GREAT LAKES FISHERY COMMISSION

2002 Project Completion Report[1]

Environmental Risk Assessment

by:

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Fifth Draft

Risk Analysis Process for the Introduction or Translocation of Fish in Great Lakes Basin

Prepared by the Great Lakes Fish Health Committee

2002

INTRODUCTION

Control of fish stocking, translocations and importation in the Great Lakes basin is the responsibility of those agencies that manage the fisheries resources. The Great Lakes Fishery Commission, comprising representatives from Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, Wisconsin, and Ontario, and the federal governments of Canada and the USA, has policies on fish disease control and health requirements for importation of salmonids, and a draft policy on introduction of exotic species[1].

The Model Program (Hnath, J.G., ed., 1993) provides guidelines for the transfer and release of fish within the Great Lakes basin. However, occasionally these guidelines fail to provide clear direction for isolated introductions. In these instances, it has been the Great Lakes Fish Health Committee (GLFHC) that has made recommendations or given approval/denial for introductions that fall outside the guidelines of the Model Program. Currently, the GLFHC only has informal means with which to address the risks associated with a proposed introduction.

The objective of the proposed process is to assess the risk to aquatic animals associated with the possible introduction and spread of pathogens and parasites that might accompany aquatic organisms being moved. The process was established to assist fishery resource managers having to make decisions involving potential introductions that are not covered by, or that are in conflict with the Model Program (refer to Annex II of the Model Program).

The process applies to all activities in which live aquatic organisms are introduced or transferred into fish bearing waters, or fish rearing facilities such as aquaculture, and for commercial and recreational fishing including biological control programs e.g. control of aquatic vegetation in the Great Lakes basin.

[1] The Great Lakes Panel on Aquatic Nuisance Species is directed to identify priority exotic species issues in the Great Lakes; assist/make recommendations to the US Task Force on Aquatic Nuisance Species; coordinate exotic species program activities in the region; advise public and private interests on control efforts; and, submit an annual report to the Task Force describing prevention, research and control activities in the Great Lakes. The Panel membership is drawn from US and Canadian federal agencies, the eight Great Lakes states and the province of Ontario, regional agencies, user groups, local communities, tribal authorities, commercial interests and the university/research community

The primary goal of this process is to provide a standardized approach for evaluating the risk of introducing undesired fish disease agents into the Great Lakes environment.

This process has several objectives:

1. To provide a standardized framework to decision-making that can be applied to all requests for introduction so that requests are assessed in an equivalent and consistent manner;
2. To provide a framework where scientific, technical, and other relevant information can be organised into a format that is understandable and useful to managers and decision-makers;
3. To make the evaluation process clear and open, with early and continuous input from all identified interested parties, and accessible to managers.
4. To establish the underlying principles used by decision-makers to assess the risks associated with introduction into the Great Lakes basin.

This process is not an environmental assessment as it only addresses the risks to aquatic animals from the potential introduction and spread of pathogens and parasites that might accompany aquatic organisms being moved. This process does not address the risks of harmful alterations to natural aquatic ecosystems, or the risks of deleterious genetic changes in indigenous fish populations.

The process was designed to be flexible and dynamic enough to accommodate available financial resources, accessibility of the appropriate biological information, and the risk assessment methods available at the time of the assessment. The process may also be quantified to the extent possible or necessary depending on the needs of the analysis (i.e., analysis requiring extensive research and sophisticated analytical techniques). Figure 1 illustrates the Import Risk Analysis Process for the Great Lakes basin.

The process was adapted from the Import Risk Analysis Process developed for the revised Manual of Compliance for Finfish (Draft Fish Health Protection Regulation, 1999). Parts of this document were also adapted from the National Code on Introduction and Transfer of Aquatic organisms (Prepared for approval by the Canadian Council of Fisheries Minister, 2001).

This document describes each step of the process, including a general description of the decision making process, and, in general terms, how such a mechanism would operate. There is also a list of definitions, a list of scientific references on the topic of introductions and transfers, and 3 appendices.

Appendix I outlines the nature and scope of information that will be required by the proponent of a proposed introduction or transfer. The information includes:

- Name of proponent (agency) making the proposal
- What is being proposed for introduction and why
- A description of the anticipated benefits and potential risks
- Source of aquatic organism and proposed site(s) of introduction or transfer
- Information on the life history of the organism
- How is it expected to interact with native species already in the waterbody(including potential contamination from waste water/effluent)
- Information about the water body into which the aquatic organism is to be stocked
- What precautions are being taken to avoid problems
- Scientific references to back up the proposal

Appendix II outlines the Risk Analysis. In some cases, the proponent will prepare the Risk Analysis and the GLFHC will review it. In other cases, the GLFHC will do the Risk Analysis or contract out the work to a competent third party. The object of the Risk Analysis is to identify whether the proposed Introduction or Transfer presents a low, medium or high risk for the receiving environment. The Risk Analysis is an adaptation of internationally acknowledged models and processes. The procedures asks questions and the answers are entered into a box in a table. Using the scientific literature and/or personal knowledge, the individual or committee conducting the risk analysis is asked to determine three possibilities associated with the introduction. These include the likelihood that a pathogen or parasite will be introduced with the introduced organism, the likelihood of a pathogen or parasite becoming established and the consequences the introduced pathogen or parasite could have on the receiving environment. Each answer should be supported with references.

In all cases, a 5-point scale must be used to determine whether a determination of low, medium or high impact was decided with certainty or uncertainty. The risk assessment procedure also asks for a description of how mitigation could reduce the risk of negative impacts (for instance, if there was concern that a species could become established in a waterbody the authorities could require that only males or females, or only sterile individuals of both sexes be introduced to prevent reproduction).

The final step in the risk analysis is to place all the answers in a summary table and, using a pre-established format, decide whether the introduction or transfer will have a low, medium or high risk of negative environmental impacts associated with pathogen/disease introduction.

Appendix III is a summary of the whole risk assessment and it is used to provide a permanent record of the proposal and the review process. It finishes with the GLFHC recommendation to the decision-making authority.

Process Initiation

Proposals to introduce fish within the Great Lakes basin that may be in conflict with the procedures described in Annex II of the Model Program must be sent to the Chairperson, GLFHC. Proposals must include the following information:

- Name and location of source facility or site
- Species of fish to be introduced (Latin and common names)
- Age of fish
- Number to be introduced and description of recipient facility or site(s)
- Other species at source facility or site
- If applicable, brief description of fish health program at source facility
- Past imports to source facility or site (list species and source(s))
- Disease history of source facility or site

- Previous detection of infection/disease, treatments/control methods used, and control/treatment success.

The chairperson will screen the proposal to ensure completeness and sufficient information has been provided to determine if the introduction is covered by Annex II of the Model Program, or if a risk assessment is required.

APPENDIX I - Proposed Introduction Assessment Form

If the need for the risk assessment process is identified, the proponent or the chairperson of the GLFHC must complete a Proposed Introduction Assessment Form. The proposed Introduction Assessment Form describes the introduction, including all the required information in a logical, structured format to determine the risk associated with the proposed introduction. Completion of the Proposed Introduction and Assessment Form will provide a single, organized document showing all the appropriate information required to assess the risks and benefits of a proposed introduction.

The data provided in the Proposed Introduction Form is organized by functional groups. These groups include:

General

This information is of a general nature and includes:

- Species
- Size or age of species proposed for introduction
- Number to be introduced
- Location or introduction sites
- History of hatchery or feral stock (highlighting known pathogens, disease etc.)
- History of production (of species proposed for introduction)
- Pathogens currently found in species proposed for introduction
- Description of the incidence/prevalence in adjoining Lakes
- Reasons why the introduction is not covered by the Model Program
- Time schedule associated with proposed introduction

Host

This grouping provides information on the host species including:

- The features of the proposed introduced species that would encourage dispersal such as migratory behaviours
- Description of the expected or observed sub clinical production losses caused by the transmitted pathogen
- What data is available on this species that could be used to predict performance in the receiving waters? (Growth, mean weight at age, survival, return to creel, return to weir, angler hours / commercial effort, etc.)
- Estimation of the capacity for the introduced agent to result in adverse health impacts on individual fish and fish populations.

Pathogen

This section provides information on the pathogen and includes:

- Prevalence of pathogen in source population(s)
- Description of known susceptible species
- Extent of infection per lot
- Description of the presence of potential pathogen vectors
- Description of the nature and properties of the agent
- Potential routes of exposure, modes of transmission and routes of entry
- Description of whether the activity of stocking these fish is likely to increase the level or geographic range of the pathogen
- Description of primary, secondary, and intermediate hosts
- Description of the potential for transmission of infection to other animals or species
- Important facts related to the host and pathogen (Stress mediated disease, etc.?)
- Likelihood of spreading the infection or disease
- A description of diagnostic test(s) used to detect the pathogen and their estimated reliability
- The effect of prophylactic and therapeutic treatment for pathogen(s)/ parasite(s) of concern

Receiving Environment or contiguous watershed

This section is intended to describe the environment in which the host and pathogen are expected to occupy and include:

- The water flow characteristics which would enhance the survival (temporal and spatial) of effects or hazards
- The presence of potential vectors
- Geographic and environmental characteristics
- The possible adverse consequences to the receiving environment
- History of the receiving waterbody with respect to this pathogen
- Forage availability in receiving water

- Biological compatibility of the host and its potential hazard(s) to receiving waters (lake temperature, salinity, forage, spawning area, nursery area, etc.)
- General stability of the system (previous epizootic(s), growth rates, presence of exotic species, extent of natural reproduction)
- The presence of susceptible species in receiving waters for pathogen(s)/ parasite(s) of concern
- Ecological factor(s) required to ensure effective contacts between introduced and at risk species

Miscellaneous

This is information that is important but does not fit well in the other groups, such as:

- Relevant data gaps (what important facts don't we know?)
- Biases or uncertainty of diagnostic testing
- Potential for an epizootic in cultured and wild stocks
- Alternatives to stocking these fish in the Great Lakes
- Ways to mitigate potential losses (stock alternative species, request assistance from other agencies, stock fewer fish, etc.)
- Statement on the fish health capability of the stocking agency

APPENDIX B - Risk Assessment Summary Report

Step 1 – Hazard identification

Hazard identification consists of identifying what actions or agents are associated with the proposed introduction, which could plausibly result in undesired impacts on native aquatic animals. In order to do this, an evaluation of what the introduced species could bring in with them (pathogen/parasite screening), as well as information on the anticipated effects of these detected risk factors, is required. The next steps are to determine whether the receiving environment will allow these hazards to manifest their effect.

Step 2 - Probability of Establishment

a) Release Assessment

Release assessment consists of describing the biological pathway(s) necessary for a risk source to introduce (i.e., release) biological agents into a particular environment, and estimating the probability that it will take place. Release assessments typically include (i) a description of the types, amounts, timing, and probabilities of the "release" of each of the potential hazards (the biological agents) previously identified, under each set of conditions, and (ii) a description of how these might be affected by various actions, events or measures. Some of the inputs that may need to be considered in the release assessment include:

- the ability of pathogens to be transmitted to successive generations
- incidence or prevalence of the pathogen or agent
- incidence/prevalence in adjoining Lakes
- species and age of fish
- ease of contamination by the pathogen
- estimated accuracy of diagnostic testing
- effect of prophylactic and therapeutic treatment

b) Exposure Assessment

Exposure assessment consists of describing the relevant conditions and characteristics of fish exposures to risk agents produced (i.e. habitat overlap between host and pathogen) or released by a given source, and estimating the probability they occur. Exposure assessments typically would include (i) a description of the intensity, timing, frequency, and duration of exposure, (ii) routes of exposure, and (iii) the number, species and characteristics of populations that might be exposed. Some of the inputs that may need to be considered in the exposure assessment include:

- presence of susceptible species in receiving waters
- water flow characteristics that could enhance dispersion of effects or hazards
- characteristics of stocked species (e.g. migratory behaviour) that could contribute to dispersion of the effects or hazards
- the presence of potential vectors
- the nature and properties of the agent
- routes of exposure, modes of transmission and routes of entry
- primary, secondary, and intermediate hosts
- geographic and environmental characteristics

Step 3 - Consequence Assessment

Consequence assessment consists of describing the relationship between specified exposures to a risk agent and the ecological and economic consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability they will occur. Some of the consequences for which the probability may be estimated include:

- transmission of infection to other animals or species
- subclinical production losses caused by the transmitted infection
- spread of infection or disease, and potential for an epizootic for cultured and wild stocks
- fish losses from death or diseases as a result of the transmitted infection

- losses from trade embargo, losses from inter-state/provincial fish movement/transfer restrictions, losses in fish marketability
- costs incurred from control and eradication, monitoring, surveillance, laboratory testing and trace back, quarantine and isolation, compensation, cleaning and disinfecting, treatment, and vaccination
- adverse consequences to the receiving environment

Step 4 - Risk Estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to assess the risks to naturally occurring and native species, populations, important fisheries or aquaculture resources, and biological communities and habitats which may be impacted by a proposed introduction. The nature of the data and general information may not allow for precise quantification of the risk associated with the proposed introduction. Therefore, a quantitative[2] or qualitative assessment will have to be generated. The framework for qualitative risk assessment is supplied (see Appendix B).

