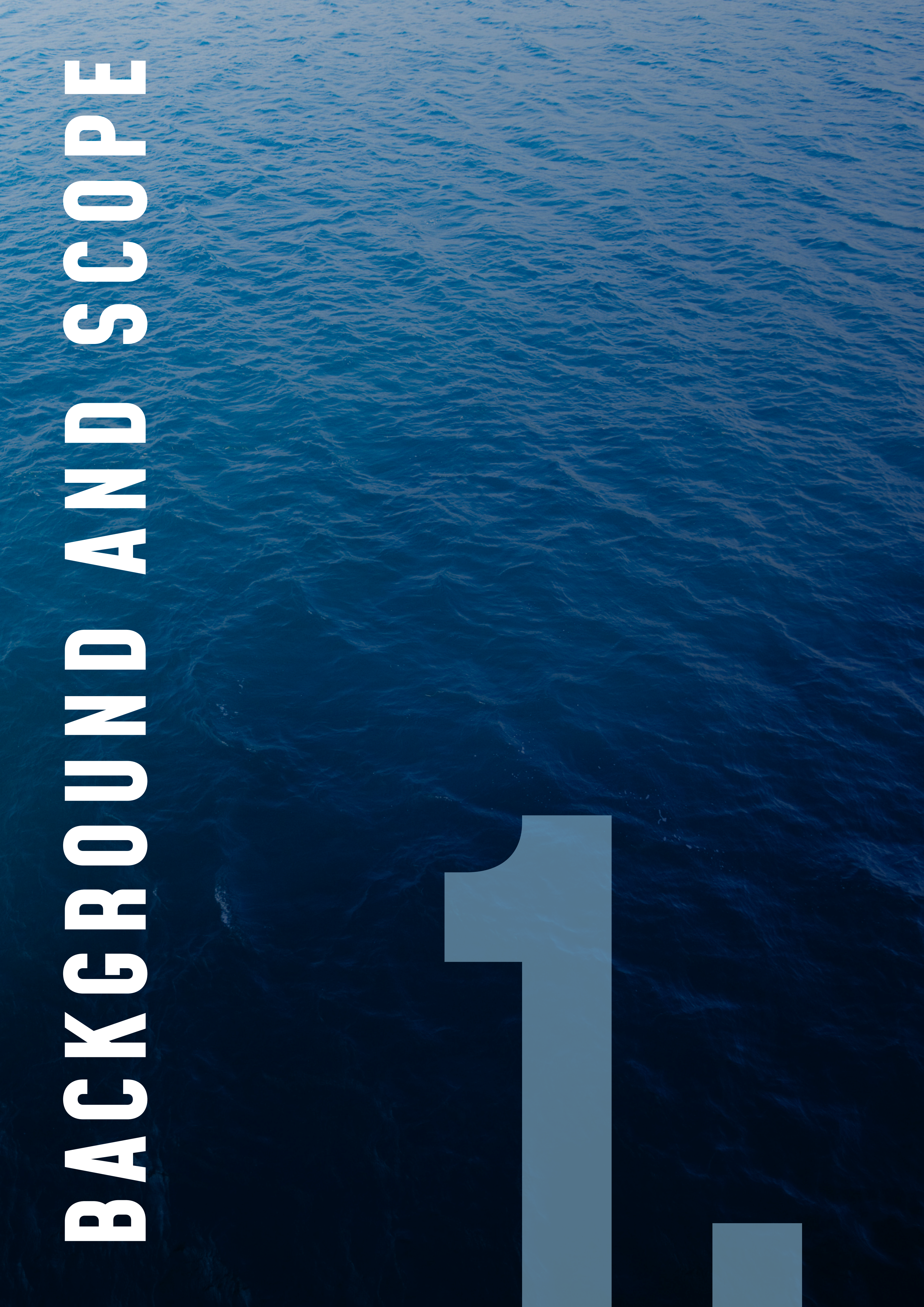
ACS – Celtic Seas
ABI – Bay of Biscay and Iberian Coast
CIS – Common Implementation Strategy
CFP – Common Fisheries Policy
EC – European Commission
EEZ – Economic Exclusive Zones
EQS – Environmental Quality Standards
ES – Spain
EU – European Union
FR – France
GES – Good Environmental Status
ICG-Eco-C – OSPAR Intersessional Correspondence Group on Cumulative Effects
ICG-Noise – OSPAR Intersessional Correspondence Group on Underwater Noise
ICES – International Council for the Exploration of the Sea
IE – Ireland
ISO – International Organization for Standardization
AMA – Macaronesia
MoP – Monitoring Programme
MS – Member States
MSFD – Marine Strategy Framework Directive
NEA – North-East Atlantic
NIS – Non-Indigenous Species
OSPAR IA – OSPAR Intermediate Assessment
PoM – Programme of Measures
PT – Portugal
RSC – Regional Sea Convention
QSR 2023 – Quality Status Report 2023
TG Seabed – MSFD Common Implementation Strategy Technical Group on Seabed
VME – Vulnerable Marine Ecosystems
WG DIKE – Working Group on Data, Information and Knowledge Exchange

LIST OF ACRONYMS



1. BACKGROUND AND SCOPE

1.1. The Marine Strategy Framework Directive

The Marine Strategy Framework Directive (MSFD) aims to achieve or maintain the Good Environmental Status (GES) of the marine environment by 2020[1]. It is an environmental initiative of unprecedented scope and scale, covering all four of Europe's regional seas (the North-East Atlantic, and the 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).

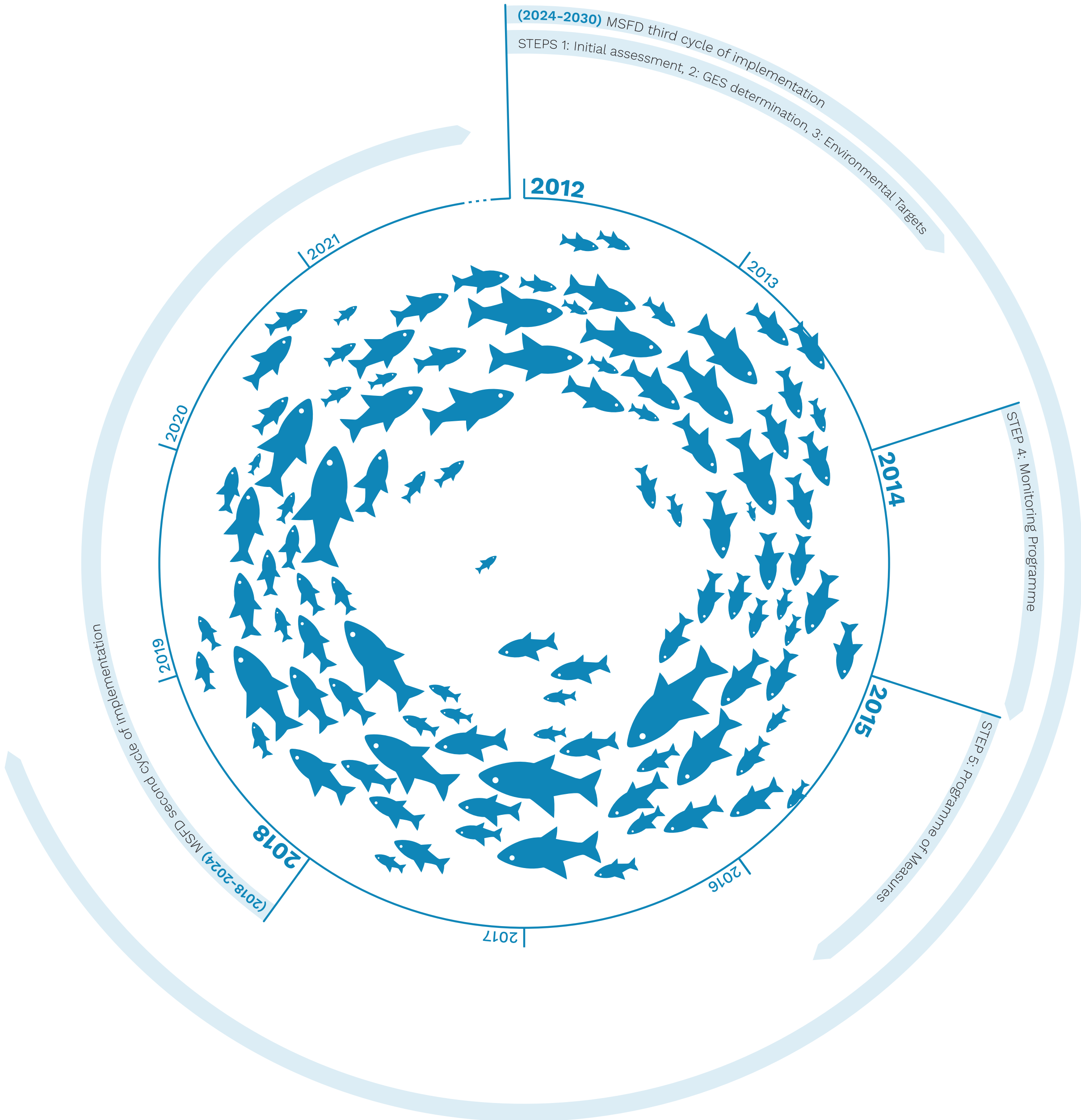


Figure 1. Overview of the MSFD cycle of implementation

[1] The process of reviewing the MSFD has started and is due by 2023.

The first three steps comprise: an assessment of the environmental status of MS' marine waters and of the environmental impact of human activities, and an economic and social analysis, including, an assessment of the cost of degradation of the marine environment (article 8); the determination of GES (article 9); and the setting of environmental targets (ET) (article 10). The fourth step requires MS to develop a monitoring programme (MoP) (article 11) to assess the environmental status of marine waters and progress towards the achievement of ET, and, finally, at the fifth and last step, MS are required to establish and implement a programme of measures (PoM) (article 13).

The Directive establishes eleven qualitative descriptors of GES, eight of which are **pressure** related: non-indigenous species (D2), commercially-exploited fish and shellfish (D3)[2] , eutrophication (D5), hydrographical conditions (D7), contaminants in the marine environment (D8), contaminants in seafood (D9), marine litter (D10) and energy, including underwater noise (D11); and three are **state** related: biodiversity (D1), food-webs (D4) and seafloor integrity (D6). Given the transboundary nature of the marine environment, for each of these descriptors, GES must be determined at the marine region or sub-region level (article 3). In fact, according to article 5 (1), and in line with the ecosystem-based approach guiding the MSFD, although marine strategies are to be applied to national waters, also the subsequent development of the ET, and the MoP and PoM, must take into account the marine (sub)region. Therefore, a suitable implementation of the Directive requires both a good understanding of the relationships between activities, pressures and the ecosystems, and the cooperation and coordination of MS, at regional and sub-regional levels, to assess possible cumulative impacts and the state of the marine ecosystem, and agree effective targets and measures.

In 2010, as a starting point for the development of coherent approaches in the preparatory stages of the marine strategies, the European Commission (EC) issued Decision 2010/477/EU, laying down a number of criteria and methodological standards to assess GES in relation to each of the eleven descriptors. Despite the guidance provided, certain pressures remain poorly understood (e.g., marine litter and noise), and for most, availability of data varies considerably amongst MS. Also, while in certain regions, cooperation structures have been established (e.g., HELCOM and OSPAR for the Baltic Sea and North-East Atlantic regions), currently, no Regional Sea Convention (RSC) covers all the waters of the Macaronesia sub-region. As a result, considerable divergence in approaches amongst MS and across regions occurred in the first cycle of implementation of the MSFD.

1.2. MSFD first cycle of implementation (2012-2018)

1.2.1. Lessons learned

The EC assessed, in accordance with articles 12 and 16, and in respect to each marine region or sub-region, Member States compliance with the requirements of the Directive on the development of their marine strategies in the MSFD 1st cycle of implementation. More recently and, in accordance with article 20, the EC also published a *Report on the implementation of the Marine Strategy Framework Directive* (EC, 2020a, 2020b and 2020c) which includes a review of progress in the implementation of the MSFD. This chapter provides a brief overview of the main conclusions and recommendations of these assessments.

Initial assessment, GES and targets

The report from the Commission to the Council and the European Parliament on the first phase of implementation of the MSFD (steps 1 to 3)[3], highlights that the quality of the

[2] D3 is also considered a state descriptor as it requires an assessment of commercial fish populations status

[3] COM (2014) 97 final

reporting in the 1st cycle of implementation varied widely between (sub)regions, MS and even within MS, with each assessment providing information based on different indicators, criteria and baseline values, and also limited cooperation between MS to determine GES and establish coordinated targets. In addition to the lack of coherence and consistency in implementation across marine regions and sub-regions, the EC reported a failure to determine baselines, GES and targets in measurable ways.

In the Commission Staff Working document[4], accompanying the report, the implementation of articles 8 to 10, in each MS, is assessed per descriptor according to completeness, adequacy, consistency, and also coherence between the reports within a marine region and sub-region, and also across the EU, between marine regions. According to this document, MS within the North-East Atlantic (NEA) region showed the highest scores in terms of adequacy (i.e. whether the reported information met the objectives of the Directive and the technical requirements of articles 8 to 10) as well as in terms of coherence. In terms of adequacy, NEA MS performed better in their initial assessment (article 8), with most assessments considered adequate or partially adequate, but less well in the determination of GES (article 9) and the definition of ET (article 10), assessed as insufficient or inadequate for most descriptors and MS. Tables 13 to 15 in Annex II summarize the evaluation, in terms of adequacy, of the reports submitted by the MS participating in the RAGES project (Ireland, Portugal, Spain and France) (Milieu, 2014 a, b, c, d) and of the overall coherence, within the NEA region, and the Celtic Seas (ACS) and the Bay of Biscay and Iberian Coast (ABI) sub-regions (the sub-regions within the scope of this project, except Macaronesia as no assessment of coherence was performed for this sub-region). Compared to the other regional seas, the implementation of the MSFD in the NEA builds from a position of relative strength, as all MS are party to the OSPAR Convention.

As a result of the assessment performed, the Commission made a number of recommendations to be taken forward at different levels. To improve adequacy and coherence of GES, proposed actions at the EU level included the revision and strengthening of the Commission GES Decision and further development of a common understanding on the obligations under article 9 (including GES assessment methods, scales and aggregation rules) to allow a pan-European assessment of marine ecosystems. At the regional level, the Commission highlighted the need to enhance regional cooperation, namely, in the context of RSC, to further develop ecosystem and region specific criteria to determine and assess GES, and to ensure a systematic identification of the knowledge gaps preventing a more ambitious risk-based setting of GES and the active collaboration between MS to close these gaps. The Commission Staff Working Document (EC, 2014b) also included recommendations to each MS. Recommendations common to two or more MS of the RAGES consortium included:

1. Improve GES definitions through regional cooperation using the work of the RSC as much as possible, focusing on those descriptors assessed as inadequate or partially adequate and on quantitative aspects and baselines, with the aim to make GES measurable (FR, PT, IE, ES).
2. Ensure that the targets cover all relevant pressures, are SMART, and sufficiently ambitious in order to achieve the requirements and timelines of the MSFD (FR, PT, IE, ES).
3. Address knowledge gaps identified in the initial assessment, through the MoP under the MSFD and research programmes, focusing on those descriptors considered as inadequate or partially adequate (FR, PT, IE).
4. Strengthen the GES definition of the biodiversity descriptors in a way which goes beyond what is in existing legislation (PT, IE).

[4] SWD(2014) 49 final

Monitoring programmes (MoP)

The assessment by the EC of the MoP established by MS was made public with the release in 2017 of the report from the Commission to the European Parliament and the Council assessing Member States' MoP under the MSFD[5]. This report assessed consistency and appropriateness of each MS MoP, as well as regional coherence, and as in 2014, the lack of consistency and comparability amongst MS was highlighted.

In the Commission Staff Working document[6] accompanying the report, the adequacy of the MoP of each MS was assessed by considering whether monitoring needs for the assessment of progress towards GES and achievement of ET were sufficient. Within the RAGES consortium, MoP appropriateness varied widely, with the MoP from ES assessed as mostly appropriate, the MoP from FR and IR as partially appropriate, and the MoP from Portugal as not appropriate. Table 16 in Annex II summarizes the technical assessment of adequacy of these MS MoP.

As in 2014, the Commission emphasised the need for further action to ensure that monitoring approaches are comparable across MS (through action at regional and sub-regional level) and appropriate to gauge the effectiveness of measures and assessing distance to targets. The need to ensure an adequate spatial coverage of the MoP by taking into account the location of predominant pressures and impacts through an analysis of the risks was also highlighted.

Programmes of measures (PoM)

The report from the Commission to the European Parliament and the Council[7] assessing MS' PoM under the MSFD concluded that improvements are needed for all PoM to be considered appropriate to meet the requirements of the Directive. MS' PoM were assessed by considering whether they addressed the relevant pressures and associated activities in a marine region[8]. Table 17 in Annex II summarizes the technical assessment of ES, FR, IE and PT's PoM, as well as regional coherence within the sub-regions within the geographical scope of RAGES. The report highlighted, amongst other recommendations, the need to improve the links between the measures reported for pressure descriptors and their potential benefits for the state descriptors (pressure-state relationship).

1.2.2. The way forward

To improve the coordination amongst MS and yield coherence and efficiency in the implementation of the MSFD, an informal programme of coordination, the MSFD Common Implementation Strategy (CIS), was set up in 2009.

Within the MSFD CIS, guidance documents are published to ensure common approaches amongst MS, and technical groups have been established to set up common monitoring frameworks, and methodological standards to define GES, including, baselines, thresholds integration rules etc. Following the recommendation regarding the need to ensure a common understanding of the obligations under article 9, a document was drafted under the MSFD CIS, *the Background document on the determination of GES and its links to assessments and the setting of environmental targets*, which highlights that: ***Implementation of the Directive can be most efficient when it is clearly focused on the anthropogenic pressures which are considered to be adversely affecting the environmental status in each region or sub-region, and on assessing the nature and scale of associated environmental impacts*** (MSFD CIS 2017). This guidance document, published in 2020 by the EC as a Commission Staff Working Document[9], provides the following stepwise approach to a prioritised implementation of the Directive:

1. Assess the distribution and intensity of human activities which are generating pressures on the marine environment.
2. Assess the distribution and intensity of the resulting pressures in the sea, identifying those which are of

[5] COM(2017) 3 final
[6] SWD(2017) 1 final
[7] COM(2018) 562 final
[8] SWD(2018) 393
[9] SWD(2020) 62 final

greatest concern.

3. Identify those aspects of the marine environment (species, habitats, ecosystem functions and processes) most (likely to be) affected by these pressures.
4. Focus monitoring and assessment on those aspects considered to be most at risk of adverse effects, to determine whether GES has been achieved or not.
5. Direct management responses (measures) towards those pressures and areas which are considered to be causing the greatest adverse effects (in terms of intensity and/or extent) and contributing most to a failure to achieve GES.

