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WP 2	Deliverables 2.3 & 2.4

Deliverables 2.3 & 2.4 Legal feasibility of implementing a risk-based approach to MRE consenting and compatibility with Natura 2000 network

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Contents

Acronym List

AA - Appropriate Assessment (or Habitat Regulations Assessment [HRA] in the UK)

AM - Adaptive Management

COM - Communication of the European Commission

CV - Coefficient of Variation

DEP - Department of Environmental Protection (Maine, USA)

DMR - Department of Marine Resources (Maine, USA)

EC - European Commission

EIA - Environmental Impact Assessment

ELD - Environmental Liability Directive

EU - European Union

EEZ - Exclusive Economic Zone

FERC - Federal Energy Regulatory Commission

IPPC - Integrated Pollution Prevention and Control

MMO - Marine Management Organisation

MS - Marine Scotland

MSFD - Marine Strategy Framework Directive

MS-LOT - Marine Scotland – Licensing Operations Team

MW - Megawatts

NOAA - National Oceanographic and Atmospheric Administration

ORE - Offshore Renewable Energy

ORPC - Ocean Renewable Power Company

SDM - Survey-Deploy-Monitor

SEA - Strategic Environmental Assessment

TFEU - Treaty on the Functioning of the European Union

UK - United Kingdom

UNFCCC - United Nations Framework Convention on Climate Change

WBD - Wild Birds and Habitats Directives

1 Introduction

1.1 General considerations

The consenting of Offshore Renewable Energy (ORE) projects has been cited as one of the main non-technological barriers to the commercial development of this sector due to the current uncertainties regarding the environmental effects created by ORE technologies. Uncertainties primarily stem from a lack or poor level of knowledge about both the baseline conditions of the receiving environment and the impacts of technologies on each individual environmental receptor. In some instances, the key issue may be getting the scientific information to the decision and policy makers. These factors can be exacerbated by under-developed Environmental Impact Assessment (EIA) guidance and the difficulties in how to comprehend unknowns in regulatory frameworks for ORE.

To address these non-technological hurdles, the objective of the RiCORE project is to promote the deployment of ORE in the European Union (EU) by reducing the time and cost taken to consent ORE projects through the development of a risk-based approach to consenting processes. A risk-based approach to consenting and determining what information is required to support the process, e.g. environmental survey data, is an element of Adaptive Management (AM): a structured process that enables learning by doing and adaptation based on what is learned. The goal of AM is to reduce scientific uncertainty. A risk-based approach is any approach that seeks to inform decision making through an understanding of the scientific uncertainties and associated consequences in terms of likelihood and magnitude of potential impact. The Survey Deploy and Monitor (SDM) policy implemented by Marine Scotland is an example of a risk-based approach with respect to project consenting and AM adopts a risk-based approach to reducing scientific uncertainties.

In RiCORE Deliverable 2.2, the structure of national consenting processes for marine renewables was compiled and reviewed. The 'one-stop-shop' approach was found to be the most desirable consenting approach. The objective of the present report is to consider and advance the recommendations for the development of a risk-based approach to determining what information and data is required to support the consenting process and the post-consent and post-deployment monitoring phases through the application of Adaptive Management. It will be demonstrated that AM should be used where EIA cannot confidently provide accurate predictions. AM is a model risk-based approach as it requires decision makers to manage the risk of unacceptable impacts occurring, whilst allowing changes in the environment to be monitored, with the aim of reducing scientific uncertainty and adapting future management on the basis of actual data derived from the monitoring programme. Such 'adaptation' might be to conditions attached to future licences/consents or a change in the assessment methods utilised to inform future decision making by the consenting authority, for example. Regardless of the adaptation implemented, the focus must be on reducing scientific uncertainty and AM could be used to reduce uncertainty around any question, not only those related to potentially significant impacts. The AM approach was first pioneered as a process for improving management actions involving natural resources (Holling, 1986). The application and benefits of AM may be transferred to mitigate risk in the management of ORE projects.

To be coherent, AM must be applied whilst simultaneously achieving the objectives associated with the network of marine Natura 2000 sites designated by Member States under the Nature Directives. If potential risks are relevant to a designated site or qualifying interest, an Appropriate Assessment will be required. If no AA is required, AM still needs to fit within EIA. Consideration is given to the compatibility of AM as a risk-based approach to reducing scientific uncertainties with the goals of the Nature Directives.

This deliverable will identify the key components of an AM approach and the underlying legal and institutional challenges that may affect its implementation. The literature would appear to utilise the term AM more than risk-based management and consequently the former is used most frequently in this report whilst the latter is the focus of the RiCORE project. This deliverable aims to assist regulators and developers with the design and implementation of an AM approach that can progress ORE projects towards commercial scale development.

1.2 Steps and methodology

The deliverable will provide some insights to the concept of Adaptive Management before analysing the feasibility of incorporating such a flexible risk-based management approach within existing regulatory frameworks. Case studies that serve as cited models of AM in pre- and post-consenting phases are examined. This task also identifies the legal amendments that may be necessary to enable the adoption of a risk-based approach.

AM and the precautionary principle have to be weighted when applied together; indeed, both are enshrined in the EU's Marine Strategy Framework Directive (MSFD). Likewise, both are risk-based approaches that aim to deal with uncertainty regarding potential adverse impacts in decision-making. AM acknowledges that scientific understanding of an ecosystem will always be incomplete and allows for management actions to be re-adjusted over time to take new scientific data and knowledge developed into account. When applied to renewable energy licensing, this approach requires the regulator to accept a certain level of uncertainty regarding the impacts of a proposed development. In contrast, the precautionary principle asserts that when scientific uncertainty is high and the potential for significant adverse effects exists, regulators should err on the side of caution. The precautionary principle does not actively seek to reduce scientific uncertainty, and does not have a goal of improving decision making over time by reducing the uncertainties.

The EIA Directive, Birds and Habitats Directives have been drafted on a strong philosophy of the precautionary principle. As a result, regulators have been traditionally more inclined to apply a precautionary approach resulting in less acceptance of impact by regulators. One potential consequence of this is more mitigation and more compensation than may be necessary owing to the potential scale and likelihood of the impacts associated with the uncertainties. A culture has developed associated with the strict application of the precautionary principle which has led to very extensive and costly EIA and AA processes for developers, which are sometimes disproportionate to the project being proposed. This is why, whilst AM is recognised as a potential best management practice to push the ORE sector to commercial development (Masterton, 2014), the precautionary principle has been criticised for potentially halting technological and development progress in some of Europe's most remote and fragile communities. As such, this Deliverable will provide information on the interplay between the precautionary principle and an AM approach, and the implication that this has for adopting a risk-based approach in Member States such as the United Kingdom and France.

It is impossible to consider the development of a risk-based approach to consenting without also addressing the question of monitoring and environmental liability. As mentioned above, employing AM entails acceptance of a certain level of risk. Successful models of AM in decision-making must be accompanied with valuable monitoring programmes that are sufficiently well designed to meaningfully inform regulators. With this in mind, monitoring programmes should provide valuable scientific data on the potential ecological impacts of a development on key receptors that will then trigger an adaptation of (or change in) management actions. As such, the application of statistical power analysis to assess the efficiency and optimise the design of monitoring has previously been recommended (Paxton & Thomas 2010, Mackenzie et al. 2013). In this Deliverable, the use of statistical power analysis to more fully inform risk-based decision making is considered. Indeed, the choice of levels of power and significance (i.e. the *P* values) may influence the regulator's position, as it may have implications in terms of liability. It may also influence developers in terms of monitoring costs and liability.

If the statistical power of a monitoring programme is too low, then there may be an unacceptable risk of failing to detect changes that are occurring. As a consequence, regulators will be more prone to make decisions believing that monitoring indicates no change beyond their preferred threshold of tolerance, when in truth greater changes are occurring. This stands in contrast to monitoring based exclusively on conventional testing for a significant result, where the results give a high level of confidence (probability of less than or equal to 5%, or $P \leq 0.05$) that if an effect beyond the tolerance threshold is observed it is truly occurring. On this point, one major question is who, between the regulator, the developer and those conducting the monitoring, is liable in the event of unforeseen impacts. The legal issues surrounding environmental liability will be dealt with in Section 6, where the Environmental Liability Directive is discussed and insight provided on the liability regime applicable to ORE developments where environmental damage may result from an unsuccessful risk-based approach. A further consideration is the need for AM risk-based approaches to be coherent in the context of the requirements of site-based protection of the Natura network.

The deliverable will draw on the US Department of the Interior Technical Guide on Adaptive Management and on scientific and legal research on the precautionary principle and AM initiated in 1990 (Walters & Holling, 1990) and conducted until 2016. Case studies of ORE developments cited to have used an AM approach are presented and discussed. These include the SeaGen Project in Strangford Lough, Northern Ireland; the Meygen Project, Scotland and the Cobscook Bay Tidal Energy Project in the United States. During numerous project workshops and meetings, such as Roundtable on Environmental Legislation and Consenting Procedures for Ocean Energy (19th February 2016), stakeholders have stressed the need for AM and their willingness to progress this approach in relation to ORE.

2. Conceptual framework for Adaptive Management

Adaptive Management is defined as a resource management framework that encourages learning-based decision-making and allows for management actions to be adjusted over time (Williams, 2011). A formal definition of Adaptive Management, provided in the Technical Guide produced by the U.S. Department of the Interior (Williams et al., 2009) is as follows:

> *'A decision process that promotes flexible decision making that can be adjusted in the face of uncertainties as outcomes from management actions and other events become better understood. Careful monitoring of these outcomes both advances scientific understanding and helps adjust policies or operations as part of an iterative learning process (…)'.*

Pursuant to the Technical Guide, AM can be seen as the application of structured decisions in which both decision-makers and developers allow for continual learning as part of an experimental decision-making process (Williams et al., 2009). AM is considered useful in situations where there is uncertainty around the long-term impacts and where future monitoring will be required to make the necessary 'adaptations' in subsequent decision-making.

