THE

FRAMEWORK FOR

AQUACULTURE ENVIRONMENTAL RISK MANAGEMENT

(FAERM)

VERSION 3.0

Developed by the Aquaculture Task Group

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PREFACE

The Canadian approach to aquaculture development and environmental regulation is currently administered under federal and provincial jurisdiction. Under a series of federal-provincial Memoranda of Understanding on Aquaculture, established in the 1980s, provinces, with the exception of Prince Edward Island, are responsible for the issuance of aquaculture site tenures and operational licences/permits. As agents responsible for ensuring best use of Crown resources, provinces have introduced various instruments to regulate environment, fish health, water quality and other potential environmental aspects. As a result several pieces of aquaculture specific Provincial legislation have been established and/or adapted.

The federal government also exerts a powerful influence over siting decisions and environmental protection, primarily through three pieces of legislation – the *Fisheries Act*, the *Navigable Waters Protection Act*, and the *Canadian Environmental Assessment Act*. As is common in Canadian environmental statutes, both ss. 35 and 36 of the Fisheries Act are written to allow extensive administrative discretion. This discretion provides desired flexibility to respond to changing knowledge and emerging impacts but at the same time, can lead to reduced consistency and clarity of review and/or decision-making processes.

The Canadian Council of Fisheries and Aquaculture Ministers (CCFAM) has recognized that the shared roles in siting and environmental protection has led to a complex regulatory regime that needs to be streamlined. (for both regulators and industry)

In September 1999 the CCFAM established an Aquaculture Task Group (ATG) with the primary mandate of resolving the duplications and gaps in the regulatory framework for the aquaculture sector, particularly those related to siting and environmental protection. Various initiatives over the years have led to some achievements at the regional level, but industry concerns about uncertainties and climbing regulatory burden continued. At the same time governments, industry, markets and the public have concern about adequate environmental protection.

The regulatory regime for aquaculture is composed of two overlapping parts - site reviews (comprehensive environmental assessments that occur before the initial approval of a site and periodically thereafter depending on the regional regulatory regime), and operational regulation (related to ongoing operations such as movement of fish onto a site, feeding, use of equipment, etc.).

Identified issues with the regulatory regime include:

- jurisdictional overlap
- long and/or unpredictable decision timelines;
- unnecessary cost to government and industry;
- lack of transparency (e.g., policy, process, criteria and/or science and other information used to support decision-making);
- lack of readily and available/publicly available core information (e.g., area occupied by leases; number of leases, production); performance (e.g., escapes) or regulatory compliance (e.g., compliance with reporting requirements or with section 35 authorizations requirements);
- lack of adequate verification of effectiveness of regulatory regime, e.g., performance against objectives and principles; accuracy of reporting; etc;

- inconsistency in approaches of regulation to different sectors;
- inconsistent application between regions.

In its 2007/08 work plan, the ATG agreed to develop a national approach for identifying, assessing, communicating and managing environmental risks of aquaculture in order to:

- Provide regulators with decision support tools that use structured approaches for assessing the environmental risks of aquaculture to improve accountability, consistency and transparency
- Support improved risk communication with stakeholders
- Provide the initial analysis to support development of recommendations for policy and regulatory change to support a streamlined approach to regulation.

The approach developed into the Framework for Aquaculture Environmental Risk Management (FAERM). In June 2008 CCFAM Deputy Ministers have endorsed progress on the FAERM and regulatory reform as the major focus for the Aquaculture Task Group.

This Framework is a joint initiative, developed in collaboration by provincial/territorial and federal regulators and is a product of the CCFAM Aquaculture Task Group (ATG).

In the Fall of 2009, it is expected that CCFAM will be asked to consider three options related to this initiative:

- Endorsement of the FAERM Guidance approach as the policy basis for harmonization of F-P/T regulatory regimes and practice, recognizing that this will require coordinated regulatory change by some or all jurisdictions (expected changes to be identified through policy analysis and presented as part of the options; the feasibility of some jurisdictions opting in or out also to be assessed), along with endorsement of the FAERM tools
- Endorsement of the FAERM Guidance Document and associated tools as information to assist their respective jurisdictions in application of their regulatory responsibilities
- No action.

1.0 INTRODUCTION

Aquaculture risks are currently considered in a variety of ways at different stages in regulatory activity by Canadian regulators. The Framework for Aquaculture Environmental Risk Management (FAERM) will help organizations situate and strengthen current risk management activities as a natural part of existing review, decision and communication processes and an integral management tool.

A particular challenge in the case of Canadian aquaculture environmental management, is the multitude of environmental regulatory jurisdictions that govern its activities, combining regulations that focus specifically on aquaculture and ones that regulate a broader range of activities.

1.1 OVERVIEW OF THE FRAMEWORK FOR AQUACULTURE ENVIRONMENTAL RISK MANAGEMENT

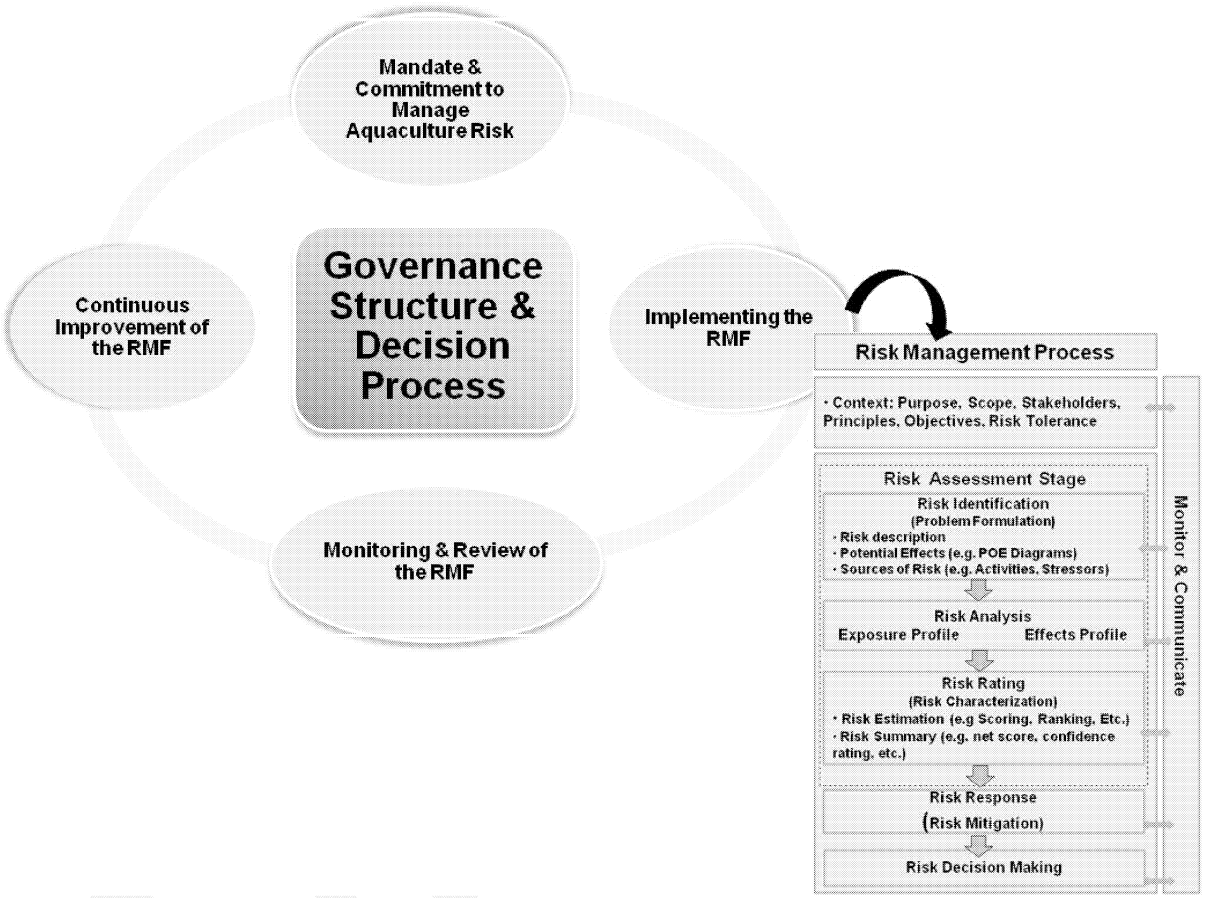
The Framework for Aquaculture Environmental Risk Management (FAERM) has been designed to align with current international ISO standards and best practice for risk management. In its development, consideration has also been given to:

- Federal risk management guidelines
- Corporate, environmental, health and food safety risk management processes in Fisheries and Oceans and other federal-provincial/territorial regulating agencies; and
- International environmental and food safety risk management initiatives.