Risk estimation should consider integrating the information from all of the groupings. Information from the general, host, pathogen, environmental, and miscellaneous should be used to assess the risks to naturally occurring and/or native species, populations, important fisheries or aquaculture resources, and biological communities and habitats which may be impacted by a proposed introduction.

Step 5 - Sensitivity Analysis (optional)

In situations where uncertainty exists, these uncertainties or unknowns must be described in terms of their significance. As opposed to including significant amount of uncertainty in the rating (i.e., uncertainty code or confidence level associated with an element rating in Step 2 and 3), a better approach would be to perform a descriptive sensitivity analysis (i.e., conduct a risk assessment for each likely scenario).

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[2] For quantitative assessments, the final risk outputs may include: probability distributions, confidence intervals, and other means to express the uncertainties present in the input and output estimates; estimated size of the population at risk; sensitivity analysis to demonstrate the most influential parameters, etc.

APPENDIX III. Risk Assessment Summary Information

The Risk Assessment Summary Information will be produced by the GLFHC after the Risk Assessment Summary Report (Appendix II) is completed. This report will focus and summarize only the most critical information that was used in the decision making process. The information in this report will form the basis for determining the overall risk associated with the proposed introduction and make recommendations regarding the introduction. One of three recommendations will be made as follows: recommend the proposed introduction as requested, recommend the proposed introduction proceed only under certain criteria, or recommend the introduction not be made. The report will document what criteria were used in the decision making process and describe why the recommendation was made.   The Risk Assessment Summary Information draws on the data provided in the Proposed Introduction form and the findings resulting from the Risk Assessment Summary Report.

Risk Management

The Chairperson should recommend the rejection of any request with risks estimated to be high. Approval for introduction should be recommended if the risk in each of the key areas of concern is estimated to be low. The Chairperson may decide that requests of intermediate risk be modified by incorporating specific preventive or mitigative plans in the proposed application, or that additional information be generated in order to estimate the risks more conclusively.

The risk management decision to stock a particular stock of fish should be based on a low probability of adverse health effects on fisheries resources; that is, the health-associated output of the risk assessment. Elements of risk management include:

- Interpreting, comparing, judging the significance of and deciding the tolerability of the risk;
- Identifying and evaluating the efficacy and feasibility of mitigation measures, in addition to those that may have been considered in the initial risk assessment, in order to reduce the risk associated with an importation or introduction. The efficacy is the

degree to which an option reduces the likelihood and magnitude of adverse biological and economic consequences;

- Level of acceptable risk.

High risk request

An introduction request should be classified as high risk when hazards related to emergency pathogens have been identified. Diseases or pathogens listed in the Emergency Fish Diseases of the Model Program can have serious deleterious impacts on fish stocks and must be kept out of the Great Lakes basin. Reportable diseases, such as those listed by the USDA, must be prevented from spreading to new areas because of the serious negative impacts they can have on fish stocks and should also be considered of high risk.

Other significant pathogens of concern that should be evaluated as high risk include those that are of current or potential international significance but that have not been included in the lists of pathogens previously addressed.

While the primary concern is the protection of health of fisheries resources, disease-related hazards that could impact other aquatic organisms should be taken into account as well. Adverse effects involving a wide range of species, a large number of individuals or target species (i.e., of special status) would be judged to have greater consequences/impacts than those that do not, and should be classified as high risk.

Risk Communication

Risk communication represents the interactive exchange of information on risk among risk assessors, risk managers and other interested parties. It begins when a risk analysis is requested and continues after the implementation of the decision on the acceptance or refusal of the stocking request.

The main principles involved with risk communication include:

- The communication of risk should be open, interactive and involve transparent exchange of information that may continue after the stocking decision;

- Peer review should be a component of risk communication in order to obtain a scientific and analytical critique of the relevant information to ensure the validity of the scientific data, methods and assumptions;
- The uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.

Recommendations to Decision-Makers

There are five possible final outcomes that can result following a risk assessment request:

1. Hazard identification fails to identify potential hazards associated with the introduction. Thus, approval of the request is denied and the import risk assessment process is terminated.
2. The request is returned to the proponent prior to or during consideration in order to obtain additional information required to assess the level of risk associated with the proposed introduction.
3. The request is recommended for approval with no conditions.
4. The request is recommended for approval with the condition that specific preventive or mitigation measures are followed before the proposed stocking takes place.
5. The request is not recommended for approval if the level of risk is deemed unacceptable. For qualitative assessment processes (as outlined in Appendix B), a stocking event will not be recommended for approval unless the risk in each of the key areas of concern is considered to be low or can be reduced to low or negligible with mitigating measures[3], and the overall confidence level for the final risk estimate is Certain or Reliable.

There should also be communication or exchange of information on the risk assessment process, the risk(s), and the risk management decision among risk assessors, risk managers and other interested parties.

Figure 2 shows the type of inputs to the decision making process for introductions or transfers of aquatic organisms.

[3]Because acceptability of a risk is a subjective decision about issues around which there may be substantial disagreement, it is recommended that a policy on standards of acceptable risk be developed. Questions to be considered in choosing a safety standard are outlined in Brunk (1992).

REFERENCES AND RECOMMENDED LITERATURE

The scientific literature covers introductions and transfers extensively. Recent references that are particularly relevant to Canada are given below, as well as the publications referred to in the text.

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Figure 1. The Import Risk Analysis Process for the Great Lakes Basin.

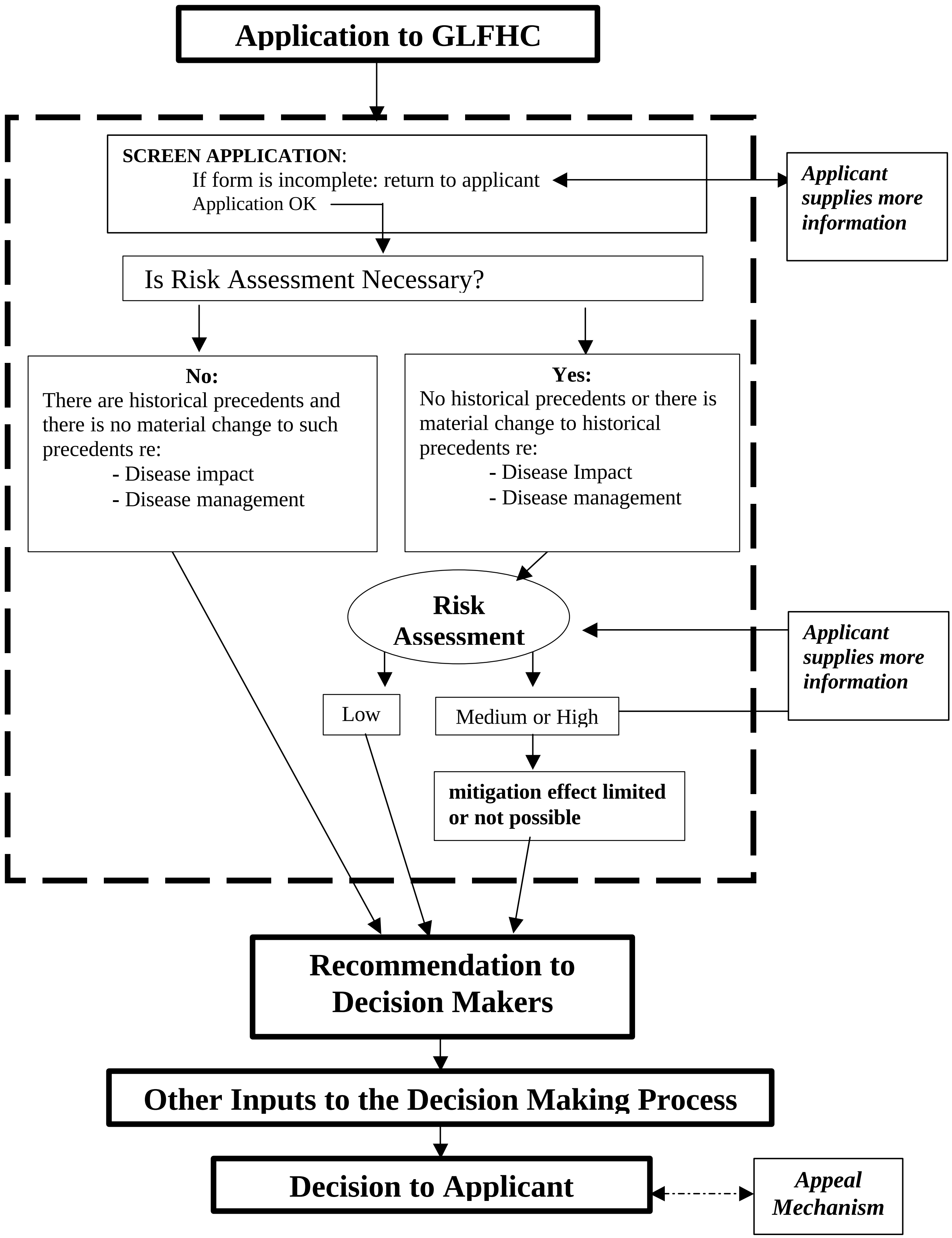
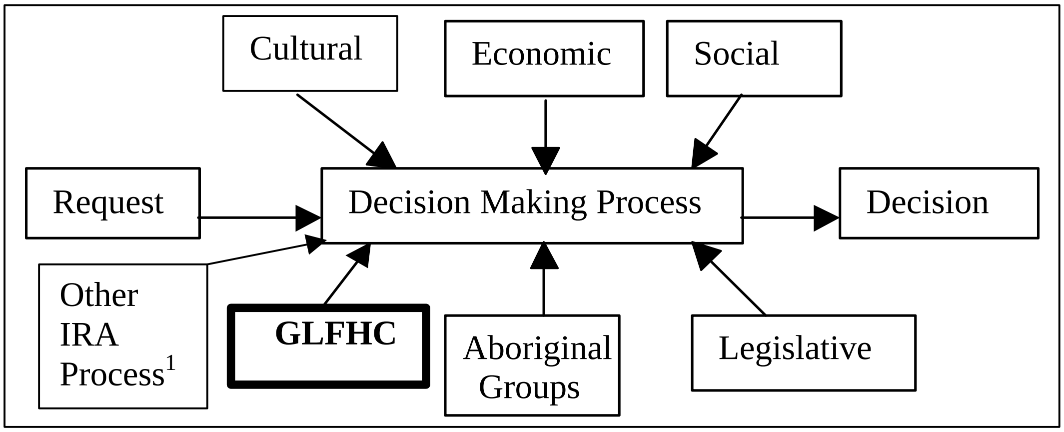


Figure 2. Inputs to the decision making process for introductions or transfers of aquatic organisms.



[1] ***Other IRA Process refers to the genetic and ecological impact of the introduced organism (i.e., not the IRA for accompanying disease agents).***

APPENDICES

APPENDIX I. Proposed Introduction Assessment Form

Information relevant to the proposed introduction. To be completed by the requesting agency, the GLFHC, or appropriate technical experts.

From:

Prepared By:

Date submitted:

GENERAL

Name (common and scientific [genus and species]) of the organism proposed for introduction or transfer:

What is the reason for the introduction and is there no alternative to introductions to meet this purpose?

Describe the characteristics, including distinguishing characteristics, of the organism. Include a scientific drawing or photograph:

Describe the history in aquaculture, enhancement or other introductions (if appropriate):

Describe the objectives and rationale for the proposed introduction, including an explanation as to why such an objective cannot be met through the utilization of an indigenous species:

What alternate strategies have been considered in order to meet the objectives of the proposal? What are the implications of a "do nothing" option?

What is the geographic area of the proposed introduction? Include a map.

Describe the numbers of organisms proposed for introduction (initially, ultimately):

Size or age of species being introduced:

Location or stocking sites:

History of hatcheryor feral stock if appropriate (highlighting known pathogens, disease etc.):

Description of the sampling and testing methods used to determine pathogen history

History of production (of requested species):

Pathogens currently found in introduced species and/or in other species at the facility or source waterbody:

Describe the ability of the pathogen (to answer for each pathogen of concern) to be transmitted to successive generations:

Describe the incidence/prevalence of introduced species in receiving environment and contiguous watershed:

State why the introduction is not covered by the Model Program:

Time schedule associated with introduction/transfer event:

PATHOGEN (for each identified pathogen of concern)

Prevalence of pathogen in the source population:

Describe ease of agent contamination:

Extent of infection per lot if applicable:

Describe the presence of potential pathogen vectors:

List potential routes of exposure, modes of transmission and routes of entry:

Is the activity of introducing these fish ~~is~~ likely to increase the geographic range or level of the pathogen:

List primary, secondary, and intermediate hosts:

Describe the potential for transmission of infection to other animals or species:

Important facts related to the host and pathogen (Stress mediated disease, etc.?):

What is the likelihood of spreading the infection or disease?