The application of AM is particularly relevant in resource management (Williams et al., 2011; Noble, 2000; Gunderson et al., 1995). This is primarily due to the fact that AM enables management decisions to take into account the changes in dynamic ecological systems through monitoring and adjustment of management actions. Indeed, the challenge confronting managers is to make "good" decisions in the face of uncertainty regarding the response of dynamic ecosystems to a particular management action. AM helps regulators to comprehend this uncertainty by allowing each management option to be evaluated and continually revisited as learning occurs through monitoring (Gunderson, 1999; McDonald, 2014). As a result, regulators are able to make better informed decisions with improved confidence, can adjust to the unexpected, and adopt the most viable management alternative at the appropriate time scale.

Monitoring is fundamental to inform the next management actions. As shown in Figures 1 and 2, AM is comprised of a set-up phase and an iterative phase. Monitoring protocols are agreed in the set-up phase between regulators and developers. Then, monitoring efforts intervene as an element of the iterative phase. The setup phase includes the framing of management objectives (e.g. the acceptable number of mortalities of a species, the acceptable level of displacement of marine mammals, the target levels of population abundance and diversity of communities, and maintenance of noise at an acceptable level), the identification of a first set of management alternatives and agreement on monitoring protocols. The iterative phase (Figure 2), utilises these elements to adjust decision-making on what is learned from previous management actions. Here, learning results from comparative outcomes of what is observed against predicted responses.

Adaptive Management comprises of eight steps according to Williams et al., 2009.

1. Stakeholder involvement
2. Objectives – Identify clear, measurable and agreed upon management objectives to guide decision-making and assess the effect of management actions
3. Identify a set of management alternatives for decision-making
4. Monitoring protocols and models that will detect changes in natural resource status
5. Implementation of monitoring plans

The iterative phase involves three additional steps applied in a cyclical manner:

6. Decision-making – Selection of management action based on management objectives
7. Implementation of monitoring to track resources dynamics and response to management actions
8. Assessment of management actions – Comparison of predicted and observed changes

The result of this assessment will trigger a change in management direction (management actions) where the effects of a particular management action deviate from previously agreed management objectives (O'Callaghan et al., 2013).

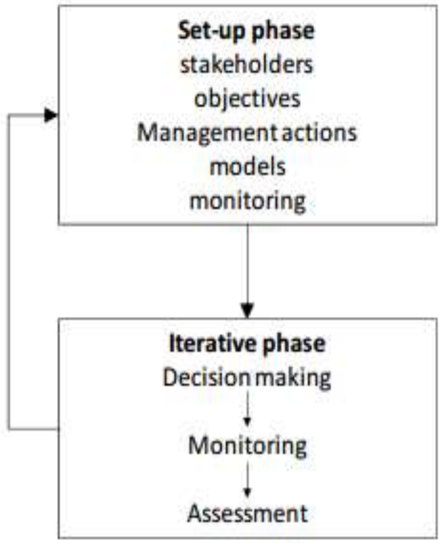

Figure 1 - The two implementation phases of Adaptive Management (from Williams, 2011)

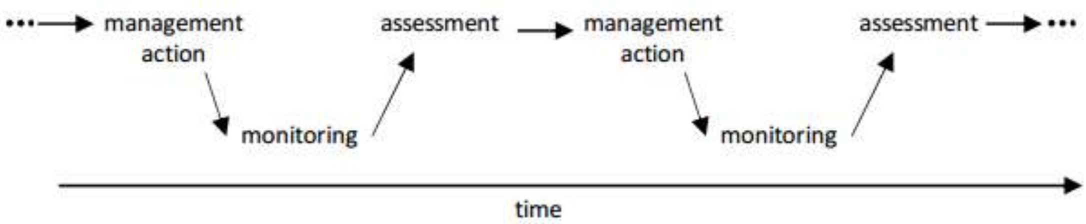

Figure 2 – Iterative phase in Adaptive Management

There are two approaches to AM: active and passive, which differ in the way they address uncertainty. Active AM aims to apply management actions for the purpose of learning. Experimental results of each management unit are collected and used to inform future decision-making; therefore, this approach has a clear emphasis on learning. With passive AM, the focus is on the effect of management actions by generating resource responses (Williams, 2011). Herein, our primary focus will be active AM.

3. Integration of Adaptive Management in legal frameworks applicable to ORE

This section focuses on compliance of Adaptive Management with EU environmental law. Amendment of the EIA Directive and the Habitats Directive may be necessary to encourage AM in consenting processes. Further consideration will be given to the operational implementation of AM by regulators in consenting systems and the integration of AM in national regulatory frameworks.

3.1 Practical considerations: Operational implementation of Adaptive Management in consenting processes

Generally speaking, when applied to ORE projects, Adaptive Management allows for consenting to be moved forward or for licensing conditions to be re-evaluated over time in order to take account of the outcomes of a monitoring programme.

3.1.1 Adaptive Management in the pre-consenting phase

The "Survey, Deploy, Monitor" (SDM) approach is a policy used in Scotland, which informs site characterisation survey requirements in the pre-consenting period. It allows for EIA requirements to be adjusted at the scoping stage in cooperation with Marine Scotland (the regulator) to reduce the burden of collecting survey data to inform EIAs on small scale projects or projects of low environmental risk.

The duration of site characterisation surveys and the level of monitoring are determined by the overall risk profile of the project. The risk profile is determined on the basis of three factors:

1. the environmental sensitivities of the area,

2. the scale of development and
3. specificities of device risks.

These factors are scored and combined to provide an overall risk profile expressed as low, medium or high. The SDM Guidance states that two years of site characterisation data would be the minimum for high risk proposals while for a medium risk proposal, their initial presumption would also require two years of site characterisation data but flexibility is allowed as Marine Scotland can relax monitoring requirements. In the SDM approach, pre-consent environmental requirements will be considered on a case-by-case basis depending on individual project risk profile. If there is low likelihood that a development will exceed the acceptable threshold of impact, there is no utility to undertake additional survey. It is likely that for small scale projects located in areas of low environmental sensitivities, only one-year site characterisation data will be required to inform the consenting process. in some instances, less than one year's of site characterisation data has been required but this is very much dependent on the specific site and level of existing data. A recent report commissioned by Natural Resources Wales (Sparling *et al*., 2016) sets out a scenario where the regulator knows the acceptable threshold of impact. They then back-calculate the densities that would need to be present for that threshold to be exceeded and if the existing information indicates there is no realistic possibility of densities being at that level, there is no utility in doing surveys. In these scenarios the SDM approach should facilitate earlier consenting decisions.

The SDM approach can be considered to enable a strategic approach to Adaptive Management at the pre-consenting phase, by demonstrating that decision-making regarding pre-consent survey efforts is risk-based and proportionate to the risk profile of a development (Bennet, 2016). The SDM approach also involves a flexible approach in the pre-consenting phase where Marine Scotland either relaxes the requirements for further site characterisation or requests additional survey efforts on a receptor-specific or risk-specific base. Pre-consent site characterisation surveys under SDM do not reduce scientific uncertainty for future decision making of other projects but it does enable this to be achieved through AM. Once the project is approved following this procedure, AM approaches can then focus efforts on the design of post-consent monitoring programmes.

The application of the SDM approach from Scotland in the same manner may not be possible in all partner countries. Some Member States do not possess the same amount of data to characterise the environmental sensitivities of their maritime regions to a similar degree. A risk-based approach to determining what information is required to inform a consent application can, however, still be assessed against technology risk and project scale in the absence of strategic baseline data. Project requirements should always be determined with these factors in mind. The mapping of constraints and environmental sensitivities is a pre-requisite to implement the SDM approach but differences between Member States in their approach to this aspect should not hamper the development of Adaptive Management strategies in the post-deployment phase. Furthermore, an Adaptive Management plan may include site characterisation programmes in the first instance, to improve scientific knowledge on the receiving environment before allowing development. Taking an Adaptive Management approach does not have to result in 'another' plan but rather should represent a working ethos towards reducing scientific uncertainties for those involved in ORE project development and consenting.

3.1.2 Adaptive Management in the post-deployment phase

In order to allow or prevent regulators from moving forward in the consenting process, AM at project-level may be implemented in post-deployment through a staged approval process or through the delivery of conditional licences (McDonald, 2014). In both cases, regulatory frameworks must prescribe site and technology specific monitoring programmes that will track changes in relevant environmental receptors (such as species' behaviours, water and/or seabed quality).

AM in phased development will ensure impacts can be monitored before full build-out, allowing a risk-based management during the entire life cycle of projects. It can also be used to monitoring during build out. The following boxes highlight existing projects where an AM approach was taken.

Meygen Tidal Energy Project, Pentland Firth, Scotland

The demonstration strategy approach at the Meygen Project in Pentland Firth is a model of commercial tidal development for which the consenting process has been divided in two distinctive phases. Phase 1 of the project was approved in September 2014 in tandem with the initiation of monitoring programmes designed to measure the behaviour of mobile species occurring in close proximity of the turbines. Phase 1 will generate an overall capacity of 86 MW. Phase 1a aims to install up four turbines of 1.5 MW each, Phase 1b aims to install six additional turbines (9MW) and Phase 1c aims to install a further 10 turbines (15MW); the last phase will be the fully operational phase, with the installation of the last set of turbines in the area generating an overall capacity of 86 MW. Each phase will be supported by a monitoring programme.

Phase 2 is conditional upon the monitoring data collected in Phase 1. Details about the Environmental Statement and the monitoring programmes in place for Phase 1 of Meygen project are available online (http://www.meygen.com/the-project/).

Phase 1a of the Project is currently being developed with the turbine installation and commissioning planned to be occur between August and October 2016.

