The Departmental Committee on Ecological Risk Assessments'

Guide to Ecological Risk Analysis

September 2009

Executive Summary

The ecological risk analysis protocol (a.k.a. the ecological risk assessment framework) described herein is structured to accurately portray ecological risks and uncertainty associate with those risks for inclusion in a larger decision-making process. That decision-making process would also consider social and economic risks and their uncertainties.

The Departmental Committee on Ecological Risk Assessment Framework (DCERAF) is constructed with triage steps and reusable modules. the recognition that to be cost-effective and practical the information for decision-making need not always require either the use of the full extent of the protocols and can use previous work rather than each time requiring the process to start *De Novo*.

The assumption is that most of time much of the information on ecosystem effects will be collected and analyzed by operational biologists. Some times the importance of an ecological assessment may be such that research scientists will be asked to produce certain parts of the analysis. To help ensure the results of these two modes of action function well together and produce results that are in accord and are repeatable the protocols highlight what information or data is required, or, where data is not available, that the assumptions that replace the data are clearly identified.

The structure of the DCERAF is initiate by an application to undertake a development or activity and policy that affects the decision making process. These are not part of the DCERAF but are necessary for development of a robust and repeatable analysis. Where no policy direction exist the assumptions that function for the non-existent policy must be identified and recorded.

The next part of the DCERAF (Hazard Identification) identifies and prioritizes what feature or processes in the ecosystem are important to protect (Valued Ecosystem Components) and how the proposed development or activity may affect these. It is recognized that in many instances the identification of hazards may be sufficient to support decision-making so a triage step that follow Hazard Identification allows direct progression to risk management and decision making processes.

If more elaborate analysis is required there are a series of steps between Hazard identification. Some of these might be supplied by researchers. There is a step that identifies what constitutes various levels of risk and what type of response would be appropriate to those levels of risk. This is a step that researchers have no role in. It should be completed before the risk assessment step is undertaken to ensure there is no possibility to suggest that after the level of risk was determined the response identified was made *a posteriori* to allow the proponent influence in what mitigation measures will be necessary to attain the government's ecological goals.

The final part of the risk analysis is risk management which includes both determination of mitigation measures, monitoring requirements and the input to the decision making process.

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Foreword

In Canada the management of the environment is based on the integration of social, economic and environmental considerations. Within DFO there are a number of risk based tool in use or under development. They are not consistent in the approaches they take and do not always conform to risk assessment or risk analysis as viewed by the Canadian Privy Council Office, Cabinet Directives or Treasury Board of Canada. The Fisheries and Oceans Canada's Departmental Committee on Risk Assessments was asked to review the situation and, if necessary, provide an Risk Assessment Framework that would make clear that what Fisheries and Oceans Science needed in order to complete Ecological Risk Assessments and what our clients might expect from Science Sector's risk assessments.

Ecological risk assessments (the prediction of environmental change and the probability that the prediction is correct) are fundamental to managing ecosystem risks. Depending on the degree of importance the environmental attributes are thought to have, those assessments may be undertaken by scientist operating in a line management role or by scientists in the Departments Science Sector. This guide is constructed with the assumption that staff in Fisheries and Ocean Canada's (DFO's) Science Sector will be requested to complete some of those assessments.

An ecological risk analysis is like a picture frame. It sets the boundaries for ecological risk assessment as a picture frame bounds a picture. As a picture frame enhances the visual and emotive impact of a picture so the ecological risk analysis enhances the impact of the assessment buy identifying what is needed from the assessment for decision making and what should be supplied to assessment so analysts can meet those needs.

This document was created to facilitate a consistent, open, transparent and inclusive process for completing the assessments in which managers and scientists with line responsibilities know what information the Science Sector scientist require to do their assessments. During an ecological risk analysis there are many places where scientists and management may need to consult with each other but when researches are asked to do an assessment they rely heavily on people in line functions to give them certain things. The quality and accuracy of Science Sector's risk assessments and state of knowledge reviews very much depends on getting the complete set of information or assumptions required.

The guide indicates the information Science sector needs for an ecological risk assessment in the context of risk management for the Government of Canada. It also illustrates where that information might be derived from in the ecological risk analysis process and what managers might expect to receive in support of their decision making process.

The guide is written for a variety of levels of information needs. Those who require an overview of the process can examine the diagrams and the text boxes whose labels begin with the word Principles. Those requiring a more in depth explanation may refer to the text in the body of the guide.

This guide provides detailed information on the roles and responsibilities as well as the necessary tasks that will help managers, scientists and line staff cost-effectively meet the Government of Canada's expectations for an ecological risk analysis in an open, transparent and inclusive manner.

List of Acronyms Used

BEST	Canadian Science Advisors' document Building Excellence through Science and Technology	**MSY**	Maximum Sustainable Yield
CEAA	Canadian Environmental Assessment Act	**NAFO**	North Atlantic Fisheries Organization
CEPA	Canadian Environmental Protection Act	**NAFTA**	North American Free Trade Agreement
CFIA	Canadian Food Inspection Agency	**NAS-NRC**	United States National Academy of Sciences' National Research Council
C-M model	Corvelo and Merkhofer's risk analysis model	**RA**	Risk Analysis
CRP	Corporate Risk Profile	**RM**	Risk Management
CSAS	DFO's Canadian Science Advisory Secretariat	**SAGE**	Canadian Science Advisors' document Science Advice for Governance Excellence
DCERAF	Departmental Committee's Ecological Risk Assessment Framework	**SPS**	The Sanitary and PhytoSanitary agreement administered by the WTO
DFO	Fisheries and Oceans Canada (formerly the Department of Fisheries and Oceans)	**TBS**	The Canadian Treasury Board Secretariat
EOAR	Ecosystem Overview and Assessment Report	**USEPA**	The United States' Environmental Protection Agency
ERA	Ecological Risk Analysis	**VEC**	Valued Ecosystem Component
FAO	The United Nations' Fisheries and Agriculture Agency	**WTO**	World Trade Organization
GATT	General Agreement on Trade and Tariffs		
HACCPC	Hazard Analysis and Critical Control Point Characterization		
ICES	International Council for the Exploration of the Seas		
IRM	Integrated Risk Management		

1.0 Introduction

"That's what I think will happen, but I can't guarantee how or when it will occur." This is the nature of the advice managers must use in many decision-making tasks. It is a prediction surrounded by uncertainty. There is nothing new in this challenge. Cavemen predicting the migration of their prey probably faced the same challenge. What has changed is that today we are expected to document how we are making the decisions and how we allow for the uncertainty in our prediction when we make a decision.

1.1 Decision Making in the Government of Canada

The "*possibility of occurrence of harm, and the magnitude of that harm*" (TBS 2001) or alternately probability and magnitude of harm (a.k.a. impact) are the definition of risk used by the Government of Canada and many international organizations (TBS 2001, PCO 2000, PCO 2006, OECD 2006, FAO 2006, FAO 2008, OIE 2009, WHO/FAO 2006). Within government and in the private sector risk assessment and/or risk analysis is a common tool for decision making. So much so that it has become a cornerstone to modern governance mechanisms (PCO 2000, 2006).

Decision making in government almost always involves evaluating changes a number of social, economic and / or environmental factors that could result from a decision (Figure 1). To standardize a common basis for decision making in government the Treasury Board and the Privy Council Office of Canada have set some of the parameters that must be assessed. In addition to the degree of change experienced decisions must also include "*the possibility of occurrence of harm and the magnitude of that harm (including the extent of possible damage, persistency, reversibility and delayed effect*" (PCO 2006).

Box 1. Principles - Defining Risk

1. Risk is the product of the magnitude the predicted harm and the probability that that level of harm will occur.
2. The magnitude of harm is described as the degree of change, the extent of possible damage, persistency, reversibility and delayed effect.

1.2 No Unnecessary Work (cost-effective)

The Privy Council Office of the Government of Canada has stated that the effort required to make decisions should be made in a cost-effective manner. It also noted that the decision should not be unreasonably delayed in order to accumulate more information (PCO 2006).

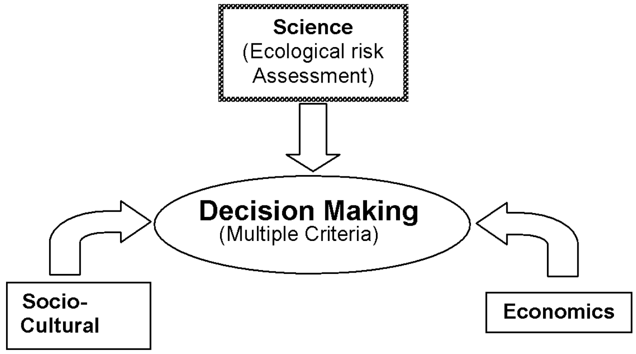

Figure 1. The context for decision making in government.

To allow cost-effective use of existing information Fisheries and Oceans Canada's Ecological Risk Analysis (also referred to here in as The Departmental Ecological Risk Assessment Framework (DCERAF)) is structured as a series of component modules. Each of these modules, once created, can form part of a library of modules associated with an ecosystem or type of activity / development. This can significantly reduce the effort required to complete similar subsequent assessments.

Examples of these modules (Figure 2) include:

1. **Ecosystem Characterization.** This module identifies what must be protected to safeguard ecosystem structure and function and how progress towards those goals will be measured (measurable endpoints or indicators). For each ecosystem this should remain consistent regardless of the proposed activities or developments in the ecosystem. Once the module is completed it should not need to be redone until our knowledge of the ecosystem changes significantly. An example of the type of ecosystem analysis that can be used for this work is the Ecosystem Overview Assessment and Reporting documents (e.g. R. Dufour and P. Ouellet 2007) and the identification of Valued Ecosystem Components such as Environmentally Sensitive Species and Community Properties, Environmentally Sensitive Habitats, Depleted Species, and Degraded Habitats.

2. The **HACCPC** (Hazard Analysis and Critical Control Point Characterization) module is made up of a set descriptions of the mechanisms leading to

Box 2. Valued Ecosystem Components

Valued Ecosystem Components (VECs) should be determined in advance of undertaking ecosystemn risk analysis. VECs are ecosystem specific attributes that are determined without reference to having any specific activities or projects in the ecosystem. They represent features of an ecosystem that have special social, economic or environmental significance. Examples of internationally recognized VECs include those benthic attributes identified by FAO (the Fisheries and Agriculture Organization of the United Nations) in their Deep Sea Fishing Guidelines (2009) as requiring special attention in ecosystems where (i.e. sponges corals and thermal vents).
Within Fisheries and Oceans Canada, environmentally sensitive habitats and species, degraded habitats, marine protected areas, and species at risk might be among the features that may be considered VECs .

changes in the ecosystem and indicators that measure the intensity of the stress on VECs (See Section 4.1.1). For example bridge building requires; disturbing the substratum, that in turn results in sediment loading to the aquatic habitat, which in turn has an effect on components of the ecosystem. The measurement unit for this stressor on the environment may be suspended particulate loadings in mg/l.

The disturbance of the dirt that result in sediment loadings can be used in the description of many types of developments such as dyke building, stream bed engineering, placement of culverts, upland development and road building. For all of these, the same description of the effects caused by disturbance of the substratum can be used as can the metric for the intensity of stressor.

