Bowtie analysis of avoidance and mitigation measures within the legislative and policy context of the Fisheries Protection Program

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Cormier, R.J, F. Savoie, C. Godin, and G. Robichaud. 2015. Bowtie analysis of avoidance and mitigation measures within the legislative and policy context of the Fisheries Protection Program. Can. Manuscr. Rep. Fish. Aquat. Sci. 3093: v + 29 p.

The *Fisheries Protection and Pollution Prevention* provisions of the *Fisheries Act*, introduced in November 2013, set the legislative requirements for managing threats to provide for the sustainability and ongoing productivity of commercial, recreational and aboriginal fisheries. The Fisheries Protection Policy Statement also introduces definitions for avoidance, mitigation and offsetting measures with a central focus on preventing serious harm to fish. Based on the suite of ISO 31000 risk management standards, this manuscript describes the use of the Bowtie analysis as a practical framework to implement a risk-based approach to the development of standards and guidelines. It integrates the fisheries protection provisions of the *Fisheries Act* and the Fisheries Protection Policy Statement within the risk management process of ISO 31000 to conduct the Bowtie analysis building upon Canadian risk management approaches.

RÉSUMÉ

Cormier, R.J, F Savoie, C. Godin, and G. Robichaud. 2015. Bowtie analysis of avoidance and mitigation measures within the legislative and policy context of the Fisheries Protection Program. Can. Manuscr. Rep. Fish. Aquat. Sci. 3093: v + 29 p.

Les nouvelles dispositions relatives pour *La protection des pêches et la prévention de la pollution* de la *Loi sur les pêches*, mises en place en novembre 2013, ont établi les exigences prévues par la loi en ce qui a trait à la gestion des menaces afin d’assurer la durabilité et la productivité continue des pêches commerciale, récréative et autochtone. L’énoncé de politique sur la protection des pêches introduit des nouvelles définitions pour les mesures d’évitement, d’atténuation et de compensation axées sur la prévention des dommages sérieux aux poisson. En se fondant sur l’ensemble des normes ISO 31000 en matière de gestion du risque, ce manuscrit explique l’utilisation de la méthode d’analyse du nœud papillon (Bowtie analysis), qui sert de cadre pratique afin de mettre en œuvre une approche basée sur le risque pour le développement de normes et de lignes directrices. Il fait l’intégration des dispositions relatives à la protection des pêches de la *Loi sur les pêches* et l’énoncé de politique sur la protection des pêches dans un processus de gestion du risque de la norme ISO 31000 et dans l’analyse du nœud papillon tenant compte des approches de gestion du risque canadienne.

INTRODUCTION

The new *Fisheries Protection and Pollution Prevention provisions* (sections *34* to *43*) of the *Fisheries Act* (Canada 2015), came into force in November 2013 and set the legislative requirements for managing threats to the sustainability and ongoing productivity of commercial, recreational and aboriginal fisheries (CRA fisheries) by avoiding, mitigating and offsetting impacts to fish and fish habitat resulting from works, undertakings and activities. Avoiding harm to fish is the first principles highlighted in the Fisheries Protection Policy Statement (FPPS) (DFO 2013a) that should be underpinned by science using a precautionary risk-based approach to decision-making (Canada 2003) as well as a standards-based approach to the management of risk within an ecosystem context. This manuscript deals with the fisheries protection provisions of the *Fisheries Act* as the pollution provisions are within the jurisdiction of Environment Canada.

In the former habitat management program, the assessment approach was based on an analysis of the pathways of effects (PoE) linking construction and operation activities to potential impacts to fish and fish habitats (DFO 2006a). Mitigation measures were then identified along the pathways between the activity and the effect as a means to reduce impacts to fish and fish habitat. This approach was used extensively to assess project proposals as well as develop guidelines for specific works or undertakings (DFO 2010). Over the years, the PoE approach was expanded recovery potential assessments of species at risk and integrated oceans and coastal management planning (Coker et al. 2010, DFO 2014c, DFO 2015a). However, the pathways of effect approach of identifying mitigation measures needs to consider the new definitions for avoidance and mitigation measures. In the new policy, avoidance measures completely prevent works, undertakings or activities from causing serious harm to fish while mitigation measures reduce the spatial scale, duration and intensity of serious harm to fish that cannot be avoided. It should be noted that offsetting measures designed to counterbalance unavoidable harm to fish (DFO 2013a) is not discussed in this document given that the focus of the discussion is on the Bowtie analysis as a technique to develop avoidance and mitigation standard and guidelines.

Risk management frameworks and processes are used in a wide range of contexts ranging from business, the environment and regulatory frameworks (Purdy 2010, GRM 2012, Cormier et al. 2013, Cormier et al. 2015; DFO 2015b). Since 2001, risk management approaches have been used in policy and programs of the Government of Canada (Canada 2010, Canada 2012). The Canadian framework is based on the core principles and approaches found in international and national standards including the International Organization for Standardization risk management standard (ISO 31000) (ISO 2009a, ISO 2009b). The Canadian policy definition for risk is based on ISO 31000 which is defined as “the effect of uncertainty on objectives”. Although there are many risk management frameworks available mostly for financial approaches (RIMS 2011), ISO 31000 is applicable to any risk and organizational policy context providing a systematic process for the setting of a course of action to reduce the uncertainties that could undermine achieving policy objectives (ISO 2009a). ISO 31000 integrates the risk assessment functions of identifying, analyzing and evaluating risks within the risk management process to inform decisions as to potential causes, events, and consequences that could affect policy objectives. In addition to being informed by the descriptive nature of risk assessments, decision-making in a risk management process is focused on an analysis of the “inherent risk” of existing or non-existing management measures in relation to the “residual risks” of enhanced or new management measures being considered. Instead of only focusing on the severity of the consequences and impacts, the attention is shifted towards the identification and implementation of management measures to control or treat the risks as is stipulated in ISO 31000. The expectations are that decisions regarding enhanced or new management measures should be effective at reducing the risks of not achieving a policy objective in addition to being feasible for operational implementation (Canada 2012). Risk management processes such as ISO 31000 has the potential to provide a standardized set of tools to implement a risk management approach for the Fisheries Protection Program (FPP). In addition to the risk management process, the ISO 31000 suite of standards also include the IEC/ISO 31010 (IEC/ISO 2009) risk assessment techniques in support of the risk assessment function of ISO 31000. Some of the techniques are familiar to ecosystem and environmental assessments such as the Delphi approach, environmental risk assessment, scenario analysis, cause and effect analysis, cost and benefit analysis to mention a few. Most of the assessment techniques are considered applicable to identify risks and analyse the nature and level of risks. However, it is the Bowtie analysis and the Layers of protection analysis of IEC/ISO 31010 that are listed as controls assessment techniques to assess the effectiveness of a system of management control and evaluate their implementation mechanisms in relation to achieving a policy objective. Adapted to the development of standards and guidelines, the Bowtie analysis is particularly useful in analysing avoidance and mitigation measures in relation to a policy objective within a pathways of effects framework similar to the approach used in the Fisheries Protection Program (FPP).

This manuscript demonstrates the application of the risk management process of ISO 31000 (ISO 2009a, ISO 2009b) as a potential process to implement a risk-based approach for FPP. In addition, the manuscript also demonstrates the use of the Bowtie analysis (IEC/ISO 2009) as a potential technique to develop and identify avoidance and mitigation measures building upon the pathways of effect approach within the legislative and policy context of FPP. The manuscript also incorporates key science advisory reports (SAR) that were produced for FPP.

PURPOSE

The purpose of this document is to demonstrate the use of the Bowtie analysis of IEC/ISO 31010 as a technique to analyse avoidance and mitigation measures in relation to serious harm to fish. Based on the legislative and policy context of FPP and scientific advisory reports, the manuscript provides a template that could support the development of standards and guidelines as well as promote sound decision-making and employ a standards-based approach. The template integrates the geographical scale and duration of a comprehensive roster of impacts in relation to the availability and condition of nearby fish habitat and relevant fish as a result of direct injury or reduced habitat functions. The template also integrates avoidance and mitigation measures along the pathways of effects with serious harm to fish as the central event to avoid. The manuscript demonstrates the use of the risk management process of ISO 31000 as an approach to evaluate existing management measures and identify the operational boundaries for standards and guidelines using a risk-based approach. This document does not delve into the complexity of estimating risk, likelihood and magnitudes for each cause, consequence and management measure as these depend on the specificities of a project, ecosystem vulnerabilities and scientific knowledge.

RISK MANAGEMENT STANDARD

The ISO 31000 risk management standard is comprised of a suite of documents that includes principles and guidelines (ISO 2009a), vocabulary and definitions (ISO 2009b) as well as IEC/ISO 31010 risk assessment techniques (IEC/ISO 2009). The suite of tools is designed for the management of any form of risk in a systematic and transparent manner within a given scope, policy objective, and continuous improvement approach. The intent of the standard is to provide managers with a framework and process to ensure that risks are managed effectively and efficiently across a given organization as well as coherently within a given policy context. Although the standard provides a set of guidance and tools to conduct a risk management process, the information, criteria and inputs to manage the process and the criteria to assess and evaluate risks must be based on policy objectives. In a science-based regulatory context, risks are identified within the scope of a particular legislation and within the context of its policies (GRM 2012). The level and the severity of risk are analysed and evaluated from standardized criteria derived from policy and underpinned by scientific and technical documentation and advice. The results of which are then used to inform management decisions regarding the need to take or not to take a course of action through the implementation of management measures designed to reduce the risks of not achieving legislative objectives. Scientific and technical risk assessments are performed within the risk management framework and process of ISO 31000. It is the legislation and policy that drives the assessment function to ensure that the science is brought to bear and is relevant to the questions and concerns of management and the stakeholders involved. Informed by the assessment, management and stakeholders can then evaluate the risks to determine which risk is unacceptable and set management priorities as to how a risk should be managed or treated as defined in ISO 31000. The standardized definitions and vocabulary of ISO 31000 provides a valuable benchmark to integrate the various scientific and technical elements of risk and the risk perceptions of management and stakeholders. ISO 31000 not only provides principles, frameworks and processes, the entire suite of documents also provides valuable definitions and assessment techniques to undertake any risk management process. The standards documents are part and parcel of the necessary documentation needed for managers and stakeholders involved in such processes eliminating the need to develop risk management process from scratch.

RISK MANAGEMENT PROCESS

It is the risk management process of the standard that provides for a practical implementation of a risk-based approach. The standard integrates the risk assessment function within the established policy context, supported by communication and consultation as well as monitoring and review procedures. The context for the process is established at the beginning of the process to set the scope, objectives, procedures, criteria for decision-making, and information needs as well as governance procedures and external stakeholders (Cormier et al. 2015). The risk assessment starts with the risk identification which is the process of describing the sources of risk, the undesired events that could happen in the presence of the sources of risk, the causes of that events and the potential consequences of that event. Within a regulatory setting, these are derived from the scope of the legislation and the objectives of the policies. Scientific knowledge of causal relationships of the pathways of risk and the potential consequences of not achieving policy objectives provides objective evidence to validate the perceptions of risk held by management and stakeholders. Subsequently, risk analysis is the process to determine the level of risk in terms of likelihood of a given event occurring and the magnitude of the consequences. In ISO 31000, the analysis of the risks also includes an analysis of the existing or non-existing management controls. The last step of the risk assessment is risk evaluation which is the process of comparing the results of the risk analysis with policy risk criteria to determine whether the inherent risks of the outcomes of existing or non-existing management controls are acceptable or not. This is the management decision point of the process where scientific and technical experts hand over their results to management and stakeholders for consideration and decision-making. Depending on the acceptability of the risk, the decision is then made as to how best reduce the risks of not achieving a policy objective by treating it. Depending on the decisions made, risk treatment follows suit with the development and implementation of management measures to reduce the risks to an acceptable residual level in order to achieve policy objectives within the scope of legislative requirements. Classical ecosystem risk assessment is mostly concerned with adequately describing potential impacts as a means to inform management and stakeholders. Risk management is mostly concerned with implementing management strategies and measures that will lead to outcomes that are in line with policy objectives within the scope of legislation.

