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A REVIEW OF ECOLOGICAL RISK ASSESSMENT METHODOLOGIES

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EXECUTIVE SUMMARY

Ecological risk assessment has traditionally been identified as a means of investigating the effects of chemical pollutants released to the environment. Indeed much of the terminology associated with this discipline is couched in terms of chemical stressors. This is an unfortunate corollary of the subject's origins, and one that often detracts from the potentially much wider application of risk assessment methods to environmental problems.

Biological stressors, such as introduced non-native species, are not governed by the same decay and dispersion relationships that typically characterise the release of chemical pollutants into the environment, and are thus fundamentally different to chemical stressors. As a result, many assessors have experienced considerable difficulty in extending traditional ecological risk assessment techniques to biological stressors. Indeed this problem continues to hamper the United States Environmental Protection Agency's attempts to develop a comprehensive and universally applicable ecological risk assessment framework.

The complexity associated with the introduction of non-native species into new localities, coupled with the difficulties noted above, have led some assessors to conclude that qualitative, delphi method assessments, are the best that ecological risk assessment for biological stressors can hope to achieve in the near term. Quantitative risk assessments, undertaken to assess the risk of disease and parasite transmission with animal product imports, however, have been successfully completed for at least two decades. Whilst these assessments have never been described as such, they bear all the hallmarks of ecological risk assessment for biological stressors.

The success of these techniques is largely attributable to the choice of simple and measurable risk assessment endpoints (namely the introduction of viable disease or parasite agents) coupled with the excellent empirical database on the incidence of specific diseases in national herds collated internationally by the Office International des Epizooties.

Furthermore it is possible to point to a variety of alternative techniques that have been successfully employed to assess both the hazards and risks associated with biological entities, and the introduction of non-native or genetically modified organisms into the environment. Many of these techniques are quantitative, and some employ novel hazard assessment methods and bio-rule approaches to assist in the identification and analysis of the risks associated with biological entities (including non-indigenous species). The application of these techniques to ballast water risk assessment warrants further consideration.

A number of conclusions can be drawn then from the current state of the art as regards ecological risk assessment for biological stressors:

1. it is unduly pessimistic to believe that the best that assessments of non-indigenous species introductions can hope to achieve are qualitative expressions of risk. Furthermore such qualitative expressions are unlikely to satisfy the requirements of environmental managers seeking to allocate risk reduction resources in the most cost efficient manner. In particular the implementation of a decision support system for ballast water management strategies, aimed at providing the most cost efficient risk reduction measures, necessarily requires a quantified metric of invasion or establishment likelihood against which the efficacy of alternative management strategies can be gauged. Without such a metric the risk

assessment framework is unlikely to serve as any more than a screening tool for invasion hazard;

2. the determination of simple and measurable, at least in principal, endpoints is critical to the successful development of any quantitative risk assessment methodology. Fortunately for ballast water introductions two suitable candidates can be identified in this regard: the likelihood of inoculation into a suitable habitat and the likelihood of establishment. The former is undoubtedly less ambitious than the latter, and for species which *a priori* are considered to be undesirable, could provide a suitable metric for decision makers. Adverse environmental or economic impact is clearly a more desirable metric but this requires the undoubtedly more complex analysis of non-native establishment and effect;

3. systematic hazard identification techniques are currently available that could be used to identify the potential adverse impacts of non-indigenous organisms and assist in taxonomic hazard analysis, particularly with respect to elucidating the plausible but low probability risk scenarios that often characterise alien species introductions. To date the application of these techniques has only been explored in relation to the release of genetically modified organisms and not to non-native species more generally. The similarity between these entities, however, at least from a risk assessment perspective, suggests that these techniques could be successfully extended to identify the hazards associated with non-native introductions;

4. the unified framework currently advocated by the USEPA for ecological risk assessment is difficult to apply to non-indigenous species. An arguably more appropriate framework, which views the risk of introduction as the culmination of a long chain of events, has been applied to import risk analysis for many decades. This framework, together with the Quantitative Risk Assessment paradigm, which emphasises that risk is a function of the frequency and consequences of undesired events, appears to provide a more suitable basis from which to tailor a specific risk assessment framework for ballast water introductions;

5. in the first instance the absence of a comprehensive and centrally collated database regarding species assemblages found under specific ballasting conditions and the frequency of successful establishment, requires that the ballast water risk assessment framework be inductive and model based. The development of such a database is, however, essential if confidence in the results of the framework is to be eventually established. Groundtruthing procedures should therefore form an important part of any ballast water introduction framework;

6. invasion success is a function of both species specific and site specific attributes. Any assessment of invasion risk must therefore adopt a species and site specific perspective and is unlikely to be successful in the absence of detailed information at both the species and site specific levels. The development of bio-rules for the species concerned could provide a means by which a quantitative expression of invasion success is possible. Again the identification of these rules pre-supposes an in depth knowledge of the life-history and bio-requirements of the species concerned. As a result the data requirements for a quantitative assessment for invasion risk will undoubtedly be onerous; and,

7. Bayes theory provides a unified statistical approach that could allow for a coherent and rigorous updating of estimates of ballast water risks as information is gathered. This

approach has been adopted within other areas of ecological risk assessment, notably fishery risk assessment, but its application to non-native introductions is yet to be tested.

In light of these conclusions this review makes the following recommendations:

1. a tailor made risk assessment framework for ballast water introductions should be developed in a manner analogous to the import risk assessment framework, but which seeks to emulate the quantitative risk assessment paradigm and employ the hazard identification techniques more commonly associated with this paradigm;

2. the framework should make provision for groundtruthing procedures against which the predictions, or prior distribution assumptions, of the risk assessment can be tested, modified and strengthened in light of empirical evidence. The Bayesian paradigm should be investigated in this regard with a view to its adoption as the framework's preferred statistical approach;

3. the risk assessment should proceed in a species and site specific manner and seek to develop an in depth understanding of the life-history of species *a priori* considered a hazard, expressed through a series of bio-rules for these species; and,

4. a general search for data requirement overlaps with other organisations, both nationally and internationally, should proceed in conjunction with the risk assessment framework to identify means of sharing the data burdens of the assessment framework.

ACKNOWLEDGEMENTS

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GLOSSARY OF TERMS AND DEFINITIONS

Acute toxicity	The adverse effect occurring within a short time of administration of a single dose of a substance or multiple doses given within 24 hours
Allelopathic	Used to describe plants which are harmful to other plants
Altricial	Altricial species produce small, incompletely developed young and are generalists capable of surviving in an unstable, uncrowded environment in which they are mainly subjected to density-independent mortality
AWQC	Ambient Water Quality Criteria
AQIS	Australian Quarantine and Inspection Service
BAT	Best Available Technology
Benthic	Associated with the sediment-water interface of marine, estuarine or freshwater ecosystems
Biomarker tests	Laboratory toxicity assays performed at the cellular or sub-cellular levels of biological organisation
BOD	Biological Oxygen Demand; an indication of the amount of oxygen needed to fully oxidise (by biological means) reducing material in the water column
CERCLA	Comprehensive Environmental Response, Compensations and Liability Act, otherwise known as the Superfund Act
Chronic toxicity	The adverse effect of a test substance following prolonged and repeated exposure for the major part of the lifetime of the species used in the test
Correspondence analysis	A geometric technique used to identify patterns and associations in large, multivariate datasets
CRIMP	Centre for Research on Introduced Marine Pests
CSIRO	Commonwealth Science and Industrial Research Organisation
Delphi method	A means of aggregating a group of experts' assessment of probability in which those participating do not usually meet face to face, interaction is restricted to distribution of anonymous assessments
Dose	The amount of chemical or xenobiotic that enters an organism, usually expressed as the amount of substance per unit of body weight

Ecotoxicology	The study of the toxic effects of chemical and physical agents in living organisms, especially on populations and communities within defined ecosystems
EC_{50}	Median effective concentration: the concentration of a toxicant which produces a specified response in 50% of a test population under specific laboratory conditions
Eutrophic	A reference to the nutrient status of lakes and rivers. Generally used to describe lakes that have high concentrations of nutrients
FAO	United Nations Food and Agriculture Organisation
GATT	General Agreement on Tariffs and Trade: multilateral institution charged with administering agreed-upon rules for trade among member countries, now replaced by the World Trade Organisation
GMO	Genetically Modified Organism
Hazard	A qualitative term expressing the potential of a given stressor to cause human harm or environmental damage under specified conditions of exposure
HAZOP	A QRA hazard identification technique which encourages a multi-discipline team to systematically apply their experience and imagination to identify hazards in complex engineering systems
Histopathology	The study of the effects of disease on the minute structure of tissues and organs
IPPC	International Plant Protection Convention, 1951
LC_{50}	Median lethal concentration: the concentration of a toxicant lethal to 50% of a test population under specified laboratory conditions
LD_{50}	Median lethal dose: the statistically derived single dose of a substance that can be expected to cause death in 50% of a given population under a defined set of laboratory conditions
NOEL(C)	No Observed Effects Level (Concentration): the maximum dose or ambient concentration which an organism can tolerate over a specific time period without showing any adverse effects, (usually expressed in terms of survival, growth or reproduction), and above which adverse effects are detectable
NRC	National Research Council (United States), part of the National Academy of Sciences
OIE	Office International des Epizooties

PAH	Poly Aromatic Hydrocarbons
Precocial	Precocial species produce large, well developed young and are specialists adapted to survive in a stable, crowded environment which is subject to density-dependant mortality
PCB	Poly Chlorinated Biphenyls
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration: analogous to the NOEL above
QRA	Quantitative Risk Assessment
QSAR	Quantitative Structure Activity Relationships: the correlation between the molecular structure of a substance and its biological activity. QSAR's are usually applied when predicting the effect that an untested chemical will have on a defined biological endpoint
Quasi-extinction	The point at which a population falls below some critical abundance or density. For example the population density below which individuals can no longer find mates for reproduction
SFG	Scope For Growth: an integrated index of physiological well-being that expresses an organisms energy input in excess of its respiratory requirements.
Stressor	Any physical, chemical or biological entity than can induce an adverse response in ecological systems
TSCA	Toxic Substances Control Act, 1976
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency

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1 INTRODUCTION

1.1 Background

In September 1996, the CSIRO Centre for Research on Introduced Marine Pests (CRIMP) was awarded a contract to undertake the second of the projects in the Australian Quarantine and Inspection Services' Strategic Ballast Water Research Program, the development of a risk assessment methodology for the introduction of unwanted marine pests through ship's ballast water and sediment discharges.

