THE TREATMENT, ANALYSIS AND COMMUNICATION OF UNCERTAINTY IN THE ENVIRONMENTAL RISK ASSESSMENT OF AQUATIC ORGANISMS, INCLUDING TRANSGENIC FISH

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PREFACE

Effective and transparent communication of risk, and the uncertainty associated with it, is an essential part of the risk assessment process. When performing qualitative risk analysis, statistically relevant data may be limited or absent. Well defined methodologies for the assessment of uncertainty in qualitative risk assessment, and for the incorporation of uncertainty into the decision making process are needed to inform qualitative risk assessments that are carried out by the Department of Fisheries and Oceans (DFO).

Recent experience with the qualitative risk assessment of a transgenic salmon identified a need for greater expertise in the analysis of uncertainty. This prompted the Biotechnology Program to look outside of DFO for experts in the fields of uncertainty analysis and aquatic environmental risk assessment, who could conduct a broad search of the scientific literature to collect and summarize the current state of knowledge. Experts at Intrinsik Environmental Sciences Inc. were petitioned to gather comprehensive information regarding the analysis of uncertainty in the qualitative environmental risk assessment of aquatic organisms, summarize the current state of knowledge, and provide advice on how the various methodologies and tools for dealing with uncertainty might be applied to risk assessments conducted by DFO.

The completed review document, presented here as a Technical Report, is intended to inform future environmental risk assessments at DFO, and encourage the use of tools for the effective analysis, treatment and communication of uncertainty.

ABSTRACT

To develop a better understanding and appreciation for the tools that are available to risk assessors for handling the analysis and communication of uncertainty in qualitative risk analysis, the DFO Biotechnology and Genomics Program commissioned experts from Intrinsik Environmental Sciences Inc. to review these issues with a focus on aquatic ecosystems and qualitative data.

Part 1 of this report reviews a selection of guidance documents from various jurisdictions. Though far from comprehensive, the examples of assessment frameworks are useful in describing the variation in how uncertainty is treated across the environmental sector. Here, effort has been made to select those risk assessment frameworks that have been, or could easily be, applied to aquatic organisms; with scenarios such as the risk assessment of aquatic invasive species, introduced species or strains, and genetically modified aquatic organisms (GMOs).

Part 2 reviews the various qualitative methods for the analysis and communication of uncertainty in environmental risk assessment. Here, we continue to focus on environmental risk assessment and uncertainty in aquatic ecosystems by providing relevant examples taken from completed risk assessments. Part 2 concludes with a brief overview of quantitative methodologies, as an introduction for those who may want to explore this line of analysis further.

The report concludes with recommendations on approaches and tools for risk assessors dealing with potential biological stressors in the aquatic environment, and when dealing with data and information that is largely, or entirely qualitative.

RÉSUMÉ

Afin de mieux connaître et apprécier les outils dont disposent les évaluateurs des risques pour analyser et communiquer l'incertitude dans les analyses qualitatives des risques, le Programme de biotechnologie et de génomique du MPO a chargé des experts de la société Intrinsik Environmental Sciences Inc. d'étudier ces enjeux du point de vue des écosystèmes aquatiques et des données qualitatives.

La première partie de ce rapport est consacrée à l'examen des documents d'orientation fournis par plusieurs administrations. Même s'ils sont loin d'être inclusifs, ces exemples de cadres d'évaluation sont utiles car ils montrent les variations dans le traitement de l'incertitude dans l'ensemble du secteur environnemental. Les auteurs se sont attachés ici à retenir les cadres d'évaluation des risques qui ont été appliqués aux organismes aquatiques ou qui pourraient facilement l'être, avec des scénarios comme l'évaluation des risques liés aux espèces aquatiques envahissantes, aux espèces ou souches introduites ainsi qu'aux organismes aquatiques génétiquement modifiés (OGM).

La deuxième partie examine les diverses méthodes qualitatives d'analyse et de communication de l'incertitude dans les évaluations du risque environnemental. Elle porte sur l'évaluation du risque environnemental et l'incertitude dans les écosystèmes aquatiques et donne des exemples pertinents tirés d'évaluations des risques déjà réalisées. Cette partie se termine par un bref aperçu des méthodologies quantitatives en guise d'introduction pour les personnes qui pourraient vouloir étudier davantage ce type d'analyse.

La conclusion du rapport est consacrée à des recommandations sur les approches et les outils utiles aux évaluateurs des risques qui doivent tenir compte d'éventuels agents de stress biologiques dans le milieu aquatique et travailler avec des données et des renseignements de nature essentiellement, voire uniquement qualitative.

1.0. INTRODUCTION

Risk assessments are performed and used as a decision aid to help protect human health and the environment. The purpose of a risk assessment is to estimate the likelihood, magnitude and potential consequences of effects that stressors may induce. This can be a challenge when assessing the environmental risk of aquatic organisms, given the complexity of the aquatic ecosystems, and the difficulties of collecting data in the aquatic environment. However, even when there is limited empirical data, which is often the case for aquatic species, accurate and scientifically defendable environmental risk assessment can still be performed and used as a useful tool to assist decision making.

Quantitative risk assessments are typically performed when there is sufficient system understanding to permit model development and input variables can be parameterized with available empirical data. In these situations, uncertainty may be quantified with a variety of statistical techniques (Hayes et al., 2007; Warren-Hicks and Hart, 2010). In other situations, risk assessment and uncertainty analysis may only be conducted qualitatively because system understanding and available empirical data are limited. *Qualitative* assessments rely on expert judgements and opinions and often use nominal or ordinal scales to categorize and order stressors in terms of relative risk. Unlike quantitative analyses, qualitative analyses do not provide an indication of the true differences that may exist between ranked stressors and, as a result, do not provide as clear of an understanding of risk (Hayes, 2011). Qualitative risk assessments have an inherently high degree of uncertainty. Failure to properly incorporate uncertainty into the risk analysis can result in incorrect decisions that lead to mitigating a system that is not truly at risk (a Type I error) or failing to mitigate risk that leads to degradation of the system (a Type II error) (Warren-Hicks and Moore, 1998).

Uncertainty can arise from a wide range of sources that include four broad categories: epistemic uncertainty, linguistic uncertainty, variability and decision uncertainty (Regan et al., 2002, 2003; Hayes, 2011). Epistemic uncertainty, or incertitude, is typically defined as the uncertainty associated with overall knowledge of a given topic. Incertitude arises because of limitations of scientific knowledge and may be reduced with additional empirical effort (EFSA GMO Panel, 2013). Linguistic uncertainty is associated with differences in the understanding and interpretations of the language used in the development and implementation of a risk assessment. Variability arises from natural stochastic events and cannot be reduced by further empirical effort (Hayes, 2011). Finally, decision uncertainty typically arises following the initial estimation of risk and is related to the measures used to describe and summarize risk (Finkel, 1990).

Governments must make decisions on how to deal with biological stressors including, for example, introduced and invasive species, or genetically-modified organisms. To guide those decisions, qualitative risk assessments are performed to determine if the biological stressors of concern pose a risk to the environment and, where possible, the relative risks of those stressors. The assessments are necessarily qualitative because of limitations in system understanding (e.g., how would invasive species interact with similar native species) and available empirical data (e.g., lack of data on competitive outcomes between invasive and native species).

To develop a better understanding and appreciation for the tools that are available to risk assessors for handling the analysis and communication of uncertainty in qualitative risk analysis, the DFO Biotechnology and Genomics Program commissioned experts from Intrinsik Environmental Sciences Inc., to review these issues with a focus on aquatic ecosystems and qualitative data.

2.0. TREATMENT OF UNCERTAINTY IN QUALITATIVE RISK ASSESSMENT OF AQUATIC SPECIES

There are a variety of risk assessment methodologies that have been suggested for use or have been used by the Department of Fisheries and Oceans (DFO) Canada, depending on the nature of risk assessment being conducted. Several methodologies developed both inside and outside of Canada’s jurisdiction are summarized below.

2.1. TRINATIONAL RISK ASSESSMENT GUIDELINES

The Trinational Risk Assessment Guidelines for aquatic alien invasive species was developed by the United States, Canada and Mexico (Orr and Fisher, 2009). The guidelines are an update of the review process developed by the Aquatic Nuisance Species Task Force (ANSTF) in the United States (ANSTF, 1996). The Trinational Risk Assessment guidelines provide a standardized procedure to evaluate the risk to biodiversity following the introduction of non-indigenous organisms into a local environment (Orr and Fisher, 2009).

To determine if a selected non-indigenous species may be of concern, organism characteristics are evaluated using a screening tool. If the species is of potential concern, the next phase is to conduct an Organism Risk Assessment to determine the probability of establishment and the consequence of establishment. There are seven elements considered in each assessment. As shown in Figure 1, the outcome of the model covers ecological, economic, social and cultural impacts.

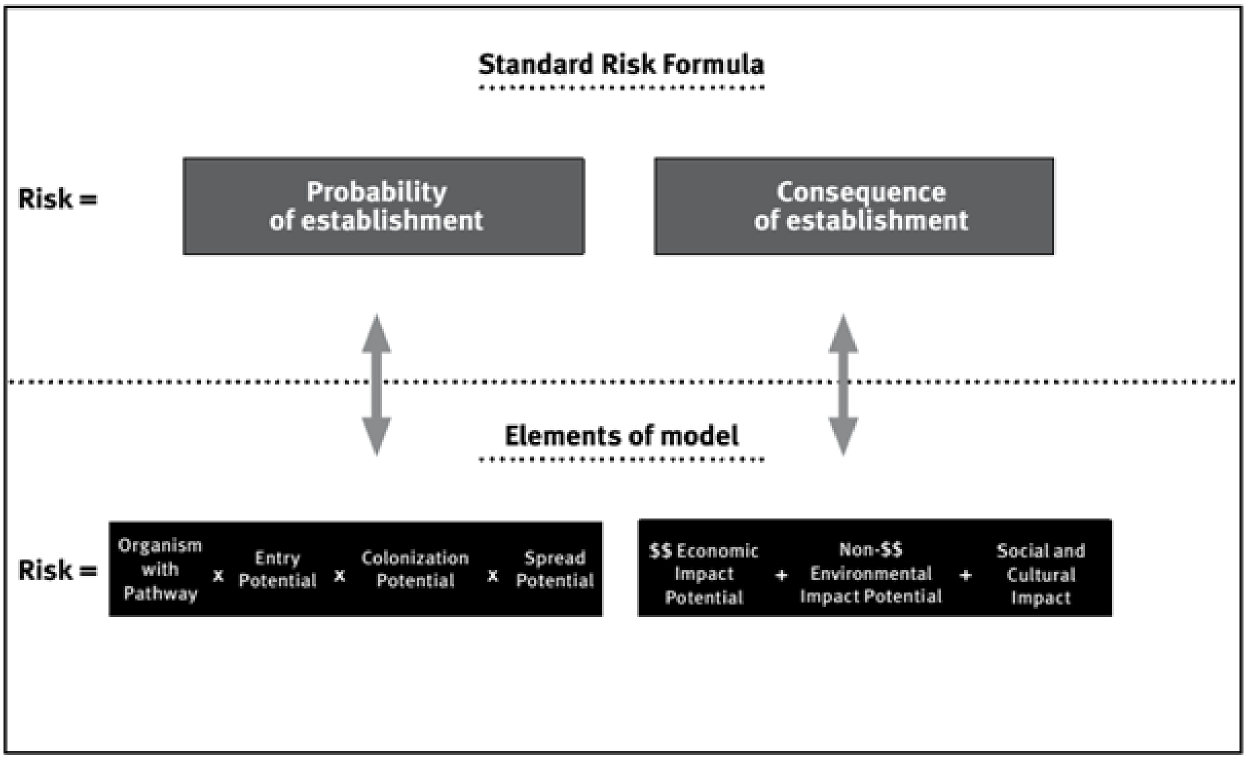


Figure 1: The seven components of an organism risk assessment (Orr and Fisher, 2009).

The estimates for the seven risk element are each rated as low (acceptable risk; no concern), medium (unacceptable risk; moderate concern) or high (unacceptable risk; major concern). To establish the organism risk potential, the Probability of Establishment and the Consequences of Establishment are first determined. For the Probability of Establishment, the lowest risk rating value is used. The three elements assessed in the Consequences of Establishment are not treated equally with the highest rating between the Economic and the Environmental element used. The Social and Cultural Impact element only provides input when both Economic and Environmental ratings are low. The organism risk potential is the highest rating assigned to either the Probability of Establishment or the Consequence of Establishment. When multiple organisms are being assessed, a final pathway risk potential is determined by taking the highest ranking organism risk potential.

No tools are provided to assess uncertainty in the model, however the use of geographical information systems, climate and ecological models, decision-making software and graphical displays of uncertainty were suggested as a way of increasing the model's precision.

Reference codes for uncertainty are based, to the extent possible, on peer-reviewed science and range from Very Uncertain (“An educated guess”) to Very Certain (“As certain as I am going to get”), as shown in Table 1.

Table 1: Trinational risk assessment of invasive species uncertainty codes (Orr and Fisher, 2009).

Uncertainty Code	Symbol	List Category
Very certain	VC	As certain as I am going to get
Reasonably certain	RC	Reasonably certain
Moderately certain	MC	More certain than not
Reasonably uncertain	RU	Reasonably uncertain
Very uncertain	VU	An educated guess

2.2. NATIONAL RISK ASSESSMENT GUIDELINES FOR ASSESSING THE RISK OF AQUATIC INVASIVE SPECIES IN CANADA

The national detailed-level risk assessment guidelines were developed to provide standards, and guidance on scientifically defensible assessments, by educating practitioners and prioritizing needs (Mandrak et al., 2011). Guidance on handling qualitative, semi-quantitative or quantitative data is provided throughout.

A detailed assessment of the likelihood of invasion and establishment as well as potential biological consequences of the invasion can be produced using the national detailed-level risk assessment guidelines. Methods detailing how to best handle uncertainty are provided, highlighting the more common sources of uncertainty and that uncertainty needed to be considered for each component of the risk assessment.