As is typical of a risk management process, the legislation and policy play a greater role in establishing the context and in risk evaluation where decisions are made to determine the need for a course of action. Science advice and reports play a greater role to identify and analyse the risks in support of the risk assessment. Legislation, policies and scientific advice also provide the basis for definitions and criteria to guide the process and to ensure coherence and consistency in the interpretation and use of information. In FPP, the context of the risk management process is guided by the scope of the *Fisheries Act* (Canada 2015) and the context of the Fisheries Protection Policy Statement (DFO 2013a). Following the risk management process of ISO 31000, various elements of the legislation, policies and scientific advice are used as inputs to establish the context, to assess the risks and evaluate the management options for the measures. The Bowtie analysis structures and links the legislation, policies and science advice to support the analysis and inform decisions as to the development needs for standards and guidelines. Figure 1 links the risk management process of ISO 31000 to the legislation, policy and scientific advice elements as relevant inputs to support the functions of each step of the process.

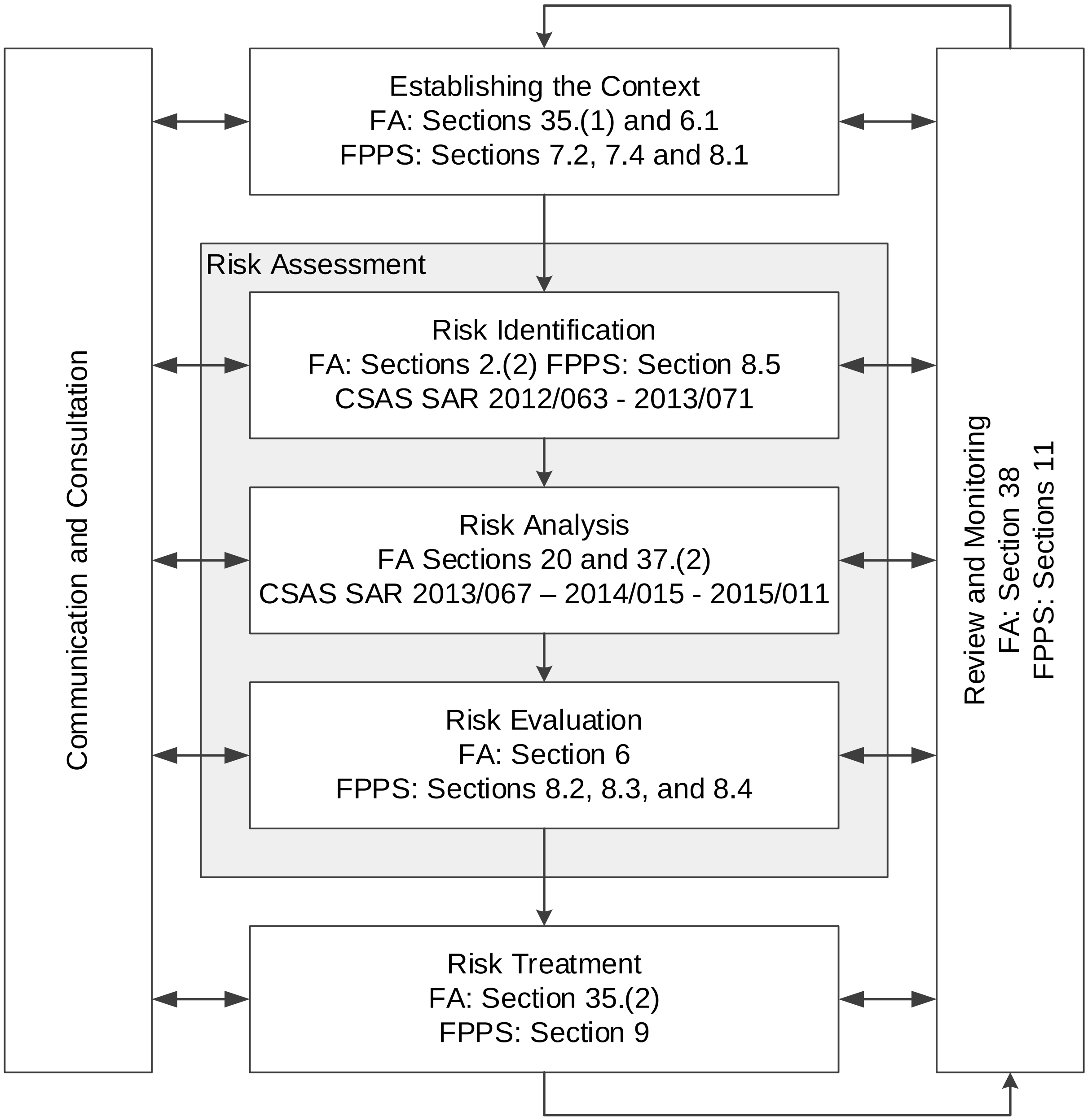

Figure 1. FPP Legislation, policy and scientific inputs to ISO 31000 risk management process (FA: *Fisheries Act*, FPPS: Fisheries Protection Policy Statement, SAR: Science advisory reports).

BOWTIE ANALYSIS

The Bowtie analysis originated from the petrochemical industries as a health and safety assessment technique in the early 1980’s (Lewis and Smith 2010, Shahriar et al. 2012, Van Thienen et al. 2014). It was later adopted as an industry standard to manage the hazards related to catastrophic events in the oil and gas industry and to provide a systematic approach of assessing and assuring control over these hazards. Since, the Bowtie analysis has been adopted by a broad range of industry sectors including aviation, mining, maritime transportation, chemical processing and health care (Vanghen et al. 2014).

With more than 30 risk assessment tools listed in IEC/ISO 31010, the Bowtie analysis and Layers of protection analysis are the two techniques listed for the assessment of a given system of management control. In a regulatory context, the system would include legislation, policies, management strategies and implemented management measures. While LOPA deals with unique pairs of causal relationships, the Bowtie analysis integrates multiple causes in relation to a central event that can subsequently lead to multiple consequences (Figure 2) (Gowland 2006).

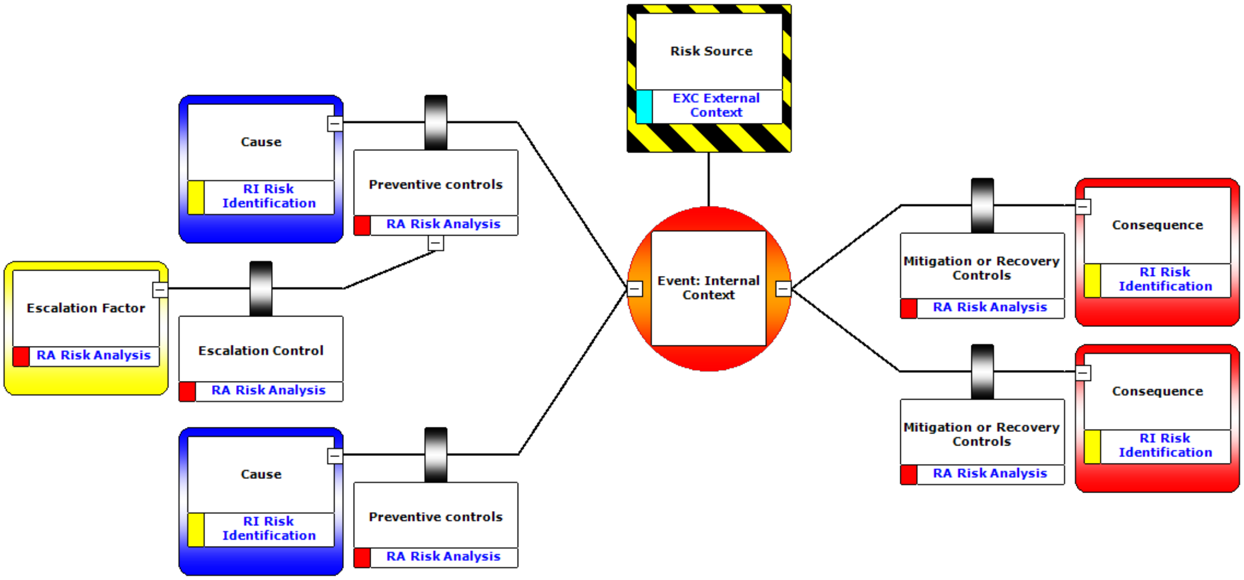

Figure 2. Bowtie analysis diagram alignment with ISO 31000 risk management process using BowTieXP (CGE 2015).

Adapted to an environmental management policy context such as FPP, this technique lends itself well to the analysis of complex pathways of effects and in the development of a management systems of avoidance and mitigation measures (ICES 2014, ICES 2015). A Bowtie analysis clearly defines the relationship and functions of prevention controls versus mitigation and recovery controls. Prevention controls are implemented to reduce the likelihood of an event from occurring by controlling the causes (left side of the Bowtie) while mitigation and recovery controls are implemented to reduce the likelihood and magnitude of the consequences of that event (right side of the Bowtie). The system of management control (e.g. prevention, mitigation and recovery controls) can only reduce the risks given that risks can only be eliminated by removing the source of the risk. In more advance analysis, escalation factors can also be added. An escalation factor is an external factor that can undermine the effectiveness or the implementation of a given control. In an environmental context, the effects of climate change or ecosystem shifts are examples of such factors that can undermine the effectiveness of given management measure. Additional escalation controls can then be added to prevent the factor from undermining a prevention, mitigation or recovery controls. In Figure 2, an escalation factor is shown for a preventive control as an example only. The Bowtie analysis is used to identify gaps, redundancies or duplication in existing prevention, mitigation and recovery controls. It diagrammatically depicts causal relationships between the source of the risk, causes, event and consequences. A Bowtie that has a predominant number of preventive controls in comparison to the number of mitigation controls is indicative of a preventive management strategy. On the other hand, a Bowtie which has a predominant number of mitigation controls is indicative of a reactive management strategy. This insight can play an important role for the development of standards and guidelines given the preference for avoidance of serious harm to fish of the Fisheries Protection Policy Statement.

The Bowtie analysis supports multiple risk management functions. Within a legislative and policy context:

- It provides a structure for the systematic identification of the source of a risk as specified in legislation, the potential undesired event that would undermine policy objectives as well as the causes that can trigger the event and the consequences of the event.
- It facilitates the identification and analysis of the system of management control necessary to prevent the causes from allowing an event to occur and controls necessary to mitigate or recover from the consequences that may result from such an event.
- It informs and educates management and stakeholders as to elements of the system of management control and the management measures needed to provide assurance that policy objectives will be achieved.
- It enhances communication and awareness of the risks and their management.
- It provides the basis for developing monitoring programs and review procedures to evaluate the effectiveness of the controls and the performance of the system of management control in achieving policy objectives.