HOST

Describe the native range and, possibly, new geographical distribution that has resulted from the establishment of past introductions of the species:

Record where the species was introduced previously and describe the ecological effects on the environment of the receiving area:

What factor(s) limit the species in its native range:

Describe the physiological tolerances (water quality, temperature, oxygen, and salinity) at each life history stage (early life history stages, adults, reproductive stages):

Describe the habitat preferences and tolerances for each life history stage:

Describe the reproductive biology:

Describe the migratory behavior:

Describe the food preferences for each life history stage:

Describe the growth rate and lifespan (also in the area of the proposed introduction, if known):

Describe the known pathogens and parasites of the species or stock:

Describe the behavioral traits (social, territorial, aggressive):

List the presence of susceptible species to the hazard of concern in receiving waters:

Describe the features of the stocked species that would encourage dispersal such as migratory behaviours:

List expected or observed sub clinical production losses caused by the transmitted infection:

What trend data is available on the recent history of this species with regards to the performance in the receiving waters (Growth, mean weight at age, survival, return to creel, return to weir, angler hours / commercial effort, etc.):

Describe the likelihood that the natural immune system will prevail over the pathogen/parasite:

RECEIVING ENVIRONMENT AND CONTIGUOUS WATERSHED

Describe physical information on the receiving environment and contiguous waterbodies (e.g., seasonal water temperatures, salinity, and turbidity, dissolved oxygen, pH, nutrients and metals):
Do these parameters match the tolerances/preferences of the species to be introduced?

List species composition (major aquatic vertebrates, invertebrates and plants) of the receiving waters:
Are any of these species known to be susceptible to the diseases and parasites found to affect the introduced species in its native range?

Describe the natural or man-made barriers that should prevent the movement of the introduced organisms to adjacent waters:

Describe the water flow characteristics that would enhance the dispersion of effects or hazards:

Describe the presence of potential vectors:

List geographic and environmental characteristics:

Describe the possible adverse consequences to the natural ecosystems:

What is the history of the receiving water body with respect to this pathogen?

Forage availability in receiving water:

How does this species biologically match the receiving water (lake temperature, salinity, forage, spawning area, nursery area, etc.)?

Describe the general stability of the receiving environment (Lake Superior more stable then Lake Michigan, no epizootics, stable growth rates, few exotics, extensive natural reproduction, etc.):

DAMAGE / BENEFITS

List possible fish losses from death or diseases as a result of the transmitted infection:

List the possible losses from trade embargoes:

List the possible losses from inter-state/provincial fish movement/transfer restrictions:

List the possible losses in fish marketability:

List the possible control and eradication costs:

List the possible monitoring; surveillance, laboratory testing and trace back costs:

List the possible quarantine and isolation costs:

List the possible compensation costs:

List the possible cleaning and disinfecting costs:

List the possible treatment, vaccination costs:

List the expected benefits or performance of the fish being requested (Survival, growth, mean weight at age, return to creel, return to weir, economic):

List the expected negative outcome of not stocking the species (Reduced creel, loss of ecological balance, loss of unique genetic material etc.):

List the potential benefits of not stocking (lowers the prevalence or prevents introduction of the pathogen in the system, improved growth rates of wild or previously stocked fish, control the geographic range of the pathogen, etc.):

List groups that would benefit from taking the risk:

MISCELLANEOUS

Relevant data gaps (what important facts don't we know?):

Describe the biases or uncertainty of diagnostic testing:

Describe the potential for an epidemic for cultured and wild stocks:

What are the alternatives to stocking these fish in the Great Lakes?

List ways to mitigate the loss (stock alternative species, request assistance from other agencies, stock fewer fish, etc.):

Provide a statement on the competency and integrity of the veterinary infrastructure of the stocking agency:

APPENDIX II. Risk Assessment Summary Report document

Step 1 – Hazard identification (see Appendix III)
Step 2 - Determining the Probability of Establishment – Release and Exposure Assessment[4]

Element Rating	**Rating Level [5] (H, M, L)**	**Confidence Level[6] (C, R, S, U)**
Estimate the probability of the hazard (hazard) successfully colonizing and maintaining a population in the intended area of introduction (Append appropriate references to support the rating given)		
Estimate the probability that the agent of concern escapes from the area of introduction (Append appropriate references to support the rating given)		
If the agent of concern escapes from the area of introduction, [7]estimate the probability of it establishing itself (Append appropriate references to support the rating given) If the agent of concern escapes from the area of introduction,[6] estimate the probability of its spreading (Append appropriate references to support the rating given)		
FINAL RATING (see explanatory notes below)		

Explanatory notes:

1. The final rating for the **"Probability of Establishment"** is assigned the value of the element with the **lowest** risk rating (e.g., a **Medium,** and **low** estimate for the above elements would result in an overall **Low** rating).

2. The final confidence level for the **"Probability of Establishment"** is assigned the value of the element with the **lowest** confidence level (e.g., a **Certain** and **Unreliable** estimate for the above elements would result in an overall **Unreliable** confidence level).

The strength of the review process is not in the rating but in the detailed biological and other relevant information statements that motivates them.

[4] Step #1 to 3 must be carried out for each hazard identified as *unacceptable outcome* in the hazard identification step.

[5] For each element rating (i.e., probability of release and probability of exposure), choose a rating from Table 1 (at the end of the appendix) that best describe the likelihood of the occurrence of the adverse event.

[6] For each element rating, choose the confidence level from Table 2 (at the end of the appendix) that best describe the level of confidence or certainty you have in your answer.

[7] If the probability of escaping is non-significant, the rating does not apply (non-applicable or NA)

Step 3 - Determining the Consequence of Establishment

Complete the following table and provide a brief rationale with appropriate references to support the rating given. The final rating of the "Consequence of Establishment" is assigned a single rating based on economic, environmental, and social/political impacts.

Element	**Element Rating[8] (H, M, L)**	**Certainty Code[9] (C, R, S, U)**
Estimate of environmental impacts, if established (i.e., Introduction of non-native pathogens or parasites into natural systems leading to ecological or genetic impact on native ecosystems both locally and within the drainage basin). (Append appropriate references to support the rating given)		
Estimate impact from social, political and/or stakeholder influences. (Append appropriate references to support the rating given)		
Estimate of economic impacts, if established. (Append appropriate references to support the rating given)		
FINAL RATING (see explanatory notes below)		

Explanatory notes:

1. The final rating for the **"Consequence of Establishment"** is assigned the value of the element with the **highest** risk rating (e.g., a **Medium, high** and **low** estimate for the above elements would result in an overall **high** rating).

2. The final confidence level for the **"Consequence of Establishment"** is assigned the value of the element with the **lowest** confidence level (e.g., a **Certain** and **Unreliable** estimate for the above elements would result in an overall **Unreliable** confidence level).

The strength of the review process is not in the rating but in the detailed biological and other relevant information statements that motivates them.

[8] For each element rating (i.e., consequence of establishment), choose a rating from Table 3 (at the end of the appendix) that best describe the likelihood of the occurrence of the adverse event.

[9] For each element rating, choose the confidence level from Table 2 (at the end of the appendix) that best describe the level of confidence or certainty you have in your answer.

Step 4 - Risk Estimation

The overall Risk is assigned a single value based on the **"Probability of Establishment"** and the **"Consequences of Establishment".**

Component Rating	**Rating Level (H, M, L)**	**Confidence Level (C, R, S, U)**
Probability of Establishment estimate[10]		
Consequence of Establishment estimate[11]		
Overall Risk Estimate		

Explanatory notes:

1. Table 4 (at the end of the appendix) provides an outline for categorizing the Overall Risk Estimate.

2. The final confidence level for the **"Overall Risk Estimate"** is assigned the value of the element with the **lowest** confidence level (e.g., a **Certain** and **Unreliable** estimate for the above elements would result in an overall **Unreliable** confidence level).

Definition of **"Overall Risk Estimate"**

- A **HIGH** rating means that the risk is a certainty, or almost a certainty (i.e., unacceptable risk). The application of appropriate mitigation measures is required to lessen the risk to a rating of LOW. With a high rating it may not be possible to apply sufficient mitigation measures to reduce the risk rating to LOW | **Recommendation to refuse importation option.**
- A **MODERATE** rating that there is a probability of negative impact that requires the application of appropriate mitigation measures to lessen the risk to a rating of LOW | **Proposal tabled for further review.**
- A **LOW** rating means that the risk is considered to be insignificant (i.e., acceptable risk). It is not likely that additional mitigation measures will be required | **Recommendation to accept importation option.**

Proposals will be recommended for approval only if all potential hazard (as defined in Step#1) for which the overall risk was estimated is LOW.

Proposals will be recommended for approval only if the overall confidence level for which the overall risk was estimated is Certain or Reliable.

[10] As estimated in step#1 " final rating level" and "final confidence level", respectively

[11] As estimated in step#2 "final rating level" and "final confidence level", respectively

APPENDIX III. RISK ASSESSMENT SUMMARY INFORMATION

Part I - Hazard Identification

Viruses:

Bacteria:

Fungi:

Parasites:

Other:

Comments:

Part II

Summary of the Request:

Summary of the Risk Assessment:

Statement on Overall Risk:

Signature of Chairmen GLFHC

Date

Table 1. Rating Criteria for the probability of occurrence of an adverse event.

Rating	Definitions
HIGH (H)	means that the adverse event is certain to occur, or almost a certainty.
MEDIUM (M)	means that the adverse event is as likely to occur as to not occur.
LOW (L)	means that the adverse event is unlikely to occur.

Table 2. Confidence level of rating level.

Rating	Definitions
CERTAIN (C)	I am highly confident that my rating level is quite close to its true value.
RELIABLE (R)	I am assuming my rating level is close to its true value, but there is some chance I am wrong.
SUBJECTIVE (S)	My answer is of pure subjective nature, and not validated against any evidence or data.
UNERELIABLE (U)	There is substantial chance that my response regarding the rating level is incorrect.

Table 3. Rating criteria for the "Consequence of establishment".

Rating	Definitions
HIGH (H)	means that the magnitude of the effects associated with the proposed importation is considered of serious importance.
MEDIUM (M)	means that the magnitude of the effects associated with the proposed importation is considered substantial.
LOW (L)	means that the magnitude of the effects associated with the proposed importation is considered negligible and manageable.

Table 4. Outline for categorizing the Overall Risk Estimate.

Probability of Establishment	Consequence of Establishment	Overall Risk Estimate
High	High	High Risk
High	Medium	High Risk
High	Low	Moderate Risk
Medium	High	High Risk
Medium	Medium	Moderate Risk
Medium	Low	Moderate Risk
Low	High	Moderate Risk
Low	Medium	Moderate Risk
Low	Low	Low Risk

RISK IS RELATIVE

A list of risky things: Which is most risky?

Event	Chance
the flesh eating bacteria.	1 in 1 million
AIDS contracted in a blood transfusion.	1 in 96,000
a lightning strike	1 in 30,000
cancer from 1 peanut butter sandwich/day	1 in 5,000
disease caused by drinking one beer/day	1 in 1,000
cancer caused by an avg number of x-rays.	1 in 700
cancer by background radiation in nature	1 in 700
disease caused by indoor radon.	1 in 440
murder, if you live in a big city.	1 in 160
a home accident.	1 in 130
disease caused by smoking 1 cigarette/day	1 in 100
disease from heavy alcohol consumption	1 in 100
a motor vehicle accident	1 in 60
disease caused by smoking 1 pack of cigarettes/day	1 in 6

Defining Risk

- someone or something that creates or suggests a hazard (lay use)
- **potential** for realization of unwanted, **adverse** consequences
- based on the **expected value** of the **conditional probability** of the event occurring times the **consequence** of the event given that it has occurred.
- Risk is not a certainty
  - Range of expectations and probabilities
  - Something may be a risk in one setting and not in another
  - Risk is relative

Measured vs perceived risk

- What affects perception?
  - Context and past experience
    - Level and nature of knowledge
  - “Rules” for weighing information
    - Value systems
  - Control
  - Predictability
  - Perceived vulnerability
  - Prevalence of the hazard
  - Previous experience with the hazard
  - Proximity in time
    - Overestimate current risk and under-estimate future risk
- These affect the public and scientists
  - How do they affect your measurements?

Environmental Risk Assessment

- RA = identifying, mitigating or managing risks.
  - Diagnosis, prognosis, therapy
    - Classify the nature of the problem, predict the fate of the patient, intervene to maintain desired state
- Systematic way to deal with systems more “complex” than an individual
  - – consistency, repeatability
  - Generating information you are able to defend when making a big decision

- Risk assessment is an emerging component of policy and environmental management
  - ICES, OIE, NASCO, WTO
  - DFO, Provinces and States
- Basis for trade dispute resolution or decisions
  - Ex BSE and Brazil, Salmon and Australia
- Goals
  - more equitable, objective and evidence-based decisions
  - Take out personal biases
  - Transparent process

Some definitions

- **Risk assessment**
  - Process of establishing information regarding acceptable levels of a risk and/or levels of risk for an individual, group, society, or the environment.
- **Risk estimation**
  - Scientific determination of the characteristics of risks, magnitude, spatial scale, duration and intensity of adverse consequences and their associated probabilities as well as a description of the cause and effect links.
- **Risk evaluation**
  - A component of risk assessment in which judgments are made about the significance and acceptability of risk.