To date, examples of the application of this approach to post-consent monitoring are scarce. The Scottish Government is currently considering appropriate refinements to the SDM policy in order to enable its application for post-consenting phases as a means to reduce uncertainties regarding particular impacts. The Meygen Project does not really represent SDM as two years' pre-consent survey was required but the phased approach based on monitoring results represents a novel way of consenting a commercial scale array.

Box 1 Meygen Tidal Energy Project

Where staged approval is not feasible, an alternative approach is to deliver a conditional licence with management objectives and monitoring and mitigation measures as a condition, meaning that the AM is also largely initiated by developers. The Cobscook example (Box 2) shows how AM can be used to reduce project requirements. This tends to happen first when monitoring is focussed on an impact mechanism e.g. noise, rather than an impact e.g. effect of noise on fish.

Tidal Energy Pilot Project, Cobscook Bay, Maine, USA

Using conditional licensing, with Adaptive Management as a basis, Ocean Renewable Power Company (ORPC) was granted a Pilot Project Licence in 2012 to develop a 300kW tidal project in Cobscook Bay, Maine, USA. One of the conditions attached to the licence was the restriction of pile-driving activities during the active season of Atlantic salmon. Mitigation measures during pile-driving operations were also required by the National Oceanographic and Atmospheric Administration (NOAA) to mitigate the impact on Atlantic salmon smolt during the active season. The Federal Energy Regulatory Commission (FERC) did state that alleviation of the restriction was dependent upon the results of a comprehensive environmental monitoring plan agreed as part of the licence conditions.

The monitoring plan agreed with OREP collected data on the propagation of noise at the location and the abundance and distribution of a number of potential receptors using a number of methods: hydro acoustics and air acoustics measurements, marine mammal observations, and seabird and shorebird surveys. On the basis of data collected, ORPC requested a modification of the conditions attached to the licence. FERC granted a licence modification to remove the Phase 1 restrictions on pile-driving based on mitigation and acoustic measurements. This is an example of how AM may be used to relax licence conditions over time.

The extent to which mitigation measures will be alleviated varies depending on the receptor concerned. Generally speaking, a licence modification includes the removal of restrictions or reduction of monitoring efforts based on increased knowledge about species presence and environmental impacts (Johnson, 2016)

Box 2 Tidal Energy Pilot Project, Cobscook Bay, Maine, USA

3.2 Legal considerations

In this section, we consider how the EIA Directive and the Habitats Directive may be applied in using an Adaptive Management framework for large scale offshore developments. These Directives can result in two forms of environmental assessments, namely an Environmental Impact Assessment (EIA) under the EIA Directive and an Appropriate Assessment (AA) under the Habitats Directive in certain circumstances. The implication of EIA and AA process in AM schemes is considered separately.

3.2.1 EIA Directive and Adaptive Management

Article 2 of the EIA Directive provides that Member States "adopt all measures necessary to ensure that, before consent is given, projects likely to have significant effects on the environment by virtue, *inter alia*, of their nature, size or location are made subject to a requirement for development consent and an assessment with regard to their effects." ORE projects belong to the category of projects listed in Annex II for which the requirement for an of EIA is decided on a case-by-case basis using either a screening system or specific thresholds, e.g. developments above 100 MW, set by Member States.

As shown in the Figure 3, the EIA process comprises of a number of inter-related steps. After the screening and scoping stage, developers submit an environmental statement/report including information about the elements of the project, a description of the likely significant impacts of the project on the environment, and a description of the characteristics of the project or measures envisaged to avoid, prevent or reduce likely significant adverse effects on the environment (mitigation measures) (Article 5 (1)). On the basis of this report submitted by developers, competent authorities then make their 'assessment' to decide on whether to grant development consent and attach any conditions that may be formulated as mitigation measures.

A monitoring stage is not part of the EIA process, but as a result of the revised EIA Directive (2014/52/EU), post-project approval monitoring will come in to effect in 2017. Recital 35 states that "appropriate procedures are determined regarding the monitoring of significant adverse effects on the environment resulting from the construction and operation of a project, *inter alia*, to identify unforeseen significant adverse effects, in order to be able to undertake appropriate remedial action". It should be noted that the recitals have no binding legal force but rather go to explaining the substantive provisions (Articles) that follow and are used regularly by the Court of Justice as an aid to interpreting the obligations set down in Directives. This can be contrasted with the substantive provisions of the SEA Directive which uses the term ‘unforeseen adverse effects’ in Article 10 requiring Member States to “monitor the significant environmental effects of the implementation of plans and programmes in order, *inter alia*, to identify at an early stage unforeseen adverse effects, and to be able to undertake appropriate remedial action”.

According to [new] Article 8a(4), Member States are to determine the procedures for the monitoring of significant adverse effects on the environment. This goes further to provide that the type of parameters to be monitored and the duration of the monitoring “shall be proportionate to the nature, location and size of the project and the significance of its effects on the environment”. It does not specify ‘unforeseen’ significant environmental effects. Overall, it would appear that the main thrust of Article 8a(4) is that it creates an obligation on Member States to monitor implementation of projects that have been subjected to EIA. This would include putting measures in place to ensure that the developer complies with any conditions attached to the development consent concerning mitigation, compensation measures etc. and monitoring to identify any significant adverse effects that might arise, including any unanticipated (unforeseen) significant effects that might surface during implementation. It is probable that the drafters of the new EIA Directive recognise that mitigation measures attached to development consents may not always operate effectively in practice, that unanticipated effects may also arise and remedial action may be required in these cases. Any such problems should be picked up by monitoring and remedied as appropriate. The EIA Directive is a procedural Directive – it does not necessarily prohibit significant environmental damage. The wording of Article 8a(4) makes this clear when it refers to offsetting significant adverse effects “if possible”: confirming that it may not always be possible to offset such effects.

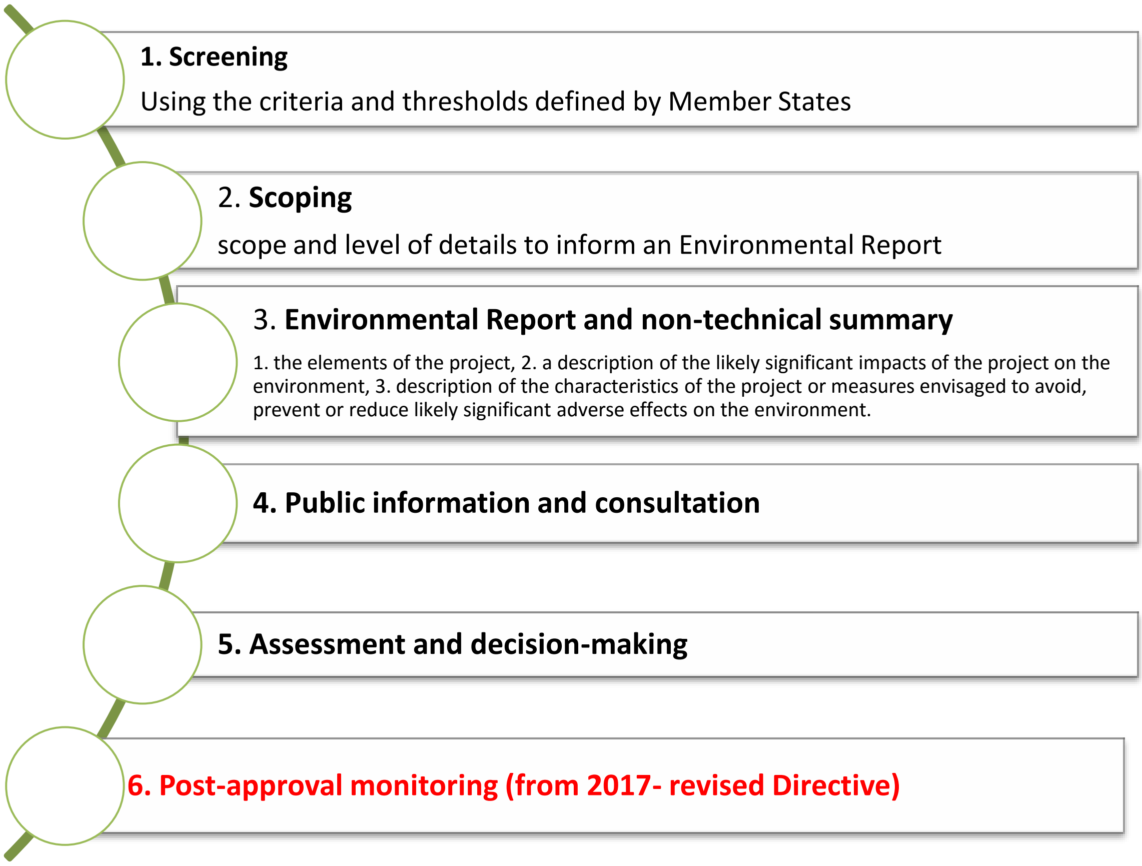

Figure 3 – The Environmental Impact Assessment Procedure

It has been suggested that the structure of the EIA process may be too rigid to deal with complex and dynamic environmental systems (Holling & Walters, 1990; Gunderson et al., 1995). This is because the environmental assessment, as provided for under the EIA Directive, endorses a single response model based on predictions about the impacts and leaves little room for adaptation in post-approval stage. The EIA scheme under the Directive relies on historical data to build a single set of fixed mitigation measures. In the pre-commissioning phase, developers are required to provide an environmental report including a description of the elements of the project, data about the predicted impacts of the project, information about alternatives considered and to define mitigation measures on the assumption that predictions about the impacts are correct. Moreover, the focus of the current practice of applying the EIA process is often concerned with maintaining the initial state or baseline conditions rather than providing a strategic plan aiming at reducing uncertainties and mitigating environmental impacts. As predictions are often incorrect, to achieve the goal of reducing the associated scientific uncertainties, the EIA structure would need to mandate the production and use of new data collected at different timescales (and not only before a consent is granted).