The FAERM situates the Risk Management Process in a broader Governance Structure and Decision Process (Figure 1.1). There are a number of key features:

- A *mandate for the FAERM by its partners, and commitment its implementation*.
- *A Governance Structure at the centre of management of the FAERM.* Incorporation of an explicit Federal-Provincial/Territorial Aquaculture Environmental Regulation Governance Structure not only reflects leading best practice, but is particularly critical for aquaculture if jurisdictions are going to achieve consensus on regulatory harmonization (or at least coordination) is being sought. The Governance Structure outlines the regulations that are to govern the sector, the roles and responsibilities for delivery, the involvement of regulators in decision-making and the coordination/oversight of other parts of FAERM (See Section xxx for details).
- The *Risk Management Process* itself including Context information (Section xx) as well as Risk Assessment (Section xx), Risk Response (Section xx), Risk Decision-making (Section x). A shared *Context* (Purpose, Scope, Objectives, Principles, Risk Tolerance, and Involvement of Stakeholders) is crucial if different organizations are going to agree to cede jurisdiction, coordinate responsibilities or possibly delegate administration of responsibilities to another entity.
- The *Monitoring and Review* of the Framework itself to ensure it continues to meet leading best practice in risk management, the FAERM objectives and principles.
- Continuous adaptation and improvement to the Framework.

Figure 1.1: The Framework for Aquaculture Environmental Risk Management Framework (in relation to the Risk Management Process)



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1.2 FAERM Purpose/Overarching Goal

The FAERM is intended to contribute to decision-frameworks that balance environmental stewardship requirements with the interests of all resource users.

FAERM Goal

The FAERM goal is to identify a national approach that will support transparent, efficient, consistent and effective environmental regulation of the sector, leading to recognition of the strength and value of the Canadian environmental management regime for aquaculture:

- In the marketplace, facilitating Canadian access to sustainability certification and related labelling;
- In the domestic and international investment community, facilitating access to capital; and
- In coastal communities, facilitating access to sites and growth opportunities.

It will contribute to this goal by providing risk management policies, information and tools required to support development and implementation of a coherent national approach to environmental regulation of the sector.

Intended Uses of the FAERM Guidance Document and its Tools

The FAERM Guidance document is meant to establish:

- The standard by which federal-provincial /territorial governments will measure their individual and combined regulatory performance; and
- A common policy framework that will guide any joint initiatives to harmonize and/or coordinate regulatory regimes.

The Guidance document and its associated tools are also intended to support:

- Sharing of risk management knowledge and practices between regulators.
- Sharing of aquaculture specific tools in support of application of risk management to aquaculture.
- Development or regulatory research priorities.

1.3 Scope of the FAERM

The scope of the Framework has been limited in order to be able to achieve a result within a reasonable time frame with the resources available. This is not meant to devalue the importance of those activities, sustainable development, and ecosystem components outside the scope. It does, however, reflect the priority of the CCFAM ATG – i.e. resolution of the environmental regulatory tangle – the aspect of the regulatory regime, where federal-provincial/territorial regulatory activities are the least clear and require joint action.

Scope of sustainability considerations - The FAERM itself is limited to policy related to *environmental* considerations but has been designed so that it can be considered in the larger decision making context including social and economic considerations of aquaculture, and includes consideration of other activities in a broader coastal management context. The decision-making section references the need to integrate socio-economic, legal and

operational risks. While the general risk management framework will be the same for socio-economic, legal and operational risks, this document and its tools do not provide specific guidance related to these aspects. That being said, it is tentatively proposed that a limited cost-benefit assessment be included during the development of Risk Response (mitigation) options. In addition, the evaluation of regulatory regimes against the framework (as well as the ongoing monitoring and review of the Framework once it is in place) will include cost-benefit analyses, as is required by Federal Treasury Board policies.

Scope of Application to Types of Operations - While the overall risk management approach and principles are broad enough for wide application across the aquaculture sector, specific aspects (e.g. Governance structures and Pathways of Effects) have been developed only to include to environmental considerations relating to *suspended and bottom culture of finfish and shellfish* including *all phases of operations on and in the water and sea/lake bed.* The FAERM does not consider land-based aquaculture at this time. Shoreline alterations (e.g., related to water access points, shore buildings) are also not included.

Scope of ecological components encompassed - The environmental risks focus on those related to *fish habitat, water quality, fish health and fish populations/communities*, where the term "fish" is very broadly interpreted to include all life stages of fish, marine plants, marine mammals, and macro and microfaunal communities (e.g., plankton, benthic communities). Aquatic birds are not included in the scope of environmental risks at this time.

Scope of Regulatory Regime Functions - The FAERM is designed to encompass all facets of regulatory management including initial risk assessment and response to risks, risk decisions (e.g., siting, approval of movement of fish), risk monitoring (performance, compliance), risk communications, and the development of science and other information bases.

Summary of Scope of FAERM

- *Sustainability considerations* - Environmental risks
- *Types of aquaculture operations* - Suspended and bottom culture of finfish and shellfish including all phases of operations on and in the water and sea/lake bed.
- *Ecological components* - fish habitat, water quality, fish health and fish populations/communities, where fish is very broadly defined (see above).

1.4 Intended Audience

The FAERM and guidance documents are intended primarily to be used by those in both federal and provincial levels of government who regulate, develop, apply policy, provide risk analysis and other science advice, undertake research, communication risks, and make decisions regarding the aquaculture industry in Canada within the Scope of the Framework outlined above

Other potential users / readers include those who are interested in how the industry is managed and the policy and information that guides those decisions, including Industry, First Nations, ENGOs, Members of the public, and International parties.

1.5 Word of Caution on Risk Terminology (to be developed)

- Risk management has a lot of differences in terminology and very strongly held opinions.

- Where possible we have gone with ISO Leading Practice
- importance of consistent terminology to communication
- reference to glossary (annex)

2.0 THE RISK MANAGEMENT CONTEXT

2.1 FAERM Governance Structure

2.1.2 Proposed Multi-jurisdictional Governance/Coordination Structure

- **F-P/T Regulatory Coordination / Oversight Committee**
- **Delineation of F-P/T Roles and Responsibilities**

2.2.3 Stakeholder Involvement

2.1.1 Summary of Legislative and Regulatory Authorities

- this section will include either a summary of existing authorities (under development); will be adapted to reflect any regulatory changes undertaken

2.1.2 **Multi-jurisdictional Governance Structure** (To be developed post decision on reform)

- **F-P/T FAERM Coordination / Oversight Committee**
- **Delineation of F-P/T Roles and Responsibilities**

2.1.3 **Roles of regulatory players in individual decisions** (e.g., separation of risk assessment from risk decision)

2.1.3 Stakeholder Involvement

- Role in FAERM Governance
- Role in individual decisions

- General advice in framing this section – All risk management activities will have a variety of federal, provincial, industry and public stakeholders. Certain jurisdictions may have pre-established mechanisms to understand, map and engage stakeholders. In the absence of such direction, risk assessors are encouraged to distinguish between primary (those stakeholders with aquaculture accountabilities and mandates) and secondary (all other).

2.2.5 Quality Assurance – Monitoring, Review and Adaptation of FAERM

2.2 Environmental Management Objectives

Leading best practice in risk management requires an objective-centric approach, meaning that management objectives are kept in mind at each stage of the risk management process. In the case of FAERM, the primary objectives are expressed as the Environmental Management Objectives (Figure 1). The FAERM develops and situates all risk information in relation to these stated objectives to enable all stakeholders to understand which objective(s) could be most impacted.

These objectives can be further refined to specify management level objectives that demonstrate how these objectives are to be met at an operational level (See Appendix xx: *incomplete*).

Figure 2.1: FAREM ENVIRONMENTAL OBJECTIVES

The overall goal under the FAERM is to support sustainable use of aquatic resources and responsible development of the sector in a manner that benefits all Canadians.

Supporting this goal, four broad national environmental objectives have been identified reflecting the scope of this initiative:

1. Protection of fish and fish habitat supporting no net loss of productive capacity
2. Protection of water quality by preventing pollution and promoting waste minimization
3. Protection of general fish health in both wild and farmed populations
4. Protection of overall aquatic population and community dynamics concerning the fitness of wild fish and trophic web interactions

It is recognized, however, that there are risk management approaches that link to aquaculture, that are applied across activities other than aquaculture. During the development of the FAERM, care needs to be taken to consider the spectrum of objectives governing risk management approaches under regulatory responsibilities such as:

- Health of Animals Act,
- National Code for Introduction and Transfers of Aquatic Organisms,
- Habitat Management Program Risk Management Framework, and
- Various provincial environmental regulations

Gaps and linkages to the FAERM environmental management objectives need to be identified and an approach agreed to at the onset respecting the integration of other related objectives before implementation of the FAERM could be considered.