The first stage of this contract required a comprehensive review of environmental risk assessment methods and techniques, particularly those pertaining to biological introductions and invasions. This report represents the fulfilment of this stage of the risk assessment project.

1.2 Objectives and structure of the review

The objectives of this review are essentially two fold:

1. to provide an indication of the current state of the art of environmental risk assessment methodologies; and,

2. to determine what techniques have been previously employed to address the risks associated with biological invasions and introductions of non-indigenous organisms in terrestrial, freshwater and marine environments.

In particular the review seeks to identify the determinants of invasion probability that have been employed in these techniques, comment on their success, and determine the extent to which similar approaches might be adopted to assess the risk of marine pest introductions into Australian coastal waters, via ballast water and sediment discharges.

The coverage of risk assessment methodologies in this report is deliberately broad. The reasons for this are to provide a good overview of the topic and to highlight the variety of very different frameworks employed for environmental risk assessment purposes. This coverage, however, is by no means omniscient. The enormous growth in popularity of environmental risk assessment, as an aid to decision makers and environmental managers, has encouraged a veritable population explosion of individual assessments – certainly too many to be reviewed under reasonable time and cost constraints. Despite this the report does contain enough examples, from widely differing perspectives, in order to provide a thorough and comprehensive review of the various applications of risk assessment techniques and the different approaches and methodologies used therein.

The individual techniques that were reviewed as part of this assessment are summarised in Appendix A through to D at the end of the report. For the sake of brevity each of the summary descriptions have been restricted to around two pages. This will have inevitably entailed a less thorough description of the methodology than some readers may have preferred. In these instances the reader is directed to the original manuscripts used in this review, details of which will be found in the reference section.

The appendices are organised in the following manner:

Appendix A Chemical risk assessment methods

Appendix B Import risk assessment methods

Appendix C Introduction risk assessment methods

Appendix D Miscellaneous risk assessment methods

In some respects this classification is largely arbitrary, particularly as regards import and introduction risk assessment methods which are essentially concerned with the same problem: the likelihood of introducing non-indigenous, and potentially hazardous, species into new localities. This classification merely reflects the main emphasis within the methodology and in many, but not all, cases is used to distinguish between alternative risk assessment paradigms. In this respect a number of the assessments were sufficiently different from all others to warrant grouping under a miscellaneous section, as has been done in Appendix D.

At this point it is important to recognise that many of the techniques summarised in this review (for example those concerned with import risk assessment) may be considered by some to fall outwith the commonly understood definition of ecological risk assessment. The inclusion of these techniques within this review is justified on two grounds:

1. these techniques are concerned with the introduction of unwanted species into new localities and are therefore relevant to the development of a ballast water risk assessment framework; and,

2. in many instances it is clear that 'traditional' ecological risk assessment methods are insufficient to address the issues associated with the introduction of non-indigenous species and thus the assessor is forced to look beyond these traditional approaches for alternative precedents.

Section 2 of the report provides an introduction to risk, hazard and risk assessment, and some of the terminology employed within these disciplines. The subject of environmental risk assessment is regrettably rife with poorly defined and badly employed terminology, particularly with respect to the difference between risk and hazards. The purpose of this section is therefore to provide a clear statement of what is meant by risk, hazard and risk assessment, and the way in which these terms will be employed throughout the remainder of the ballast water risk assessment project. A glossary of definitions and terms employed within the report is also provided to assist the reader in this respect.

Section 3 provides a discussion on each of the assessment frameworks represented by the individual techniques reviewed in the appendices, together with a brief commentary on their historical development. In this context it is important to recognise that environmental risk assessment is employed in a wide variety of disciplines, to many different environmental problems, involving many different hazards. As such there is no single risk assessment framework which adequately provides for all the potential applications of the risk assessed approach. Attempts to provide such a framework have generally been reduced to no more than a few keywords (the lowest common denominator) or have openly acknowledged their restriction to a sub-set of the complete set of potential risk assessment applications.

Section 4 describes two different ballast water risk assessments that have been completed to date. The first concentrates on the introduction of toxic dinoflagellates into Australian waters and attempts to quantify the likely economic and environmental costs associated with subsequent blooms of these species. The second takes a markedly different approach, attempting to quantify the degree of environmental similarity between the ports of Queensland and some of the international ports which ‘export’ ballast water to these ports, and thereby provide a metric of establishment risk for non native species.

In section 5 the applicability and utility of the techniques reviewed in the report are examined from a ballast water perspective. The extent to which any facets of these techniques could be employed within a quantitative assessment of the risks associated with ballast water discharges is also addressed. Whilst it is clear that a generic risk assessment framework for ballast water introductions does not currently exist, there are a number of important lessons to be learnt from the methodologies and approaches adopted for other environmental hazards.

Section 6 draws a number of conclusions from the review which are pertinent to the development of a generic ballast water risk assessment framework, and in particular recommends a broad strategy for the development of this framework.

2 AN ANATOMY OF RISK, HAZARD AND RISK ASSESSMENT

2.1 What is risk?

Risk is defined as the likelihood of an undesired event occurring as a result of some behaviour or action (including no action). Risk assessment is the means by which the frequency and consequences of such events are determined, and should properly be accompanied by an expression of any uncertainty in the assessment process.

The consequences of the undesired event in question are usually adverse (ie one does not usually consider the risk of winning the lottery) and are expressed in terms of the assessment endpoints. Assessment endpoints are simply an expression of the values that one is trying to protect by undertaking the risk assessment procedure, and thus distinguish environmental risk assessment (ecological endpoints) from human health risk assessment (human fatality or injury endpoints).

The risk associated with ship's ballast water and sediment discharges can be defined as the likelihood of an undesired event occurring as a result of these actions. It is important to recognise that the interpretation of this definition is entirely dependant on the endpoint of the assessment. If the endpoint is establishment of an exotic species in a new locality, then the risk is expressed in terms of the likelihood of establishment. If the endpoint is environmental damage (notwithstanding that here the assessor may face additional problems of definition), then the risk must be defined as the likelihood of environmental damage arising as a result of the introduction and establishment of an exotic species.

Notice how the definition of risk is sensitive to the assessment endpoint (which in itself is simply an expression of value). In the first part of the paragraph above, risk was expressed in terms of the establishment of an exotic species – there is thus an implicit assumption that the establishment of any exotic species in a new locality is an undesired event. This is equivalent to an expression of environmental value that wishes to preserve 'natural' or existing species assemblages. By contrast, in the second part of the paragraph, risk is defined in terms environmental damage. In this definition the establishment of a new species *per se* does not constitute the undesired event to be avoided – one is merely concerned with the subsequent environmental damage that could arise as a result of this. Thus if an assessor could guarantee that a particular exotic species would have no adverse effect on the environment, then under this definition, there would be no risk.

Of course one can never guarantee that an exotic species, once established, will truly have no adverse environmental effect, and thus in practice there is always the potential risk of environmental damage arising as a result of the introduction of an exotic species to a new locality. The point, however, should be clear: an individuals understanding and perception of risk is defined as a function of their environmental values.

This intrinsically subjective perception and understanding of risk is the very reason why decisions regarding the acceptability of risk are correctly taken out of the risk assessment process and are made part of a much wider socio-economic and political debate. Thus risk cannot be defined in terms of what is acceptable or unacceptable during the risk assessment process. Rather the risk must be assessed, the uncertainty associated with this assessment communicated, and then the acceptability, or otherwise, of the risk gauged by a wider audience.

2.2 What is hazard?

Hazard can be defined as a situation that in particular circumstances could lead to harm (The Royal Society, 1983) or alternatively considered as a substance's or activity's propensity for risk. Hazard is often perceived as solely a function of a substance's intrinsic properties but, as emphasised in the definition above, it is more usefully conceptualised as a function of both the intrinsic properties of a substance and circumstance. A simple if somewhat contrived example will make this clear. Oxygen in air would not ordinarily be considered as a hazardous substance, but when compressed with air and used by divers at depth, it is poisonous if not breathed in the correct atmospheric proportions.

Thus a substance's intrinsically hazardous properties can often only be realised under a very specific set of circumstances. Any expression of hazard should properly acknowledge both the intrinsic properties and the circumstances required in order for harm to be realised. The measure of the likelihood of these circumstances and the magnitude of the subsequent harm is a measure of risk. Put another way hazard becomes risk only when there is a finite probability of a manifestation of the hazard (Beer & Ziolkowski, 1995).

Accordingly hazard assessment must address both a substance's intrinsic properties and the circumstances required for the manifestation of harm as a result of these properties. This is particularly true for introduced species because the likelihood of an introduced organism becoming established, and the effects that follow, depend on the characteristics of the organism (its intrinsic properties) and the environment to which it is introduced (the circumstances).

Much of past invasion theory, however, has tended to focus on only one half of this equation, expressing invasion hazard in terms of characteristics that make a species invasive. Indeed as noted by Parker & Kareiva (1996), the idea of using life history traits alone to predict invasiveness has been considered as a basis for US federal policy on the importation of exotic species, and for assessing the risks associated with Genetically Engineered Organisms.