The methods described are clear and have been refined through peer review workshops (DFO, 2009). Following problem formulation, information describing the hazard, including a biological synopsis of the invasive species and vector and pathway details are provided. The biological risk assessment determines the likelihood of introduction by ranking four elements: arrival, survival, establishment and spread. The results are then multiplied by the magnitude of biological consequences of the species introduction.

A ranking of uncertainty is provided (Table 2) along with rankings for the likelihood of exposure (Table 3), biological consequences (Table 4), and risk (Table 5). Here, numerical values are encouraged to decrease confusion from the use of an ambiguous narrative, and to provide a common scale.

A well-defined matrix is used to summarize and effectively communicate the overall results of the risk assessment by combining the likelihood of introduction with the magnitude of consequences. The matrix is comprised of three risk levels: low, medium and high. Overall uncertainty is determined by the highest uncertainty level described in the likelihood of introduction and magnitude of consequences sections. However, the criteria used to determine the level of uncertainty associated with the probability of an introduction are ambiguous, and rely heavily on expert interpretation. The guidelines suggest the use of quantitative methods whenever possible to determine the overall distribution and spread of risk estimates.

Table 2: Relative uncertainty categories in the national detailed-level risk assessment guidelines (Mandrak et al., 2011).

Uncertainty Level	Category
± 90%	Very low uncertainty (e.g., extensive, peer-reviewed information)
± 70%	Low uncertainty (e.g., primarily peer-reviewed information)
± 50%	Moderate uncertainty (e.g., information and expert opinion)
± 30%	High uncertainty (e.g., little information, largely expert opinion)
± 10%	Very high uncertainty (e.g., no information, expert opinion)

Table 3: Likelihood values and interpretation in national detailed-level risk assessment guidelines (Mandrak et al., 2011).

Likelihood	Values	1-Likelihood
Negligible	0-0.001	Almost certain
Very unlikely	0.001-0.05	Very likely
Low	0.05-0.4	High
Moderate	0.4-0.6	Moderate
High	0.6-0.95	Low
Very likely	0.95-0.999	Very unlikely
Almost certain	0.999-1.0	Negligible

Table 4: Ratings for biological consequences and associated descriptions in the national detailed-level risk assessment guidelines (Mandrak et al., 2011).

Impact Rating	Description
1. Negligible	Undetectable change in the structure or function of the ecosystem. No management action required.
2. Low	Minimally detectable change in the structure of the ecosystem, but small enough that it would not change the functional relationships or survival of species. Unlikely to affect management of the ecosystem.
3. Moderate	Detectable change in the structure or function of the ecosystem that would require consideration in the management of the ecosystem.
4. High	Significant changes to the structure or function of the ecosystem leading to changes in the abundance of native species and a need for management to adapt to the new food web. May have implications beyond the extraction or use of ecosystem resources.
5. Extreme	Impacts that restructure the ecosystem resulting in, for example, the extirpation or extinction of at least one species and the need for significant modification of the management of the ecosystem. Will probably have implications beyond the extraction or use of ecosystem resources.

Table 5: Overall ranking of likelihood of introduction in the national detailed-level risk assessment guidelines (Mandrak et al., 2011).

Element	Likelihood	Uncertainty
Arrival	Almost certain	Low
Survival	Moderate	Moderate
Establishment	High	High
Spread	Very likely	Moderate
Overall	Moderate	High

2.3. NATIONAL CODE ON INTRODUCTIONS AND TRANSFERS OF AQUATIC ORGANISMS

The Code was developed to provide a consistent and objective decision-making framework for the risk assessment of intentional introductions and transfers of aquatic organisms either between or within Canadian provinces or territories (Price et al., 2003). It provides guidelines on how to conduct a risk assessment to determine if the proposed introduction or transfer of aquatic species presents a low, medium or high risk for the receiving environment (Price et al., 2003), and was adapted from the review process developed by the Aquatic Nuisance Species Task Force (ANSTF) in the United States (ANSTF, 1996).

The risk assessment is comprised of two major sections where the ecological and genetic risks are first assessed, and subsequently, pathogen, parasite or fellow traveler risks are assessed. In each of the components, a multi-step process is outlined where the probability of establishment, consequences of establishment and estimation of the organism risk potential are determined. Low, medium and high ratings are used to describe risks throughout.

The level of certainty is ranked on scientific knowledge, experience, or whether it was a best guess scenario. Uncertainty is ranked as, very certain, reasonably certain, reasonably uncertain and very uncertain, however there is no explanation of how each ranking is determined. This would be provided and would have to be defined in the problem formulation. Consequently, a high level of verbal uncertainty is found in the element ratings definitions for high, medium and low as well as in the levels of uncertainty.

The final rating and level of certainty for the probability of establishment and the consequences of establishment are then used to determine the final risk estimate. As shown in Table 6, a precautionary approach is taken such that the final risk estimate takes the value of the higher of the two probabilities, unless there is a probability increment between the two estimates. A high risk estimate indicates that the organism is of major concern and requires major mitigation. A low risk estimate indicates little concern and no mitigation is required. As with the guidelines for invasive species, the overall level of uncertainty that is assigned to the final estimate of risk is taken from the element (likelihood or consequences) with the lowest certainty level.

In the second section of the Code, the pathogen, parasite or fellow traveler risk is assessed using similar methodologies, i.e., the probability and consequences of establishment are determined using the low to high ranking for each hazard identified.

Uncertainty is evaluated using the same ranking system identified in the first section of the risk assessment.

Table 6: Determination of final risk estimate (Price et al., 2003).

Probability of Establishment	Consequences of Establishment	Final Risk Estimate
High	High	High
High	Medium	High
High	Low	Medium
Medium	High	High
Medium	Medium	Medium
Medium	Low	Medium
Low	High	Medium
Low	Medium	Medium
Low	Low	Low

The National Code guidelines are straightforward and easy to follow. They are, however, limited as they only apply to intentional introductions and transfers and do not assess unintentionally introduced invasive species with the potential to spread to other areas of Canada or are not yet present in Canada (Mandrak et al., 2011). In addition, a high level of verbal uncertainty is found in the element rating definitions for high, medium and low as well as in the levels of uncertainty.

2.4. EUROPEAN UNION ENVIRONMENTAL IMPACTS OF ALIEN SPECIES IN AQUACULTURE

As part of the European Non-native Species in Aquaculture Risk Assessment Scheme (ENSARS), the *Risk Assessment Protocols and Decision Making Tools for Use of Alien Species in Aquaculture and Stock Enhancement* was published (Copp et al., 2008). ENSARS was adapted from the pest risk analysis support scheme of the European and Mediterranean Plant Protection Organisation (EPPO). The EPPO scheme was developed using the guidelines of the International Plant Protection Convention (IPPC) International Standards for Phytosanitary Measures on pest risk analysis, recognized by the Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO, 1995).

ENSARS was designed to provide a framework to evaluate the risk of escape, introduction to and establishment in open waters, of any non-native aquatic organism being used in aquaculture. It was divided into seven modules. The first six modules evaluate entry, invasiveness, organism, facility, pathway and socio-economic impact. In the invasiveness module, subsets of modules assess the potential invasiveness of Amphibia and of freshwater and marine fish through generic and taxon-specific analyses.

Questions and response options are provided to help the assessor in each module. The responses include justifications and cite bibliographic or expert opinion as appropriate. Levels of confidence and certainty for each response are also provided using a ranking system similar to that recommended by the International Programme on Climate Change (IPCC, 2005). Confidence level rankings are assigned a numerical value ranging from 0 to 3. The degree of confidence is used to characterize uncertainty regarding the correctness of a statement or analysis (IPCC, 2005). Ranks for confidence are:

- 0 = Low confidence (2 out of 10 chance),
- 1 = Medium confidence (5 out of 10 chance),
- 2 = High confidence (8 out of 10 chance), and
- 3 = Very high confidence (9 out of 10 chance).

Several attributes, such as likelihood, number, extent and frequency are then assessed in response to questions on a five point scale (Table 7).

Table 7: ENSARS attributes in the risk assessment modules (Copp et al. 2008).

Type	Scale Point				
	0	**1**	**2**	**3**	**4**
Likelihood	Very unlikely	Unlikely	Moderately likely	Likely	Very likely
Number	Very few	Few	Moderate number	Many	Very many
Extent	Very rare	Rare	Occasional	Frequent	Widespread
Frequency	Very rarely	Rarely	Occasionally	Often	Very often
Speed	Very slow	Slow	Intermediately	Rapid	Very rapid
Controllability	Very easily	Easily	Some difficulty	Difficult	Very difficult
Importance	Minimal	Minor	Moderate	Major	Massive
Effect	Minimal	Minor	Moderate	Major	Massive

2.5. GUIDELINES FOR ENVIRONMENTAL IMPACT ASSESSMENT AND LIST CLASSIFICATION OF NON-NATIVE ORGANISMS IN BELGIUM

A non-native terrestrial, freshwater and marine species information system known as Harmonia was developed to help standardize information on exotic species believed to be detrimental to native biodiversity in Belgium (Branquart et al., 2009). This list category system only includes organisms already established in Belgium or in neighbouring areas with similar ecological systems and climates. Harmonia was based on a simplified version of the Invasive Species Environmental Impact Assessment (ISEIA).

The ISEIA relies on documented invasion histories in previously invaded areas of Western Europe (Branquart et al., 2009). Non-native species are assigned to different hazard categories, to identify those of greatest concern while minimizing the use of subjective opinions (Branquart et al., 2009).

Explicit details on how to incorporate uncertainty or minimize uncertainty are not provided. Instead, uncertainty is incorporated into the ranking of risk, by placing limitations on the number of risk categories that can be reported. When background information about the species has been documented in the scientific literature or reports, a three point scale is used as the basis of the scoring system.

L = low, score = 1

M = medium, score = 2

H = high, score = 3

If there is little documentation or scientific background available, and the assessment weighting is based more on expert judgment and the scoring system is adapted to reflect increased uncertainty.

Unlikely, score = 1

Likely, score = 2

Finally, when little scientific literature or no reliable background information is available about the species in question, no score is assigned due to deficient data (score = 0).

The environmental hazard assessment component is divided into four sections:

- dispersion potential or invasiveness

- colonization of high conservation value habitats
- adverse impacts on native species
- alteration of ecosystem processes

The global environmental risk is assessed with equal weightings assigned to each of the four sections. The global ISEIA score is determined by calculating the sum of the risk ratings scores and is subsequently used to allocate the non-native organism to a risk category (Table 8).

Table 8: Classification of non-native species in Belgium (Branquart et al., 2009).

ISEA Score	List Category
11-12	A (black list)
9-10	B (watch list)
4-8	C

As mentioned above, the Belgian guidelines rely on historical data of previous invasions in Western Europe. Consequently, when there is no previously documented invasion, the guidelines become difficult to apply.

2.6. THE UK RISK ASSESSMENT SCHEME FOR NON-NATIVE SPECIES

The risk assessment protocol for non-native species in the UK is based on international risk standards provided by the European and Mediterranean Plant Protection Organisation (EPPO) pest risk assessment scheme (EPPO, 2006). These techniques were adapted and developed to provide a generic scheme that could be applied to all non-native taxa (Baker et al., 2008). The risk assessment component of the scheme is divided into two sections: a preliminary assessment and a detailed risk assessment. The preliminary assessment consists of 14 yes or no questions to determine if further risk analysis is required. The detailed risk assessment scheme contains 51 questions designed to assess the potential for entry and establishment, the capacity for spread, and the economic, environmental or social impacts.

Specialized modules have been developed to assist in determining the relative weighting of invasive attributes, entry pathways, vulnerability of receptors, and the consequences of implemented policies (Figure 2). Within each module, guidance is provided on how to determine the level of uncertainty. For example, in the economic loss module, an adapted table from Standards Australia and Standards New Zealand (2004) is used to assign a score of 1-5 on the likelihood of impacts occurring within a given frequency ranging from 1 in 10,000 years to once a year (very unlikely to very likely, respectively). The likelihood rating is combined with an impact level (minimal, minor, moderate, major and massive) to derive the final risk conclusion (Table 9). A likelihood rating (likely, possible, unlikely, and very unlikely) is combined with an impact level (minimal, minor, moderate, major and massive) to derive the final risk conclusion. One of five levels of response (from very low to very high risk) and one of three levels of uncertainty (low to high) are assigned in each assessment, and each ranking is justified with a written and referenced comment. In the final module, scores are summarized using a five point ordinal scale ranging from very low (0) to very high (4) under each major heading (entry, establishment, spread, impact) to determine the aggregated measures of risk.

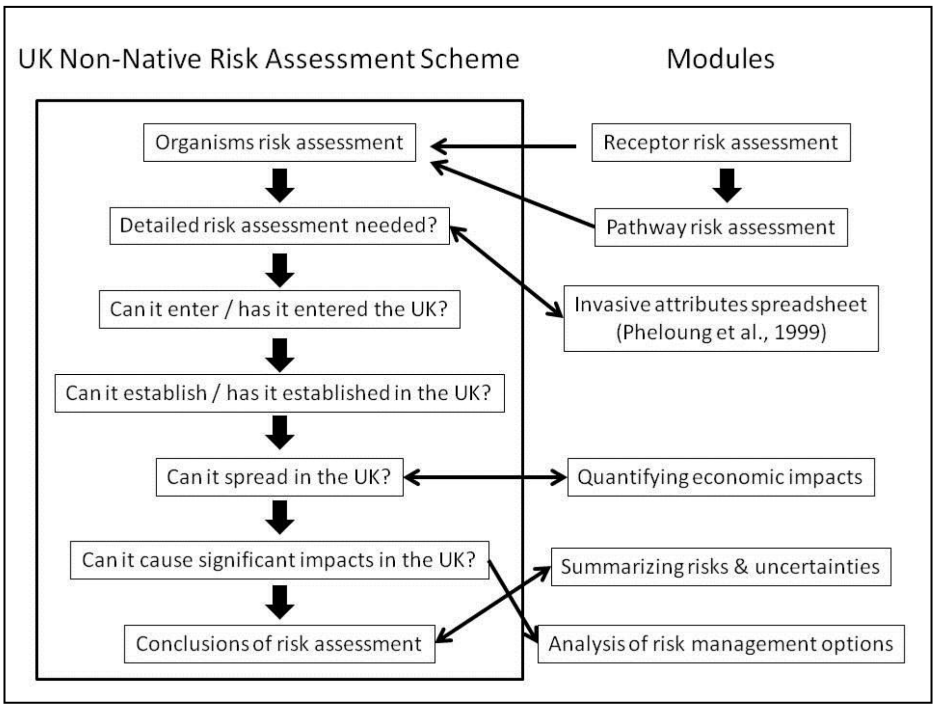


Figure 2: UK risk assessment scheme (Baker et al., 2008).