2.3 Determining Acceptable Levels of Risk *(to be developed)*

Rating of risks requires an understanding amongst regulators of what constitutes 'acceptable environmental risk'. In developing the FAERM, an initial set of national risk criteria will be developed in discussion with senior management. The addition of regional or zonal risk criteria may be appropriate. These risk criteria will then be used by risk assessors when applying the risk management process.

2.4 FAERM Principles

Principles are often identified to help guide the development of significant policy and its subsequent implementation.

The following principles have been adapted from a wide range of domestic and international sources to support the development and application of the FAERM.
They are expected to be reflected in regulatory regimes and in regulatory practice that fall under the scope of this initiative. They are intended to be used in the evaluation of current regulatory regimes and in the ongoing application of future regimes as part of a systems audit. Further details can be found in Annex B.

Figure 2.2: FAERM PRINCIPLES

1. *Uncertainty* in information is expected and is explicitly identified, considered and communicated.
2. The *precautionary approach* is used in decision-processes.
3. An *understanding of the complex interrelationships* that exist in the ecosystem and the impact of human activity on the ecosystem is to be conveyed.
4. *Risk descriptions* are based on peer-reviewed, scientific knowledge, complemented by traditional knowledge as appropriate
5. *Performance-based management* approaches to reduce risk levels are encouraged rather than prescriptive regulation.
6. *Plain language and concise synthesis* of information supports a common understanding of risks across a broad diversity of decision-makers and stakeholders.
7. Risk decisions *maximize net benefit* to Canadians to the extent possible, considering costs and benefits of potential management actions and non-actions.
8. *Stakeholders* are appropriately engaged in order to access the full range of knowledge available, to better understand interests and positions, to support common understanding of risks and options, and to improve accountability.
9. The basis for decisions is *transparent*, decision-making processes are *coherent* across jurisdictions yet there is adequate *flexibility* to reflect regional and biophysical differences in acceptable levels of risk
10. Risk management under the FAERM is consistent with Risk Approaches used in other sectors and decision-making structures.

2.5 Key Success Factors in Implementing the FAERM

- *Senior level support for the framework*: when the framework is applied, the output is intended to inform senior level decision-making processes regarding the regulation of aquaculture. Regulatory decision-makers are therefore principle beneficiaries of the FAERM as they seek to ensure they have the best quality information available on risk and uncertainty in any situation. Their support in developing and then ensuring effective implementation of the FAERM is essential.
- *Integration of FAERM to existing processes:* Understanding and managing risk takes time and effort that can be optimized if the FAERM is applied to key existing processes of regulatory organizations. FAERM should first identify, integrate and align existing risk processes to the framework (including legal, decision making and review activities related to decision making)
- *Strengthen risk management capacity*: As the Canadian public sector renewal proceeds and knowledge about risk in regulation transitions, regulators and industry should ensure they have adequate risk management skills to meet an increasingly complex environmental risk landscape through such mechanisms as Tools, Training and a community of practice.
- *Implementation Approach:* The approach to implementing the FAERM should be determined based on an analysis of the current regulatory environment in each jurisdiction. Implementation may be phased in based on specific needs and capacity to implement.

- *Evergreen FAERM:* As the FAERM is applied, lessons learned at every phase of the risk management process and overarching Framework should be captured and leveraged in an effort to maintain relevance.

3.0 FAERM RISK ASSESSMENT PROCESS

(NOTE: this whole section suffers from risk mgt's general struggle with terminology; one term will be developed for each for this document with a glossary and cross walk; tone is not yet right – still more of a discussion paper format that a "this is what is being done") **WG** has not had much discussion to date on sections 3.2-3.4)

The risk management process requires that risks associated with the proposed activity be identified and rated. Once all risks have been rated, the result will be a risk profile for the activity which helps decision makers to readily understand what risks are the most significant and require maximum effort by the applicant and regulator in actioning and monitoring.

The Risk Assessment stage of the FAERM has three main steps outlined in the following sections. These have been modified from USEPA 1998, 2004, NOAA 2005). A comparison of approaches and terminology can be found in the discussion paper on Risk Assessment Approaches (Floyd; Appendix xxx).

3.1 Risk Assessment

3.1.1 Identification of Risks

Also called planning and problem formulation, this stage in risk assessment includes scoping the problem or issue and identifying biological or ecological effects[1].

The information developed during this stage can be presented in different ways. The categorization of ecosystem risks under any system is by its nature, somewhat arbitrary. It is most important to present and explain the methodology and results in a transparent way. In addition, under a harmonized, or at least coordinated approach, the methodology needs to be consistent (or at least comparable).

The FAERM follows a model developed by DFO Oceans Habitat, Pathways of Effects (POEs).

ADD IN GENERIC FLOW DIAGRAM
VERIFY WORDING WITH HABITAT

These flow diagrams are useful because they visually illustrate the cause and effect linkages between activities or practices of the operator down to the most salient changes in the actual functioning of the ecosystem. This is particularly useful when determining/conveying appropriate Responses to Risk and in assessing/illustrating the rationale for the final residual risk assessment after all risk mitigation has been incorporated. The POEs utlilize the following terms in outlining the cause – effect relationships.

- *Activity* – the actions undertaken by the site operator to establish, operate and close operations;

[1] Note that the USEPA and NOAA call this section the "Planning and Problem Formulation". More recent international standards for risk management have separated out much of the planning elements (e.g., scope, general objectives, etc.) into a Risk Context stage that comes before Risk Assessment, and which applies to the entire Risk MANAGEMENT framework. This RMF follows this approach, with a separate context section. This section, is therefore limited to "Problem formulation".

- *Stressor* – a change in the state of the ecosystem as a result of Activities interacting with the natural environment. In ecological sense, the term stressor is neutral – it is not meant to imply "positive" or "negative" connotations as those values can depend on the perspective of the individual. While some Risk Management processes and their Risk Assessment stages specifically state that only "negative" stressors and effects are to be described, the FAERM principles commit to examining and considering both positive and negative effects in the final Risk Assessment.
- *Effect* – A change in a particular component of the ecosystem as a result of the change in the Stressor.

There are a number of challenges to the POE approach that the FAERM tries to address:

- Complex schematics frequently result, making it difficult to see the cumulative impacts, and/or to discern individual causal links. *The FAERM mitigates this by providing matrices that summarize the information in the diagrams (See Tables 3.1, 3.2)*
- The diagrams cannot easily convey ecosystem complexity such as links between effects. *The state of knowledge reports supporting risk descriptions are expected to convey this information even if it does not appear in the diagrams.*
- Due to the complexity of arrows that results (or the plethora of individual scale diagrams), the POEs focus on the highest level of effects, and do not go down to the "ecological" endpoints. The definitions of terminology used for the POEs are meant to capture most if not all aspects of this (see Appendix xx: POE Glossary of Terms). *As well the state of knowledge reports supporting risk descriptions are expected to convey this information even if it does not appear in the diagrams.*

Step 1: Identification of Risks - Identifying Sources of Risk

This step focuses on the identification of the sources of risk (i.e., what activities are being undertaken), that would lead to environmental stressors, consistent with the scope of the overall environmental management objectives.

Within the scope of FAERM, aquaculture activities that could lead to environmental stress have been identified as follows (to be verified through engagement particularly with site operators to confirm actual practices):

- *Site and Stock Management* which includes, but is not limited to: defouling, net changing, on-site housing, predator management, waste management, chemical storage, handling and use, use of lights, mortality removal, stocking/transport of fish on site (including nursery and relay), feeding, disease and pest management, grading, harvesting/slaughter on site. Note that not all subactivities may occur on every, or even most, sites.
- *Placement and Removal of Site Infrastructure* which includes but is not limited to: addition/removal of items such as long-lines, anchors, moorings, berms/cobble, rafts, cages, barges/platforms, buoys, French tables. Note that not all subactivities may occur on every, or even most, sites.
- *Use of Industrial Equipment* such as boats, pumps, generators, feeders.

The above aquaculture activities have been tentatively linked under the FAERM work to the following categories of stressors (categories have been developed through extensive discussions with regulating groups and have been presented at a workshop with industry, ENGO and FN representatives; unlikely to change at this point):

- Physical alteration of habitat structure,
- Alteration in light,
- Release/removal of organic material and nutrients,
- Noise,
- Release of chemicals and litter,
- Release of pathogens, and
- Release of cultured species.

Step 2: Identification of Risks - Identifying Potential Effects

Once potential sources of risk (activities and sub-activities) and stressors have been identified, there needs to be an identification of potential effects that could occur as a result of the stressors; within the scope of the overall management objectives (see Context Section xxx).