For activity-based (e.g. fisheries or marine transportation) environmental perturbations, a similar approach can be used. (e.g. the fisheries component trees of the Australian Fisheries National Ecologically Sustainable Development Reporting Framework for Australian Fisheries (Fletcher *et al.* 2002 and FRDC 2005), and the DFO review of fishing gear effects on the environment "Impact of Trawl Gears and Scallop Dredges on Benthic Habitats, Populations and Communities" (CSAS 2006) If a gear review or component tree has been identified for a very similar fishery it would make no sense in repeating the work when you can use the outcome of the previous work.

1.3 Common Variations in the Approach to Managing Risk.

The discipline of managing ecological risk first developed momentum in the early 1980's with the United States National Academy of Sciences' National Research Council's (NAS-NRC) publication of the "Red Book" (NAS-NRC 1983). At that time the focus was on risk's associated with toxic chemicals and food quality. An embedded assumption was that a dose-response relationship would be adequate to predict the effect on individual organisms and that this type of function could be generalized to all manner of environmental phenomenon. This assumption remains today in the United States Environmental Protection Agencies (USEPA) approach to environmental risk assessment (USEPA 2004).

This assumption was questioned in the 1990's by Vincent Covello and Miley Merkhofer (1993). They pointed out that many processes at the level of populations and ecosystems do not fit the assumptions of a dose-response model. Covello and Merkhofer proposed a more general model (C-M model) for the evaluation of risk within which the USEPA model can be treated as a specialized form.

Today, both models are still in use. However, internationally the only standard that exists, and is enforceable, is the model used in the component parts of the Sanitary and Phytosanitary agreement under the General Agreement on Trade and Tariffs (GATT). The World Trade organization uses these to adjudicate on non-tariff trade barriers in international trade. The GATT is patterned after the C-M model

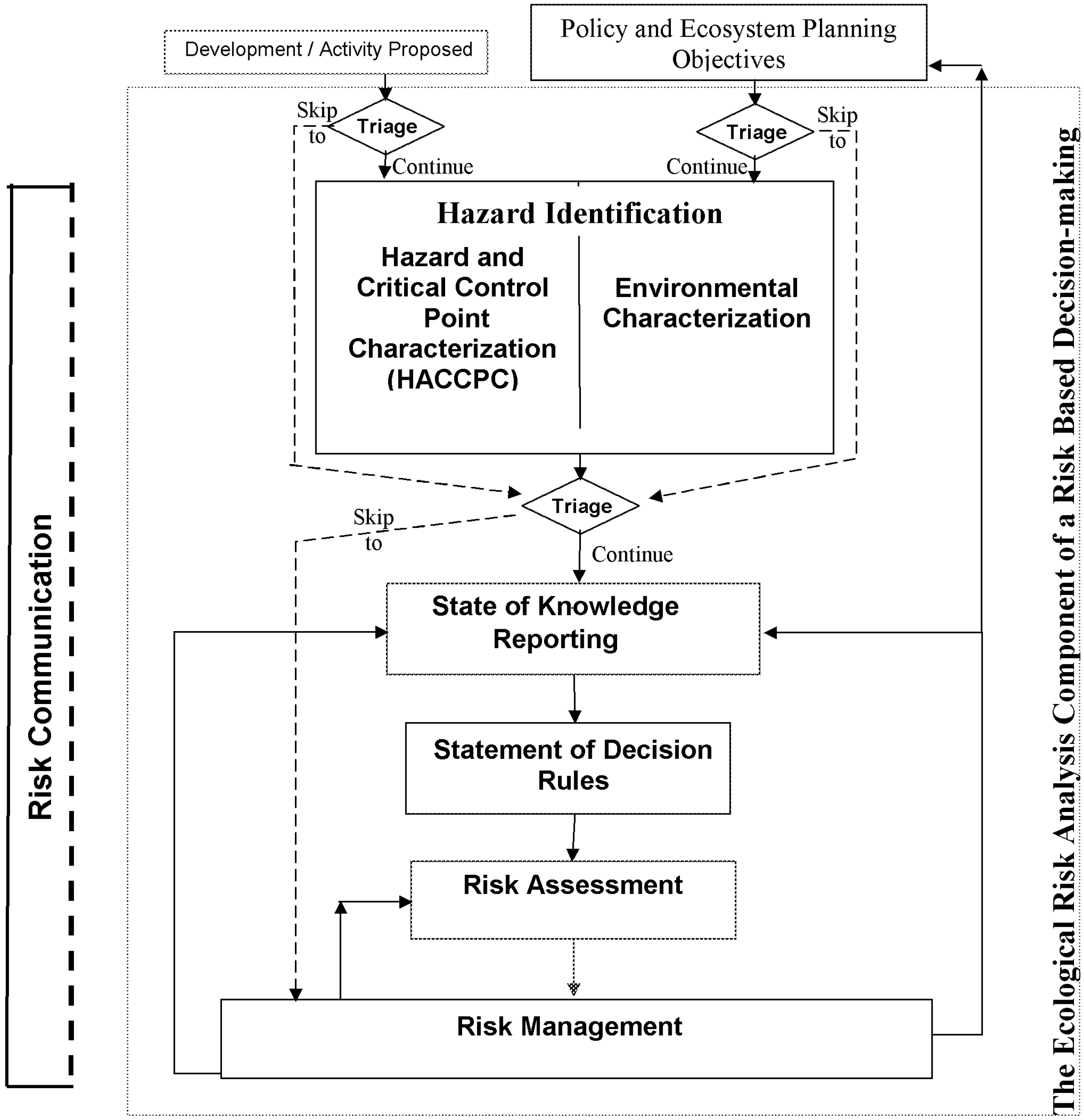

Figure 2. The general structure of the DCERA risk assessment framework. The bold dashed line on the Risk Communication box indicates that all the boxes to the right of it should be involved in two-way communication between the analyst and interested parties. The lightly dashed line represents possible redirection from triage processes. The dotted line encircles the DCERAF components.

In Canada we use both models. The Canadian Environmental Protection Act that was derived to deal with toxins and their effects uses the USEPA (United States Environmental Protection Agency) model. The Canadian Food Inspection Agency, Agriculture and Agrifood Canada and the department of Fisheries and Oceans use the GATT model for animal and plant diseases. The Department of Fisheries and Oceans also uses the GATT model for evaluating risks associated with the introduction and transfer of aquatic organisms.

1.4 Confusion

For many scientists, and perhaps more so for managers, discussions of risk are often confusing. Unfortunately the terminology and the approach to risk communication in the GATT and USEPA models are contradictory. In the GATT model the whole process of evaluating, managing and communicating risk is called "Risk Analysis". In the USEPA model it is called "Risk Assessment". In the GATT model "Risk Assessment" is a subcomponent of "Risk Analysis" In the USEPA model "Risk Analysis" is a subcomponent of "Risk Assessment". The GATT model also predicates its communication strategy on an open, inclusive and transparent process involving partners while the USEPA model focuses on a command and control communication model which vets all communication trough government managers rather than deriving and sharing the communication message with the partners without the modification by policy considerations. To limit the confusion in discussing the DCERA framework a list of terminology as used in the framework is given below.

1.5 Terminology for the DCERA Ecological Risk Analysis

Compliance Indicators – Parameters that measure the intensity of a development or activity.

Decision Making Process – The integration of environmental social and economic factors to decide a path of action. Explorations of the implication of alternate decisions are often explored utilizing a scenario building exercise that would have rules for how to value different types of outcomes. The precautionary approach is not defined here but this is where it is applied. If the rules for applying precaution are defined at this point it may lead to the perception that the rules are biased to deliver a preordained decision.

Decision Rules – Risk-Based rules founded on classification of the risk by magnitude of the effect and certainty in the prediction (risk) and gives instruction on which action should be taken for each class of risk.

Environmental Characterization – Identifies the components of the ecosystem which are important to maintaining its structure and function (usually from a list of valued ecosystem components effort (VECs) developed as part of an objective or planning development exercise). Environmental Characterization includes the identification of parameters (performance measures) by which changes in VECs can be measured and some indication of what constitutes the boundary between an acceptable and unacceptable change in the environment. That level of change is often determined as part of planning and objective development.

Hazard Analysis and Critical Control Point Characterization (HACCPC) – Identifies the mechanisms by which the type of activity or development is known to affect the environment. The HACCPC includes the identification of a parameter (Compliance measure) that will be used to measure changes in the level of activity or development (In a fishery this is often a measure of fishing effort.).

Hazard – An attribute of an activity or development that may cause environmental change (e.g. sediment loading, increased filtration of bivalves in culture, a chemical or biological agent that causes environmental change).

Hazard Identification – composed of three sub-processes: environment characterization; hazard analysis and critical control point analysis (HACCPA); and, their conjoined analysis. These processes identify compliance and performance indicators as well as limit and action reference points in terms of environmental performance. These then are used to limit the potential for an undesirable change in the environment based on past experience or theory. It does not estimate the level of environmental change or the likelihood of that prediction will be accurate for this site-specific development/activity. The precautionary process is not to be applied herein. Hazard Identification simply identifies potential hazards to environmental attributes.

Impact - An environmental change which when viewed from a socio-economic perspective is considered negative. Science predicts environmental change. It is only when viewed through the socio-economic lens does it become an impact. Some environmental changes may be positive (e.g. reduction of phytoplankton by bivalve culture in a eutrophied system).

Performance Indicators – Parameters that measure environmental change.

Risk – The likelihood (probability) of an undesired outcome of a certain magnitude (severity). That outcome occurs within a specified time period at a specified location (place-based) with a specified degree of change in the performance measure. It is always calculated as an incremental (marginal) change in risk thereby recognizing that there are likely to be other activities in the ecosystem (including natural variability) which may result in the same undesirable outcome.

Risk Analysis – The entire process of effective risk communication, hazard identification, clearly defined decision rules, risk assessment and risk management.

Risk Assessment – The prediction of environmental change caused by a specific development or activity at a specific location and associated uncertainties. The severity of environmental change is characterized by the intensity of change, the geographic extent of change and the duration of change. The precautionary process is not to be applied herein. Risk Assessment simply predicts the likelihood of potential environmental changes.

Risk-based Decision Rules – These are rules based on probability and severity that indicate how to respond when limit or action reference points are surpassed. The rules also say how those responses should change for different levels of uncertainty (in effect defining how and when to apply precaution). This is the first place in the path to estimating risk where uncertainty in the estimated outcome is considered. These activities should be completed prior to the estimation of risk in order to avoid to the perception that the rule are biased to deliver a preordained decision.

Risk Management – Decides on the acceptability of risk associated with a proposal. Should it accept the proposal its decision should include instruction on risk mitigation, and monitoring. As part of the derivation of the instructions on risk mitigation it should assess the opportunities for risk mitigation, selection of risk management technologies/approaches (including monitoring protocols) and the need for additional research to reduce uncertainty in the estimations of probability.

State of Knowledge – A hypothesized and testable relationship between an environmental performance indicator and a compliance indicator for an activity or development. The results of monitoring can be used to verify and or modify the relationship to make it more accurate and precise. The relationship is not an assessment of risk though when the proposed activity/development is mapped on the relationship graph in the risk assessment step it does illustrate the level of risk.