In this manuscript, the Bowtie analysis follows the risk management process of ISO 31000. The “Risk Source” and the “Event” (Figure 2) are identified from legislation and policy as part of the function of “Establishing the Context” (Figure 1). To fulfill the requirements for “Communication and Consultation”, the Bowtie analysis would also identify the stakeholders contributing to the “Causes”, the stakeholders that have an interest in avoiding the “Event”, the stakeholders that can be potentially affected by the “Consequences”, and the stakeholders that have to implement the management “Controls”. The “Cause” to “Event” pathways and the “Event” to “Consequences” pathways are also identified from legislation and policy in “Risk Identification” informed by scientific and technical knowledge and advice. In “Risk Analysis”, the “Causes” and “Consequences” are expanded to reflect localized environmental vulnerabilities and includes the analysis of the effectiveness of “Prevention”, “Mitigation” and “Recovery” controls used to reduce the vulnerabilities and ultimately the risks of not achieving the objectives. Based on the spatial scale, duration and intensity of the “Causes”, the primary output of the “Risk Analysis” is the likelihood of the “Event” and the magnitude of the “Consequences” inherent to the existing controls compared to the residuals of any additional controls being considered. In “Risk Evaluation”, risk matrices are used to categorize the severity of the potential outcomes of existing and additional controls. Thus, “Risk Evaluation” and the “Risk Matrix” is used to compare the “inherent risks” of the existing controls and the “residual risks” of the additional controls to inform decisions related to a given course of action to be taken. In “Risk Treatment”, the Bowtie becomes the risk register of the implemented controls. In addition, accountabilities and operational activities are assigned for each control. Monitoring activities and conformity assessments are then added for each control in preparation for future reviews as stipulated in “Review and Monitoring”.

Bowtie diagrams presented in this manuscript were produced with the software BowTieXP (CGE 2015) which is structurally based on IEC/ISO 31010. The software has additional functionality that is also used where appropriate to demonstrate the use of the Bowtie analysis.

FPP BOWTIE ANALYSIS

The Bowtie analysis proposed in this manuscript uses the same review and decision-making process of the policy statement (Box 1) for projects to determine the conditions for when a standard or guideline can be used. The intent of standards and guidelines is to provide a set of requirements for a group or class of works, undertakings or activities where similar management measures are most often required. In the event that the conditions are not adequate, a regulatory review would be needed. In addition to setting avoidance and mitigation measures considered adequate to avoid harm to fish, the Bowtie analysis could also identify the types of causes and consequences that cannot be addressed by a standard or a guideline that subsequently form the basis for operational boundary conditions (Figure 2). From an environmental risk management perspective, the concept of low risk is a reflection of the reliability of the system of management control (measures and conditions) at achieving a policy objective combined with inherent vulnerabilities of the receiving environment where the management controls are implemented.

Box 1. Fisheries Protection Policy Statement Section 8.5 Review and Decision-making Process.

When considering whether a project is likely to cause serious harm to fish and requires an authorization, proponents should identify:

1. Impacts to fish and fish habitat caused by the project: For example, have all potential impacts been considered? Pathways of Effects diagrams, available on the Department's website, may help proponents determine what kinds of impacts can be expected from typical developments.
2. The expected duration of impacts: For example, is the duration short enough that it does not diminish the ability of fish to carry out one or more of its life processes? It is important to note that, for many projects, the duration of impact will be longer than the duration of the work taking place in or near the water.
3. The geographic scale of impacts: For example, is the scale small enough that the disturbance will not displace fish that would otherwise be occupying the habitat?
4. The availability and condition of nearby fish habitat: Is the habitat that is being altered or destroyed the only habitat of its type and quality in the area of the project?
5. The impact on the relevant fish: For example, are the fish that are affected by the proposed project likely to experience increased mortality rates, increased stress and reduced fitness as a result of direct injury or reduced habitat function such that a localized effect on a fish population or stock is possible?
6. Proposed avoidance and mitigation measures: Will measures to avoid and mitigate serious harm to fish be applied such that all serious harm to fish is avoided? If so, an authorization is not required. If serious harm to fish remains after all avoidance and mitigation measures have been applied, an authorization may be required. Proponents should apply for an authorization following the Applications for Authorization under Paragraph 35(2)(b) of the Fisheries Act Regulations.

A Bowtie template used for the development of a standard or a guideline should be based on a normalized roster of causes and consequences within the context of the event that should be avoided and mitigated. Standardized templates of causes, event, and consequences prevent inadvertent omissions or oversights when conducting the Bowtie analysis and ensures that relevant avoidance and mitigation measures have been considered within the scope of the policy for a given standard or guideline being developed. It also provides assurance that standards and guidelines are being developed consistently and that these are coherent in terms of legislation and policy requirements and definitions. A roster of causes helps answer the questions 1 and 2 of the review and decision-making process (Box 1), while a roster of consequences can help answer the questions 3, 4, and 5. The Bowtie analysis identifies conditions, avoidance and mitigation measures needed to answer question 6 of the review and decision-making process (Box 1). It is the combination of questions 1 to 6 that guides the Bowtie analysis in order to characterize the risks that will be managed and the risks that cannot be managed by a given standard or guideline. This is considered as the operational boundaries of the system of management control. These are discussed further in the following sections providing suggestions as to how such rosters and conditions could be developed within a Bowtie analysis approach for standards and guidelines.

Figure 1 shows the various legislative, policy and science inputs in relation to the risk management process of ISO 31000. Figure 3 shows these inputs in terms of the generic Bowtie structure of Figure 2 and includes the risk source, causes, event, consequences and management measures as defined by FPP legislation, policy and scientific advisory reports. Based on the ISO 31000 risk management process, the following sections demonstrate how the legislative, policy and scientific input are used to build a generic Bowtie template for the development of standards and guidelines as shown in Figure 3. The operational boundaries of the template in relation to the FPP Review and Decision-making Process (Box 1) is also discussed within the context of the Bowtie analysis.

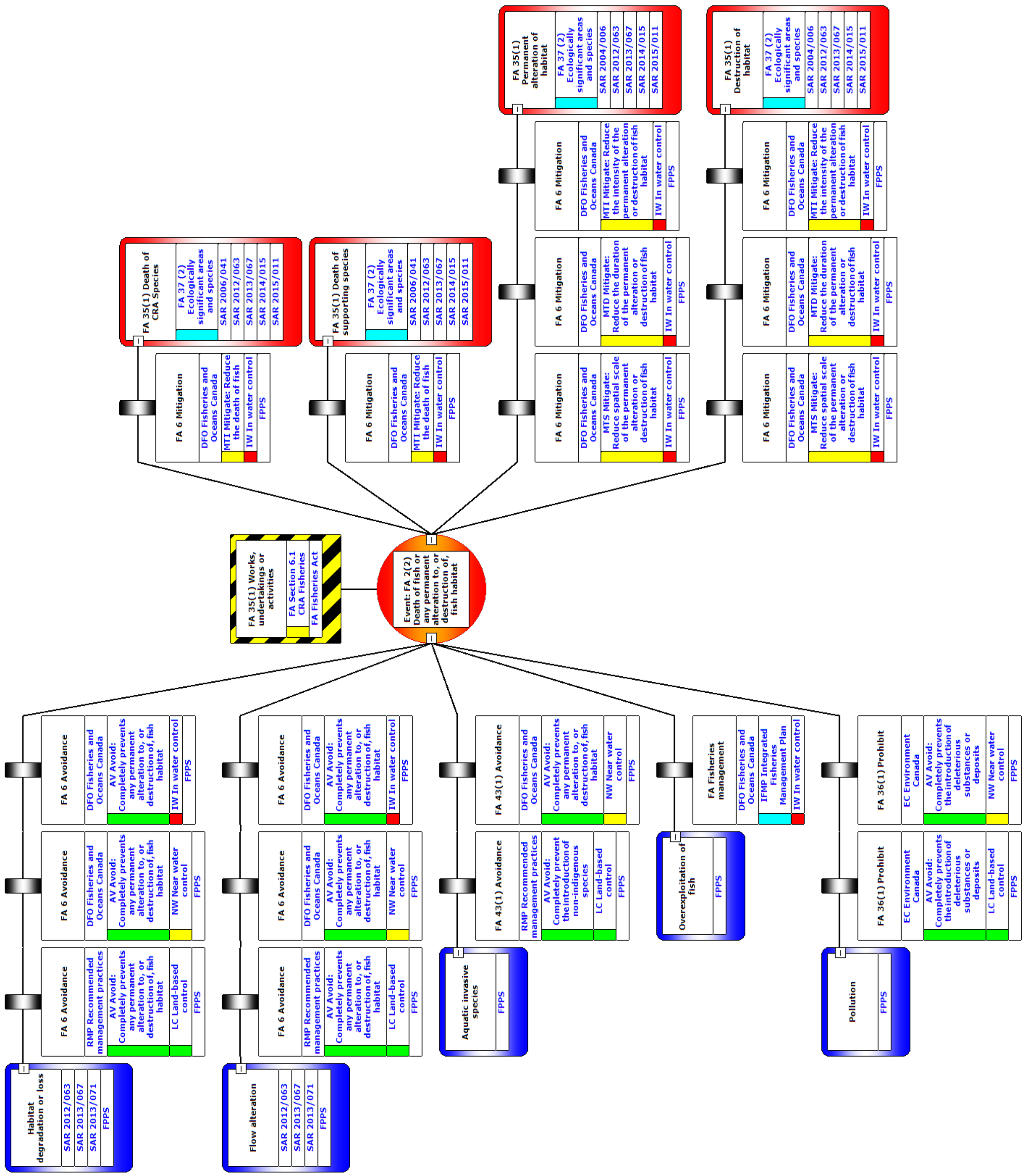

Figure 3. Bowtie template of FPP Legislation, policies and science advisory reports.

Establishing the risk management context

Based on ISO 31000, the risk management process is a systematic approach to understand the risks in order to implement, where needed, risk management strategies and practices to reduce the effect of uncertainty on achieving policy objectives. Establishing the risk management context is the first step in setting the stage for the process. It includes defining the scope, policy objectives, responsibilities for the process, and accountabilities for decisions. In a science-based management context, it also includes defining assessment methodologies, data and studies needed to support the process as well as performance and effectiveness indicators for the process. However, it is the risk criteria and definitions that play the most important role in decision-making as it defines the nature of the risks, the relevant causes and consequences, the range of likelihoods and severities of acceptable and unacceptable management outcomes as reflected in policy.

In a Bowtie template for FPP, the legislative and policy context is expressed in terms of Subsections 2(2) and 35(1) of the *Fisheries Act*. Given the prohibition Section 35(1) of the *Fisheries Act,* "works, undertakings or activities" are identified as the source of the risk that can cause serious harm to fish as defined in Subsection 2(2) of the *Fisheries Act*. The Bowtie knot (Figure 4) also highlights the authority being under the *Fisheries Act* and that the ultimate outcome of the Bowtie is to provide for the sustainability and ongoing productivity of CRA Fisheries as described in Subsection 6.1 of the *Fisheries Act*.