Some of the most sophisticated invasion hazard assessments, using for example discriminant analysis (Rejmanek, 1996) or correspondence analysis (Richardson *et al*, 1990), serve only to enforce the point by concluding that chance interactions can confound invasion predictions based on life history characteristics alone. In this manner they further underscore the idiosyncrasies inherent in biological invasions, and as Orr (1995) correctly concludes, these chance idiosyncrasies cannot be predicted in advance by general statements based only on the biology of the organism.

This not to say that life history based hazard assessment approaches are not useful, they do undoubtedly hold some predictive ability (refer to Appendix B8 and B9 for good examples in this context), but rather they will never be able to provide a complete description of invasion hazard or invasion risk.

2.3 What is ecological risk assessment?

Risk assessment is a general term that is used (often loosely) to describe an array of methodologies and techniques concerned with estimating the likelihood and consequences of undesired events.[1] Risk assessments can be qualitative or quantitative, and can be a valuable decision aid if completed in a systematic and rigorous manner.

Qualitative risk assessments, however, often provide little assistance in cost-benefit or risk-benefit decisions, especially where limited funds have to be allocated in a manner that optimises risk reduction and maximises societal benefit. It is perhaps unfortunate then that this situation is characteristic of many modern environmental management problems. These types of problems, which clearly include the ecological risks posed by ballast water and sediment discharges, require a quantified metric of environmental risk.

Quantitative Risk Assessment (QRA) aims to replace qualitative expression of risk, such as high, medium or low, with probabilistic statements and, in contrast to the above, is very rigorously defined as the quantitative evaluation of the likelihood of undesired events and the likelihood of harm or damage being caused as a result of these events, together with value judgements concerning the significance of the results. The harm or damage referred to in this definition is usually expressed in terms of human fatalities or injuries (the assessment endpoints).

Borrowing from this, quantitative ecological risk assessment might be defined as the quantitative evaluation of the frequency and consequences (expressed in terms of environmental harm) of undesired events, together with value judgements concerning the significance of these events.

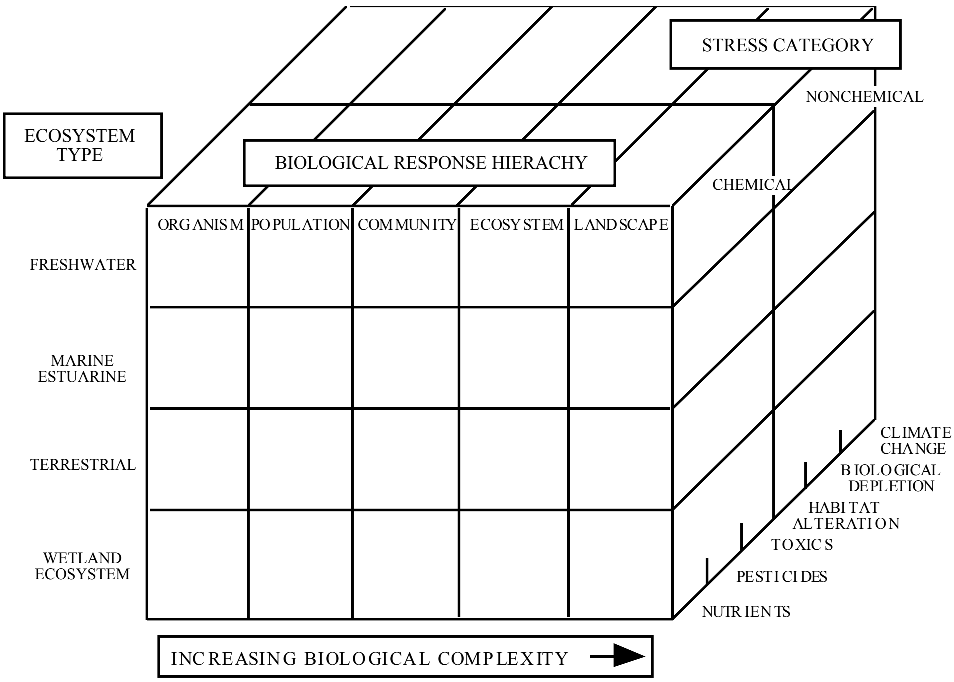
This definition is, however, not without its difficulties. Whilst we may at first sight readily empathise with the meaning of 'harm to the environment', and the desirability of avoiding it, in practice it is much more difficult to delineate and quantify this phenomena, let alone value it or identify what constitutes acceptable harm. In risk assessment terms harm is expressed through the assessment endpoints, and is synonymous with human injury or fatality. The most easily expressed environmental endpoints are those that refer to the impacts on specific species, particularly commercially valuable or endangered species. Alternative endpoints could, however, include the effects on species which are of no direct value to man, or further the effects on fundamental ecosystem processes. In many instances, however, the assessor will be unsure of the ecological effects of an undesired event, and indeed may be relying on the assessment process to identify these effects. This *inter alia* requires a rigorous and systematic framework with which to address ecological risk and environmental harm, coupled with an expression of impact (or harm) that facilitates the definition of acceptability criteria.

Despite considerable efforts on behalf of a number of national agencies (most notably the United States Environmental Protection Agency) there is to date no universally applicable

[1] Beer & Ziolkowski (1995) note that in the United States the term risk assessment refers to the actual calculation of likelihood and consequence, whilst risk analysis describes the wider process including risk management, risk perception, etc. By contrast, in Australia, risk analysis is widely used to describe the calculation component, whilst risk assessment is understood to be the wider process. These semantic differences are unecessary, serve only to confuse the issues, and are simply avoided in this report.

procedural framework for conducting ecological risk assessment, rather the subject area is characterised by a multiplicity of techniques and methods used to assess environmental risks. This is due in part to the relative immaturity of ecological risk assessment as a discipline, but also in part to the complexity of environmental management issues, the variety of possible stressors and endpoints, and thus the widely different types of assessment that are required. Indeed it might be considered surprising if such a single procedural framework could be developed to cover every conceivable application of risk assessment within an ecological scope.

An insight into the depth and breadth of this scope is offered by Gentile *et al,* (1993), who suggest that five variables capture the essential features of ecological risk assessment processes: type of stressor, level of ecological organisation, ecosystem type, and spatial and temporal scale (Figure 2.1). These provide a multi-dimensional approach to classifying the types of ecological risk assessment that might be undertaken and suggest the types of issues associated with a risk based evaluation of environmental problems.



(Source: Gentile *et al,* 1993)

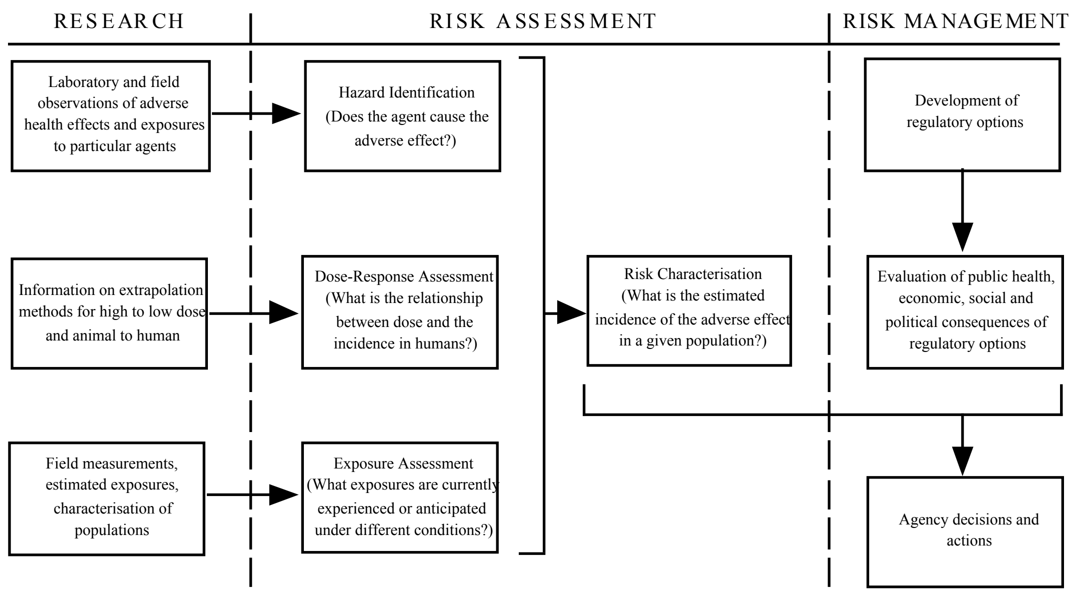
Figure 2.1 Three dimensional matrix of ecological risk organising principles

Suter (1993) suggests that ecological risk assessments can be further categorised into predictive and retrospective assessments. All predictive assessments begin with a proposed source of stress (a new chemical effluent for example) and proceed to estimate the risk of adverse effects. Retrospective assessments, however, can be further sub-divided on the basis of the initiating problem: source driven retrospective assessments result from observed pollution that requires elucidation of possible effects, effects driven assessments result from the observation of apparent effects in the field that require explanation, and exposure driven assessments are prompted by evidence of exposure without prior evidence of source or effects.

2.4 The USEPA framework for ecological risk assessment

In 1989 the USEPA commenced a long term project to develop agency wide guidelines for ecological risk assessment. This has resulted in the most notable attempt to date to provide a unified framework for ecological risk assessment.

In 1990 the USEPA Risk Assessment Forum and the National Research Council's (NRC) Committee on Risk Assessment Methodology, began to study the 1983 NRC risk assessment paradigm (Figure 2.2) as a possible foundation for ecological risk assessment. The NRC paradigm is concerned with assessing the potential adverse health effects of human exposure to environmental hazards (usually chemical pollutants), and since its inception has been extensively used to conduct health risk assessments under various environmental regulatory requirements, (Galbraith *et al,* 1993).