Table 9: UK risk assessment scheme uncertainty table (Baker et al., 2008).

Likelihood Class	Uncertainty				
	Minimal	**Minor**	**Moderate**	**Major**	**Massive**
Very unlikely	Negligible	Negligible	Justifiable (low)	Justifiable (low-med)	Justifiable (med -high)
Unlikely	Negligible	Justifiable (low)	Justifiable (low-med)	Justifiable (med -high)	Justifiable (high)
Possible	Justifiable (low)	Justifiable (low-med)	Justifiable (med -high)	Justifiable (high)	Unacceptable
Likely	Justifiable (low-med)	Justifiable (med -high)	Justifiable (high)	Unacceptable	Unacceptable
Very likely	Justifiable (med-high)	Justifiable (high)	Unacceptable	Unacceptable	Unacceptable

Scores are then treated as probabilities to overcome the impact that extreme scores have when calculating an average. When uncertainty is high, scores tend to center on the mid-point and averaging can have a diluting effect on the extreme responses. Baker et al. (2008) argue that by calculating the conditional probability, the levels of uncertainty are better accounted for since mid-point scores have no effect on the outcome, and progressively higher weight is given to scores as they diverge from the mid-point. Using examples, it was shown that when expert judgment is used, the probability calculation provided increased discrimination and accuracy of the assessor's judgment of risk, when compared with taking the average score.

The risk assessment scheme has adapted methods that are well refined and based on internationally recognized assessment protocols for the assessment of freshwater fish, invertebrates and amphibians. The assessment itself takes into consideration all components and potential areas of impact following invasion, however the terms used to rank risk and uncertainty are poorly defined, and the automated risk calculation is not transparent (Verbrugge et al., 2010).

2.7. RISK ANALYSIS AND PRIORITIZATION FOR INVASIVE AND NON-NATIVE SPECIES IN IRELAND AND NORTHERN IRELAND

Protocols for conducting risk analysis of non-native species in Ireland and Northern Ireland are divided into two primary components (Kelly et al., 2013): prioritization risk assessment to develop the understanding and relative risk associated with an array of species, and a detailed assessment of risks and uncertainties associated with each species of concern. The prioritization assessment is typically used to provide information to governmental agencies to assist in decisions and actions to be undertaken. The more detailed risk assessment is designed to support trade restrictions and legislative developments through understanding overall risks and possible mitigation options (Kelly et al., 2013).

The prioritization risk assessment consists of ten questions designed to determine relative risk by accounting for establishment success, spread potential, suitability of habitats, propagule pressure, invasion history, vectors and pathways. A risk rating score of low, medium or high is assigned with reference to published evidence. Separate assessments have been conducted based on whether the species has already been detected in Ireland or if it is a potential invasive species. In the latter case, the likelihood of arrival, ability to survive, spread and impact the conservation goals and economy of an area are assessed, scores are added, and the species is assigned to a low, medium or high risk category.

Sources of uncertainty are identified in individual assessments by including the source of uncertainty as a distinct component of the questionnaire. Overall data availability is also used to judge the level of confidence in the assessment conclusion using the following uncertainty rankings (Kelly et al., 2013):

- **Documented**: Reliable documented evidence to support the assessment is available. Relevant references are added to the reference database.
- **Expert Opinion**: The assessor's knowledge of a species, or that of an identified expert, provides sufficient information to support an assessment.
- **Probable**: The evidence consulted or the species characteristics indicate that the described impact could reasonably occur in Ireland or Northern Ireland.
- **Uncertain**: There was insufficient evidence to confidently assess the species.

Unfortunately, the development of the scoring system and weighting of factors in the prioritization risk assessment are not clearly explained, and the boundaries of the low, medium and high risk rating scores appear to be arbitrary. Explicit details on how to incorporate uncertainty or minimize uncertainty is not provided.

2.8. GERMAN-AUSTRIAN BLACK LIST INFORMATION SYSTEM

The German-Austrian Black List Information System (GABLIS) was developed by Essl et al. (2011) and is designed to assess the risk that invasive aquatic species pose to native biodiversity. In the GABLIS, invasive species are assigned to one of three main categories, White, Grey or Black lists, based on potential risk (Figure 3). The Black and Grey lists are divided into sub-lists according to the distribution and eradication measures available and certainty of the assessment, respectively.

The threat to native biodiversity provides the basis of assignments to a category. The threat is assessed using five main criteria that provide confirmation of negative impacts by 'yes' or 'no' responses if there are sufficient scientific data to substantiate the responses. If there are not enough data or if contradictory data exist, but it remained probable that the introduction of the species may have adverse impacts, the conclusion 'evidence-based assumption' is assigned. The conclusion 'unknown' is used for cases where data are missing or background knowledge of the species is highly incomplete. The allocation to a list is based on the precautionary approach, i.e., if there is at least one criterion with a positive response, then the species is assigned to the Black List.

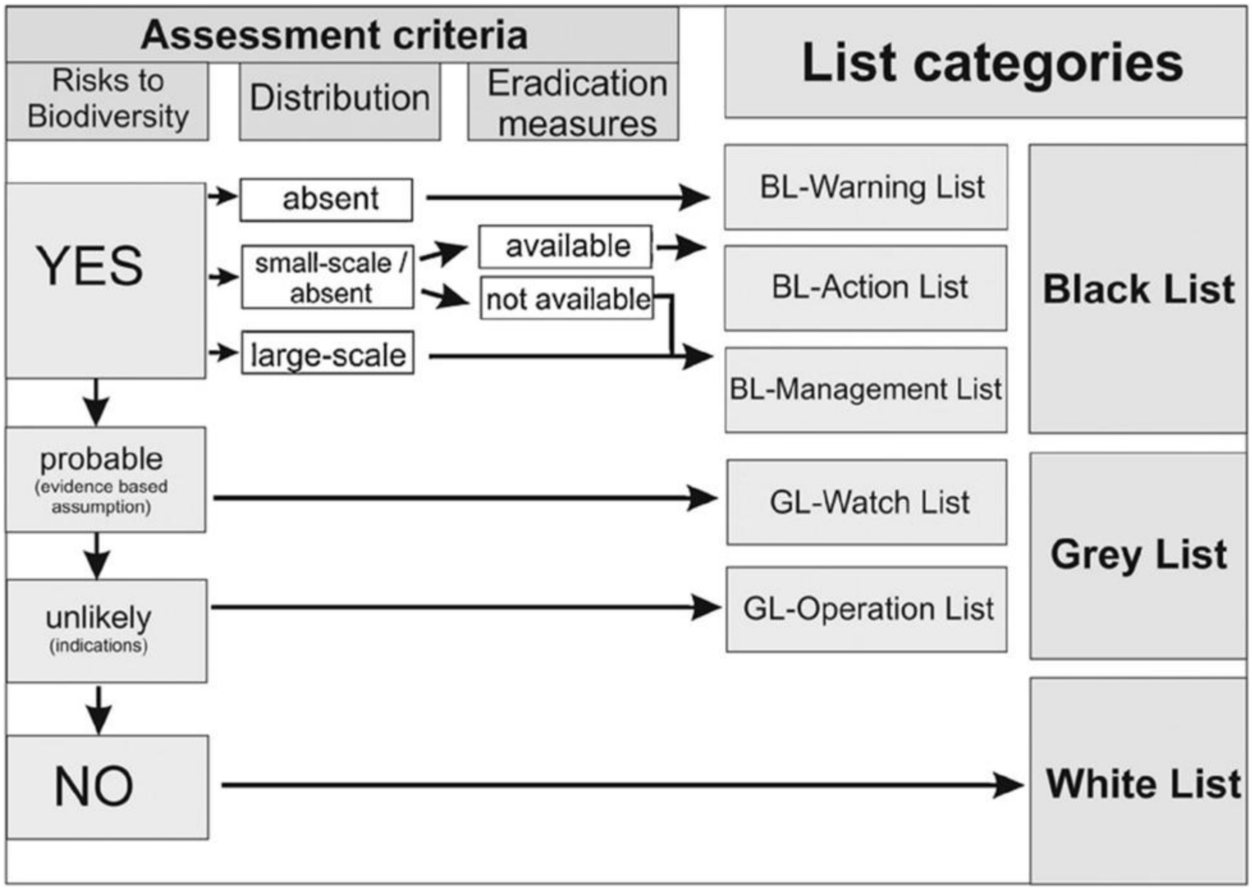


Figure 3: List of major categories and subdivisions used in GABLIS (Essl et al., 2011).

Uncertainty plays a role in the assignment of species. For example, when there are no ‘yes’ responses and at least one ‘evidence-based assumption’ response, the species is assigned to the Grey List. Further, even if there is only one ‘unknown’ response and the rest are “no”, the species is assigned to the Grey List Watch List or the White List. If all criteria are assessed with ‘no’, the alien species is assigned to the White List.

The GABLIS protocol recognized that data used for the assessment may have originated from a range of sources. These sources have varying degrees of reliability, including scientific reports and peer-reviewed publications, but also expert judgment and referrals to ecologically similar areas or surrogate species. The transfer of experience gained from invasion in climatically and ecologically similar areas provides an opportunity to determine risk for alien species not yet present, or that are just beginning to spread. The increased uncertainty associated with these scenarios was accounted for by placing alien species for which negative impacts on biodiversity are insufficiently known on the Grey List.

The manner in which the GABLIS guideline is structured with ‘yes’ or ‘no’ answers makes it easy to follow and understand. The assignment of species to different lists provides a clear indication of management options and helps ensure that a precautionary approach is followed. The GABLIS does not, however, incorporate economic or health impacts. In addition, some of the criteria used are not specific and may require detailed data or high levels of expertise to effectively carry out the assessment (Verbrugge et al., 2010).

2.9. EUROPEAN UNION GUIDANCE DOCUMENT ON THE ECOLOGICAL RISK ASSESSMENT OF GENETICALLY MODIFIED ANIMALS

In 2013, the European Union (EU) published the Guidance Document on the Environmental Risk Assessment of Genetically-Modified Animals, with a focus on living GM animals to be placed on the EU market according to Regulation (EC) No. 1829/2003 or Directive 2001/18/EC. These guidelines provide the rationales for data requirements for a comprehensive Environmental Risk Assessment (ERA) assessing the potential adverse effects that GM animals may have on the environment and human and animal health (EFSA GMO Panel, 2013).

A number of areas of risk are considered for GM fish, insects, mammals and birds, including:

- Persistence and invasiveness of the Genetically Modified (GM) animal, including vertical gene transfer (VGT);
- Horizontal gene transfer;
- Interactions of the GM animal with target organisms;
- Interactions of the GM animal with non-target organisms (NTOs);
- Environmental impacts of the specific techniques used for the management of the GM animal;
- Impacts of the GM animal on biogeochemical processes; and
- Impacts of the GM animal on human and animal health.

The risk assessment process includes problem formulation, hazard, exposure and risk characterization, management and overall risk evaluation (Figure 4).

The magnitude of hazard is defined as the qualitative and/or quantitative evaluation of environmental harm. It may be expressed in a quantitative rather than qualitative manner and ordered using categorical descriptors from negligible, low, moderate and high. In cases where it is not possible to show an adverse effect in a particular environment, the risk is considered negligible or insignificant.

Exposure characterization is used to estimate the likelihood of adverse effects following the identification of direct and indirect routes of exposure. Here, the assessment is to be related to the intended use of the GM animal and its level of release.

If possible, the likelihood could be characterized in a quantitative manner providing a relative measure of probability from 0 to 1, where 1 is a high level of certainty. As there are often limited data available to accurately estimate the likelihood of occurrence, potential exposure can be qualitatively expressed using ordered categorical descriptions similar to those used in the hazard characterization, ranging from negligible to high.