Identification of the environmental effects is defacto the formal and clear identification of the environmental characteristics the FAERM is intended to protect. Effects should be:

(1) ecologically relevant (i.e. they reflect important characteristics of the ecosystem),
(2) susceptible to the stressors of concern,
(3) measurable, directly or indirectly, to evaluate the effects of a given stressor, and
(4) relevant to environmental management objectives.

The FAERM work to date has identified the following ecological effects potentially linked to aquaculture activities within the scope of this exercise:

- Change in contaminant concentration
- Change in substrate composition
- Change in structure, cover and vegetation
- Change in oxygen (water column, benthos)
- Change in wild /farmed fish health
- Change in wild fish populations/ communities
- Change in food availability/ food supply
- Change in primary productivity
- Change in water flow
- Change in access to habitat /migration routes
- Change in suspended sediments

The FAERM results to date for Steps 1 and 2, can be summarized in the highest level Aquaculture Pathways of Effects diagram (See Appendix xx for detailed diagrams)

The POE diagram information can also be summarized in matrix tables.

Tab1e 3.1: Summary of Aquaculture Activities and Their Potential Resulting Environmental Stressors
(anticipated linked indicated by presence of X in cell)

Stressors		Major Aquaculture Activities		
		Site & Stock Management (1)	Placement/ Removal Site Infrastructure (2)	Use of Industrial Equipment (3)
Alteration of light	Photoperiod manipulation	X		
	Shading adjustments		X	
Release of chemicals and Litter	Release of litter	X		
	Release of antifoulants	X		
	Release of therapeutants	X		
	Release of cleaners & disinfectants	X		
	Spills/ release of fuels, lubricants			X
Physical alteration of habitat structure	Addition/removal of shoreline/bottom structure		X	X (e.g., bottom shellfish)
	Addition/removal of vertical site infrastructure		X	
	Re-suspension/entrainment of sediment		X	X
Noise	Noise			X
Release/removal of organic material & nutrients	Release of fouling organisms	X	X	
	Release of human waste/pathogens	X		
	Release of excretory waste & excess food	X		
	Release of harvest waste and mortalities	X		
	Removal of food/oxygen (due to increased biomass)	X		
Release of pathogens	Release of aquatic animal pathogens	X		
Release/removal of fish	Release of cultured organisms	X		
	Removal of predators (To be completed – new)			
	Entrainment/ crushing killing of organisms.		X	X (e.g., bottom shellfish)

Table 3.2: Summary of Potential Aquaculture-related Environmental Stressors and Potential Effects

In the following table, the presence of a number in a cell indicates that the FAERM working group has identified a possible causal link between a stressor and effect (scientific basis for each cause/effect to be verified through the national CSAS process). The number entered in each cell indicates a possible link between the stressor and a particular aquaculture activity as follows: (1) Site/stock management; (2) Placement/removal of site infrastructure; (3) Use of industrial equipment (activity/stressor links to be verified through engagement, particularly with site operators). Yellow highlights indicates uncertainty by group tasked with drafting.

Stressors		Effects										
		Change in contaminant concentration	Change in substrate composition	Change in habitat structure, cover & vegetation	Change in oxygen (water column, benthos)	Change in wild /farmed fish health	Change in wild fish populations/communities	Change in food availability/ food supply	Change in primary productivity	Change in water flow	Change in access to habitat /migration routes	Change in suspended sediment concentration
Alteration of light	Photoperiod manipulation			1		1	1					
	Shading adjustments			2				2	2			
Release of chemicals and Litter	Release of litter		1	1								
	Release of antifoulants	1				1	1					
	Release of therapeutants	1				1	1					
	Release of cleaners & disinfectants	1				1	1					
	Spills/ release of fuels, lubricants	3				3	3					
Physical alteration of habitat structure	Addition/removal of shoreline/bottom structure		2,3	2,3			2,3		2,3			
	Addition/removal of vertical site infrastructure		2	2				2		2	2	
	Re-suspension/entrainment of sediments	2,3	2,3		2,3		2,3			2	2	2
Noise	Noise						3	3			3	
Release/removal of organic material & nutrients	Release of fouling organisms		1		1		1	1	1			
	Release of human waste/pathogens		1	1	1		1	1	1			
	Release of excretory waste & excess food		1	1	1	1	1	1	1			
	Release of harvest waste and mortalities		1	1	1		1	1	1			
	Removal of food/oxygen (due to increased biomass)				1		1	1	1			
Release -pathogens	Release of pathogens					1	1					
Release/removal of fish	Release of cultured organisms					1	1	1				
	Removal of predators											
	Entrainment/ crushing killing of organisms.		2,3	2,3	2,3		2,3	2,3				

Step 3: Identification of Risks – Subeffects or Ecological Endpoints

Some Risk Assessments (e.g. USEPA) take the effect analysis one step further than the current FAERM POE diagrams with effects "unpacked" to identify the specific "ecological endpoints" (sub-effects) that are impacted. This approach is also consistent with DFO Science's proposed approaches. A challenge is that these "endpoints" or "sub-effects" cannot always be measured directly or it may be possible to measure them but only at a relatively high cost. On the other hand, they provide greater clarity in the cause/effect evaluation, and a better idea of the actual risks involved and allows for better (more specific) evaluation of mitigation options.

According to the USEPA (1998), assessment endpoints express the specific environmental aspects that are of concern and provide further information. To illustrate, in FAERM, ecological endpoints related to the effect, "Change in Fish populations/ communities" would address the questions:

- What is the change within the population that is of concern – A change in fitness of individuals? A change in survival rates? A change in population biomass? A change in proportion of alleles in a population? etc.
- What is the change within the fish communities that is of concern – A change in diversity in benthic communities? A change in relative abundance of predator/prey? Etc.

3.1.2 Risk Analysis

Risk analysis is the second stage of risk assessment, where existing scientific data, modeling and expert opinion/knowledge are synthesized to develop factual descriptions of state of knowledge with respect to:
Note: Should see how to link in TBS/DFO Corporate Risk guidance, e.g., definitions of "likely", "impact" – won't translate directly but would be useful to come as close as we can

1. *The description of exposure*[2], which includes details on the activity and sub-activities (source of risk), the stressor, the environment; and the contact between the stressor and the environment (e.g., biological, physical or chemical features), and
2. *The description of ecological effects* that may occur as a result of exposure to a stressor.

Note: DFO Habitat does not explicitly discuss exposure in its risk approach; CFIA does in its Animal Health Risk Assessments, although some terminology may differ from what is presented here. Under FAERM, it is intended that descriptions of both exposure and ecological effects will be undertaken.

The Risk Analysis phase refines the information and analysis related to each activity-stressor-effect link. This information will provide the scientific basis for estimating and describing risks in the Risk Characterization phase (USEPA 1998).

It is important to note that the Risk Analysis is an iterative process and as scientific information is assembled specific effects may be refined or deemed insignificant and dropped from the POE Diagrams.

The intent in the FAERM initiative is that national risk analyses be completed through the DFO Canadian Science Advisory Secretariat process. *Add some info on the general CSAS process; link to meeting some Principles*

3.1.2.1 Description of Exposure

The description of exposure involves the measureable, qualitative or quantitative description[3], of the degree and likelihood that the environment will be exposed to

[2] The USEPA RMF Guidelines refers to this section as the Characterization of Exposure, but to avoid terminology overlap with the Risk **Characterization** Phase (separate stage), this section will be termed the "Description of Exposure". Similarly the USEPA RMF Guidelines uses "Characterization of Ecological Effects" rather than "Description of Ecological Effects".
[3] See Section on Likelihood for a discussion on use of "qualitative vs quantitative" data.

specific stressors. The output of is referred to as the "exposure profile" and is combined with the "effects profile" in the "risk rating" stage in order to estimate the risk. The description of exposure should reach a conclusion about the degree and likelihood that the environment will be exposed to a given stressor (i.e. that there will be a link between a given stressor and effect) and answer the following questions (modified from USEPA 1998):

To be modified to reflect final questions for CSAS papers

- What is the likelihood that exposure will occur?
- What is exposed?
- How does exposure occur?
- How much exposure occurs? When and where does it occur?
- How does exposure vary?
- How uncertain are the exposure estimates?

The above questions are responded to in a structured manner so as to develop an exposure profile. The following table outlines the proposed characteristics to be used in the FAERM exposure profiles (modified from CFIA and the USEPA).