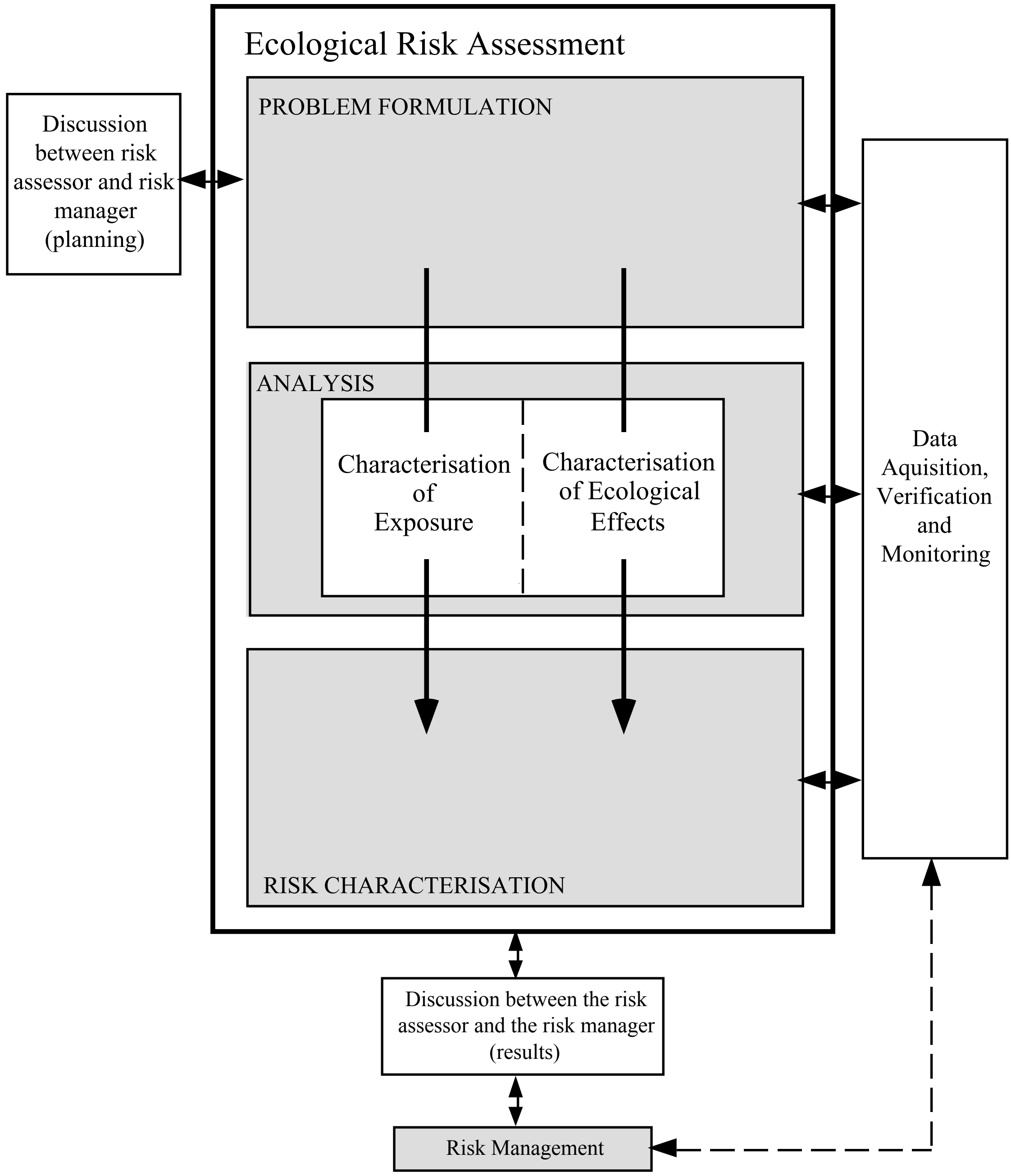


(Source: NRC, 1983)

Figure 2.2 The NRC risk assessment paradigm

Against this background it is perhaps unsurprising that the ecological risk assessment framework subsequently developed by the USEPA (Figure 2.3) shows a number of clear parallels with the original NRC paradigm. The framework, published in 1992, describes the basic elements for evaluating scientific information in relation to ecological risk assessment, which is defined as a process that evaluates the likelihood that adverse ecological effects may occur, or are occurring, as a result of exposure to one or more stressors (USEPA, 1992).

The framework recognises three distinct phases in the risk assessment process: problem formulation, analysis and risk characterisation. The problem formulation phase involves identifying the ecosystems at risk, evaluating the potential stressors and the anticipated ecological effects. From this impact hypotheses are developed and appropriate endpoints



(Source: USEPA, 1992)

Figure 2.3 The USEPA ecological risk assessment framework

are selected with which to express the impact of the stressors concerned. The endpoints fall into two distinct groups:

1. assessment endpoints, meaning the specific properties of the ecosystem at risk, or more generally the explicit expressions of environmental values that are to be protected by the assessment process; and,

2. measurement endpoints, meaning those aspects of the ecosystem that are to be measured within the assessment in order to characterise the assessment endpoints.

Data on ecological effects, stressor response relationships and exposure to stressors are evaluated in the analysis phase. Finally in the risk characterisation phase, exposure and effects information are integrated, principal uncertainties summarised and the ecological significance of observed or predicted changes evaluated.

Whilst the framework is conceptually similar to that of the NRC human health risk assessment paradigm, it has a number of distinctive differences. In the first place it considers effects beyond the individual, placing the emphasis at the ecologically more meaningful population, community or ecosystem level. It also explicitly recognises that there is no single set of ecological values, analogous to human fatality or injury, that can serve as the assessment endpoint.

The framework was originally envisaged to be all encompassing and applicable to all type of ecological stressors (chemical, physical and biological) as was clearly implied on publication of the framework documentation in 1992[2]. By 1994, however, there was an explicit recognition that the framework, as specified at that time, was not applicable to biological stressors such as introduced species (USEPA, 1994).

Simberloff & Alexander (1994) provide a detailed exposition for the reasons behind this, noting in particular that the key differences between biological stressors and other types of stressors, and thus the main reasons why the USEPA framework is not applicable to such entities, are:

1. biological stressors reproduce and multiply. With chemical stressors arresting the source of the contaminant inevitably leads to a lessening of risk of any ecological effects as the substance is degraded and dispersed within the environment. With a living organism, however, arresting its introduction to a site need not necessarily lower the risks of adverse ecological effects, so long as the organism can reproduce and multiply at that site;

2. biological stressors disperse in a myriad of means, often in 'large jumps', that are inherently more difficult to model or predict than the equivalent dispersal mechanisms for chemical stressors;

3. their interactions with other biotic and abiotic components of the ecosystem are extremely difficult to predict. The complexity of ecosystem dynamics can not beadequately described by the chemical dose-response concept. The effects of an introduced species can be both direct (predation, consumption, etc.) or indirect (resource base modification, habitat alteration, etc.). The complexity and multiplicity of these potential ecological effects is not adequately dealt with in the USEPA framework, and further complicates the issues of endpoint selection; and,

4. biological stressors have the potential to evolve, and this evolution has large elements of chance. Evolution of an introduced species within a new locality may alter the inherent

[2] In the executive summary of the *Framework for Ecological Risk Assessment* (USEPA, 1992) the term stressor is defined as any chemical, physical or biological entity that can induce adverse effects on individuals, populations, communities or ecosystems.

hazardous properties of the stressor in a largely unpredictable manner, particularly since these alterations need not necessarily progress in an incremental manner. Furthermore the continued potential for evolutionary change undermines any attempt to place temporal limits on the risk assessment process.

As a consequence biological stressors present a number of unique challenges to risk assessment, which are currently outwith the scope of the USEPA risk assessment framework. In more general terms biological stressors such as introduced species are likely to present a challenge to any type of risk assessment framework, particularly one that strives towards a quantitative expression of risk. Indeed Simberloff & Alexander (1994) doubt whether a rigorous quantitative risk assessment is currently possible at all and as a result conclude that qualitative Delphic risk assessment procedures, such as that adopted by the United States Department of Agriculture (refer to Appendix B7) provide the most reasonable starting point from which to commence introduced species risk assessments.

3 ECOLOGICAL RISK ASSESSMENT METHODOLOGIES

3.1 Chemical risk assessment

The modern chemical risk assessment paradigm traces its origins to the environmental risk assessment framework elucidated by the NRC in 1983, (NRC, 1983). The NRC defined environmental risk assessment as the characterisation of the potential adverse health effects of human exposures to environmental hazards, and outlined a four step assessment framework:

1. hazard identification – the determination of whether a particular chemical is or is not causally linked to particular health effects;

2. dose-response assessment – the determination of the relation between the magnitude of exposure and probability of occurrence of the health effects in question;

3. exposure assessment – the determination of the extent of human exposure before or after application of regulatory control; and,

4. risk characterisation – the description of the nature and magnitude of human risk, including attendant uncertainty.

In 1989 this paradigm was extended by the NRC's Committee on Risk Assessment Methodology (CRAM) to include ecological effects. The resulting ecological risk assessment framework was defined as the characterisation of the adverse ecological effects of environmental exposures to hazards imposed by human activities[3], but otherwise remained largely unchanged, in particular retaining the four step risk assessment procedure. Importantly this approach to ecological risk assessment presumed that the exposure and dose-response concepts utilised for chemical contaminants could be equally applied to physical and biological stressors (Barnthouse, 1994). In practise, however, this has proved problematic (refer to section 2.4).