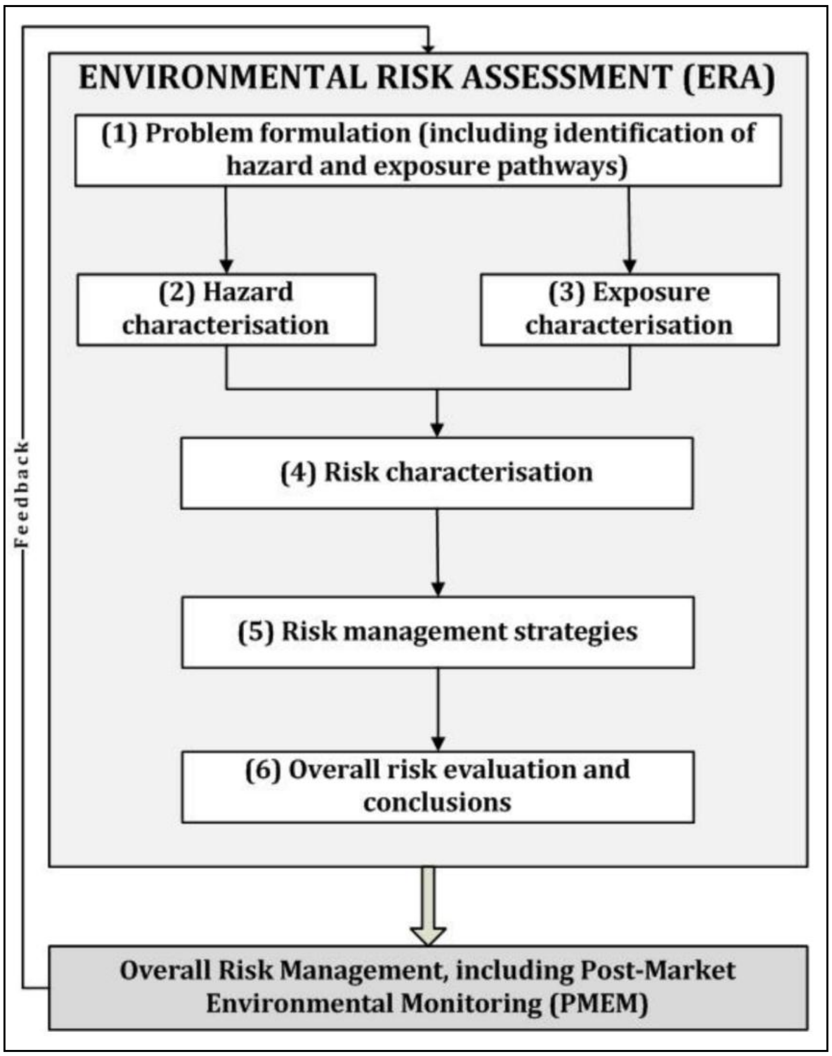


Figure 4: Stages of the EFSA environmental risk assessment (EFSA GMO Panel, 2013).

When using qualitative terms, a link between likelihood and probability of occurrence has been provided based on a numeric scale of 0 to 1 indicating the range for the term chosen. The hazard and exposure estimates are then combined to characterize risk. Risk may be described as a quantitative or semi-quantitative estimate of the probability of occurrence and magnitude of harmful effects.

Throughout the risk assessment, sources and types of uncertainty are identified for each scientific output in addition to descriptions of their relative importance and influence on the outcome. For each identified risk, an overall assessment and analysis of uncertainty is conducted and properly communicated. The formal analysis addresses the main sources of uncertainty, including linguistic, variability and incertitude. The guidelines reference Burgman (2005), Kapuscinski et al. (2007) and Hayes (2011) as guides for suitable approaches to assess uncertainty, but with no clear indication of which methods or techniques would be best to follow.

The EFSA guidelines and supporting Directive 2001/18/EC document provide clear suggestions on the use of comparators and non-GM surrogates that are not found in other guidelines. In addition, in-depth descriptions on cross-cutting considerations are provided, including how to assess experimental design in GMO experiments, statistical analyses, long-term effects and uncertainty analyses. A wide range of areas are considered in the assessment, however, the socio-economic impact of GMOs is not incorporated. Endpoint definitions used in the assessment, including reproductive, developmental, and phenotypic effects, are ambiguous and open to interpretation.

2.10. AUSTRALIAN RISK ANALYSIS FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS

The Risk Analysis Framework was published in November 2013 by the Department of Health and Ageing, Office of the Gene Technology Regulator (OGTR, 2013). The guidelines provided by this document fall under the Gene Technology Act 2000 and the Gene Technology Regulations 2000 and were based on the Australian and New Zealand Standard 4360:2004 on Risk Management.

Risk assessments in the area of genetically-modified organisms may be based on both qualitative and quantitative data. The risk assessment has three steps including hazard identification, consideration of the likelihood and severity of an adverse outcome (consequences), and risk estimation to determine the probability that potential harm would be realized. The risk estimate is a combination of the likelihood and consequences of an adverse outcome but also incorporate consideration of uncertainty. In cases where qualitative assessments are conducted, precautions to avoid specific weaknesses typically associated with these types of assessments are suggested. Specifically, the precautions aim to reduce ambiguity through the use of defined terminology, variation between assessors through quality control measures such as internal and external reviews, and biases through the use of clear descriptions of what is being protected by the Act.

Risk is estimated by combining the likelihood that a hazard will occur and the seriousness of the adverse outcomes (Table 10). Each are rated using prescribed terminology to reduce ambiguity. The likelihood assessment is rated in one of five categories, from highly unlikely to highly likely. The consequence assessment is rated in one of four categories, from marginal to major in terms of the negative impact on individuals or biological and physical disruption of ecosystems, communities or species.

Table 10: Australian risk matrix to determine level of risk (OGTR, 2013).

Likelihood Assessment	**Level of Risk**			
Highly likely	Low	Moderate	High	High
Likely	Low	Low	Moderate	High
Unlikely	Negligible	Low	Moderate	Moderate
Highly unlikely	Negligible	Negligible	Low	Moderate
	Marginal	**Minor**	**Intermediate**	**Major**
	Consequence Assessment			

The guidelines suggest that the risk assessment process identify sources of uncertainty encountered in determining the likelihood and consequences of risk. A list of uncertainties often encountered in conducting risk analysis of GMOs that should be considered, including epistemic, descriptive, cognitive, complexity and intrinsic uncertainties, are provided. However, the guidelines do not provide clear methods for dealing with uncertainty in the risk assessment. Though the risk framework provides clear definitions of potential levels of harm to health and the environment, linguistic uncertainty is present in the definitions of the likelihood assessment scale and may be subjective.

3.0. REVIEW OF METHODS FOR THE ANALYSIS OF UNCERTAINTY

Decisions on complex environmental issues are made through an evaluation and analysis of the potential magnitude and consequences a stressor may induce. Such decisions are often made with limited empirical data and system understanding thereby creating a considerable amount of uncertainty. In risk analyses involving invasive species or genetically-modified organisms, it may be difficult to estimate uncertainty using strictly quantitative methods. However, a range of qualitative tools and techniques are available and may be used to understand the relative level of uncertainty regarding estimates of risk.

One major issue with qualitative risk analyses is that they have a high level of linguistic uncertainty and do not address uncertainty arising from incertitude and variability (Hayes, 2007). Quantitative risk assessment can also suffer from linguistic uncertainty, but explicitly incorporates variability and incertitude (Hayes, 2007). Regardless of the method selected to determine uncertainty, there are criteria that should be met to ensure that the analysis is effective. The method should be clear, reproducible, presented in a manner which decision-makers can easily understand and highlight uncertainties that may impact the decision making process.

Though there is a large amount of literature on quantitative uncertainty analysis methods, only in the past decade has there been increased focus on subjective or preference-driven risk analysis methods (Sikder et al., 2006; Knol et al., 2010). In this chapter, we review methods that may be used in a qualitative or semi-quantitative uncertainty analysis for invasive species and genetically-modified organisms.

3.1. UNCERTAINTY MATRIX

An uncertainty matrix is a tool that can be used to identify and prioritise important sources of uncertainty in an assessment (Refsgaard et al., 2007). One of the advantages of an uncertainty matrix is that it provides a graphical overview of the sources of uncertainty that may impact the decision-making process (Walker et al., 2003). In addition, an uncertainty matrix captures both quantitative and qualitative aspects and provides an analysis of complex environmental policy issues (van der Sluijs et al., 2005). As a result, various forms of uncertainty matrices are often suggested for use by regulatory agencies in qualitative or semi-quantitative risk assessments.

In an uncertainty matrix, the sources of uncertainty are listed as well as the level and type (e.g., variability or incertitude) of the uncertainty. A template of an uncertainty matrix is provided in Table 11. As highlighted by Walker et al. (2003), the level of uncertainty can be viewed as a “continuum of uncertainty” ranging from total ignorance to full knowledge or determinism of the given phenomenon.

Table 11: Uncertainty matrix (Walker et al., 2003; Refsgaard et al., 2007).

Source of Uncertainty		**Level of Uncertainty**				**Type**	
		Statistical	**Scenario**	**Qualitative**	**Ignorance**	**Epistemic**	**Stochastic**
Context	Natural, technological, economic, social, political						
Model	Model structure						
	Technical model						
	Parameters						
Inputs	Driving forces						
	System data						
Outcome							

The matrix represents a complete inventory of sources of uncertainty, their level and type, and can be used to determine which sources are priorities for further data collection. The importance of each source of uncertainty on the overall assessment can be assigned a weighting. When the uncertainty matrix is first developed, not all sources of uncertainty or their weightings may be evident. As a result, the matrix will likely need updating as data collection, information gathering and the risk assessment progress (Refsgaard et al., 2007; Walker et al., 2003).

The development and interpretation of the uncertainty matrix is relatively straightforward. One of the drawbacks of using an uncertainty matrix, however, is the reliance on expert judgement. Expert judgment can be biased, unreliable, or value laden. The matrix can be used in conjunction with other uncertainty assessments to minimize the impact of these subjective components (Carey et al., 2005). Typically, the results in the matrix are expressed linguistically to provide meaningful details of the location of uncertainty and, depending on the structure of the matrix, management options. Coding can also be used to easily identify relevance or location of uncertainty sources (e.g., A = critical, B = important, C = negligible). Additional tables can be used to provide further explanation of the terms used in the matrix and may include references to the literature.

3.2. EXPERT ELICITATION

When there is a paucity of data to conduct quantitative assessments, one may consult with experts to inform decisions (Sikder et al., 2006; Hetes et al., 2011). Expert elicitation methods have been used in the development of risk models for invasive species (Maguire, 2004; Sikder et al., 2006).

Expert opinion can be used throughout the risk assessment process to pass judgments on qualitative rating categories (Maguire, 2004). Such judgments are typically associated with a large amount of uncertainty, primarily due to language-based uncertainties. Maguire (2004) provides an example of where differences in values and interpretation of language could lead to significant changes in responses from experts. For instance, consider the question of whether an invasive pest is “expected to cause significant direct environmental effects such as extensive ecological disruption or large-scale reduction in biological diversity”. Although the question appears straightforward, what can be considered to be “significant”, “extensive” or “large-scale” varies between individuals based on personal definitions, experience and knowledge of the topic (Maguire, 2004).

Systematic protocols have been developed to improve the quality, reproducibility and transparency of the use of expert judgments and opinions (Morgan and Henrion, 1990; Refsgaard et al., 2007; Knol et al., 2010; Hetes et al., 2011). Expert elicitation represents a formal systematic process that enables the probabilistic quantification of expert judgments about uncertain quantities (Hetes et al., 2011). The methodologies used in the application of expert elicitation are flexible and, as a result, the design for each expert elicitation requires professional judgment. The US EPA (Hetes et al., 2011) has provided a number of elements of good practice including:

- Clear problem definition;
- Appropriate structuring of the problem;
- Appropriate selection of experts to conduct the elicitation;
- Protocol development and training, including considering group processes and methods to combine judgments when appropriate;
- Procedures to check expert judgments for internal consistency;
- Clear and transparent documentation; and
- Adequate peer review.

Suggested steps to perform a formalized expert elicitation were prepared by Knol et al. (2010) for integrated environmental health impact assessments (Figure 4). These steps can be generalized and others have suggested similar methods (Refsgaard et al., 2007).

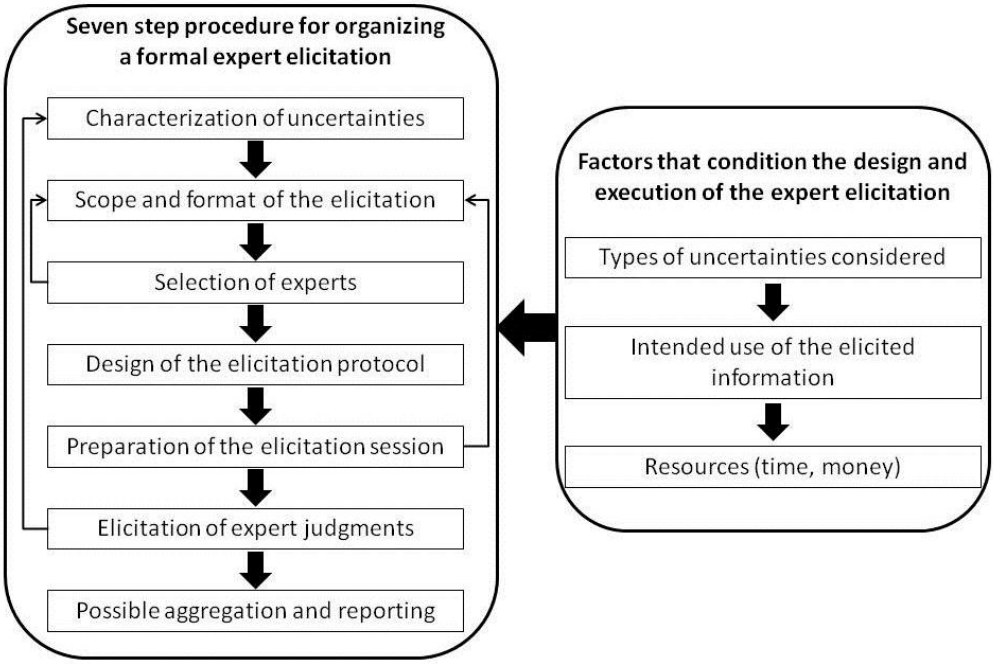


Figure 5: Seven step procedure for formal expert elicitation (Knol et al., 2010).

The number of experts required in a reliable expert elicitation depends on the complexity of the problem, financial constraints, availability of experts and desired range of perspectives (Hetes et al., 2011). Theoretical models suggest that the ideal number of experts is between six and 20, with more experts required when substantial differences in opinion develop (Hogarth, 1978; Cooke and Probst, 2006). Using a greater number of experts may provide marginal returns (Clemen and Winkler, 1985). An informal review of expert elicitation investigations showed that the majority used 11 experts or less (Walker, 2004). Information from experts can be elicited via interview or by survey (Knol et al., 2010). A critical step of the procedure is designing the elicitation protocol. The protocol contains the questions and determines the desired format (i.e., quantitative or qualitative estimates) for the answers.