Role of risk assessment in management decisions

Risk Assessment

- process of identifying a hazard and estimating the risk presented by it (likelihood adverse and consequence)
- estimates uncertainty
- objective, repeatable & scientific

Risk Management

- process of identifying, evaluating, selecting & implementing alternatives to mitigate risk.
- managers make implicit judgments about safety of a course of action

Use of RA in policy and regulations

- Used to determine “acceptable” levels for regulations
- Site-specific information to guide land or water use
- Help set priorities (ie. Which issue to tackle first)
- Helps make risks substitution decisions

The 4 steps of risk assessment (version 1)

- Step 1 - Identify the **Hazard**
- Step 2 - Estimate the **Probability** of impacts due to the hazard
- Step 3 - Estimate the **Severity** of the impacts due to the hazard
- Step 4 Identify and **Communicate** ways to prevent risks

The 4 steps of risk assessment (version 2)

- **data collection and evaluation**
  - quantity and quality of available environmental data often determine the level of evaluation
- **exposure assessment**
  - determination or estimation of the magnitude, frequency, duration, and route of exposure for each potential or actual receptor population to be evaluated
- **hazard assessment**
  - weigh available evidence regarding the potential for a chemical to cause adverse effects
- **risk characterization.**
  - incorporates the outcome of the previous activities

My version

- **What could happen** in this circumstance?
  - Not just a theoretical list, but a consideration of real-world obstacles and opportunities for trouble
- **Who cares**?
  - What elements of the environment could be affected by this?
- **Why do they care**?
  - Are their concerns reasonable
    - » Is the evidence sound, are their concerns big enough, is there enough uncertainty in the presence of enough plausibility
- **Should they care**?
  - Is the bad thing scary enough and/or likely enough?
  - Is there a reasonable basis for concern?

Who are “they”?

What is the “unit of concern”?

- People
  - Individual disease (ex Toxins)
  - Population health (WHO)
  - Community well-being/economics
- Non-human biota
  - Individuals
    - » Ex. endangered species
  - Population, community
- Environment
  - Biotic, abiotic
  - Social
  - Concept of ecosystem health
    - » Social values vs energy flows
- All of the above

PURPOSE of an ERA

- Evaluate relevant environmental effects of a proposed or ongoing human activity before irreversible damage is done
  - Born from toxicology
- Can we do an ERA from a non-human perspective?
  - issues of how to evaluate and compare
    - » ex. economics of wanting to see a bird vs "development" of a rookery
  - Subjects other than people - more subjective
- People as risk factors and people as risk groups

History of ERA

- 1970’s UN recognizes resource depletion and economic risks
  - 1970’s Canada Environmental Assessment and Review Process
- 1980’s concept of sustainable development
- leads to new economic ideas of carrying capacity and integrated resource management
- 1992 Rio Conference on protection of biodiversity
  - Precautionary principle appears
- 1995 - Canadian Environmental Assessment Act
- Need to assess risks of irreversible or significant damage in the absence of perfect knowledge

Why are they started?

- industry requests new commodity or product
- a new pest or pathogen is identified
- a specific hazard associated with a project is thought to be linked to human or environmental risks
- changes in regulations
- new information on old projects arises

Most ERA are subjective

- Recent Examples
  - BC Salmon Aquaculture Review
  - Fish Transplant Committee/NASCO
  - Import of BC salmon products into Australia
  - In each case, these were fundamentally qualitative
- Lack of Quantitative Data
  - re: origins in toxicology
- Trade-offs between social expectations and what we know of ecosystem function
- RA tries to be objective, explicit and fair

S.I.R.

- **Systematic**
  - all-inclusive, objective and logical consideration of potential effects
- **Interdisciplinary**
  - ecosystem approach that includes human ecology
- **Reproducible**
  - must be clear, acceptable and understood by others

Key Steps of a Risk Assessment

- What is/are the question(s)?
- Identify the hazards
- Evaluate the Probability and Significance of the Impacts for this Case
- Identify key areas of uncertainty
- Recommendations

What are the questions?

- What is the situation being assessed?
  - detailed project description and the ecological footprint of the project
- Laws, policies, guidelines or regulations
  - Who will implement the above
  - Do they deal with this situation already?
- What are the concerns of the public, industry and government about the project
- RA methods developed for toxicology, but most fish health issues are biotic
  - Infectious disease ecology more complex that effects of toxins?

Risk profile - describe the setting

- description of the relevant issues (W5)
- values threatened & social perception of the risk
- who benefits from producing the risk
- who benefits or must manage the risks
- who are the risk producers & risk bearers

First Questions

- Is there enough information to assess potential impacts?
- Can the conditions of the specific project result in unacceptable risks?
- How much uncertainty are you willing to accept?

Identify Hazards

- **What could go wrong?**
  - Review similar situations - what is reasonable to expect
  - List key issues and potential impacts
- **Who or what will be affected?**
  - What is within the ecological footprint
  - Are their key/special groups or feature at risk
- **Not really a simple dichotomy.**
  - Hazard to something, not hazardous to another

Which hazards do you assess?

- Nothing is without risk
- Four key features of something to worry about
  - significant negative effects on health, environment, or economy possible
  - have the potential to increase their effects or distribution
  - can affect previous efforts to reduce risks
  - Significant public concern

Consequence of the hazard

- Estimating the effect of fish disease
  - confounded by environmental, social, management variables
    - ex. Whirling disease
- Preventing disease vs. population function
  - reproduction, predation, diversity and community structure influenced by disease
- Consequences range from individual to ecosystem to economic level
  - No description of the scale of hazards to consider in most regulations

Probability of Impacts

- Quantitative models preferred by many decision makers
  - but data often lacking
- Three key probability considerations
  - introduction of hazard to the area of concern
  - potential for “at risk” groups to be exposed
  - the potential for the hazard to be spread beyond the initial area of entry

Getting probability estimates

- Personal experience
  - concerns with bias or lack of breadth
- Expert opinion
  - similar problems to above, but more breadth
- Published data
  - are they similar enough to the specific project?
- Prospective studies
  - take time and money

Probability of event

- Emphasis on probability in policy
  - Assume that movement of pathogens = bad
  - Ex. NASCO introductions
- Never possible to know a fish or region’s disease status
  - characteristics of a group sample
    - homogenous methodology imposed on heterogeneous system
    - test limitations (PPV, NPV)
  - surveillance deficits (what is known)
  - Makes it hard to establish the “prior probability”

If an effect were to happen….

- … how widely would its effects be felt?
  - geographic spread
  - spread between species, populations, ecosystems
  - duration in time
- … how severe would the effects be?
  - trade barriers, species loss, deaths

Dealing with uncertainty

- Often, especially with environmental health issues, there is much that is unknown
  - important to be clear on your assumptions
- Sensitivity analysis
  - consider how changes in your assumptions affect risk assessment
- Often a political decision
  - need to explain how uncertainty can affect decisions

Recommendations

- Do nothing - allow the system to function without restriction or intervention
- Impose controls or bans - restrict human activity with certain safeguards
- Delay decision until better information is available
  - when is enough data enough
    - ex. Water quality at major Aquaria

Recommendations

- On a net basis, your recommendations should not increase risks
  - 1st do no harm
  - Then do the right thing
  - Then do the right thing right
- Trade-offs
- Consider economics, social, biological effects
- Consider short, medium and long-term
- Take a broad view

Trade-offs are a part of Risk Assessments

- Often, the goal is risk reduction, not risk elimination
- First reduction easiest and least expensive
- Successive gains often are hard to attain and are costly
- By applying resources to reduce 1 risk, you are eliminating resources to address another
- Need to set priorities

Many criticisms of risk assessment as a basis for management decisions

"Shot-gun marriage between law and science" (W. Ruckelhaus)

Overestimates risk

- possibility vs. probability
- leads to excessive control

Underestimates risk

- unknown, unexpected or synergist effects
- values vs. data
- precautionary approach
  - insufficient protection

Application of science methods to administration and legislation but fails to satisfy either

Sources of criticism

- **Unrealistic expectations of RA**
  - Want the right answer with certainty
    - RA are exercises in probability
- **Poor basis for prediction**
  - Lack of data on all ecological aspects
  - Lack of understanding of effects of perturbations in complex systems
  - Stochastic error (Several alternate and unpredictable factors)
  - Systematic error (Ecological relationships affecting outcomes largely unknown)
- **Lack of integration of scientific, management and societal concerns**
  - Results in real and perceived conflicts
  - widespread lack of public confidence in traditional narrowly-framed, expert-based, quantitative approaches

Risk Assessment Can

1. Identify significant hazards
2. Identify significant unknowns
3. Identify regulatory and policy goals and priorities
4. Communicate issues clearly and objectively
5. Examine issues comprehensively and completely

Risk Assessment Can't

1. Determine if a risk is acceptable or not
2. Make the decision for you
   - Ultimate decision is a societal or political choice
   - RA assist in informed decision making

What is at risk?

- Health vs. disease regulations
  - Absence of disease vs. capacity to fulfill expectations
  - Regulations focus on acute visible outcomes
  - Little work on medium – long term outcomes
    - Nor to effects on ecological structure or function
- Determinants of health
  - Whose health?
    - Fish, population, community, people, ecosystems?

Dealing with Complexity

Few programs look at risks in a comprehensive fashion

- mixed populations, multiple hazards, various strains - leads to uncertainty
  - Risk assessments don't resolve complexity, but illuminate it
  - Current approaches don't fully illuminate risk components
- Few policies specify the breadth of species, hazards, time-frames or benefits when discussing risk assessment

Every problem has multiple values

- Risk means different things to different people

Science – focuses on probability and impact measures

Society focuses on aspects of the hazard

Features of hazards increasing risk perception

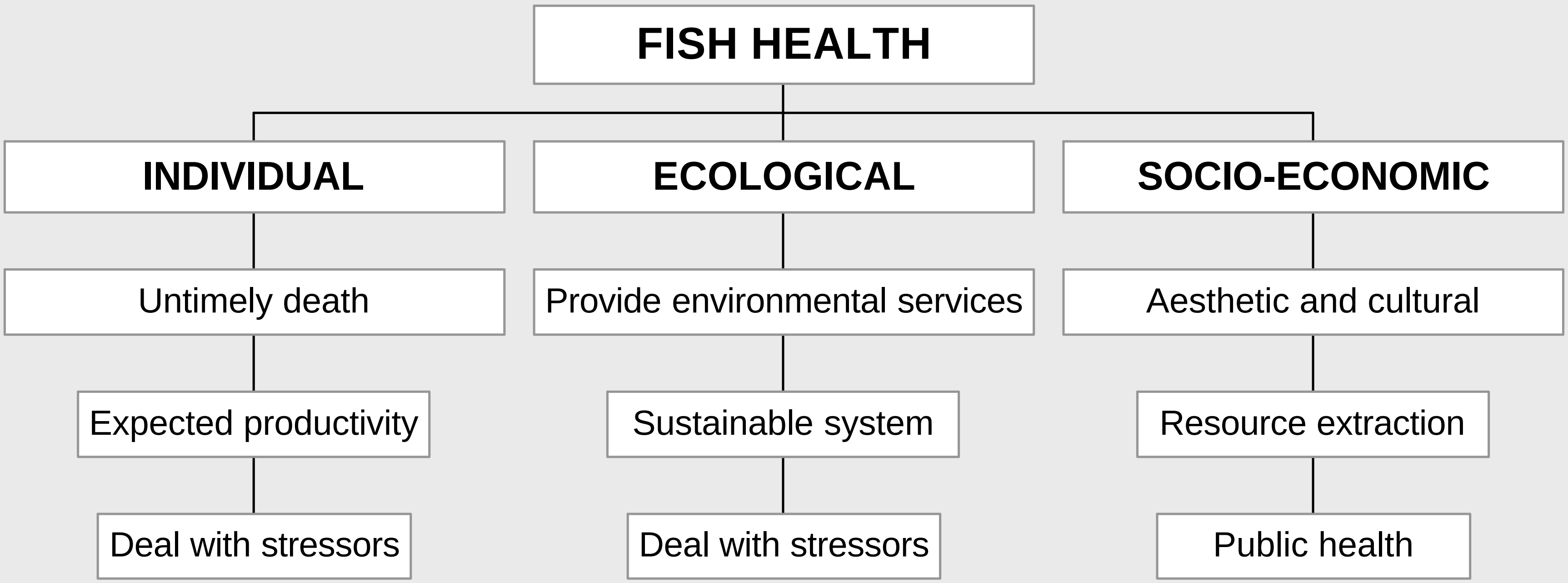
Not observable	Uncontrollable	Not easily reduced
Effects delayed	Dreaded outcome	Risk increasing
New risk	Catastrophic outcome	Involuntary
Risk unknown to science	Not equitable	Hi risk to future generations