Monitoring in the post-consenting phase will be a requirement of the revised EIA and Member States will have to apply these rules from 16 May 2017 at the latest. Article 8(a), as inserted by the revised EIA Directive, requires that Member States, shall determine, as part of the development consent, the procedure regarding the monitoring of significant adverse effects on the environment. The inclusion of monitoring in post-deployment will facilitate AM by clearly acknowledging uncertainty and proposing practical monitoring arrangements to verify the correctness of the predictions. This amendment will permit a move away from the static/reactive approach of EIAs based on predictions and a single response model towards a more flexible EIA. Work conducted on the US system found that post-approval monitoring may help current EIA structures to move towards a 'predict-mitigate-implement-monitor-adapt' model of management (National Environmental Policy Task Force, 2003).

Member States should be further encouraged to integrate monitoring outcomes into regulatory processes and to engage in iterative EIA decision-making in post-project approval. Even though 'adaptive management' is mentioned in the MSFD and hence has a legal basis, a clear explanation of what is meant by the term is absent. Inclusion of the approach in the EIA Directive would also be valuable, particularly since post-consent monitoring will be required in coming years. Updated guidance which provides clarification on the inclusion of Adaptive Management and how developers and regulators can reflect multiple management scenarios in the environmental assessment process is necessary to assist regulators and developers with their obligations to comply with EIA in an Adaptive Management framework.

3.2.2 Appropriate Assessment and Adaptive Management

The Habitats Directive endorses the use of the precautionary principle which may limit the feasibility of Adaptive Management. Strict protection that seeks to avoid effects cannot easily be reconciled with management strategies that seek to reduce the scientific uncertainties associated with the mechanisms that cause impacts. This dilemma should be carefully considered by regulators. Under Article 6(3), the competent national authorities shall consent to a plan or project affecting a designated Natura 2000 site, only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public. The structure of the Appropriate Assessment is similar to that of the EIA procedure. As mentioned previously, a step-by-step assessment of projects includes a screening phase, a scoping phase and an assessment.

Article 6(3) of the Directive provides that any plan or project not directly connected with the site but likely to have a significant effect on it, either individually or in combination with other plans or projects, is subject to Appropriate Assessment (AA) of its implications for the site in view of the site's conservation objectives. Competent national authorities may approve the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned. The main difference between an EIA and an AA lies in the fact that the Appropriate Assessment is determinative of decision-making (the EIA is only informative and does not dictate any particular outcome). If the Appropriate Assessment is negative and, despite mitigation measures, there are residual negative impacts on integrity, the plan or project can only be authorised in the absence of alternative solutions, if the plan or project is justified by imperative reasons of overriding public interest [IROPI] (Article 6(4)). If the project does not meet these criteria, the project cannot be authorised.

A diagram highlighting the key steps of the Appropriate Assessment under Article 6(3) is shown in Figure 4. This Figure has been provided by DGMAR.

Possible negative impact on a Natura 2000 site? (Screening)

- ✓ No: Consent can be granted
- ✓ Yes: Appropriate Assessment is required
  - No impact on integrity: consent
  - Negative impact on integrity: alternatives?
  - There are alternatives ⇨ no authorisation ⇨ new assessment
  - No alternative: Imperative reason of overriding public interest (IROPI)?
    - ❖ No IROPI: no authorisation
    - ❖ IROPI: priority species/ habitats affected?
      - No: consent with compensation measures
      - Yes: EU Commission opinion required

Figure 4 – steps in Appropriate Assessment (DGMARE)

Under the Habitats Directive, the precautionary principle is enshrined in Article 6(3). The interpretation of Article 6(3) and its implications for plans and projects in or near designated sites have been the focus of many ECJ cases such as the *Waddenzee* Case[1]; *Commission* v *Italy*;[2] *Sweetman* case[3]; and most recently the *Briels* case.[4] In the *Waddenzee* case the ECJ held that if a plan or project is likely to undermine a site's conservation objectives, it must be considered likely to have a significant effect on that site. The assessment of the associated risk must be made in the light of the characteristics and specific environmental conditions of the site concerned. The Court also held that the aspects of the plan or project that affect the conservation objectives must be identified in the light of the best scientific knowledge in the field. In relation to the situation which arose in the *Waddenzee* case, the ECJ held that the competent authority could authorise the activity only if they have made certain that it will not adversely affect the integrity of that site and that is the case where no reasonable scientific doubt remains as to the absence of such effects (paras. 56 and 57).

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[1] *Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging tot Bescherming van Vogels v Staatssecretaris van Landbouw, Natuurbeheer en Visserij [Waddenzee* case], C-127/02
[2] C-304/05
[3] *Sweetman and Others* v *An Bord Pleanála,* C-258/11
[4] *Briels and Others v Minister van Infrastructuur en Milieu*, C-524/12

In *Commission* v *Italy*, the documents submitted as part of the AA process were deemed by the Court to be preliminary in nature and lacking in definitive conclusions. The Court held that in that situation the studies lacked complete, precise and definitive findings and conclusions capable of removing all scientific doubt as to the effects of the works on the designated site concerned. Accordingly, the competent authority could not have the level of certainty necessary to authorise the works proposed. In *Sweetman and Others* v *An Bord Pleanála*, the Irish courts referred two questions to the ECJ for decision. One of those was whether the application of the precautionary principle has as its consequence that a plan or project cannot be authorised if it would result in the permanent non-renewable loss of the whole or part of the habitat concerned. The Court found that a plan or project not directly connected with, or necessary to, the management of a site will adversely affect the integrity of that site if it is liable to prevent the lasting preservation of the constitutive characteristics of the site that are connected to the presence of a priority natural habitat whose conservation was the objective justifying the designation of the site and that the precautionary principle should be applied for the purposes of that appraisal (para. 48).

The *Briels* case complements earlier ECJ decisions but focuses specifically on mitigation and compensation measures. In that case the project was found to have negative implications for a Natura 2000 habitat but overall the completed proposed project was going to increase the habitat concerned. The Court was tasked with deciding on what was mitigatory and what was compensatory, holding that the measures were not aimed at avoiding or reducing the significant adverse effects for the habitat concerned but rather tended to compensate after the fact for those effects.

In the EC's guidance on the implementation of the Birds and Habitats Directives, it has clarified that inherent scientific uncertainties need not preclude an assessment of no impact to integrity under Article 6(3) by using a flexible approach stating that *'minor remaining uncertainties should however not block or restrain projects indefinitely'* (EC, 2011, p.29). The EC guidance goes further stating that the nature of remaining uncertainties should be managed "through targeted monitoring and adaptive strategies" (EC, 2011, p.29). The guidance is targeted at estuaries and coastal zones so the extent to which it is transferrable to the specifics of ORE is not clear.

As previously noted, the wording of the Habitats Directive may limit the feasibility of AM if the conservation objectives of qualifying interests of sites that form the basis of the site integrity leave no opportunity under Article 6(3) for experimentation and post-project approval monitoring of a potential effect. A key challenge for both regulators and developers is the level of risk that is acceptable with respect to integrity is not prescribed in law, nor can it be derived from case law as yet, and accordingly regulators and competent authorities are forced to make a decision on this. Whilst the Directive does allow for derogation [IROPI test] through Article 6(4), this can only apply after the implications of a plan or project have been established in accordance with Article 6(3). It is often the case that both EIA and AA processes rely on single response models/historical data and proposed mitigation measures are based on the assumption that predictions are true. Models rely on inductive reasoning and assessments using models cannot have deductive certainty and therefore cannot remove risk. AM strengthens the capacity of the environmental assessment process to accurately predict impacts with confidence and reduce uncertainties by adapting mitigatory goals to changing conditions and learning from past mitigation measures (Noble, 1995).

The EU should consider providing guidance on how the EIA and Habitats Directives can reflect and enable AM processes for developments that have scientific uncertainties associated with them. In particular, consenting authorities in Member States have done relatively little to date that openly and transparently demonstrates the level of risk they deem to be compatible with the objectives of these Directives. A pre-requisite of risk-based strategies should be more effective communication of the risk appetite possessed by different consenting authorities. Updated guidance on how an EIA and AA can be progressed in an AM context will be important as the revised Directive (EIA Directive 2014/52/EU, Article 2(3)) imposes a mandatory simplification of environmental assessment through joint procedure or coordinated procedure where both an EIA and an AA are required. Such guidance should not prescribe the level of risk to be taken by Member States but rather should clarify to regulators that they need to be clear and transparent about the risk that they believe is acceptable in different contexts.

It is also clear from the findings of the RiCORE project that if risk-based approaches are to be adopted to reduce scientific uncertainties associated with the consenting of MRE devices then the coherence of AM with marine Natura 2000 sites requires careful consideration. The mobile nature of marine mammals, seabirds and other qualifying interests of protected sites comprising the Natura 2000 network results in the likelihood of connectivity between the location of MRE devices and protected features. Whilst the relative risk of inter-actions can generally be expected to be greatest where both overlap spatially and temporally, (e.g. an operational MRE device in a protected area of foraging importance for seabirds during the breeding season) the risks are not necessarily removed by locating MRE devices in locations remote from protected areas. As such, policy goals that are based on strict protection and zero-tolerance of potential change to mobile qualifying interests are not going to be compatible with consenting requirements of MRE devices. Consequently, it is necessary for the tolerance of the risk of potential impacts from human activities to be reflected in the conservation objectives of qualifying interests of Natura 2000 sites. Without a degree of tolerance, no impacts can be accepted and AM approaches will not be suitable. If it is the case that marine Natura 2000 sites have strict protection conservation objectives applied to them this is unlikely to be compatible with AM within the spatial area considered for which the qualifying interest has connectivity. This spatial area may extend over hundreds of kilometres reflecting the foraging and migratory use of the marine environment by many species.