This stepwise approach, provides a method to tackle a number of the other recommendations mentioned above, namely, the need to focus monitoring on predominant pressures, under the MoP, and to improve the link between the adoption of measures and expected improvements on the state of the environment, within the PoM. It also supports the drawing of cost-effective and feasible measures that give due consideration to the social and economic impacts of the PoM as required by article 13(3).

Following the technical assessments of the implementation of the Directive in the 1st cycle, Decision 2010/477/EU was replaced by Commission Decision (EU) 2017/848, of 17 May 2017, to ensure greater coherence in the 2nd cycle (2018-2024) in the determination and assessment of GES. Given, however, the uncertainties regarding the structure and functioning of marine ecosystems and the impacts of activities on the marine environment, as well as the need for sub-regional harmonisation of lists of elements and assessment methods, the definition of GES remains to be established for most descriptors. A preliminary analysis in EC latest report on the implementation of the MSFD has already signalled considerable disparities among GES determinations in the ongoing 2nd cycle (EC, 2020a). As both natural environmental and anthropogenic factors determine the survival and reproductive success of individuals, and thereby the stability of a population in most cases, it is difficult to describe and quantify the effects from a specific pressure on a population or habitat, and particularly at the ecosystem level. The inability to define thresholds or to establish with certainty pressure-state relationships should not, nonetheless, prevent MS from taking action if the risk of not achieving or maintaining GES is considered high. In fact, risk assessment has been proposed as the first of a series of steps when implementing environmental policy under uncertainty (Knights *et al.*, 2014).

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). Assessing risks will improve the adequacy of MoP and PMo and therefore the likelihood of achieving or maintaining GES.

1.3. RAGES project scope

The RAGES project aims to develop a risk-based approach to support coordinated regional and sub-regional implementation of the MSFD based on Decision 2017/848 on Good Environmental Status by providing a replicable, transparent and standardised environmental decision support process based on international best practice in risk assessment and management.

The Risk-based Approaches to Good Environmental Status (RAGES) is a two-year project funded by DG Environment, comprised of a consortium of thirteen partners including the competent authorities for the implementation of the MSFD in Ireland, France, Portugal and Spain, plus universities and research institutes with expertise in marine environmental sciences and risk assessment.

The RAGES project area (Figure 2) comprises three of the four sub-regions of the NEA: the Celtic Seas (ACS), shared between Ireland and France, the Bay of Biscay and Iberian Coast (ABI), shared by France, Spain and Portugal and Macaronesia (AMA), which includes the Portuguese archipelagos of the Azores and Madeira, and the Spanish Canary Islands. Notably, the EEZ of these four MS are amongst the largest in the EU. Table 1 summarises the area and proportion of each MS' EEZ in the study area.

Table 1. Area of national EEZ in the NEA region and proportion in each sub-region

Member State	EEZ in NEA (Km^2)	Macaronesia (%)	Celtic Seas (%)	Bay of Biscay and Iberian Coast (%)	North Sea (%)
Portugal	1,729, 000	82	-	18	-
Spain	748, 000	60	-	40	-
Ireland	427, 000	-	100	-	-
France	258, 000	-	17	73	10
TOTAL	**3,894,000**	**48**	**24**	**21**	**8**

Following the considerable lack of coherence and cooperation across the NEA sub-regions in MSFD 1st cycle of implementation, and the need to address the insufficient data and knowledge on marine ecosystems in the largest sub-regions of the NEA to assess GES, the RAGES project has been put forward to enhance cooperation between MS in the ACS, ABI, and AMA sub-regions, and to provide a common approach to deal with the scientific uncertainties and limited knowledge on marine ecosystems.

The work to be developed by competent authorities and scientific experts together, aims to provide a common approach to risk as, though the use of a risk-approach in the implementation of the MSFD has been suggested, namely, in the MSFD CIS draft Background document on GES, no common framework has been yet agreed to assess and address risk. The RAGES project aims to fill this gap.

The RAGES geographical scope comprises three of the four sub-regions of the NEA: the Celtic Seas (FR and IE), the Bay of Biscay and the Iberian Coast (ES, FR and PT) and Macaronesia (ES and PT). Its main goal is to propose a risk-based framework to address the existing uncertainties in view of improving the implementation of the 2017 GES Decision, the determination of GES and its assessment.

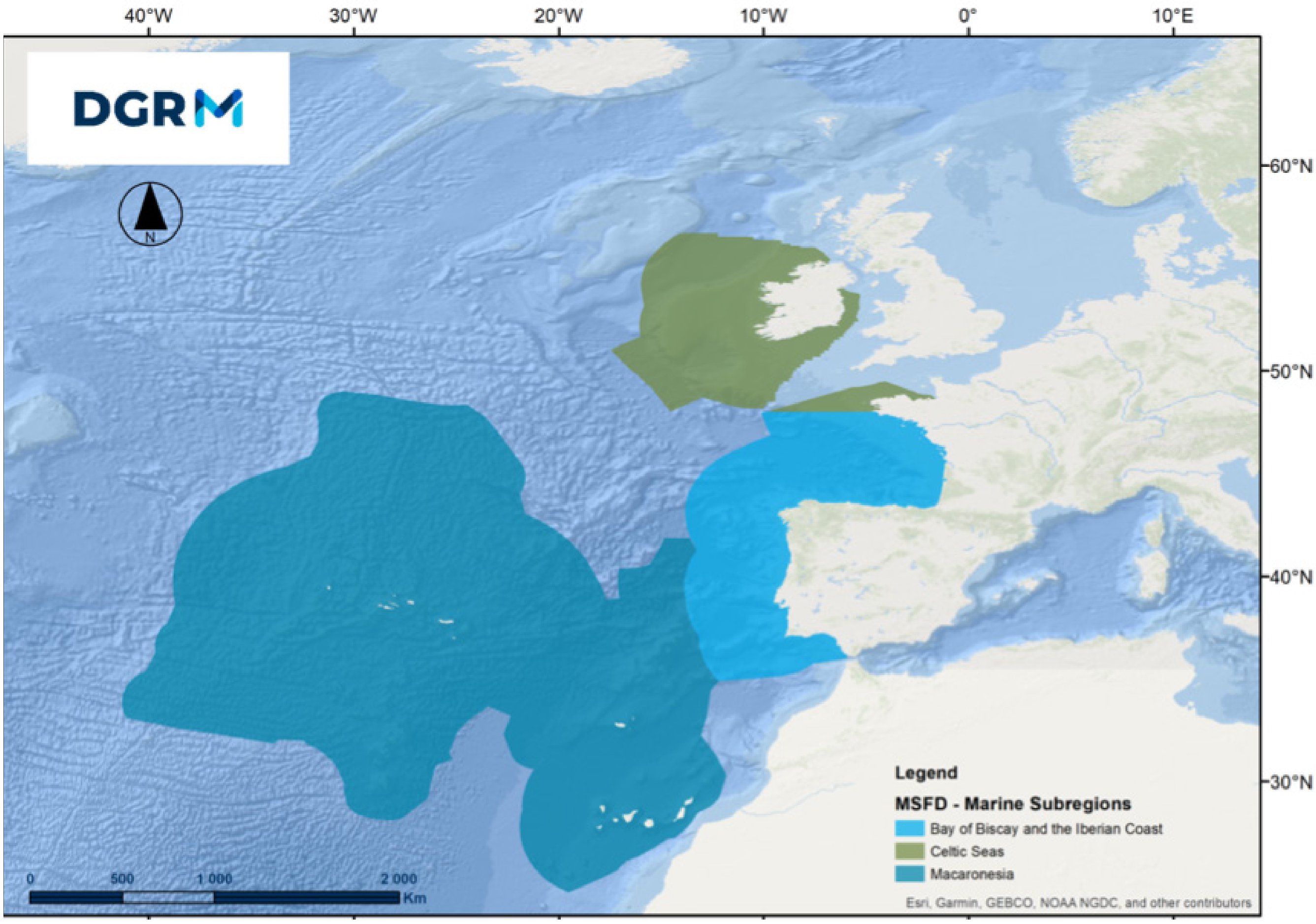


Figure 2. Geographical scope of the RAGES project

2

UNDERSTANDING RISK

This chapter starts off by identifying the main references to risk in the Directive and GES Decisions to show how central risk is for the effective implementation of both the MSFD and the 2017 GES Decision. In the subchapters that follow, the concept of risk and also how it has been addressed so far in the MSFD is briefly explored. Finally, an approach to reach a common understanding regarding risk and risk management, is suggested as a starting point to put forward a risk-based framework to improve chances of reaching GES in EU waters.

2.1. Risk in the MSFD context

While MSFD article 1(1) establishes that the overall aim of the Directive is to reach GES of the marine environment by 2020, paragraph 2 lays out its two specific objectives:

a) *protect and preserve the marine environment, prevent its deterioration or, where practicable, restore marine ecosystems in areas where they have been adversely affected.*
b) *prevent and reduce inputs in the marine environment, with a view to phasing out pollution as defined in Article 3(8), so as to ensure that there are no significant impacts on or **risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea**.*

The concept of risk is, therefore, already introduced in the objectives of the MSFD, and although the Directive does not explicitly mandate MS to carry out a risk assessment, article 14 (4) clearly states that MS may not take further steps beyond article 8 if there are no significant risks to the marine environment. This means that, in practice, it is expected that MS focus, via articles 9, 10, 11 and 13, on those pressures and areas, presenting higher risks.

The 2010 Commission Decision on GES upheld this risk-based approach, highlighting in PART A of its Annex, on general conditions of application of the criteria for GES that *"a combined assessment of the scale, distribution and intensity of pressures, and the extent, vulnerability and resilience of the different ecosystems components allows the identification of areas where marine ecosystems have or may have been adversely affected and facilitates the development of specific tools that can support an ecosystem-based approach to the management of human activities required to achieve good environmental status through the identification of the sources of pressures and impacts".*

The Commission Decision (EU) 2017/848 provides an even more explicit link to risk, stating in **recital 6** that *"the number of criteria that Member States need to monitor and assess should be reduced, **applying a risk-based approach** to those which are retained in order to allow Member States to focus their efforts on the main anthropogenic pressures affecting their waters"* and, in **recital 18**, that *"Member States should have sufficient flexibility, under specified conditions, to focus on the predominant pressures and their environmental impacts on the different ecosystem elements in each region or sub-region in order to monitor and assess their marine waters in an efficient and effective manner and to facilitate prioritisation of actions to be taken to achieve good environmental status. For that purpose, firstly, Member States should be able to consider that some of the criteria are not appropriate to apply, provided this is justified. Secondly, Member States should have the possibility to decide not to use certain criteria elements or to select additional elements or to focus on certain matrices or areas of their marine waters, provided that this is based on a **risk assessment** in relation to the pressures and their impacts".* These recitals are reflected in **article 3**: *"secondary criteria and associated methodological standards, specifications and standardised methods laid down in the Annex shall be used to complement a primary criterion or when the marine environment is **at risk of not achieving or not maintaining good environmental status** for that particular criterion".* For pressure descriptors, most primary criteria set in the Annex are, in line with this approach, pressure criteria[10], i.e., criteria aimed at assessing the extent, frequency or intensity of pressures, while impact criteria are mostly secondary criteria[11], i.e., criteria aimed at assessing the level of impact from a pressure on an ecosystem component.

Furthermore, the Decision established the need for a number of criteria to be assessed via threshold values which, according to **article 4** must be set on the basis of significance of an adverse effect and the precautionary principle, reflecting potential risks to the marine environment. Existing thresholds to assess D8 and D9 criteria elements (Environmental Quality Standards and Maximum Levels Allowed) have been established via risk assessments and therefore, indirectly (via the regulations under which D8 and D9[12] criteria must be assessed), risk assessment methodologies are already embedded, in practice, in the implementation of the GES Decision. An example of the adoption of a risk based approach to set thresholds in the MSFD, not supported by other EU legal instruments, is the risk-based framework adopted by TG Noise.

The EC Decision 2017/848 follows, therefore, a two-fold risk based approach to the monitoring and assessment of GES by: 1. prioritizing the assessment of pressure criteria, and requiring the assessment of impact criteria only if there is evidence that there is risk of not achieving GES for those criteria based on the pressure assessment, and 2. requiring the assessment of pressure criteria via thresholds established taking in consideration risk.

The reference on recital 18 regarding the selection of criteria elements, matrices and areas, is reflected on the Annex namely in the following criteria: D1C1[13];D2C2[14]; D2C3[15] ; D8C2[16]; D9C1[17] and D10C4[18] . Also for the monitoring of D5, the Decision establishes that monitoring beyond coastal waters may not be necessary due to low risk, such as in cases where the threshold values are achieved in coastal waters. Finally, the selection of species and habitats under Themes *'Species groups of marine birds, mammals, reptiles, fish and cephalopods'*, *'Pelagic habitats'* and *'Benthic habitats'* must be based on a number of scientific criteria, namely, that the species or habitat is relevant for the assessment of a key anthropogenic pressure to which the ecosystem component is exposed, being sensitive to the pressure and exposed to it in the assessment area. This means that the selection of species and habitats should, itself, be based on a risk assessment exercise.

Chapter 7, of the Commission Staff Working Document on determination of good environmental status and its links to assessments and the setting of environmental targets (EC, 2020c), explicitly deals, with "risk-based approaches", identifying a number of elements for the implementation of the Directive that would benefit from the use of a risk-based approach. Such list (mostly selection of criteria and parameters and criteria elements) mirrors the guidance provided in the EC Decision but does not provide further guidance or methodology on how to implement such a risk-based approach.

It stands out, therefore, that despite multiple references suggesting the use of a risk-based approach within the

[10] Pressure criteria that are not primary criteria are: D2C2, D7C1 and D10C3
[11] Impact criteria of pressure descriptors that are not secondary are: D3C1, D5C2, D5C5
[12] Commission Regulation (EC) No 1881/2006 of 19 of December 2006
[13] Species of birds, mammals, reptiles and non-commercially-exploited species of fish and cephalopods, which are at risk from incidental by-catch in the region or subregion
[14] Species to be assessed under D2C2 must include the species on the list of Invasive Alien Species, a list which is to be updated regularly based on species or genus specific risk assessments
[15] Species groups and broad habitats type that are at risk from non-indigenous species, selected from those used for Descriptors 1 and 6
[16] Species and habitats which are at risk from contaminants
[17] MS may decide to not consider contaminants from Regulation (EC) No 1881/2006 where justified on the basis of a risk assessment
[18] Species of birds, mammals, reptiles, fish or invertebrates which are at risk from litter

MSFD, EC Decisions on GES, and MSFD CIS guidance documents, a methodological framework to address risk in the MSFD is lacking.

It is also worth mentioning that a risk-based approach offers a process to address the increasingly important concept of cumulative impacts of human activities in the marine environment (see for instance in section 2.3 how the bow-tie model can help understand how different pressures create cumulative risks and impacts).

Indeed, since uncertainty is an integral part of environmental management, the use of risk assessment procedures plays an explicit and important role in a number of environmental regulations and associated guidance documents. Examples include the REACH - Registration, Evaluation, Authorisation and Restriction Of Chemicals Regulation[19] , the Environmental Liability Directive[20] , the Regulation on the prevention and management of the introduction and spread of invasive alien species[21] , the Water Framework Directive (WFD)[22] and the Floods Directive[23] , amongst others[24]. The subsequent chapters aim to provide a common understanding on how to more broadly and explicitly address risk **within the MSFD**, both conceptually and in practice.

2.2. Key concepts

For risk to exist there must be an interaction between the anthropogenic activity and the ecosystem elements, in most cases, through a pathway (Figure 3).

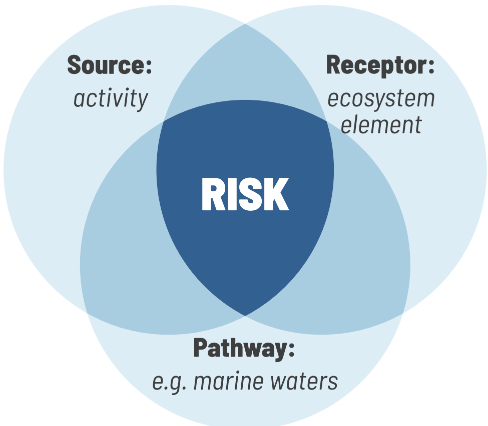


Figure 3. Source - Receptor - Pathway conceptual model

Accounting for the pathways (e.g., marine waters, food webs) means that the area potentially affected by a given activity may be far larger than the distribution of the activity itself, hence the importance of considering the overlap between the **pressure** (which incorporates the pathways) or pressures, resulting from an activity, and the ecosystem element, rather than the activity and the ecosystem element (see example on Figure 4). If one considers the case of collisions between vessels and marine mammals, the spatial overlap between the pressure (collision) and the ecosystem element potentially at risk is equivalent to the spatial overlap between the activity (shipping) and that ecosystem element; but if one considers the potential impact of noise, as it propagates underwater, the distribution of the pressure (input of noise) will be far greater than the distribution of the activity (shipping) and result in greater spatial overlap and therefore risk.