The NRC 1983 framework was also utilised by the USEPA as a foundation for its subsequent *Framework for Ecological Assessment* published in 1992. Despite a number of similarities with the NRC approach, the USEPA framework is much more explicitly orientated towards ecological systems, in particular providing for effects assessment at the more meaningful population, community or ecosystem level. Furthermore the framework attempts to explicitly provide for all types environmental stressors, but again has not been entirely successful in this respect (refer to the discussion in section 2.4).

Appendix A provides a representative summary of a variety of chemical risk assessment frameworks, ranging from simple hazard screening guides (for example the Department of the Environment's substance selection scheme, Appendix A3) to site specific, state of the art, retrospective ecological risk assessment procedures (for example the marine ecological risk assessment at the Naval Construction Battalion Centre, Appendix A6). In this context it is

[3] In this context it should be noted that a number of authors maintain a distinction between environmental risk assessment (concerned with adverse human health effects following exposure to environmental hazards) and ecological risk assessment (concerned with adverse ecological effects following exposure to hazards imposed by humans). This distinction is not maintained in this report.

important to recognise that the techniques summarised in Appendix A represent a spectrum of assessment methodologies, at one end of which sits environmental hazard assessment, whilst at the other sits environmental risk assessment.

The environmental hazard assessment paradigm was developed primarily as a means to apply toxicological information to regulatory decisions about the release, use or marketing of chemical substances. In essence it consists of comparing the expected environmental concentration of a substance with an estimated toxic threshold, usually expressed in terms of a no effect concentration, and making a judgement as to whether the proposed use of the substance is safe, hazardous or not sufficiently characterised to allow a conclusion to be reached. In particular it does not use probabilistic methods, and does not attempt to predict the nature or magnitude of effects (Suter, 1993). Despite its terminology, the ‘risk assessment’ procedure described in EC Commission Regulation 1488/94 (Appendix A4) falls firmly in this camp.

Environmental hazard assessments also typically use generic or standardised parameters when estimating the dispersion of substances in the environment. For example, both the EC risk assessment model (Appendix A4) and the CHARM model (Appendix A5) identify ‘standard European environment parameters’ and ‘indicative North Sea environment parameters’ in the dispersion algorithms used to estimate environmental concentrations of substances within various environmental media. This approach facilitates regulatory decisions since it obviates the need to undertake costly and lengthy data collection programs. By the same token, however, it makes no allowance for the probability that a toxic threshold in the environment may be exceeded due to variations in environmental parameters in space and time, and thus clearly cannot be construed as risk assessment.

Further difficulties arise because there is no clear delineation between hazard assessment techniques and risk assessment techniques, rather there exists a gradient along which each individual assessment lies. Thus it is possible to identify hazard assessment methodologies that adopt simple probabilistic methods and/or attempt to quantify the magnitude of possible effect. For example the environmental hazard and risk assessment procedure formulated for the purposes of the United States Toxic Substances Control Act, (Appendix A2), identifies a crude scale of effect, the hazard profile, which describes both chronic and acute toxic effects across a range of chemical concentrations and species. Furthermore the methodology uses empirical streamflow data to represent uncertainty in the dilution of substances released to surface waters and hence in the expected environmental concentration.

Despite the differences in the individual techniques, the chemical risk and hazard assessment paradigms are perhaps best characterised by the use of the risk quotient. The risk quotient expresses the risk of environmental harm as the ratio of the expected environmental concentration of a substance and a benchmark concentration. The latter is usually chosen to represent the concentration of that substance below which there will be no measurable effect. The implication within this is that the lower the ratio is from one, the further the release of the substances is from causing an effect, and conversely the more this ratio exceeds one the larger the actual effect.

The risk quotient is a central precept of the chemical risk assessment paradigm and is predicated on the assumption that ecosystems have an assimilative capacity that allows them to accept a certain contaminant dose without exhibiting ‘harm’. This capacity arises because ecosystems possess mechanisms which degrade contaminants or alternatively isolate them, thereby rendering them effectively ‘harmless’.

The chemical risk assessment paradigm thus attempts to manage contaminant inputs to levels well below the effects (harm) threshold. In this respect, however, it suffers from a number of problems:

1. in energetic terms it is arguable whether a no effect threshold actually exists. Whilst a low level of substance contamination may not elicit a measurable effect in terms of mortality, Scope for Growth arguments would suggest that energy expended by an organism in detoxifying, metabolising or otherwise coping with anthropogenic contaminants, detracts from energy investment in areas such as growth, gonad development and fecundity. These arguments would therefore suggest that the first physiological functions to suffer in any contaminant loading scenario are functions such as growth, reproduction and health, which in terms of population dynamics certainly constitute ‘an effect’[4]. Rarely are such considerations taken into account in chemical risk assessments. The marine ecological risk assessment described in Appendix A6 is, however, a remarkable exception to this [5];

2. the risk quotient does not necessarily provide a linear measure of effect and, in the absence of dose response information (or alternatively the rate at which the effect threshold is approached from below and departed from above), cannot provide a measure of risk reduction (ICIT, 1994). The CHARM model in particular (Appendix A5) falls foul of this point as it attempts to utilise the reduction in its risk quotient to define cost efficient risk management strategies;

3. an ecosystems assimilative capacity (or sensitivity) varies as a function of space and time in response to a wide variety of natural and anthropogenic factors. Thus ecological risk needs to be estimated against the background of natural environmental variability, or ‘natural risk’ (Power *et al*, 1994). The risk quotient, however, implicitly assumes that the environment’s assimilative capacity remains constant. Indeed very site and species specific assessments are required in order to properly address this issue (see for example the assessment undertaken at the former metals mining site in Kansas, Appendix A7); and,

4. because the assimilative capacity is not invariant with time, the dose-response relationship is also unlikely to remain constant. This is particularly important in relation to chronic contaminant exposure in which effects may be postulated over relatively long time scales (Power & McCarty, 1997). This can cause further problems when attempting to use the hazard quotient as a measure of risk reduction.

In conclusion the risk quotient is an effective hazard assessment tool in so much that it enables a relatively quick, generic assessment of chemical hazard relative to the test conditions under which the quotient is developed. Its use in ecological risk assessment, however, should be approached with caution.

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[4] Refer, however, to Underwood (1990) and Power & McCarty (1997) for a discussion of the difficulties that may arise when interpreting the ecological significance of sub-organismal measures of effect.

[5] It is interesting to note that the risk quotients calculated in this study suggested that no adverse effects could be attributed to the contaminants loadings in the study area, whilst the Scope for Growth assessments suggested reduced physiological conditions in bivalve populations.

3.2 Import and pest quarantine risk assessment

Imports of live animals and plants (and their processed products) represent an important transmission vector for the spread of diseases and pests into nations which may have historically been free of such agents. In an economic era of free trade, however, it is increasingly important for nations to demonstrate a significant import risk prior to the implementation of trade or quarantine restrictions. Indeed the Uruguay round of the General Agreement on Tariffs and Trade (GATT) established the basic tenet that import measures applied in the name of protecting animal and human health should be 'based on sound science and risk assessment principles and should not form disguised barriers to trade' (Kellar, 1993).

The two leading international agencies in this respect are the Office International des Epizooties (OIE) and the United Nation's Food and Agriculture Organisation (FAO). The OIE was mandated by the International Agreement of the 25 January 1924 to ensure that import controls are formulated with the full knowledge of the most recent disease prevalence information, and since then has been responsible for maintaining sanitary standards in animal imports, largely by requiring compliance with the various editions of the OIE *International Animal Health Code.* Section 1.4 of this code now provides for import risk analysis in response to the GATT direction (refer to Appendix B1).

The United Nation's Food and Agriculture Organisation (FAO) houses the secretariat of the International Plant Protection Convention (IPPC), signed in 1951, with the explicit aim of promoting international cooperation in controlling pests of plants and plant products. The secretariat prepares international standards and guidelines to achieve international harmonisation of phytosanitary measures without unjustifiably hindering international trade. Thus the FAO's International Standards for Phytosanitary Measures require that quarantine and import restrictions 'shall be consistent with the pest risk involved and…shall result in the minimum impediment to the international movement of people, commodities and conveyances' (FAO, 1996)[6]. Plant pest risk assessment is seen as a key component to the successful implementation of these standards and the FAO has accordingly implemented guidelines in this respect (Appendix B5).

Despite their common rationale animal health and plant health risk assessments appear to have developed largely along separate routes, (and in isolation from the other related environmental risk assessment frameworks that were in place at the time of their inception). For example all the risk assessments associated with animal product imports reviewed as part of this exercise are quantitative, whilst those associated with the importation of plant pests are largely qualitative, although in some instances a quantitative approach is advocated. The reasons for this are unclear, particularly since each are essentially dealing with the same problem.

3.2.1 Animal import risk assessment techniques

The quantitative approaches to animal import risk assessment look upon the transmission of disease agents via animal commodity imports as the climatic conclusion to a complex series of

[6] It is interesting to note here the clear parallels that exist with the Australian Quarantine and Inspection Services' Ballast Water Management Strategy, whose stated purpose is 'to seek to avoid adverse economic and environmental impact of unwanted aquatic marine organisms by minimising their risk of entry…whilst not unduly impeding trade' (Paterson, 1995).

events (Kellar, 1993), commencing with the incidence of the disease agent in exporting nation's stocks. Morley (1993) summarises this series of events as follows:

1. the import commodity is infected with the agent;
2. the agent survives commodity handling, treatment or in-transit time;
3. the commodity is exposed to susceptible animals or humans in the import nation;
4. the agent is exposed to a portal of entry and is transmissible;
5. the agent induces infection;
6. the infection induces disease; and,
7. the disease spreads and is detected in the importing nation.