Decision makers are likely to take a case-by-case approach to consenting project proposals, which will take account of specific circumstances that may be unique. This can be expected to include case specific information on the impacts of the project proposal to features afforded protection under the Nature Directives. Ultimately the level of risk that is considered acceptable by the decision maker will be based upon the conservation objectives for qualifying interests of sites. A key finding of this project is that in order for AM approaches to be applied in a manner that remains coherent with the Nature Directives, the need for a flexible approach to risk by consenting authorities should be recognised in the conservation objectives of protected sites. If qualifying interests of sites are considered to require strict zero tolerance protection the expected outcome is that the zone of spatial connectivity will be regarded as poorly suited to the uptake of AM, and potentially MRE more generally unless its impacts are already considered benign.

3.2.2 Integrating Adaptive Management in national legal frameworks for ORE

Adaptive Management principles have not been codified in any Member State statutory or regulatory texts but tend to be agreed and added to terms and conditions of a licence on a project-by-project basis. With respect to the US situation, Fischman (2007) states that without more specific statutory or regulatory grounding, commitments to AM are generally not binding on the agency. Arguably incorporating AM in the legal framework is not an empirical necessity as AM, if implemented through licence terms, will have sufficient enforceable grounding through those licences. Where a developer fails to comply with the obligations to monitor as stipulated in the licence, this failure is a lawful cause of revocation or non-renewal of the licence. In contrast to the U.S, where AM plans are part of the consenting process, what is being advocated in RiCORE for EU Member States is that AM should become a philosophy and operational approach behind consenting processes. This would equate to a change in mind-set of the authorities involved rather than an additional plan to be prepared by the developer. A key feature of AM is that the management involves a continual learning process that is not bifurcated into 'research' and 'regulatory' activities. In other words, AM recognises that our understanding of natural systems is continuously changing.

Incorporating AM in the legal framework governing licensing of ORE projects increases the legitimacy of the concept and without such there is a danger that AM could become authority rhetoric with little practical meaning (Benson & Garmestani, 2011). If adaptive management is codified into law, it should be implemented on a voluntary basis insofar as it affects the financial risk profile of ORE projects. If codified in law, an AM philosophy would be inherent in consenting decisions and easily identifiable in subsequent monitoring plans. A provision stating that no licence shall be granted without the development of an adaptive management programme, which allows for monitoring environmental impacts and subsequent adjustment of decision making, may be considered. However, a counter-argument has been suggested by Oram & Mariott (2010) and Masterton (2014) for the United States whereby AM should be undertaken on a strictly voluntary basis so as to encourage trust and collaboration between industry and regulators and to avoid creating barriers to market entry. Developing an AM plan without having the certainty that a licence will be granted would not be acceptable to developers who may be required to gather large quantities of data and incur substantial monitoring programme costs. Instead of amending primary legislation, another approach has been developed in the United States to mandate AM through the adoption of regulations regarding compliance with the National Environmental Policy Act (NEPA). The Forest Service advanced rules to update its procedures for NEPA compliance with several references to AM. The Department of the Interior adopted NEPA implementation rules directing that '*bureaus should use Adaptive Management as part of their decision-making […] in circumstances where long-term impacts are uncertain and future monitoring will be needed to make necessary adjustments in subsequent implementation decisions*'.[5]

Lessons could be drawn from the United States where the Marine and Hydrokinetic Renewable Energy Promotion Act (2011) attempted to create an Adaptive Management Fund to cover the costs of environmental studies and monitoring needed for demonstration projects to assist developers with complying with their Adaptive Management Plans, required under NEPA provisions. This Bill was introduced in 2011 but was not enacted. The RiCORE project workshops did not identify broad support for AM approaches to be codified in law in Europe. Attendees considered that it could be

[5] Fed Reg. 126, 135 (Jan. 2, 2008)

supported as an underpinning philosophy to ensure licensing regimes are able to address key scientific uncertainties to be identified on a case-by-case basis, recognising that demonstration projects may be used to address uncertainties that apply to all Member States (e.g. collision risk). The opportunity to develop an Adaptive Management Fund should be promoted as it may help to alleviate some of the problems associated with the costs of developing and implementing long-term monitoring programmes. The establishment of an Environmental Grand Programme would act as an incentive for developers to progress with AM and in an EU context could help to strategically address environmental uncertainties with respect to migratory species, etc. Providing funds as an approach to integrate AM into the framework for ORE would work well in conjunction with amendment of primary legislation or adoption of rules grounding AM in the permitting processes. A co-ordinated programme would enable collective learning and could be expected to be more cost effective than alternative models.

3.3 Institutional arrangements

Employing a risk-based approach has institutional implications. First, AM should be initiated by regulators and developers in the pre-application stage and continue throughout the operation phase. This will assist project developers in moving forward from pilot projects to commercial developments based on increased knowledge about their devices and their interaction with the receiving environment. Institutional challenges, however, have been recognised as one of the greatest barriers for the implementation of AM in ecological systems (Garmestani *et al*., 2009). Critics of AM view it as an excuse to allow agencies an unreasonable amount of discretion in decision-making (Doremus, 2002). Secondly, employing an AM approach should be coupled with streamlined licensing processes, such as the SDM policy, to reduce timescales. Streamlined permitting systems contribute to reducing costs and timeframes related to consenting. As outlined in the RiCORE Deliverable 2.2, the adoption of a 'one-stop-shop' licensing approach is a key condition to address time-consuming, burdensome and expensive consenting processes (Le Lièvre and O'Hagan, 2015). Arguably, it may be easier to incorporate risk-based approaches in the modus operandi of a single authority responsible for decision-making rather than multiple authorities.

The licensing approach in Scotland may explain why the country has been relatively successful, in comparison with other EU Member States, in implementing AM at project levels. Marine Scotland is the only point of contact with developers for the issuing of Marine Licences under the Marine (Scotland) Act 2010, Section 36 Electricity Act 1989 consents and related environmental assessments and approvals (EIA, AA and EPS Licences). It is likely that developers will be more inclined to bear the expense of monitoring within an AM framework if cost-effective consenting processes are in force, perhaps if 'savings' have been realised at earlier stages such as during site characterisation surveys. Therefore, streamlined consenting approaches would be favourable to AM inasmuch as they help reduce development costs caused by long timeframes associated with a multi-consent and multi-authority system and help to ensure that data and information generated will be used to answer questions stemming from uncertainty. In circumstances where the 'one-stop-shop' approach is not possible, better coordination between institutions responsible for issuing permits has been called for (Jansujwicz and Johnson, 2015; Masterton, 2014).

A further strength of the licensing approach in Scotland identified through the RiCORE workshops is the staffing of scientific experts within the 'one-stop-shop' administration of Marine Scotland. On technical aspects, Marine Scotland's Licensing Operations Team (MS-LOT) is supported by Marine Scotland's Science Team (MSS) which has expertise in a range of topics that are key to understanding the marine environment. This enables opportunities for AM approaches to be identified and applied in-house, thereby improving the likelihood that post-consent monitoring is fit for the purpose of improving future decision making. This is considered important because the design of post-consent monitoring programmes may not be fit for purpose, and the underlying causes associated with low statistical power require technical expertise to ensure robust monitoring (MMO, 2014).

A key challenge posed by embedding an AM approach to consenting is the time frames involved. The overarching objective of taking an AM approach is to reduce scientific uncertainty. Often, this cannot happen quickly. Consequently, there is a salient need for the consenting authority to decide whether it is content to make consenting decisions based on the existing level of knowledge or whether it wishes to take a more progressive approach and reduce scientific uncertainty through embedding AM principles in its processes and procedures. The latter approach should not be restricted to ORE consenting processes but rather, in the interests of fairness, should be implemented across all marine sectors. This would also assist in the implementation of broader marine management objectives, such as the MSFD, where the programmes of measures designed to achieve Good Environmental Status are required to be “flexible and adaptive and take account of scientific and technological developments” (MSFD, preamble 34). Institutions that seek to implement AM should seek opportunities for learning outcomes that change their behaviours and assessment methods. This may entail a degree of cultural change moving towards approaches that are open and transparent about the need to make decisions in the face of uncertainty, and the need to learn by doing and thereby open to changing institutional objectives and advice in light of new knowledge. This cultural change by institutions is critical to achieving a balanced and proportionate approach to the application of AM. When engaging in AM, regulators must have sufficient scientific background to interpret monitoring results submitted by developers requesting modification to their licence conditions.

4. Balancing the Precautionary Principle and Adaptive Management

Principle 15 of the Rio Declaration on Environment and Development (1992) requests that countries apply the precautionary approach so as to protect the environment. This states that were there are threats of serious or irreversible damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation (UN, 1992a). Similarly, the 1992 Framework Convention on Climate Change (UNFCCC) requires that precautionary measures are taken “to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects" by providing that "where there are threats of serious or irreversible damage, lack of scientific certainty should not be used as a reason for postponing such measures […]" (UN, 1992b). The Convention on Biological Diversity prescribes that "where there is a threat of significant reduction or loss of biological biodiversity, lack of full scientific certainty should not be used to as a reason for postponing measures to avoid or minimize such a threat" (UN, 1992c). The precautionary principle therefore has a strong presence in various sources of international environmental law.

The precautionary principle is formulated in EU primary law under Article 191 of the TFEU. On the grounds that EU policy on the environment aims at a high level of protection, the European Courts held that, where there is uncertainty as to the existence or extent of risks to human health or the environment, "the Institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent" (T-13/99[6]; C-77/09[7]; C-446/08[8]; C-343/09[9]). The EC, in its Communication on the Precautionary Principle (COM (2000) 1 final), states that "the precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inconclusive nature of the scientific data" (EC, 2000, p.13).