[19] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006
[20] Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004
[21] Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014
[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000
[23] Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007
[24] See for example also: N2K 2017. *Overview of the potential interactions and impacts of activities apart from fishing on marine habitats and species protected under the EU Habitats Directive* and N2K 2015. *Overview of the potential interactions and impacts of commercial fishing methods on marine habitats and species protected under the EU Habitats Directive.*

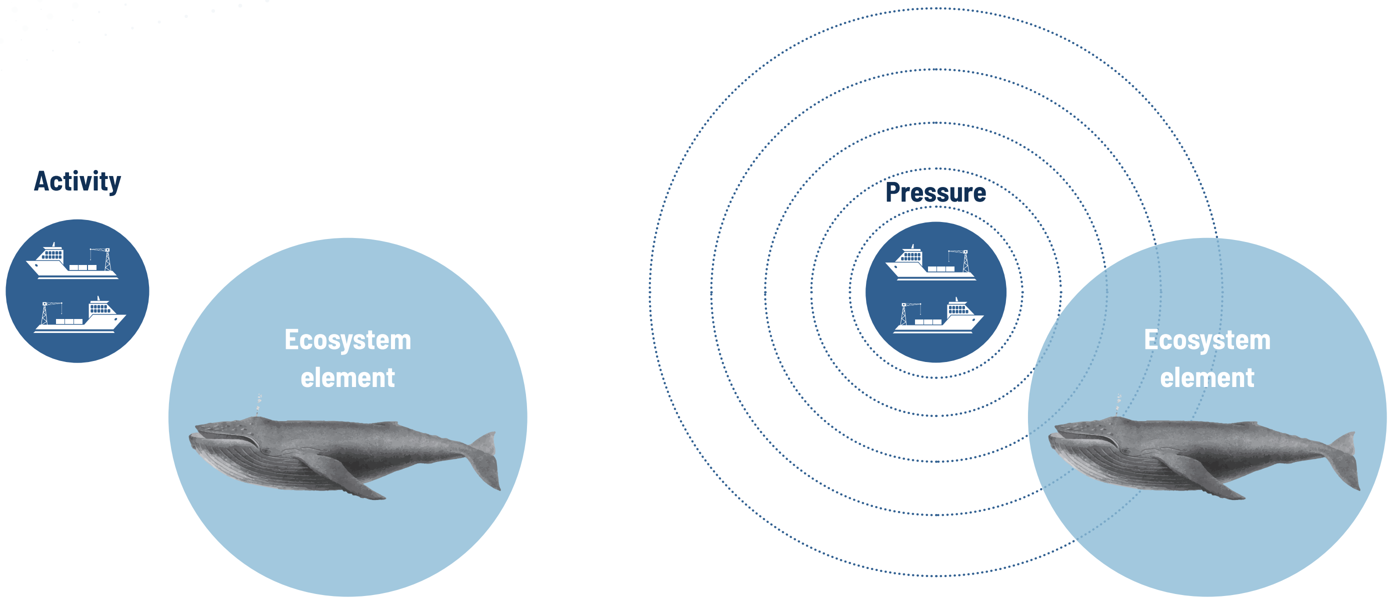


Figure 4. Conceptual illustration of how considering the activity rather than the pressure may affect risk assessment. In this example, we illustrate the difference between considering the activity (shipping) and the pressure (input of noise) to assess risk to a whale population

In cumulative impact assessments, for each activity (e.g. fishing), multiple pressures with different footprints (e.g., by-catch, noise and abrasion), and which may affect different ecosystem elements (e.g., seabirds, baleen whales and habitats) need to be considered.

There is, however, no agreed definition of the concept of risk. Some definitions are based on probability or chance; some on undesirable events; and others on uncertainty. A common short definition of risk is that ***risk is the probability of an undesired outcome.*** In 2009, to allow other measures besides probability to express uncertainty, the International Organization for Standardization (ISO) defined risk as the ***effect of uncertainty on management objectives*** (ISO 31000:2009)[25]. For Aven (2012 and 2017), these definitions are not sufficiently precise and the author suggests that risk is best described in terms of both ***consequence*** (to something that it is valued, such as environmental assets) and ***uncertainty*** (probability being a widely used tool). The definition of level of risk, provided in the ISO standard, agrees well with this perspective: *magnitude of a risk, or combination of risks, expressed in terms of the combination of consequences and their likelihood* (ISO 31000:2009).

RISK = CONSEQUENCE X LIKELIHOOD (ISO 31000:2018)

[25] 2009 International Standard on Risk management replaced in 2018 by ISO 31000:2018 (https://www.iso.org/standard/65694.html)

For the US Environmental Protection Agency, risk is the ***chance of harmful effects to human health or ecological systems resulting from exposure to an environmental stressor*** *(any physical, chemical, or biological entity that can induce an adverse response)*[26]. This definition is useful as it draws attention to the elements of risk which have to be defined in order for risk to become an operational concept, i.e., to be assessed: what is at risk (e.g., human health, protected species, and seabed habitats), what is the **consequence** or adverse effect (e.g., mortality, loss of habitat and toxicity) and what is its **likelihood**. Risk assessment is, therefore, the process of evaluating how much and how likely the environment may be adversely affected by the 'stressor'.

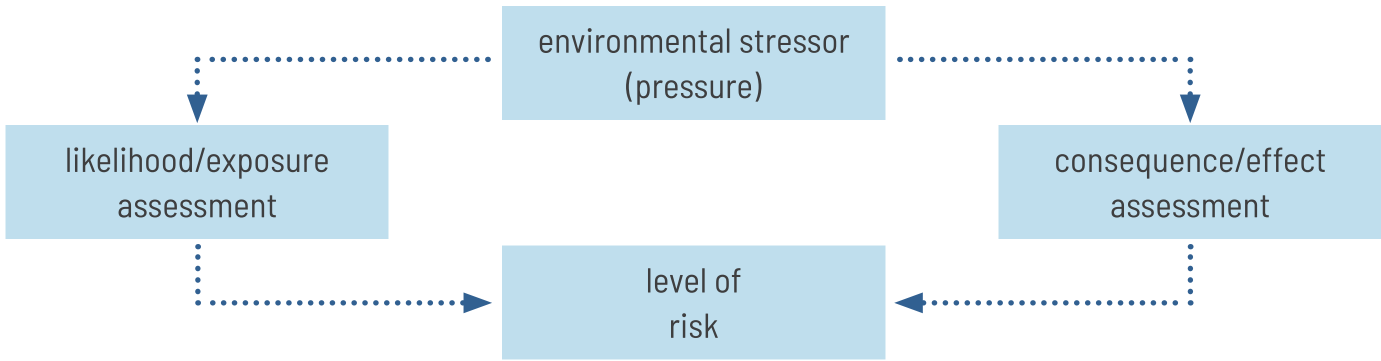


Figure 5. Level of risk resulting from the combination of consequence and likelihood

The qualitative consequence-likelihood (C x L) methodology more commonly applied involves multiplying the scores from ratings of consequence and likelihood to calculate risk scores (Fletcher, 2015). Table 2 depicts a standard four-level system consequence x likelihood **risk matrix.**

Table 2. Consequence x Likelihood matrix (source: Fletcher, 2015)

Consequence		**Likelihood**			
		Remote	Unlikely	Possible	Likely
		1	**2**	**3**	**4**
Minor	**1**	1	2	3	4
Moderate	**2**	2	4	6	8
Major	**3**	3	6	9	12
Extreme	**4**	4	8	12	16

If the relationship between likelihood and consequence is extensively studied and understood, it may be possible to establish a quantitative **dose-response relationship**, or **exposure-response relationship**. Dose-response relationships describe the magnitude of the response of an organism (or population), as a function of exposure (or doses) to a stressor and are usually described by dose-response curves (see Figure 6).

[26] https://www.epa.gov/risk/about-risk-assessment#whatisrisk

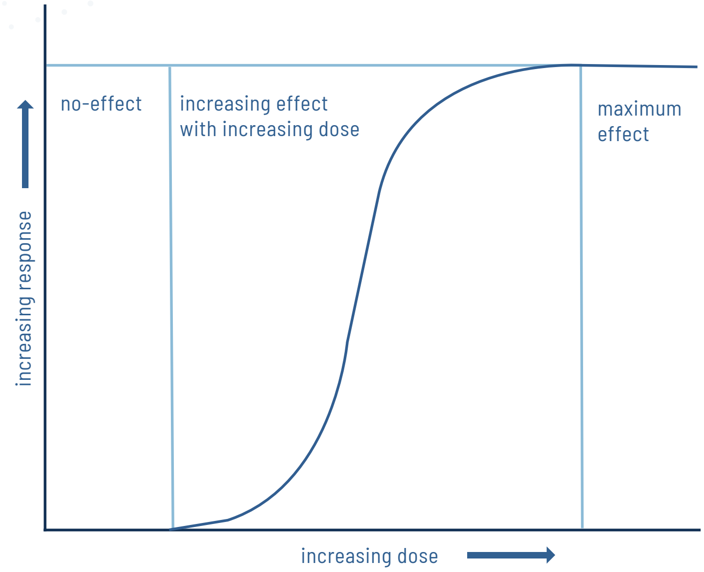


Figure 6. A simple example of a dose (stressor) -response relationship

In this document, based to a great extent on the ISO standard mentioned above, and to ensure greater coherence, risk is mostly described via likelihood and consequence. However, depending on the type of risk being assessed and how it is assessed, other variables/metrics may be more appropriate to characterize risk, such as, *vulnerability*, *sensitivity*, *productivity*, *degree of impact*, *hazard*, *susceptibility* and *exposure*. While such myriad of terms may be confusing at first, all aim to describe either the likelihood of an event/interaction (e.g., exposure, susceptibility) or the consequence of that event/interaction (e.g., sensitivity, degree of impact, hazard), in order to assess risk levels. Given the scope of the MSFD and the multiple pressures and ecosystem elements which must be considered, it is likely inappropriate to suggest the use of a specific and single metric. The suitability of the metrics will depend on the pressure under assessment and how risk will be assessed and, metrics appropriateness can always be questioned (SRA, 2015). Annex I provides a list of definitions in view of clarifying the concepts and terminology most commonly used by managers and researchers engaged in managing or assessing risks. Definitions of risk basic concepts provided are mostly based on the Society for Risk Analysis Glossary[27] and the ISO 31000:2018.

2.3. Risk frameworks within the MSFD: present status

As mentioned above, the determination and assessment of GES, as established by the GES decision, relies to a great extent on existing or yet to be determined thresholds. These thresholds are ideally based on dose-response relationships and indicate values above which risk is deemed high. For exemple, under Descriptor 3, the Maximum Sustainable Yield values used to assess the status of the comercially-exploited species, are values above which the risk from fishing is considered high, Also to assess both D8 and D9, thresholds have been established for a number of contaminants through quantitative toxicological risk assessments. Thresholds at which pressures switch from having negligible to moderate risk, and moderate to severe risk, are, however, difficult to establish as the relationship between impact and pressure or activity levels is rarely known to a fine degree of detail (Freedman and Kerckhove, 2015) due to both lack of data and knowledge, i.e, uncertainty.

The need to develop risk assessment tools in order to deal with uncertainty and identify priorities, in the marine environment, in a coherent, structured and systematic manner, has been addressed by past and ongoing projects, and initiatives, at the local, national, regional and

[27] http://www.sra.org/risk-analysis-overview/glossary/

international levels. A review of the main outputs of EU funded projects, including VECTORS, ODEMM, DEVOTES and ECAPHRA, as well as examples of risk-based approaches to the management of the marine environment, applied by countries, such as Canada and New Zealand, was carried out within the MISTIC SEAS II project (see MISTIC SEAS II, 2019).

This chapter provides a brief description of the currently most widely used frameworks to address risk in the marine environment within the context of the MSFD: the DAPSI(W)R(M) and the Bow-Tie frameworks.

- **Linkage frameworks**

Linkage frameworks, such as the Source-Pathway-Receptor (SPR), or the Pressure-State-Response (PSR), or its more common derivation, the Drivers-Pressures-State-Impact-Response (DPSIR) conceptual framework aim at establishing the links between human activities, their pressures and consequent impacts allowing policy makers to understand more easily environmental problems (Maxim *et al.*, 2009). Linkage frameworks provide accurate descriptions of linkages (e.g., stressor-receptor or pressure-state) and can be informed by qualitative, quantitative, or expert based assessments, or any combination of these (Knights *et al.* 2014).The DPSIR model has undergone a number of iterations (see Elliot *et al.*, 2017 for a review) leading to multiple definitions of each of its elements and, in particular, of Drivers and Pressures, and State and Impacts, which have been regarded as impacts on natural systems, on human systems and on both.

Figure 6 illustrates the DPSIR framework more widely used within the MSFD context, and also adopted by OSPAR, the **DAPSI(W)R(M)** framework (expanded from Elliot *et al.* 2017), according to which **Drivers** are human needs prompting human **Activities**, which lead to **Pressures**, which may have an actual or potential effect on the ecosystem and cause changes in the **State** of the natural system, that may lead to **Impacts** on human **Welfare** (ecosystem services, goods and benefits). These state changes and associated impacts may lead to the adoption of **Responses**, understood as policy measures, which in the MSFD context include the definition of environmental targets and the adoption of measures which may be directed towards the **A**ctivities, **P**ressures, **S**tate or **I**mpact elements of the framework.

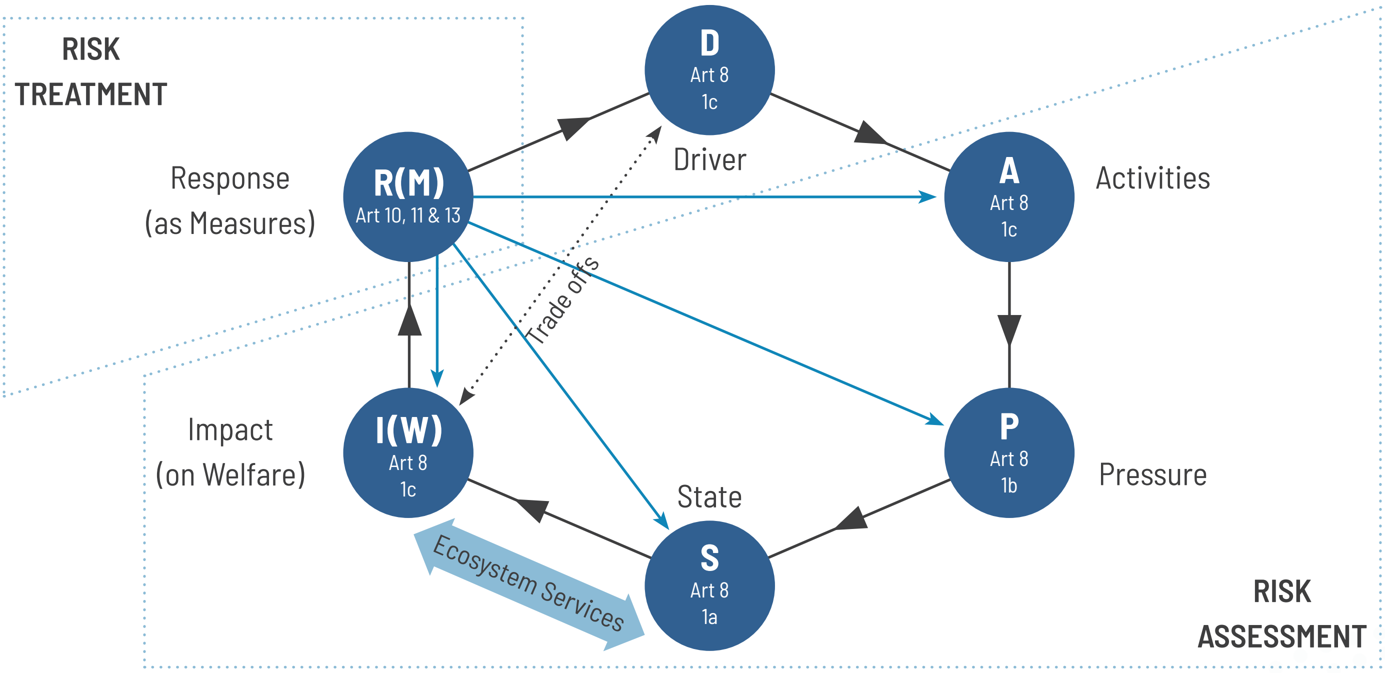


Figure 7. DAPSI(W)R model with each element associated with MSFD relevant articles

The draft MSFD CIS *Background document of the determination of good environmental status and its links to assessments and the setting of environmental targets*, illustrates how the elements of this framework can be closely associated with the different steps of MSFD implementation (also in Figure 7). Accordingly, in the MSFD CIS Guidance document *Reporting on the 2018 update of articles 8, 9 & 10 for the Marine Strategy Framework Directive*, the EC suggests MS to outline the reports to be submitted by in accordance to the DPSIR framework, addressing sequentially **1. Drivers:** uses and human activities of the marine environment – article 8(c) and MSFD Annex Table 2a; **2. Pressures:** on the marine environment – article 8(b), GES Decision Part I and MSFD Annex III Table 2a; **3. State:** of the marine environment - article 8(a), GES Decision Part II and MSFD Annex III Table 1; **4. Impact:** cost of degradation - article 8(c); **5. Response:** environmental targets - article 10.

The DAPSI(W)R(M) model describes the pathway between the activity and the environmental change and is therefore useful to both identify and communicate risk within the MSFD, as well as supporting competent authorities in the identification of measures to prevent or reduce risk. It does not, however, provide a process to characterize the levels of risk associated with each pathway.

- **Bow-Tie model**

The bow-tie model consists of a diagram that allows a simple and visual identification of the causes and consequences of a top-event identified as the incident associated with an existing hazard that, if not prevented or mitigated, can trigger negative effects (Figure 8). The integration of the DPSI(W)R(M) model with the bow-tie model has been suggested to support the identification of prevention, mitigation and recovery measures that can limit the severity of the top event.

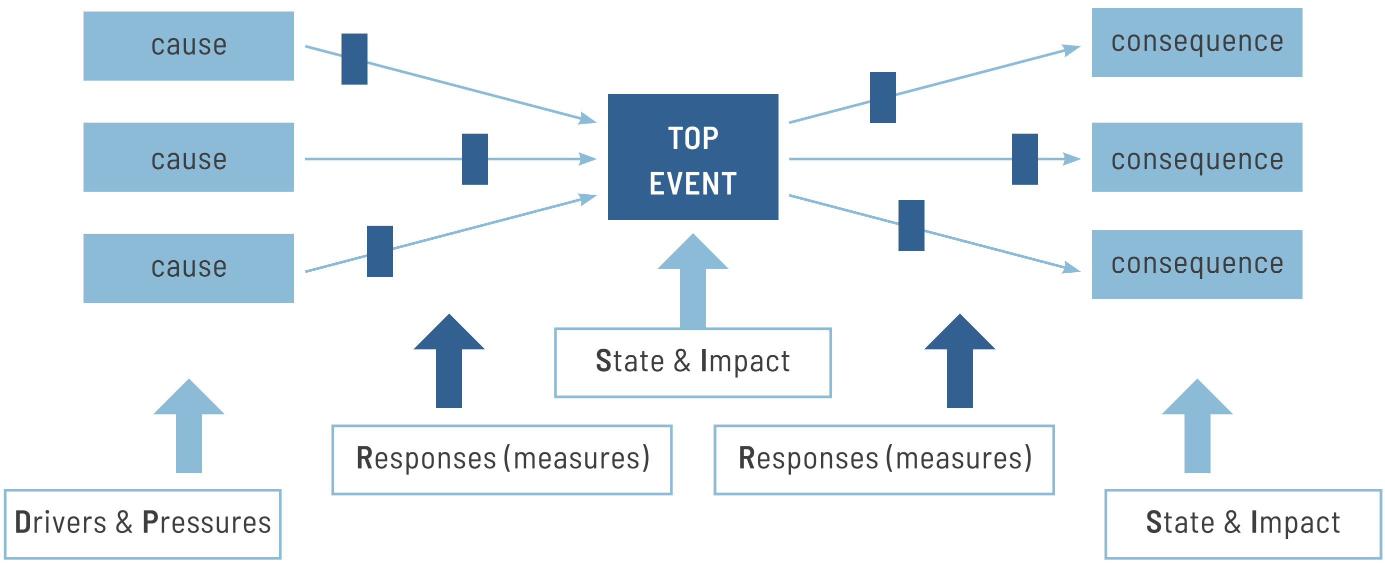


Figure 8. Bow-tie model linked to the DPSI(W)R framework (Elliot *et al.* , 2017)

Within OSPAR, a conceptual modified bow-tie model approach to cumulative effects is being developed for the Ecosystem Assessment Outlook component of the OSPAR Quality Status Report 2023 (OSPAR Agreement 2019-01). It aims to provide an overview of how source-effects pathways, describing the sources of pressure (sectors and activities) and the consequences (effects) on each OSPAR indicator, are interconnected and may act cumulatively (Wood *et al.*, 2019). Case studies to test and describe the practical application of the cumulative effects approach chosen are also being undertaken. In a case study developed by the Netherlands an investigation on the cumulative effects of human activities on the harbour porpoise (OSPAR, 2017[28]) resulted in a schematic overview of the relative importance of each potential effect pathways through which the harbour porpoise population could be affected (see Figure 9). The bold lines indicate a proven relationship that is also, in all probability, relatively important. The relationships shown by thin lines have also been demonstrated but their relative importance is thought to be much less. The dashed lines show relationships that are assumed to exist but which have not been proven to exist or cannot yet be quantified. The thickness of the dashed lines also indicates the relative importance of these relationships. Bycatch of marine mammals has a direct and measurable impact, whereas exposure to impulsive underwater sound will not generally kill an animal directly but may affect its behaviour and, ultimately, its fitness/chances of survival and reproduction. The pressure-effect relationships in the case study are supported by a review of the literature and the knowledge base within OSPAR committees and thematic work streams. The pressures suspected to have a strong impact on the harbour porpoise population in the North Sea and for which enough quantitative information is available to estimate the effect on the population are: fisheries bycatch (increased mortality), impulsive underwater sound (displacement/habitat loss), and pollutants (reduced fitness/impaired reproduction).