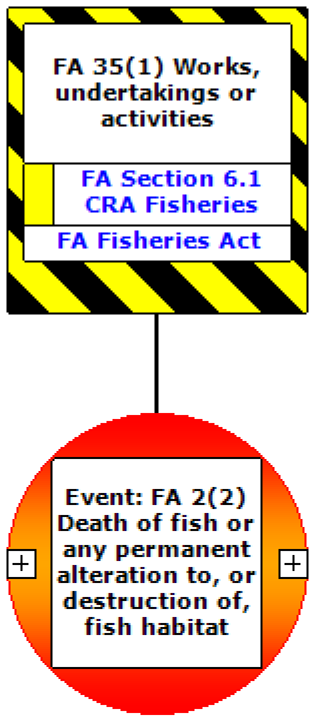

Figure 4. Risk Management Context based on a Bowtie analysis of FPP legislation and policy.

Having established the central policy focus for the Bowtie, risks are subsequently identified in relation to the causes of serious harm attributed to changes introduced by works, undertakings or activities and the consequences in terms of the impacts to CRA species, supporting species and habitat types as a result of serious harm to fish. The risk statement emerging from this could be as follows:

> *"there is a risk that works, undertakings or activities introduce changes to the state of species and habitats that may have an effect on the productivity of CRA Fisheries as a consequence of the death of fish or any permanent alteration to, or destruction of, fish habitat".*

Definition of Risk and Uncertainty

ISO 31000 defines risk as the "effect of uncertainty on objectives". In risk management, uncertainty considerations are broader than what is typically understood to be scientific uncertainty (Table 1). Scientific uncertainties play a significant role in risk identification and risk analysis while operational and management uncertainties play a role in risk evaluation and risk treatment. The development of standards and guidelines is mostly concerned with operational and management uncertainty. In the Bowtie analysis, the operational uncertainties are addressed by the effectiveness and feasibility of the avoidance and mitigation measures while the management uncertainties are addressed by the performance of the entire system of management control that includes the operational boundaries conditions for a given standard or guideline. To answer question 6 of the review and decision-making process (Box 1), the standard or the guideline should reduce the operational and management uncertainties to a level as low as reasonably practicable (Rice et al. 2005). Although the Bowtie analysis maps the controls and conditions, effectiveness, feasibility and performance require additional qualitative and quantitative analysis and studies.

Table 1. Summary of uncertainties in FPP implementation SAR 2014/015 (DFO 2014d).

Uncertainty	Description
Scientific	• Uncertainty about impact prediction • Uncertainty about the future states of nature • Uncertainty about the effectiveness of mitigation and offsetting of impacts
Operational	• Uncertainty about project design and implementation • Uncertainty about the feasibility of avoidance, mitigation and offsetting measures
Management	• Lack of clear or multiple incompatible objectives • Communication error between management, proponent, science, and the public • Lack of coordination between management jurisdictions/authorities • Enforceability of management requirements • Lack of monitoring and adaptive management to reduce future uncertainty

Risk Identification

Based on ISO 31000, risk identification is primarily a process of describing the causes of the undesired event, based on the source of the risk, and the potential consequences resulting from an event if it occurs. Although the *Fisheries Act* subsection *35(1)* is used to identify the sources of risk and Subsection *2(2)* is used to define the event to avoid (Figure 4), a comprehensive list of causes and consequences are needed for the Bowtie analysis template to avoid inadvertent omissions and oversights as mentioned earlier. Irrelevant causes and consequences can be discounted later in risk analysis or new ones can be added where needed in relation to the specific standard or guideline being developed. The roster of causes and consequences is a starting point to answer question 1 of the review and decision-making process (Box 1).

From the risk statement enunciated in "Establishing the Context", a risk identification questions for causes and consequences can be written as follows:

- ***Causes****: What are the changes to the state of species and habitats that can be introduced by works, undertakings or activities that can cause the death of fish or any permanent alteration to, or destruction of, fish habitat?*
- ***Consequences****: What are the consequences of the death of fish or any permanent alteration to, or destruction of, fish habitat that can potentially have an effect on the productivity of CRA Fisheries?*

In a Bowtie analysis, serious harm to fish is likely to occur if no avoidance measures are implemented to control causes. Figure 5 shows the causes of serious harm to fish based on the threats identified in the Fisheries Protection Policy Statement. The policy statement lists habitat degradation or loss, flow alteration, aquatic invasive species, overexploitation of fish, and pollution as key threats to the sustainability and ongoing productivity of CRA Fisheries. Given that aquatic invasive species, overexploitation of fish and pollution are outside this Bowtie analysis, there are, however, many types of habitat degradation or loss and flow alteration that can be introduced by works, undertakings and activities.

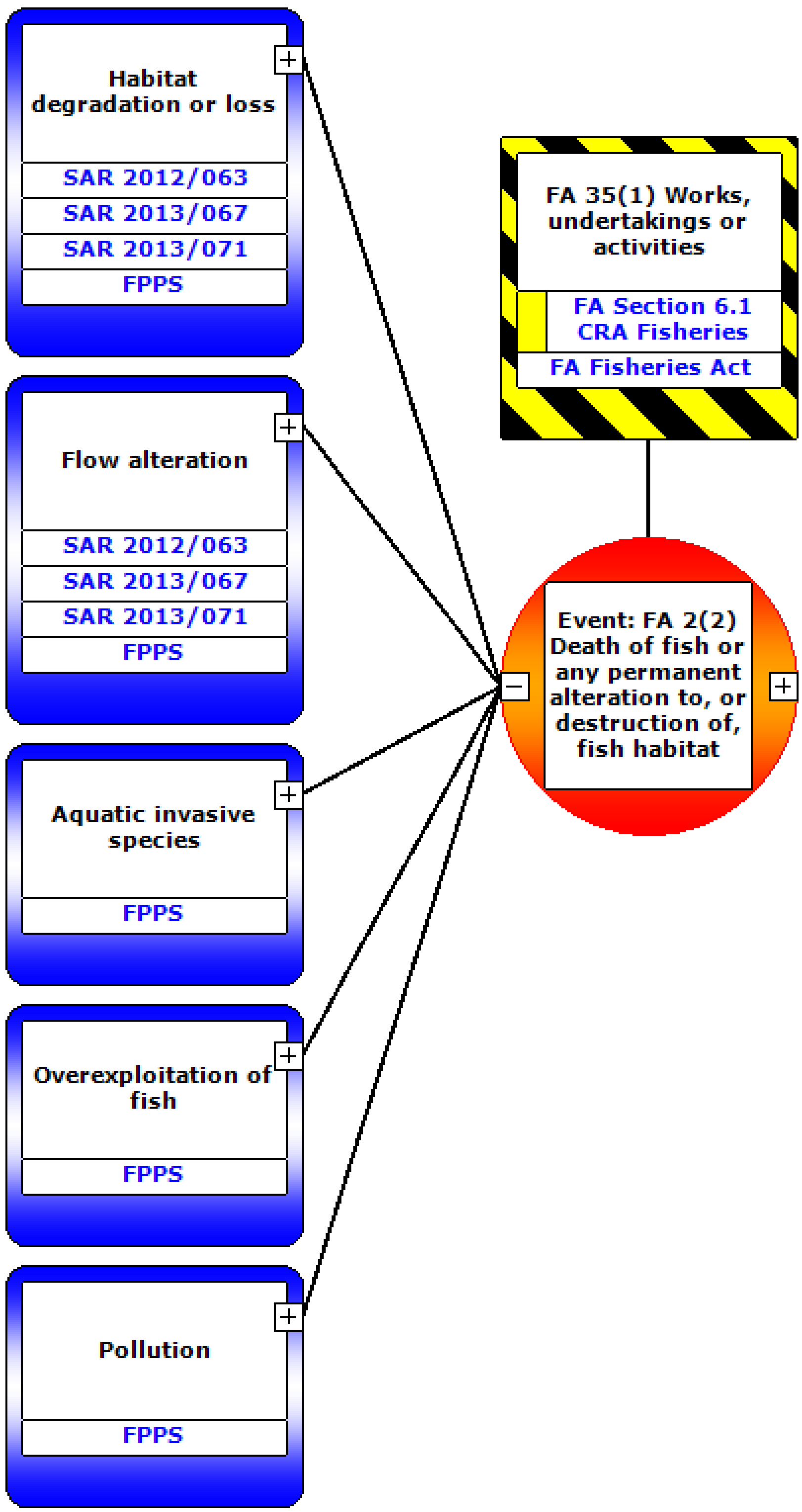

Figure 5. Causes of serious harm to fish based on the Fisheries Protection Policy Statement.

SAR 2012/063 (DFO 2013b) and SAR 2013/071 (DFO 2014a) provide the basis to create a roster of the causes of serious harm to fish resulting from works, undertakings or activities. Specifically, SAR 2013/067

(DFO 2014b) provides a comprehensive list of causes of serious harm to fish based on the pathways of effect of changes to the state of affected species or habitats. Thirteen PoE endpoints are described as follows:

1. **Direct mortality**: Direct mortality refers to the killing of fish, at any life stage, by any human induced mechanism other than fishing. Typically this can occur through rapid increases in pressure, crushing, entrainment/impingement, stranding and/or lethal changes in oxygen, temperature, sediments or nutrient enrichment.
2. **Decreasing structure and cover**: A change in structural heterogeneity results from projects that reduce habitat complexity (e.g., dredging, channel realignment, shoreline stabilization, riparian clearing), or less frequently from projects that increase structural habitat complexity (e.g., habitat restoration via addition of boulders, woody debris, etc.).
3. **Decreasing vegetation**: A change in structural heterogeneity results from projects that reduce habitat complexity (e.g., dredging, channel realignment, shoreline stabilization, riparian clearing), or less frequently from projects that increase structural habitat complexity (e.g., habitat restoration via addition of boulders, woody debris, etc.).
4. **Decreasing access to habitat**: Physical barrier or a reduction in accessibility to habitats due to changes in hydraulic conditions or other factors. Impacts linked to change in access to habitat include infilling/footprint, changes in flows/water levels and permanent watercourse alteration
5. **Decrease in dissolved oxygen**: Industrial or development activities can directly affect dissolved gases (e.g., bubblers, turbulent super-saturation). Indirect effects on dissolved oxygen content in water include modification of water temperatures that in turn affects oxygen saturation levels or air exchange (e.g., thermal effluents, drawdown, stratification changes, ice dynamics, hydrodynamic changes, salinity changes, or sedimentation). Some activities increase biological or chemical oxygen demand in water (e.g., excessive nutrients, contamination, algal blooms, aquatic vegetation changes, suspended solids), which may reduce oxygen available for fish.
6. **Decreasing food supply**: Activities leading to change in food supply include riparian and aquatic vegetation removal, water flow alteration, dredging, or the placement of structure in water (e.g., aquaculture facilities).
7. **Decrease or increase in ambient temperature**: Industrial or development activities can directly affect water temperatures through heated thermal effluents, changes to groundwater exchange, or dams discharging hypo limnetic water. Projects that affect light penetration or clarity affect water temperature (e.g., riparian planting or removal, aquatic vegetation removal or addition, shading structures, suspended sediments, algal blooms, or contaminants). Projects that affect water depth or hydrodynamics also affect water temperature (e.g., filling/dumping, dredging, water drawdown, impoundment or release, shoreline modifications, channelization, and dams or dykes).
8. **Decreasing wetted areas**: Loss of wetted area is a permanent loss in surface area (from wet to dry) of river, lake, estuary or coastal marine habitat. Loss of wetted area impacts fisheries productivity because it results in a reduction in the habitat available for occupancy and consequently may reduce the maximum sustainable population size (carrying capacity). Typical causes are any in-water project that results in a loss of wetted area, including infilling, i.e., the deposition of materials onto the bottom of any water body; placement of structures in water that create a footprint (e.g., footings for bridge); whole lake destruction (such as lake disposal of tailings from a mine); or, man-made barriers that prevent fish access to habitat (described under: "Change in Access to Habitat").
9. **Change in flow**: Changes in base flow can be defined in a very broad context but as a standalone endpoint it occurs with respect to alterations of ground water. Changes through this mechanism can reduce fisheries productivity by altering water temperature, oxygen levels and nutrient concentrations which can lead to a reduction in habitat quality. Base flow reductions can also lead to a loss of wetted area. The change in hydrodynamics by the placement of large structures in flowing water can lead to changes in sediment erosion and transport which will reduce both habitat quality (sediment concentration) and quantity (altered substrate composition).
10. **Increasing sediment concentration**: A change in sediment concentration can result from increases in either suspended sediment in the water column or fine material in the streambed. This endpoint appears in most of the current PoE from both land-based and in-water activities. It

is well documented that response of fish to suspended sediment is a function of sediment concentration and duration of exposure.

