CHAPTER 2.2.

USA COMMENTS

IMPORT RISK ANALYSIS

Note : All of the suggested revisions to Chapter 2.2, Risk Analysis, are predicated upon four US National Research Council reports. Stakeholders have invested considerable effort in conjunction with the National Research Council to publish these reports. However, most of these reports build upon the 1983 report that U.S. Federal agencies commonly refer to as the "red book." All of the reports can be read on-line for at www.nap.edu.

- Risk Assessment in the Federal Government: Managing the process 1983 http://www.nap.edu/catalog.php?record_id=366
- Issues in Risk Assessment 1993 http://www.nap.edu/catalog.php?record_id=2078#toc
- Understanding Risk: Informing decisions in a democratic society 1996 http://www.nap.edu/catalog.php?record_id=5138
- Science and Decisions: Advancing risk assessment 2009 http://www.nap.edu/catalog.php?record_id=12209

NRC (National Research Council). 1983. Risk Assessment in the Federal Government: Managing the Process. The National Academy Press, Washington, DC. 191 pp.

NRC (National Research Council). 1993. Issues in Risk Assessment. The National Academy Press, Washington, DC. 356 pp.

Stern, P.C. and H.V. Fineberg (eds). 1996. Understanding Risk: Informing Decisions in a Democratic Society. The National Academy Press, Washington, DC. 249.

NRC (National Research Council). 2009. Science and Decisions: Advancing Risk Assessment. The National Academy Press, Washington, DC 403 pp.