Triage - Triage rules are generalized rules for how the process for risk analysis will be executed for each analysis. They are process oriented and should be activity and environment insensitive. Triage asks the question: "What components of the following analysis do not need to be done for this application of the framework?" Triage rules do not estimate probability of occurrence of an undesirable outcome for the site-specific site situation in question. They can help avoid work on issues that past experiences suggest should not be a serious concern.

Uncertainty – For risk, uncertainty is the distribution of errors associated with each estimate of the risk parameters (probability and severity).

2.0 The DCERA Model

2.1 The Context for the development of the DCERAF

2.1.1 Corporate and Ecological Risk Assessments

It is important to differentiate between corporate integrated risk management (IRM) exercises and the technical risk assessment that scientists utilize. The IRM is an explicit and systematic approach to managing strategic, operational and project risk to organizational objectives, from an organization-wide perspective. In particular it helps senior management to meet its risk management imperative of having and providing assurance that all significant risks are identified, assessed, managed and controlled, within available resource limits. Senior management must understand the full extent and consequences of exposure to risk. The information on this exposure must be used explicitly to inform business planning, resource allocation, performance management and decision-making generally.

Risk management (RM) is recognized as an integral part of sound modern management practice. It is a key over-arching element in the government's management agenda and is anchored in a number of key Treasury Board Secretariat (TBS) policies:

- TBS Integrated Risk Management Framework
- TBS Internal Audit Policy, and
- TBS Management Accountability Framework(MAF).

All departments are rated for the 10 MAF elements (one of which is Risk Management). Risk Management continues to be considered an important element of sound management as exemplified by the following: for MAF VII assessment, RM will now be considered a "core" Area Management and assessed annually by TBS and the Clerk, in his July 9, 2009, message stated that "the Public Service will effectively manage risk".

Over the years, the Fisheries and Oceans Canada (DFO) has taken many steps to become a risk-smart organization. Among other things it has developed several foundation documents on integrated risk management including:

- Integrated Risk Management Policy: containing the guiding principles designed to influence decisions, establish accountability, and degree of control.
- Integrated Risk Management Guidelines: including the standards established by DFO protocol, benchmarks, and definitions.
- Integrated Risk Management Annual Cycle Process: describing a comprehensive process to operationalize IRM at DFO
- Integrated Risk Management Handbook to be completed in the fall (2009)

In April 2009, DMC approved the department's Corporate Risk Profile (CRP) for the first time, the culmination of considerable effort by many areas of the department. The CRP is generated by analyzing and synthesizing all the duly approved risk profiles from across the department. The CRP contains

- Identification, assessment and prioritization of key corporate risks
- Assignment of senior management accountabilities for managing the mitigation of each of the key risks
- Clarification of mitigation priorities and development or confirmation of specific mitigation strategies for the key risks

One of the key differences between the corporate integrated risk management and ecological risk assessment is that corporate risk management manages risk to organizational objectives, while ecological risk analysis helps manages risks to ecosystems structure and function. It is not surprising therefore that the corporate risk management estimates of risk are derived in a manner distinct from that used for ecological risk assessments. Though these are different types of analyses they can and should be clearly linked.

In order to demonstrate progress towards limiting the identified corporate risks, each of the corporate risk management plans should identify performance measures. Technical (ecological) risk assessments may link to corporate risk management through these performance parameters. For example, the departmental objective of sustainable ecosystem identifies lack of sufficient information for decision making as one of the major risks it faces.

If the performance measures include the need for clear documentation of the scientific evaluation ecological risks associated with decisions then tracking the number of ecological risk assessments (e.g. risk assessments undertaken to support fishing quotas) can be used to demonstrate progress towards reducing the risk of lacking insufficient information for decision making.

In reporting technical risk assessments it is important to explicitly state how the assessment supports technical objectives (e.g. no more than a 10% reduction in population size of species X) and how that, in turn, supports the corporate objectives (a sustainable ecosystem).

Performance measures are not always preset, or may be formulated in a way that may make it difficult to see a clearly how technical risk assessments help limit corporate risks. In such instances the technical analyst should document how they assume the linkages work. (E.g. DFO's corporate objective is sustainable ecosystem. Species X is a keystone species in this ecosystem. Fisheries appear to be the most important factor controlling this species abundance. A 10% reduction in the species is considered enough to harm the ecosystems structure. This analysis will inform decision-makers of the risk that fisheries will result in a reduction of the species abundance of greater than 10%.)

The DCERAF (Departmental Committee's Risk Assessment Framework) can also help the development or updating of corporate risk management plans. For example, if DFO was facing decisions on a large number of similar applications (e.g. renewal of fish farm licences), risk analysis may suggest a greater or lesser proportion of these need to undergo a detailed review in order to control against the risk that fish farms might affect the sustainability of ecosystem. This then, may have considerable financial and staffing implications which in turn may require redistribution of corporate resources presently allocated to controlling other corporate risks.

Ecological risk assessments may be undertaken by staff in the operational sectors (e.g. Fisheries, and Aquaculture Management, Oceans, Habitat and Species at Risk sectors) or Science Sector. When DFO Science Sector is involved it creates and presents documents that predict environmental change or advice on what science can predicted using utilizing a peer-review based system. DFO's Science Management Board, in its efforts to ensure relevant, effective, affordable and valued input to decisions, has directed its staff to phrase its knowledge of environmental effects from an ecosystems perspective.

Box 3. Principles - Linking corporate and ecological risk evaluations.

3. Each ecological risk analysis (ERA) should have an explicit statement on how the ecological risk analysis will support corporate risk management.

4. ERAs focus on achieving environmental objectives while corporate risk assessments focus more broadly on achieving corporate objectives.

The development of this DCERAF was initiated in August 2008 and developed by a committee of the Science Sector's researchers and clients representing all sectors and regions within DFO to act as a framework for effectively integrating science information into risk based.

2.1.2 The SAGE and CSAS foundations of DFO's DCERAF

As this is a science-based risk assessment framework, it is designed to work with the Government of Canada's principles (see box below) for Science Advise for Government Effectiveness (SAGE) created by the Canadian Science and Technology Advisors (1999). Those principles require uncertainty and risk to be part of the science advice and that the process is inclusive and, open and transparent.

Box 4. The SAGE Principles

Principle I: Early Issue Identification
The government needs to anticipate, as early as possible, those issues for which science advice will be required, in order to facilitate timely and informed decision making.
Principle II: Inclusiveness
Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion.
Principle III: Sound Science and Science Advice
The government should employ measures to ensure the quality, integrity and objectivity of the science and science advice it uses, and ensure that science advice is considered in decision making.
Principle IV: Uncertainty and Risk
Science in public policy always contains uncertainty that must be assessed, communicated and managed. Government should develop a risk management framework that includes guidance on how and when precautionary approaches should be applied.
Principle V: Transparency and Openness
The government is expected to employ decision-making processes that are open, as well as transparent, to stakeholders and the public.
Principle VI: Review
Subsequent review of science-based decisions is required to determine whether recent advances in scientific knowledge have an impact on the science advice used to reach the decision.

The Framework also supports the DFO's internal standards for the delivery of science advice as developed for the Canadian Science Advisory Secretariat (CSAS), (DFO 2004) (see box listing **Goals for DFO's CSAS process).**

Box 5. Goals for DFO's Canadian Science Advisory Secretariat (CSAS) process

- That it ensures DFO science information and advice to clients meets all the SAGE principles;
- That it be timely, cost-effective, and reliable;
- That it provides all clients with stable and consistent service, with roles and responsibilities clearly understood by all participants; and,
- That it has full accountability to the Department

3.0 Work Required Prior to Undertaking an Ecological Risk Analysis

3.1 DFO's Ecological Risk Analysis as part of a Risk Analysis for Decision-Making

An assessment of ecological risk is always an assessment of the incremental change in risk (marginal risk assessments). This is because there is always a finite risk that a particular negative outcome may occur without human intervention. Also, we will never know or be able to quantify all the factors that contribute towards a possible change.

A good risk management process is an iterative process. The quality of a risk assessment depends heavily on the process leading to the assessment and what is done with the information from the analysis when it is completed (i.e. the component of risk analysis before and beyond risk assessment).

One of the reasons risk management is an iterative process is that the environment and human activities and

Box 6. Principles – General Principles for the DCERAF

5. Optimal management of risk requires an approach that integrates effective risk communication, hazard identification, clearly defined decision rules, risk assessment and risk management. In Canada the Cabinet Directive on Smart Regulation requires that that process be open, transparent and inclusive.
6. All risk assessments are an assessment of the marginal change in the level of risk. An assessment of absolute risks is not possible.
7. All risk analysis and risk assessments should include an explicit statement of the expected period and geographic range over which the analysis/assessment should be considered to be applicable.
8. Ecological risk assessments focus on products not processes (e.g. a fish farm site not fish farming) or a specific development not development in general. The products are characterized by the hazards they present to the environment.

values are constantly changing. Consequently each risk analysis or assessment has a limited period over which it is valid. That period should be explicitly stated as part of the preparation for an analysis.

3.2 When to use the Ecological Risk Assessment Framework?

The foremost reason to do Risk Analysis (RA) is to support better decision making through a rigorous, open, transparent and defensible process. In the Canadian government, risk-based decision-making utilizes; ecological, social and economic information. The Departmental Committee's Ecological Risk Assessment Framework (DCERAF) component of an RA is a science-based and open, transparent and defensible process supplying the ecological information.

The decision to use or not use this framework for a particular project is a function of national or operational policy direction. There are a number of factors that may influence that decision. Those include:

1. Canada's International commitment to United Nations (e.g. United Nation General Assembly recommendations such as the Rio Declaration on the Environment and Development 1992) and its subsidiary bodies' recommendations (e.g. The United Nations Food and Agriculture Organization's recommendations for the development of sustainable fisheries and aquaculture);
2. the General Agreement on Trade and Tariffs (GATT), its subsidiary body the World Trade Organization (WTO) and the North American Free Trade Agreement (NAFTA)which relies on the GATT / WTO trade dispute mechanism (See Text Box):
3. Canada's commitment to regional fisheries organizations (e.g. North American Fisheries Organization (NAFO)) or international science advisory bodies (e.g. the International Council for the Exploration of the Seas (ICES)) that may require or request the use of risk-based decision making;
4. Canadian legislation may request or require use of a risk analysis process. These include the Canadian Environmental Assessment Act (CEAA) and the Canadian Environmental Protection Act (CEPA);

Box 7. International Trade and ERAs

Canada is signatory to GATT and the World Trade Organization (WTO) agreement (1995). As part of our commitment we have signed the Sanitary and Phyto-Sanitary Agreement (SPS Agreement). Under the SPS agreement, the WTO limits member-states' reglatory policies relating to food safety as well as animal and plant health (phytosanitary)and it has the scope for application to trade disputes relating to a country's environmental objectives.

The SPS agreement gives the WTO the power to override a country's use of the precautionary principle – if there is no scientific certainty about potential threats to human health and the environment. Under SPS rules, the burden of proof is on the countery regulating trade to demonstrate scientifically that something is dangerous before it can impede international trade.