11. **Increasing nutrient concentration**: Activities leading to increased nutrient concentrations from point source and non-point source pollution; including removal of riparian or aquatic vegetation, row crop agriculture, organic debris management, livestock grazing, and industrial, agricultural and municipal wastewater management and habitat modification such as dredging.
12. **Increasing noise level**: Seismic surveys, pile driving, increased vessel traffic, mid- and low-frequency sonar equipment, underwater dredging and drilling activities, construction noise, land-based activities like excavation and drilling work.
13. **Increasing changes to magnetic field**: Underwater electric cables and generators from renewable energy sources such as offshore wind power, wave and tidal power, and in-river hydrokinetic turbines.

A Bowtie analysis would start with these endpoints as a roster of causes. From a technical perspective, there would be cause (blue box) for each endpoint. As mentioned at the beginning of risk identification, serious harm to fish will occur if relevant avoidance measures not are implemented between the changes introduced by works, undertakings or activities and the event being serious harm to fish as defined by Subsection 2(2) of the *Fisheries Act*. This approach is similar to cutting the lines of the pathways of effects.

The consequences of serious harm to fish is shown as the death of a CRA species, death of a supporting species, permanent alteration of habitat or destruction of habitat (Figure 6). The consequences are likely to occur if relevant mitigation measures are not implemented between the event (e.g. serious harm to fish) and the consequences. As with the causes, the consequences should also be a comprehensive list of species type and habitat types to avoid omissions and oversight.

Although Subsection 37(2) of the *Fisheries Act* requires that additional review be undertaken in the presence of ecologically significant areas, SAR 2004/006 and SAR 2006/041 (DFO 2004; DFO 2006b) provide a comprehensive set of ecosystem components and criteria to characterize ecologically significant areas (EBSA) and species (ESSCP) in a Bowtie analysis. Initially developed for marine areas within the context of an ecosystem approach to management under the *Oceans Act*, the criteria are based on ecological principles and call attention to areas and species of particularly high ecological and biological significance. The intent is that these areas and species require a "*greater-than-usual degree of risk aversion*" in setting management priorities where the outcome of perturbation would result in ecosystem wide changes. Two subsequent science advisory reports also advise that these concepts and criteria are applicable to other management contexts (DFO 2011) including freshwater ecosystems (DFO 2014e).

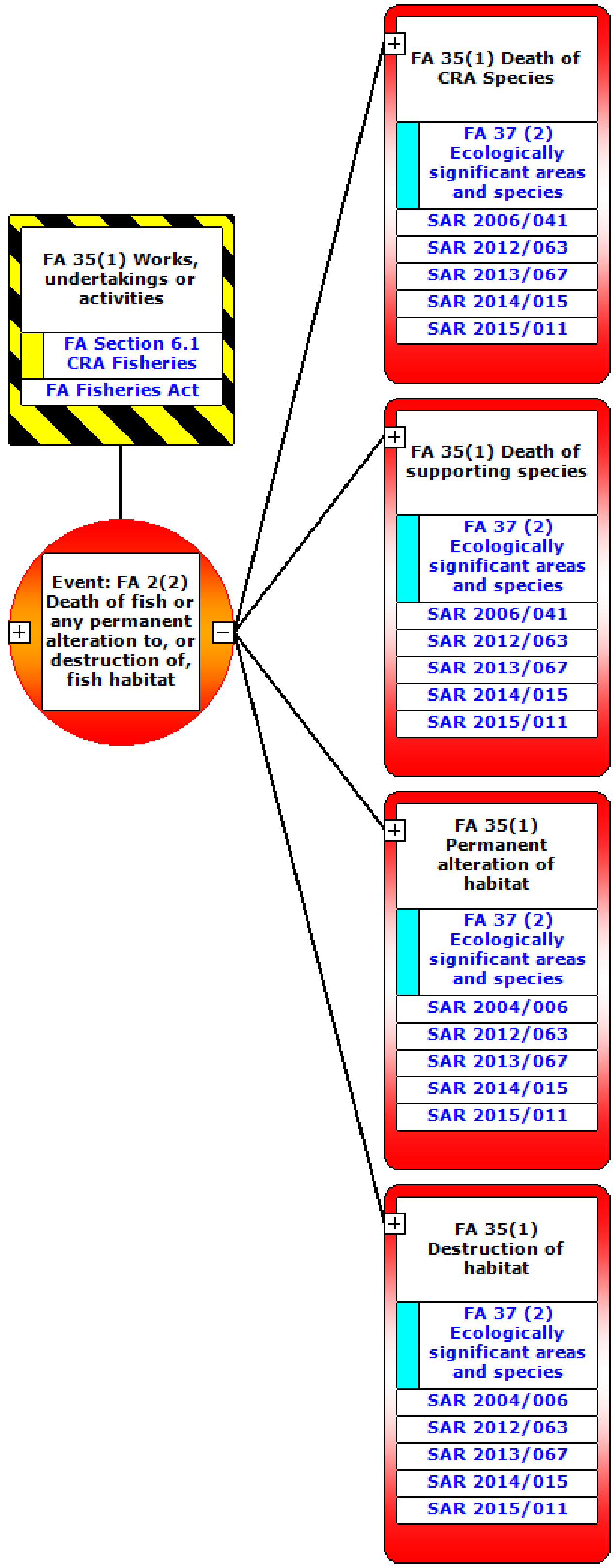

Figure 6. Consequences of serious harm to fish as described in the Fisheries Protection Policy Statement.

The EBSA and ESSCP criteria can be used to characterize vulnerabilities to localized effects on productivity based on the significance of the affected species and habitats within the footprint or vicinity of the project and their susceptibility to changes introduced by works, undertakings or activities. The EBSA and ESSCP criteria provide three main criteria:

- **Uniqueness:** Ranked from areas whose characteristics are unique, rare, distinct, and for which alternatives do not exist in comparison to areas whose characteristics are widespread with many areas which are similar in most important features.
- **Aggregation:** Ranked from areas where most individuals of a species are aggregated for some part the year; or most individuals use the area for some important function in their life history; or some structural feature; or ecological process occurs with exceptionally high density in comparison to areas where individuals of a species are widespread and even areas of comparatively high density do not contain a substantial portion of the total population; or individuals may congregate to perform a life-history function, but the area in which they perform the function varies substantially over time; or structural property or ecological process occurs in many alternative areas.
- **Fitness Consequences**: Ranked from areas where the life history activity or activities undertaken make a major contribution to the fitness of the population or species present compared to areas where the life history activity or activities undertaken make only marginal contributions to fitness.

With two additional criteria for consideration in the first three above:

- **Resilience:** from areas where the habitat structures or species are highly sensitive, easily perturbed, and slow to recover to areas where the habitat structures or species are robust, resistant to perturbation, or readily return to the pre- perturbation state.
- **Naturalness:** from areas which are pristine and characterised by native species to areas which are highly perturbed by anthropogenic activities and/or with high abundances of introduced or cultured species.

Existing marine EBSA that were identified within Oceans policy context may not be usable within an FPP context. The suggestion made here is that the EBSA and ESSCP criteria provide a comprehensive set of habitat and species characteristics that could be used to classify the importance or, rather the significance of local ecosystem features and functions. A Bowtie diagram would use the EBSA and ESSCP criteria to characterize serious harm to fish (Table 2).

Table 2. Ecologically significant component vulnerabilities to serious harm to fish.

Species and Habitats	**Vulnerability to Serious harm to fish (Subsection *2(2)* of the *Fisheries Act*)**
CRA species	Death of fish
Key trophic species	Death of fish that supports a CRA fishery
Structure providing species	Death of fish that supports a CRA fishery
Species properties at the community level	Death of fish that supports a CRA fishery
Feeding area	Permanent alteration or destruction of fish habitat
Migration area	Permanent alteration or destruction of fish habitat
Nursery or rearing areas	Permanent alteration or destruction of fish habitat
Spawning or breading areas	Permanent alteration or destruction of fish habitat
Physical oceanographic features	Permanent alteration or destruction of fish habitat

Similar to the causes, a Bowtie analysis would start with the 9 ecologically significant areas and species as the roster of consequences for the analysis. From a technical perspective, there would be a consequence (red box) for each of the 9 ecologically significant areas and species.

Standards and guidelines may be developed for multiple types of works, undertakings or activities. A comprehensive roster of causes and consequences ensures that the Bowtie analysis of the avoidance measures considers each relevant cause and mitigation measures considers each relevant consequence.

Risk Analysis

Based on ISO 31000, risk analysis is a process to determine the level of risk in terms of likelihood of an undesired event and the magnitude of the consequences resulting from that event. This is the step that most resembles what is typically understood as ecological risk assessments and can be qualitative or quantitative. However, risk analysis also requires an analysis of the existing or non-existing controls to determine the level of risk. In a Bowtie analysis, prevention controls are examined in terms of their effectiveness in reducing the likelihood of the undesired event while the mitigation and recovery controls are examined in terms of their effectiveness in reducing the likelihood and magnitude of the consequences of that event. The output of the risk analysis is a risk matrix used to classify the severity of the outcomes of a given set of management controls being considered by management and stakeholders. Several iterations of the risk analysis can be undertaken when considering multiple controls in the design of an entire system of management control to reduce the uncertainty of achieving policy objectives. Scientific and technical subject matter experts may also provide advice and knowledge.

Section 8.3c of the Fisheries Protection Policy Statement further defines the expected outcomes of “measures and standards to avoid, mitigate or offset serious harm to fish” in relation to paragraph *6(c)* of the *Fisheries Act*:

- **Avoidance** is the undertaking of measures to **completely prevent serious harm to fish**. Avoidance measures may include locating infrastructure or designing a project or one or more of its components to avoid serious harm to fish. Careful timing of certain activities may also avoid harm to fish and fish habitat. For some projects, serious harm to fish may be fully avoided while for others, serious harm to fish may only be partially avoided. When serious harm to fish cannot be fully avoided, mitigation measures should be undertaken.
- **Mitigation** is a measure to **reduce the spatial scale, duration, or intensity of serious harm to fish that cannot be completely avoided**. The best available mitigation measures or standards should be implemented by proponents as much as is practically feasible. Mitigation measures include the implementation of best management practices during the construction, maintenance, operation and decommissioning of a project.