Table 4.1 – Proposed FAERM Exposure "Characteristics" (i.e., information gathered to describe exposure)

Information	Description	
Source	The place where the stressor originates or is released (e.g., brood stock, equipment) or the management practice (e.g., harvesting, net cleaning) that produces stressors.	Likelihood and Uncertainty
Routes of Exposure	How exposure occurs (e.g., ingestion, spill, escapes).	
Time	Includes aspects of duration, frequency, and timing (e.g., Does the timing of exposure overlap with a particularly sensitive life-stage).	
Space	Spatial distribution of stressors in the environment (Does the distribution of exposure overlap with habitat that a species is particularly dependent upon).	
Intensity	Amount of stressor per unit area or per unit time.	
Receiving Environment Characteristics	What populations, species and characteristics of relevant ecosystem components might be exposed (relates to rarity, species at risk) \; **and** How characteristics of the environment (abiotic and biotic) or characteristics of the receptor mediate exposure (related to sensitivity).	

Actual "estimation of risk" does not occur during this phase but instead focuses on describing and recording scientific information on exposure in a structured manner (exposure profile).

3.1.2.2 Description of Ecological Effects

The description of effects identifies and describes any effects (positive or negative in the case of FAERM) caused by a stressor. To properly analyze the potential ecological effects, a risk assessment requires:

- *Causality* - an evaluation of the evidence that the stressor causes the effect;
- *Stressor- Response Relationship* - an evaluation of how the effects vary with stressor levels

- *Biological indicators of effects* – description of how changes in effects can be evaluated in monitoring programs

Causality - Establishing Cause-and-Effect Relationships

Causality is the relationship between cause and effect (i.e., evidence that exposure to stressors causes an observed response). Without a sound basis for linking cause and effect, uncertainty in the conclusions of an ecological risk assessment is likely to be high and risk may be over-estimated.

Table 3.x: FAERM proposes to use the following criteria when analyzing causality:

	Causality strongly affirmed	Weak causality
Degree of Association	Statistical significance of causal link	
Consistency of Association	Cause/effect demonstrated repeatedly	Stressor present without expected effect, or effect occurs but stressor not found
Specificity of association	More specific or localized, easier to identify cause	Direct association not easily identifiable?
Predictive performance	Effect follows a change in the hypothesized cause	Temporal incompatibility - presumed cause does not precede effect
Plausibility	Demonstrated link present, e.g., effects decrease with distance from stressor	Factual incompatibility with experimental or observational evidence

Stressor-Response Relationship

To evaluate ecological risks, one must understand the relationships between stressors and resulting responses. In other words, as stressor intensity increases, what is the estimated or observed response of an ecosystem component.

Table 3.x: FAERM proposes to use the following characteristics or attributes when describing the stressor-ecological response relationships (provide the detailed descriptors developed in workshops?):

- The intensity of the effect(s),
- The spatial extent of the effect,
- The time scale for recovery (resilience, and recoverability/ reversibility, duration),

More particularly, the descriptions should indicate how the characteristics change with the degree of change in the stressor.

Biological indicators of effects

Measurability of change is a key criteria for the identification of effects to be considering in the risk analysis. The rational for the linkages between effects and indicator of change needs to be specifically outlined (ecosystem "performance" indicators). *DFO Science is currently leading an initiative to establish criteria for the selection of such ecosystem indicators and a process to review the scientific basis for proposed indicators for specific purposes such as this framework. A next step in the FAERM is to complete the compilation of indicators currently in use, and evaluate them against the*

criteria that are being developed by DFO Oceans/Science. The information will be summarized here.

3.1.2.3 Summary Profile (POE descriptions)

Summary profiles combining the descriptions of exposure and effects will provide the scientific basis for estimating risks in the Risk Rating (Characterization) phase (USEPA 1998). Once appropriate the FAERM tool box will contain:

3.1.3 Risk Rating

Also termed Risk Characterization, the Risk Rating relies on the summary of information from the Risk Profiles in a format to be communicated to the decision maker. Rating risks enables decision makers to compare the relative importance of all risks in relation to each other and determine which risks have been rated as warranting maximum effort and attention. May also be able to provide insight as to the inter-risk relationships as well i.e. if one risk is mitigated, it may lessen the potential impact of another risk at the same time

This step involves professional judgment, and is a separate from the Risk Analysis stage, which conveys state of knowledge information. Along with professional judgment this phase also introduces values for the risks as well as risk tolerance. Risk ratings are, in effect, an expression of a decision maker's tolerance for risk. Results from the risk assessment are presented in relation to the decision maker's expressed tolerance

Establishing and agreeing on the approach that will be used to rate risks is a discrete step in the risk management activity. Depending on the risk context, organizations may develop one risk rating approach for all types of risks and all scenarios. Other organizations may choose to use one rating approach for most risks and adapt that approach for certain unique risk situations.

Irrespective of the approach used, it is imperative that the risk rating approach have the visibility and support of the decision makers in advance of applying the risk ratings and conducting any risk assessment activities.

3.2 Responding to Risk (To be developed)

Risk Mitigation – need to discuss when/where mitigation gets considered in the process. Risk analysis is run at least twice if significant residual risk is identified:

- in a less theoretical context (i.e. where regulatory context is more certain), the usual risk management practice is to include any "standard" mitigation measures in the original round of risk analysis; in this case, responding to risk refers only to the "extraordinary" actions, perhaps unique to an unusual site condition. Residual risk then refers to the risk that cannot be eliminated through responses to risk.
- in aquaculture (because of its relative newness, the uncertainty of the regulatory environment and/or the uniqueness of sites?) the literature often refer to "significance" of risks in absence of regulatory or other standard mitigation. The Responding to Risk process then involves two to

three rounds of risk analysis – a round pre any mitigation, followed by a round post "standard" mitigation, followed by a round post "extra" mitigation.

3.2.1 Additional responses, treatments or controls

3.2.2 Considering the cost-benefit of potential management actions

3.3 Environmental Risk Assessment Residual Result

- residual risk after all but extraordinary mitigation that is to be considered as options in decision-making
- talk about national risk; site specific factors & how each to be handled

4.0 FAERM RISK DECISION MAKING

4.4 Risk Results Integration of Environmental Risk Results

- With socio-economic considerations
- With broader coastal zone management considerations

Socio-economic considerations/cost-benefit analysis.

- Important to capture clear statements around decisions here as this is the ultimate outcome of this document
- The document should support both yes and no responses and be able to justify/support decisions
- Good idea to have decision flow diagrams as one of the tools to support this section

5.0 RISK MONITORING (To be developed)

5.1 Implementing identified risk response measures

5.2 Monitoring for impacts - Adaptive Management/Continuous Improvement

5.3 Monitoring for regulatory compliance/Compliance Strategy

5.4 Quality Assurance / System Audits (Matt & Checklist)

Some points to consider here:

- Link to Principles, particularly guidelines to application
- Science validation needs to occur throughout several components of the FAERM (e.g. POEs, Risk Description Tables, etc.).
- Process – these workshops, senior mgt processes
- Need for external input as well (stakeholders): acceptance, buy-in, Science (descriptions) + process.
- Possible approaches – CSAS (need a question/s). Sub-group to develop proposal for science validation. May be reflected as a staged approach

6.0 RISK COMMUNICATION (To be developed)

APPENDICES

Appendix A – Glossary of FAERM Terms

- **Risk Management Terms**
- **Environmental, Aquaculture and other terms**
-

Various comments: Need more work here/Provide summary of defn's and how we arrived at choice for the group (should not be included in the document itself but as a background paper)

Examples:

Issue:	a current problem that exists now that where an organization must take action against in order to achieve its aquaculture objectives.
Risk:	Adverse risk is a possible future adverse event that might prevent an organization from achieving its aquaculture objectives.

Appendix B: FAERM Principles

The following principles have been adapted from a wide range of domestic and international sources to support the development and application of the FAERM.

It is the intent that these principles will be:

- applied in the development of the guidance document and its associated tools;
- reflected in regulatory regimes and in regulatory practice that falls under the scope of this initiative;
- used in the evaluation of current regulatory regimes; and
- used in the ongoing evaluation of future regimes as part of a regulatory system performance audit.

The detailed section on each principle outlines the following information:

- Background on the principle and its importance to risk management;
- Relevance of the principle to the RMF; and
- "Guidelines for application" which follows the description of each principle is intended to provide concrete advice on how to apply the principles and to indicate how performance in the above areas would be assessed in an evaluation.