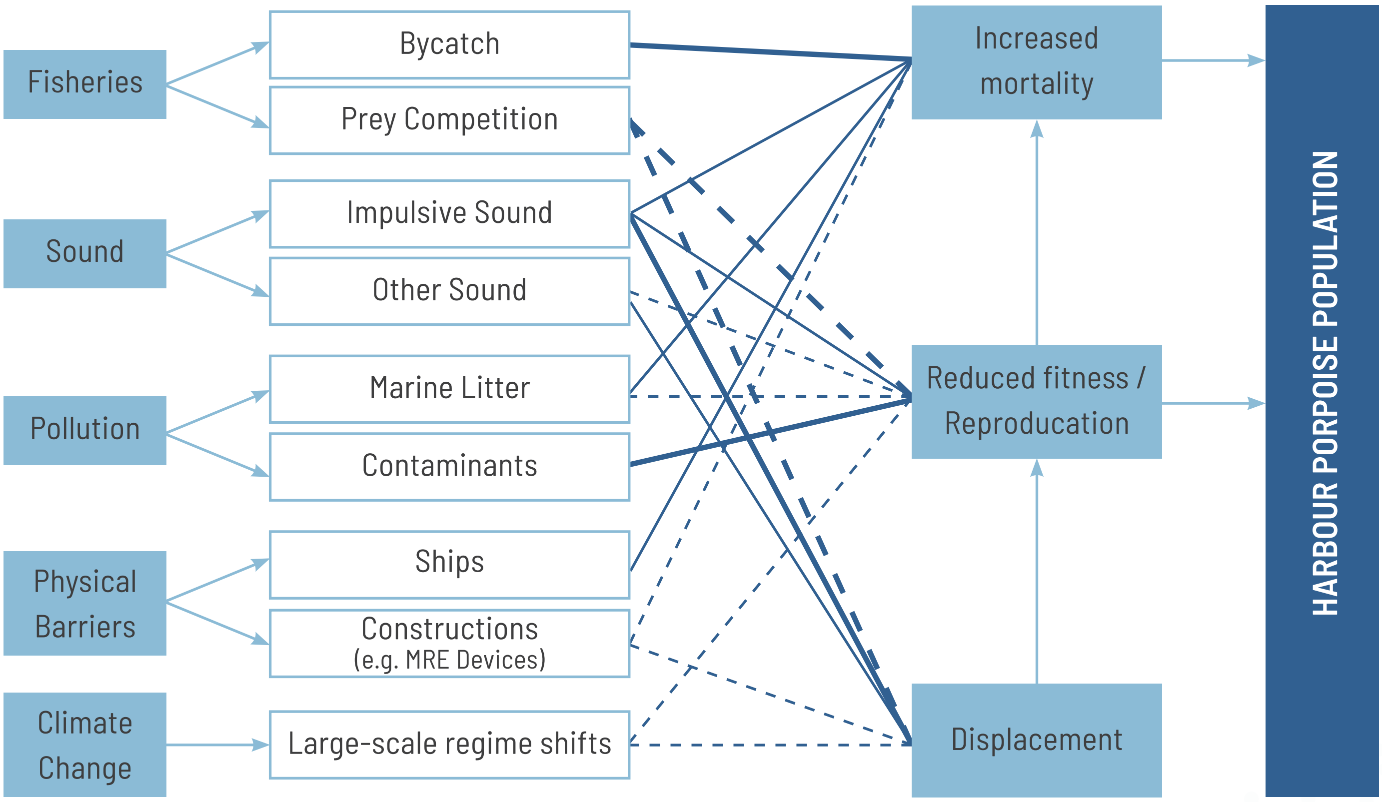


Figure 9. Potential effect pathways affecting the harbour porpoise (source: OSPAR, 2017)

[28]https://oap.ospar.org/en/ospar-assessments/intermediate-assessment-2017/chapter-6-ecosystem-assessment-outlook-developing-approach-cumul/

OSPAR approach to cumulative risk is a noteworthy step towards the implementation of a risk-based ecosystem approach to the management of the marine environment. It allows priorities to be set for monitoring, by distinguishing between those relationships that are better understood, from those for which knowledge and data available are still lacking, as well as, for establishing measures addressing main pressures or impacts. However, the assessment of these relationships, is based on literature reviews and expert input, and therefore the criteria used to assess whether a pressure or activity is more or less relevant are not clear, thus compromising consistency across indicators, over time and in other regions.

While useful to identify risk pathways and to illustrate how risk may be reduced via measures to prevent or mitigate it, the bow-tie framework, as the DAPSI(W)R(M), does not provide a method to assess the risk levels associated with different pathways, and is therefore insufficient to assist MSFD competent authorities in setting priorities. Both the DAPSI(W)R(M) and the bow-tie frameworks must therefore be incorporated in a wider framework addressing risk that covers also the need to estimate and communicate risk levels. The risk framework described in the next chapter provides a process that includes steps not only to identify and address risk through measures but also to assess levels of risk.

2.4. Reaching a common understanding

A standardized approach to risk management was developed in 2009 by the ISO with the publication of an International Standard on Risk management establishing the principles and guidelines to make risk management effective (ISO 31000:2009, replaced by ISO 31000:2018). As in other fields, a broader use of risk-based management and assessments would benefit from consistency in approaches and terminology. Compliance with the ISO standard definitions and process has been suggested as a good way to ensure that consistency (Fletcher, 2015).

According to the ISO 31000, the process of **risk management** implies establishing the context, assessing risk (**risk assessment**), treating it (**risk treatment**) and ensuring regular monitoring (Figure 10). This standard defines risk assessment as the overall process of (i) **risk identification** (ii) **risk analysis** and (iii) **risk evaluation.**

For each of the risk assessment steps different models and methodologies may be adopted, with varying levels of complexity, depending on the data and resources

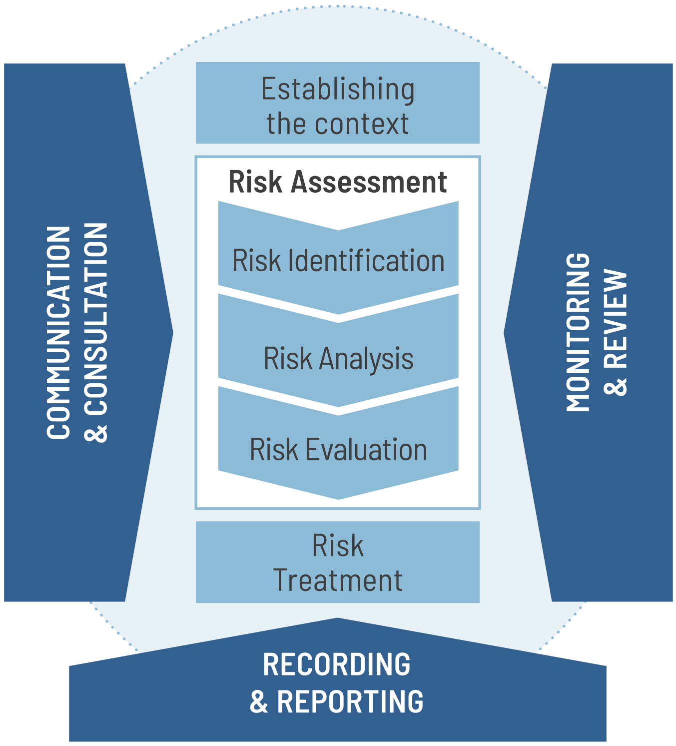


Figure 10. Risk management framework according to the ISO 31000:2009

available. The ISO 31000 is therefore not a substitute for the several current assessments in use for environmental management, which will, instead, inform the different steps of the risk management process. ISO 31010, a supporting standard for ISO 31000, provides guidance on the selection and application of a number of techniques to assess risk.

Risk assessment plays, therefore, a central role in risk management providing a science based process to manage the widespread uncertainty within the field of marine environment management, and to improve communication between scientists, competent authorities and civil society. Currently, the lack of sufficient data and/or methodologies to assess the criteria established by the GES decision leads to a wide use of expert judgment in the assessments of certain descriptors. While such assessments play an important role, and data-based results should probably always be subject to expert interpretation, expert judgements are not always clear or well communicated, potentially leading to a lack of consistency across descriptors and MS, and over time, as noted in the 1st cycle of implementation.

It follows that the risk management cycle, set by the ISO 31000: 2018, matches closely the MSFD cycle and the requirements set by articles 8, 9, 10, 11 and 13, allowing the process of risk management to be easily integrated by MS in marine strategies (Figure 11). The data and information required to update articles 8 and 9 may be used to assess risk, and risk treatment is foreseen in the MSFD via the definition of ET (art. 10), MoP (art.11) and PoM (art.13).

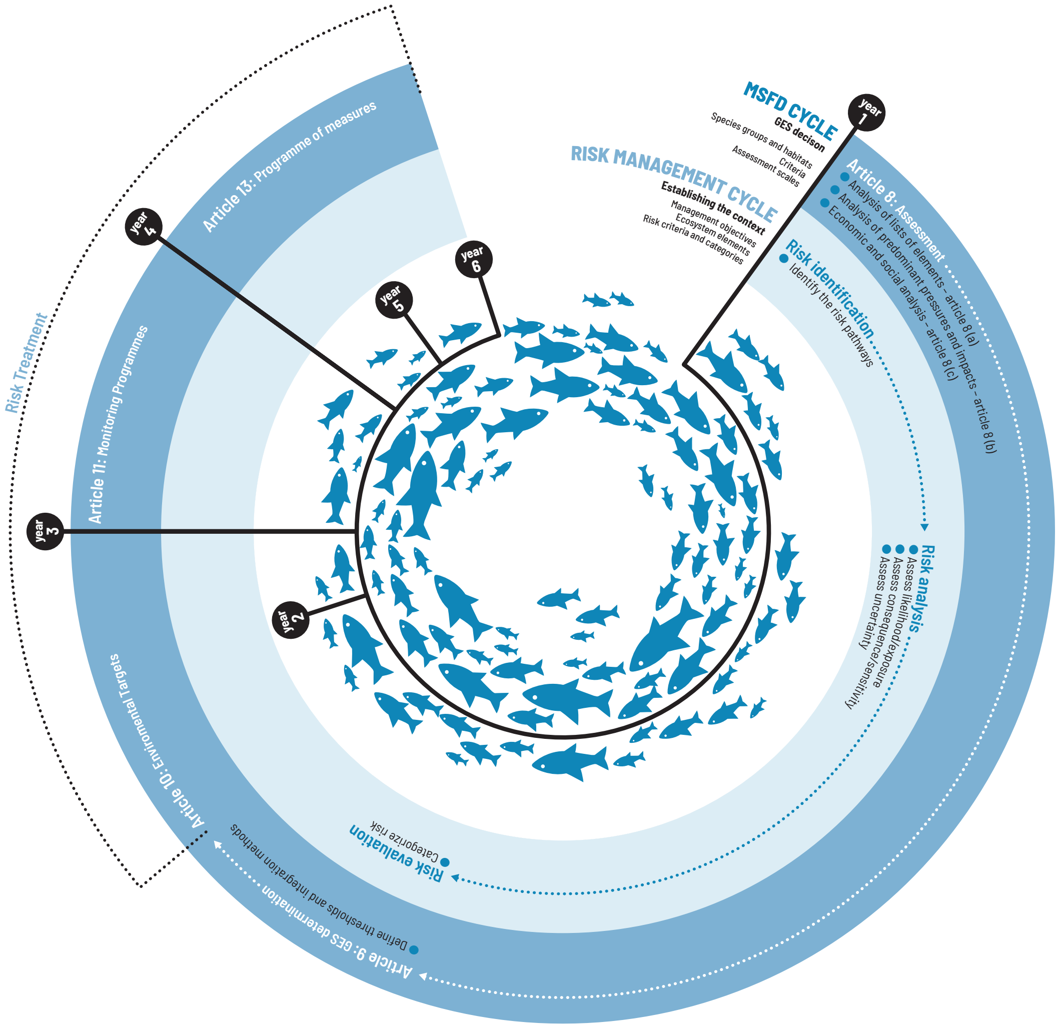


Figure 11. The Marine Strategies and the Risk cycles: the risk management cycle may be performed step-by-step, alongside the implementation of each article of MSFD, providing MS with solutions to deal with the scientific uncertainties arising due to the current incomplete knowledge of marine ecosystems

Figure 12, provides a decision-tree to guide competent authorities about when to perform a risk assessment in the development of marine strategies, namely, towards the implementation of **article 8**, when GES is not known due to the lack of methodologies, thresholds or data, of **article 9**: determination of GES, and also of **articles 10, 11 and 13**. The risk framework steps described in the next chapter provide further guidance regarding the selection of relevant ecosystem elements and criteria to assess GES and thus to an improved implementation of the GES decision.

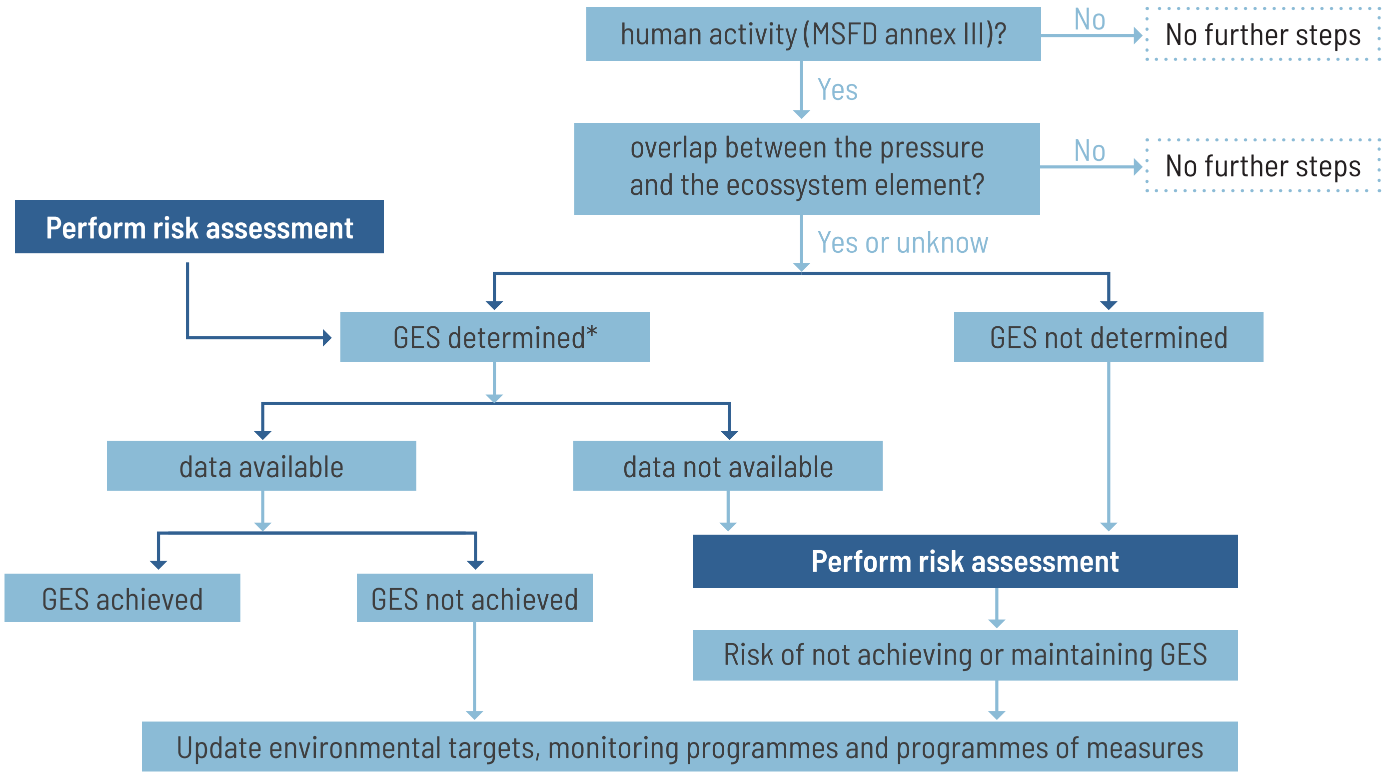


Figure 12. Decision-tree for competent authorities regarding the use of risk assessment

A risk-based approach should be adopted to determine GES, but also to deal with the lack of data when GES has been determined at the (sub)regional level. Risk assessment will assist competent authorities to set priorities in a transparent way considering the higher levels of risk identified, and set ET, and subsequent MoP and PoM, accordingly, towards an effective implementation of the MSFD.

3. DEVELOPING A RISK FRAMEWORK TO REACH GOOD ENVIRONMENTAL STATUS

3.1. A framework to manage risk within the MSFD

A framework to address risk in the marine environment, within the MSFD, is presented below (Figure 13). It is based in the ISO 31000:2018 and it aims to provide a clear, straightforward and transparent working method to address risk and enable an informed and priority-based decision process that results in MoP and PMe fit for purpose, using existing knowledge and data, and the available resources. The proposed methodology provides a process to be undertaken step-by-step according to the scheme shown in Figure 13.