The SPS protocols have an embedded protocol for risk analysis. The DCERA Ecological Risk Assessment Framework, CFIA's Risk Analysis and DFO's Code for Introduction and Transfer of Aquatic Animals are consistent with the SPS protocols for risk analysis.

5. Government of Canada policy on decision making in government (e.g. Cabinet Directive on Streamlining Regulation 2007) and the use of science in decision making (e.g. the Canadian Science and Technology Advisors publications such as Building Excellence with Science and Technology (BEST) 1999, and Science Advice for Government Effectiveness (SAGE) 1999 and The Assistant Deputy Ministers' Science Integration Board report Technology in Support of Mission Critical Goals 2005);

6. Departmental Policy on the development of science advice for science in decision making and policy development (Canadian Science Advisory Secretariat (DFO 2004)); or,

7. When the decisions be may contentious with other governments, first nations, industries, non-governmental bodies, special interest groups or the public

Use an ERA when you feel it is necessary.

3.3 The Modular Nature of DFO's DCERAF

In many instances some of the analysis may already exist and can be used to support parts of the analysis to be undertaken. To benefit from this prior work and limit the work required for subsequent analyses DFO' DCERAF has a number of components that have been designed to be reused (modularized components). When properly done, this can markedly reduce the effort required for an analysis. Such modules could include ecosystem objectives, characterization of the ecosystem in question, hazard analysis and critical control point characterization and decision rules. The modules are reused where the same type of development / activity or same ecosystem is to be used in a new analysis. Examples of the application of the modules include:

1. **Ecosystem Characterization** is a module that identifies ecosystem objectives (what must be protected to safeguard the structure and function of the ecosystem) and how progress to wards them will be measured (measurable endpoints or indicators). This should remain consistent regardless of the proposed activity or development in the ecosystem. Thus once done it should not need to be redone until our knowledge of that ecosystem changes significantly. Examples of ecosystem work presently done by DFO that can be incorporated into this work includes: the Ecosystem Overview Assessment and Reporting documents (e.g. Estuary and Gulf of St. Lawrence Ecosystem Overview and Assessment Report (EOAR) January 15, 2007 version); the identification of Valued Ecosystem Components (e.g. Environmentally Sensitive Species and Community Properties, Environmentally Sensitive Habitats, Depleted Species, and Degraded Habitats); and, pathways of effects analysis as presently used by Habitat Branch and as being developed for integrated resource management.

2a. The **HACCPC** process for place-based developments consists of the description of a set of mechanism and indicators that identify the possible stresses on ecosystem components or processes. The concept is that each development is made up of a series of activities. For example bridge building requires disturbing the ground. That in turn may result in sediment loading to the aquatic habitat, which in turn has an effect on components of the ecosystem. That description of the process, from the disturbance of the ground to the sediment loadings, can be used for many types of activities or development such as dyke building, stream bed engineering, placement of culverts, upland development and road building.

The **HACCPC** process for fisheries or other activity-based environmental perturbations is similar to that for Development focused HACCPC. It contains a description of the mechanism resulting in changes in VECs and indicators that measure the intensity of the stress on the environment. An example of that can be seen in the DFO review of fishing gear effects on the environment "Impact of Trawl Gears and Scallop Dredges on Benthic Habitats, Populations and Communities" (DFO 2006). As with the HACCPC for developments, where a gear review or component tree has been identified for a very similar fishery it would made no sense to repeat the work. Simply utilize the outcome of the previous work.

3. The **State of Knowledge Reporting** component of the framework may not required to be created for each new DFO Science Sector analysis. It should however, always be part of a risk management loop where the most recent information is used to validate the model used to make the next prediction of a change in the state of the environment. An example of a State of Knowledge report would be stock-recruitment curves used to manage the use of existing stock recruitment relationships in the management of a salmon fish sock. These relationships have been developed over many years

4. **Decision Rules** are rules for action to attain an objective (e.g. to achieve conservation objectives for a fish stock). They should not be constructed on an analysis by analysis basis. One set of rules should be applied for all analysis used to attain a specific environmental objective. An example of this would be the document "A harvest Strategy Compliant with the Precautionary Approach" (DFO 2006b). In that document clear instruction is given on how to determine action reference points (thresholds) and what action should be taken when those thresholds are passed. It applies to all fisheries. Once a set of rules for obtaining an objective have been derived there should be no need for creating new rules for a new analysis with the same objective.

3.4 Prior to Starting the Ecological Risk Assessment Framework

In the DCERAF an application for a permit for a development (e.g. construction activity in or near water, and changes in water flow regimes) or a licence to undertake an activity (e.g. a fishing licence or permit for creation of genetically modified organisms) may be the reason to initiate an analysis utilizing the DCERAF. Alternately a planning process for integrated resource management may also require input from DCERAF when exploring different scenarios for resource utilization. Without regard to the reason for the analysis one of the very first considerations should be who is going to use the results of the ERA and who has to believe the results. A communication strategy is fundamental to effective use of ERAs.

3.4.1 Communication

The need for and development of a risk communications strategy is the first thing that should be considered when the government receives a proposal for a development or activity. Managing communications is primarily the responsibility of management with the exception of those communications necessary to complete the CSAS review of the science products (State of Knowledge reports and the risk assessment) as noted in section 2.1.2. The manager's identification of who should be convinced of the DCERA however may require science to include certain experts in it peer review rather than others. A useful introduction to managing risk communications can be found in Morgan (*et al.* 2002) and GESAMP (2008).

3.4.2 Applications or Proposals for an Activity or Development

To ensure early and complete identification of potentially important interactions of a development or activity with its host ecosystem/s you have to be clear on the proposal and what it is that is to be avoided. The first of these is adequate documentation of what is being proposed. It is the responsibility of management to ensure the appropriate information is captured in the application. Management may wish to consult with science on the parameters and/or scales that should be described in the application.

For science's DCERAF it is important to determine if the proposal represents an undertaking which may include multiple stages, some of which may be a development (e.g. the construction of a culvert) others may be an activity (e.g. an ongoing change in flow regime due to channeling caused by a culvert).

For each phase the science analysis must be supplied with the intensity of the activity or development (e.g. fishing effort, or degree of habitat disturbance), the geographic location and extent of the development or activity, and the temporal aspects of the activity or development, including the duration of the activity or development, any lag time associated with development of the pressure on the environment and the duration of the effect after the activity or development has finished (particularly in cases of contamination by chemicals that remain active in the environment long after the cessation of the activity or development).

Science will also need to know who is likely to be affected by the decision to ensure its review process is open, transparent and includes all the appropriate sources of scientific expertise. At the same time it is expected that the manager responsible for the decision will determine the nature of the communication strategy use to inform parties that may have an interest in the outcome of the decision making process.

3.4.3 Policy and Ecosystem Planning

The other necessity to ensure early and complete identification of potentially important interactions is to have clear operational objectives for the analysis.

This may be in the form of a pre-set objective (e.g. no stock will be reduced in size below the size necessary for maximum sustainable yield (MSY)) or the in the form of a series of *pro-temp.* objectives that may be used to explore the effect of decision making on environmental, social and economic conditions. (e.g. if stock abundance is kept at 80%, 100%, 120%, or 140% of MSY what would be the likely effect on environmental, social and economic conditions).

For ecological risk assessment the objective must be concrete enough to be directly translatable to a measurable parameter. For example, hypothetically to obtain MSY for species X in stock Y a stock size of 100,000 tones may be required. The 100,000 tomes of biomass is the concrete parameter derived from the objective of MSY. Non-technical values such as health, good, bad, acceptable *etc.* may be used in the overall decision making process but, they are inappropriate for ERA objectives.

Box 8. Principles - Environmental Planning and Policy

9. Environmental planning and policy objectives should be explicitly expressed prior to initiating Hazard Identification. They should also include the description of the physical boundaries of the ecosystem in question as well as the temporal time frame for the risk to be considered. Where these have not been formally derived, assumed objectives and scalars should be recorded.

10. Risk-based decision making in resource management requires environmental assessment to be combined with economic and social values. Valuation (e.g. establishing what is; acceptable or not acceptable, good or bad, better or worse) is a socio-economic process. Estimating value is not part of a scientific ecological risk assessment. They are part of the environmental policy process and are used in the decision making process.

11. Other developments or activities that may result in environmental change (cumulative effects) should also be accounted for as part of the policy and planning function that feeds a risk assessment.

ERA objectives must also be explicit on the geographic extent. That geographic extent may be the range of a species (e.g. species X, stock Y) or it may be the geographic extent of an ecosystem (e.g. the Straight of Georgia. For an objective based on a species range, during the analysis it will ultimately be necessary to identify the ecosystems that that species or stock uses. As part of the outcome of the hazard identification process, it should be clear whether the effect of the specie or stock on the function or structure of those ecosystems is evaluated.

In the objectives it is also imperative that there be a clear statement of the temporal context for the analysis (e.g. the objective might be to maintain 100.000 tonnes of stock Y for species X for the next decade.) This is necessary because due to natural events there are different levels of productivity for many stocks. (e.g. On the west coast there are natural decadal scale fluctuations in the oceans ability to sustain productivity of pink or sockeye stocks. So the MSY identified at a point in time may entirely change in the next decade.) In addition human uses of an ecosystem change over time and changing resource use patterns also can affect the ability of an ecosystem to support a development or activity.

4.0 The Ecological Risk Assessment Framework

The ecological risk assessment framework (Figure 2) covers those portions of the analysis that neither the decision-maker for a project or activity, nor science are responsible for. In this guide the decision-maker and science are not responsible for formulating the proposal for an activity or development. They are also not seen as responsible for the creation of the ecosystem objectives or planning for development of the resources though the decision-maker may have input to their development.

4.1 Triage

The purpose of triage herein is to help ensure the cost-effective application of effort in any risk analysis undertaken as mandated by cabinet directive. That does not mean an economic analysis must accompany every decision to deny or permit an action. It means that every decision to regulate an activity must be made with the recognition that the decision inevitably incurs costs and no cost should be accepted if it does not lead to an improvement of the situation. By extension no more effort should be applied to making a decision than is warranted.

Box 9. Principles - Creating Triage Rules

12. The decision on what rules are to be use should be made by management but may be informed by science.
13. Triage rules are project / development independent
14. Triage rules specify the circumstances under which all, part, or none of the analysis need not be undertaken for a project or development.

Triage rules state the conditions under which the analysis can be simplified. That simplification can range from a decision to record the nature and scale of the development / activity and record the out come of the decision making process, to a decision to do a complete and detailed Ecological Risk Analysis. Many decisions will require something between these extremes.

4.1.1 What triage is, and is not.

Triage is a project-independent decision process that tells the manager to initiate all, part, or none of the framework structure. It answers the question "For this analysis, what portions of the framework is it not necessary to do?"

In contrast to the triage, prioritization processes ask the question “What is the order of importance for completing tasks?” There are a number of places in the framework where prioritization is applied. An example is during the Hazard Analysis and Critical control Point Characterization (HACCP) that describes all possible interactions of the project or activity with the ecosystem. In the unlikely event that the required resources were available a risk assessment of all possible interactions might be done. The more likely scenario is that resources will limit the number of assessments that can be done, so the assessments have to be ranked according to criteria such as which ones present the greatest hazard to VECs identified in the Ecosystem Characterization process.