Each of these events is addressed within a prescribed (and internationally endorsed) framework for animal import risk assessment (Morley, 1993). A risk assessment is normally instigated when a new transmission vector is identified, for example a new import request or the identification of a new (or more potent) disease agent. Due to the multiplicity of disease agents, the former start point often requires a hazard analysis to determine which disease or pest agents could be associated with the import commodity. This is usually done on a qualitative basis. The framework requires that multiple, agent specific, assessments are undertaken in the event that several disease agents of concern are potentially associated with the import commodity.

The quantitative analysis usually commences with an assessment of prevalence in the exporting nation in order to determine the probability that any animal chosen at random will be infected. The multiplication of these estimates by the number of animals involved in any one shipment provides an estimate of the expected number of infected animals (or equivalent animal units) in the shipment. This part of the assessment is usually supported by the excellent disease incidence records published annually by the OIE in *World Animal Health*.

If the import consists of live animals then it is usually assumed that the disease agent is viable at the point of embarkation. If the import consists of a commodity other then a live animal, the assessment usually provides for any risk reduction measures associated with the processing that the product characteristically undergoes.

Arguably the most complex link in the chain (and thereby the most difficult to quantify) is the probability of exposure and disease transmission in the importing nation, reflecting the complex combination of possible exposure routes and scenarios. The approach advocated in this respects is to identify the most likely exposure and transmission scenario and quantify import risk on this basis alone. All other exposure scenarios can be ignored on the assumption that the assessment will thus be sufficiently conservative. The framework, however, provides little guidance at this point, relying on the individual assessor to provide a quantified estimate of the likelihood of exposure and transmission.

The relative simplicity and efficiency of this type of risk assessment approach is well suited to the routine application of import risk assessment decisions, allowing a quick and, more importantly, transparent decision to be made on import applications. There are, however, a number of limitations within this framework:

1. in its simplest form the assessment provides single value estimates for each point in the introduction chain, (see for example Appendix B3). Such a deterministic approach provides no indication of uncertainty within the risk estimate. Each of the variables in the risk algorithm should properly be described by a probability distribution since they are all inherently variable. This facet is recognised, however, in a number of later assessments which specify probability distributions for each component of the algorithm, using Monte Carlo techniques to sample from each of these during the risk calculation, (see for example Appendix B4);

2. the nature of the disease outbreak reports (collated by the OIE on a nationwide basis), upon which much of the assessment relies, infers spatial uniformity in the incidence of disease within the exporting nation, and in many of the assessments this assumption is carried through to the likelihood estimate of exposure and disease transmission in the importing nation, (see for example Appendix B2 and B3). Thus the risk associated with exports from a state or region which suffer a higher than average incidence of the disease (for whatever reasons), could potentially be understated in this approach. Again, however, this facet is often recognised by many of the later assessments and in some instances some attempt is made to incorporate a spatial dimension into the risk calculation, (refer to Appendix B4 for an example); and

3. the framework makes no allowance for the occurrence of unplanned events along the introduction chain, and indeed is predicated on the assumption that the processing and importation from the exporting state, and any subsequent transport and processing within the importing nation, proceeds in a manner usual for the commodity type. It is not inconceivable, however, that accidental events along the introduction chain could effectively short circuit the assessment process and significantly increase exposure within the importing nation.

With these considerations in mind, the assessments are all generally of a good standard reflecting their relatively long historical development and the excellent data support provided under the OIE's disease reporting requirements. Their quantitative nature also provides a good basis from which to assess the cost efficiency of quarantine and other related management strategies.

3.2.2 Plant import risk assessment techniques

In general terms the models employed to assess plant import risk (Appendix B5 to B9) are qualitative and more diverse than those of animal import risk assessment. Indeed plant import risk assessment lacks the detailed, prescriptive and internationally implemented risk assessment paradigm that characterises animal import assessments. International guidelines do exist for plant pest risk assessment (refer to Appendix B5), and these are undoubtedly emulated in some national schemes (Appendix B6 and B7), but there is clearly no plant counterpart to the standard assessment model for animals described by Morley (1993) above.

The initiation of a plant import risk assessment is likewise triggered by the identification of a new transmission vector (usually a new commodity import) or a new potential plant pest, and again the former usually entails a qualitative hazard assessment to identify all the potential pests and plant pathogens that may be associated with the commodity. At this point most of the schemes reviewed employed a set of decision rules to ascertain which pests warranted further assessment, in particular requiring that the species is not already present in the importing nation and has the potential to establish and exert adverse environmental effects on native flora.

Plant species and pathogens which satisfy these criteria are carried through to the risk assessment proper which addresses:

1. the plants bio-requirements and the likelihood that it will survive, establish reproducing populations and spread in the importing nation; and,

2. the propensity of the species to subsequently have an adverse environmental impact.

The individual components of a plant import risk assessment are best summarised in the framework advocated by the United States Department of Agriculture (Appendix B7) and in this there are clear parallels with the QRA paradigm employed by the nuclear and chemical process industries (with the important exception that there is no uncertainty or significance assessment stage, see below). At this point, however, the parallels with the QRA paradigm and that employed for animal import assessment cease. In all of the plant assessment models the individual elements of the risk potential were qualitatively reviewed and allocated to either low, medium or high risk categories. In some instances the assessment framework provides no additional guidance to the assessor regarding these ratings. Orr (1993), stresses that no definition or measurement scales for these categories can be provided because the value of the elements contained under probability of establishment are not independent of the rating of the consequences of establishment. The reasons for this, however, are not entirely clear, and indeed the framework adopted by the Canadian Animal and Plant Health Directorate (Appendix B6) provides very explicit definitions for each rating within the probability of establishment and the consequences of establishment.

At this point it should be noted that the Australian Weed Risk Assessment (WRA) model (Appendix B8) and the South African screening system (Appendix B9) take markedly different approaches. The former requires the assessor to score their response (1 for yes, 0 for no, etc.) to 49 questions regarding the biogeography, biology/ecology and undesirable attributes of the species concerned, whilst the latter uses an expert system to track the assessors response to 24 questions and maintain consistent decision rules through the assessment.

The individual techniques also differ in the final characterisation of the plant pest risk. The USDA framework provides very specific decision rules regarding the overall risk categorisation arising from the different possible combinations of high, medium and low scores allocated to the individual risk elements. The Canadian framework, however, gives no guidance in this respect merely remarking that the probability and impact estimates are summarised in an overall risk rating of negligible, low, medium or high.

The Australian WRA results in an overall score for the species in question which determines whether the import request is rejected, accepted or subject to further evaluation. Whilst this approach is ultimately qualitative, the whole process is given an interesting empirical rigour because the decision rule boundaries on the overall score were calibrated by running the risk assessment against 370 plant species of known weed status, and defining the allocation boundaries and bin widths so as to maximise the number of weeds correctly rejected, whilst minimising the number of useful plant species rejected.

The South African expert screening system simply allocates the species in question to high or low risk categories largely on the basis of the assessors qualitative responses to a set of predetermined queries. The approach does, however, utilise some quantitative data regrading environmental parameters such as rainfall, and biological parameters such as juvenile period.

Each of the approaches successfully identifies the constituent components of the introduction process and thus provide a good basis with which to address pest risk. The USDA framework is particularly commended by the way in which it explicitly derives the fundamental risk variables; the frequency of undesired events and the consequences of undesired events. With the possible exception of the Australian WRA and South African system, however, the utility of these approaches are seriously undermined by the qualitative nature of the assessment and the manner in which they express uncertainty. Both the USDA and Canadian frameworks are notable for the absence of any formal consideration of uncertainty and significance assessment in the risk analysis process.

Qualitative risk assessments of this type fail to satisfy a number of key criteria:

1. if risk assessment is to be scientific then it must be repeatable, separate assessors undertaking the same assessment should arrive at largely the same conclusion. Qualitative assessment frameworks that utilise ratings such as high, medium or low to describe the likelihood and severity of events, however, place an enormous emphasis on the judgement of the assessor. Judgement is not impartial and will therefore vary as a function of both the situation and the perception of the hazard, and the assessor concerned. This problem is simply exacerbated in those instances where no guidance is provided as to what is meant by ‘low probability’ or what it means in terms of overall risk to have rated the likelihood of an event as low but its potential consequences as high;

2. qualitative assessments of this type do little more than pay lip service to the uncertainty associated with both the physical situations they describe and our limited ability to represent and understand this. They provide no yardstick against which to gauge the likelihood or return period of low probability events, and worse do not distinguish between knowledge uncertainty, due to incomplete understanding or inadequate measurement of system properties, and stochastic variability due to random variability in natural systems. As a result an event can be classified as low probability because its causative combination of events are physically unlikely or simply because the assessor is unfamiliar with the system and fails to identify the complete set of possible causative combinations. This distinction is clearly of concern to decision makers; and,

3. qualitative assessments are a poor basis on which to determine cost-effective risk management strategies as they provide no indication of the relative value of alternative risk reduction measures.

Thus the plant pest risk assessments reviewed as part of this exercise are not as effective as their animal counterparts.

The Australian WRA (Appendix B8) warrants a separate consideration due to its more rigorous approach and empirical basis. By explicitly requiring the assessor to consider a more detailed set of questions, the framework places less reliance on the individual's perception of risk and is thereby more likely to be repeatable. Furthermore by calibrating the score against a large sample set of species of known pest status, the assessment allows a relatively objective interpretation of the essentially subjective risk scores, and thereby provides decision makers with better confidence in the results of the analysis. There remains little scope within the framework, however, for the assessment of effects beyond establishment or the development of risk management strategies.