Principle I: The precautionary approach - *The precautionary approach will be incorporated to avoid serious or irreversible harm to the ecosystem.*

Principle II: Incorporating uncertainty - *Uncertainty in information will be explicitly identified, considered and communicated in order to support informed and transparent decision-making.*

Principle III: The ecosystem approach - *The work and decisions undertaken as part of this RMF will reflect the interrelationships that exist between elements of the ecosystem and people's activities and use of resources. (Note - this principle now refers to the incorporation of both positive and negative effects to meet ATG direction to include consideration of the full range of possible change in the RMF).*

Principle IV: The evidence-based approach - *The use of sound, peer-reviewed scientific knowledge in developing risk assessments, complemented by traditional knowledge as appropriate, will be used to support transparency and to support informed decision-making in the best interests of Canadians.*

Principle V: Performance-based approach - *In order to promote best environmental performance and effective management, conservation objectives, mitigation and compliance measures will focus on performance based approaches to the full extent possible.*

Principle VI: Clear communication - *Plain language and concise synthesis of information will be used in order to support common understanding of risks across a broad diversity of decision-makers and stakeholders.*

Principle VII: Costs and benefits - *Consideration of costs and benefits of potential management actions and non-actions will be explicitly integrated into risk management decision-making processes in order to support transparency of final decisions.*

Principle VIII: First Nations and stakeholder involvement - *First Nations and industry and public stakeholders will be appropriately engaged in the development and ongoing governance of the RMF in order to access to the full range of knowledge available, to better understand interests and positions, to support common understanding of risks and options, and to improve accountability.*

Principle IX: Consistency, transparency, and flexibility - *A consistent and transparent basis for decision-making will be incorporated into the RMF and its guidelines, supporting justifiable flexibility as required to meet regional and biophysical differences.*

Principle X: Implementation - *A clear management and accountability framework will be established to support timely implementation of commitments under the RMF within the fiscal framework available..*

Principle I: The precautionary approach

The precautionary approach will be incorporated to avoid serious or irreversible harm to the ecosystem.

The precautionary approach is a guiding element of the sustainable development framework of DFO and a distinctive decision making approach within the emerging risk management framework for fisheries resource management. The Rio Declaration of the UN Conference on Environment and Development (UNCED) defines the precautionary approach as follows:

> *Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent such environmental degradation.*

The principle of the precautionary approach is intended to take into account the fact that governments often act to deal with risks in the absence of scientific certainty, particularly with respect to new and emerging activities. It is frequently impossible to prove harm, and seldom possible to prove with absolute certainty that something is not harmful.

Given this challenge, decisions about managing risks will be based on scientific evidence to the extent possible, acknowledging that where scientific evidence cannot provide certainty, decisions must be guided by judgment. The objective of risk management is not zero-tolerance of risk or protection of environment from any change at any cost. There is however, an obligation to undertake all reasonable steps to prevent serious or irreversible harm.

This framework will rely on working definitions that are being developed by Fisheries and Aquaculture Management for the following key concepts:

- *Serious harm* is a residual negative impact to the ecosystem (i.e., impacts after planned regulatory and mitigation measures are implemented) in the form of impaired productivity that would be serious or difficult to reverse.
- *Critical thresholds* are points at which a change in the ecosystem is such that there is high threat of serious harm to the ecosystem. *Where warranted by risk assessment, "caution" ("alert") thresholds may also be established where increased monitoring actions and "preliminary*

prescribed management actions may be required. (Determination of when such a point is reached is measured through ecosystem performance indicators.)

- *Prescribed management actions* are additional mitigation measures that, if implemented after a *critical threshold* is breached or approached, are expected to reduce impacts back to a level where there is a low threat serious harm to the ecosystem.
- *Accounting for uncertainty* in performance measures and the effectiveness of prescribed management actions in reducing risk is required so that there is confidence that if the prescribed management actions are taken that they will have a high probability of preventing serious harm from occurring. This recognizes that there will be "confidence limits" around both the measurement of performance and the assessment of likelihood of success for the prescribed management actions.

Guidelines to support application of this principle in the RMF and subsequent decisions

- *Potential environmental effects that would constitute serious harm if they were to occur must be identified in advance. This serious harm must be described in a manner consistent with available means to monitor and measure change in that condition over a time frame that supports an effective response.*
  - Clear, measurable conservation objectives relevant to the activities within the scope of the RMF are to be articulated.
  - Knowledge relevant to each risk identified through the Risk Assessment - Problem Formulation Stage is to express whether or not there is the possibility of occurrence of serious or irreversible harm, using a consistent approach.
  - While scientific information does not need to demonstrate definitively the cause-and-effect relationship between risk and serious harm, assessments are to demonstrate that such a risk "reasonably" exists;
  - Methods to monitor and effectively measure change (performance) with respect to these effects (subeffects?) are to be identified in advance based on clearly defined criteria for selection of ecosystem performance indicators as will appropriate c*ritical (performance) thresholds*; and
  - The limits of knowledge (uncertainty) are to be clearly articulated.
- *Prescribed management actions must be identified and prescribed in advance; this is consistent with adaptive management and implies that when "critical thresholds" are breached agreed-on management actions will be implemented to bring an operation or sector "along the curve" towards a "healthy" state.*
  - The contribution and limitations of planned measures to risk reduction are to be articulated, including accounting for uncertainty; and
  - Where there is an identified residual risk of serious harm, additional management actions are to be prescribed in advance, indicating what measures would be taken should a breach of a critical threshold occur along with a description of the contributions and limitations of the additional measures, including an accounting of uncertainty.
- *Explicit accounting for uncertainty in setting critical thresholds and prescribed management actions*
  - The level of uncertainty around performance measurement data results are to be described.
  - The likelihood of success of additional prescribed management actions are to be discussed including information on certainty.

Principle II: Incorporating uncertainty (this section to be adapted once discussion paper on uncertainty has been commented on)

Uncertainty in information will be explicitly identified, considered and communicated in order to support informed and transparent decision-making.

Application of the precautionary approach requires explicit consideration of uncertainty, as do best international practice in risk management. Government of Canada Science & Technology guidance also requires that scientific uncertainty is given appropriate weight in decisions.

The understanding of uncertainty is inversely related to the perception of risk—the greater the understanding of uncertainty, generally the lower the perception of risk. Uncertainty needs to be conveyed in a predictable and transparent manner that is scientifically defensible and generate reliable and robust results.

An explicit treatment of uncertainty allows users to evaluate the analysis, conclusions, and limitations better. When the analysis ignores or pays inadequate attention to uncertainty, the risk assessment becomes vulnerable to the following common, potentially serious pitfalls (NRC, 1994):

- Decisions do not allow for optimal weighting of the probabilities and consequence of error;
- Advice does not permit a reliable comparison of alternative decisions.
- Advice fails to communicate the range of control options that would be comparable with different assessments of true state of nature.
- Advice precludes the opportunity for identifying research initiatives.

Uncertainty is difficult to define, but can be understand it by looking at why it exists and in what situations it arises. Uncertainty may arise, among other things, due to:

- lack of precise knowledge or, incomplete data on cause-effect relationships between stressors and effects;
- disagreement between information sources;
- error in measurements;
- simplifications and approximations introduced in the process of analysis;
- differing results or interpretation of results from various scientific studies;
- linguistic imprecision.

Confusion of uncertainty often occurs with two related concepts: variability and likelihood.

- *Variability* refers to quantities that are distributed within a population. Variability can only be understood or characterized but will never disappear with better measurement while uncertainty can often be reduced through further investigation (e.g., by increasing sampling size). Variability implies that a single action or strategy many not emerge as optimal for each of the individuals and consequently any decision made will go too far for some and not far enough for others, but overall it may be optimal for the population. By contrast, uncertainty implies that we might make a non-optimal choice for a population because we may expect one outcome but something quite different might actually occur (Thompson, 2002).
- *Likelihood* is assessed to determine the level of risk associated with an event. Uncertainty relates to data accuracy. Risk decisions consider likelihood, but while making such decisions we acknowledge, implicitly or explicitly, that the likelihood is an estimate with a certain degree of uncertainty. *(see also RMF likelihood discussion paper)*

It is important to distinguish between the different types and sources of uncertainty, since they need to be described in different places and treated differently. For the purposes of this RMF, a classification of "uncertainty" has been developed primarily related to the "source" of that uncertainty in order to

facilitate verification that uncertainty has been taken into account, and to support development of appropriate, prioritized action plans to reduce uncertainty. Four major types of uncertainties are identified:

- *Effect uncertainty* - Expected to be the principal source of uncertainty in the RMF, this arises from a lack of precise knowledge of stressors and of their effects. If important relationships are missed or specified incorrectly, the risk characterization may misrepresent actual risks. Uncertainty arises from lack of knowledge about how the ecosystem functions, failure to identify and relate temporal and spatial parameters, omission of stressors, or overlooking secondary effects. In some cases, little may be known about how a stressor moves through the environment or causes adverse effects. While models such as DEPOMOD can be used to estimate risks, modeling relies on assumptions that in turn rely on state of knowledge - if the uncertainty in assumptions is not clearly articulated in the model, decision-makers (and other stakeholders) may assume a greater certainty in estimations than actually exists.
- *Ecological performance monitoring uncertainty*[4] – Uncertainty related to In Risk Management monitoring requirements, arises in three areas:
  - Is the indicator being used a truly representative measure of the change in ecosystem that is of concern?
  - Is the c*ritical* threshold the "true" point at which irreversible or serious harm may occur?
  - Do the monitoring results, which are typically point estimations with a confidence interval, reflect the real change?
- *Implementation uncertainty*[5] - This occurs in the process of predicting the effectiveness of prescribed management actions should a critical threshold be approached. It relates to the degree of certainty that the prescribed management actions will be sufficient to avoid *serious harm* (*see discussion in Principle I: Precautionary Approach)* and arises from uncertainty in three areas:
  - *Technical knowledge* - will the prescribed action have the ecological impact expected?
  - *Compliance* - will the proponent comply with the measures? Non-compliance can happen for a number of reasons including unclear communication/understanding of responsibilities, financial hardship and/or intentional non-compliance.
  - *Subjective judgment*, particularly when such a judgment is made based on observations and experiences in the absence of sufficient systematic data.
- *Linguistic uncertainty* – This can take many forms but more often occurs while articulating contextual information, technical/theoretical expressions, and communication. In everyday conversation as well as in professional communication, people refer to events and quantities with imprecise language that would not pass the clarity test. Likewise, risk managers use phrases like "rare", "unlikely", "almost certain" which yield to different meanings. In one view, uncertainty arising from such expressions should simply be eliminated by providing a careful specification of all events and quantities so that they can pass the clarity test; in another view, it is an unavoidable aspect of human discourse which should be explicitly handled by a formal system for reasoning (Morgan & Henrion, 1990

Uncertainty can be described both qualitatively and quantitatively. Decision makers and the public often prefer quantitative data because it appears certain and to have more rigor than qualitative descriptions *(see the RMF discussion paper on quantitative versus qualitative approaches*).

[4] *Monitoring and Implementation uncertainties are key considerations in putting Principle I (Precautionary approach) into action.*
[5] *See footnote 1.*

This has implications for the application of the precautionary principle. If we are to be more cautious in the face of uncertainty, and if most ecological effects are uncertain by their very nature, then it could be interpreted that actions that might generate negative effects should be avoided.

However, uncertainty is only one of a range of factors that must be given due weight in decision making; and this is implicit in the wording of the Rio Declaration of the precautionary principle which uses the qualifiers of *serious or irreversible* to the word *harm*, and *cost-effective* to the word *measures.* In other words, the presence of uncertainty alone does not imply that actions with potential negative effects should be avoided altogether (Hambrey & Southall, 2002).

The high level of uncertainty inherent in this type of risk management also implies the need for use of informed professional judgment rather than purely scientific decision making process (Environment Canada, 2001).

Guidelines to support application of this principle in the RMF and subsequent decisions

- The RMF is to place emphasis on follow-up scientific activities, including further research and scientific monitoring to reduce scientific uncertainty with respect to emerging risks and to allow improved decisions to be made in the future (Environment Canada, 2001).
- The RMF is to verify? that scientific uncertainty is explicitly identified in scientific results and is communicated directly in plain language to risk managers (decision-makers) [and stakeholders]. (Government of Canada science & technology advice). Guidance on how to do this? Where to do this?
- Mechanisms such as CSAS are to be used to discuss with stakeholders and the public the degree and nature of scientific uncertainty and risks, as well as the risk management approach to be used in reaching decisions Government of Canada science & technology advice.
- Communications initiatives are to be undertaken to reduce uncertainty.
- The RMF is to the full extent possible clarify information that is knowledge-based, levels of uncertainty and areas where use of professional judgement has been incorporated.

Principle III: The ecosystem approach

The work and decisions undertaken as part of this RMF will reflect the interrelationships that exist between elements of the ecosystem and people's activities and use of resources.

An ecosystem approach aims to understand the interrelationships that may exist between the elements associated with the natural environments and their economic and/or social use. It encourages consideration of the elements of ecosystem composition, structure and function, and an understanding of how people's actions affect this environment [Convention on Biological Diversity]. The change that results could be negative, neutral or positive from an ecological perspective.

A part of the ecosystem approach is the identification of ecologically significant "ecosystem features" (i.e., *Ecologically and Biologically Significant Areas*, and *Ecologically Significant Species and Community Properties*) in order to protect overall ecosystem structure and function. This is not a general strategy for protecting all "features" that have some ecological role. Rather, it is a tool for calling attention to a "feature" that has particularly high ecological significance, to facilitate provision of a greater-than-usual degree of risk aversion in management of human activities that may affect such a "feature."

A second part of the ecosystem approach is the use of "Conservation objectives" related to the health of the ecosystem and its conservation and protection through the identification of significant community properties, species and areas, as well as other important ecosystem considerations.

Guidelines to support application of this principle in the RMF and subsequent decisions

- The RMF is to adopt the DFO Science/Oceans general definitions (year?) for *Ecologically and Biologically Significant Areas (EBSAs)*, and *Ecologically Significant Species and Community Properties (ESSCPs)*
- The RMF Risk Analysis – Problem Identification is to incorporate conservation objectives that reflect these ecologically significant ecosystem features.
- The RMF Risk Analysis – Risk Assessment – Exposure Description is to incorporate DFO Habitat's working definitions for Sensitive Species and Habitat as being consistent with the EGSAs and ESSCPs.
- The RMF Risk Analysis – Risk Assessment – Effects Description is to describe both potential negative and potential positive changes to the ecosystem.

Principle IV: The evidence-based approach

The use of sound, peer-reviewed scientific knowledge in developing risk assessments, complemented by traditional knowledge as appropriate, will be used to support transparency and to support informed decision-making in the best interests of Canadians.

The use of scientific information helps to address public confidence and ensures that decisions are being made in the best interests of Canadians. Likewise, decision makers become more confident that the advice they are using is based on a rigorous and objective assessment of all available information and that there is a clear description of any uncertainty.

Science generates data through rigorous methods and processes them to convey information about causes and effects. A peer-review process can assess the soundness of the scientific evidence and its inherent credibility within the scientific community.

Risk assessments and responses to risk should be based on the best available scientific information/current state on knowledge. This means that scientific knowledge:

- Should be drawn from a variety of sources and experts;
- Should reflect the full diversity of scientific interpretations consistent with the evidence available;
- May be complemented by professional experience and traditional knowledge (experiential knowledge) to bridges gaps where scientific information is not available.

Both scientific information and experiential/traditional knowledge change as a result of new studies or in response to new experiences.

Guidelines to support application of this principle in the RMF and subsequent decisions

- Risk assessment descriptions is to summarize the existing state of knowledge, provide scientific views on the reliability of the assessment and account for remaining uncertainties.
- Through the Responding to Risk section and its Governance structure, the RMF is to incorporate process to identify and prioritize risk areas for further scientific research or monitoring.

- The RMF is to incorporate adaptive management processes to regularly update the risk descriptions and responses to risk to reflect new knowledge and information.

Principle V: Performance-based approach

In order to promote best environmental performance and effective management, conservation objectives, mitigation and compliance measures will focus on performance based approaches to the full extent possible.

All regulation is (or should be) "performance-based" in the sense that all regulation is (or should be) directed at changing the behavior of regulated entities ways that improve their performance in terms of enhancing social welfare.

A performance standard ***specifies a required outcome***, but leaves the means of achieving that outcome to the discretion of the regulated entity. Performance standards can be distinguished from "means-based" standards which specify exactly how the regulated entity must act (in order to achieve a desired level of performance). Means-based standards are also known as prescriptive standards, command and control regulation, specification standards, design standards, and technology-based standards

Means-based standards were traditionally used in regulatory design, and are frequently still used in some circumstances. However, a number of disadvantages have been identified:

- for some regulated entities, the mandated means may not prove as effective as other means;
- For some regulated entities, the mandated means may prove to be more costly than other equally effective means; and
- By specifying how to act, means standards can inhibit innovation

In contrast, by giving firms flexibility to choose their own means to achieve the desired goals, performance standards allow firms to select the most effective or lowest cost options. As well, performance standards may place fewer obstacles in the way of innovation. Within the realm of performance standards, there are variations on approaches:

- Specificity (loose vs. tight)
- Proximity between legal command and regulatory goal (close vs. distant)
- How performance is determined (measured vs. predicted)
- Basis for the standard (ideal vs. feasible)
- Unit of analysis (individual vs. aggregate)
- Burden of Proof (regulator vs. regulated)

These distinctions matter because the different types of regulatory instruments, as well as different types of performance standards, create different incentives and costs for firms. Generally, the more costly it is for a regulated firm to demonstrate performance, the less innovation will take place, all other things being equal. (Presentation to DOJ by C. Coglianese Chair, Regulatory Policy, Harvard University, 2003).