In Figure 7, a Bowtie analysis would identify avoidance measures tailored for each cause to **completely prevent the death of fish or any permanent alteration to, or destruction of, fish habitat**. Similarly, mitigation measures would be tailored for each consequence to **reduce the spatial scale, duration or intensity of the death of CRA fish or supporting fish species as well as the types of fish habitats being impacted**. Avoiding serious harm to fish is more effective than mitigating the consequences of serious harm once it has occurred given the uncertainties involved. In the development of standards and guidelines, a Bowtie analysis of the effectiveness of the avoidance measures is about reducing the likelihood of serious harm to fish (event) and the effectiveness of mitigation measures is about reducing the likelihood and magnitude of the impacts to fish and fish habitat (consequences).

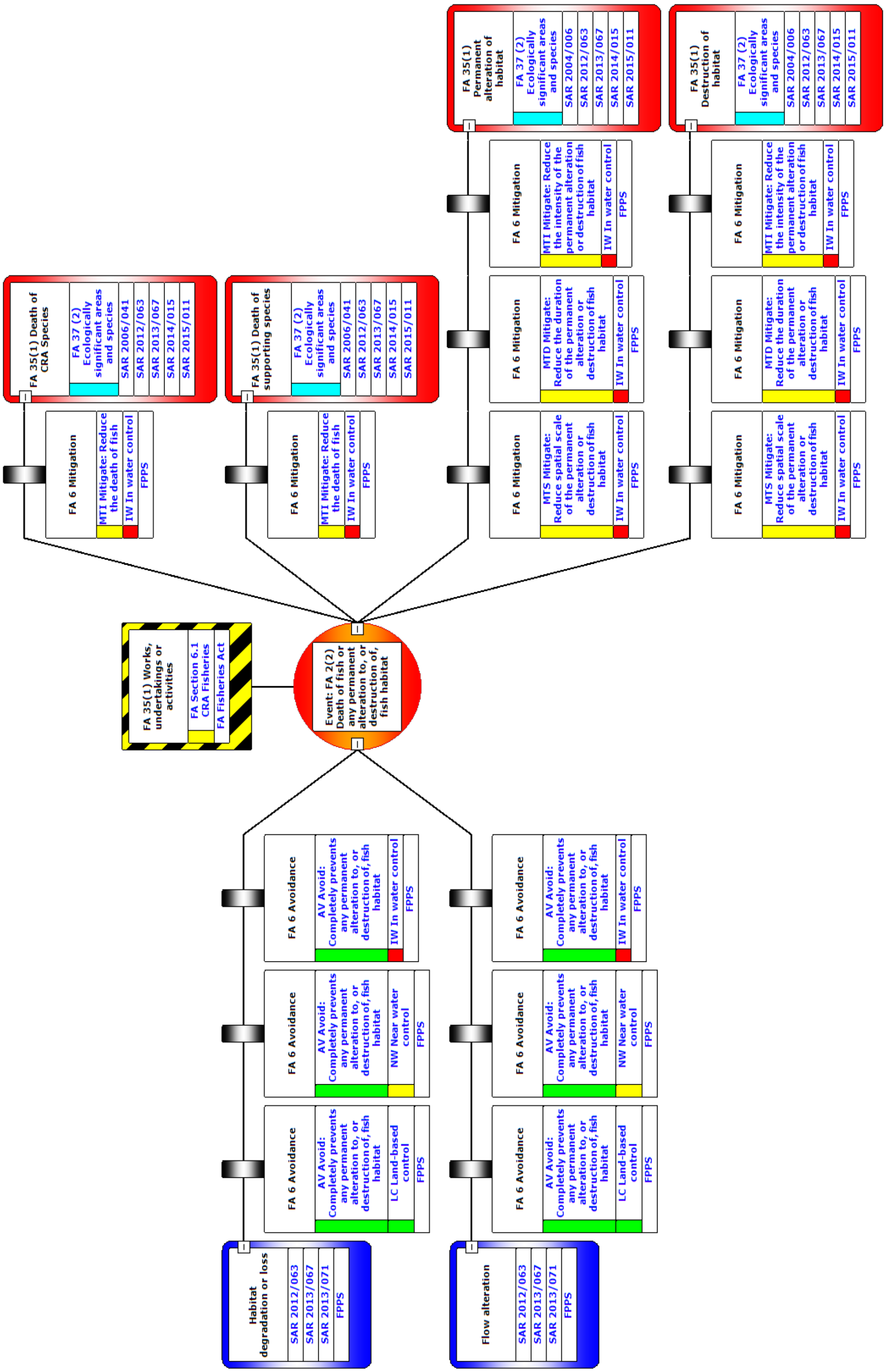

Figure 7. Bowtie representation of the avoidance and mitigation in relation to serious harm to fish.

Given the operational and management uncertainties of any management strategy, the assumption is that a suite of avoidance and mitigation measures that are part of a standard or a guideline would reduce the risks to a level that is “as low as reasonably practicable”. Additional conditions defining the operational boundaries for a standard or a guideline would also be used to trigger a review. The analysis of the operational boundaries conditions and the effectiveness of the avoidance and mitigation measures may require additional scientific or technical advisory processes. It may also be based on existing standards or guidelines used in other jurisdictions or sectors of operation.

In terms of the causes, operational boundary conditions could be established in consideration of questions 2 and 3 of the review and decision-making process (Box 1). In a standard and guideline development context, however, the question needs to be asked differently as these examples:

- Should there be a limit on the duration of the changes to species and habitat introduced by works, undertakings or activities to ensure that the ability of fish to carry out one or more of its life processes is maintained?
- Should there be a limit on the geographic scale of the changes to species and habitat introduced by works, undertakings or activities?
- Are there causes for which no reliable avoidance measures are available and will require a review?

In cases where such operational boundary conditions are set, a proponent would have to submit the project for review if the changes introduced are anticipated to be outside the conditions set in the standard or the guideline.

The location of the management measures also contributes to the likelihood of serious harm to fish. In the example of the Bowtie template shown in Figure 7, a management measure for land-based activities has a lower likelihood of causing serious harm to fish in comparison to a near-water or in water management measure. In land-based activities, there is a potential for serious harm to fish because of external events such as sedimentation and erosion resulting from rainfall and runoff. In a Bowtie analysis, these are called escalation factors and provide a rationale for additional measures such as sediment and erosion avoidance measures. Although near-water operations are not in-water either, there are more escalation factors that have the potential of causing serious harm to fish. In-water operations are the most likely to cause serious harm to fish as they are directly affecting fish and fish habitat within the foot print of the project and may also result in effects within the vicinity of the project. A standard or a guideline must ensure that management measures address adequately all potential and direct causes of harm to fish as a result of land-based, near-water and in-water activities. Such considerations can also be added as operational boundary conditions of a given standard or guideline such as operating in clement weather. For example, a standard or a guideline may be applicable to land-based or near-water operations and require a review when operations occur in water given the higher risk of serious harm to fish. In this Bowtie example, avoidance measures are mostly considered for land-based and near-water operations as the outcome of such measure has to **completely prevent serious harm to fish** in comparison to in water operations which mostly require mitigation measures to **reduce the spatial scale, duration or intensity of serious harm to fish that cannot be completely avoided**. This approach is provided for illustration purposes only and would require validation by subject matter experts.

Additional operational boundary conditions could also be developed for the consequences to fish and fish habitat. These conditions would reflect questions 4 and 5 of the review and decision-making process (Box 1) as well as localized effect or marginal habitat considerations. The EBSA and ESSCP criteria (DFO 2004; DFO 2006b) could be used to coherently characterize the significance of the fish and fish habitat within the footprint or vicinity of the project. For example purposes, Table 3 is an extract of the high and low significance criteria for spawning/breeding areas (DFO 2004). Notice the difference between high and low in terms availability of habitat and uses by species. Similar criteria are provided for each of the ecologically significant species and areas as listed in Table 2 above.

Table 3. Ecologically significant area criteria for spawning/breeding (DFO 2004).

Significance	Uniqueness	Aggregate	Fitness consequences
High	Only one suitable spawning site known to exist for a species; Site used for spawning by many species.	High percentage of total population use the area. Noteworthy percentage of many species use the area.	Semelparous, so loss of one spawning event poses risk of loss of lineage; or a single site's quality or quantity of breeding habitat greatly affects the productivity of the population.
Low	Suitable spawning sites are widespread over a large number of at least partially disjunct areas	Only a small portion of the population(s) is present at any given time.	Continuous reproduction throughout the year, over many years. Reproduction occurs at many sites. A single site's quality or quantity of breeding habitat has little effect on the productivity of the population.

These criteria could be used as a set operational boundary conditions for a given standard or guideline. For example, conditions could specify that the standard or the guideline can be used for projects occurring in waters where there are no ecologically significant species or habitats as well as in cases of low ecological significance situations. Another option could stipulate that any consequences to fish and fish habitat cannot be tolerated in any areas that have high ecological significance and would require a project review. The criteria could provide the necessary ecological characteristics for CRA species, supporting species and habitat permitted for the use of a given standard or guideline while being in line with Subsection 37(3) of the *Fisheries Act*.

Depending of the type of works, undertakings or activities, a given standard or guideline would be a combination of conditions coupled with avoidance and mitigation measures required to avoid serious harm to fish. Several iteration of the risk analysis process to compare inherent and residual risks of various combinations in the development of a standard or a guideline. Risk matrices would be produced for each combination being considered to enable and facilitate comparison and decision-making processes for management and stakeholders in risk evaluation.

Risk Evaluation

Based on ISO 31000, risk evaluation is a process of comparing the results of the risk analysis against a set of risk criteria to determine whether the risks are acceptable or not. It is the key management decision-making step of the risk management process. The purpose of risk evaluation is to inform decision-making in the selection of courses of action that could be taken to achieve a policy objective.

As discussed above, risk matrices do not make decisions *per se*. They are intended to consistently and coherently inform management and stakeholders of the potential outcomes of the various management options being considered for implementation. They do not provide management strategies or measures *per se*. Developed in relation to policy objectives, the risk criteria expressed in a risk matrix provides a terms of reference of likelihoods and severity of potential outcomes within the policy context. Risk matrices are also used to compare management strategies (Cox et al. 2005). A risk matrix is typically used to show the "inherent risk" of existing or non-existing management measures compared to the "residual risks" of prevention or mitigation controls being proposed. The risk criteria and matrix ensures that "inherent risks" and "residual risks" are compared within a common benchmark of severity (Vaughen et al. 2014). As mentioned above, the output of the risk analysis is the risk matrix which shows the likelihoods and outcomes of each management option analysed.

The role of a scientific and technical advisory process is to provide objective evidence without severity considerations (Figure 8 left side). The left matrix of Figure 8 is a fictitious example of a risk analysis output. E_I represents the likelihood and outcome as the inherent risk of an existing management controls. In comparison, A_R represents the residual risk for an avoidance control showing a reduction in the likelihood of the outcome. M_R represents the residual risks for a mitigation control showing a reduction in the magnitude of the outcome.