The degree of belief an expert has in their response can be represented as a subjective probability density function. Though responses from individual experts will vary due to differences in background information, interpretation of the linguistic description and fundamental disagreements, the consistency of the experts can be examined. One method to measure consistency is to include seed variables in the questions asked. The performance on these specific questions can then be used to assess the overall performance on the variables of interest. Internal consistency can be measured by having experts comment on one outcome in two or more different ways (Tversky and

Kahneman, 1981). For more detailed descriptions of recommended protocols for expert elicitation, please refer to Knol et al. (2010), Hetes et al. (2011) and Wittmann et al. (2014).

Expert elicitation provides a formalized method for gathering information and knowledge that would otherwise not be available. However, there are shortcomings associated with this method. Common shortcomings include low reliability of opinions, uncertainty due to different interpretations of the language used in both the questions and responses, and the possibility of a general lack of knowledge of specific topics among experts (Knol et al., 2010). Overall, this method provides a means to identify areas of uncertainty and, in some cases, appropriate management strategies that otherwise may not be incorporated into the assessment.

Case Study: Using Structured Expert Judgment to Assess Invasive Species Prevention

In this case study, Wittmann et al. (2014) used expert elicitation to quantify the uncertainty of the effectiveness of various strategies aimed at preventing the invasion of Asian carp into the Great Lakes.

A structured, performance-based method to elicit and aggregate expert judgments was used based on procedures developed by Cooke (1991). Eleven experts were selected based on their expertise in fisheries biology and specific experience in the Great Lakes or Asian Carp species, or both. Following the selection process, prospective experts received an elicitation questionnaire, background information about the methods involved in expert elicitation, the Great Lakes and carp.

In-person interviews were conducted where experts were asked to quantify their response as the 5th, 50th and 95th percentiles of their subjective probability distribution. Of the 84 questions asked, 20 were calibration questions (i.e., seed variables) that originated from the experts' field. The calibration questions were included to provide a basis for a performance score. Information scores were determined by the width of the confidence band of a given expert and showed the degree to which experts' distributions were concentrated relative to background measures. The authors subsequently calculated the product of the calibration and information scores to provide a weighting that was assigned to each expert (see Wittmann et al., 2014 for further details).

The results of the investigation showed that hydrologic separation of the Mississippi River and the Great Lakes basin was considered the most effective prevention strategy. In addition, the uncertainty ranges for hydrologic separation approach were smaller when compared to any other prevention strategy, which indicated a high level of certainty among the experts. Electric barrier and the acoustic-bubble-strobe combination of deterrent technologies were rated to be similar in effectiveness, though the latter had a wider uncertainty range. Through the use of expert elicitation, the authors were able to provide additional information to increase the effectiveness of future risk assessments and aid in the decision making.

3.3. FAULT TREE ANALYSIS

Fault tree analysis is a graphical hazard and risk assessment tool that can be used to identify a pathway of events that lead to the occurrence of a hazard (Hayes, 2002; Dana et al., 2013). This technique allows for the formalization of conceptual models by identifying the occurrence (or non-occurrence) of other events (Bedford and Cooke, 2001; Acosta and Forrest, 2009). Two logical functions are used, an “AND” gate and an “OR” gate (Hayes, 2002). The “AND” gate provides the intersection of events attached to the gate and can have a number of inputs associated with it. However, all preceding conditions must be met for the event above the gate to be realised (Hayes, 2002; Hayes et al., 2013). The “OR” gate represents the union of events and can have a number of branches running into it. Only one preceding condition needs to be met for the gate to be realized (Hayes, 2002; Hayes et al., 2013). An example of a fault tree analysis is presented in Figure 5, with an explanation of the symbols in Figure 6 (Hayes, 2002).

The tree structure used for the analysis is often constructed with the top event representing the risk assessment endpoint (Hayes and Hewitt, 1998). A number of symbols are used to construct a fault tree analysis. In the example provided in Figure 6, the risk assessment endpoint would be the successful infection of the port that receives the ballast water from a vessel (i.e., the recipient port). For a successful infection to occur, two functions must be met:

- A viable pest is discharged into the recipient port; AND
- The pest is able to survive in the recipient port

Similar assessments are made for each gate. The fault tree analysis helps ensure the analyst takes into consideration all possible mechanisms for the assessment endpoint to occur in a transparent graphical depiction that is relatively easy to interpret. In addition, the construction and analysis of the tree can help identify possible mitigations that will minimize risk. An additional advantage of the fault tree method is that, if data are available, probabilities of specific steps can be added and used to quantify the overall probability of the risk assessment endpoint occurring (Hayes et al., 2013).

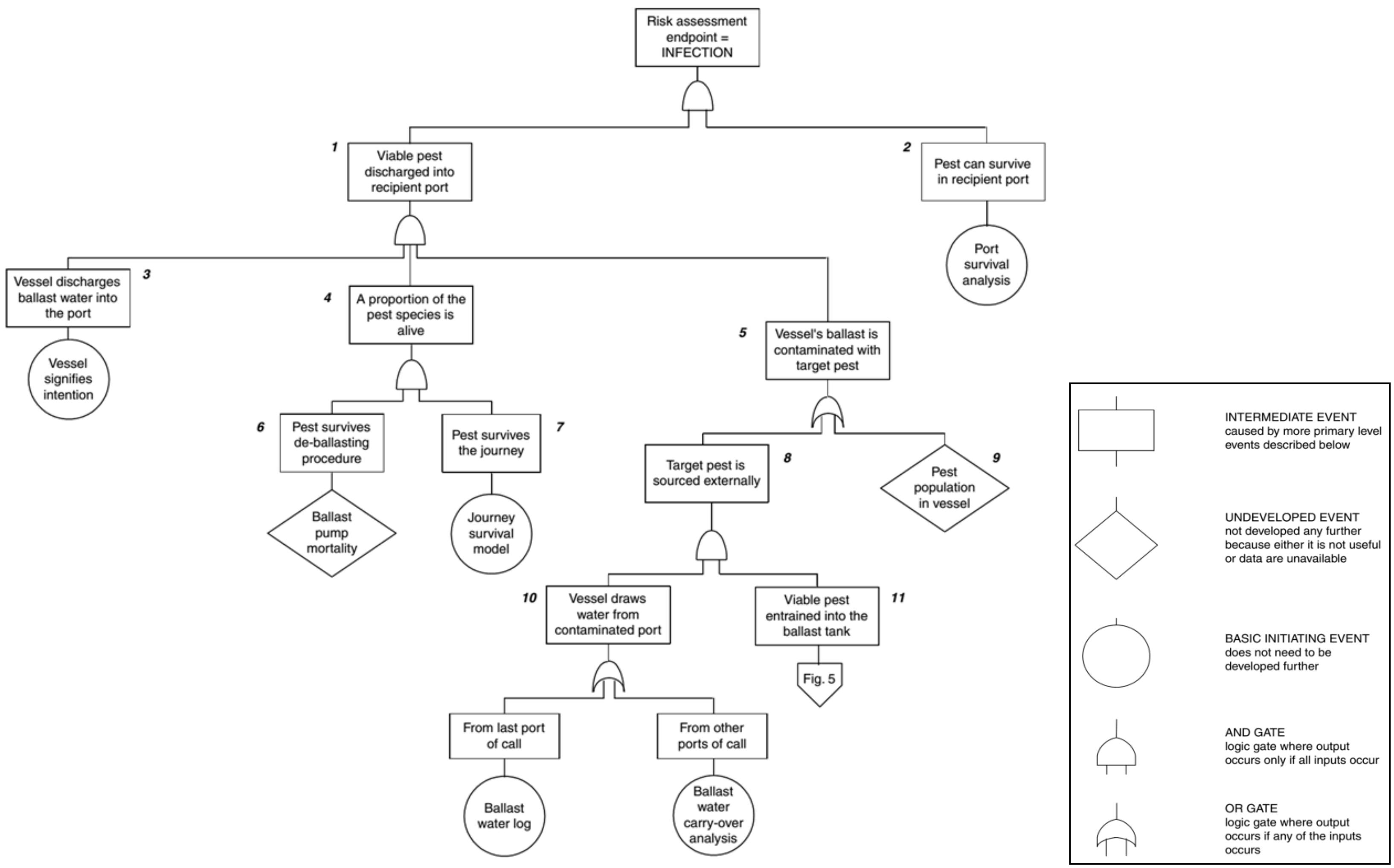


Figure 6: Fault tree analysis used to assess ballast-water introductions of non-indigenous species (Hayes, 2002).

Fault tree analysis has some drawbacks. For example, the utility of the analysis depends on the expertise of assessors. If there is limited knowledge of the system, pathways that may lead to the occurrence of the endpoint may be omitted. To address this issue, it is possible to use expert elicitation techniques to identify and prioritize hazards (Dana et al., 2013). Fault tree analysis represents a snapshot of the system of interest. The logical functions (i.e. AND, OR) do not provide an opportunity to fully capture the importance of time-dependent variables, which are often pivotal in biological systems. As a result, fault tree analysis may be viewed as a heuristic exercise and a precursor to a more rigorous risk assessment (Hayes, 2002).

The results of the fault tree analysis depend on the amount of data available to incorporate into the model. If sufficient data are available, the output can represent an overall probability that the top event will occur. If fewer data are available, the analysis can identify potential locations of uncertainty that need to be accounted for in the risk assessment.

Case Study: The Spread of Marine Non-indigenous Species via Recreational Boating

The purpose of this investigation was to develop a conceptual model that would examine the consecutive steps required for non-indigenous species to be introduced in marine environments via recreational vessel movements (Acosta and Forrest, 2009). The authors used a fault tree analysis in conjunction with expert elicitation to characterize potential invasion pathways. A panel of experts was used to ensure the model was comprehensive and did not omit potential hazards.

A series of fault trees was first developed that showed the events preceding the release of a non-invasive species from an infected vessel into a new area. The trees were then integrated into an initial conceptual model. Personal observations, interviews and surveys of recreational boat owners were used to determine which events would be incorporated into the model. Expert elicitation was then used to refine the model. An initial introductory exercise was provided to the panel of ten experts. This exercise provided an explanation of fault tree analysis techniques as well as background information regarding the issues of non-indigenous species invasions. Experts were then asked to analyze the model and incorporate any changes considered necessary to ensure that the framework was comprehensive and accurate. Following this revision, suggestions and comments from an additional six marine scientists and five recreational vessel owners were incorporated into the model. Efforts were made throughout the process to reduce linguistic uncertainty generated by ambiguity, under specificity and context dependence.

A section of the final model is shown in Figure 7, and represents the introduction of a non-indigenous species (“S”) present in area “Y” and could potentially be introduced to area “Z”. The authors point out that though the model includes the arrival and survival of the species in area “Z”, the primary focus of the model was on the release process. For area “Z” to become infected with species “S”, the following three events must occur:

- Species S arrives in Area Z; AND
- Species S is released into Area Z; AND
- Species S survives in Area Z

Additional fault trees are provided that depict the release of species “S” in area “Z” from a number of different origins, including the hull, deck, internal spaces, anchor and fishing gear (for detailed accounts of these analyses, see Acosta and Forest, 2009). The investigation then provides specific invasion scenarios to demonstrate the applicability of the model by using the realized or potential release and establishment of non-indigenous organisms in the region.

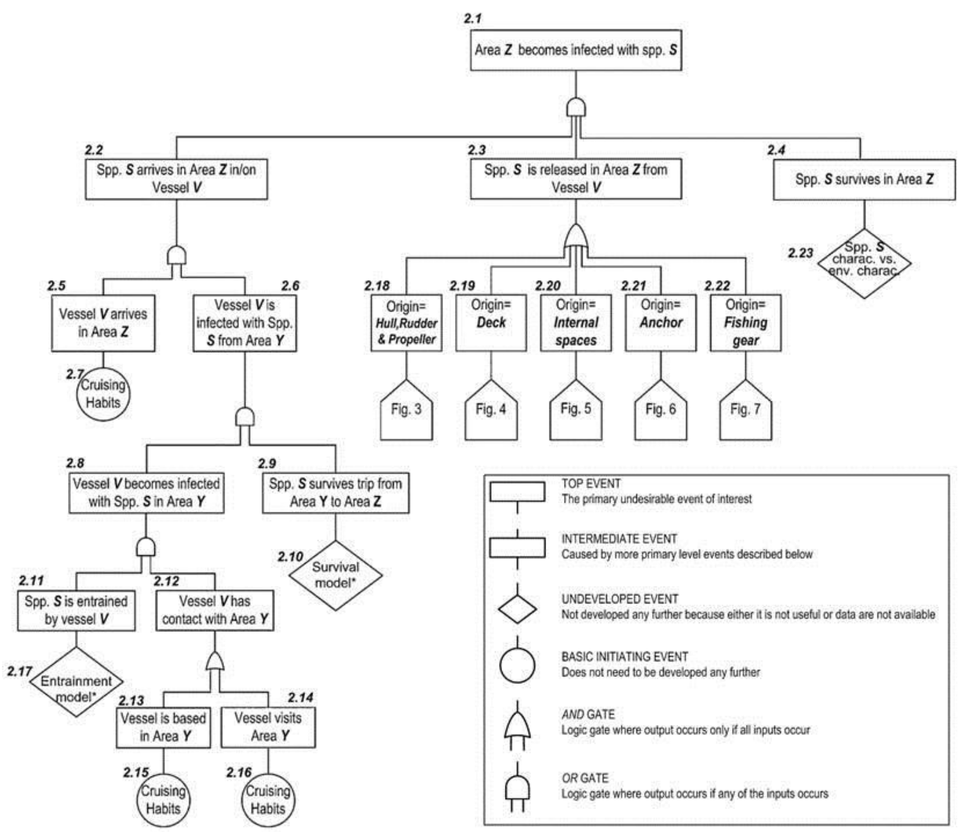


Figure 7: Example of fault tree analysis used to assess the spread of marine non-indigenous species via recreational boating (Acosta and Forrest, 2009).