<u>Guidelines to support application of this principle in the RMF and subsequent decisions</u>

- Regulatory and mitigation measures are to focus on performance-based approaches to the full extent possible but where other approaches are utilized, explanations will be provided.

Principle VI: Clear communication

Plain language and concise synthesis of information will be employed in order to facilitate common understanding of risks across a broad diversity of decision-makers and stakeholders.

Clear communication relies on two major aspects – use of a "shared" language and brevity.

While it primarily informs regulators and decision-makers, the RMF documentation is meant to be shared with a wide audience of stakeholders who will have varying levels of knowledge of technical terminology related to acronyms, regulations, scientific terms, ecosystems and aquaculture. Plain language is important to develop common understanding but also to resolve conflicts and achieve consensus among stakeholders.

Concise and synthesized information also enhances communication. Although risk management decisions will be based on rigorous analysis of scientific and traditional evidence, summary documents should highlight only that information that has direct relevance to risk estimates, uncertainty, and management decisions (DFO, 2005).

Guidelines to support application of this principle in the RMF and subsequent decisions

- It is recognized that the RMF and its related documents will require producing and drawing on many technical documents. However, summaries of key documentation are to be developed in language appropriate for a variety of targeted audience(s). This may be approached by using a "linked" document approach that allows readers to drill down from very broad summaries that use more general language to progressively more detailed information (note that while this works well electronically, it can have challenges in paper documentation).
- To support communication, substantive RMF inputs (discussion papers, etc) are to be posted on the DFO website with links from and to other appropriate regulatory agencies.
- The use of technical jargon is to be minimized to the extent possible.
- A glossary of terms is to be provided, as will acronym charts.

Principle VII: Costs and benefits

Consideration of costs and benefits of potential management actions and non-actions will be explicitly integrated into risk management decision-making processes in order to support transparency of final decisions.

A key requirement of the federal *Cabinet Directive on Streamlining Regulation* (2007) is that departments and agencies assess regulatory and non-regulatory options to maximize net benefits to the society as a whole. All regulatory departments and agencies are expected to show that the recommended option maximizes the net economic, environmental and social benefits on Canadians, business and government over time more than any other type of regulatory or non-regulatory action.

The *Canadian Cost-Benefit Analysis Guide* has been developed for the use of federal departments and agencies as they perform cost-benefit analysis to support regulatory decisions (both decisions to proceed and not to proceed with an activity). Any new regulations or review of existing regulations requires a proper assessment to ensure they will not impose excessive burdens on Canadian businesses that would reduce their international competitiveness. While it is important to protect the environment and

safeguarding the health and safety of Canadians regulatory actions need to be carried out in a way that allows for private sector innovation to take place.

Initially all the possible impacts should be listed and evaluated in consultation with experts in the field, describing the assumptions made about the projection of benefits and costs over the future. Care needs to be taken to include all the potentially significant impacts, and make a list of the minor impacts that can be expected to occur. Whenever possible, the likely sector or group should be identified that will be the beneficiary or bearer of the cost of the impact.

The types of impacts resulting from environmental, health, safety, security and other regulatory policies are often not valued through a market process but affect human welfare directly through changes in living conditions or processes. Such impacts would include such things as a health improvement or an ecological improvement or protection.

- Quantification and valuation of these impacts is quite different from simply looking at conventional market prices. Nevertheless, monetary values of a policy's impact are very important because they allow decision makers to compare costs and benefits. The challenge facing analysts is how to value these effects in monetary terms. If an original estimation of the benefits for the specific situation is too difficult or will take too much time, then one must try to draw upon existing valuation estimates made by others in similar circumstances.
- The preferred approach to measure non-monetary costs and benefits for social-economic "welfare" economics is the willingness to pay (WTP) principle - the amount (demand price) that an individual is willing to pay for an incremental unit of a good or service measures its economic value to the demander and hence its economic benefit to the economy. Conversely, willingness to accept (WTA) compensation is the minimum amount of money an individual is willing to accept for not receiving the improvement.

However, the guide is also clear that the approach used for cost-benefit analysis should be guided by the principle of proportionality - in other words, the effort to do the cost-benefit analysis should be commensurate to the level of expected impacts on Canadians.

Guidelines to support application of this principle in the RMF and subsequent decisions

- This larger issue is being examined by DFO Oceans as part of its Oceans Action plan, and is therefore put aside for the purposes of this RMF, at this time. Considerable resources and specialized expertise are required.
- Within the RMF, regulatory decisions and requirements for mitigation have costs and benefits where proportionality of benefits and costs should be assessed. The RMF is to elaborate an approach for assessing the relative balance between costs and benefits related to mitigation measures, and overall decisions to proceed/not proceed. The approach is to reference the Context, particularly the section on Acceptable risk.

Principle VIII: First Nations and stakeholder involvement

First Nations and industry and public stakeholders will be appropriately engaged in the development and ongoing governance of the RMF in order to access to the full range of knowledge available, to better understand interests and positions, to support common understanding of risks and options, and to improve accountability.

Risk management decisions that are made in collaboration with First Nations and stakeholders are more effective and durable, especially when there are many conflicting interpretations about

the nature and significance of the risk. First Nations and stakeholder involvement provides opportunities to bridge gaps in understanding, language, values, and perceptions (The Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997).

Engagement with First Nations and stakeholders at specific stages in the assessment process demonstrates commitment to openness and inclusiveness, and supports good risk communication. DFO has developed a consultation framework (2004), which provides general principles and guidelines for good practice in First Nations and stakeholder engagement. At the same time, severe fiscal limitations and the lack of existing engagement structures are the current reality.

For the purpose of the RMF, the definition of stakeholders includes representatives of the aquaculture sector (e.g., farms, processing, suppliers, fish health professionals, associations), fisheries associations, community groups and environmental groups.

Guidelines to support application of this principle in the RMF and subsequent decisions

- Processes are to be identified that engage key stakeholders in the following areas:
    - validation of problem identification (POE diagrams) and risk descriptions (knowledge validation);
    - validation of overall risk management framework approach (principles, approach to risk assessment, etc.)
- The following provides a partial list of engagement approaches:
    - CSAS processes;
    - Governance advisory structure; and
    - Existing engagement processes will be sought.

Principle IX: Consistency, transparency, and flexibility

A consistent and transparent basis for decision-making will be incorporated into the RMF and its guidelines, supporting justifiable flexibility as required to meet regional and biophysical differences.

The ability to demonstrate consistency and, hence predictability, in decision-making supports perception that the process is fair and rational and eases communication with all interested parties. Transparency implies a clear articulation of how processes have been carried out and how decisions are reached and communicated to stakeholders. It also implies that the information is readily available to interested parties and stakeholders. Consistency and transparency are supported when there is a clear documentation of the considerations, assumptions, uncertainties, and differences involved in risk management.

At the same time, virtually all decisions have some element of uniqueness in the circumstances. These differences may occur at the regional or local/site level and adequate flexibility needs to be built into the national framework to reflect these legitimate variations.

Guidelines to support application of this principle in the RMF and subsequent decisions

- The RMF Governance model is to incorporate criteria and measures to assess the general level of consistency in decision-making under the framework.

- The implementation of the RMF is to support flexibility to reflect appropriate differences in regional management and bio-physical differences are incorporated in the decision making process. These differences in approach and/or application will be clearly identified and justified.

Principle X: Implementation (*to be developed as RMF progresses*)

A clear management and accountability framework will be established to support timely implementation of commitments under the RMF within the fiscal framework available.

A management and accountability framework (MAF) will be established to support ongoing evaluation and performance improvement with respect to the commitments under this RMF. The framework will recognize that there are time and fiscal constraints that mean all activities cannot be equally addressed at once. Therefore, there will need to be a prioritization of resources and effort between "elements" of the RMF and within "elements". Prioritization criteria will be established as part of the MAF.

RMF elements of particular importance during implementation are expected to include:

- RMF governance
    - Compliance with Principles
    - Stakeholder involvement
    - Research program
    - Adaptive management
    - Maintenance of the RMF
- Responding to Risks
    - Performance
    - Compliance
    - Enforcement

Partial list of references

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Appendix B – Supplemental Guidance Documentation and Tools

- POE Diagrams & Matrices of stressors/effects
- Risk Description (Tables)
- Operational Level Objectives
- Mitigation Practices & Regulatory Tools

Appendix C - Common Risk Assessment Documentation

Appendix D – Background Discussion Papers

- **Regulatory Framework**