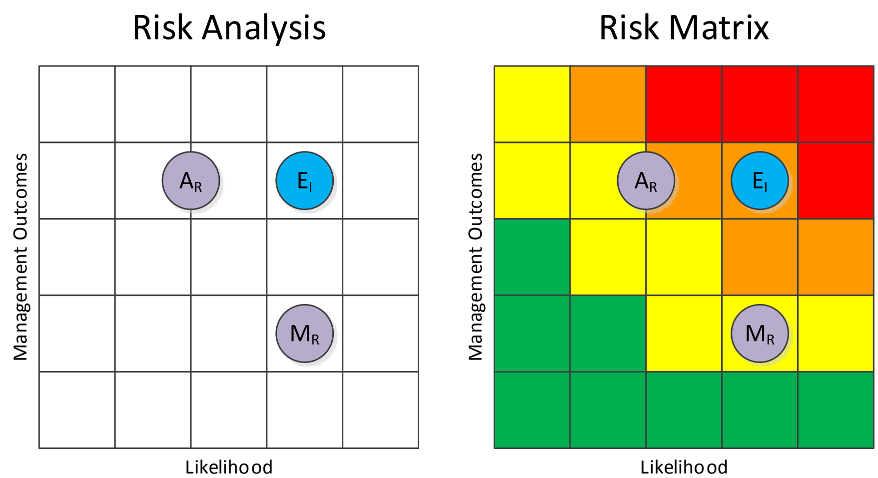

Figure 8. Risk matrices of the likelihood of outcomes and severity for existing and proposed management controls. (E_I: Inherent risk of existing management controls, A_R: Residual risks of avoidance controls, M_R: Residual risk of a mitigation control).

However, it is the role of management and stakeholders to evaluate the severity of the outcomes related to each management option being considered for implementation (Figure 8 right side) (Renn 2008). The color layout of the risk matrix defines the severity of the outcomes. For discussion purposes only, red could be indicative of a type of works, undertaking or activity that cannot be managed by a standard or a guideline given the level of scientific, management or operational uncertainties involved. Orange could be indicative of the need for additional conditions while yellow could be indicative of the need for additional monitoring and reporting. Green could simply mean that a given standard or guideline can avoid all potential serious harm to fish. The intent of this discussion is not to establish a risk criteria and risk matrix *per se*. It simply illustrates the use of such matrices in decision-making. The criteria would have to address question 6 of the review and decision-making process (Box 1).

The software BowTieXP provides a risk matrix for the event and the consequences. Figure 9 is a simplified example of a Bowtie showing the risks of serious harm to fish for avoidance measures and the risks of the consequences of serious harm to fish for the mitigation measures. In this fictitious example, several risks are presented.

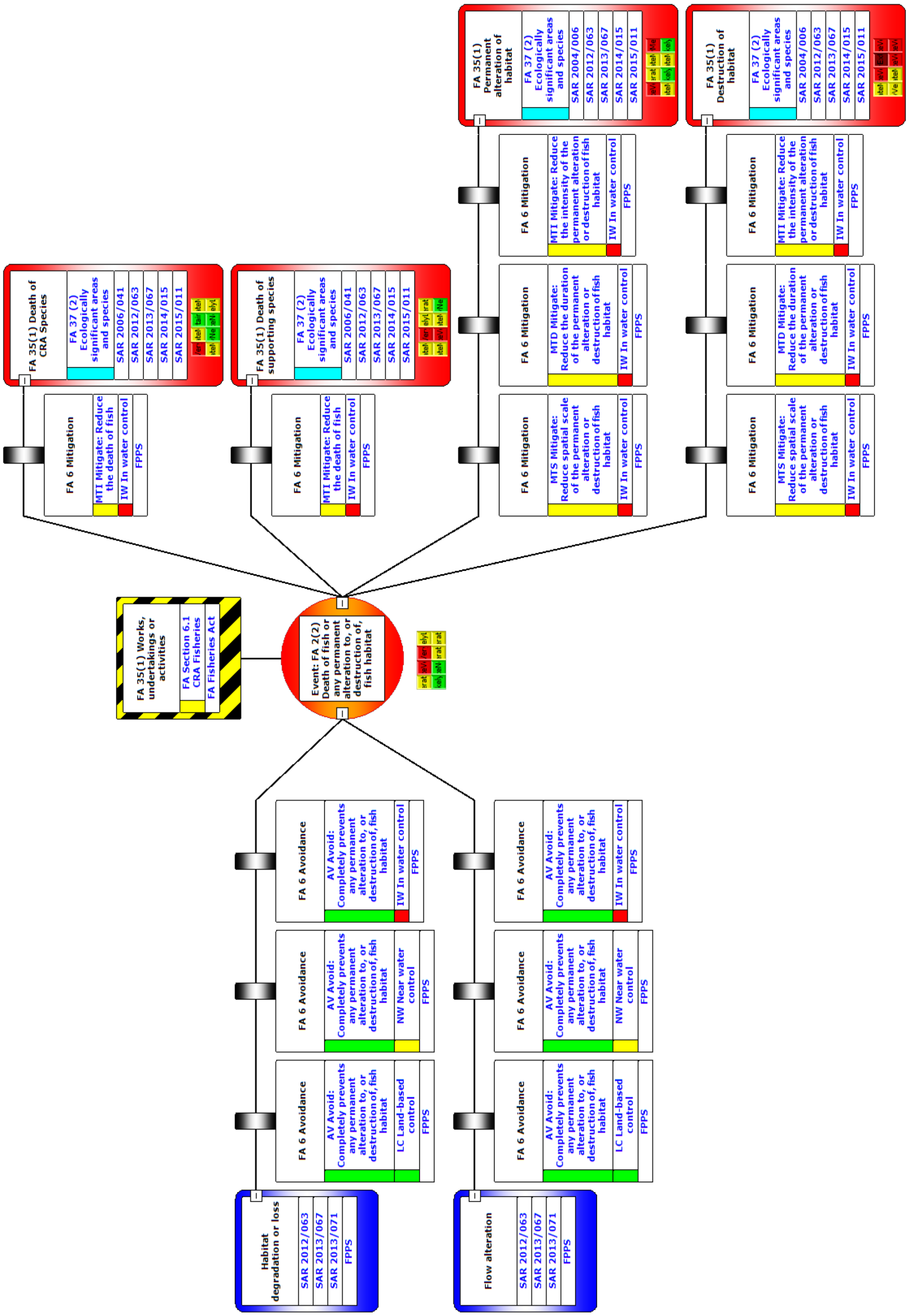

Figure 9. Risk matrices for serious harm to fish and the consequences of serious harm to fish (e.g. colored thumbnails under event and each consequence).

Risk Treatment

Based on ISO 31000, risk treatment is the step where management measures are implemented to achieve the policy objective. It basically reflects the decisions made in risk evaluation regarding the preferred course of action as outlined in policy. The operational feasibility in terms of implementation costs, human resource capacities, legislative authorities, and accountabilities are also considered in risk treatment. In the risk evaluation step a decision is made regarding which course of action to take. In risk treatment, decision-making is about operation implementation of the controls and conformity and compliance to guidelines, standards, or legislation.

Guidelines are usually non-binding or not compulsory. They can recommend a preferred course of action, design specifications, implementation and monitoring requirements, management or construction practices. Although conformity to a guideline can still be assessed and corrective actions required to address non-conformities, the obligation to implement the guideline and any subsequent corrective action is voluntary. A standard can also provide similar requirements, specifications including guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose (ISO 2009b). A standard usually sets quantifiable levels of controls in relation to a quality standard or a regulatory requirement. A standard operating procedure prescribes a series of detailed steps that must be carried out in implementation. A deviation from a standard or standard operating procedure is a non-conformity that can result in non-compliance in relation to the requirements of a contract, certification or regulation.

A risk management process determines the need for managing risk in relation to a policy context and then decides on the preferred courses of action to take. It does not start by asking "*What are the standards and guidelines needed?*". It starts by establishing the policy context, identifying the risks, analysing the existing management controls, and evaluating the system of management control that best match a course of action to achieve policy objectives. Risk treatment determines the best mechanisms for implementation and may include a combination of guidelines, standards or regulation. It also considers the reliability of the controls, the capability and capacity of the people having to implement the controls and the level of enforceability needed for the controls in relation to the severity of the risks and scientific, operational and management uncertainties involved.

In an FPP context, risk treatment involves decisions as to how recommended avoidance and mitigation measures should be implemented. Section 6 of the *Fisheries Act* provides the authority to develop regulations within the context of the *Fisheries Protection and Pollution Prevention* provisions. Subsections *35(2)* and section *37* of the *Fisheries Act* provides authorities to develop regulations in relation to:

- prescribed works, undertakings or activities
- prescribed fisheries waters
- prescribed conditions
- ecologically significant areas

Using the concepts above, a list of standards or guidelines may stipulate avoidance conditions or benchmarks in relation to preventing serious harm to fish in relation to PoE endpoints or causes (e.g. change in flow, increasing sediment concentration). Mitigation conditions could set limits for mortality rates for species or spatial, temporal or intensity levels of localized effects resulting from serious harm to fish. They can also provide procedures or design requirements for specific works, undertakings or activities to prevent serious harm to fish. Conceptually, a standard is usually viewed as a set of compliance requirements and guidelines as a set of procedures to meet the standard. The key in selecting a standard or a guideline is mostly related to the level of compliance and conformity needed to address the risks.

Similar to the approach of PoE analysis, avoidance and mitigation measures are implemented along the pathways of effect in order of criticality or importance. A system of management control is a system of critical and redundant management measures that are implemented to reduce the possibility of the whole system of management failing. In a Bowtie diagram, the management controls are also aligned in order of criticality or importance.

The output of risk treatment is a risk register of the system of management control and may stipulate additional operational boundary conditions to ensure the performance of the system. Once vetted by management, this is where the Bowtie diagram becomes a reference standard of the system avoidance and mitigation controls. In cases where the effectiveness or reliability of specific management controls are not well understood, the Bowtie can also help identify scientific research needs and monitoring requirements. The Bowtie facilitates the communication of requirements and the policy rational for the implementation of avoidance or mitigation controls.

Monitoring and Review

Based on ISO 31000, monitoring and review is part of the risk management process and involves regular and planned checking or surveillance. This risk management process step is the only way to determine if the system of management control is actually achieving the policy objectives. It informs management and stakeholders as to the effectiveness of the operational boundaries and management controls and the performance of the system of management control. Although not suggested formerly in this manuscript, this is where quality management systems organize the necessary documentation and information (e.g. records keeping, maintenance schedules, reporting requirements) used to conduct reviews. A quality management system comprises of quality assurance activities and quality control requirements.

ISO 31000 (ISO 2009b) defines monitoring as the "*continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected*". This is the role of environmental effects monitoring, conformity assessments, and field inspections (ISO 2004, ISO/IEC 2006). A review, however is defined as an "*activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives*". This is primarily the role of performance evaluations or audits. Monitoring collects the necessary non-conformity and compliance data to support a review aimed at improving the system of management control. It also provides valuable insight in the interpretation of observations and results of scientific research and monitoring activities. Although a management control may be effective, it may not be implemented properly resulting in environmental effects being observed or is simply not designed to address the environmental effect of concern. In a regulatory and policy context, monitoring determines if regulatory requirements are being met while a review determines if the policy objectives are being met.

Section 38 of the *Fisheries Act* and Section 11 of the Fisheries Protection Policy Statement provide the requirements for monitoring and reporting of serious harm to fish as well as corrective measures. In a Bowtie setting, monitoring can be performed for the causes, the effectiveness of the preventive controls, the occurrence of the event, the effectiveness of the mitigation and recovery controls as well as the consequences. In FPP, as in any environmental management context, this is mostly what environmental effect monitoring and impact monitoring is about. In a standard or a guideline setting, conformity assessments (ISO/IEC 2006) or audits (ISO/IEC 2012) would be performed on the avoidance and mitigation controls to determine if they are being implemented as planned. Performance evaluation could examine if the operational boundaries are being followed or examine if the risks are being adequately reduced.