In triage policy, legal or regulatory considerations such as the existence of a park, marine protected area, species at risk or its critical habitat may prohibit undertaking the proposed activity or development. Under these circumstances a prior decision makes risk assessment unwarranted.
Decisions on the appropriate degree of analysis to undertake can be divided into two approaches: those that reasonably limit the extent of the process and, those that limit the detail of the assessment. Triage only deals with the former. Triage does not define the level of detail to be used in predicting effects in the “Risk Assessment” component of the framework. The question of choosing a level of detail for a risk assessment can be illustrated by the Australian Fisheries Risk Assessment proposed by Hobday *et al.* (2007) wherein there is a stepped wise approach to increasing the detail of the assessment undertaken. The level of risk is determined in each of three increasing levels of detail. As long as the risk is determined to be moderate or high the analysis proceeds to the next level of detail until, the final level of detail is a full quantitative assessment of risk.

4.1.2 When should triage be used

There are three strategic places in the framework where triage might be considered: prior to Environmental Characterization; prior to Hazard Analysis and Critical Control Point Characterization (HACCPC); and, after completion of the Hazard Identification. Triage is not an evaluation of risk; it is a review of the adequacy of our knowledge of the potential hazards. The decision to use a triage is the responsibility of the decision maker though she or he may wish to discuss the adequacy with representatives of the Science Sector.

4.1.3 Triage Prior to Environmental Characterization

When this triage point is reached management should have identified the operational objective, the boundaries of the ecosystem or ecosystems and, the VECs that will be affected. Management should also have determined a time frame within which the analysis is expected to be applicable. If previous work has completed the environmental characterization for that combination of objective, ecosystem VECs and timeframe already exists there is no need to repeat the Environmental Characterization process.

4.1.4 Triage Prior to HACCPC

When the request for a permit for a development or activity is received it should identify the type of operation (e.g. construction of a road culvert or a fishery for species X with gear Z). Details of the application should also be clear on:

- if it is a development that will occur once (e.g. construction of a road culvert);
- if it will be cyclic/seasonal (e.g. fishing activity); or,
- if it will continuous (e.g. a long term change in water flow characteristics due to placement of a culvert)

The application will should also contain information on the duration of the development or activity or if a cyclic activity how many iterations will occur over the period covered by the risk analysis. The final piece of required information is the geographic extent of the area of the activity / development and the likely down stream distribution of this effect (e.g. siltation due to the construction of a culvert). If previous work has completed a HACCPC for that combination of conditions there is no need to repeat the Environmental Characterization process.

4.2 Hazard Identification

Hazard Identification (Figure 3) is one of the most important parts of the risk assessment framework to get correct. It determines the potential for serious hazards and prioritizes them. It does so by answering the questions:

- What features and processes in an ecosystem are known to be affected by the activity or development under consideration?
- How widely are the agents causing these effects likely to spread?
- What would be an appropriate parameter to measure to track the intensity of the development or activity (e.g. in a fishery it might be the effort put into the fishery intensity measures as the number of fishing days)?
- What features or processes (VECs) do I need to protect in the ecosystem/s in question?
- What is the Distribution of these VECs?
- What would be an appropriate parameter to measure to track changes in the VECs?
- How much change is acceptable (similar to setting a limit reference point) in the VECs of concern?
- Where do the distributions of VECs and the effects of the activity or development overlap?
- What is the order of priority for addressing the effects of the development or activity?

During the process of hazard identification the Hazard and Critical Control Point Characterization (HACCPC) and, the Environmental Characterization may inform each other. The relative importance of the hazards is identified trough a conjoined analysis of the outcomes of the HACCPC and Environmental Characterization processes. The hazard identification step does not deal with risk as no part of it makes a prediction of the level of environmental response or the probability of the prediction being accurate.

4.1.1 Hazard Analysis and Critical Control Point Characterization

The key questions to be answered in HACCPC are:

- What features and processes in an ecosystem are known to be affected by the activity or development under consideration?
- How widely are the agents causing these effects likely to spread?

- What would be an appropriate parameter to measure to track the intensity of the development or activity (e.g. in a fishery it might be the effort put into the fishery intensity measures as the number of fishing days)?

The question "What features and processes in an ecosystem are known to be affected by the activity or development under consideration?" requires presenting the mechanism/s by which the activity or development affect the environment.

The description of the mechanism resulting in environmental change developed for a HACCPC would start with an activity or development such as the development of a public bathing beach. That would then be broken down in to a series of sub-activities. One of the in water sub-activities (as opposed to terrestrial sub-activities) might be the removal of unwanted aquatic vegetation.

The question of "How widely are the agents causing these effects likely to spread?" has both a geographic and a temporal aspect to it. In the case of the removal of vegetation sub-activity if the vegetation is achieved by mechanical means it is not likely that the removal of the weeds will happen outside of the harvest area. In the case where a chemical agent is used to kill the vegetation the waterborne chemical may well distribute outside of the intended "kill zone" and this should be considered when considering the geographic extent of the effect.

In terms of temporal considerations, with the chemical solution the chemical may persist and be active for some period of time but the plants killed are destroyed all the way to the roots. In the case of the mechanical solution viable roots or parts there of may be left behind to regrow. This may necessitate multiple plant harvests each year.

For the question "What would be an appropriate performance parameter to measure or track the intensity of the development or activity?" the parameter chosen should have 3 components in the metric. It should have degree of change in the pressure on the ecosystem component, and temporal and geographic components. For example, if the concern was annual eutrophication in a lake then a possible measure might be the annual loading of phosphorus (e.g. Kg P/yr / ha).

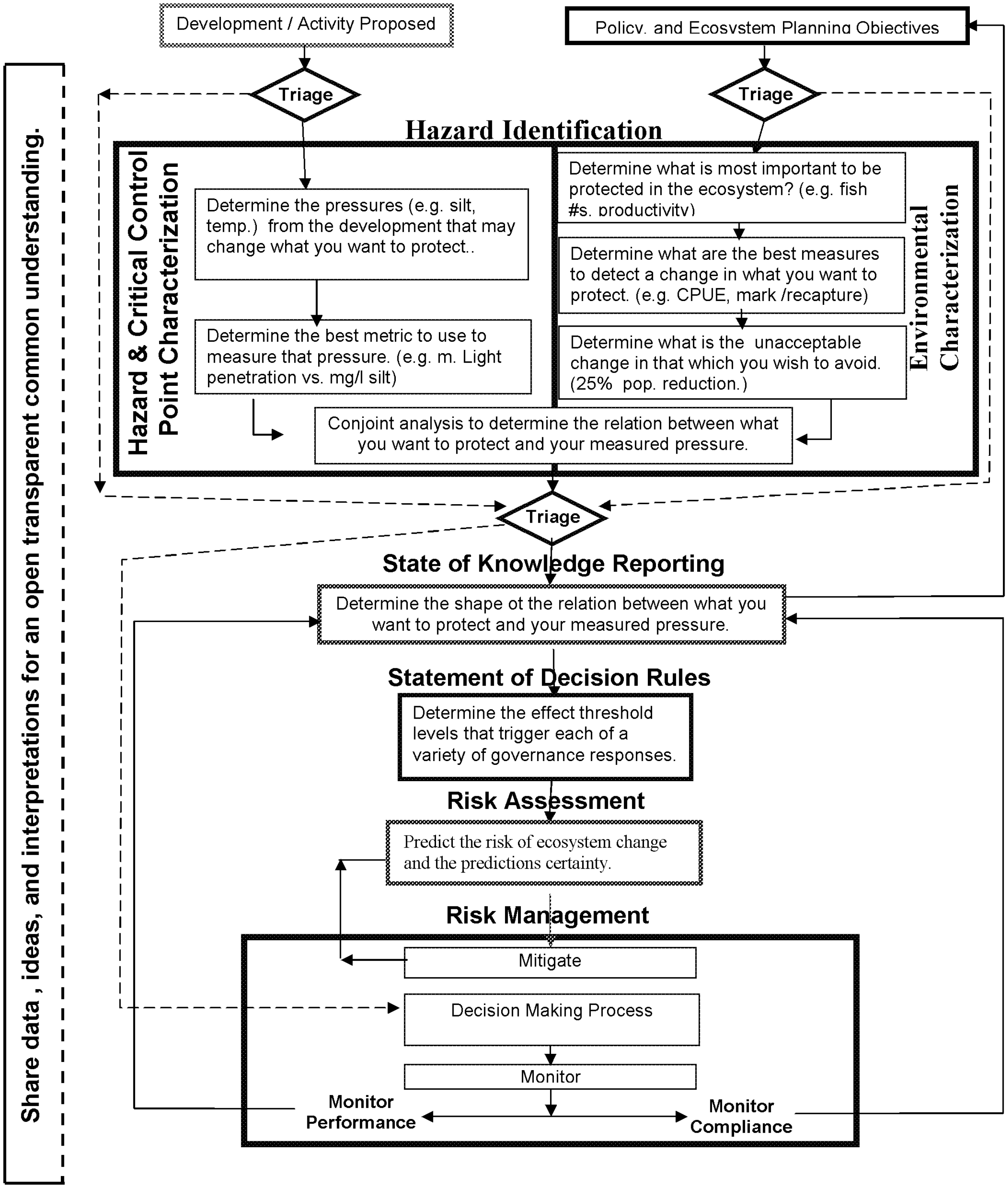

Figure 3. Functional details of the DCERA risk assessment framework structure.

Box 10. Principles - HACCPC

15. Each hazard should be identified along with the environmental change/s it might cause.

16. HACCP should yield a cost-effective measurable indicator for the pressure the development or activity will exert on the ecosystem.

17. Identification of a hazard should be based on recorded evidence not opinion. Undertake an exposure assessment, (i.e. describe the process by which the hazard is released and the probability and intensity of the release) in as much detail as possible. Collate information on factors that may enhance or inhibit exposure.

22. Hazard Identification may be finished without complete information on the site in question by drawing on relevant scientific information and experience in similar or related circumstances. All of these assumptions however must be documented in the Hazard Identification.

4.2.1 Environmental Characterization

Environmental Characterization answers the questions:

- What features or processes (VECs) do I need to protect in the ecosystem/s in question?
- What would be an appropriate parameter to measure to track changes in the VECs?
- What is the temporal and geographic Distribution of these VECs?
- How much change is acceptable (similar to setting a limit reference point) in the VECs of concern?

Environmental Characterization identifies what are the features and processes that are important to protect. There are a number of activities which may contribute to identifying these. It may be desirable to protect species recommended for protection by the COSEWIC (Committee On the Status of Endangered Wildlife In Canada), or the Species At Risk Act. It is also important to consider protecting ecosystems features and processes that have been identified as VECs in support of ecosystem structures and functions. This might include degraded or rare habitats, diversity, critical habitats for maintaining the diversity of the flora and fauna.

For the question "What would be an appropriate parameter to measure or track changes in the features or process of concern?" the parameter chosen should have 3 components in the metric. It should have degree of change in the ecosystem component, and temporal and geographic components. For harvested fish species the parameter used might be the percentage of vegetation lost, in the ecosystem, annually (% per year). For an effect on fish populations, it might be the percent reduction in stock Y of species X on an annual basis (% loss per year)

When there is more than one viable performance parameter it may be useful to consider if some are more meaningfull for the socio-economic factors involved in the decision making.