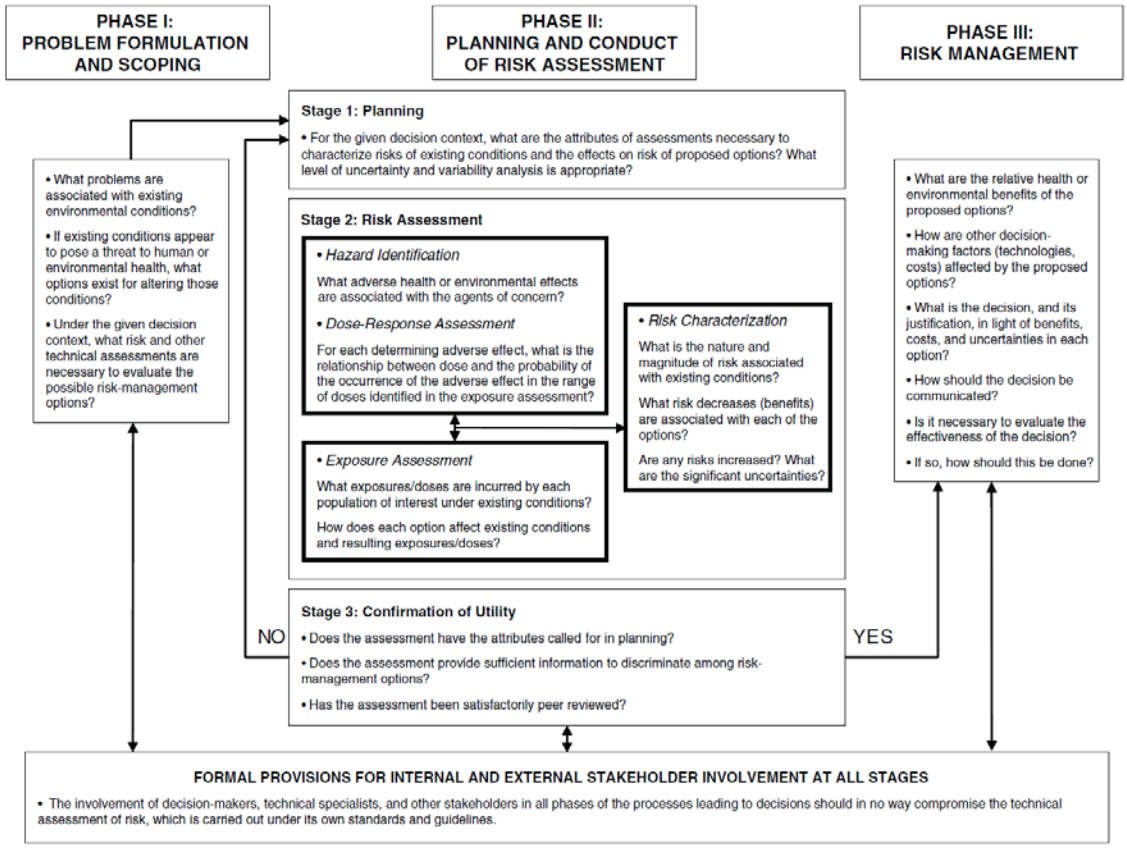
Introduction

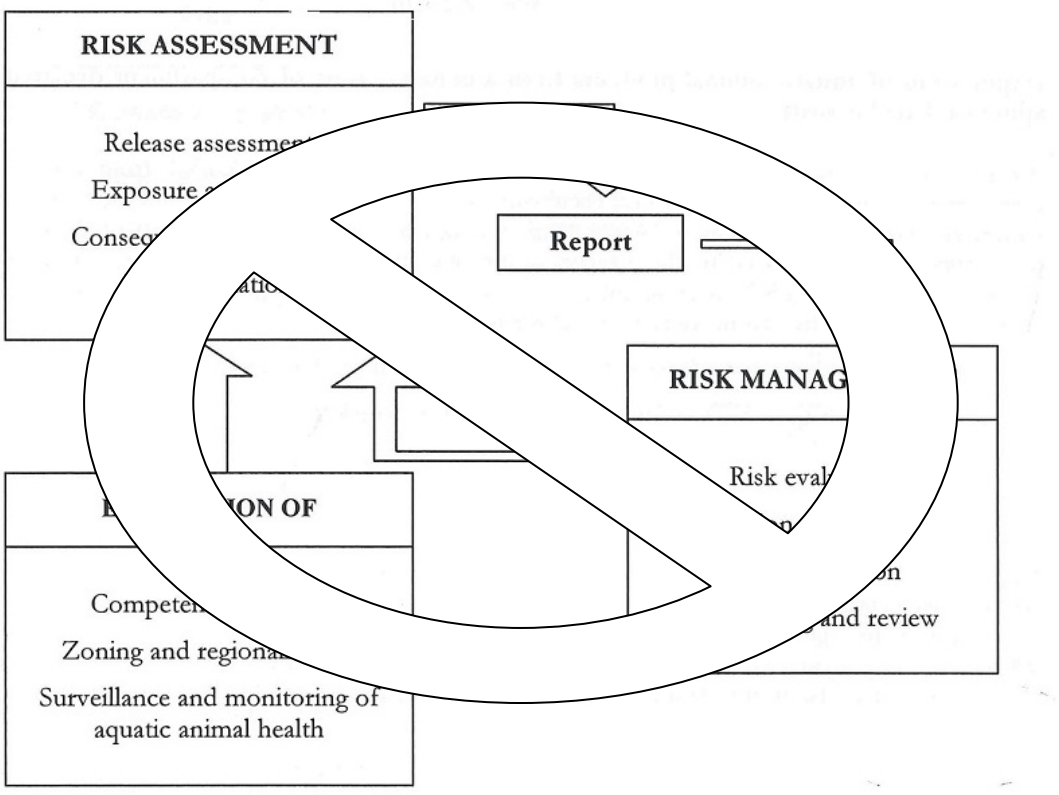
An import *risk analysis* begins with a deliberative planning and scoping activity designed to describe the problem and yield an operational structure for the analysis. This planning and scoping effort should include: 1) Identifying subject matter experts (risk managers, scientists, stakeholders); 2) A description of the *commodity* proposed for import and the likely annual quantity of trade. It should be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the *risk* estimate, it may not be readily available, particularly where such trade is new; and 3) *Hazard identification* that is an essential step that should be conducted before the *risk assessment*.

The *risk assessment* process consists of four interrelated and interactive steps. These steps clarify the stages of the *risk assessment*, describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the conclusions (or 'outputs'). The product is the *risk assessment* report, which is used in *risk communication* and *risk management*.

The relationships between *risk assessment* and *risk management* processes are outlined in Figure 1.

Fig. 1. **The relationship between risk assessment and risk management processes**





Rationale for offering an alternative diagram for Figure 1 : The alternative diagram was produced by the National Research Council to integrate problem formulation, scoping, risk assessment, risk management and risk communication.

Article 2.2.2.

Planning and Scoping

A team of decision-makers, stakeholders and risk assessors identifies the issue to be assessed and establishes the goals, breadth, depth, and focus of the assessment. The outcome of this effort should create a common understanding of why the risk assessment is being conducted, the boundaries of the assessment (time, space, regulatory options, and impacts), the quantity and quality of data needed to answer the assessment questions, and how decision-makers will use and communicate the results.

Hazard identification

Hazard identification involves identifying the *pathogenic agents* that could potentially produce adverse consequences associated with the importation of a *commodity*.

The *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each *hazard* is already present in the *importing country*, and whether it is an *OIE listed disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as *hazards* or not *hazards*. The *risk assessment* should be concluded if *hazard identification* fails to identify *hazards* associated with the importation.

The evaluation of the *Aquatic Animal Health Services*, *surveillance* and control programmes, and zoning and regionalisation systems are important inputs for assessing the likelihood of *hazards* being present in the *aquatic animal* population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Aquatic Code*, thus eliminating the need for a *risk assessment*.