Through the use of fault tree analyses, the authors were able to develop a conceptual model that provided a framework for assessing ecological risks and mechanisms that could contribute to the invasion of non-indigenous species. The complexity of the issue was made evident through the use of the fault tree analysis. This complexity would need to be taken into account for future management programs to be successful.

3.4. NUSAP METHOD

The NUSAP method has been used as a systematic qualitative approach to assess uncertainty in environmental risk assessments (van der Sluijs et al., 2005). The method provides an assessment of both quantitative and qualitative dimensions of uncertainty using the various aspects of the NUSAP acronym as defined by van der Sluijs et al. (2005):

- Numeral: typically a number but can also represent a general quantity (i.e., “a million is not the same as the number lying between 999,999 and 1,000,001”)
- Unit: the conventional unit, but could also provide additional information
- Spread: similar to statistical variance in the statistical sense and can be conveyed as ±, %, or factors. Methods to address spread can be statistical data analysis, sensitivity analysis, or Monte Carlo analysis, possibly in combination with expert elicitation
- Assessment: qualitative judgments about the information and can range from a numerical value to qualifiers of the numerical estimates such as “optimistic” or “pessimistic”
- Pedigree: uses qualitative expert judgment to assess the process and different phases in which information was obtained and knowledge developed.

Uncertainty related to numerical values is addressed by providing insight into the spread (i.e., inexactness) and strength (i.e., methodological and epistemological limitations of the underlying knowledge base) (van der Sluijs et al., 2005; Refsgaard et al., 2007). The assessment of pedigree can also integrate societal dimensions of uncertainty (Refsgaard et al., 2007). To effectively code qualitative expert assessments, a pedigree matrix can be used for varying criteria. This matrix contains criteria to represent the critical components used in the knowledge base development. To help minimize arbitrariness and subjectivity in measuring strength, expert assessment for each criterion will be entered on a scale from zero to four (weak to strong). Linguistic descriptions of each level are provided as guidance on the scale. An example of a pedigree matrix that was developed to address assumption in model-based environmental assessments is provided in Table 12 (Kloprogge et al., 2011).

Table 12: Example of a pedigree matrix used in the assessment of a value-laden assumption (Kloprogge et al., 2011).

Value type		Practical	General epistemic		Disciplinary-bound epistemic	Socio-political		**Influence on results**
Criterion		Influence of situational limitations	(Im)plausibility	Choice space	(Dis)agreement among peers	(Dis)agreement among stakeholders	Sensitivity to view and interests of the analyst	
Score	***2***	Choice assumption hardly influenced	The assumption is plausible	Hardly any alternative assumptions available	Many would have made the same assumption	Many would have made the same assumption	Choice assumption hardly sensitive	The assumption has only local influence
	1	Choice assumption moderately influenced	The assumption is acceptable	Limited choice from alternative assumptions	Several would have made the same assumption	Several would have made the same assumption	Choice assumption moderately sensitive	The assumption greatly determined the results of the step
	0	Totally different assumption had there not been limitations	The assumptions are fictive or speculative	Ample choice from alternative assumptions	Few would have made the same assumption	Few would have made the same assumption	Choice assumption sensitive	The assumption greatly determined the results of the indicator

Another example where a pedigree matrix was used can be found in the Guidelines for Environmental Risk Assessment and Management (Green Leaves III) by the UK Department for Environment, Food and Rural Affairs (Gormley et al., 2011).

Using the example of the pedigree matrix produced by Kloprogge et al. (2011), assumptions that would lead to a low score have increased potential to be value-laden. Low scoring assumptions have an increased influence on the results of the assessment and therefore could be viewed as problematic and potential “weak links” (Kloprogge et al., 2011). Average pedigree scores can be calculated for assumptions over the number of pedigree criteria. A diagnostic diagram could then be used to visualize the assumptions based on the estimated influence of the assumption on the assessment results and the average pedigree scores. One suggested format of this diagram is shown in Figure 9, where those in the “danger zone” represent assumptions that have a high potential for being value-laden and have a significant influence on the assessment (Kloprogge et al., 2011).

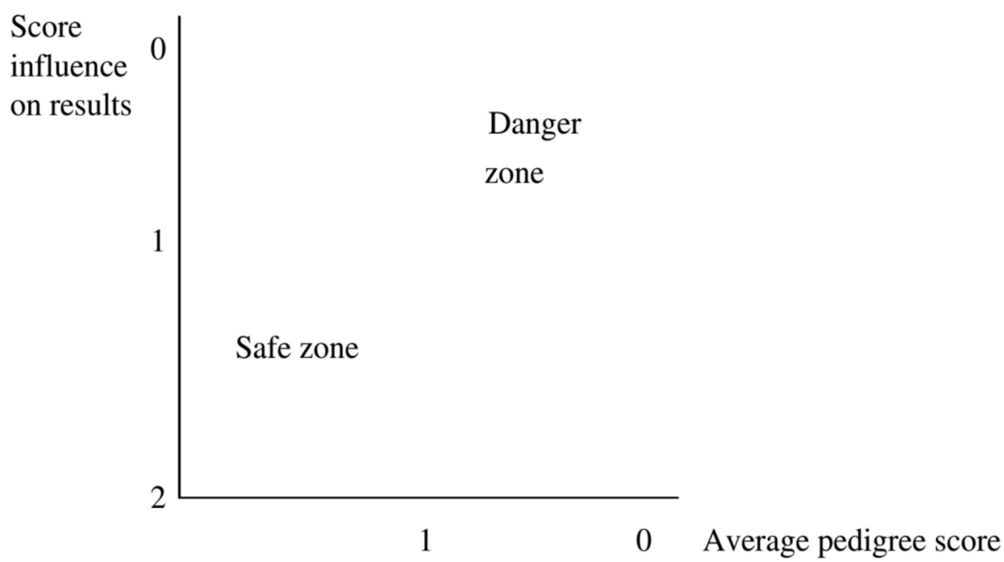


Figure 8: Diagnostic diagram used to assess potential value-laden assumptions (Kloprogge et al., 2011).

A NUSAP analysis can integrate both quantitative and qualitative uncertainty at varying levels of comprehensiveness (Refsgaard et al., 2007). However, as the pedigree scoring relies heavily on subjective judgments, the outcomes may be sensitive to the selection of experts. Using some of the methodologies outlined in expert elicitation could enhance this process as the outcome of the model could be influenced by the selection of experts (Refsgaard et al., 2007).

The results from the expert elicitation can be quantified through the use of probability density functions (see section 3.2) and scoring the results of the pedigree matrix. Monte Carlo analysis or sensitivity analysis can be used to determine overall contribution to the level of uncertainty for each variable. The outcome displayed in the diagnostic diagram is easily interpreted and quickly highlights attributes of key parameters and their overall influence on the quality of the result.

3.5. LOOP ANALYSIS

Loop analysis is also referred to as qualitative modelling and has been recommended for ecological assessments of potential hazards. The method emphasizes how the structure of a system can influence the way in which other variables respond to a perturbation through structural feedback, rather than precise species interactions (Marzloff et al. 2011; Hayes et al. 2013). Loop analysis represents an intermediate step between completely qualitative and fully quantitative models that can be used to explore the effects of stress on a given system (Orme-Zavaleta and Munns 2008). Loop analyses are most effective in the early stages of the risk analysis to help minimize the effects of linguistic uncertainty (Hayes, 2011). In addition, structural uncertainty can be propagated through the assessment (Hayes et al., 2013).

Loop analysis uses signs to designate interactions between variables that are graphically depicted as nodes. The relationship between variables is shown by sign-directed graphs. For example, a link between variables that shows an arrow (→) designates a positive interaction (e.g., births produced by consumption of prey); a line with a filled circle (—●) represents a negative effect (e.g., death from predation); and self-effects are shown as lines that originate and terminate at the same node (Marzloff et al., 2011; Hayes et al., 2013). Loop analysis considers pairwise relationships by assigning unit signs, -1, 0 or +1, to each interaction. By only using signs to describe the interactions between variables, those that are poorly quantified within a given system can also be incorporated (Orme-Zavaleta and Munns, 2008).

A perturbation on the system that results in a change to the rate of birth, death or migration of a species is defined as a press perturbation (Dambacher et al., 2002). In a fairly simple system, the impact of a press perturbation can be assessed by calculating the product of the sign of the direct effects from the impacted node to all other nodes. The influences of variables not within the direct path of the perturbation are also considered. With increased complexity in the system, such straight multiplication is not feasible. In these cases, equivalent algebraic analysis is conducted using the system's community matrix.

An example of three qualitative models and the associated community matrices are provided in Figure 9 (Hayes, 2011). Here, possible interactions between an invasive shrimp species and four components of the invaded ecosystem are assessed.

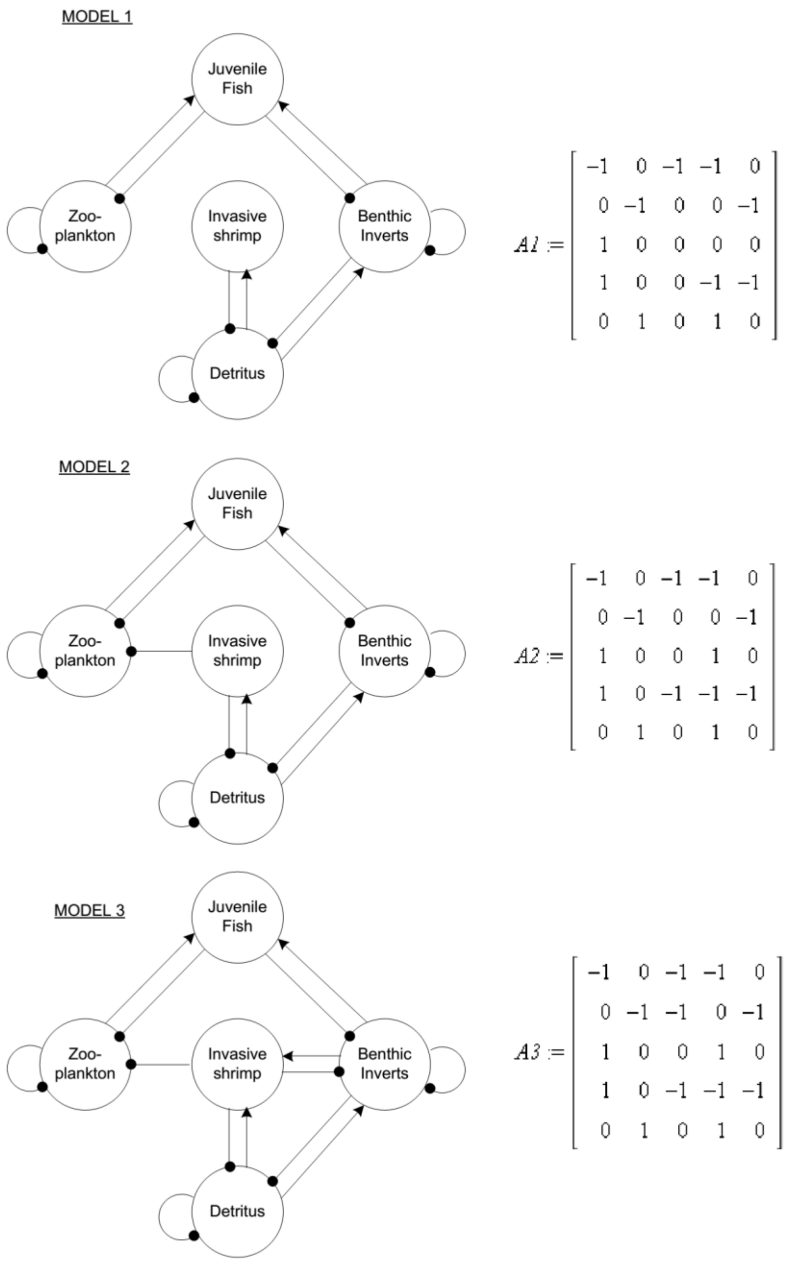


Figure 9: Three models of loop analysis and equivalent community matrix (Hayes, 2011).

The three models were used to examine different hypothesis: 1) shrimp only feed on detritus, 2) shrimp feed on detritus and competitively interfere with zooplankton, and 3) shrimp feed on detritus, benthic invertebrates and competitively interfere with zooplankton (see Hayes, 2011 for further details). The positive or negative signs in the community matrix on the right hand side of Figure 9 describe the interaction between species and their physical resource. By identifying the sources of structural uncertainty in the community matrix, it is possible to explore the directional change of any component of a community structure (Hayes et al., 2007).

In their case study, Hayes et al. (2013) discuss how loop analysis could be applied to genetic control techniques for the Common Carp in Australia. The benefits of using loop analysis with a limited understanding of a complex and variable ecosystem are discussed (Hayes et al., 2013). The signed directed graphs depicting an ecosystem model of an Australian billabong with stocking and genetic-control of non-native carp under drought conditions is shown in Figure 10. These models were developed from trophic interactions and were being used, along with fault tree analysis and Bayesian network analysis, to illustrate a risk assessment framework for genetic bio-control technologies (Hayes et al., 2013).

<u>Case Study: Exploring Ecological Shifts Using Qualitative Modelling</u>

In an investigation by Marzloff et al. (2009), loop analysis was used to help elucidate the dynamics of Tasmanian rocky-reef communities and assess the impact of fishing on these communities. The authors aimed to develop an understanding of phase shifts between stable states on the rocky reefs and how such shifts affect other species. In addition, the study aimed to identify the mechanisms that led to these phase shifts and whether the use of qualitative modeling would be appropriate to investigate the ability of natural systems to produce alternative stable states and predict their effects.