In the lake example above eutrophication (coloration of the water) could also be measured as peak secchi depth reading (the depth at which a white disc is no longer visible from the surface) averaged across the lake. Discolouration of the waters (a frequent outcome of algal production from excessive nutrients) tends to reduce the aesthetic values of the lake which inturn can affect real estate values and the attractiveness of the area for the tourism trade.

Once the parameters have been identified the analyst should consider their temporal and geographic distribution. For example for most fish species have breeding habitat varies in both its size (for some species like herring it can also vary in its distribution) and the usage of the breeding habitat at various times of the year.

How much change is acceptable in the species or VECs of concern? In a directed fishery for one species this is the limit reference point beyond which further fishing should be avoided. For a habitat it may be a limit to how much of a habitat can be allowed to be changed.

The level of protection specifies the acceptable degree of change (intensity of change) over a specified geographic extent for a specified period of time. The resource manager is responsible for designating what is an acceptable level of protection (limit and action reference points) for each performance parameter. Science may inform the manager of environmental changes associated with the proposed reference points but should not decide what the reference values should be. To the degree possible levels of acceptable protection should not differ from those applied to other human activities that could result comparable in environmental change.

Box 11. Principles - Environmental Characterization

19. Sources of hazards that could add to the cumulative effects on these ecosystem structures and functions.

20. Each potential environmental change of concern should have a measurable endpoint parameter identified that can be used to quantify the severity of change(an environmental performance indicator).

21. Acceptable levels of protection for each environmental change (as per endpoint parameters) must be created prior to undertaking a risk assessment. (i.e. Make a clear statement and decision table expressing acceptable levels of protection from the endpoints arising from the hazard being examined.)

The question of acceptable level of change is very important if a full risk assessment is to be undertaken as it determines what temporal and geographic resolution must be achieved for any prediction or monitoring exercise.

4.2.2 Conjoined analysis of Environmental Characterization and HACCPC

When analysing the implication of HACCPC and environmental characterization it is important to recognize that risks are always incremental and relative. Ecosystem risk is incremental in as much as many, if not most ecosystems, have other developments and activities beyond the one under examination. Frequently there are activities and developments that already stress the VEC you wish to protect, so the activity or development represents an increment in the stress on the VEC. Usually there is no way you can estimate the total level of stress applied but you can estimate the additional stress that would be applied to the VEC.

As a corollary, even if no development or activity is undertaken the situation you wish to avoid may occur. Ecosystems constantly vary and evolve. For example with the warming of the oceans it is reasonable to expect that some species may not be able to live in the warmer waters and may be driven from an ecosystem with or without development.

Box 12. Principles - Conjoint analysis

19. Risk is always incremental and relative (compared to alternates including natural variation in an ecosystem).

4.2.2.1 Relative Importance of potential hazards

This step in the hazard identification addresses the question: "What is the order of priority for addressing the effects of the development or activity?" The first part of responding to the question is relatively simple - look at the outputs from the HACCPC and the Environmental Characterization to identify if the important structures of the ecosystem overlap (geographically and temporally) with the distribution and timing of the effects of the development or activities to be undertaken.

How many categories there are under each of geographic overlap, temporal overlap, level of activity and importance is up to the analyst and decision maker. The number of levels and rules for their evaluation should be assigned before the susceptibility analysis is undertaken in order to avoid accusations that the rules were developed after the analysis so that a desired level of susceptibility would be the result. Table 1 is an example of a set of evaluation rules where in each of the categories can be assigned to one of 3 levels (**H**igh, **M**edium and **L**ow). Table 2 is a hypothetical example of the analysis the potential importance of a development or activity on a series of VECs. It is important to that each cell be treated independent of its neighbours. This means each cell should be read as the effect of the development on the VEC in terms of its geographic overlap with the VEC, its temporal overlap with the VEC, and the level of activity affecting the VEC.
Some times after looking at the co-occurrence of hazards and VECs, the resultant list of VEC/Hazard has more pairings that resources allow to be addressed. Below are a couple of considerations that might help you prioritizing the list.

	Temporal Overlap		Geographic Overlap		Level of Activity			Importance
(	H	,	H	,	H	)	=	H
(	H	,	H	,	M	)	=	H
(	H	,	H	,	L	)	=	H
(	H	,	M	,	H	)	=	H
(	H	,	M	,	M	)	=	H
(	H	,	M	,	L	)	=	M
(	H	,	L	,	H	)	=	H
(	H	,	L	,	M	)	=	M
(	H	,	L	,	L	)	=	M
(	M	,	H	,	H	)	=	H
(	M	,	H	,	M	)	=	H
(	M	,	H	,	L	)	=	M
(	M	,	M	,	H	)	=	H
(	M	,	M	,	M	)	=	M
(	M	,	M	,	L	)	=	M
(	M	,	L	,	H	)	=	M
(	M	,	L	,	M	)	=	M
(	M	,	L	,	L	)	=	M
(	L	,	H	,	H	)	=	H
(	L	,	H	,	M	)	=	M
(	L	,	H	,	L	)	=	M
(	L	,	M	,	H	)	=	M
(	L	,	M	,	M	)	=	M
(	L	,	M	,	L	)	=	M
(	L	,	L	,	H	)	=	M
(	L	,	L	,	M	)	=	M
(	L	,	L	,	L	)	=	L

Table 1. An example of evaluation rules for determining importance.

Activity or Development / VEC	Geographic Overlap (High, Medium, Low)	Temporal Overlap (High, Medium, Low)	Level of Development or Activity (High, Medium. Low)	Importance (High, Medium. Low)
Breeding area for species X	High	Medium	High	High
Primary Productivity	Low	Low	Low	Low
Abundance of forage species	Medium	High	High	High
Trophic Web Structure	Low	Medium	Low	Medium
Abundance of top predators	Medium	High	High	High
Water Quality	Low	Low	Low	Low
Diversity of fish species	High	Medium	Medium	High

Table 2. An example of determining the importance of hazards posed to a number of VECs
For example, if we rank the susceptibility as **H**igh, **M**edium or **L**ow, the proximity to LRP as **C**lose, **M**oderate or **D**istant and the level of activity as **B**ig, **M**oderate or **S**mall then, the rules for combining proximity to LRP and the level of activity where each of these has three levels are shown in table 3.

4.2.2.2 Susceptibility of the VECs

One of the attributes that can help prioritize is the susceptibility of the VECs. Just how close is the present state of the VEC to its limit reference point (LRP) and how much of a development or activity will it take to get there? Normally, there will not be the data necessary to numerically quantify this. It can however, be done qualitatively based on expert opinion. How many categories there are under each of the proximity to LRP, the level of activity and susceptibility is up to the analyst and decision maker. The number of levels and rules for their evaluation should be assigned before the susceptibility analysis is undertaken in order to avoid accusations that the rules were developed after the analysis so that a desired level of susceptibility would be the result.

As with all analyses included in the framework, record the outcome of the susceptibility analysis before proceeding to the next step in the framework.

	Proximity to LRP		Level of Activity			Susceptibility
(	C	,	B	)	=	H
(	C	,	M	)	=	H
(	C	,	S	)	=	M
(	M	,	B	)	=	H
(	M	,	M	)	=	M
(	M	,	S	)	=	S
(	D	,	B	)	=	M
(	D	,	M	)	=	M
(	D	,	S	)	=	S

Table 3. An example of rules for assigning the level of Susceptibility.

VEC	**Proximity to LRP** (Close, Moderate, Distant)	**Level of activity / development** (Big, Moderate, Small)	**Susceptibility** (High, Medium. Low)
1. Breeding area for species X	Close	Moderate	High
2. Abundance of forage species	Distant	Moderate	Moderate
3. Abundance of top predators	Moderate	Big	High
4. Diversity of fish species	Moderate	Small	Low

Table 4. An example of an analysis of susceptibility.

4.2.2.3 Achievability of mitigation.

Another way to prioritize hazards is to examine known applicable mitigation and ask the question "Given a set of hazards, what do we know of the success of mitigation technologies used to control the effects of these hazards on the environment?" Below (Figure 5) is a "Heat Map" graphic displaying what the answer might look like. Heat maps are visual aids for decision makers. The colour of the individual cells represents the outcome of a decision rule. For example: any evaluation of susceptibility and achievability that end as a point in a red cell (e.g. # 3 in Figure 5) may trigger a decision to not allow a development or activity or to proceed; any evaluation that end as a point in the yellow (e.g. # 2 and #3 in Figure 5) may suggest a decision to proceed cautiously with a full risk assessment; and, any evaluation that end as a point in the green (e.g. # 3 in Figure 5) may suggest that the activity or development may be allowed to proceed without a risk assessment.

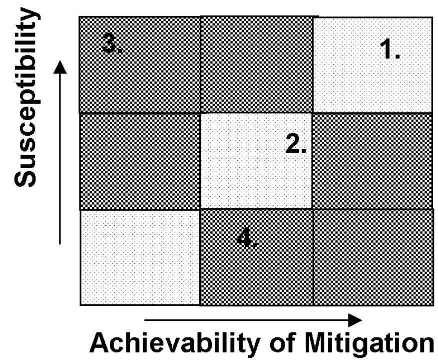

Figure 4. An example of how the outcome of susceptibility and achievability analysis might be recorded.

4.3 Triage after the Hazard Identification Process

Not all activities or developments require an ecological risk assessment to justify licensing or permitting an activity or development. All decisions however, should at a minimum have considered the elements in the hazard identification process. Once Hazard Identification (Environmental Characterization, HACCPC and their conjoined analysis (see section on hazard identification)) is completed it should be clear what mechanism and effects are most important. At this point the decision-maker may decide they do not have adequate information to reasonably proceed to the Decision-Making without completing a risk assessment.

4.4 Probability, Likelihood and Uncertainty

Probability, likelihood, and uncertainty are three terms that can cause confusion as they are often inconsistently used. In this framework probability and likelihood are synonyms while uncertainty is something entirely different.

Figure 5 examines the probability and uncertainty that are associated with the two parameters that define risk – the level of effect predicted and the probability that that prediction is accurate. In that sense, probability is an estimate of the likelihood that a predicted value for a parameter is true (the star in Figure 5 (Top diagram). If the same estimate was made independently by a series other people there would be variation in the estimate but the most frequent estimate would be where the star is. The frequency of occurrence of other estimates would the frequency of occurrence of those estimates of the probability (the curved line in Figure 5). The same applies to the estimates of the "level of effect" parameter (Figure 5 Bottom).