Similarly the assessment procedure for invasive alien plants in the South African fynbos (Appendix B9) is largely concerned with the potential for establishment and does not address subsequent effects or risk management strategies, but nor was it designed to. The assessment approach is more notable for both its quantitative elements, particularly with regard to the match between environmental conditions within the fynbos and the species bio-requirements, and the use of expert systems to provide additional rigour to the assessors qualitative responses. Furthermore, the approach focuses much more strongly on specific ecological interactions than any of the other plant risk assessment techniques examined above, and thus marks an important shift away from generalised expressions of invasion risk. It is, however, undoubtedly assisted in this by the very peculiar environmental stresses, or invasion barriers, imposed by the fynbos environment.

3.3 Introduced species risk and hazard assessment

Outside of the assessment techniques concerned with import risks, there are a number of other risk assessment frameworks or methodologies associated with the introduction of non-indigenous species more generally. Much of the attention in this area has focussed on assessing the risks associated with introductions of non-indigenous fish for aquaculture and aquarium purposes. Three alternative approaches are summarised in Appendix C in this respect. Orr (1995), provides a generic risk assessment framework designed to meet the requirements of the US Aquatic Nuisance Prevention and Control Act (1990), and therefore, in theory, applicable to the introduction of non-indigenous species through ship's ballast water discharges (Appendix C3).

An equally prolific source of risk assessment methodologies is the current debate regarding the risks associated with the introduction of Genetically Modified Organisms (GMO's) into the environment. This debate has provided considerable impetus for the development of techniques with which to address the risks associated with such introductions, five of which are further summarised in Appendix C.

The extent to which a GMO can be considered a non-indigenous or 'new' species remains the subject of considerable controversy. Many geneticists working within this field emphasise that the genetic modifications made to an organism are similar in result to the 'classical' techniques of domestication and hybridisation, practised in agriculture for hundreds of years, resulting in no new or inherently different hazards (NRC, 1989). Many ecologists, however, take a different view. Regal (1994), for example, provides a summary review of this ongoing debate, concluding that genetic engineering does have the potential to create types of organisms that can interact with biological communities in novel competitive or functional ways or at new levels of impact, underlining the analogy with an introduced, non-indigenous organism.

Despite these various arguments, it is clear that from a risk assessment perspective the introduction of genetically modified organisms and non-indigenous organisms are essentially the same [7], if for no other reason than both involve biological stressors which are not subject to the same physio-chemical laws of dissipation and decay that govern chemical contaminants or physical stressors in the environment [8]. On this basis alone the traditional toxicological risk assessment paradigm is unlikely to prove sufficient (refer to section 2.4 for further discussion in this context), thereby forcing environmental managers to look to alternative methodologies for risk assessment. Furthermore as Suter (1993) points out, the effects of an introduced organisms depends on its ecological properties and not on whether it was a product of natural selection, selective breeding or genetic engineering.

The similarity of problems posed by non-indigenous and genetically modified organisms is further underlined by Fiksel & Covello (1985), who identify the following challenges to biotechnology risk assessment:

1. the ability of micro-organisms to mutate, adapt and multiply as they proliferate, raising the possibility of complex and intricate interactions with existing ecosystem processes;

2. the ability of micro-organisms to instigate feedback mechanisms with the ecosystem processes that they interact with; and,

3. the multiplicity of ecological consequences that could arise as a result of introductions of genetically modified organisms into the environment.

Each of the above is equally applicable to non-indigenous species introductions.

Given the similarity of challenges posed by GMO's and non-indigenous species introductions, it is perhaps unsurprising to find that many of the risk assessment methodologies developed to address these challenges suffer from much the same problems. Each of the risk assessment frameworks summarised in Appendix C more or less correctly identify the key components of invasion risk, notably the initial introduction, propagule survival and reproduction, finally leading to establishment, spread and manifestation of ecological effects. This is perhaps best conceptualised in the model developed by Orr (1995) for non-indigenous species introductions (Appendix C3) but given a more detailed exposition by Kohler (1992), for aquaculture escapes (Appendix C1) and by De Moor and Bruton (1993), for the importation of alien aquatic organisms (Appendix C9).

Each of these assessment frameworks, however, are characteristically qualitative, and in many instances provide little guidance as to how the risk assessment is to be actually completed. So whilst all more or less agree on the risk assessment components that need to be considered,

[7] It is also interesting to note that since DNA is a chemical, recombinant DNA technologies fall within the remit of the US Toxic Substances Control Act and thus theoretically are required to be subject to an assessment of risk under this act (refer to Levin & Strauss, 1991).

[8] Most authors agree on this issue, calling for a biological rather than physiochemical perspective to risk assessment (Barnthouse *et al*, 1988). There are, however, a few dissenting voices, see for example Travis & Hattemer-Frey (1988).

none are able to provide a blueprint as to how this might be accomplished in a quantitative and rigorous manner. The decision protocol advocated by De Moor and Bruton (1993) is a notable exception. Here we see the first signs of a quantitative assessment of the likely survival of a non-native introduction based on the temperature tolerances of all the life stages of the species concerned in relation to the temperature regime in the target environment.

For the main part, however, the ecological risk assessment frameworks for introductions of novel (including genetically modified) organisms, reviewed in this exercise, largely reduce to qualitative expressions regarding:

1. the probability that the introduced species will survive in its new environment;

2. the probability that the species will establish self-sustaining populations; and

3. the probability that the species will subsequently cause environmental harm.

In this context the methodologies advocated by Orr (1995), Kohler (1992) and De Moor and Bruton (1993) are arguably the most sophisticated in so much that they provide a relatively rigorous framework within which experts can apply their judgement to each of the criteria above. As noted in section 3.2.2, however, qualitative assessments of this kind are not necessarily repeatable, inevitably provide poor expressions of uncertainty and significance of risk, and are not very effective risk management tools.

The NRC risk assessment framework (Appendix C4) is particularly poor when evaluated against these criteria, requiring a simple yes/no answer to a series of questions. The poor performance of this methodology is exacerbated by a clear presumption in favour of the release (albeit for field trials) of genetically modified plants. Also note that the risk assessment framework developed by researchers at Cornell University and the Institute for Comparative and Environmental Toxicology (Appendix C6), explicitly includes cost/benefit analysis as an input to the derivation of risk management strategies but, in common with the other frameworks reviewed, fails to provide a unified metric against which to gauge either the risk reduction or concomitant benefit gained through the implementation of such strategies.

Each of these assessment frameworks also suffer from a more subtle and insidious problem which arises due to the potentially complex interaction between a non-indigenous organism and the functional and structural forms of the environment into which it is introduced. Suter (1993) identifies at least four major classes of risk assessment endpoints for the direct effects of exotic organisms (Table 3.1), whilst emphasising that a myriad of indirect effects are also possible. Simberloff & Alexander (1994) stress that indirect effects could be quite difficult to identify much less predict, whilst Fiksel & Covello (1985) re-iterate this point noting that the multiplicity of endpoints and hazard mechanisms associated with biological stressors represents a substantial challenge to predictive risk assessment methodologies.

In face of this complexity it is important that rigorous hazard identification techniques are provided for within any assessment framework designed to address the risks associated with biological stressors. None of the frameworks reviewed in Appendix C, however, include a systematic means to identify the ecological implications of a non-indigenous introduction, and thereby fail to provide confidence that all of the plausible effect scenarios have been considered, even if only qualitatively.

Table 3.1 Major classes of endpoints for direct effects of exotic organisms

1.	Reduction in populations of non-target organisms by pathogenicity, parasitism or predation
2.	Changes in the composition or production of a community due to changes in the physical or chemical characteristics of the habitat (modification of element cycles, pH, soil structure, etc.)
3.	Competitive displacement of a valued native species
4.	Proliferation to the extent of becoming a pest

(Source: Suter, 1993)

The GENHAZ methodology (Appendix C8) is an important exception in this regard. The methodology utilises HAZOP techniques, more commonly employed in the chemical process industry to identify hazard pathways and effect scenarios in complex industrial systems, to identify the potential hazards associated with releases of genetically modified organisms into the environment. This example provides an interesting insight into the possible extension of traditional QRA hazard identification techniques into ecological risk assessment frameworks.

The report's authors stress that unexpected interactions between seemingly safe components, or the development of system conditions that had not be envisaged, may lead to hazards as readily in ecosystems into which introductions are made as in complicated manufacturing plant (Royal Commission on Environmental Pollution, 1991). This suggests that there is further scope for the application of industrial hazard assessment techniques to ballast water introductions and biological systems in general. This perspective surely merits further attention.

The risk assessment methodology advocated by Parker & Kareiva (1996), Appendix C7, is also interesting in that it represents the first steps towards the development of a quantitative metric of invasibility. Whilst the assessment is relatively limited in scope, namely a comparative assessment of the reproductive vigour of genetically modified plant strains relative to their parent lines, under optimal greenhouse conditions, it does provide an example of the way in which quantitative metrics of relevance to invasion success can be derived using a mixture of experimental studies and biological relationships, or bio-rules. In this context the authors utilise the relationship between the expected number of flowers and seeds per adult plant (the bio-rule) with an estimate of germination and survivorship probability based on greenhouse studies, to generate a quantitative measure of an individual plant's finite rate of increase. It is perhaps not difficult to envisage the way in which these types of relationships could be successfully incorporated into a wider invasion risk assessment framework.

Finally it is instructive to note that the NRC, in their frameworks for assessing the risks associated with the release of genetically modified plants and micro-organisms (Appendix C4), chose to use the concept of familiarity with previous release as the key criteria against which to determine the safety of field trials with genetically modified organisms. The concept of familiarity essentially reduces to having sufficient information on the species concerned in order to be able to provide a reasonable commentary on its behaviour in its native habitat (or under previous release scenarios), and thereby provide informed judgements of its potential behaviour under novel conditions. The approach adopted by the NRC simply underlines the importance of species specific information in ecological risk assessment[9], a point often re-

[9] Compare, however, the NRC approach with that of De Moor and Bruton (1993) in which a non-native import is banned if there is insufficient information to complete the decision protocol.

iterated in the scientific literature. For example in the assessment of the pest risk associated with the importation of *Pinus radiata*, *Nothofagus dombeyi* and *Laurelia philippiana* logs from Chile (refer to Appendix B7) the assessors were forced to exclude a number of potential pests known to be associated with some of the log products simply because there was insufficient information regarding these species even for a qualitative assessment of risk. Recognising this uncertainty the assessment could do no more than hope that the risk management strategies developed in response to the species for which information was available, would also provide protection from those species for which it was not.