Monitoring activities should be planned and conducted in relation to the scope and intent of the specific standard or guideline. In addition to providing valuable ecosystem knowledge, research and monitoring also provide insights as to the natural trends occurring and external factors that might be undermining the effectiveness of the management controls (e.g. escalation factors). Technical studies are better suited to determine the effectiveness of a particular management control and its design. However, operational and management uncertainties are addressed through inspections, conformity assessments and auditing activities. The combined results of all the monitoring activities provides the basis for reviews to inform decisions regarding the need to improve controls or the redesign the entire system of management control. In principle, the monitoring and review function of ISO 31000 adheres to the principles of adaptive management principles (Holling 1978).

Compared to environmental effects and impact monitoring, an inspection, a conformity assessment or an audit is a systematic and, in some cases, an independent examination to determine whether the management controls are being implemented as planned in daily operations. In a regulatory context, it determines whether the expected outcome of these measures are compliant to legislative and policy requirements. For comparison purposes only, inspection activities may include measuring, examining, testing one or more characteristics of a product, establishment or service and comparing these with specified standards or guidelines to determine conformity and compliance. Depending on the case, a performance evaluation or audit usually carries a broader role to determine if the management strategies and the system of management controls are meeting broader policy or program objectives. Audit and inspection criteria have similar information requirements as the following example:

- **Objectives**: Statement of what the monitoring and review activities is to accomplish (e.g. environmental monitoring, inspection, conformity assessment or audit);
- **Scope**: legislation, policy and management measures covered by the monitoring and review activities;
- **Condition**: Factual description of the actual situation or circumstance observed;
- **Criteria**: Standard measure (regulation, ISO standard, policy, guideline) against which to assess the conformity of the existing conditions to the standard;
- **Evidence**: Fact or information used to assess or prove if conditions conform to criteria;
- **Finding**: Statement of fact which are the result of fact-finding, analysis and comparison. The person in charge of the monitoring or review activity observes and describes a condition and compares the condition (what exists) with the criteria (what should be).

Field inspections typically monitor compliance of a specific project in terms of stipulated requirements that may lie in legislation, regulations or standards. Conformity assessments can also play a similar function. However, conformity assessments tend to focus on conformity to a guidelines, procedures documentation and the like. A performance audit tends to be conducted for the implementation of several standards or guidelines to determine the effectiveness or feasibility of a given management control or the performance of the system of management control.

For standards and guidelines, a roster of monitoring and review questions that are within the scope of the legislation and objectives of the policy ensures that such activities are conducted consistently and coherently across a given program. It enhances efficiencies in delivering such activities by reducing preparation time. Also needed are standardized criteria of conformity for assessing the implementation of standards as well as guidelines. The BowTieXP software can integrate survey questions, criteria and information requirements for a broad range of monitoring and review activities as well as record the analysis of their results. Results can be viewed for a specific inspection, conformity assessment or audit or the combined results of multiple monitoring and review activities (Figure 10). In this fictitious example, results are color coded as pass/fail frequencies.

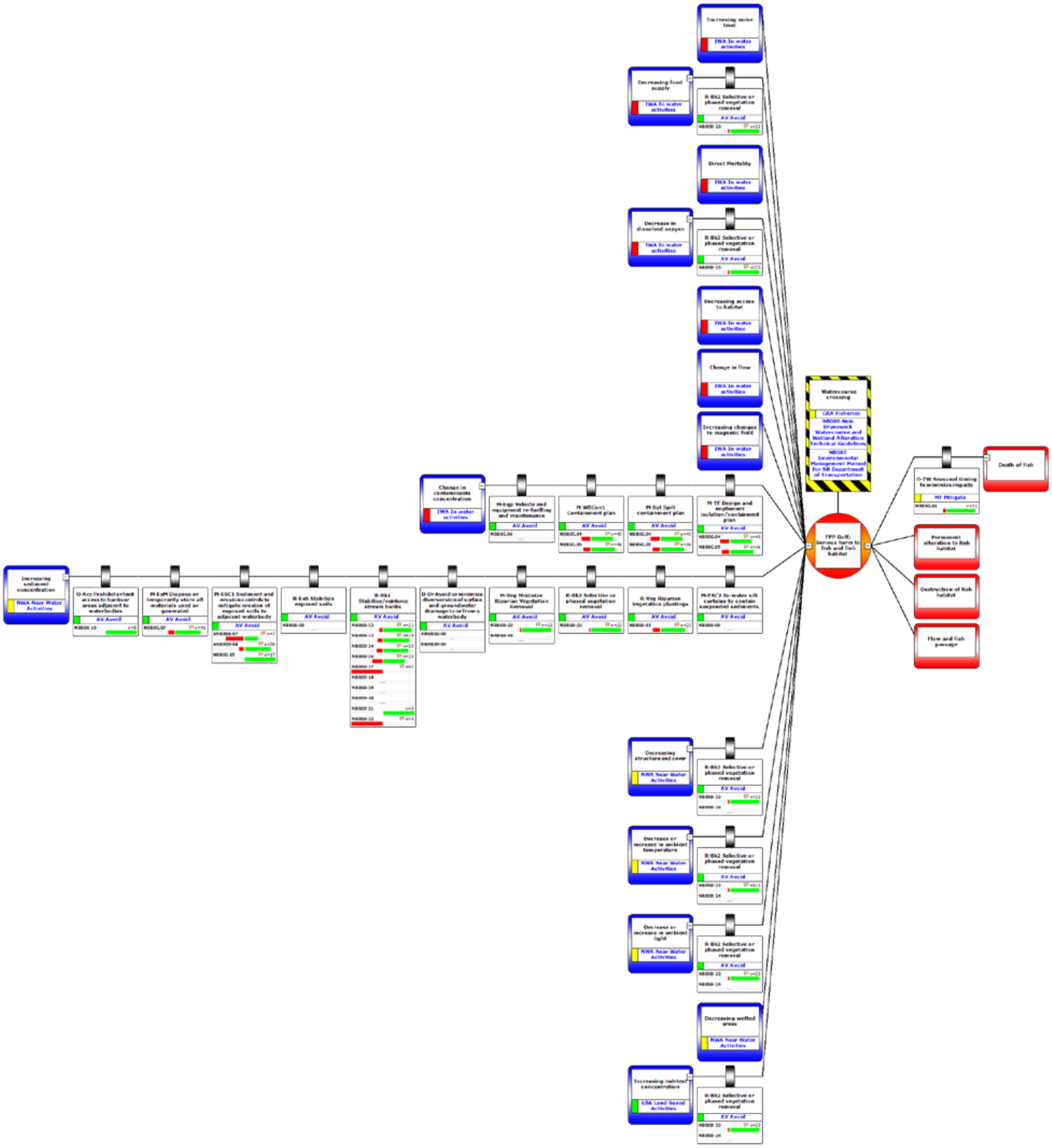

Figure 10. Example of conformity assessments conducted for individual management measures (Not an actual conformity assessment).

As shown in Figure 1, monitoring and review also occurs along the entire risk management process. These activities also include scientific, technical or policy advisory and review procedures. Figure 1 provides some insight as to the type of review required in relation to the inputs needed for each step of the process. Monitoring and review activities can also be undertaken in relation to the interpretation and use of legislation, policies and science in each of the process steps.

Communication and Consultation

Based on ISO 31000, communication and consultation activities should take place with relevant external and internal stakeholders throughout the process. This includes the need to develop communication and consultation plans in relation to considerations and findings to be taken into account for each step of the process. Consultation can ensure that the context is adequate, that the interests of the stakeholders are understood, that risks are identified and understood by management, stakeholders, scientists and subject matter experts. This section does not provide extensive details as to how to approach this function of the risk management process as it is guided by existing communication and engagement policies.

Risk Management Overview

In a regulatory context, the most notable aspect of a risk management process is that it provides a basis for transparently informing decisions regarding courses of actions to achieve policy objectives within a legislative context. By setting this context at the beginning of the process, it ensures that the risks identified and analysed are within the scope of the legislation and that the courses of action evaluated and selected reduce the uncertainties and risks of not achieving policy objectives. The process simply provides for good governance. It informs decisions and does not make the decision.

The Bowtie analysis structures the information and elements to be taken into account during the entire process. Advanced software such as BowTieXP adds functionalities to facilitate and enable the integration of reference documentation such as legislation, policies and guidance documents as well as roles and responsibilities and monitoring activities. As a risk register, a Bowtie diagram ensures consistency and coherence the development of standards and guidelines by providing a standardized roster of causes, consequences and management controls. The risk management process ensures consistency and coherence in the development of standards and guidelines by ensuring that risks and their management controls are determined first before a decision is made as to how such control should be implemented. However, it is the monitoring and review functions that provides the basis for continuous improvement of the system of management control. The effectiveness of a given management control or the performance of the entire system of management control can only be determined by monitoring and review activities.

CONCLUSION

As part of the ISO 31000 risk management standard, the Bowtie analysis is one of the techniques to assess the effectiveness of the system of management control in relation to a policy objective following a risk-based approach. This manuscript demonstrates that the newly implemented changes introduced by the *Fisheries Protection and Pollution Prevention* provisions of the *Fisheries Act* and the Fisheries Protection Policy Statement can be supported by the risks management process of ISO 31000 and the Bowtie analysis. It adapts the PoE approach by aligning avoidance and mitigation measures with a cause and effect relationship with serious harm to fish as the center event to be avoided in relation to works, undertakings or activities. The Bowtie examples, discussed in this document, introduced the need for a coherent set of causes and consequences as an example for this type of analysis. The Bowtie diagram can be used as a reference standard for project reviews and decisions regarding the development of avoidance or mitigation standards and guidelines.

Bowtie analysis can be used to identify gaps, redundancies or duplication of measures within existing standards and guidelines in relation to the new policy context and definitions of FPP. Such reviews would avoid dedicating resources to developing new standards and guidelines from scratch when enhancements could be made to existing guidelines. In the development of standards and guidelines, the Bowtie analysis can be used to review existing measures from other jurisdictions and industries transparently. The Bowtie can be used to develop monitoring and review activities such as inspections, conformity assessments, and performance audits as well as scientific research and monitoring. A Bowtie analysis of management measure ensures that there are enough redundancies in the measures even though a few may be critical to avoid serious harm to fish. Redundancy is also a management strategy to address scientific, management and operational uncertainties.

Once standards and guidelines have been established for a given POE (DFO 2014b), the Bowtie itself can be used as reference standard of the minimal avoidance and mitigation requirements for project reviews. Proponents could also use the Bowtie itself to identify the relevant management measures to be implemented for a given work, undertaking or activity. The Bowtie diagram also facilitates communication and engagement of proponents and assessors in the review of projects and the public at large. The Bowtie analysis incorporates consultation processes as well as cost and benefits analysis as part of a regulatory impact assessment. The Bowtie analysis discussed in this manuscript is a controls assessment techniques of IEC/ISO 31010 (IEC/ISO 2009). BowTieXP is a third party software that adds significant functionality to the construction and maintenance of the Bowtie diagrams (CGE 2015).

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