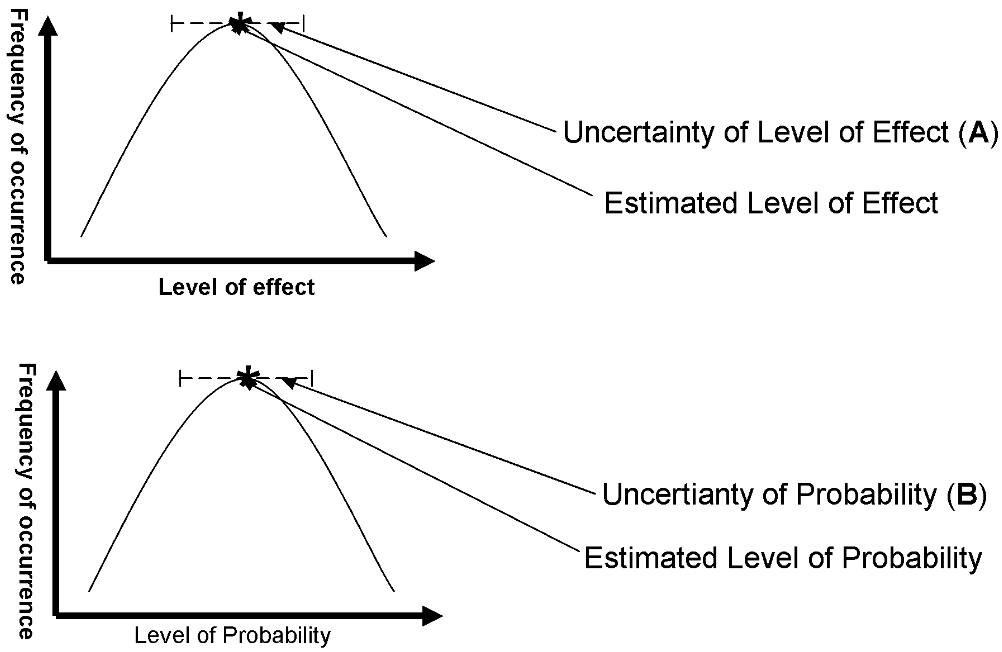

Figure 5. Probability and uncertainty in the two parameters that define risk.

In figure 5 levels of uncertainty for the estimated level of effect (A) and the estimated probability (B) are represented by wisker-bars, These are a measure of the variance (or standard deviation) of the distribution the estimate around the predicted point (the stars). Figure 6 illustrates the difference between highly certain (diagram on the right) and highly uncertain (diagram on the left) estimates.

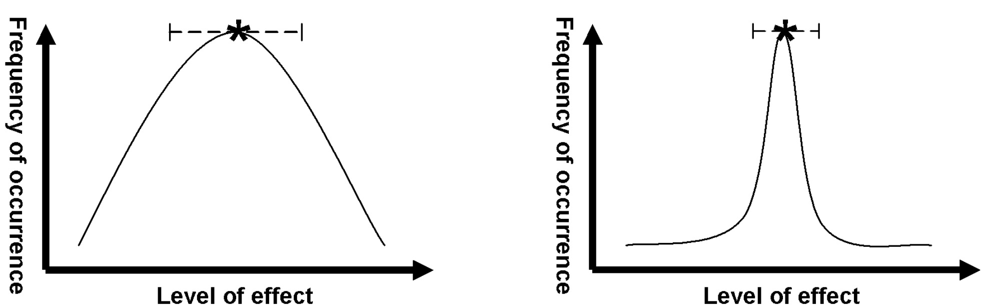

Figure 6. An illustration of the different between a highly uncertain (imprecise) estimate and a highly certain (precise) estimate.

When examining risk, the "level of effect" parameter is a compound parameter. It is made up from estimates of 3 independent parameters: level of intensity, level of persistence and geographic extent (Figure 7). Usually the highest level of uncertainty among the 3 independent parameters determines the uncertainty for the "level of effect" parameter.

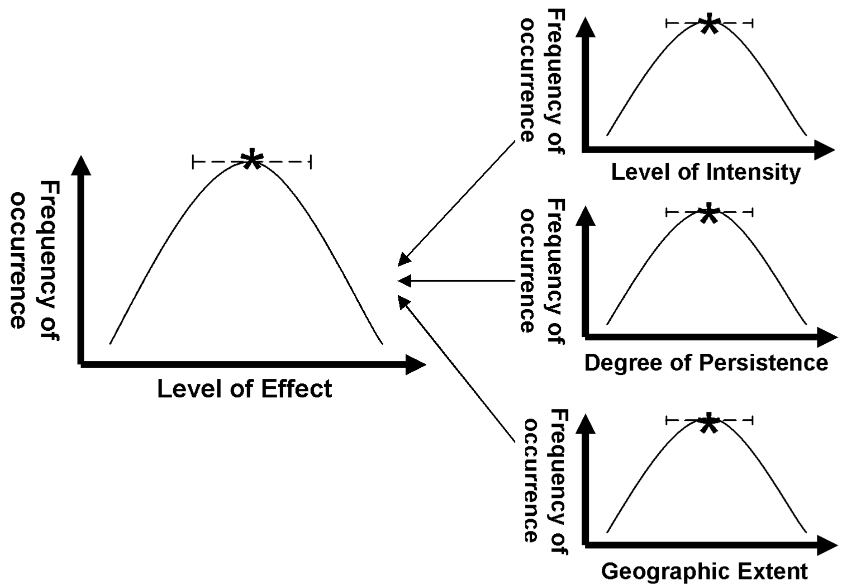

Figure 7. Components contributing to the uncertainty in the level of effect

On a heat map the uncertainty could be illustrated by a cloud around the plotted point (the star in Figure 8). The A and **B** in figure 8 refer to the estimates of uncertainty illustrated in figure 5. Uncertainty is not used in assessing ecosystem risks though it is estimated at the same time. The uncertainty estimated in the risk assessment step is used in the decision making process where uncertainty associated with ecosystem is combined with social, economic uncertainty and other sources of uncertainty as part of the application of precautionary in decision making.

The framework has other sources of uncertainty in formulating an ecological risk analysis. The decision-maker must also be informed of these prior to combining the outcomes of the ecosystem, social and economic analyses in the risk-based rational for the decision. There is uncertainty associated with the identification of VECs, and uncertainty that the development or activity will be executed as planned. There is uncertainty associated with the state of knowledge report and the formulation of effective decision rules as well as with monitoring. How those are combined is the decision of mangers. Generally, where estimates of a parameter are derived independently the largest uncertainty is considered the appropriate level of uncertainty. Where a parameter is dependent on prior estimates from previous steps then the estimates of all previous steps are combined.

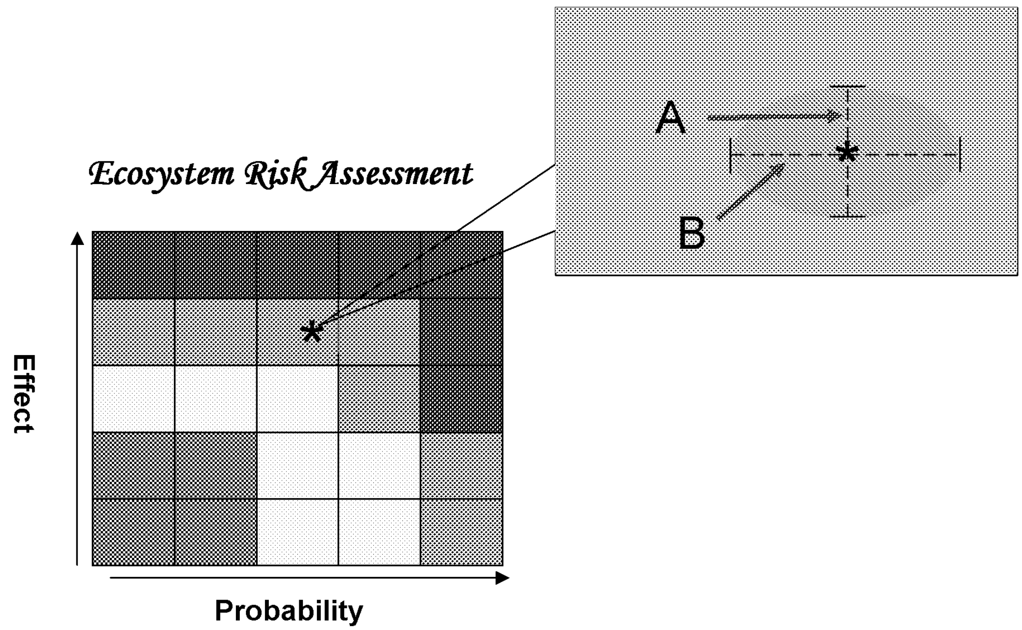

Figure 8. An example of the illustration of uncertainty on a heat plot for an ecosystem risk assessment.

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4.4 State of Knowledge Review

Once the decision-maker decides more than just hazard identification is required before a proposal can be adjudicated, the next step is to formally review existing scientific information on the shape of the relationship between the activity or development and the VEC/s of concern. The objective of this review is to create an explicit model describing the dynamics of the processes linking the HACCPC with the aspect of the environment to be protected.

Generally scientists will be asked to develop the state of knowledge report. It may require peer review through the Canadian Science Advisory Secretariat.

Consider figure 9 as an example of the state of knowledge for the hazard of sediment loading to a fish population. The Hazard Identification process will provide the compliance and environmental performance parameters (loading of silt and percent of the original population size respectively) and the metrics by which they will be measured (Mg/l and %). It will also provide limit reference point (75% of the original population size). This is the point at which the bolded dashed arrow on the performance axis (Figure 9). It is the point below which the decision-maker has decided that the population size will be unacceptable.

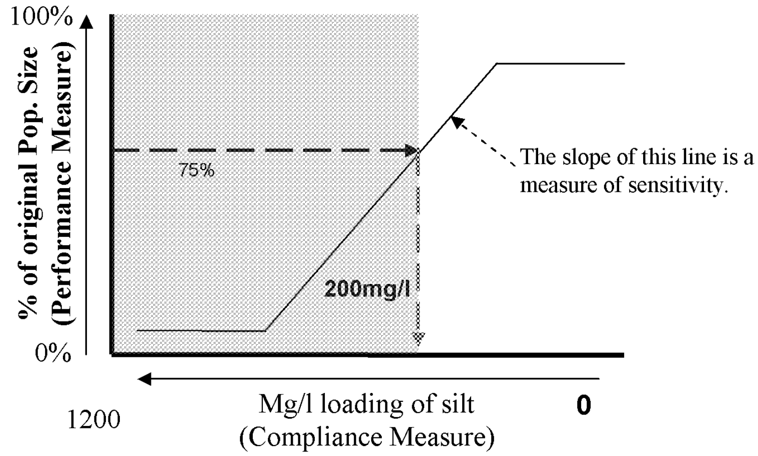

Figure 9. An example of an output of the state of knowledge reporting.

At this point published literature or theory can be used to draw a line (data-based or presumptive) representing the best understanding of the functional relation between the performance and the compliance parameter. From this relationship the analyst can move from the performance threshold (75%) along the black arrow to the functional relationship line and then down the bolded dashed red arrow to the compliance axis to set the compliance threshold (200 mg/l) that must be met in order to protect the fish population.

It is important to set performance and compliance thresholds at this time because if it requires an inordinate level of sampling (temporal and spatial) to detect the necessary changes in the performance or compliance parameters it may require a re-examination of the compliance and/or performance parameters to see if more cost-effect parameters can be arrived at.

Then to supply the information required for building a decision that incorporates the precautionary principle it is necessary to examine the uncertainty associated with the relationship. The uncertainty of concern here is in the exact shape and placement of the line representing the functional relationship (note the greyed area in figure 10). This relationship can now act as the putative predictor for estimating the site specific effect of the activity/development in the risk assessment.