In international law, both the threshold of irreversible damage and scientific uncertainty trigger the application of the precautionary principle. In the EU's legal framework, there is no need to prove that the risk of damage is irreversible or significant. There is a strong appreciation of the precautionary principle that suggests that regulation may be taken whenever there is a possible risk to the environment regardless of whether such a risk is irreversible. The TFEU does not define either the precautionary principle or the threshold of uncertainty that triggers its implementation. The degree of coherence in the application of the precautionary

[6] *Pfizer Animal Health SA v. Council*, para 119.
[7] *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute*
[8] *Solgar Vitamin's France and Others v Ministre de l'Économie, des Finances et de l'Emploi and Others*
[9] *Afton Chemical Limited v Secretary of State for Transport*

principle by the EU Courts has been hampered by the existence of a number of regulatory contexts and also by the fact that the precautionary principle is eminently discretionary (C-174/82[10]; T-13/99[11]).

The level of precaution applied has been primarily influenced by the standard set out in secondary law (Jiang, 2014). EU practice, though complex, has been refined by case law and the EC Communication (EC, 2000). In earlier judgements of the ECJ, the precautionary principle was applied where potential risks existed, even in the absence of tangible evidence (C-318/98[12]; C-180/96[13]). It is now well established in the case law of the European Courts that the conduct of a risk assessment and the existence of concrete evidence of risk of harm are preconditions to the adoption of the precautionary principle (Cases T-13/99[14]; T-70/99[15]; C77/09[16]; C-192/01[17]; C-236-01[18]). The fact that it might be impossible to conduct a full risk assessment should not be an obstacle to the adoption of protective actions.

Questions arise as to whether the precautionary principle, when justified by evidence of risk of harm, would impair the development of ORE technologies whenever the magnitude of harm is not well established. Where the European Courts have adopted a strong formulation of the precautionary principle in specific cases to ban the exportation of bovine products (C-180/96[19]) or refuse authorisation to commercial fishing (C-127/02[20]), it is not evident that the precautionary principle will systematically lead to a ban on new activities or technologies. With regard to undertakings at sea, Sunstein (2003) argues that a strong precautionary approach calls

[10] *Sandoz BV* [1983] ECR 2445, para 11-20.
[11] *Pfizer Animal Health SA v. Council* [2002] ECR II-03305, para. 160.
[12] *Fornasar et al v. Italy* [2000], ECR I-4785
[13] *UK v. Commission* [1998], ECR I-2265
[14] Op. cit. Para 143
[15] *Alpharma Inc v Council of the European Union* [2002] ECR II-3495, para. 151
[16] *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute,* [2010] ECR I-13533
[17] *Commission of the European Communities v Kingdom of Denmark,* ECR I-9693, para. 51.
[18] *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others,* ECR I-8105
[19] *Op. cit.*
[20] *Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging tot Bescherming van Vogels v Staatssecretaris van Landbouw, Natuurbeheer en Visserij [Waddenzee* case].

for a strong control of threats to marine mammals. For Sunstein, such stringent regulations impose a burden of proof on proponents that cannot be met due to the absence of authoritative scientific evidence. Given the lack of understanding regarding the interaction of ORE technologies with the marine environment, an overly precautionary approach would paralyze the development of greener technologies and thus encourage society to rely on well-established fossil fuels or coal power plants. In this respect, the precautionary principle reduces both the economic benefits associated with the emergence of ORE and the wider sustainability benefits including the ecological benefit of reducing global warming.

Moreover, the EC in its Communication on the Precautionary Principle (COM (2000) 1), has stated that not allowing activities to proceed may not be a proportional response in all cases. Risk reduction should include less restrictive measures which make it possible to achieve an equivalent level of protection. When applied to ORE, restrictive measures may entail limiting the numbers of tidal turbines owing to the perceived collision risk, or the reduction of exposure to noise for marine mammals, adoption of provisional limits on exploitation permits and/or tightening of controls. The implementation of precautionary measures may also entail the adoption of a moratorium until further scientific data become available. This entails a stop or holding action until uncertainties are resolved (Myers, 2000). The precautionary principle also encourages the consideration of alternatives in EIA (the Wingspread Statement). In considering potential alternatives, developers must demonstrate that there is no alternative that would be more environmentally-friendly than the proposed development.

If the precautionary principle allows the development of new ORE technologies despite uncertainty, it could be argued that this could improve scientific knowledge through experimentation. As the ORE sector is in its infancy (especially tidal and wave energy), uncertainties about the interactions of technologies with the physical environment and with key receptors need to be addressed through *in situ* monitoring. Therefore, MRE devices should be put in the water and monitored appropriately, to improve the state of scientific knowledge regarding their ecological implication. Approaches to the precautionary principle that are overly risk averse are not suited to this requirement.

Uncertainties will always remain about the impact of ORE technologies on wildlife, particularly, given the rapid evolution of the technologies. It is important to collect data at different spatial and temporal scales to identify a range of alternative responses to environmental impacts and assist in updating and adjusting policy accordingly (Noble, 2000). This also holds true for other marine sectors and activities. AM is well suited to actively promote the development of ORE technologies, as it encourages monitoring to reduce key scientific uncertainties and iterative decision making. AM and the precautionary principle are not contradictory and may be implemented simultaneously to improve scientific understanding. The concept of precaution can be fulfilled in AM when management objectives defined by regulators and stakeholders are relatively protective. The previous discussion in section 3 with respect to the need for conservation objectives for marine Natura 2000 sites that avoid a goal of strict protection from any risk of impact is consistent with this conclusion. AM in the operational phase of ORE may be designed to supplement and enhance the precautionary principle (Koppel *et al.,* 2014). Likewise, precaution may ensure that management actions are not likely to cause unacceptable environmental damage (Doremus, 2007).

Impact assessment is a precondition of the precautionary principle; when the EIA provides evidence of risks but where uncertainty remains with regard to the likelihood and magnitude of potential damage, the precautionary principle should trigger protective environmental measures but still provide scope for the development of mitigation measures. An AM approach might reduce uncertainty in the long term but not impact, and this may be viewed as a weakness of the approach. However, the precautionary principle can be applied in a framework for learning when there is uncertainty (Jasanoff, 2000). Doremus (2007) argues that precaution can improve science in the sense that the precautionary approach means that experts have to acknowledge that there is a risk of adverse environmental impacts. As such the precautionary principle can be seen to complement the need for AM approaches, providing the scientific uncertainty associated with potential changes arising from the proposed activity is deemed acceptable.

Monitoring and future management actions shall then contribute to the improvement of science and allow a move away from precaution to more realistic and informative assessments that provide regulators and stakeholders with higher levels of confidence. "Learning while doing", rather than freezing the *status quo*, is thus the appropriate type of caution when protective measures agree with AM principles. This is consistent with the view of the EC, which recommends that precautionary measures should be maintained as long as scientific data are inadequate, imprecise, inconclusive and that such measures have to be modified in the light of new scientific findings (EC, 2000, p.20). In this respect one way to deal with uncertainty associated with ORE, while enabling the industry to further develop, would be to incorporate elements of precaution at the same time as undertaking monitoring. Such precautionary measures in the operational phase may include limiting the scale of deployment in a phased approach. Where the outcome of monitoring programmes show that risks have been overestimated in the set-up phase, the mitigation measures may then be reduced or progressively removed in subsequent management decisions. This is highlighted by the example from the SeaGen tidal turbine in Strangford Lough, Northern Ireland in Box 3.

SeaGen Tidal Turbine, Strangford Lough, Northern Ireland

Deployment of the SeaGen tidal turbine was heralded by the consenting authority and the developer as taking an AM approach. The EIA identified a number of receptors (marine mammals, benthic ecology, tidal flow and energy) for which the nature and intensity of impacts were unknown. The main concern was whether the turbine would have an impact on the breeding harbour seal (*Phoca vitulina*) population. There was also a risk of potential impact on grey seals (*Halichoerus grypus*) and harbour porpoises (*Phocoena phocoena*). As a consequence, a number of management objectives were defined, these included:

1. No mortalities of marine mammals as a result of physical interaction with the turbine rotors;
2. Ensuring that the abundance of marine mammal population is not affected by the presence of the turbine;
3. Ensuring that the turbine does not create a barrier to the free passage of marine mammals in the Strangford Narrows;
4. Ensuring that the number of harbour and grey seal adults and pups present within the Strangford Lough SAC does not decrease significantly as a result of the installation and operation of the SeaGen Turbine;
5. Ensuring that the sub-surface noise generated by the turbine does not cause a level of disturbance to marine mammals sufficient to displace them from areas important for foraging and social activities.

The licence was conditional upon the undertaking of several monitoring projects in a customised Environmental Monitoring Programme (EMP) comprising sonar monitoring, seal telemetry studies, observation and monitoring during pile driving process, shoreline visual survey and aerial survey with associated mitigation measures:

- Marine Mammal Observer (MMO) to manually shut down the turbine for a short period of time when marine mammals were located within 200m of the turbine.
- After three years of post-installation monitoring, it was found that seals were not going to collide with the tidal turbine in the agreed perimeter of the 'shutting down' action (Royal Haskoning, 2011).
- Over time the mitigation measures attached were re-adjusted to progressively decrease the shutdown action distance from 250m to 100m within eight months, 50m after four months and then 30m after a further six months.

Data about marine mammal behaviour showed that changes in distribution of harbour seals, grey seals and harbour porpoise were mostly the result of inter-annual variations and not the result of the installation or operation of the turbine (Royal Haskoning, 2011, p. 33)

Box 3 SeaGen Tidal Turbine, Strangford Lough, Northern Ireland

It would appear the plan was designed specifically to relax a mitigation measure in this one site, but not to provide information that would inform better decision making using collision risk modelling at other locations. A key limitation to the usefulness of the approach taken in Strangford is that it has not allowed regulators to revise estimates of avoidance rates of marine mammals and accordingly regulators are not better informed and have not meaningfully learnt from this approach.