Uncertainty, surprise & values

- RA tends to deny the prospect of surprise and neglects the implications of divergent values
  - Many of the recent “big issues’ were surprises (ex. BSE, endocrine disrupters)
- RA is inapplicable to the condition of ignorance
  - probabilities +/or the possibilities subject to incomplete knowledge
- Basic principle in rational choice theory
  - no definitive 'rational' way to combine different value judgements or framing assumptions in appraisal
  - Single value RA meaningless

Assessment vs Management

- Weighing social and economic factors = role of the manager
- Identification of values at risk = role of the assessor
- Assessment of science without the context of social and management objectives can lead to irrelevant assessment
- Regulations lack specific methods for applying risk assessment
  - Regulations speak of risk assessment and assume a risk management approach will follow


FISH HEALTH
INDIVIDUAL
ECOLOGICAL
SOCIO-ECONOMIC
Untimely death
Provide environmental services
Aesthetic and cultural
Expected productivity
Sustainable system
Resource extraction
Deal with stressors
Deal with stressors
Public health

Fish Health Risk Issues

DISEASE OF AQUATIC SPECIES	ECOSYSTEM VALUES AND SERVICES	PUBLIC HEALTH	SOCIAL, CULTURAL & ECONOMIC VALUES

Health Intelligence - *proactive identification of hazards*

Scoping issues – *describe the nature and scope of the problem*

Risk Assessment - *synthesis and explicit description of the issues and unknowns*

Dissemination- *information presented to those that need to know*

Follow-up – *evaluate and archive of results*

IDENTIFY & PRIORITIZE PROBLEMS	ASSESS SEVERITY & PROBABILITY OF OUTCOMES	DETERMINE LEVEL OF UNCERTAINTY	SUPPORT RISK MANAGEMENT PLANS

Management and Policy Plans and Priorities

Managing Aquaculture Risks

- Policies relevant to aquaculture were designed for wild fisheries
  - Initial agencies responsible had little or no experience in growing food
  - Rapid expansion of aquaculture locally and internationally outran the adaptation of policies and practices
- Policy decisions are being made in the limelight of concerns from environmental groups & pressures from coastal communities
- Regulatory authorities have turned to risk assessment as a means to make “objective and transparent” policy decisions

Risk and Decisions Making

- Uncertainty about the future effects of today's decisions is the reason for risk assessment and management
- Can make decisions intuitively or explicitly and systematically
- Aquaculture illustrates limitations to "traditional" risk assessment.

<u>Decision cascade</u>

- Clarify the major issues
- Determine what is preventing a decision
- Identify a clear course of action to decision makers
- Justify the basis for the decision to supportive and doubtful stakeholders

Clarifying the Major Issues Risks from Aquaculture

Risk to Society

- Food safety
  - Contaminants (drugs and biological), disease, quality
  - Farmed and wild species
- Economic
  - Risks to other sectors (wild fisheries, tourism)
- Culture
  - Infringe on First Nations
  - Change fabric of rural economies (industrial activity)

Risks to the Environment

- To other species
  - Disease
  - Genetic
  - Ecological
  - Killing wildlife
- To habitats
  - Nearshore development and beach modification
  - Wastes and pollution
  - Water quality

Clarifying the Major Issues Risks to Aquaculture

- Policy
  - Location & expansion, regulatory costs-of-production, drug use, egg imports
- Perception
  - Affects market access
- Environment
  - Disease (in the wild and "continued by culture")
  - Water quality (Algae)
  - Inability to regulate growing environment
  - Problems of confinement (escapes, growing technology)

What is preventing a decision?

- Decision maker has to choose between alternatives (each with their own outcome)
  - If the likelihood of the outcome is known, the decision is based on the preference for the various outcomes
  - In uncertainty – either need to model the outcomes or use game theory or other devises to rank outcomes

Setting a clear course of action

Methodological

- Specific unknowns that should be locally addressed
  - Drug residues in food and environment, # of mammals killed, stream survey for escapes
- New methods
  - incorporate diverse information to assist decisions
  - Dealing with uncertainty

Managerial

- Specific rules recommended
  - based on 1st principles
- Need a coordinated approach
  - Duplication, poor communication, contradictions & conflict
- Coastal zone planning
- Consider aquaculture as an agri-business

Avoiding Surprise (Levins 1995)

- Improve predictions by studying problems in socio-economic framework
- Improve capacity to detect problems through collaborations
- Reduce vulnerability by maintaining adaptable systems
- Expand prevention into larger systems so they can influence events before they occur

Aquaculture Risk Management

Risk detection

- Things that indicate an increased likelihood or severity of -ve outcome
  - Outbreaks, drug use
  - Market trends, coastal development
- Proactive not reactive
- Prevention model
  - Early detection = early intervention

Risk Assessment

- Comprehensively describe
  - Determinants of risk
  - Determinants of preferences
- Sensitivity analysis
  - outcomes of decision alternatives
  - Influence of uncertainty

Aquaculture Risk Management

Risk Management

- Ways to reduce risk
  - Dx and Mgt of disease
    - Impacts on people and other food stuff
- Rules to reduce risk
  - Codes of practice
    - Evidence based
  - Integrate with DFO Fisheries Policies

Risk Communication

- To Markets
  - Establish safety of product and production
- To Industry
  - Primary prevention
- To Regulators
  - Timely response and reasonable reaction
  - Decision alternatives
- To Public
  - Rational food selection

Step 1- Describe the Issue

- **Scoping**
  - Complete description of the project or event that is to be evaluated
    - In order to identify components of the biophysical and social environment that may be impacted
- Needs to be the first thing done
  - Needs to be of <u>sufficient</u> detail
- **Set clear boundaries**
  - What is included/excluded?
  - What is the system(s) of concern?
- **Set priorities**
  - Big concern vs little
  - Big info needs vs little
- Does public input start now?

Deciding on the issues

- **Legislation**
  - May be a define scope of issues
- **Experts**
  - Defer responsibility
  - Critical appraisal
  - Systematic methods for seeking expert opinion
- **Public and stakeholders**
  - Ask what people care about
  - Social values, economic, health
  - Focusing on concerns of public and stakeholders is a good place to start
- **Proponent**
  - They should have identified the risks
  - Goal – prevent unacceptable risks, so better work together

Boundaries

- Need clear objectives to narrow the scope
- Are there units of special interest at risk?
  - Endangered species, high risk people, critical habitat
- Risk/benefit analysis
  - Someone is doing the project for some benefit
    - Is there unequal distribution of benefits?
  - Are risks unequally distributed?
- Spatial boundaries
  - Ecological footprint concept
- Temporal boundaries
  - Short, medium and long-term
    - Planning to project end
  - Longer the time, harder the prediction
- Legislative boundaries
  - Where does you level of involvement start and end?

What species do you pick?

- Site and issue specific
- Some features to consider
  - Species that play an important role in community structure or function
    - e.g. keystone species, top predators, major herbivores
  - Diet or habitat preference and behaviours that make the species likely to contact the hazardous agent
  - Species from different taxa that might show a range of effects
  - Local species of regulatory concern

Valued Ecosystem Components

- Those components of the ecosystem considered important
  - Ecologically and/or socially
- Need to place the project in an ecological context to identify VECs
  - Ecosystem structure (biodiversity, habitat features)
  - Ecosystem function and functional relationships
  - Are there weak points?
    - Resilience, redundancy, anticipated uses, keystone species
- Need to know legal status
  - Parks, protection
- Need to know social importance
  - Harvest, culture

DATA EVALUATION

- Rely heavily on existing/historical data in order to reduce cost and time
- Maintain a consistent standard for weighing and accepting evidence and observations
- Identify key information gaps
  - Help focus prospective data needs
  - Often lack site-specific information
- What is evidence?
  - Experimental data vs personal observation
  - Not all data is of the same value
  - Need a system for critical evaluation and weighing
  - Hard to do for value judgments
    - Willingness to pay methods
- Critical review of literature

Critical Review of the Literature

- Why bother?
  - –Rarely is there time or money to do prospective research
  - –Need the literature as key evidence to assist in making predictions and to estimate probabilities and severities
  - –Literature growing at alarming rates
    - Need a system to quickly find the articles that will help you
- Need to find those that are valid and applicable to your problems of interest
- **Big problem**
  - –Accepting only the best evidence will greatly reduce your selection

First Quick Steps for selecting the ones to read further

- Title
  - Does it seem relevant?
- Authors
  - Do they come from a reputable facility? What is their track record?
- Abstract/Summary
  - If the conclusion is valid, is it of interest to you?
- Consider the site/study group
  - Is the site and study group sufficiently similar to the one that interests you to apply the conclusions (if valid) to the issues concerning you?

Conclusions giveth, Materials and Methods taketh away

- You need to read the materials and methods to make sure the results are valid.
- Was the study design suited to the objectives of the study and/or can it generate data to support conclusions?
  - Effects of an intervention
    - Randomized clinical trial
    - Blinded study in an appropriate setting
  - Determine etiology
    - Experimental, case-control, cohort
  - Forecast the fate of a group
    - Cohort, survival analysis
  - Describe population features
    - Cross-sectional studies, surveys

Just saying you designed the right study is not enough

- Sample selection
  - Who/what did they look at?
  - Appropriate spectrum of measurements included in this group?
  - Were samples selected in a way that they represent the target population? What is the target population?
- Sample size
  - Large enough to take variation into account? How did they decide on the sample size?
- Definitions and classification
  - Do you accept their classifications
    - Are misclassifications an issue?
- Did they analyze the data appropriately
  - Meaningful and valid measures of effect
  - Appropriate statistical tests

Subject allocation

- How were subjects selected?
  - If not random, were there biases
- How were they assigned to comparison/control groups
  - Based on disease status, exposure status, or randomly
    - Was it appropriate for the study design?
    - Random vs "haphazard or purposively unbiased"
    - Did they "control" for the right things?
- Who was excluded and why?
- Were all those selected accounted for in the results
  - Was there a reason for the drop-outs?
- Were those included in the study enough like the population you are interested in to generalize the results?

Results

- Once you have decided that the methods can answer the questions look at the results
- Outcomes measured
  - Were they relevant?
    - Did it measure the effect you are interested in. Does it reflect the problem accurately? Is it measurable? Can you apply it?Were others measures needed as well?
  - What was the size of the effect measured
    - Biological vs statistical significance
- Do all the numbers add up?
- Do the results make sense?
  - If surprising, are they plausible or just wrong?

Key Points

- Remember, biology emerged before statistics
  - Use biology to select statistics and not vice versa
    - Problem dictate the methods
- Occam's razor vs Gaia
  - Hypothesis is the simplest one possible, consistent with the evidence, with the fewest unknowns.
  - Life is complex and interrelated
    - Ecology of complexity
    - Role of describing your ecosystem
    - How to pull together isolated experiments into ecological reality?
- Tests of hypotheses are based on estimates of the "cost" of being wrong
  - What is a p-value?

Key Points

- Science is the “construction of models of nature”
  - Don’t mistake the model for reality
    - All models are abstractions and simplify reality
    - For better and worse
    - Massive amounts of data don’t alone improve a model unless they are collected with specific hypotheses in mind
- Most statistical tools assume randomness and independence.
  - Lack of independence is the more serious problem
    - Can’t fix after the data collected
  - Ecological data rarely fits undergrad stats
    - Missing data, different kinds of measures, randomness, non-normal data etc

Key Points

- Samples are collected by some methods that is not 100% efficient or unbiased
  - What population are you really sampling?
- All stats and measures are false to some degree
  - Issues is not if assumptions are met, but whether the plausible violations have serious consequences
- Are the data presented in a way that helps in prediction of future events

Important questions

- Have they considered temporal and spatial variation?
  - Can the sampling scheme appropriately capture variations or are you getting “snapshots”
- Is the sample size appropriate to the size, density and distribution of the organisms to be sampled?
  - Remember, a good sample is a large sample, but a poorly designed sample is poor no matter the size
- Do the analytical methods consider the nature of the data?
  - Can violations to assumptions be dealt with
- Can you accept the outcome?
  - Did you accept or discard the unexpected results or did you hunt for a methods to give you what you want

Conclusions

- Are the conclusions supported by the results?
- Were the objectives met? What was the answer to the study question?
- If causal statements are made, are there data or references to fulfill criteria for causation?
- Are there conclusions made beyond what the results and references can support?
- Can they make generalizations?
- Are appropriate biases accounted for the direction and magnitude of their effects taken into account?

Bias in Observational Studies

- Dozens of possible biases
  - In general, selection bias, misclassification bias
- Basically need to know
  1. Are we properly classifying study subjects
  2. Are we adequately reflecting the population of concern
  3. Are we properly measuring the results?
  4. Have we made appropriate conclusions?