STEP 1	**Risk Context**	• **Define:** - Management objectives - Ecosystem elements - Assessment scale - Risk assessment parameters and categories
STEP 2	**Risk Identification**	• **Identify:** - Drivers-Activities-Pressures-State Change pathways
STEP 3	**Risk Analysis**	• **Assess:** - Likelihood/Exposure and Consequence/ Sensitivity - Uncertainty
STEP 4	**Risk Evaluation**	• **Categorize:** - Level of risk (high, medium, low)
STEP 5	**Risk Treatment**	• Review (**based on risk priorities**): - Environmental targets (art. 10) - Monitoring programme (art. 11) - Programme of Measures (art. 13)

Figure 13. Framework to manage risk within the MSFD context

By focusing on the interaction between a pressure and an ecosystem element in an area, the methodology aims at tackling the interactions assessed as most likely to affect GES. Its steps may be applied to select species, set criteria thresholds, to determine GES but also to assess marine waters, when such assessment is not possible via the assessment methods proposed by the GES Decision (either because thresholds have not been established, GES has not been determined at the level of the marine region or sub-region or there is not sufficient data to assess it). The process may therefore be applied iteratively to answer different needs and focusing on different steps in each iteration.

3.2. STEP 1 - Establishing the context: what risk will be assessed and how?

In this step the objectives and process of the subsequent risk assessment must be made clear. Since the Decision (EU) 2017/848 provides criteria to assess each descriptor, as well as guidance on how to select the ecosystem elements that should be assessed and at what scale, it provides the basis to establish the context. This exercise cannot be overlooked as it provides the backbone to the process, describing what is going to be assessed and how.

In this step, the management objectives, ecosystem elements, assessment scale and assessment parameters must be identified to answer the following questions:

1.1. What are the management objectives that may be at risk?

The criteria established by Decision (EU) 2017/848 to assess GES provide the basis for the definition of the management objectives. If GES has been determined for a particular pressure or ecosystem element, the achievement of GES as determined, may be the management objective which may be at risk. If GES has not yet been determined then the management objective may initially be based on the qualitative description of GES Decision criteria. As thresholds are established and GES determined through increasingly data-rich risk assessments, management objectives will be updated accordingly.

As stated above, however, the methodology described here, may be used to answer different questions. A management objective may relate to a particular adverse effect, from a certain pressure or activity, on a specific ecosystem element (e.g. marine birds, deep sea habitats or sharks), or rather consider a number of adverse effects, from a number of pressures, and more than one ecosystem element. It is important that the management objective is explicit and clear, as that will limit the impact pathways that will have to be considered in the subsequent steps.

1.2. What are the ecosystem elements that may be at risk?

Risk assessment will typically require the selection of ecosystem elements, either species or habitats, which may be affected by the pressures under assessment, a requirement in line with what is requested by the Commission Decision 2017/848 regarding the selection of the criteria elements. Table 3 identifies the criteria elements for status, impact and pressure criteria, by descriptor, as per the Commission Decision to show that for most **state** and **impact** criteria established to assess GES in EC Decision, there is a need to select the ecosystem elements that may be at risk. For pressure criteria D11C1 and D11C2, although the need to select species or habitats is not explicit in the GES Decision, the selection of indicator species that are particularly sensitive to noise has been established as a requirement to assess if GES is achieved or not for D11. Also, for D8 and D9 **pressure** criteria, impact is built into the pressure via the setting of Environmental Quality Standards (D8) and maximum levels allowed (D9) established through risk assessments[29] .

[29] Technical Guidance Document for Risk Assessment in support of Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment for new notified substances.

Table 3. Criteria elements according to the EC Decision 2017/848, per type of criteria and by descriptor (*thresholds required; ** no thresholds required; criteria highlighted in orange do not require selecting ecosystem elements to be assessed directly, or indirectly, via thresholds)

	STATUS		IMPACT		PRESSURE	
	CRITERIA	CRITERIA ELEMENTS	CRITERIA	CRITERIA ELEMENTS	CRITERIA	CRITERIA ELEMENTS
D1	D1C2* D1C3* D1C4* D1C5**	Species of birds, mammals, reptiles fish and cephalopods	D1C1*	Species of birds, mammals, reptiles and non-commercial fish and cephalopods, which are at risk from incidental by-catch	-	-
	D1C6**	Pelagic broad habitats				
D2	-		D2C3*	Species groups and broad habitat types that are at risk from NIS	D2C1*	Newly introduced NIS
					D2C2**	Established NIS *which may have adverse effects on particular species groups or broad habitat types*
D3	D3C2* D3C3*	Commercially-exploited fish and shellfish	D2C1*	Commercially-exploited fish and shellfish	-	-
D4	D4C1* D4C2* D4C3*	Trophic guilds of an ecosystem	-		-	
D5	-	-	D5C2*	Chlorophyll a	D5C1*	Nutrients in the water column
			D5C3*	Harmful algal blooms		
			D5C4*	Photic limit		
			D5C5*	Dissolved oxygen		
			D5C6*	Opportunistic macroalgae		
			D5C7*	Macrophyte communities		
			D5C8*	Macrofaunal communities		
D6	D6C4* D6C5*	Benthic broad habitats	D6C3*	Benthic broad habitat	D6C1** D6C2**	Physical loss and disturbance
D7	-	-	D7C2*	Benthic broad habitat	D7C1**	Hydrographical changes
D8	D8C2*	Species and habitats which are at risk from contaminants	-		D8C1*	Contaminants
	D8C4**	Species of the species groups, and benthic broad habitats			D8C3**	Acute pollution events
D9	-		-		D9C1*	Contaminants
D10	D10C4*	Species of birds, mammals, reptiles, fish or invertebrates at risk from litter	-		D10C1*	Litter
					D10C2*	Micro-litter
					D10C3*	Litter and micro-litter assessed in species from the following groups: *birds, mammals, reptiles, fish or invertebrates*
D11	-		-		D11C1*	Impulsive noise
					D11C2*	Continuous noise

For some impact and pressure criteria (highlighted in orange in Table 3) related to the arrival of new non-indigenous species (D2C1), eutrophication (D5), and litter (D10C1 and D10C2), the potential adverse effects are not limited to species groups or habitats but will likely affect the structure and function of the entire affected area. For D2C1, thresholds have not been agreed but the criterion states that *the number of newly introduced NIS should be minimized, and where possible reduced to zero*. Such strict recommendation follows a precautionary approach, as one single species with invasive behavior may cause significant adverse effects on the ecosystem of the area in which it spreads. For D5, thresholds for both pressure and impact criteria have been established for coastal and territorial waters under the Water Framework Directive[30] , according to a degree of change that goes beyond expected natural variations and that can therefore have wide impacts in the ecosystem. For the D10C1, a provisional threshold has been established not considering harm to the environment due to lack of information and for D10C2 it is also still unclear how to assess harm. For these criteria, when assessing risk of not achieving GES, it may be sufficient, for now, to assess exposure within a certain area and not for specific elements of the ecosystem. Results will allow establishing priorities for monitoring and action considering the precautionary principle.

Both scientific and practical criteria to select the species and habitats under the themes 'Species groups of marine birds, mammals, reptiles, fish and cephalopods', 'Pelagic habitats' and 'Benthic habitats' for the assessment of Descriptors 1 (Biodiversity), 4 (Trophic guilds) and 6 (Seafloor Integrity) established by the 2017 GES Decision, may be applied for the selection of ecosystems elements to assess risk of harm from human activities. Other criteria more adequate and specific for the pressures under assessments may, however, be applied.

The specifications established by the Decision are:

- *Scientific (ecological relevance):*
  - » *Representative of the ecosystem component (species group or broad habitat type), and of ecosystem functioning (e.g., connectivity between habitats and populations, completeness and integrity of essential habitats), being relevant for assessment of state/impacts, such as having a key functional role within the component (e.g., high or specific biodiversity, productivity, trophic link, specific resource or service) or particular life history traits (age and size at breeding, longevity, migratory traits).*
  - » *Relevant for assessment of a key anthropogenic pressure to which the ecosystem component is exposed, being sensitive to the pressure and exposed to it (vulnerable) in the assessment area.*
  - » *Present in sufficient numbers or extent in the assessment area to be able to construct a suitable indicator for assessment[31].*
  - » *The set of species or habitats selected shall cover, as far as possible, the full range of ecological functions of the ecosystem component and the predominant pressures to which the component is subject.*
  - » *If species of species groups are closely associated to a particular broad habitat type they may be included within that habitat type for monitoring and assessment purposes; in such cases, the species shall not be included in the assessment of the species group.*

- *Practical:*
  - » *Monitoring/technical feasibility*
  - » *Monitoring costs.*
  - » *Adequate time series of the data.*

[30] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000
[31] According to the draft Guidance for Assessment under Article 8 of the MSFD, rare or endangered species should not be excluded on this basis, all mammals and reptiles listed in Annex II of the Habitats Directive must be included

The selection of the ecosystem elements via this or another set of criteria (see for e.g. the sensitivity index to select species to assess noise adverse effects proposed in RAGES WP4), is in fact a preliminary risk screening as experts are asked to identify those ecosystem elements most likely to be at risk. The following steps of risk assessment will focus on the selected ecosystem elements.

1.3. What geographical area will be assessed?

The RBA may be applied at different scales: local, national and (sub)regional. MS may apply it in their national waters to support the development and implementation of their marine strategies, or locally focusing on a particular area, identified previously as a risk hot-spot. However, to assess risk at the appropriate scale, it is recommended to apply the RBA to the area ecologically relevant for the ecosystem elements under assessment. Although the Commission Decision (EU) 2017/848 provides guidance regarding the scale at which each criteria should be assessed, the appropriate geographical area for carrying out the risk assessment, will be determined, first, by the management objective and must be discussed with the experts on pressures and on the ecosystem elements that are going to be assessed. The scale agreed will likely be determined by the availability of data, but should consider both ecological and management aspects.

Besides the geographical dimension of the assessment, there is a temporal dimension that needs to be made explicit. Although, it is expected that MS perform the update of marine waters assessments based on data collected in each 6 year cycle, assessing risks may also consider known near future development scenarios. Such exercises are typically performed under strategic environmental assessments, which can therefore be a great tool to promote the integration of the MSFD and the Marine Spatial Planning Directive.

1.4. How will risk be assessed?

To analyse risk two main aspects must be considered: the **likelihood**, of an event, or interaction between the ecosystem element and the pressure (or activity as a proxy), and the **consequence** (of that event or interaction) for the ecosystem element (species, habitats, or other element of the ecosystem). The parameters selected to assess likelihood and consequence will depend, first of all, of the management objective, and then, to a great extent, on the resources, data and knowledge available.

To assess the likelihood of interaction, attributes like temporal and spatial distribution, frequency, extent or intensity of the pressure and the degree of overlap with the ecosystem element may be considered. If pressure data is not available, activity data could be considered as a proxy. To assess consequence, attributes must be selected regarding the ecosystem element characteristics (biological and/or ecological) and the nature of the impacts (Figures 14 and 15). Numerous approaches to assess the sensitivity of receptors (such as birds, fish, mammals and habitats) have been developed, for a variety of management questions. The different approaches fall into three main classes: 1) empirical techniques aimed at specific pressures or activities (e.g., fishing and aggregate dredging), 2) biological traits-based approaches (considering for example: sexual maturity age, fecundity and/or longevity) and 3) evidence-based and/or expert judgement based approaches (Roberts *et al.*, 2010).

The parameters selected will be assessed in the risk analysis step according to categories also defined in this STEP. The definition of these categories plays a central role in risk assessment and relates directly to the type of assessment: qualitative, semi-quantitative or quantitative:

- **Qualitative** approaches are easiest to apply, demanding least resources and skills, but provide the least degree of insight. Likelihood and consequence are determined purely qualitatively;
- **Semi-quantitative** approaches, likelihood and consequence are quantified within ranges or scores, providing a specific, quantitative meaning to terms like 'Low probability';
- **Quantitative** approaches require full quantification, using **dose/response relations**, and directly provide a measure of the consequence, provided that the level of exposure is known, There are therefore the most demanding resources wise (HSE, 2001).

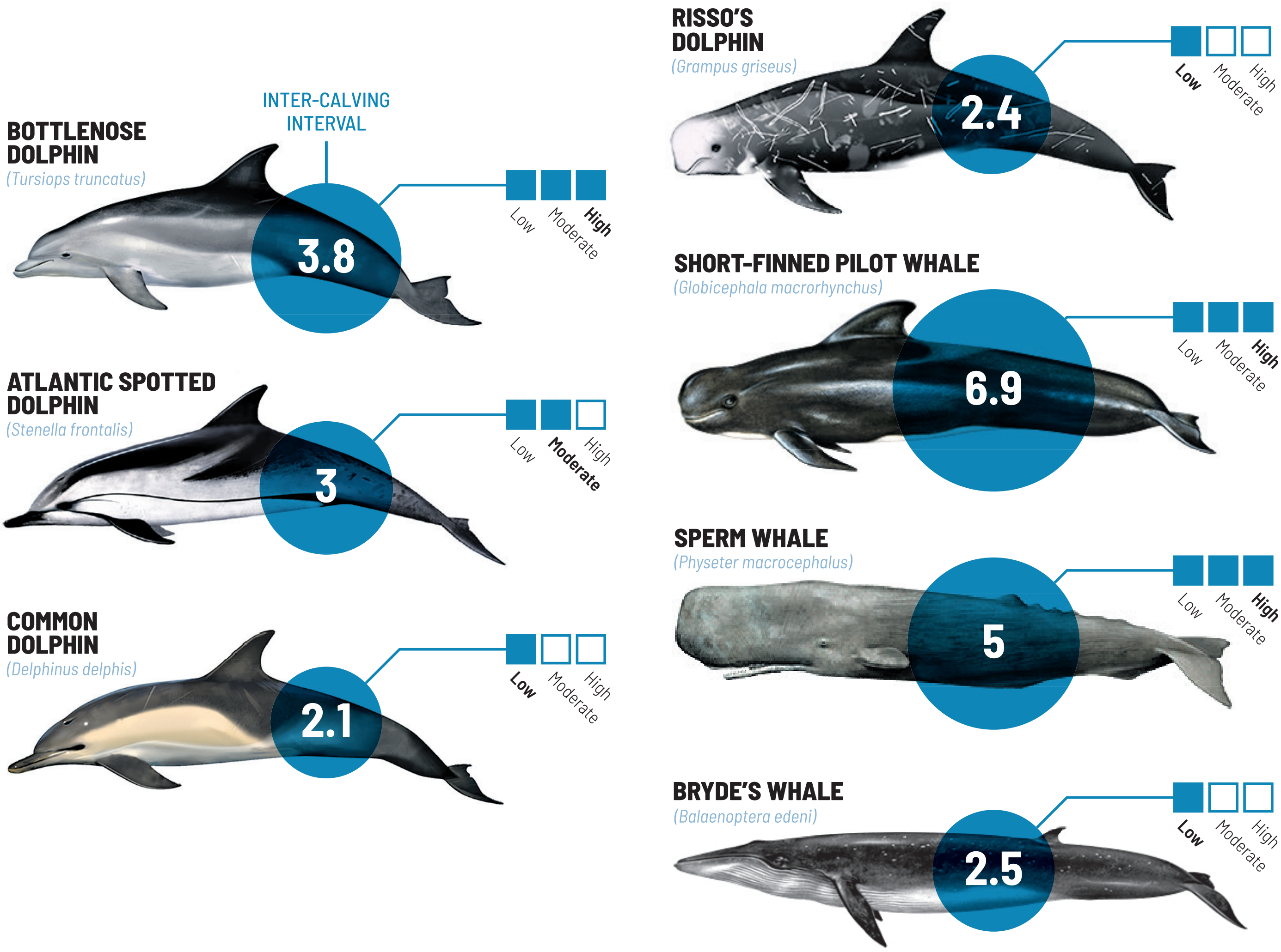


Figure 14. Inter-calving values (Taylor *et al.*, 2007) and related risk categories (Brown *et al.*, 2013) may be used to assess the recovery potential of different cetacean species.

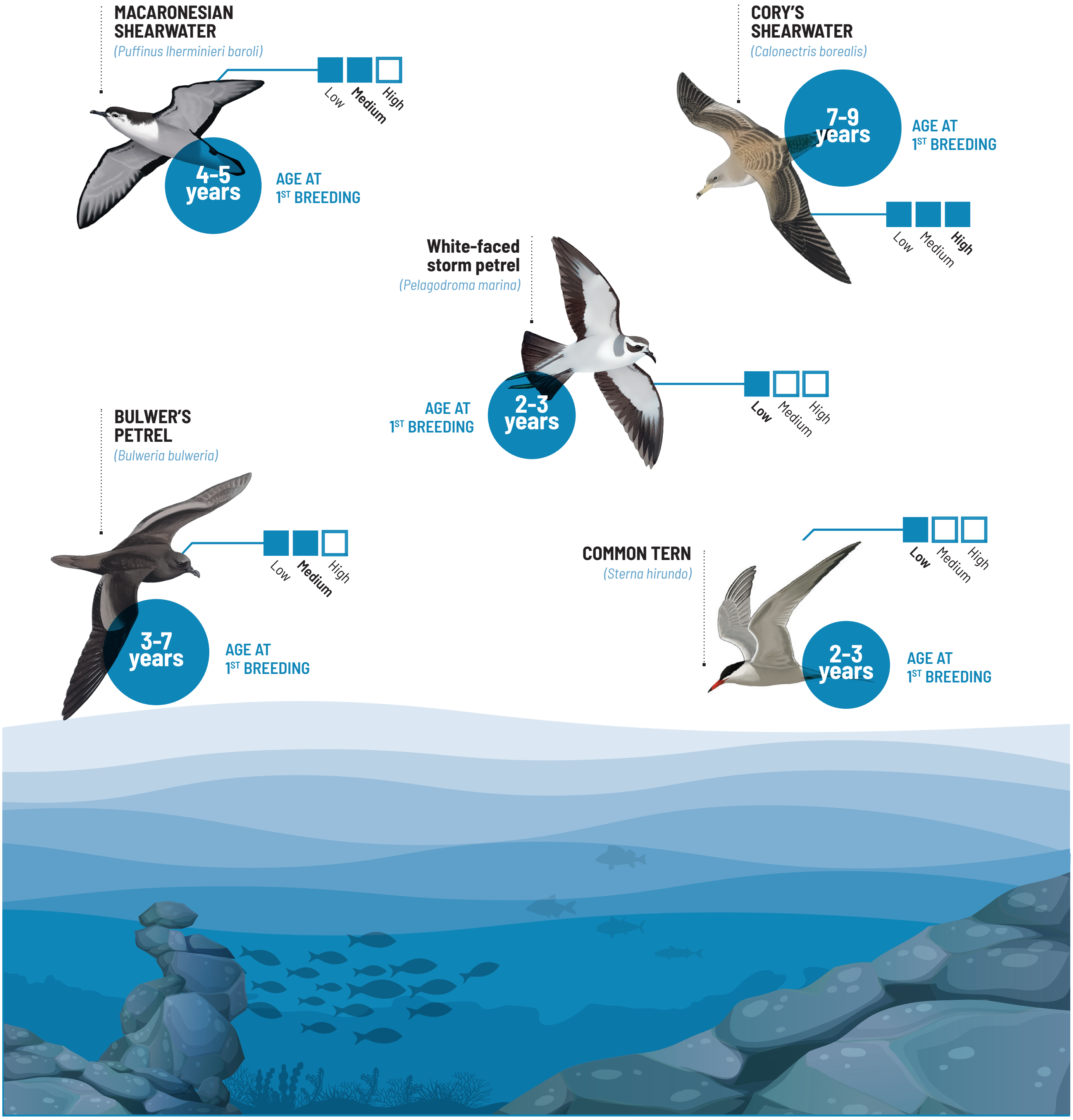


Figure 15. Medium age at first breeding and associated risk categories for seabirds (Rowe 2010) may be used to assess the recovery potential of different seabird species.