Loop analysis was used to provide a framework to examine the effects of sustained press perturbations on the dynamics of the communities of interest and make qualitative predictions of potential outcomes. Available empirical data describing different components of the ecosystem were pooled. The summary of interactions investigated is provided in Table13, including links between the seaweed beds (SW), long-spined sea urchin (CR), southern rock lobster (RL), black lip abalone (AB), ‘brown’ epilithic understory of sessile invertebrates and a matrix of filamentous algae and sediments (BU), ‘pink’ epilithic understory of non-calcareous encrusting algae and non-geniculate coralline algae (PU) and drift algae (DA). As the focus of the investigation was on the dynamics of two main alternative states of the reefs and the impact of commercial fisheries, two subsystems were outlined (Figure 11).

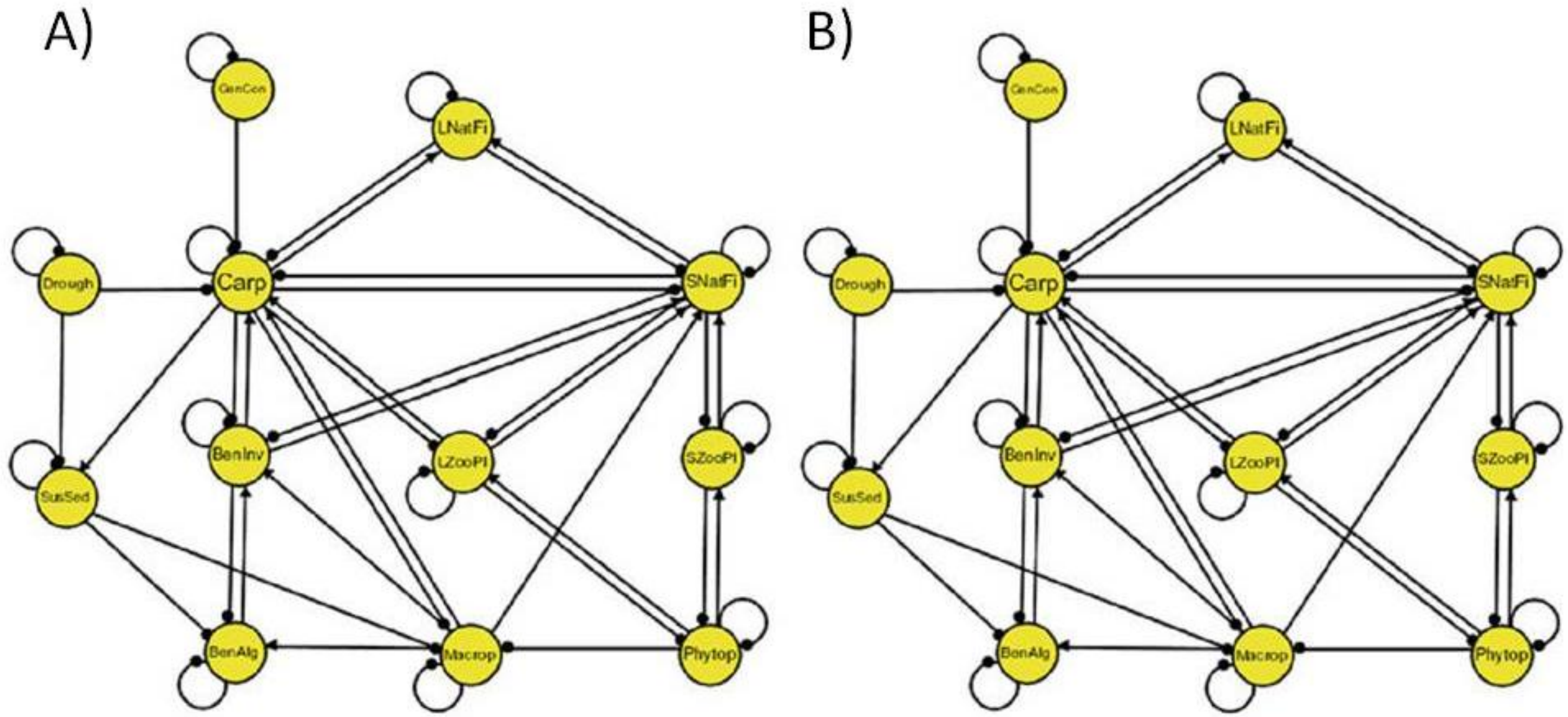
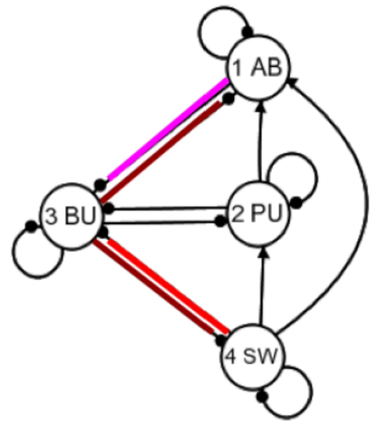


Figure 10: Loop analysis graphs based on an ecosystem of an Australian billabong. A) Stocking of carp under drought conditions. B) Genetic control of carp under drought conditions. Variables include: Carp; Small Native Fish (SNatFi); Benthic Invertebrates (BenInv); Large Native Fish (LNatFi); Large Zooplankton (LZooPl); Small Zooplankton (SZooPl); Phytoplankton (Phytop); Macrophytes (Macrop); Benthic Algae (BenAlg); Suspended Sediment (SusSed); Drought (Drough) and Flood; Stocking (Stock) and Genetic Control (GenCon) (Hayes et al., 2013).

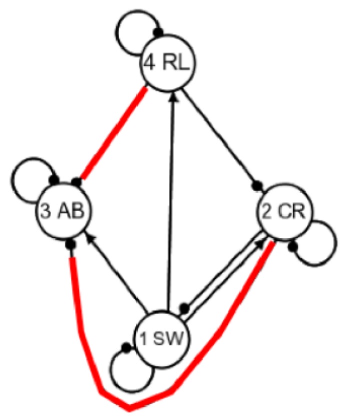
Understorey dynamics



Pink versus brown understorey:

Models focusing on the different states occurring in the understorey algal communities. Capturing the effects of abalone grazing and the influence of canopy-forming macroalgae on the composition of the understorey assemblages.

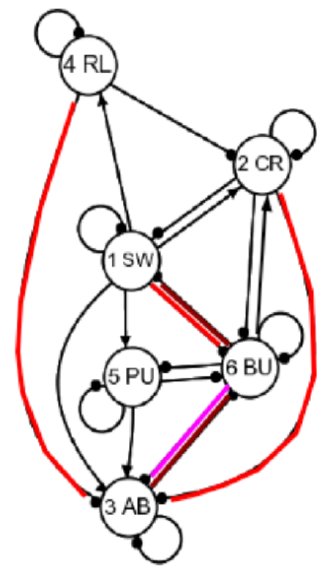
Overstorey dynamics



Productive kelp bed versus urchin barren:

Models focusing on the gross dynamics of the seaweed bed and on the effects of urchin grazing on the canopy. General description of urchin barren formation and its effects on the main commercial fisheries, for abalone and rock lobster.

Models A to D



Overall models

Coupling overstorey and understorey dynamics.

Figure 11: Loop analysis models portraying the dynamics on Tasmanian rocky reefs. Alternative states of the basal level of the benthos are defined as pink and brown epilithic understory. Red interactions are defined as weak or uncertain (Marzloff et al., 2009).

Table 13: Summary of interactions in Tasmanian rocky reefs used to identify links in the loop analysis (Marzloff et al., 2009).

Model interaction	Description	Strength
SW → RL	Provision of habitat and food	Strong
SW → AB	Provision of habitat and food (drift materials)	Strong
SW → CR	Source of food	Strong
SW —● PU	Provision of optimal light conditions through shading	Strong
SW —● BU	Sweeping of young plant recruits	Variable (shallow)
RL —● CR	Predation	Strong
RL —● AB	Predation; reduced growth	Weak (uncertain)
CR —● SW	Grazing	Strong
CR —● AB	Competition for space and resource	Weak
CR —● BU	Grazing	Strong
AB —● BU	Grazing and trampling (bulldozing)	Variable
PU → AB	Provision of habitat for adult and juvenile stages	Strong
PU —● BU	Anti-fouling by sloughing of epithelial cells, allelochemicals	Weak
BU —● PU	Competition. Overgrowing of the pink algae	Strong
BU → CR	Source of food	Strong
BU —● SW	Sediment accumulation can block algae recruitment	Variable (weak)
BU —● AB	Once established, hostile habitat for adult and recruits	Variable

The authors concluded that the use of qualitative models provided an effective way of assessing the impact of fishing lobster and abalone on the overall functioning of rocky-reef communities. In addition, analysis of alternative model structures provided the opportunity to test the effects of uncertainty within the model and the basis to develop a fully quantitative model of reef communities.

3.6. FUZZY COGNITIVE MODELS

Fuzzy cognitive maps (FCM) are viewed as an intermediate between fully qualitative analysis of system feedback structure and the fully quantitative models (Kosko, 1986; Ramsey and Veltman, 2005; Hayes et al., 2011). The term FCM refers to a causal map of variables considered important to a problem. The maps used in FCM are the same Sign Directed Graphs used in loop analysis and highlight positive and negative causal effects between variables (Hayes et al., 2011). Linking the variables are direct effects, also referred to as arcs, edges or interactions, with associated “fuzzy” degrees of causality (Ramsey and Veltman, 2005).

Generally, the strength of the causal weights can vary from -1 to 1. In some instances, precise numbers are used whereas in others they are fuzzy sets that may be more qualitative, using linguistic measures of relative abundance for instance (Ramsey and Norbury, 2009; Hayes, 2011). When a connection exists between two variables, the value is coded in a matrix (i.e., between -1 and 1). The value of each node or variable within the map is defined as $S_i \in [0,1]$ and represents either partial membership or partial "activation" (Figure 12). However, the overall interpretation of the node value can vary depending on the analysis approach. In some instances, it may be a fuzzy set membership number that portrays whether the variable meets a logical proposition, a normalized value, or the probability of an event occurring (Hayes, 2011).

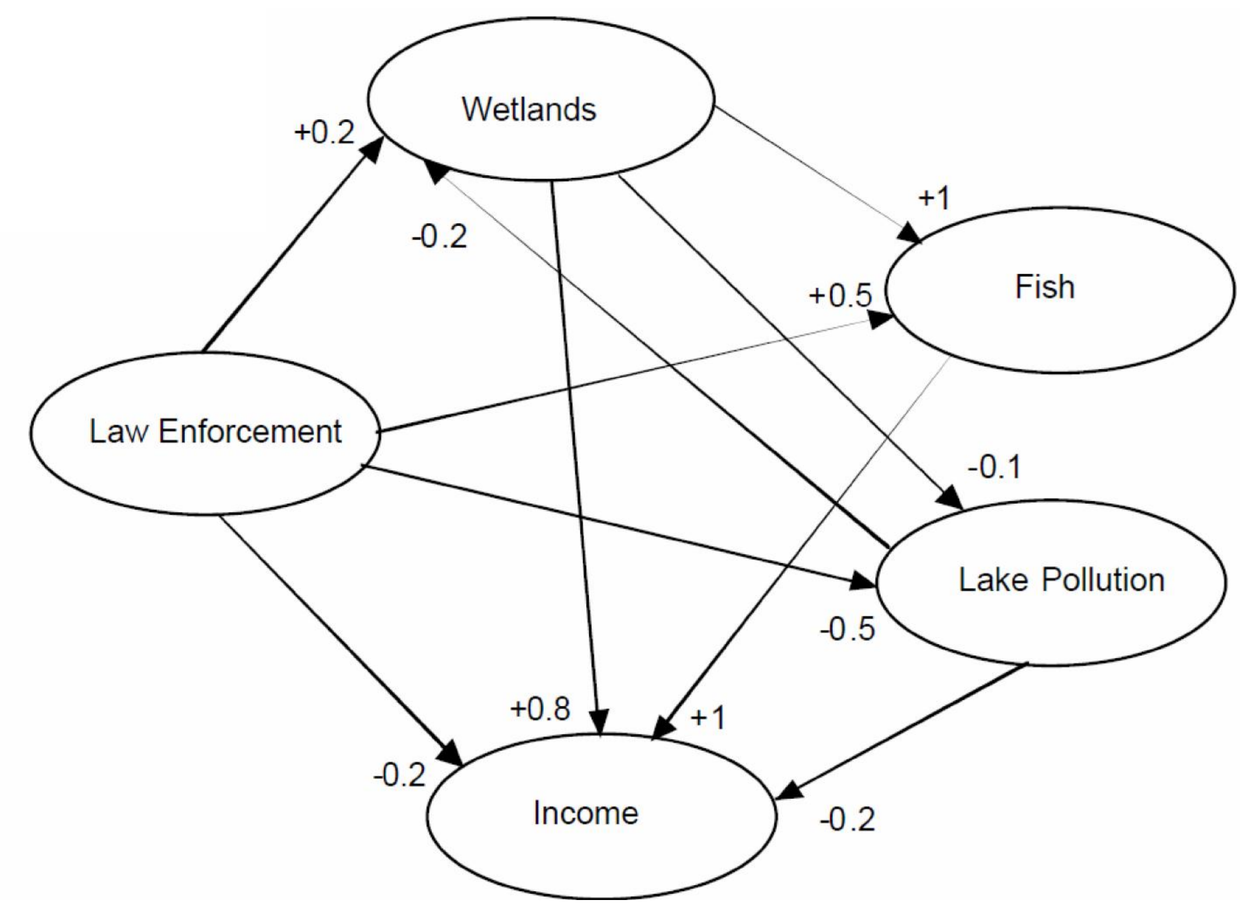


Figure 12: Fuzzy Cognitive map depicting variables assessed in Uluabat Lake, Turkey (Özesmi and Özesmi, 2004).