Biases in references

- Rhetoric bias
  - Authors don't base statements on reason or references
- Positive results bias
  - Tendency not to publish negative results
- One-sided reference bias
  - Only references supporting a view are presented or those contradicting the author's view are not weighed appropriately

Biases in specifying the sample

- Capture bias
  - The ways subjects are entered to a study depends on how you get them
  - Many causes
    - Ex. Microbial culture methods used
- Unmasking bias
  - Some factor (perhaps another exposure) makes you suspect an outcome, even though it is not a causal factor.
    - This prompts you to look carefully for the outcome
      - Ex. the use of pencillin in a case makes you use anaerobic culture to look for Clostridial overgrowth
    - Careful with being too restrictive in dealing with this bias as it may restrict samples selected

Bias in Measuring Outcomes

- Exposure suspicion bias
  - A knowledge of a subjects outcome status affects how hard you look for an exposure
- Treatment perception bias
  - Investigator not blinded and interprets effects differently in treated vs controls
- Missing data bias
  - Why are they missing; Because they are normal, negative, not measured, or not recorded?
- Insensitivity Bias
  - Measurement used can't detect clinically significant differences

Bias in analyzing the data

- Post-hoc significance bias
  - Change criteria for deciding significance to get the results you want
- Data dredging bias
  - Data are reviewed for all possible associations without a prior hypothesis
- Tidy-up bias
  - Extreme or unaccepted results excluded from analysis
- Missing data
  - Not all cases are included in the data analysis

Bias in interpreting results

- Magnitude bias
  - Selection of the scale of a measurement affects the interpretation
    - Ex. $1,000,000 vs 0.0003% of national budget
- Correlation/Association bias
  - Mistake correlation/association with causation
- Significance bias
  - Statistical vs biological significance
  - Accept small associations or marginally statistically significant results as strong evidence

Preventing biases

- Best to do it by design
  - Easier for measurement biases than sampling biases
    - Blinding
    - Establishing explicit outcome or exposure criteria
    - Using independent sources to get exposure information
- Sampling biases
  - Work hard to get a the sample size and make-up needed
    - Can be very expensive and time-consuming
- If you can’t prevent, consider in the conclusions
  - Magnitude and direction of the effect on the estimate of risk

Measurement is the issue

- Quantitative vs qualitative?
  - Is the number meaningful?
  - Will a single number really describe the issue fully?
  - Is some number better than some warm fuzzy description
- It all starts with a good description
  - Think of ecology
    - Descriptive (what) functional (how) evolutionary (why)
  - All RA should be qualitative and some may ALSO be quantitative

Ways to do assessments

- **ad hoc**
  - Large multidisciplinary teams focus on big areas of impact rather than defining specific parameters
  - often produce qualitative statements frequently based on subjectivity and intuition.
- **Checklists**
  - Variant of ad hoc, but prescribe the things to consider
  - No guidance on how to integrate or weigh information
- **Matrices**
  - visually describe relationships between specific environmental components and specific activities/risk factors.
    - Cells in the matrix filled with qualitative or quantitative data.
    - Weighing schemes may be used to total all cells in the matrix to develop an “impact score”
    - examine cause-effect relationships between isolated pairs of factors

What could go wrong?

- First think about the targets
  - hazards to me not necessarily the same as a fish
- Consider time scales
  - Immediate vs long-term
- Consider interactions
  - Cumulative impacts
  - RA born of single effects from single agents
  - ERA- need to think of interacting insults affect different populations made up of individuals of differing susceptibility
- Direct and indirect effects
  - Ex. Insults that don’t affect macrobiota may affect microbes. This in turn affects primary production & decompositions that then affects macrobiota and system therodynamics

Int’l Animal Health Code

- Emphasis on pathogens
- Surveillance is a weak point
  - How do we know the pathogen distribution in all possible targets
    - Even true for some aquaculture, especially true for wild fishes
    - Relies on zoning and surveillance of a competent authority
    - Assume tests and surveillance work
- Requires a split – hazard or not
  - What about highly susceptible groups?
  - Immunocompromised, species difference
- Not unlike other agencies dealing with fish concerned with import/export
  - Not really set up to think ecologically

Your Goals

- Help people make good decisions about
  - What actions they should take in response to a perceived change in fish health
  - The need and nature of actions to protect health
- Provide evidence that health changes
- Provide evidence that a factor changes health
  - Risk factors
  - Treatments and vaccines
- Show that an management action is worthwhile
  - Economically, ecologically, animal welfare

Fish Health

- What is health? (An evolving concept)
  - Absence of death
  - Absence of disease
  - Ability to deal with stressors/changes
  - Absence of risk factors
  - Ability to meet expectations
    - Biological, ecological, social
  - State characterized by anatomical integrity, ability to perform expected individual, population and community roles; ability to deal with physical, biological and social stresses, and freedom from risk of disease and untimely death
- Why worry about fish health?
  - Disease is a major limiting factors in culture
  - Role of disease in wild stocks
  - Fish as bioindicators
  - Food safety
  - Want to associate a cause with an effect to prevent, control or reduce the effects of disease on individuals, economics and ecosystems

Infection vs Disease vs Health

- Clinical disease = a state of dysfunction detectable by the clinician's senses.
  - Illness/sick = the patient perceives the problem
- Subclinical disease = a state of dysfunction not detectable by the clinician's senses.
- Incubation = time between exposure to an etiologic agent and the manifestation of disease
- Infection = the presence of an infectious agent in a fish
  - Parasites or chemicals
- Important distinction
  - Transplant permits/policy
  - Salmon Aquaculture Review

Things Needed to Study Fish Health

- Know what it is we are measuring
  - Health, disease, infection
- Accurately classifying the health of individuals & populations through careful clinical observation, reliable tests and precise counts of cases and non-cases
- Sub-divide and enumerate the population into those that are healthy, those that are not and those that are at risk
- Able to characterize the populations and environments where cases and non-cases occur

Studying disease

- Early fish disease – taxonomy of parasites
- 1950's aquaculture and pollution
  - Interest in pathology and etiologic agents
  - Aquaculture – infectious/parasitic
  - Bioindicators - chemicals
- Epidemiology
  - The population approach is rare: Why?
  - Training – reductionist
  - Methods – how to study populations
  - But – this is the level of management and ecology
- "While it may be possible to relate the effects of a single factor to the well-being of a single fish, it is another matter to interpret the response of multi-species fish communities to a suite of stressors, of which disease is only one"
  - Most fish health research = looks at isolated parts of isolated disease
  - Not necessarily reflecting reality

Why the population approach?

- 5 variables determine whether or not an infectious or parasitic agent will persist in a population:
  - the density of the hosts,
  - the probability of transmission per contact between susceptible and infectious hosts,
  - the disease-induced mortality rate;
  - the per capita death rate of uninfected hosts and
  - the rate of recovery from infections
- Reed-Frost Model
  - Disease management requires population management
  - Lab studies tell use mechanisms of disease, but populations studies tell us about how disease works in nature
    - Key determinants of causation
- Individual fish not independent in a group

Describing what you see

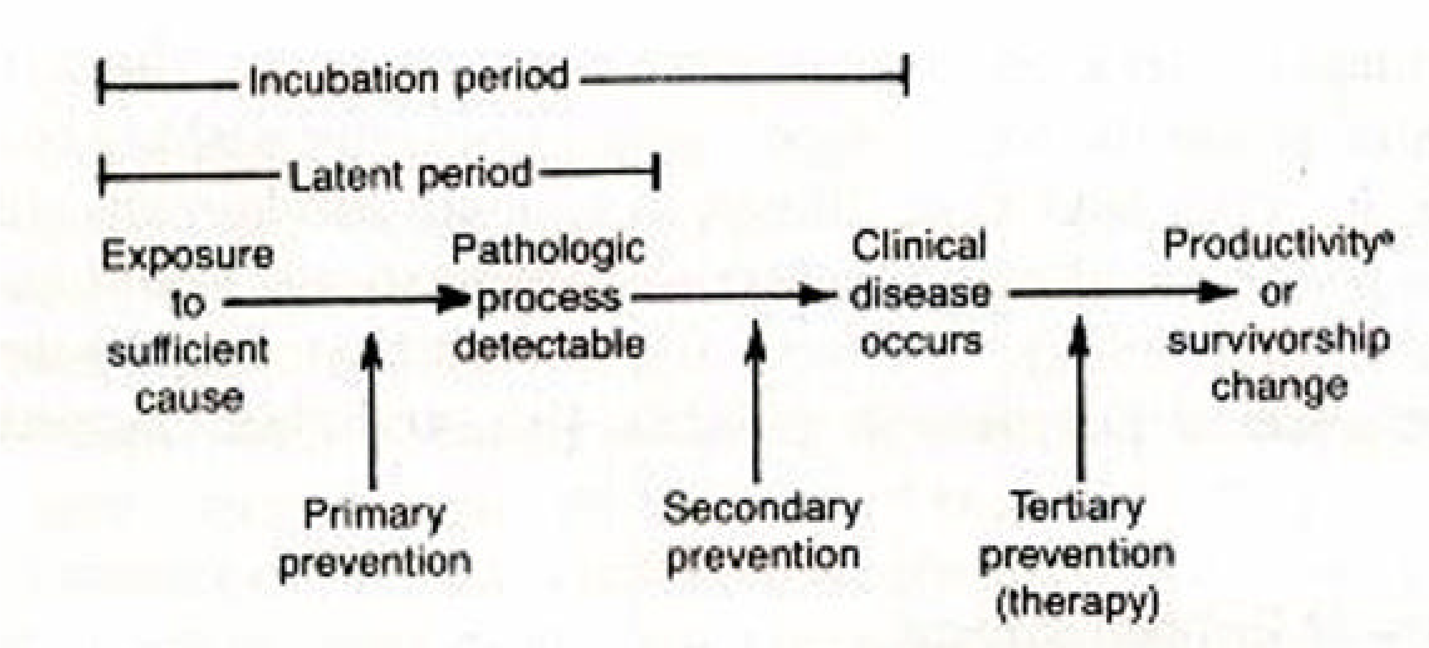
- To identify the fate of a fish, associate its health with a specific risk factor or select a specific intervention to manage health requires that we consistently label and classify a fish's health status
- Need to know
  - What is normal or expected
  - How to make a diagnosis
  - What a test results means
  - How to predict the future (prognosis)
- Health/disease is a spectrum
  - The location of the cut-offs is important
  - Incubating, subclinical, clinical, lethal or recover
- Very little work done in fish to characterize how well tests predict reality
  - Also little done on looking at tests at a group level

Diagnostic consistency

- Can be compromised by many factors
  - the failure to apply standards case definitions,
  - the use of imprecise tests,
  - reliance on subjective or overlapping diagnostic criteria,
  - unequal diagnostic experience
  - poor quality diagnostic material
- You can control some of these, but simply acknowledge the others when reaching your conclusions
- We can never know the truth
  - All tests are estimates of the true health status
  - What is their predictive value?

Numbers are necessary

- Fish are managed as populations
  - Many of the expectations are based on productivity (harvest, growth, mortality)
  - Many of the first indicators of illness are seen as a failure to meet these expectations
- The need for rates
  - Numerator = number of cases
  - Denominator = population/time
  - Risk of changing pictures of disease due to changing populations
    - Ex. Marine Anemia



-Primary = prevent exposure (prevent the onset of pathological process)

-Secondary = detect disease before clinical illness (prevent someone from getting sick)

-Tertiary = treatment (prevent severe disease)