In conclusion, balancing the precautionary principle and AM within a regulatory framework for ORE is feasible if regulators and developers agree appropriate mitigation measures in the set-up phase. Subsequent adjustment of licence conditions should then allow more activities and not require more mitigation (Bennet, 2016).

5. Challenges and limits to the feasibility of Adaptive Management

5.1 Environmental receptors

The AM approach may not be applicable to all environmental receptors. The potential value of AM in individual management decisions is dependent on being able to acquire understanding of changes quickly enough to apply subsequent management options (O'Callaghan, 2013). Understanding of impacts on certain receptors cannot be obtained in a short-term or medium-term basis. Some species require long-term monitoring to detect changes. If reducing scientific uncertainties will take too long or be too expensive, regulators may prefer to accept the prevailing levels of uncertainty when making decisions. In addition, it may be the case that conservation objectives for species or habitats afforded protection under the Nature Directives involve targets of strict protection, with no tolerance of potential changes from human activities.

5.2 Financial risks

Developers may be reluctant to support an AM approach insofar as this approach may affect financial risk profiles of projects. This will be the case if it is unclear what the level and duration of monitoring will be or what actions regulators will take in light of the results. In the longer term as scientific uncertainty is reduced through AM, there could be less monitoring required provided the data can support such a position. However, AM can be expected to increase the costs that developers will have to bear in order to collect sufficient data to meaningfully study questions.

The costs of consenting and ongoing monitoring are relatively small (5-10% of CAPEX) in comparison to the lifetime costs of an offshore renewable energy project (Accenture, 2012; Leete *et al.*, 2013; MacAskill and Mitchell, 2013) but analysis of selected offshore wind projects in the UK identified that overall costs of meeting consenting conditions have increased by a factor of seven in the period 2002-2013 (Hawkins *et al.,* 2014). For developers, certainty regarding financial risk profiles is a pre-requisite to secure investments. Leete *et al.* (2013) carried out a survey of investors in marine renewable energy and identified that none of the participants who had invested in early stage MRE device development were likely to invest again in the future. The stability of overarching Government renewable energy policy and financial support mechanisms were seen as the major issues affecting the investment appetite and risk profiles of marine renewable energy projects. However, none of the respondents viewed the consenting and licensing process in itself as a major area of concern for investors, although it was clearly something that was part of their risk analysis when assessing projects, with unpredictability of costs and the time for projects to progress through consenting being key concerns.

In the UK, it is highly unusual for an offshore project to be refused consent (when a determination has been sought) on the grounds of impacts upon biological receptors, although the Docking Shoal offshore wind project was refused consent principally on the grounds of potential impacts on Sandwich Tern populations in combination with two other nearby projects. It is interesting in this case that the regulator decided not to permit the three projects together with phased building constraints, preferring instead to refuse consent for Docking Shoal on the basis that the other two projects would be given consent for their full capacities, thereby giving greater confidence to investors in the two consented projects. This example is discussed further in Box 4.

Docking Shoal Offshore Wind Project, Lincolnshire and Norfolk, England

The Docking Shoal offshore wind project was formally refused consent under Section 36A of the Electricity Act 1989 by the Secretary of State for Energy and Climate Change in July 2012. The principal concern of the regulator was the impact of the project on the nearby population of Sandwich Terns in The Wash and the North Norfolk Coast, both in isolation due to the Docking Shoal project and in combination with two other projects, Race Bank and Dudgeon.

In December 2011, the developer (Centrica) had asked the Secretary of State if the Docking Shoal application (with amendments to use fewer, larger turbines) could be placed into abeyance while further environmental information relating to bird impacts could be gathered. This was refused by the Secretary of State as he considered that placing an application into abeyance did not remove it from the planning system, and the in-combination effects of Docking Shoal still had to be considered alongside the other project applications that were in the planning system.

Consequently, the Appropriate Assessment for the project identified two options that were considered by the Secretary of State:

i) Consent two (Race Bank and Dudgeon) of the three applications with no building constraints
ii) Consent all three projects with building constraints.

The Secretary of State decided that refusal of consent for Docking Shoal (and giving consent to the other two projects) would be "more efficient overall in terms of UK renewable energy generation policies…." (DECC, 2012) than to consent Docking Shoal and the other two projects with phased building constraints. In doing so, the Secretary of State sent a clear message to investors that the projects at Race Bank and Dudgeon could be developed to their proposed full capacities, reducing uncertainties that a phased building approach could lead to reduced project sizes in the light of new environmental data.

Box 4 Docking Shoal Offshore Wind Farm, Lincolnshire and Norfolk, England

5.3 Availability of monitoring methodologies

The success of AM in the ORE sector is still dependent on the availability of monitoring methodologies to reduce scientific uncertainties created by ORE devices on pre-identified environmental receptors (O'Callaghan *et al.*, 2013b). These uncertainties must be reduced by either considering changes against a baseline or by improving the confidence associated with assessment and modelling frameworks by gathering new baseline data sets that can be used to add new parameters. Without effective post-consent monitoring methodologies, it is not possible to detect changes in marine ecosystems and to propose responsive management decisions. Commonalities exist in pre-consent practices regarding methodologies to be applied for the purpose of site characterisation. If receptors and methodologies used for the purpose of baseline characterisation are well-established, there remains a lack of guidance on how to adopt question-led approaches that promote meaningful post-consent monitoring. It is important to acknowledge that the methodologies identified during the pre-consent site characterisation stage may be adequate to inform decision making regarding the acceptability of potential changes to receptors caused by the presence of ORE technologies, however, they may not provide an adequate baseline for the purpose of meaningful post-deployment monitoring. These aspects are discussed in more detail in Deliverable 4.3. It is also necessary to promote the lessons learned from various monitoring methodologies in terms of what has worked and what is less effective. This will assist in helping future developers avoid unnecessary expenditure on insufficient methodologies.

6.4 The use of power analysis and variation in thresholds of significance

Increasing numbers of researchers are beginning to advocate and acknowledge the value of power analysis for optimising the design of monitoring programmes (Paxton & Thomas 2010, Mackenzie et al. 2013). Understanding how statistical power can be improved is fundamentally important for making informed decisions when designing and implementing 'fit for purpose' monitoring programmes. Generally speaking, the ability to increase statistical power is dependent on a number of factors, which include sample size, survey length/duration, frequency and the characteristics of the data (e.g. rate of change in the quantity being measured and the measure of precision). For a detailed discussion of power analysis from the perspective of survey design and the practical application of varying thresholds of significance, see Section 4 in D4.3 (Culloch et al., 2015). Herein, the present section focuses on the use of power analysis and varying thresholds of significance from the perspective of risk-based decision making in the context of AM and the considerations that will need to be taken into account by the regulators, developers and stakeholders.

High statistical power pertains to the ability of a monitoring programme to detect trends if they are occurring. Therefore, if regulators are aware of the statistical power attributed to a monitoring programme, they are better informed when entering into the decision making process. However, for a complex ecological scenario such as quantifying the potential impact of ORE on numerous receptors (e.g. benthos, seabirds, marine mammals), power analysis has shown that the statistical power of many monitoring programmes, when using the conventional significance threshold ($P \leq 0.05$), is often low (see Culloch et al., 2015). Therefore, in these scenarios, there is a real risk of failing to detect an impact (even if present) on the receptor of interest, which may result in an unacceptable and undetected change (e.g. population abundance).

In real terms, where $P = 0.05$, there is a 1 in 20 chance of falsely identifying a significant trend based on the results of monitoring when it does not exist in reality. Under the approach of varying the significance threshold based on the findings of a statistical power analysis (see Culloch et al. (2015) for further discussion), a significance threshold of $P \leq 0.2$ could be considered, for example. In real terms in this case, where $P = 0.2$, there is 1 in 5 chance of falsely identifying a significant trend that does not exist. Therefore, when using a threshold of $P \leq 0.2$, there would be a greater risk of incorrectly identifying a significant difference. If, as a consequence, the regulator required additional mitigation this would create additional costs which would not be required to protect the biodiversity feature to the standard considered necessary. Additional monitoring would also add costs but would reduce the risk of reaching false positive conclusions (e.g. by setting the threshold at $P \leq 0.05$). In scenarios where there are high levels of uncertainty, a sequential approach to use of P values may allow a project to move forward, where more conventional approaches increase the risk of either reaching false conclusions of no impact, or fail to minimise the time and cost requirements associated with levels of monitoring. Inevitably, to best identify an acceptable significance threshold requires information that goes beyond the science of ecology and biology, combined with statistics. Knowledge regarding the receptors of interest is of relevance, as is an understanding of the uncertainty associated with the potential effect(s) of the ORE devices, but so too are the wider socio-economic trade-offs that can inform risk-appetite.

6. The issue of environmental liability

Consenting procedures and engagement with AM involves a certain degree of acceptance regarding the risks that a development may cause to the marine environment. Both regulators and developers should consider the risk of environmental liability when deciding how best to moderate the use of the precautionary principle. The risk-appetite of developers and licensing authorities when engaging in a risk-based approach may depend on the liability regime applicable to their activities. The issue as to who is financially liable to remedy environmental damages when they occur is partially addressed in the Environmental Liability Directive (2004/35/EC).

In line with the ‘polluter pays’ principle, the Environmental Liability Directive (ELD) aims to hold the developer financially liable for the costs of preventing and remedial actions in the event of environmental damage or imminent threat of environmental damage. ORE development belongs to the category of occupational activities to which the Directive applies. Occupational activities are defined in Article 2 as any activities carried out in the course of an economic activity, a business or an undertaking, irrespective of its private or public, profit or non-profit character. Thus ORE either developed for commercial or testing purposes enters the scope of the occupational activities carried out in the course of an economic or non-profitable purpose.