The amount of data, knowledge and resources available will therefore greatly affect the type of assessment performed. If enough data is available, a quantitative approach, based on thresholds, may be performed. In such cases, either established thresholds are used (based on literature or legislation) or determined according to the parameters and method agreed in this step. For most pressures, however, such dose-response relationships are not yet established and it has been argued, that due to the uncertainties in the estimates of quantitative approaches the arbitrariness in the numbers produced could potentially be significant and may not justify the level of resources put into it (Aven, 2008). If knowledge and data available, or resources, are clearly insufficient, qualitative approaches may be applied using broader categories (e.g., Low, Medium and High) to characterize both exposure and consequence but semi-quantitative approaches, based on existing data, are preferable to purely qualitative approaches so a clearer definition of categories, and therefore, risk is attained. Exposure or likelihood are more likely to be assessed based on representative measured data and/or modelling, as distribution of activities are usually known and easier to characterize, while consequence is typically associated with higher uncertainties.

Under this step, not only the way likelihood and consequence will be assessed must be defined, but also how overall risk will be evaluated. A simple approach to start evaluating risk is to plot the results of risk analysis (likelihood and consequences scores), in which case, overall risk may be calculated by the Euclidean Distance to the origin and risk categories may be produced by dividing the area of the plot into equal thirds (as in Figure 16).

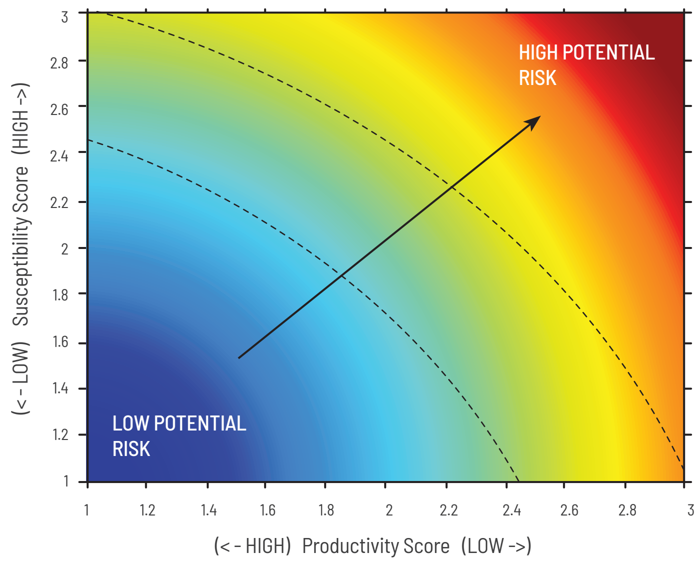


Figure 16. Medium age at first breeding and associated risk categories for seabirds (Rowe 2010) may be used to assess the recovery potential of different seabird species.

The most common method, involves developing a risk evaluation matrix, in which red or darker colours usually describe the combinations of likelihoods and consequences that are not tolerable whereas green or lighter colours designate the tolerable combinations from a policy perception (Cormier & Londsdale, 2020).

...in a nutshell

In this step, competent authorities together with experts, set the scene for the following steps. It is paramount that each question is carefully considered, regardless of the need to review and adjust some elements later in the process. The participation of experts on the pressures as well as on the ecosystem elements being assessed is one of the great benefits of adopting a risk based approach and should be foreseen from the beginning. To gather in the same room experts on different descriptors, pressures and ecosystem elements, and promote the exchange and cross analysis of data and knowledge on activities, pressures and biodiversity, will promote the ecosystem approach at the heart of the MSFD. Experts on risk management and/or assessment may also play an important role in facilitating and guiding discussions, clarifying concepts and building trust. Their presence in the discussions is highly desirable to ensure a common understanding and approach.

Table 4 provides a basic checklist for competent authorities engaging in a risk management process in the context of the MSFD.

Table 4. Step 1 guidance highlights

STEP 1 - ESTABLISHING THE CONTEXT	
Who to involve	• MSFD competent authorities (to coordinate the work, provide resources, establish timeframes) and other relevant competent authorities (e.g., conservation, environmental, energy) • Experts on pressures, activities and on the ecosystem elements (e.g., marine birds, marine fish, marine mammals, habitats) • Experts on risk management and/or assessment (to guide and facilitate the process) and multicriteria decision-making
Level of coordination	• Sub-regional or regional (the selection of the ecosystem elements and of the parameters to analyse risk should be agreed amongst MS experts within the sub-region or region) • National or local (if risk is to be assessed on national waters)
Sources of information and guidance	• EC Decision 2017/848, of 17 May 2017 • Guidance for Assessments Under Article 8 of the MSFD • Literature reviews (to assess available data) • Expert knowledge (to select species and/or habitats, define appropriate scale of assessment and agree on the parameters to be used in risk analysis)
Key outputs	**1. Management objective definition** **2. Geographical areas and timescale to be covered** **3. Ecosystem elements to be assessed** **4. Parameters to assess likelihood and consequence**

3.3. STEP 2 - Risk identification: what are the risk pathways?

Risk identification involves listing the risk sources and their potential consequences to the receptor, which may prevent the achievement of the management objectives. Considering the management objective, all relevant pressures (unless the management objective concerns a specific pressure, e.g. underwater noise or physical disturbance), and existing human activities behind those pressures, should be identified (Knights *et al.*, 2015) in view of developing a comprehensive list of risks pathways via historical data, theoretical analysis and expert opinions (see pages 48—49 for an illustration of multiple risk sources to different ecosystem elements). From such list, the most relevant pressures or activities may be selected to be analysed in the subsequent steps. This prioritization step may consider the data availability and the certainty regarding the pathways identified.

Under RAGES WP4, focused on assessing risk from underwater noise, difficulty in addressing STEPS 1 and 2 separately was reported, and it was suggested that the selection of metrics under STEP 1 already had to take into account the pathways being considered. Indeed if the management objective is such, that only one pressure resulting from a particular maritime activity will be considered and analysed, STEP 2 may be of little relevance. Yet, it is encouraged here, as laying down clearly the maritime pathway being considered, including which adverse effects are being taken into account, will be valuable to communicate to the public, both the process and its the outcomes.

The terms: pressures, activities, drivers, and sectors, have been used with ambiguity and often defined/ used differently, namely in the first version of Annex III of the MSFD. Work by MS experts of the working group DIKE and the EC, led to the replacement of this Annex by Commission Directive (EU) 2017/845, which lays in Table 2, a list of “Anthropogenic pressures, uses and human activities in or affecting the marine environment”. To avoid a multiplication of lists, Table 2 will be used but given its relevance, the pressure “Death or injury by collision” was added to Annex III list of pressures in the scope of this report. Tables 5 and 6 below provide the list of activities and pressures to be considered.

Table 5. List of “drivers” and activities, to be considered, as in Directive (EU) 2017/845

Drivers	Activities
Extraction of living resources	• Fish and shellfish harvesting (professional, recreational) • Fish and shellfish processing • Marine plant harvesting • Hunting and collecting for other purposes
Transport	• Transport infrastructure (e.g., ports and marinas) • Transport — shipping • Transport — air • Transport — land
Production of energy	• Renewable energy generation (wind, wave and tidal power), including infrastructure • Non-renewable energy generation • Transmission of electricity and communications (cables

>> Cont.

>> Cont.

Production of living resources	• Aquaculture (marine, including infrastructure) • Aquaculture (freshwater) • Agriculture • Forestry
Extraction of non-living resources	• Extraction of minerals (rock, metal ores, gravel, sand, shell) • Extraction of oil and gas, including infrastructure • Extraction of salt • Extraction of water
Urban and industrial uses	• Urban uses • Industrial uses • Waste treatment and disposal
Tourism and leisure	• Tourism and leisure infrastructure • Tourism and leisure activities
Security and defence	• Military operations
Education and research	• Research, survey and educational activities
Physical restructuring of rivers, coastline or seabed	• Land claim • Canalisation and other watercourse modifications • Coastal defence and flood protection • Offshore structures (other than for oil/gas/renewables) • Restructuring of seabed morphology, including dredging and depositing of materials

Table 6. List of pressures adapted from Directive (EU) 2017/845

Pressures	• Disturbance of species due to human presence
	• Extraction of, or mortality/injury to, wild species (by commercial and recreational fishing)
	• Death or injury by collision[1]
	• Input or spread of NIS
	• Input of microbial pathogens
	• Input of genetically modified species and translocation of native species
	• Loss of, or change to, natural biological communities due to production of animal or plant species
	• Physical disturbance to seabed
	• Physical loss
	• Changes to hydrological conditions
	• Input of nutrients – diffuse and point sources, atmospheric deposition
	• Input of organic matter – diffuse and point sources
	• Input of other substances – diffuse and point sources, atmospheric deposition and acute events (referred in this report as input of contaminants)
	• Input of litter
	• Input of anthropogenic sound (impulsive and continuous)
	• Input of other forms of energy
	• Input of water

[1] Added to the list of pressures of Annex III.

Pressures correspond to the mechanisms leading to state changes, so in order to inform risk analysis and attain effective risk management responses, it is essential to understand the interactive patterns between pressures and state (Smith *et al.*, 2016). DEVOTES conceptual model (Smith *et al.*, 2014) has refined pressure-state change links allowing a good understanding of the mechanisms underlying known impact chains. This model enables the identification, at an individual level, of both immediate lethal effects, and sub-lethal responses (physical, chemical or biological damage caused by the pressure whereby the organism survives but its performance is compromised), as well as the potential resulting effects at the individual and population level (and consequently at community and ecosystem levels). Impacts that are deleterious for the individual, but not directly lethal, become relevant to populations if many individuals are affected (Kuhn *et al.*, 2015). Such exercise can support the Risk Analysis process that follows Risk Identification and, therefore, the use of a simplified DEVOTES model (Figure 17), focusing on the identification of lethal and sub-lethal effects at the individual level and subsequent effects at the population level, is suggested.

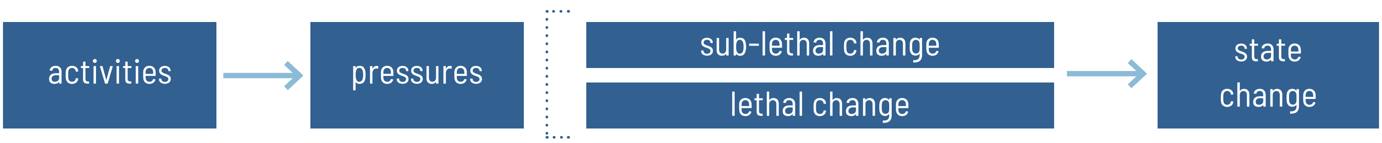


Figure 17. Simplified DEVOTES conceptual model (adapted from Smith *et al.*, 2014).

As DAPSIR frameworks over-simplify the "real world" by addressing each chain separately and therefore, omitting the connections between different pressures and their potential to act in a synergic or antagonistic manner (Smith *et al.*, 2014), the bow-tie models may be used in parallel to identify cumulative effects. Once activities, pressures, lethal and sub-lethal changes at the individual level and potential state changes at the population level, are identified, OSPAR conceptual modified bow-tie model or other approaches to indirect and to cumulative effects may be applied to provide an overview of how these are interconnected and may act cumulatively.

Table 7 provides the basic checklist for competent authorities to put this step in practice.

Table 7. Step 2 guidance highlights

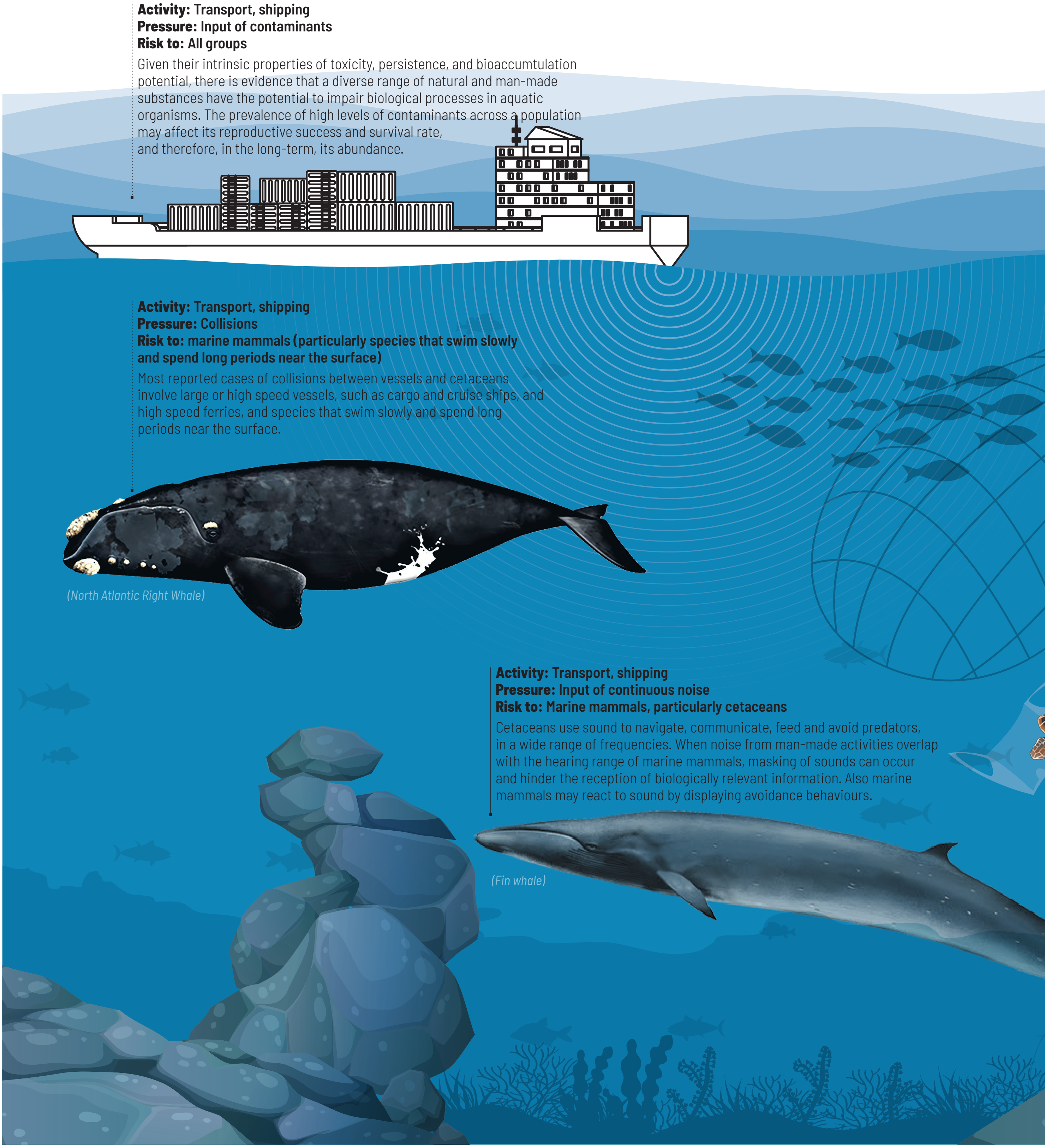
STEP 2 - RISK IDENTIFICATION	
Who to involve	•Competent authorities (to provide resources, establish timeframes and to assure regulation compliance) •Experts on pressures, activities and on the ecosystem elements (e.g., marine birds, mammals, fishes and habitats) •Experts on risk management and/or assessment (to guide and facilitate the process) and multicriteria decision
Level of coordination	•Member State level: identification of existing activities and pressures •Sub-regional level: selection of most relevant pressure
Sources of information	•Commission Directive (EU) 2017/845 •Article 8 reports (identification of MSFD relevant activities and pressures at MS level) •Maritime Spatial Plans •Literature reviews (to develop risk pathways) •Existing linkage frameworks (e.g. ODEMM, Teixeira *et al.*, 2018) •Expert knowledge (to develop risk pathways and select the most relevant pressures)
Key outputs	**•Member State level: identification of existing activities and pressures** **•Sub-regional level: selection of most relevant pressures**

Prioritizing species and risk pathways might involve the use of scoring systems or multicriteria decision-making. Authorities must ensure that relevant experts in the field are included in the process, and that good practice are applied, such as to include an explicit treatment of uncertainties in the process.