Within the FCM, variables are typically divided into those that are calculated by solving the FCM and those that are fixed by the user and typically represent press perturbations. Once the cognitive map has been developed and the matrix coded, the model can be run to determine how the system will react if the variables were to remain the same (Özesmi and Özesmi, 2004). This will determine the system's steady state. The auto-associative neural network method, which focuses on inferences rather than the structure of the map, is used to do these calculations (Kosko, 1987; Özesmi and Özesmi, 2004). The steady state calculation provides an indication of the variable ranking in relationship to each other according to how the system is perceived in the FCM (Özesmi and Özesmi, 2004). The steady-state solution associated with the FCM show in Figure 12, can be seen in Table 14. In this particular model, the pollution units are lower than the fish population or livelihood, suggesting that pollution does not have significant adverse effects on fish populations or livelihoods (Özesmi and Özesmi, 2004).

Table 14: Calculation of steady-state for the FCM shown in Figure 11 (Özesmi and Özesmi, 2004).

	Amount of Wetland	**Fish population**	**Pollution**	**Livelihood**	**Enforcement of laws**
Amount of wetland	0	1	-0.1	0.8	0
Fish population	0	0	0	1	0
Pollution	-0.2	-1	0	-0.2	0
Livelihood	0	0	0	0	0
Enforcement of laws	0.2	0.5	0.5.	-0.2	0
FMC simulation					
Initial state vector	1	1	1	1	1
Steady state	0.5	0.525	0.470	0.570	0.5
	0.5	0.514	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5
	0.5	0.513	0.485	0.536	0.5

FCMs share many of the same characteristics and advantages as loop analysis. Namely, FCM analyses are relatively quick to conduct, transparent, easily interpreted, and can assess how diverse opinions may affect the model structure (Hayes, 2011). The model can be constructed with minimal knowledge or imprecise data. In addition, linguistic uncertainties can be incorporated into the model. FCM also suffers from some disadvantages. For example, the units of causality can be vague and therefore are not always easily interpreted. There are also concerns regarding the lack of stability analysis (Hayes, 2011). In addition, the parameter estimates may be imprecise or the relationship between variables unknown. Fuzzy cognitive maps represent a transparent method of incorporating this imprecision in the analysis (Ramsey and Veltman, 2005).

3.7. BAYES NETWORK ANALYSIS OF MODEL STRUCTURE

A Bayesian network is a graphical model, also referred to as a Directed Acyclic Graph (DAG) that can be used to represent complex systems. Bayesian networks are advantageous for assessing environmental systems as they are can integrate complex factors through the use of probabilities of states at any given time. Interactions and consequences within the system are used to represent both quantitative and qualitative information (Kipkemboi et al., 2007). Bayesian network analysis is particularly useful in assisting decision making when there is incomplete information (Orme-Zavaleta and Munns, 2008) or high levels of uncertainty (Hayes, 2011).

The Bayesian network consists of nodes and arcs, where the nodes represent variables and the arcs represent conditional dependencies between the nodes (Orme-Zavaleta and Munns, 2008). The nodes, or variables, in the system are linked and probabilities are expressed for each link (Jensen, 1996). If there is a large amount of uncertainty at the time of the model development, additional information can be integrated as it becomes available. The conditional probabilities that are provided for each variable can be determined using different methodologies, including statistical regression models or decision trees (Hayes, 2011). The general structure of a Bayesian network model that was developed for evaluating population viability outcomes can be seen in Figure 13.

Bayesian networks have been used to determine how well qualitative models fit with observations (Hayes et al., 2013). This method allows for forward uncertainty propagation based solely on expert opinion and is able to integrate statistical values when data eventually become available. In Hayes et al. (2013), the authors used Bayesian network analysis to determine which loop analysis was most consistent with observations of community response following the removal of carp from Australian billabongs.

Bayesian belief networks developed using expert opinions have also been used in cases where significant gaps in data exist. As discussed in Hosack et al. (2008), this approach can be hindered by the requirement to use large conditional probabilities tables and accurately assessing complex ecological feedback cycles. The authors suggest a novel modeling approach whereby signed directed graphs typically used in qualitative modeling (i.e., loop analysis) were merged with Bayesian network analysis (Hosack et al., 2008).

The outcome of a Bayesian network analysis provides a description of the relationships in a complex system. Such analyses have been applied to depict potential outcomes of alternative management activities on ecological predictor variables (McCann et al., 2006) and species-habitat relationships (Marcot et al., 2007). Through the calculation of expected values of alternative options shown in the decision nodes and sensitivity analysis of the model, Bayesian networks can be used to rank management options based on decisions that will most likely lead to the optimal outcome (McCann et al., 2006). In addition to providing probabilities of alternative model outcomes (i.e., forward propagation), Bayesian analysis can provide the most likely set of conditions that will derive a given predetermined or desired outcome (i.e., backward propagation) (McCann et al., 2006).

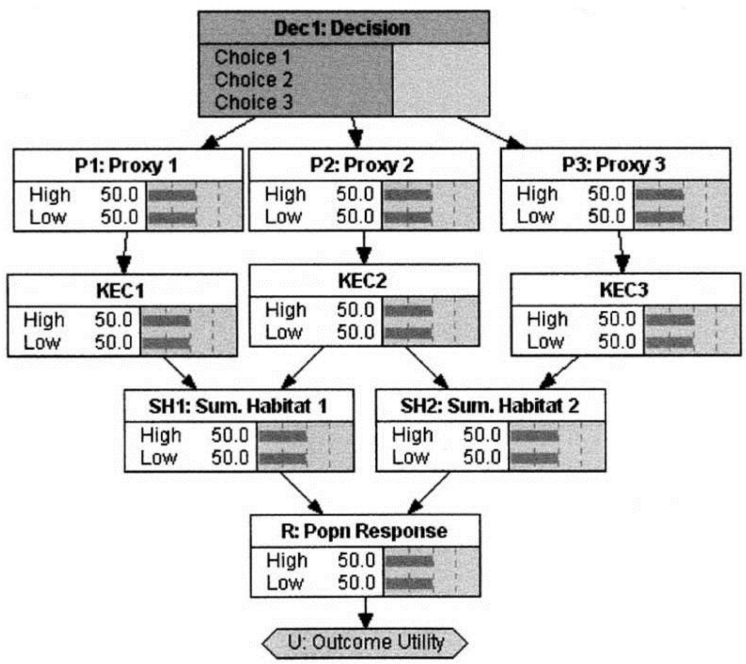


Figure 13: General structure of a Bayesian network model developed to evaluate population viability outcomes of wildlife species (Marcot et al., 2001).

3.8. QUANTITATIVE UNCERTAINTY ANALYSIS METHODS

Some sources of uncertainty are quantifiable, some not. A properly conducted risk analysis results in both a quantitative and qualitative set of information from which the severity, validity, robustness and usefulness of the risk estimates may be judged (NRC, 2009). There are many approaches to quantitative uncertainty analysis and they are commonly used in chemical risk assessments. However, for some types of risk assessment, e.g., those dealing with invasive species or genetically-modified organisms, fully quantitative uncertainty analysis may not be feasible. In the text that follows, we briefly describe the more common methods that may be used to conduct a quantitative uncertainty analysis; more detailed descriptions can be found in a recently published book, Application of Uncertainty Analysis to Ecological Risks of Pesticides (Warren-Hicks and Hart, 2010). The choice of which method to use depends on a variety of factors including data availability, intended use, and preferences of the analyst, risk manager and stakeholders. In data-rich situations, first-order Monte Carlo analysis would likely be the method of choice. Where incertitude is prevalent, second-order methods (e.g., second-order Monte Carlo analysis, probability bounds analysis) should be considered to determine the potential influence that the incertitude may have on estimated risks. Bayesian methods may be used for a wide variety of data-rich and data-poor situations (see Section 3.7).

First-order Monte Carlo simulation is a widely used approach for quantitative uncertainty analysis. The method requires the specification of the statistical distributions of each of the input variables and their interdependencies as measured by correlations. Computer software packages such as Crystal Ball® or @Risk® are used to “sample” from the distributions and compute the risk expression many times so as to build up a histogram that serves as the estimate of the full distribution of risks. First-order Monte Carlo simulation has been used in numerous ecological exposure and risk assessments involving chemicals as stressors (e.g., Wang et al., 2009; Luo et al., 2011; Moore et al., 2014).

Second-order Monte Carlo simulation is designed to handle both incertitude and variability in a comprehensive manner without confounding the two. It is a Monte Carlo simulation nested within a separate Monte Carlo simulation. Even though this approach has high computational costs, it can easily be performed on current desktop computers. The inner Monte Carlo simulation represents variability while the outer simulation represents the analyst’s incertitude about the values of the parameters of the distributions that describe variability (Moore et al., 2010). The output from a second-order Monte Carlo simulation is a large number of distributions. The slopes of those distributions represent uncertainty due to variability whereas the spread between the distributions represents uncertainty due to incertitude (Moore et al., 2010). If the spread of the distributions is too wide to promote effective decision-making, then additional data are required. Although not used often in ecological risk assessment, second-order Monte Carlo has been used in human health risk assessment (e.g., Franz et al., 2010), management of fishery resources (e.g., Wu and Tsang, 2004) and other fields.

Probability bounds analysis is an exact numerical approach (not based on simulation) that takes as input the same probability distributions used in Monte Carlo simulation, or, when they are difficult to specify precisely, uses the outer bounds on these distributions and rigorously computes bounds on the output cumulative distribution functions (Ferson, 2002). Probability bounds analysis is useful when independence of assumptions is untenable (such as between body mass and inhalation rate), or when sparse empirical data make it difficult to quantify the correlations among variables (Ferson et al., 2004). This approach is closely similar in spirit with so-called robust Bayesian methods (Berger, 1985; Ferson et al., 2010). Probability bounds analysis was used in a large-scale ecological risk assessment for a PCBs-contaminated site near Pittsfield, MA (EPA, 2004) and has been used in an assessment of risk to an endangered species, the northern spotted owl (Goldwasser et al., 2000).

Bayesian methods encompass a wide variety of uncertainty analysis techniques (see Berger, 1985 and Warren-Hicks and Hart, 2010). Bayes' theorem is a mathematical procedure for updating a previously known ("prior") distribution about a random variable with a likelihood function arising from new experimental results. The result is a posterior distribution for the random variable of interest. Bayesian prior and posterior distributions are representations of the degree of belief that an investigator has with regard to a random variable. A major advantage of the Bayesian framework is the ability to make probability statements across a hierarchy of data levels (e.g., for a species sensitivity distribution, uncertainty exists on many levels including between species, between tests for particular species, and between individuals within a test). For more on Bayesian methods, see Gelman et al. (1998), Congdon (2001) and Evans et al. (2010).

Summary statistics may be used to characterize uncertainty in data sets where the focus is on a single variable (e.g., numbers of an invasive species in different water bodies). A variety of summary statistics are available to estimate centrality (e.g., median, arithmetic mean, geometric mean, harmonic mean, etc) and spread (e.g., standard deviation, absolute deviation, quartiles, range, etc) in a data set (Sokal and Rohlf, 1980). Such statistics are relatively straightforward to calculate.

First-order moment propagation is a distribution-free approach that uses the elementary laws of probability to estimate the means and variances of sums, products, differences and quotients based on the means and variances of the input variables (Slob, 1994). This approach is useful when it is hard to specify the statistical distributions of the input variables but their means and variances are known. It is a fairly crude approach, but can be useful with simple models (Morgan and Henrion, 1990).

Fuzzy arithmetic is the arithmetic used to add, subtract, multiply and divide fuzzy numbers. A fuzzy number is a generalization of a regular, real number in the sense that it does not refer to one single value but rather to a connected set of possible values with a minimum of zero (impossible values) and a maximum value of one (values are entirely possible) (Kaufmann and Gupta, 1985; Dubois and Prade, 1988). To our knowledge, fuzzy arithmetic has not been used in ecological risk assessment (but see Van der Werft and Zimmer, 1998; Darbra et al., 2007) although it is widely used in other fields, including human health risk assessment (Duckstein et al., 1990; Bardossy et al., 1991) and management of fisheries resources (Ferson, 1993).

Dempster-Shafer theory combines the Bayesian concept of degree of belief and discrete evidence into Bayesian theory and thus can be used to combine multiple lines of evidence. It has been used in engineering applications (Sun et al. 2006; Gao et al., 2011) and other fields but was only recently applied for the first time in an uncertainty analysis for a chemical risk assessment (see Park et al., 2013).

4.0. CONCLUSIONS

Many jurisdictions worldwide have developed guidelines and protocols for evaluating the risks posed by non-native and genetically-modified organisms. In general, the approaches rely heavily on expert judgment to derive qualitative exposure, hazard and risk metrics. Where data permit, semi-quantitative and quantitative methods may be used in some jurisdictions. Our review indicated that all jurisdictions are acutely aware that major sources of uncertainty exist in assessments of the risks posed by biological stressors. The available guidelines and protocols recommend identifying major sources of uncertainty and, to the extent possible, categorizing the importance and potential influence of each major source of uncertainty. In some cases, semi-quantitative and quantitative approaches to uncertainty analysis are suggested.

The available scientific literature indicates that formal semi-quantitative methods are available for estimating the importance of uncertainty in risk assessments involving invasive species, introductions, and genetically-modified organisms. Several of these methods including expert elicitation, fault tree analysis and loop analysis have a track record of use and could be considered for implementation in DFO programs. Others such as fuzzy cognitive models and Bayesian network models require considerable expertise and do not have a track record of use in assessments of the risks posed by invasive species and genetically-modified organisms. Nevertheless, they could prove useful in the future. Fully quantitative methods such as Monte Carlo simulation, Bayesian methods and probability bounds analysis are well-known methods with a long history of use. The issue with these methods, however, is that they generally require well-formulated models and sufficient empirical data to parameterize input distributions (though expert elicitation methods can be helpful with the latter). Such models and empirical data are generally not available in aquatic assessments for invasive species and genetically-modified organisms. As the field develops, it may be possible to move to more quantitative uncertainty analysis methods in the future.

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