Under the ELD, environmental damage means: damage caused to protected species and natural habitats which has significant adverse effects on reaching or maintaining the Favourable Conservation Status (FCS) of such habitats/species; as well as water damage which is any damage that affects the ecological, chemical and/or quantitative status and/or ecological potential of the waters concerned by the Water Framework Directive (coastal waters). However, the extent to which the ELD applies to the territorial sea and Exclusive Economic Zone (EEZ) is determined by the presence of protected species and natural habitats in these areas. The qualitative 'operator' covers the quality of ORE developers since it pertains to any private or public person who operates or controls such occupational activity (Article 2(6)).

One of the major improvements introduced by the ELD is that operators now bear a primary responsibility to prevent, notify and remedy environmental damage without being ordered to do so (Winter et al., 2008). Under the Directive, developers and/or operators are always liable in the first instance to prevent and remedy damages caused by their occupational activities. This applies even in situations where the damage was caused by a third party or resulted from compliance with an order or instruction of a Public Authority. According to the 'polluter pays' principle, an operator causing environmental damage or creating an imminent threat of environmental damage should, in principle, bear the cost of these preventative and remedial measures (Recital 18).

The ELD distinguishes between environmental damage or threat of such damage caused by any occupational activities listed in Annex III and damage to protected species and natural habitats caused by occupational activities not listed in Annex III. Where the extensive primary liability applies to the occupational activities in Annex III, regardless of whether or not the operator is at fault or negligent, activities outside the scope of Annex III are not considered as occupational activities to which strict liability applies (Article 3). Therefore, if offshore developments come within the spatial scope of the ELD, ORE projects are not listed in Annex III as activities to which the regime of strict liability applies (nor are the cables used to connect ORE installations to terrestrial grids – as these are not referred to as industrial activities under the IPPC Directive

96/61/EC). In other words, ORE developers are liable in the first instance to prevent and remedy damages only if they have been at fault or negligent.

Likewise, under Article 3(1)(b), ORE developers would only be required to prevent and remedy damage or threat of damage to biodiversity which refers to species and natural habitats protected under the Birds (79/409) and Habitats Directives (92/43), only. This excludes water damage (e.g. ecological and/or chemical qualitative status of marine waters) and damage caused to certain categories of species other than those listed in the Birds and Habitats Directives. Given that ORE installations will be located in offshore areas, it may be difficult to prove the fault or negligence of developers. One may consider that a developer will be at fault if they have not complied with the conditions attached to a marine licence or other consent. However, where conditions attached to a licence to construct and operate ORE facilities have been fulfilled, the extended primary obligation of developers to take measures and to bear the costs of preventive or remedial actions would not be enforceable on developers: this is a major drawback of the ELD.

An additional issue associated with the liability system of the ELD is that the competent authority is not obliged to take preventive or remedial measures in the place of the operator (Article 5(4), Article 6(3)). This means that where the developer is not at fault or negligent, and thus not obliged to treat environmental damage, the competent authority may decide to leave environmental damage unabated or untreated where budgetary restrictions hamper any action (Winter et al, 2008). This legal deficit can be addressed by Member States if more stringent legislation regulating activities failing under the scope of the ELD are in force in national legal frameworks. Some Member States have used their rights under Article 173 TFEU and Article 16(1) of the ELD to transpose the Directive more stringently.

In Ireland, for example, the EC (Environmental Liability) Regulations 2008 adopts this approach by providing a strict liability regime for damage or threat of damage to protected species and natural habitats by any occupational activities. In Spain, strict liability applies to preventive and emergency remedial actions for non-Annex III (including ORE development) and Annex III activities (BIO Intelligence Service, 2013). In other words, the environmental liability regime applicable in each Member State may influence the development of a risk-based approach to consenting processes. Where the strict-based liability regime has been extended to biodiversity, ORE developers are strictly liable for damage caused to protected species and natural habitats in coastal areas (as defined under the Water Framework Directive) but also in the Territorial Sea and EEZ whenever such species and habitats are located in these maritime zones. Therefore, the context of strict liability, may have a bearing on the risk-appetite of developers when they engage in a risk-based approach.

7. Conclusion

Due to scientific uncertainty on the environmental effects of ORE technologies, competent authorities have been inclined to apply an overly precautionary approach, requiring mitigation for impacts that may not be occurring and have established cultures of imposing monitoring requirements based on conventional approaches to statistical significance testing that can provide data-rich but information-poor results. This combination of issues can be addressed through taking an adaptive and risk-based approach to monitoring and consenting. Evidence from legislation and case law on risk-based approaches is limited and in some jurisdictions competent authorities have become risk averse. Cases like the *Sweetman*[21] case indicate that the burden of proof has been raised to a very high, almost criminal level.[22] Interpretation of risk and clarification of risk-appetite can be meaningfully, but not exclusively, informed by scientific and statistical information. This is considered to be useful compared to attempts to construe legal wording of court rulings and Directives without recourse to the best available science and case specific contexts.

[21] *Sweetman and Others* v *An Bord Pleanála,* C-258/11, particularly the Advocate General's opinion.
[22] Traditionally in criminal cases this is 'beyond reasonable doubt' whereas in civil cases the standard is on the 'balance of probabilities'.

Adaptive management is particularly relevant where decision makers consider that the level of scientific uncertainty needs to be reduced. Such scenarios are likely to be case specific, not being prescribed by statute, and adoption of AM can only be considered appropriate where it is coherent with conservation objectives for statutory designated/protected areas. Judgements around the use of AM approaches can be informed by a fuller understanding of the scientific uncertainties that would be the focus of the approach. Promotion of environmental assessments that quantify scientific uncertainties, will make decision makers more informed about the levels of confidence they require. Competent authorities need to be clear on whether the objective of monitoring is to reduce the scientific uncertainty associated with a one-off issue at a project level or to achieve learning that can be applied to future decisions by improving the confidence associated with assessment frameworks that rely upon quantitative modelling. The latter is one type of assessment approach but learning can still be achieved and applied to future decisions without quantitative modelling. The greatest value of AM to wider society is likely to be in an approach that exemplifies the goal of learning by doing. In this instance AM is more closely aligned with policy goals associated with future projects or phases of an existing project rather than the goal of relaxation of stringent management at the project site where data are gathered. It can be seen that AM offers flexibility in how it is applied under consenting processes but the underpinning philosophy and associated transparent consideration of risk-appetite are fundamental and existing risk-averse cultures associated with institutional and administrative systems may impede uptake.

AM is risk-based. Implementing AM entails decision-making based on acceptable levels of change combined with a proportionate approach to the need for mitigation measures based on first predictions of the impacts. The requisite balance needs to be protective enough to ensure, from the outset of the commissioning phase, that the development will not cause unacceptable change whilst also recognising that some changes are acceptable. AM need not be limited to reducing uncertainty associated with the overall levels of change resulting from ORE projects. Uncertainty regarding the efficacy of mitigation and compensation measures can be reduced by monitoring programmes. Where AM is being applied in the context of the precautionary principle, with the goal of moving towards more realistic assessments with improved accuracy and precision, then subsequent adjustments can be expected to be more likely to allow more activities rather than requiring more mitigation to existing activity (Bennet, 2016).

Despite the advantages of adaptive management, this approach to management should be applied with caution. In fact, this approach should not relieve developers and regulators from precaution. Doremus (2002) argued that 'in situations where action is perceived to be necessary but its consequences are uncertain, both an urge toward precaution and a commitment to science suggest that we look for ways to act incrementally while learning'. AM and the precautionary principle are not contradictory and should be implemented simultaneously to improve scientific understanding. Balancing the precautionary principle and AM in a regulatory framework for ORE is feasible if appropriately protective objectives and restrictive mitigation measures are agreed upon from the outset (set-up phase) to manage the risk of negative impacts to a level considered acceptable by regulators and stakeholders. Decision makers should strive towards making scientifically robust assessments of impact whilst taking account of the risks associated with the distribution of probabilities. Subsequent assessments should become progressively more robust with higher levels of confidence in the predictions. These can be used by decision makers to inform their decisions regarding existing and future projects.

There is a clear need for research on better AM practices and how it can be meaningfully applied. EU policymakers will need to consider how AM approaches can be further advanced and articulated with existing environmental legislation. In particular, the Habitats Directive relies on a formulation of the precautionary principle with the Appropriate Assessment being decisive for decision-makers. A key finding is that the conservation objectives for qualifying interests of sites must be coherent with the need for AM to measure a hypothetical effect in order to reduce uncertainty. Strict protection of highly mobile species with zero tolerance objectives will serve to limit the uptake of ORE and AM practices throughout the ranges of these species. In the context of the marine environment this would cover very large spatial areas. Though the EU has published some Guidance considering the use of AM in the implementation of the Habitats Directive, it is far from clear what the appropriate levels of risk appetite should be for decision makers. As joint or coordinated assessment procedures between the EIA and the Habitats Directives is now mandatory under the revised EIA Directive, further guidance is needed on what the Commission consider as AM and how it can be implemented in the frame of these joint assessment processes. Collaboration is key to the success of AM and further information is needed on how consenting authorities currently engage with academia and industry so as to ensure collaboration is occurring. Greater consideration will also need to be given to who pays for the monitoring and research needed to underpin AM if the approach is to be implemented more broadly.

The Environmental Liability Directive does not provide conclusive solutions about who is liable for environmental harms caused by ORE developers who have not been at fault or negligent. The competent authority who authorises the development is merely entitled to take remedial actions in the place of the developer but it is not obliged to do so. The extent to which regulators and developers will be willing to engage in a risk-based approach may also depend on the threshold of liability applicable to damages caused to marine and coastal waters and biodiversity in respective national legal frameworks.

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