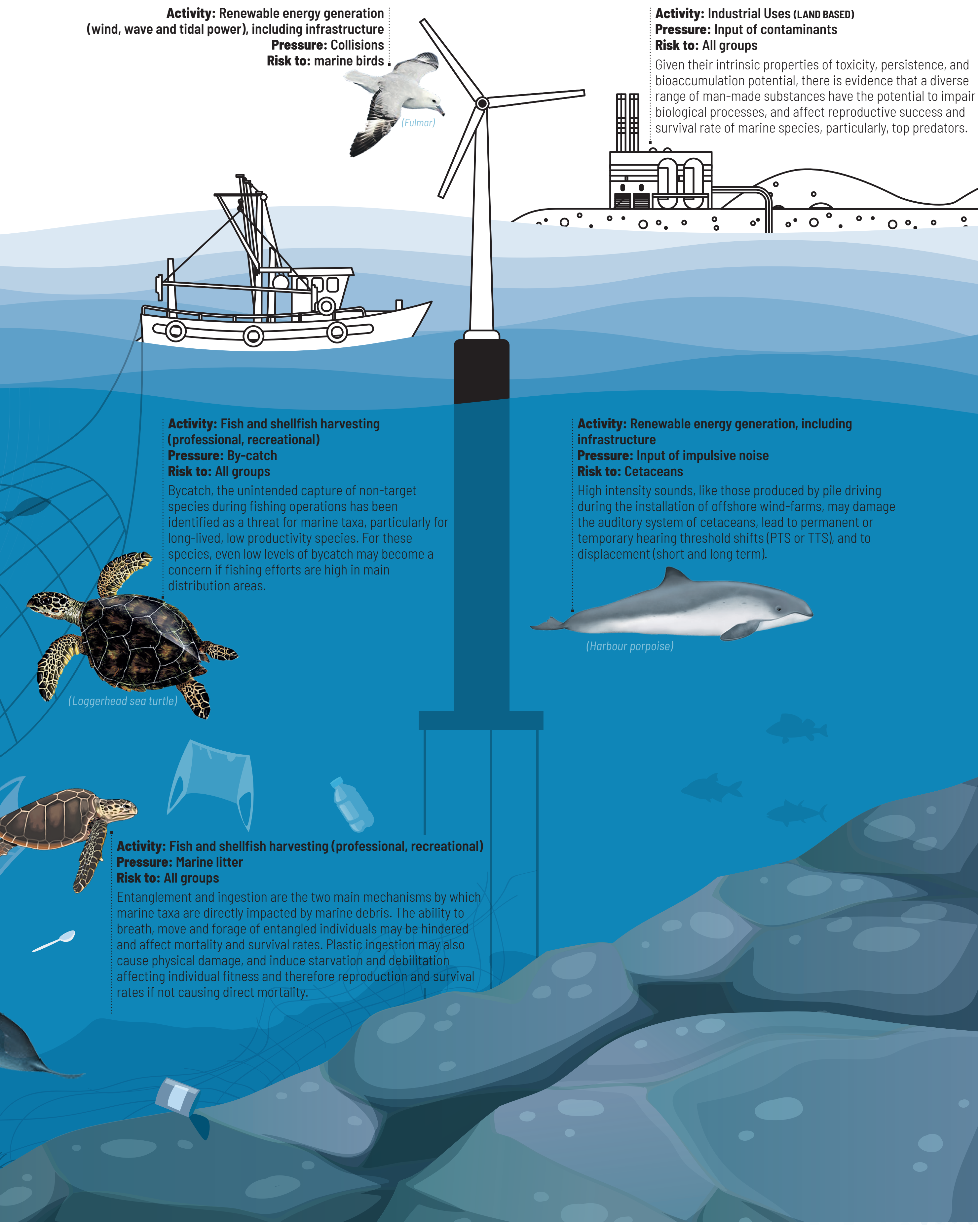
Figure 18. Illustration of potential risk sources to different groups of species

Risk identification: making a list of risk sources

For the US Environmental Protection Agency, risk is the chance of harmful effects to human health or ecological systems resulting from exposure to an environmental stressor (*any physical, chemical, or biological entity that can induce an adverse response*).



Source: US Environmental Protection Agency


Activity: Renewable energy generation (wind, wave and tidal power), including infrastructure
Pressure: Collisions
Risk to: marine birds
(Fulmar)
Activity: Industrial Uses (LAND BASED)
Pressure: Input of contaminants
Risk to: All groups
Given their intrinsic properties of toxicity, persistence, and bioaccumulation potential, there is evidence that a diverse range of man-made substances have the potential to impair biological processes, and affect reproductive success and survival rate of marine species, particularly, top predators.
Activity: Fish and shellfish harvesting (professional, recreational)
Pressure: By-catch
Risk to: All groups
Bycatch, the unintended capture of non-target species during fishing operations has been identified as a threat for marine taxa, particularly for long-lived, low productivity species. For these species, even low levels of bycatch may become a concern if fishing efforts are high in main distribution areas.
Activity: Renewable energy generation, including infrastructure
Pressure: Input of impulsive noise
Risk to: Cetaceans
High intensity sounds, like those produced by pile driving during the installation of offshore wind-farms, may damage the auditory system of cetaceans, lead to permanent or temporary hearing threshold shifts (PTS or TTS), and to displacement (short and long term).
(Harbour porpoise)
(Loggerhead sea turtle)
Activity: Fish and shellfish harvesting (professional, recreational)
Pressure: Marine litter
Risk to: All groups
Entanglement and ingestion are the two main mechanisms by which marine taxa are directly impacted by marine debris. The ability to breath, move and forage of entangled individuals may be hindered and affect mortality and survival rates. Plastic ingestion may also cause physical damage, and induce starvation and debilitation affecting individual fitness and therefore reproduction and survival rates if not causing direct mortality.

3.4. STEP 3 - Risk analysis: how likely and severe?

Risk analysis is the actual determination, qualitatively or (semi)quantitatively, of likelihood and consequence, providing an assessment of the interactions identified previously and creating the basis for risk evaluation (Robinson *et al.*, 2013). In this step, the parameters selected in STEP 1 to assess likelihood and consequence are estimated, or scored according to the categories also defined previously.

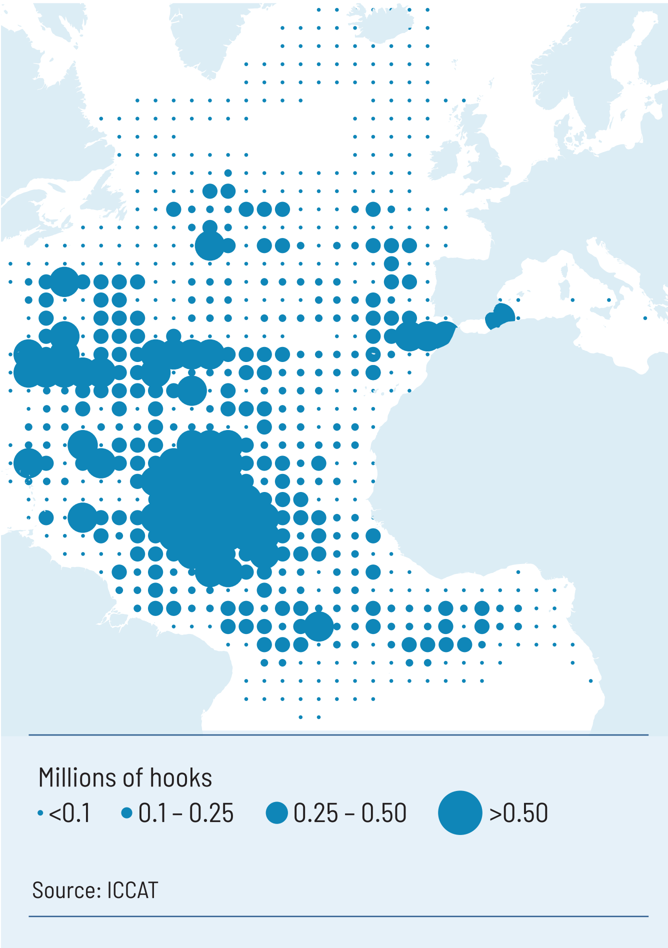


Figure 19. Pelagic longline-fishing effort in January 2019 (adapted from Tuck *et al.*, 2011): example of an analysis of the spatial and temporal distribution and intensity of an activity (fishing) to start assessing exposure of seabirds to bycatch.

Usually, the spatial, temporal distribution and/or intensity of the relevant anthropogenic activities (see Figure 19), and associated pressure(s), whenever possible, are characterized, at first, and the resulting overlap with the ecosystem elements under assessment (if applicable) estimated.

The magnitude of the adverse effects considering the demographic, biological and/or ecological characteristics of the target groups is assessed qualitatively or semi quantitatively, unless a quantitative approach is possible and dose-response relationships or other method to quantify the adverse effects from a given pressure on the ecosystem elements under assessment are available. If applying a qualitative analysis experts should be provided with available literature and enough time to discuss and reach consensus providing a rationale to each score attributed. In some cases the uncertainties regarding become unacceptably high. The methodologies implemented in these cases will likely need to be limited to identifying the emission sources in order to identify where exposures could be minimised. In other words, when uncertainty on potential effects is such that it cannot be even qualitatively assessed, exposure may be used as a proxy for risk.

The ISO 31010, which supports ISO 31000, mentions a useful concept to be applied at the beginning of risk analysis: the **preliminary analysis**. Under such preliminary analysis, risks may be again screened in *order to identify the most significant risks, or to exclude less significant or minor risks from further analysis* based on criteria defined in the context (ISO 31010). The purpose is to ensure that resources will be focussed on the most important risks though care should be taken not to screen out low risks which occur frequently and have a significant cumulative effect.

Under the MISTIC SEAS II project, as despite monitoring efforts, the environmental status of most species can not yet be assessed, neither at the archipelago or subregional level, due to lack of sufficient data to detect trends (see Saavedra et al., 2018), the risk of anthropogenic pressures affecting population abundance such that its long-term viability may be compromised was assessed based on expert assessment in Machico Workshop. Experts performed the risk analysis, considering a number of parameters to estimate exposure[32] and sensitivity[33] indices, for the pressures identified as most relevant previously in a workshop at Faial, (MISTIC SEAS II, 2019).

Analysing likelihood and consequence, may be achieved by developing risk scenarios. In the face of uncertainty, such scenarios may consider different current or future situations, both for the ecosystem state as for the pressure level, and also consider different levels or types of controls that may be adopted to prevent or mitigate risk, an exercise especially useful to support risk evaluation and treatment.

As uncertainty is inherent to risk assessment, a critical element of risk analysis is the **confidence assessment**. The confidence analysis informs about the amount and degree of certainty on the background knowledge and data used, an analysis crucial to identify knowledge gaps and research priorities. It may therefore trigger further monitoring programs, measures and procedures among other actions (Cormier *et al.*, 2017; Stelzenmüller *et al.*, 2020; Stephenson *et al.*, 2019) and help prioritize actions under STEP 5.

Confidence may be estimated on a qualitative or quantitative basis via statistical analysis of the data and/or the results.

An example of qualitative confidence categories that can guide the confidence assessment is provided in Table 8 but additional categories to evaluate not only data and knowledge availability but the methodologies used or the final assessment with regard to its adequacy and completeness may be adopted (see also OSPAR QSR 2023 Guidance Document[34]).

[32]Selected parameters to assess exposure in MISTIC SEAS II: spatial overlap (area of overlap between the pressure and the ecosytem elements), temporal overlap (fraction of the year in which the pressure overlaps with the ecosystem elements), intensity (effort, density, amount or strength of the pressure), management effect (effectiveness of current management measures to mitigate impacts)
[33]Selected parameters to assess sensitivity in MISTIC SEAS II: resistance (acute change - levels of mortality when interaction between the pressure and ecosystem element occurs; chronic change - potential severity of sub-lethal effects; vulnerability to other pressures - likelihood to suffer cumulative effects) and recovery potential (for cetaceans: oldest reproducing female; inter-calving interval; genetic isolation; conservation status).
[34]Agreement 2019-02

Table 8. Confidence categories based on the uncertainty categories definitions [in O. M *et al.* (2015), based in categories outlined in Therriault and Herborg (2008) and Therriault *et al.* (2011)].

Confidence category	Value	Literature	Description
Very high	1	**Extensive**	Extensive scientific information; or peer-reviewed information; *or* data specific to the location; *or* supported by long-term datasets
High	2	**Substantial**	Substantial scientific information; *or* non-peer-reviewed information; *or* data specific to the region; *or* supported by recent data (within the last 10 years) or research
Moderate	3	**Moderate**	Moderate level of information; *or* first hand, non systematic observations, *or* data with more than 10 years from the area of interest; *or* data from comparable regions
Low	4	**Limited**	Limited information; *or* based on third-party observational information or circumstantial evidence
Very low	5	**Little or none**	Little or no information; based on general knowledge

Table 9 provides the basic checklist for this STEP.

Table 9. Step 3 guidance highlights

STEP 3 - RISK ANALYSIS	
Who to involve	• MSFD competent authorities (to coordinate the work) and other relevant competent authorities (e.g. conservation, environmental, energy) • Experts on pressures and on the ecosystem elements (e.g. marine birds, habitats, marine mammals) • Experts on risk management and/or assessment (to guide and facilitate the process)
Level of coordination	• Sub-regional or regional
Sources of information	• Monitoring Programmes • MS article 8 reports • Literature reviews (to support exposure/likelihood and consequence/sensitivity assessment) • Expert knowledge (to support likelihood/exposure and consequence/sensitivity assessment)
Available methodologies	• Qualitative • Semi-quantitative • Quantitative

3.5. STEP 4 – Risk evaluation: is the risk acceptable or not?

Risk evaluation involves comparing estimated levels of risk with risk criteria defined when the context was established, in order to determine the significance of the level and type of risk (ISO 31010:2009). Up to this STEP, risk is described in terms of likelihood and magnitude of consequences. Qualifiers such as acceptable, severe, harmful, serious or significant are not used in the identification and analysis of the risk (Cormier & Londsdale, 2020). The qualifiers of risk, will be attributed in this step considering the risk criteria, i.e., the combination of likelihoods and consequences, to deliver an idea of the combinations that would be acceptable or not as a matter of policy. These risk criteria should already be established in STEP 1 but may need to be revisited at this stage as risks are better understood.

Figure 20 illustrates an example of how overall risk from different pressures could sit on an evaluation matrix (based on qualitative categories). Without the colours, the matrix would be an independent risk analysis of likelihoods and consequences, it is the colour scheme that translates the combination of likelihoods and consequences into a "priority action plan".

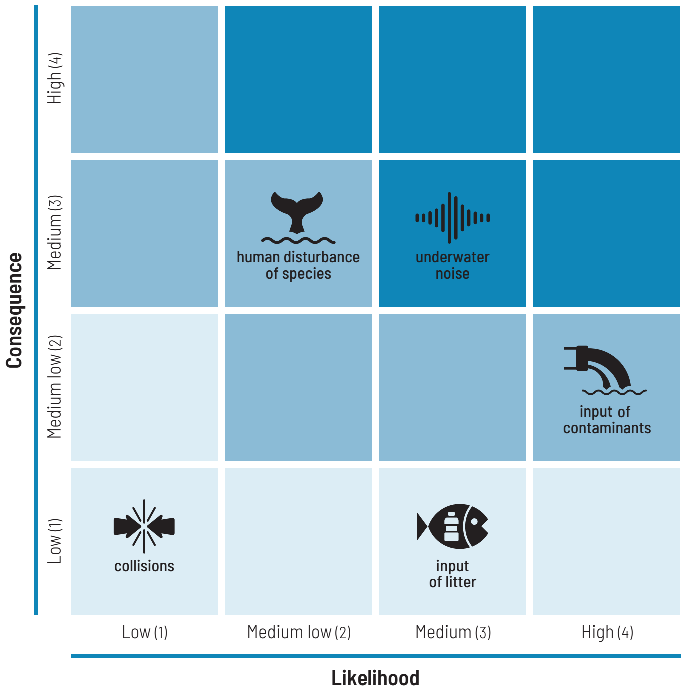


Figure 20. Ilustration of relative overall risk results from different pressures to marine mammals (for illustrative purposes only).

If higher numbers of categories (qualitative or semi-quantitative) were developed to assess likelihood and consequence, greater resolution may be attained, but functionally most matrices will provide the same information at this step: risks that are not of concern, those of some concern, and those of great concern. If risk analysis was purely quantitative, and a single threshold defined, evaluation will be as simple as evaluating whether a given measurement exceeds a predetermined value (in which case the risk will need to consider for treatment). This is the evaluation scheme foreseen in the GES Decision.

The risk evaluation involves also a decision as to whether or not a risk should be treated, the priorities for treatment and the number and types of pathways that must be addressed and this must take into consideration the understanding of risk obtained during risk analysis, but also the costs and benefits of implementing measures, as per MSFD article 13(3), and other policy considerations, including public perceptions of risk.

Combining risk and confidence levels can help to set priorities transparently: for instance, for similar risk levels, higher confidence could trigger higher priorities. For these higher priorities, risk treatment is likely essential whatever its cost, while for middle levels of risks, costs and benefits, are taken into account, and opportunities balanced against potential consequences, and for the low levels of risk no risk treatment measures are needed.

Table 10. Step 4 guidance highlights

STEP 4 — RISK EVALUATION	
Who to involve	• Competent authorities • Experts on pressures and on the ecosystem elements (e.g., marine birds or seabed habitats) • Experts on risk management and/or assessment (to guide and facilitate the process) • Citizens and NGO
Level of coordination	• Sub-regional or regional
Available methodologies	• Euclidean distance from the origin • Risk matrix • Expert judgment
Key output	**1. Identification of priorities for action**

3.6. STEP 5 - Risk treatment: how will risk be reduced?

Risk treatment, in the MSFD context, may include the revision of the ET, and the subsequent implementation of MoP and PMe (Figure 21). Based on the outputs of the risk evaluation and whether (i) no new measures are needed, (ii) existing measures are adequate, or (iii) new or enhanced measures need to be implemented, the ET are revised and the MoP and PMe adjusted by taking into account the higher levels of risk and confidence level results. For outputs (i) and (ii) and considering the knowledge and data gaps identified, updating the MoP may be sufficient to address uncertainty, while (iii) requires the adoption of measures, via the PMe, to reduce risk. Operational controls to human activities, may include input controls (including spatial and temporal distribution controls) aiming at limiting human activities, or output controls, directed at limiting the pressures resulting from the activities (e.g. technological changes), or both (Cormier *et al.*, 2019). MSFD Annex VI provides a list of types of measures that MS should consider when devising their measures. The bow-tie analysis, is of particular interest to this step, as a controls assessment technique of the prevention (including reduction), mitigation and recovery controls of risk (IEC/ISO 31010). It emphasizes the need to incorporate the causal pathways of risk with an analysis of the controls effectiveness which can be assessed by developing different management scenarios under the risk analysis STEP (Cormier & Londsdale, 2020).