Epidemiology involved in all 3 levels of prevention

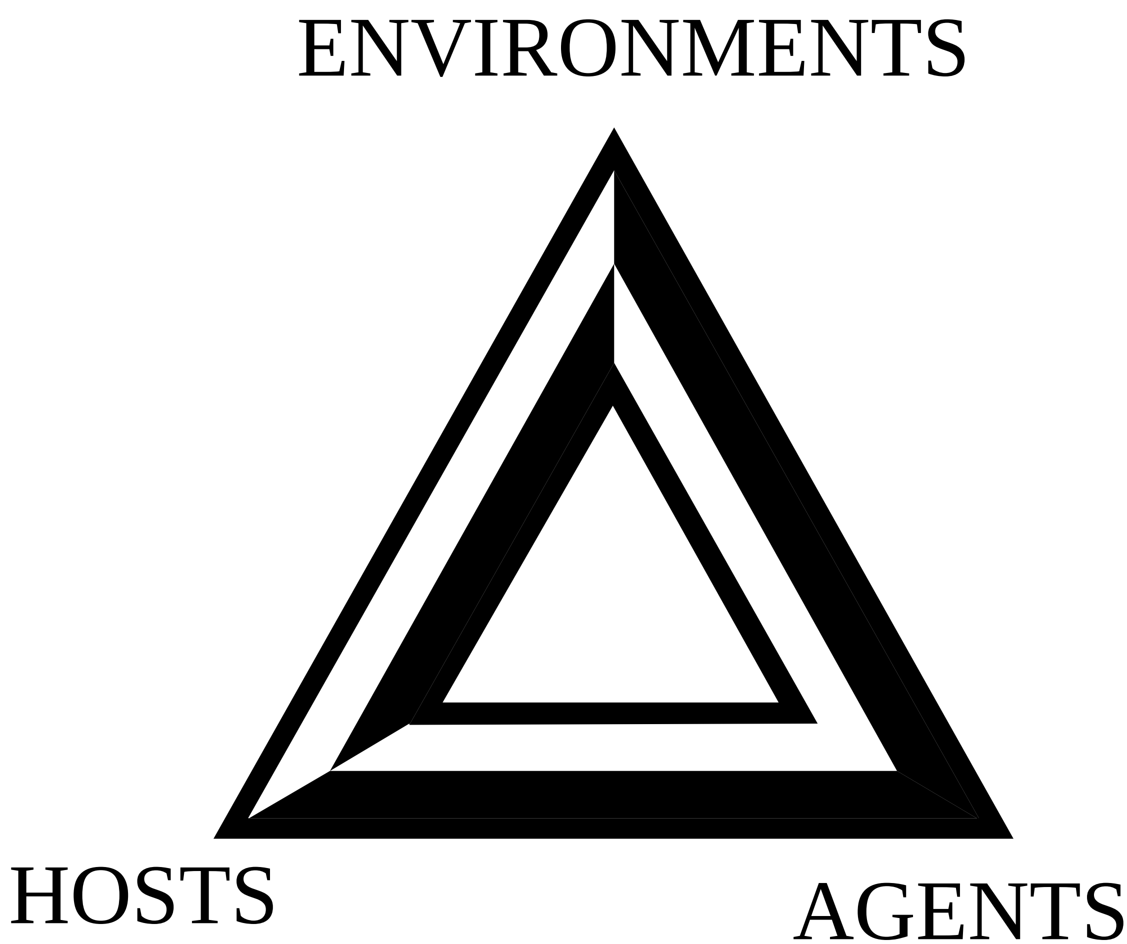
Health at various levels

- A fish can be healthy, even if it is not perfect
  - Ex. deformed Chilean salmon grow well
  - Ex. infested with a few lice
  - Ex. Kudoa
- A group of fish can be healthy, even if it has some diseased fish in it
  - Ex. Mortality rate is never zero
- What about fish communities?
  - Diversity, abundance, size distribution
  - Ex. tumors in flatfish
- What about ecosystems?
  - What is ecosystem health?
  - Energy flow, biodiversity, resilience etc
  - Fish populations often used as indicators

Practical Considerations

- For fish, expectations (and thus, definitions of health) will vary from situation to situation
  - Ex. Fish culture – feed conversion
  - Ex. Wild stocks shifting from maximum harvest to preservation ethic
- You need to understand what expectations are for the group of interest
- Then you need to make sure you present an unbiased and accurate description
  - Bias and accuracy – think of a bullseye
- Then you need to interpret what those descriptions means in terms of impacts and actions
  - Not just a science issue
  - Sociology, economics, ecology, risk assessments

Classical Triad



Determinants of Disease

- Any characteristics that affects health
- Intrinsic determinants
  - Organ failure (cardiomyopathy)
  - Behaviour (rockfish lip lesions, aggressive interactions)
- Extrinsic determinants
  - Trauma (handling and descaling)
  - Chemicals (pollutants and tumors)
  - Diet (fatty liver)
  - Parasites, bacteria, viruses
- But these do not work alone… they interact with other determinants
  - age, species, hormone status (spawning), nutritional status, climate, etc

Ecosystem Health

- Ecosystem = interacting living organisms & non-living components of the environment to form 1 physical system
- 3 major problems
  - Lack of consistent, simple and comprehensive way to classify and compare health
  - Not enough data to characterize complexity
  - Too much data, but it is not collected with the same shared purpose
- Tiered approach to collecting and organizing data
  - Screening to detailed testing
- Defining health = a key problem
  - Part philosophy, part lack of key indicators
  - What are normal/expected values
- Defining patients is another problem
- Identifying disease is a third
  - Variation over time = normal, but when do we cross a threshold to danger?

Diagnosis?

- Is there an objective set of measures to classify ecosystem health?
- Need to identify states of normality and spectrum of disease
    - When is a change predictive of a bad outcome?
  - Measurable parameters and their variation
  - How to interpret and analyze what you measure
- Disease due to damage of the parts
- Health due to optimal performance and relationships
- Disease is 1 thing that impairs health
  - Lack of ability to adapt, lack of resources to respond are others
  - Do we exceed homeostatic capacity?
  - Ecosystem respond slowly, therefore, hard to see when the change occurs

Signs of ecosystem distress

- Reduction in native species
- Regressive succession
  - Change back to an earlier state of succession
- Rapid change in biomass (up or down)
  - Can be normal, but is it sustainable?
  - Biomass is a reservoir of energy and material
  - Changes= accumulations or losses of this matter
- Changing gross or net primary productivity
  - Amount of energy changes, the system changes
    - Changing energy flows
  - Consumers and decomposers
- Changes in mineral macronutrient stocks
- Changes in ability to respond to change
- What about the social perspective
  - Meets needs and expectations
  - Environmental services (food, air, water)
  - Economic services (harvests, industry)
  - Cultural services

Tracking health

- Looking at 1 species – miss the whole
- Looking at all species – not possible
- Dynamic
  - Succession – sign of health.
  - Change – health
  - Modify criteria as things change
    - Normal succession vs unsustainable
    - Thermodynamics often the “common currency”
- Isn't defined by a single number
  - Suite of measures of structure, function and relationships
  - Work hierarchically
    - Don’t start with the details with knowing how they relate to the whole
- Use measures that are meaningful and interpretable
  - Consider expected variations in space and time
    - Ex. biomass will vary in a lake with depth (temp, nutrients, light)
- How can we have a standard approach applicable over heterogeneous ecosystems?

Health Impacts

- Depends on how you define health
- Depends on what your targets of concern are
  - Regulations often assume individual impact=pop impact = ecosystem impact
- Need to consider > individual
  - Sustainability is a goal for the GLFC
    - May not be for trade
  - Reed Frost Model
    - Cases increase if susceptibility or exposure is increased
- Need to consider outcomes more than death

Significant health effects

- Concept of significant cannot be separated from “adverse” and likely”
- Central tenet of many laws is whether or not the risk is significant
- Canadian Environmental Assessment Act sees something as significant only if:
  - Causes direct change in the environment
  - The environmental change causes
    - Health and socio-economic effects
    - Effects on physical or cultural heritage
    - Effects on traditional aboriginal land use
- What about ecological function
  - Is this physical heritage?

Framework for finding significance

- Decide whether the effect is adverse
  - Compare the quality of existing environment with the predicted quality due to the hazard
    - Implies pre-existing monitoring and good predictive ability
- Effects on environment include
  - -ve effects on health of biota
  - Threats to rare or endangered species
  - Reduction in diversity of disruption of food webs
  - Discharge or release of persistent and/or toxic chemicals, microbes, nutrients
  - Population declines
  - Loss of commercial species

- Removal of resources
- Transformation of natural landscapes
- Obstruction of wildlife pasage or migration
- -ve effects on biophysical properties of the environment (water quality, soil loss etc)
- Effects on People
  - -ve effects on health & quality of life
  - Unemployment
  - Reduced recreation quality or quantity
  - Cultural impacts
  - Foreclosure on future land use potential
- Duration, frequency, distribution
- Reversibility

Benchmarks for significance

- Need to pick between the real vs perceived; the likely vs unlikely and the kind of bad from the really bad
- Need to identify impacts of most concern that will require avoidance, prevention or mitigation
- Need to rank significance to help compare alternatives
  - Nothing is zero risk, but not every risk is horrible
- Elements to consider
  - Distributions
    - In time (frequency of insult), spatial and target
  - Magnitude
    - Significance is not magnitude alone
    - Established standards
  - Likelihood

Describing significance

- Now it gets tricky
- Why?
  - Need to communicate the meaning of all the stuff you have done up to now
    - To decision makers, stakeholders and public
    - Can you have a shared language
  - Need to be able to compare
    - So we need a comparable scale for significance
    - Hard to do when we have had so many opportunities for opinion in the process
      - Hence the appeal of a computer model
      - But there are still lots of decisions made for models
- Options
  - Descriptive terms (high, medium, low0
  - Numerical weighing scales

Subjective weights – options

- Panel of public, scientists, managers, politicians etc
  - Option 1 - Each person ranks all impact areas and compares in a pair-wise fashion the degree of the worst with the one next to it
    - Provide a scale for comparison
      - A problem scored 4 must be twice as bad as 1 scored 2
    - Willingness to pay approach
  - Option 2- Delphi exercise
    - Solicit opinions and ranking. Collect all answers, get central tendency and variation.
    - Feed back to participants so they see how they scored compared to others
    - Allow them the chance to change based on where they compare
    - Cycle until you get stability
      - Then either identify areas of great agreement or see some agreements emerge

Standards vs acceptability

- A common way to judge significance is to turn to guidelines, standards or published objectives
  – Only available for a relatively small number of hazards, species and settings
  – Generally, don't consider multiple or interacting hazards
- What is an acceptable level of risk?
  – Public sentiment
    - Hard to communicate risk to people, let alone to get informed opinion on ecological effects
  – Cost-benefit analysis
  – Conventional wisdom = acceptable is a risk between 1 in 10,000 to 1 in 1,000,000.
    - But meaningless without magnitude associated

Exposure Assessment

- We have a list of what could go wrong and who/what is in the system.
  - But a hazard won’t become a risk if I am not exposed
  - Need to do exposure assessment to determine what could go wrong
- Determine the pathways & rate of movement of the hazard, its transformation & degradation in order to see if susceptible are exposed to enough to cause significant effects
- Characterizes the exposure setting
  - What are the routes of exposure
  - Who/what is in those routes
  - What activities/characteristics increase or decrease exposure along the route

- Most publications on exposure assessment are for contaminants
  - Dose-response done in labs
  - Environmental fate models for some
    - Can question ecological reality
  - Problems with measuring effects at the cellular level, but being concerned with populations
    - Ex. Exxon Valdez and herring
- What are relevant exposures for infectious agents?
  - Colonization vs infection vs disease
  - How to measure relevant environemtnal levels
    - Microbial ecology of the organisms
    - Niches outside of main host
    - Viable but non-culturable
    - Environmental effects on transmission and survival
    - Host population dynamics a major factor in determining effective transmission and propagation

- Environmental simulation models for fate of toxins
  - Similar models not available for pathogens/parasites or “atypical” pollutants like drugs
  - Watch the assumptions
  - Look closely at the data used to develop the model
- “Personal exposure monitor” is the ideal
  - Ex. sour gas and cattle
  - Best to link cause and effect and best to measure level of exposure
  - When this isn’t possible, need to consider things like:
    - Form of exposure
    - Frequency of exposure
    - Duration of exposure
- Concept of connectivity is important

Connectivity

- important effects on ecosystems arise from the ways in which different sites interact
  - Ex. dispersal important for competition and reproduction
- effects of ecological processes across an entire landscape are often different from their effects within a small area
  - Locally unstable, globally stable
- Sites in a landscape are "connected" if there are patterns or processes to link them in some way
  - Structural links and functional links
  - Small shifts in connections can produce large effects

What affects exposure?

- Normalizing factors
  - For contaminants
    - Body weight, growth, metabolic rate
- Contact route
  - Oral exposure
    - Food ingestion rates, dietary preference, water ingestion, soil ingestion
  - Contact exposure
    - Inhalation and dermal
      - Similar for fish
    - Surface area of exposed tissues, environmental concentration
- Population dynamics
  - Distribution
    - Social organization, density, home range
  - Birth, death, maturation, movement, seasonal aggrgation

Agent effects on exposure

- Effective Contact
  - Enough agent, surviving long enough
  - Route between hosts
    - High enough threshold density of susceptible hosts
    - Hardy environmental stages
    - Other things move it (vectors/fomites)
- Abiotic limits of transmission
  - Can the agent live in the environment of interest?
    - Temp, pH, salinity etc
- Biotic limits
  - Mass Action principle
  - Threshold theory

What could go wrong in exposed groups

- Might vary with the amount of exposure
- Step 1 – Biological plausibility
  - Science based – Does current biological knowledge but the description and data for this suggest that something undesired could happen
  - Passive methods
    - Previous cases (analogy)
    - Based on known mechanisms
    - Based on ecosystem factors including host susceptibility
    - Literature, expert opinion
  - Active methods (experimental or observational)
    - What happens if exposed in a controlled setting
      - Hard to replicate ecosystems, so tends to be looking at isolated effect on single species
        - » Typically looks at mortality and not other ecologically important outcomes
      - May use artificial microcosms with microbes, insects when looking at ecosystem effects
    - Pay attention in the early days or during ongoing risks
      - Will you be too late?