Article 2.2.3.

Principles of risk assessment

1. *Risk assessment* should be flexible in order to deal with the complexity of real-life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.

2. Subject matter expert (risk managers, scientists, affected stakeholders) involvement is crucial to ensuring that science is utilized effectively to inform decision-makers' concerns. Risk managers provide input as to the practicality of the assessment and the management options proposed. Stakeholders contribute a sense of realism and purpose to the analysis.

~~2~~ 3. Both qualitative and quantitative *risk assessment* methods are valid.

~~3~~ 4. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.

~~4~~ 5. Consistency in *risk assessment* methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision-making and ease of understanding by all the interested parties.

~~5~~ 6. *Risk assessments* should document the uncertainties, the assumptions made, relative quality of the scientific information available, and the effect of these on the final *risk* estimate.

~~6~~ 7. *Risk* may increase~~s~~ with increasing volume of *commodity* imported.

~~7~~ 8. The *risk assessment* should be amenable to updating when additional information becomes available.

Article 2.2.4.

Risk assessment steps

1. Entry~~Release~~ assessment

Entry ~~Release~~ assessment consists of describing the biological pathway(s) necessary for an importation activity to ~~'release' (that is,~~ introduce~~)~~ a *hazard* into a particular environment, and estimating the likelihood of that complete process occurring. The entry ~~release~~ assessment describes the likelihood of the ~~'release'~~ entry of each of the *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry ~~release~~ assessment are:

a) Biological factors

- Species, strain or genotype, and age of *aquatic animal*
- Strain of agent
- Tissue sites of *infection* and/or contamination
- Vaccination, testing, treatment and *quarantine*.

b) Country factors

- *Incidence/prevalence*
- Evaluation of *Aquatic Animal Health Services*, *surveillance* and control programmes, and zoning systems of the *exporting country*.

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity of *commodity* to be imported
- Ease of contamination
- Effect of the various processing methods on the *pathogenic agent* in the *commodity*
- Effect of storage and transport on the *pathogenic agent* in the *commodity*.

If the entry ~~release~~ assessment demonstrates no significant *risk*, the *risk assessment* does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the *importing country* to the *hazards* and estimating the likelihood of these exposure(s) occurring.

The likelihood of exposure to the *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number, species and other characteristics of the human, *aquatic animal* or terrestrial animal populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

- Presence of potential vectors or intermediate hosts
- Genotype of host
- Properties of the agent (e.g. virulence, pathogenicity and survival parameters).

b) Country factors

- *Aquatic animal* demographics (e.g. presence of known susceptible and carrier species, distribution)
- Human and terrestrial animal demographics (e.g. possibility of scavengers, presence of piscivorous birds)
- Customs and cultural practices
- Geographical and environmental characteristics (e.g. hydrographic data, temperature ranges, water courses).

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity and seasonality of *commodity* to be imported
- Intended use of the imported *aquatic animals* or *products* (e.g. domestic consumption, restocking, incorporation in or use as *aquaculture feed* or bait)
- Waste disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* should conclude at this step.

3. Consequence assessment

Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process should exist by which exposures to a *hazard* result in adverse health, environmental or socio-economic consequences. Examples of consequences include:

a) Direct consequences

– *Aquatic animal infection*, *disease*, production losses and facility closures

– Adverse, and possibly irreversible, consequences to the environment

– Public health consequences.

b) Indirect consequences

– *Surveillance* and control costs

– Compensation costs

– Potential trade losses

– Adverse consumer reaction.

4. Risk estimation

Risk estimation consists of integrating the results of the entry ~~release~~ assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus *risk* estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

– The various populations of *aquatic animals* and/or estimated numbers of *aquaculture establishments* or people likely to experience health impacts of various degrees of severity over time

– Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates

– Portrayal of the variance of all model inputs

– A sensitivity analysis to rank the inputs as to their contribution to the variance of the *risk* estimation output

– Analysis of the dependence and correlation between model inputs.

Article 2.2.5.

Principles of risk management

1. *Risk management* is the process of ~~deciding upon~~ evaluating, selecting and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under international trade agreements.

2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions of the standards or other recommendations of the SPS Agreement.

Article 2.2.6.

Risk management components

1. *Risk* evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.

2. ~~Option~~ Risk Benefit evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.

3. Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.

4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 2.2.7.

Principles of risk communication

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2. A *risk communication* strategy should be put in place at the start of each *risk analysis*.

3. The *communication of risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups.

5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.

6. Peer review of *risk analyses* is an essential component of *risk communication* for obtaining a scientific critique aimed at ensuring that the data, information, methods and assumptions are the best available.

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