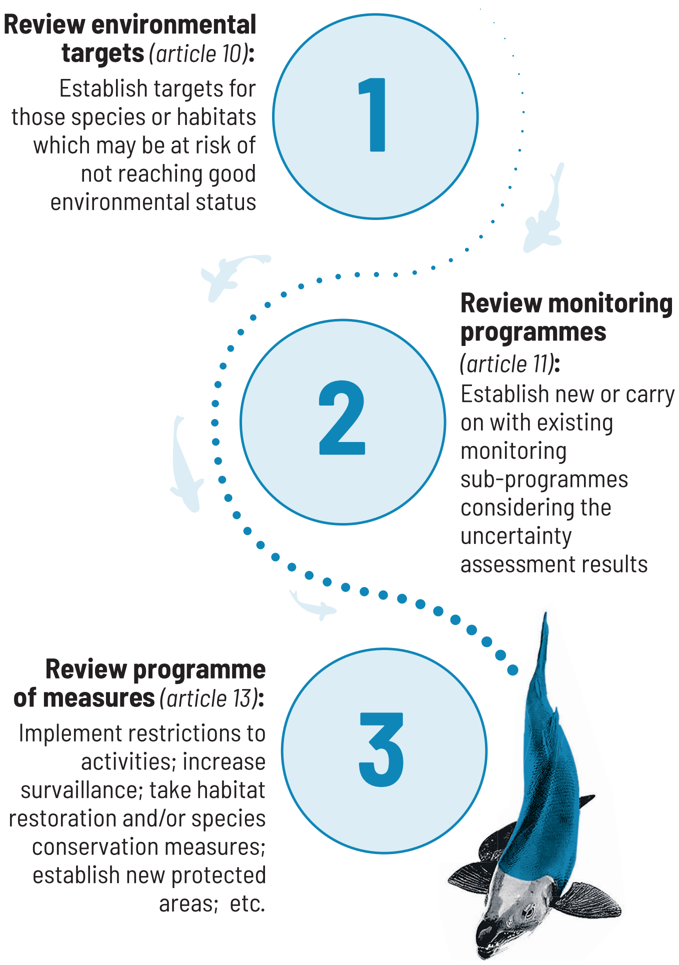
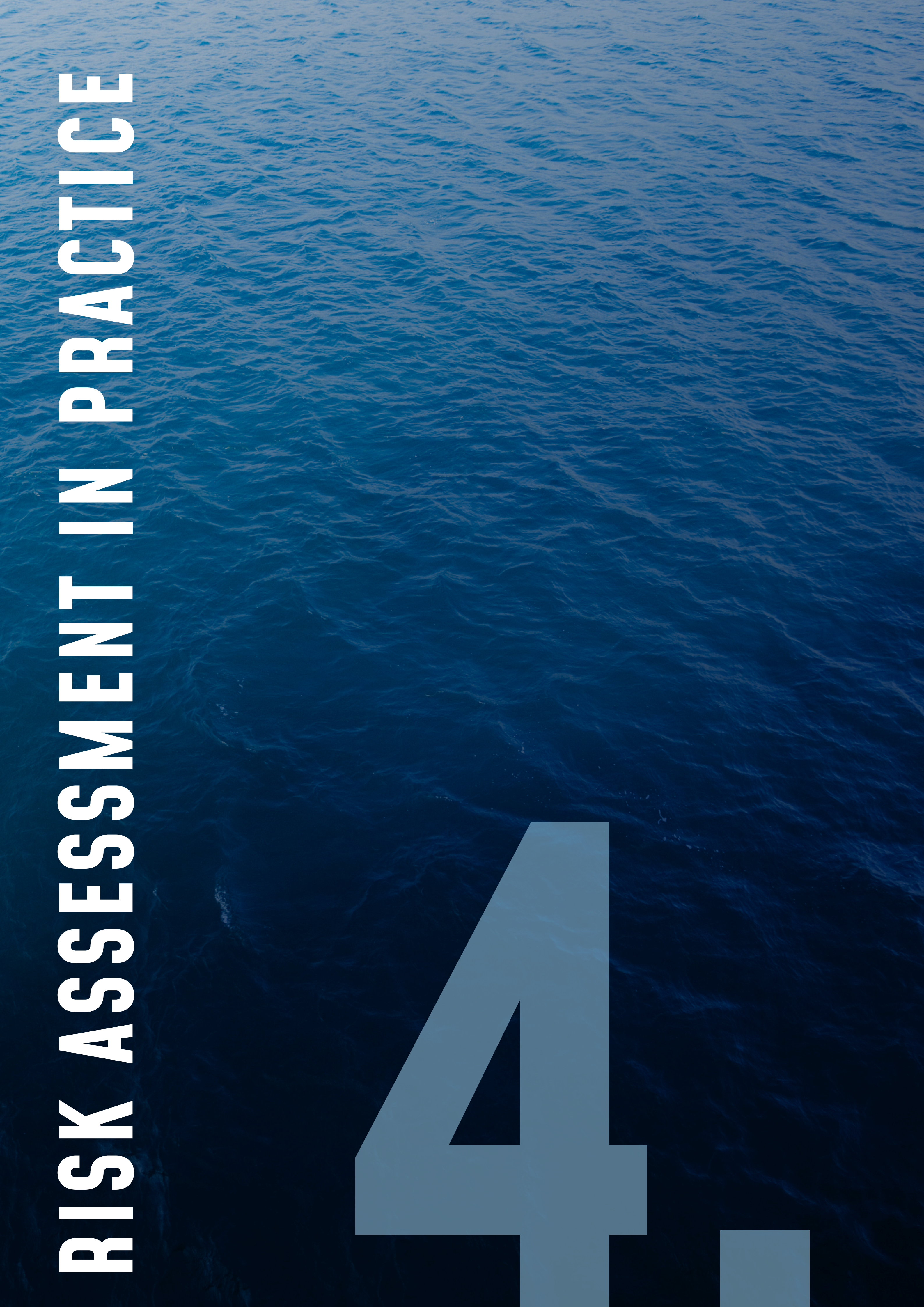


Figure 21. Illustration of the risk treatment process within the MSFD

Table 11. Step 5 guidance highlights

STEP 5 - RISK TREATMENT	
Who to involve	• Competent authorities • Experts on pressures and on the ecosystem elements (e.g., marine birds or seabed habitats) • Economic and social stakeholders
Level of coordination	• Sub-regional or regional
Sources of information	• Risk assessment results • Existing Environmental Targets, Programmes of Measures, and Monitoring programmes • Expert knowledge
Available methodologies	• Bow-ties • DAPSI(W)R(M)
Key outputs	**1. Measures to reduce risks in order to achieve GES** **2. Priorities for R&D (data and knowledge gaps)**



4. RISK ASSESSMENT IN PRACTICE

To test the step-by-step methodology and guidance provided in RAGES Deliverable 2.1, an inception version of this Deliverable, the methodology was applied to two pressure descriptors, **NIS** (D2) and **noise** (D11), pressures for which uncertainties regarding impacts, and also lack of data, remain particularly high. Such exercise provided important feedback and recommendations regarding the methodology and the guidance initially provided, improving the final version of the methodology and the description of each of its steps, within this Deliverable.

Given the great number of institutions and groups engaged in the development and implementation of marine strategies (see RAGES Deliverable 2.2: O'Higgins *et al.*, 2019), reaching a common understanding of concepts and processes is key but also difficult to achieve. The work undertaken both in WP3, focused on NIS, and WP4, focused on underwater noise, demonstrated the importance of following an agreed methodology and terminology when implementing a risk management process in the context of the MSFD, as the incorrect interpretation and use of risk concepts and terms may have a great impact on the analysis of risk and interpretation of results, and thous undermine the goal of supporting an effective implementation of MSFD (and therefore of reaching GES).

Deliverables from **WP3** (Bartilotti *et al.*, 2020a, 2020b and 2020c; Hollatz *et al.*, 2021a and 2021b), and **WP4** (Silva *et al.*, 2021; Verling *et al.*, 2021a and 2021b), are all available[33] for more information, and show how risk approaches may be used to support competent authorities in the identification of priorities for action and research. As in previous exercises (see MISTIC SEAS II, 2019[34]), the effort made, both in WP3 and WP5, to cross data on activities, with data on pressures, and data and knowledge on species and habitats, is highly relevant and useful to identify areas of most concern for competent authorities to focus on, but also to communicate and justify to the public, the ET, MoP and PMe adopted. Further to these deliverables, Deliverable 5.1 (Ducommun *et al.*, 2021) provides some recommendations regarding those primary pressure criteria for which applying a risk approach, given the lack of data and knowledge, may be particularly relevant, namely, for D6 (seafloor integrity).

[33] Here: https://www.msfd.eu/rages/
[34] Here: https://misticseas3.com/pt-pt/page/resultados-mistic-seas-ii

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ANNEX I

Table 12. Risk terminology

RISK TERMS	DEFINITION
DRIVER	An activity or process intended to enhance human welfare (Cooper, 2013)
CONSEQUENCE	effects of an activity with respect to the values defined (human life and health, environment and economic assets), covering the totality of states, events, barriers and outcomes (SRA, 2018)
	outcome of an event affecting objectives (ISO 31000:2009)
EVENT	occurrence or change of a particular set of circumstances (ISO 31000:2009)
EXPOSURE	being subject to a risk source (SRA, 2018)
	contact or co-occurrence of a stressor with a receptor (EPA, 1998)
HAZARD	risk source where the potential consequences relate to harm (SRA, 2018)
LIKELIHOOD	chance of something happening, described using subjective/qualitative or objective/quantitative tools (ISO 31000:2009)
PRESSURE	means by which one driver or more cause or contributes to a change in state (Cooper, 2013)
RECEPTOR	ecological entity exposed to the stressor (EPA, 1998)
RISK	uncertainty about and severity of the consequences of an activity with respect to something that is value (SRA, 2018)
	possibility of an unfortunate occurrence (SRA, 2018)
	the effect of uncertainty on management objectives (ISO 31000:2009)
RISK MANAGEMENT	Coordinated activities to direct and control an organisation with regard to risk (ISO 31000:2009)
SOURCE	element which alone or in combination has the potential to give rise to specified consequences (SRA, 2018)
RESILIENCE	ability of a system to sustain or restore its basec functionality following a risk source or an event (SRA, 2018)
	ability of a receptor to recover from disturbance or stress (Holling, 1973)

RISK TERMS	DEFINITION
RESISTANCE	resistance characteristics indicate whether a receptor can absorb disturbance or stress without changing character (Holling, 1973)
RESPONSE	action taken to prevent or reduce risk
SENSITIVITY	likelihood of change when a pressure is applied to an ecosystem element and is a function of the ability of the feature to tolerate or resist change (resistance) and its ability to recover from impact (resilience) (Tillin &Tyler-Walters, 2014)
	refers to how an organism/population is affected by a particular stressor. Sensitivity measures may include mortality, adverse reproductive effects from exposure to toxics or others
STATE	an attribute or set of attributes of the natural environment that reflect its integrity as regards a specified issue (or change therein) (Cooper, 2013)
SUSCEPTIBILITY	ecological resources are 'susceptible' when they are sensitive to a stressor to which they are, or may be, exposed
UNCERTAINTY	imperfect or incomplete information/knowledge that might affect risk elements. Usually we distinguish between epistemic (lack of knowledge) and stochastic (variation in) uncertainty (SRA, 2018)
VULNERABILITY	degree to which a system is affected by a risk source; it is risk conditional on the occurrence of a risk source; may be interpreted as uncertainty about and severity of the consequences given the occurrence of a risk source (SRA, 2018)

ANNEX II

Table 13. Technical assessment of article 8 (initial assessment) adequacy in the RAGES study area [IE: Ireland; PT: Portugal; ES: Spain; FR: France; N: not reported and IN: inadequate (in red); PA: partially adequate (in yellow); A: adequate (in green)] and of regional coherence in the North-East Atlantic (NEA) region and in the Celtic Seas (ACS) and Bay of Biscay and Iberian Coast (ABI) sub-regions [H: high (in green); M: medium (in yellow); L: low (in red)]. Based on EC, 2014b.

Descriptor		**Initial Assessment**						
		adequacy				**regional coherence**		
		IE	**FR**	**ES**	**PT**	**NEA**	**ACS**	**ABI**
D1 Biodiversity	Pressures	IN	PA	A	A	H	H	H
	Features	IN	PA	A	A	L	M	M
D2 NIS		A	A	PA	A	H	H	H
D3 Commercial fish		A	A	A	PA	H	M/H	M/H
D4 Food webs		See D1	See D1	See D1	See D1	See D1	See D1	See D1
D5 Eutrophication		A	PA	A	PA	H	H	H
D6 Seafloor integrity		See D1	See D1	See D1	See D1	See D1	See D1	See D1
D7 Hydrographical conditions		PA	A	PA	PA	M	H	H
D8 Contaminants		A	PA	A	PA	H	H	M
D9 Contaminants in seafood		IN	PA	A	PA	H	H	M
D10 Marine litter		PA	A	A	A	H	H	H
D11 Underwater noise		PA	A	A	N	H	H	M

ANNEX

Table 14. Technical assessment of article 9 (Good Environmental Status) in the RAGES study area [IE: Ireland; PT: Portugal; ES: Spain; FR: France; N: not reported; IN: inadequate (in red); PA: partially adequate (in yellow); A: adequate (in green)] and of regional coherence in the North-East Atlantic (NEA) region and in the Celtic Seas (ACS) and the Bay of Biscay and Iberian Coast (ABI) sub-regions [H: high (in green); M: medium (in yellow); L: low (in red)] Based on EC, 2014b.

Descriptor	Good Environmental Status						
	adequacy				regional coherence		
	IE	FR	ES	PT	NEA	ACS	ABI
D1 Biodiversity	IN	PA	A	IN	L	M	L
D2 NIS	PA	IN	PA	IN	L	M	L
D3 Commercial fish	PA	IN	IN	IN	M	L	L
D4 Food webs	PA	A	IN	IN	L	L	L
D5 Eutrophication	PA	PA	PA	IN	H	H	M
D6 Seafloor integrity	IN	PA	PA	IN	L	L	L
D7 Hydrographical conditions	PA	A	PA	IN	H	H	L
D8 Contaminants	PA	A	PA	IN	H	H	L
D9 Contaminants in seafood	IN	A	A	PA	H	H	L
D10 Marine litter	IN	A	IN	IN	H	M	M
D11 Underwater noise	IN	A	IN	IN	L	H	L

ANNEX

Table 15. Technical assessment of article 10 (environmental targets) in the RAGES study area [IE: Ireland; PT: Portugal; ES: Spain; FR: France; N: not reported (in grey); IN: inadequate (in red); PA: partially adequate (in yellow); A: adequate(in green)] and of regional of coherence in the North-East Atlantic (NEA) region, Celtic Seas (ACS) and Bay of Biscay and Iberian Coast (ABI) sub-regions [H: high (in green); M: medium (in yellow); L: low (in red)]. Based on EC, 2014b.

Descriptor	Good Environmental Status						
	adequacy				regional coherence		
	IE	FR	ES	PT	NEA	ACS	ABI
D1 Biodiversity	N	IN	PA	N	L	L	L
D2 NIS	PA	IN	PA	N	L	H	L
D3 Commercial fish	PA	IN	PA	N	L	L	L
D4 Food webs	See D1	See D1	See D1	See D1	L	L	L
D5 Eutrophication	A	IN	PA	N	M	H	L
D6 Seafloor integrity	See D1	See D1	See D1	See D1	L	L	L
D7 Hydrographical conditions	PA	IN	A	N	H	H	M
D8 Contaminants	PA	IN	PA	IN	H	H	L
D9 Contaminants in seafood	PA	PA	PA	IN	H	H	M
D10 Marine litter	IN	PA	PA	IN	M	M	H
D11 Underwater noise	N	PA	IN	IN	L	L	M

ANNEX

Table 16. Technical assessment of article 11 (Monitoring Programmes) in the RAGES study area (IE: Ireland; PT: Portugal; ES: Spain; FR: France; NO: no coverage (in red); PC: partly coverage (in yellow); FC: full coverage (in green); -: no target) and of regional coherence in the North-East Atlantic (NEA) region, Celtic Seas (ACS), Bay of Biscay and Iberian Coast (ABI) and Macaronesia (AMA) sub-regions; H: high (in green); M: medium (in yellow); L: low (in red) * PT does not report a sub-programme for D5 or D7) ** Azores and Madeira do not report MoP for D8 and for D9 and D11 it was not possible to assess due to lack of information. Based on EC, 2017b and Milieu, 2015.

Descriptor		Monitoring Programmes											
		adequacy								regional coherence			
		IE		FR		ES		PT		NEA	ACS	ABI	AMA
		GES	ET	GES	ET	GES	ET	GES	ET				
D1 Biodiversity; **D4** Food Webs	**Birds**	NO	-	PC	PC	FC	PC	PC	PC	M	no overall assessment		
	Mammals & reptiles	PC	-	PC	PC	FC	PC	PC	PC	H			
	Fish & cephalopds	PC	FC	PC	PC	FC	PC	PC	PC	M			
	Water column	PC	-	PC	PC	FC	PC	PC	PC	M			
D1, **D4**, **D6** Seafloor integrity		PC	FC	PC	PC	FC	PC	PC	PC	M			
D2 NIS		NO	NO	NO	NO	FC	PC	PC	PC	M	L	M	M
D3 Commercial fish		FC	FC	FC	PC	FC	FC	FC	FC	H	H	H	H
D5 Eutrophication		FC	FC	FC	PC	FC	FC	-*		H	H	H*	-*
D7 Hydrographical conditions		NO	PC	PC	PC	FC	FC	-*		M	H	H*	-*
D8 Contaminants		PC	PC	FC	PC	FC	FC	NO	NO	H	M/H	M	-**
D9 Contaminants in seafood		FC	FC	PC	FC	FC	PC	NO	NO	H	H	M	-**
D10 Marine litter		PC	FC	FC	FC	PC	FC	FC	PC	H	M/H	H	M
D11 Underwater noise		PC	FC	FC	FC	PC	PC	NO	FC	M	M/H	M	-**

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Table 17. Technical assessment of article 13 (Programmes of Measures) in the RAGES study area (IE: Ireland; PT: Portugal; ES: Spain; FR: France; NA: not addressed/reported (in red); IN: inadequate; PA: partially adequate (in yellow); A: adequate (in green) and of regional coherence in the North-East Atlantic (NEA) region, Celtic Seas (ACS), Bay of Biscay and Iberian Coast (ABI) and Macaronesia (AMA) sub-regions [H: high (in green); M: medium (in yellow); L: low (in red)]. Based on EC, 2018b.

Descriptor		Programme of Measures							
		adequacy				regional coherence			
		IE	FR	ES	PT	NEA	ACS	ABI	AMA
D1 Biodiversity; **D4** Food Webs	**Birds**	A	A	A	PA	M	M	M	L
	Mammals & reptiles	A	A	A	PA	M	M	M	M
	Fish & cephalopds	A	A	A	PA	M	H	H	M
	Water column	PA	PA	A	PA	M	M	M	M
D6 Seafloor integrity		PA	PA	PA	NA	M	M	M	L
D2 NIS		A	A	A	NA	H	H	M	L
D3 Commercial fish species		PA	A	A	A	H	H	H	H
D5 Eutrophication		A	PA	PA	PA	H	H	M	M
D7 Hydrographical conditions		A	A	A	NA	M	H	M	L
D8 Contaminants		A	A	A	PA	H	H	H	M
D9 Contaminants in seafood		A	A	A	PA	M	H	M	L
D10 Marine litter		A	A	A	PA	M	M	M	L
D11 Underwater noise		A	A	PA	PA	M	H	M	L

ANNEX

rages

risk-based approaches to good environmental status

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