- Step 2 – Social reaction –Main issues to consider
  - Human health and safety
    - Food safety a primary route
  - Loss of species of commercial value
    - Can be tricky ball to juggle
  - Demands on public resources
    - Potential cost of mitigation, prevention or reaction
    - Cost-benefit analysis in risk management phase
  - Effects on trade or free-movement of goods
    - NAFTA, FAO, OIE rules
  - Recreational, aesthetic or cultural value
    - May just have to document these issues
  - Fairness
    - Fair process
    - Fair distribution of risks and benefits

- Networks
  - try to describe linkages within the entire system.
    - Relative interdependencies, feedback loops and other such relationships are accounted for.
    - help to describe how interactions between components within the system might modify the predicted effects.
  - often, by necessity, an oversimplification
  - Like checklists and matrices, networks cannot deal with temporal changes very well.
- Computer models
  - critically dependent on the mathematical and ecological assumptions
- Expert systems
  - incorporate the knowledge and experience of experts from relevant fields into a structured decision-making analytical tool.
  - are not as restricted as task-specific computer models as they allow for value judgements and “best-guesses” to be included.

Estimating Probability

- All health measures are probability estimates
  - with experience, our predictive ability increases by decreasing errors around probability estimates
- Probability can outweigh impact in regulatory considerations
  - impact seems “more subjective” but is it?
- Ideally, quantify. In reality, subjective estimates
- Two probabilities of interest
  - Under pre-project situations
  - Under post-project setting
  - Can’t forget baseline occurrence of outcomes of concern

Probability of a hazard being established

- **Entry Potential**
  - The likelihood of a hazard's entry into a region or food chain or host(s) of concern.
    - includes consideration of several factors related to the source of the hazard, survival of the hazard in transit or processing, and the general distribution of the hazard.
- **Exposure Potential**
  - availability of habitat and susceptible hosts is assessed
  - may be appropriate to estimate the critical threshold of inoculum or exposure that is required to cause a negative impact
- **Spread Potential**
  - considering the destination and intended use of the hosts, potential hosts, vectors, domestic trade, common source foods or critical processing or environmental factors

Ways to estimate probability

- Personal experience
- Expert opinion
- Published data
- Prospective studies

Personal Experience

- Use prior experience with similar situations to estimate probability
  - is this feasible for complex systems?
- Factors affecting personal experience
  - Representativeness
  - Availability
  - Anchoring and Adjustment
- Cognitive psychology has show that personal experience is an error-prone way to estimate probabilities
  - what are the sources of error?

Representativeness

- Probability is based on how close the essential features of this situation resemble the features in the base of experience
- Errors
  - Ignore how common the problem is in the units of concern (prevalence)
    - over estimate role of the dramatic
  - Use clues that do not accurately predict a problem
    - are there casual links?
  - Use redundant predictors as new clues
    - internal consistency doesn’t = accuracy
  - Compare to a small base of experience

Availability

- The probability of an event is based on the ease with which similar events are remembered
  - easily remembered, vivid and more recent events are more likely to be remembered especially if they have bad consequences

Anchoring and Adjustment

- Special characteristics influence estimates
  - initial estimates of likelihood often too extreme
  - fail to appropriately use new information

Expert Opinion

- Review Articles
  - going out of favour
  - meta-analysis taking over
- Consensus conferences
  - can be influenced by strong personalities
- Delphi exercises
  - a systematic way to reach consensus
  - reduce variation in opinion through iterations of recycling responses

Published data

- Useful for several reasons
  - reports on uncommon events reflect a larger collected experience that 1 individual can claim
  - data presented may organize issues in a manner that assists decision making
  - help to identify the frequency, severity and cause-effects relations of events
- Critical review
  - Validity - Are the conclusions true?
  - Applicability - Does this matter to my case?
  - Generalizability - Can the conclusions be extrapolated beyond the specific

Prospective studies

- Risk is about associating hazards with outcomes
- Epidemiological methods are "robust"
  - set up for outcomes for individual people, but applicable across taxa and at higher levels of organization

Measurement and Classification

	Affected	**Unaffected**
Exposed	True Positive Case	False negative
Unexposed	False Positive	True Negative Case

Validity

- Are you measuring the right thing?
  - all measurements are surrogates of the truth
    - all are affected by what we select to represent the truth
  - does your measurement measure what it purports to measure?
    - ex1. force expiratory volume = respiratory function
    - ex 2. skinfold thickness does not = how fat or lean a person is

Accuracy

- How close to the bulls-eyes are you?
  - how close does the measurement come to the true value?
    - ex 1 Temperature - core vs rectal vs axillary
    - ex 2. Temperature - thermometer is broken and measures 39.5 rather than 40^{o}C
- Can be valid and precise, but inaccurate
  - measure what you want with little variation, but off target

Precision

- How scattered is your shot?
  - how sharply defined are the measurements?
- Measurement errors
  - quality and scale of the measurement device
    - rounding errors (terminal digit bias)
  - faulty reagents or impurities
  - individual making the measurement
  - circumstances under which measurements are made

Reproducibility and Reliability

- How consistently can we classify cases or exposures?
- Faults in the instrument or observer
  - observer variation
- Lack of case definition or standard measurements
  - ex. Histopathology, radiology = low intra and inter-observer repeatability
    - big issues for studies of neoplasms

Confounding

- Effects of 2 processes are not independent
  – you study factor A, but effects of factor B distorts the observed effect of A
  – factor A and B both component causes
  – without controlling for the effects of B, it's hard to judge effects of A
- Ex. Coffee, cigarettes and oral cancer

Criteria for Causation

- cause precedes effect
- more exposure in cases
- more cases in exposed
- gradient of effect along a gradient of exposure
- relationships statistically valid and biologically credible
- experimental manipulation
- elimination of exposure decreases effect
- prevention of host response decreases outcome
- consistent with what we know

Case series

- Just look at the problem
- Characterize features of a problem
  - Who has it? Who is affected by it? What are their characteristics?
  - Case definitions to aid further detection
    - define the spectrum of effect
- Is this new or more than expected?
  - is it a problem?

Cross-sectional studies

- Random sample of a defined subject
- Unlike a survey, hypothesis focused
- Describe the amount of effect and exposure
- Cross-section in time - look for gradients
  - prevalence (new and old cases)
- Can’t characterize exposure histories
- Comparability of cases and non-cases
  - can’t control for comparison

Case-Control Studies

- Select subjects on basis of health status
    - compare their exposure histories
- Selection of controls is key
    - exactly the same as cases except for exposure
- Carefully control of bias and confounding
  - misclassification = key
    - ie. is an ecosystem healthy or not?
- Cheap, fast, use existing data (issues of quality)
    - Hard to get good exposure history

Cohort Studies

- Select subjects on basis of exposure
  - follow over time to look for new cases (incidence) or changes in health status
  - strongest method
- Complete exposure data, precise case classification - control over measurements
- Need lots of subjects
  - especially for rare disorders
  - lots of time and money

Clinical Trials

- Do interventions affect outcomes?
- Randomized clinical trial
  - strict rules regarding inclusion and effects criteria
    - randomize patients into tx vs non-tx
  - blinding is a big issue
  - ethical issues
    - who gets treated (especially at systems level)
      - are we ready?

Outbreak Investigations

- clusters are often the first clues of new risks of problems
- use all the tools available, but lack the time to do them ideally
  - describe and verify the problem
  - is it more than expected
  - describe/define cases (time, space, features)
  - comparisons to identify the “pump handle”

Are there special issues for ecosystems?

- N=1
- Misclassification
  - which ecosystem is healthy
  - exposure is multiplicative, not just single exposures
- But - same issues in people
  - at the start - lack of understanding of systems
    - John Snow and Cholera
  - now - recognizing interactions

Key Issues for Field Studies

- Classify cases consistently and correctly
- Measure exposures appropriately, accurately, and at biologically relevant levels.
- Include subjects in studies in a manner that allows hypotheses to be tested and results to be generalized

Uncertainty

- Can we really characterize ecological risk in a single value?
  - Need to gauge the degree of certainty we have in the point estimate
  - Qualitative vs quantitative
- Ask the following
  - What do I know with certainty?
  - For uncertain things are they uncertain because they are unknown or variable?
  - Can I include the variability to the assessment
    - Sensitivity analysis
      - Vary inputs into the RA and see how it would affect the final assessment
  - Is it “natural” or model uncertainty
    - Do we not have the right model to look at this issue or is nature too uncertain?
      - What can you fix, what do you have to accept?

Parameter uncertainty

- First – what is the assessment endpoint?
  - What variables affect the endpoint? What is unknown
    - The nature of the variable
    - The measure of the variable
- Can the variability be defined statistically?
  - Confidence interval
- Can the variability be modeled?
  - Monte Carlo simulations
- Is there experience or analogy to estimate true ranges/values?
- How important are the uncertainties?
  - Do they impacts significant outcomes or would they just be nice to know?
- Usually need some expert option to determine the magnitude and significance of the uncertainty
  - So are quantitative measures really that much better than a good description of relationships and estimates of effects?

- What is you have no idea of the uncertainty?
  - Ignore it and risk misleading outcomes
  - Expert opinion
  - Mathematical models
- Control what you can
  - Assumptions used in statistical analyses
  - Testing error
  - Good description of the setting, hazards and relationships
- Modeling and elk – a cautionary tale (or is it tail?)
  - Careful with using readily purchased risk assessment software
- Remember your goal – decision support, not mathematical beauty

Confidence limits

- A characterize where the true value is likely to be
  - Small CI – better point estimate with higher certainty in the result
  - Large CI – harder to pinpoint the true value, less certainty
- Calculations based on similar information needed for tests of statistical significance
  - Properties of the sampling distribution
    - Sample size, range, variance etc
- Same issue apply as for statistical tests
  - Independence of observations, sufficient replication, etc
  - Can we achieve this in field studies?
- Statistical vs ecological significance

Weight-of-evidence approach

- All good RA start with “once upon a time”
- Need a convincing story as rarely can we accumulate sufficient proof
- By looking at an issue by a variety bof methods, seek to find agreement
- Some specific methods such as meta-analysis fro reviewing the literature
- Also allows one to bring in public concerns
  - What is evidence?
    - Something that provides proof
    - Something submitted to ascertain the truth

Making decisions

- We do risk assessments to help someone make a decision
  - Shouldn't do RA ignorant of this fact
  - But, need to avoid worrying about the final decision while doing the RA
- Weight costs and benefits
  - If 2 things are equally likely and equally good/bad, we will pick the least costly
  - What costs becomes an issue
- Risks are not a linear sum of isolated probabilities and outcomes
  - Interacting forces, conditional probabilities, variation and uncertainty
  - Is decision analysis a better approach?

Good Decisions

- Considered choice based on the rational interpretation of available information
- Efficiency
  - good process
  - able to get the information needed to a manner well-suited to answering the right question
- Effectiveness
  - good outcome
  - predictions were right
- Equity
  - Very important for public and stakeholders
  - Also an issue for assessment-to-assessment consistency

- Decision theory states
  - preferred management option = one with the greatest expected value
    - expected value is an average of values across all possible outcomes that are weighed by their probability of occurrence
    - Decision trees
- Problem with probability
  - For the average “patient”, not the specific case
- Problem with value
  - What is the common currency
- Risk managers must rely on 2 broad principles of decision-making under conditions of incomplete and uncertain information:
  - precautionary principle
  - principle of sound science.

Precautionary Approach

- An important guiding principle of environmental decision making
- NASCO = absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures
- Requires
  - Consideration of future generations
  - Avoidance of irreversible change
  - Not delay until perfect knowledge if there are reasonable grounds to suspect adverse effects
  - priority to be given to conserving the productive capacity of the resource where the likely impact of resource use is uncertain
  - while scientific uncertainty may exist, there still has to be some sound scientific basis for a decision;
  - while scientific uncertainty may exist, there still has to be some sound scientific basis for a decision;

Sound Science

- requires a careful collection and analysis of data before causal significance can be confirmed to a set of observations
- Science is subject to 2 types of errors
  - those that accept missing a few “real” effects in favour of minimizing false associations and
  - those that trade off the risk of missing a real effect by having false-positive results.
  - What one do you want to accept?
- Makes the issue of criteria for evaluating evidence is important

Risk Communication

- Getting and giving information
  - Good communication = better decisions
- 6 rules
  - Accept that the public is part of this
  - Plan &evaluate communication efforts
  - Listen to public's specific concerns
  - Be honest, frank and open
  - Speak clearly
  - Recognize the different needs of different audiences
- Trust and credibility
  - 4 factors of for building trust: empathy and caring; competence and expertise; honesty and openness; dedication and commitment
  - Hard to build harder to regain
- Risk – hazard + perception +emotion

Barriers to effective risk communication

- Access to information
  - You need, they want it
  - Dealing with private or proprietary information
- Lack of participation in the process
  - When involved, less likely to challenge outcome
- Differences in perception
  - Need to try to get down to a common language
  - Watch for unstated assumptions
- Lack of understanding of the process
  - How is evidence generated and weighed