The feature of this scientific risk assessment from other science informed risk assessment is that the state of hypothetical relationship as depicted in figure 20 can be tested through any compliance and performance data acquired through monitoring. This allows the general knowledge and knowledge of the relation for that particular ecosystem to develop over time.

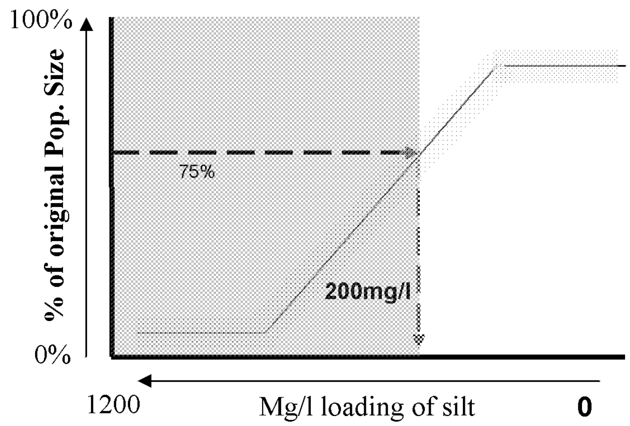

Figure 10. Uncertainty associated with the functional relation developed in the state of art reporting.

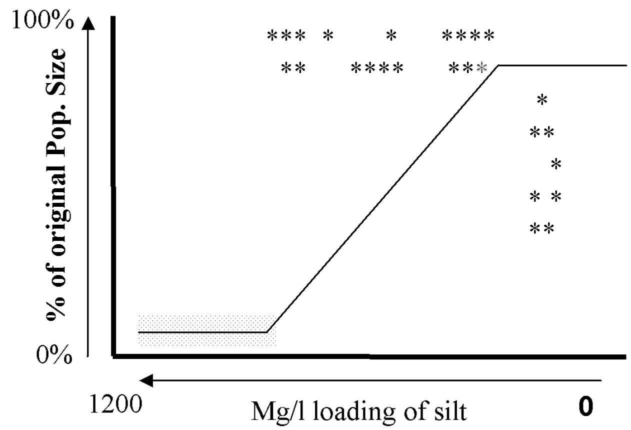

Figure 11. An example of monitoring data patterns that suggest in the present ecosystem changes in the ecosystem are independent of industries activities.

A pattern similar to those of the green stars in figure 11 suggests that for some reason regardless of the loading the VEC fails to change. Possible reasons for this are that the temporal and/or geographic scale of the interaction of the interaction is wrong. The pattern of the blue stars in figure 11 suggest that even with no variation in the stress the development or activity places on the environment the VEC differs significantly. Possible causes for this could include that there is an unrecognized problem of cumulative effects on the VEC or that some other factor actually controls the variation in the VEC

4.5 Definition of Decision Rules

To ensure that the independence of science and policy is apparent it must always be apparent that the decision rules were made before the risk assessment is done. This helps avoid the perception that the rules were designed to result in a pre-ordained decision. It should be done by a group of people to show convincingly that no individual designed the rules to serve their personal purpose. For example in figure 4 activities or developments that have their risk assessment plot out in the red cells may be designated as to high a risk to allow them to proceed under all except very exceptional circumstances. Projects or developments that have their risk assessment plot out in the yellow cells may be designated as doable but under condition that certain mitigation and monitoring goals are met. For those that plot in the green zone the monitoring conditions may be much reduced and no mitigation conditions may need to be put forward.

Decision rules determine what action will be taken for a series of levels of risk. As mentioned earlier these can be represented by coloured cells on the heat map (Figure 4). Cells of the same colour would be within one range of risk and have a common decision rule.

Decision rules should clearly state what level of uncertainty should be calculated for use in decision making. As indicated earlier uncertainty is a measure of the distribution of estimates of a parameter. In working with uncertainty will it cover 99% of the distribution of the estimates or is 66% sufficient. The analyst must consider the cost of sampling required the measure significant differences with such a high level of certainty (99%). Frequently it is not justified and a lower level of certainty (e.g. 75% or 66%) is more cost effective.

The boundary between areas of different colours represents thresholds or reference points. There are usually two types of reference points, a limit reference point and action reference point. In figure 4 the limit reference point would be the red yellow boundary the action reference point would be the yellow-green boundary. There may be more than the single action reference point shown in Figure 4. Each additional action reference point boundary would require a differently coloured area on the heat map. For example as risk increases you may cross a series of action reference points each of which may require more stringent monitoring and mitigation requirements.

Setting the decision rules is wholly a management responsibility. In deriving the rules for an ecosystem Management should be informed by social and economic values associated with that particular ecosystem.

Safety factors are often used in setting thresholds for managing toxicological effects. For example a manager may decide the generally accepted threshold for cadmium of 2 ppb is not enough. Society wants more protection. So they could multiply the present limit by of 0.5 to achieve a limit that more reflects society's aversion to certain types of risk. This safety factor is a result of the social analysis it is not part of the ecological risk assessment.

Management should also be informed of science's ability to detect the changes in the ecosystem small enough to resolve the difference between adjoining differently coloured cells on the heat map. The manager should consider whether the cost of getting the data to detect those differences and whether those costs are reasonable. That person should also be aware that there is no such thing as a zero risk option.

While management is responsible for deciding the decision rule, they may wish to consult with scientists on aspects such as the nature and amount of sampling complying with the rules might entail. The scientist should also be able to supply some sense of the cost that would be associated with that level of sampling.

Box 13. Principles - Decision rules

20. Setting the decision rules is wholly a management responsibility.
21. Decision rules should be made and seen to be made independent of the assessment of risk.
22. The degree of certainty (e.g. 66%, 75% or 95% of the variance in the estimates) to be used in the decision rules should be stated in the development of decision rules.
23. The decision rules should be developed in relation to a set of limit and action reference points developed for the ecosystem under consideration.
24. The effect of levels of uncertainty on the acceptable levels of sampling must be documented prior to undertaking a risk assessment.
25. The desire level of certainty determines the effort required to monitor the effectiveness of the implementation of the regulatory decision and therefore has a strong impact on the cost-effectiveness of monitoring.
26. There is no such thing as a zero risk option.

4.6 Risk Assessment

Risk assessment is the prediction of the incremental change in an ecosystem that might be the consequence of a proposed development or activity. As a picture frames is what surrounds the picture so it is that a risk assessment framework is what surrounds the assessment. The diversity of assessments DFO may undertake is so broad that it makes it impossible to give a single methodology for all possible DFO ecosystem risk assessments.

Each ecosystem risk assessment is particular to the place and activity/development to be undertaken. For example a bridge over a maritime waterway may not use the same model for assessment that a bridge or culvert crossing over a fresh water stream or river night use.

Even with those caveats it is possible to identify what scientists will need, in a general sense, to do a risk assessment. These include:

- clear operational objectives. (section 3.4.2 in this guide);

- the physical boundaries of the ecosystem, (section 3.4.2 in this guide);
- the performance parameter/s and the geographic and temporal scales at which they are to be measured and the precision needed in these measurements Section 4.2.1 in this guide);
- the magnitude, and the temporal and geographic scale of the proposal (Section 3.4.1 in this. guide);
- the compliance parameter/s and the geographic and temporal scales at which they are to be measured and the precision needed in these measurements (Section 4.2.2 in this guide);
- uncertainties associated with all aspects of the hazard identification characterization (Section 4.4 in this guide); and,
- a review of the state of knowledge of prediction of the link between the development/activity and the environmental effects and associated uncertainties (Section 4.4 in this guide).

Scientist are those best trained to structure and undertake ecological risk assessments in DFO and the DFO Science sector already has a peer review mechanism in place to review such assessments. To ensure high quality work conforming to the Sage Principles and the CSAS objectives (Section 2.1 in this guide) science sector is responsible for constructing and reviewing ecosystem risk assessments.

At the same time there are a number of outputs from the assessment that the decision-maker should receive. For each ecosystem and proposal combination these should include;

- a prediction of the geographic, timing and intensity of the change to be anticipated and,
- the level of uncertainty associated with the prediction.

Managers should not ask scientists to say if these changes are good or bad. That is the role of the social and economic analysis. Ecosystem risk assessment is a traditional science, in that it measures and predicts but does not have a methodology for setting a value on the changes. From an economic point of view it does not predict the dollar value of the change and from a social perspective it can not evaluate if that change is acceptable (good) or unacceptable (bad) for society.

Box 14. Principles - Risk assessments

27. Each risk assessment unique for the combination of places and activity/development involved.

28. Common to all ecosystem risk assessments are the type of information needed to do a good job and the type of information a manager can expect from the assessment.

4.7 Risk Management

Risk Management in this framework covers mitigation, decision making and monitoring. Management should be responsible for the delivery of all of these functions. Science may be of more import in advising the decision-maker on sampling strategies and cost associated with mitigation and monitoring issues. In the decision making process, of central concern is the balance of and the recording of the social and economic factors that complimented the ecosystem analysis in the decision making process.

4.7.1 Mitigation

Mitigation techniques at this point in the risk analysis are specifically tailored to the combination of the site and nature of the proposed activity or development. This differs from discussions of mitigation in Hazard Identification (Section 4.2.2.3 in this guide) wherein the question of how achievable is based on historical effectiveness of the mitigation technique.

Mitigation considerations at this point are developed iteratively with the risk assessment until such a point as the decision-maker decides the level of environmental change associated with the proposal is acceptable or the proponent withdraws the proposal.

Different mitigation approaches may affect the social and/or economic consideration of the risk analysis. For example consider the effect of changing the site for a fish farm, within an ecosystem, as part of the mitigation strategy. A fish farm in highly populated area may be less desirable than one in a rural area where both jobs and similar pressures on the system are lacking.

4.7.2 Decision making

The decision making process is entirely the prerogative of management. Usually, it involves balancing, and recording all or the relevant social, economic and ecosystem considerations. This is the only place in the ecological risk assessment framework where the precautionary approach should be used. It is not part of the ecosystem risk analysis because it utilized values (e.g. serious or irreversible harm).

The DCERAF contributes to decision making and risk communication by being a transparent ecological analysis, designed to allow inclusion of clients or interested parties in the analysis, addressing explicit objectives and using HACCP-like threshold setting.

4.7.3 Monitoring

Monitoring is an important tool in risk management. It is useful to demonstrate that industry is complying with restrictions government may have placed on their operation and that the environment is remaining in the desired state.

From a science point of view it can go beyond that. When both compliance and performance measures are taken together (Represented by the compliance and performance measuring lines linking monitoring and the state of knowledge boxes in figure 3) it can demonstrate that the prediction of the environmental changes is accurate and contribute to improving the precision of the prediction and it can or show that fluctuations in the environment are not affected by the developments or activities that have been allowed to proceed. It can also help detect previously undetected problems in past considerations of an ecosystems total carrying capacity.

Through this constant testing of the relationship between developments or activities and environmental change it can also identify when policies or objectives may need reconsideration ((Represented by the dashed line linking the state of knowledge and the ecosystem planning and objectives boxes in figure 3).

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