3.4 Miscellaneous risk assessment techniques

Appendix D provides five examples of ecological risk assessments applied to a variety of environmental problems, and approached in a number of different ways. The assessments also demonstrate a variety of spatial and temporal scales, and work at a number of different levels of biological organisation, thereby underlining the potentially diverse domain of ecological risk assessment (refer to Figure 2.1). Despite these differences the assessments do have a number of elements in common, most notably they all make explicit use of relatively detailed environmental models and each provides a relatively good exposition of the results of the model under uncertainty.

Uncertainty has been described as a measure of incompleteness of one's knowledge or information about a quantity whose true value could be established if a perfect measuring device were available (Taylor, 1993). It is important to recognise, however, that this is only applicable to empirical quantities, and that the risk assessor and decision maker may be faced with uncertainty regarding decision variables or value parameters which may not have a "true value" (Morgan & Henrion, 1990). In this sense it is possible to identify at least four possible sources of uncertainty in environmental risk assessment modelling (Table 3.1). Hession *et al* (1996) adopt a slightly different perspective, distinguishing two types of uncertainty:

1. knowledge uncertainty, due to incomplete understanding or inadequate measurement of system properties, which can be further sub-divided into model and parameter uncertainty; and,

2. stochastic variability, due to random variability of the natural environment, which can be further sub-divided into spatial and temporal variability.

Table 3.1 Types of uncertainty in environmental risk assessment

Assessment parameter	Characteristic	Methods for reducing uncertainty
Empirical quantity	Measurable (at least in principle) property of real world systems	Simple analytical techniques where the number of variables is low. Where the number of variables is high: Monte Carlo simulation, sampling from n dimensional space defined by ranges in n uncertain parameters
Index variable (independent variable)	Identifies a location or cell in the spatial or temporal domain	Careful ring fencing of analysis. It does not make sense to be uncertain about index variables, however, one can be uncertain about the most appropriate resolution (see below)

Model domain parameter	Domain or scope of the system being modelled, generally defined by the range and increments for index variables	Chosen as a balance between ensuring the model deals adequately with the full range of the systems behaviour and computational costs. No ‘true’ value, but can be uncertain about appropriate value. A prior truncation of biological parameters may be drawn from empirical evidence
Value parameter	Aspects of the preferences of decision makers or the people they represent	Again no ‘true value’. Switch over techniques may allow explicit analysis of when and why a decision changes. Previous precedence may allow categorisation of acceptance criteria. Managing risk to a point that is As Low As Reasonably Possible (ALARP) between acceptance criteria

(adapted after Morgan & Henrion, 1990)

Each of the assessments in Appendix D are notable for the excellent way in which they deal with and communicate uncertainty in parameter values and environmental stochastity. The Wister lake water quality assessment (Appendix D1), for example, allows for variation across 17 model parameters, specifying simple probability distributions for each, whilst also explicitly recognising stochastic variation in annual weather conditions by fitting a log-normal distribution to annual rainfall using empirical rainfall data from a nearby weather station.

Probability distributions for the 17 model parameters were specified as either uniform (indicating no preference between upper and lower limits) or triangular (indicating a symmetrical reduction in preference around a most likely value). The relevant parameters of the probability models were selected on the basis of values quoted in the literature. Monte Carlo techniques were then used to sample from these distributions and run a lake eutrophication model with the subsequent parameter values. In this respects the approach is similar to a number of other risk assessment procedures. For example, compare this with the approach adopted by MacDiarmid (1994) in assessing the risks associated with salmon imports (Appendix B4).

Two of the approaches summarised in Appendix D are also interesting for the way in which they mix tenants of the chemical risk assessment model, namely the risk quotient approach, with environmental modelling capabilities. The risk assessment described by Munns *et al* (1989), for example, utilises a copepod population dynamics model, with sewage sludge dose-response estimates on mortality and fecundity, to investigate the potential impact associated with sewage sludge disposal at sea (Appendix D2).

Matsinos *et al* (1994) meanwhile, use an object orientated approach to investigate the acute and chronic effects of PCB contaminants in a spatially heterogenous Heron nesting colony environment (Appendix D3). The results of the assessment demonstrated that whilst the PCB pollution was unlikely to have a direct effect (expressed in terms of acute toxicity), its indirect impact on the foraging efficiency of the Heron could still drive the colony to extinction. This assessment serves to underline some of the difficulties associated with toxicological risk assessments undertaken solely on the basis of laboratory information, highlighted in section 3.1.

This last example is also particularly interesting for the way in which it explicitly generates and utilises bio-rules to describe the behaviour of individual Herons within the colony. A similar but simpler approach was demonstrated by Parker & Kareiva (1996) to assess the relative invasive ability of Genetically Modified Plants (Appendix C7). Matsinos *et al* (1994), however, develop this approach much more thoroughly and thereby provide an excellent demonstration of its utility in environmental risk assessment.

The fishery risk assessment undertaken by Francis (1992), Appendix D4, has at its core a detailed population model of the orange roughy fishery. The author makes some allowance for parameter uncertainty by constructing a probability density function for the virgin unfished biomass at the start of the fishery, and by allowing recruitment within the model to vary as a log-normal variable. The main thrust of the assessment, however, is to investigate the effects of different fishery management strategies (expressed in terms of the rate of reduction of the Total Allowable Catch) upon the risk of collapse of the fishery. In this respects the assessment provides a good example of how effective quantified environmental risk assessment can be in cost-benefit decision analysis applied to risk management strategies; clearly such an analysis would not be possible with qualitative expression of risk.

The Bayesian fishery risk assessment techniques described by Punt and Hilborn (1997), of which Appendix D5 is an excellent example, are arguably the most sophisticated and probably the most controversial approach to fisheries decision and risk assessment. The techniques utilise Bayes theorem in order to modify the analyst's prior uncertainty regarding alternative hypothesis, in this context the likely value taken by an important parameter in a fisheries model, in light of new or additional data which has some bearing on the problem, for example data from observations of the stock in question (trends in catch rate, age-composition, etc.), represented in the form of a likelihood function. The influence of the resulting modified, posterior probability distribution can be evaluated by running the fisheries model under different management strategies. Monte Carlo sampling from the posterior distribution allows the enumeration of conditions under which the biomass of the stock in question falls below some pre-assigned level, thereby completing the risk assessment.

One of the major benefits of the Bayesian approach is the ability to incorporate prior information regarding models and parameter values into the analysis, indeed the approach requires this information, forcing the assessor to be much more explicit about his uncertainty. This can be contrasted with the more usual approach to fisheries modelling based on conditional maximum likelihood estimation in which important model parameters are fixed in light of historical catch or survey data (for an example refer to Appendix D4). The derivation of the prior distribution can be made on the basis of information regarding related stocks or species, or on the basis of no prior information at all, in which case it is common to specify a uniform prior distribution.

It is important to recognise, however, that Bayesian statistical inference is a wider discipline in its own right, and as such the approach is largely independent of the context (in this case fisheries modelling) in which it is used. Indeed it has a potentially wider application to all forms of ecological risk assessment models so long as it is possible to provide prior probability distributions for the parameters within the models. Conceptually the approach allows the assessor to express his uncertainty in these parameters on the basis of no more than 'gut feeling' and intuition, and therein lies the source of much of the controversy regarding the use of the Bayesian approach. For example it is common in fisheries risk assessment to specify 'non-informative priors' in terms of a uniform distribution function. The implication being that the assessor has no prior information which suggests that any one value of the parameter concerned is more likely than any other. The question immediately arises as to what bounds are placed on the distribution. In practise these bounds are often specified with little or no justification, certainly none that is consistent with a situation of no knowledge.

Despite these criticisms the Bayesian perspective is undoubtedly a more logical and attractive statistical paradigm for risk assessment in situations where there is relevant prior information. In particular the approach encourages:

1. a more explicit expression of the nature and severity of the uncertainty in the assessment process;

2. the rapid incorporation of new information as and when it becomes available without the need to completely re-formulate the analysis;

3. the contributions of scientists who may not be familiar with the assessment models in question, but nevertheless can make valuable contributions through the specification of prior probability distributions for important parameters within these models; and

4. the correct interpretation of the assessment results and the implications of uncertainty on these results, by environmental managers who may not be familiar with the mathematics.

Each of these would form valuable attributes of any risk assessment framework, and clearly warrant further investigation of the application of the Bayesian paradigm in ecological risk assessment.

Taken together the examples in Appendix D can be considered as indicative of the state of the art of quantified environmental risk assessment, and demonstrate the central role that environmental modelling plays in this. It is important to recognise, however, that each of the assessments act under the restraints of the models which they employ. Francis (1992) provides a timely word caution in this respects, noting that the results of a risk assessment should not be interpreted too literally. If the assessment is conducted in a systematic and rigorous manner, however, this type of approach provides the best surrogate for 'true risk' assessment, and the only approach capable of providing a quantified metric against which the relative cost-effectiveness of different risk management strategies can be evaluated.

4 RISK ASSESSMENT FOR BALLAST WATER INTRODUCTIONS

Cargo vessel ballast water was first mooted as the vector responsible for the dispersal of non-indigenous marine species over 90 years ago (Hallegraeff and Bolch, 1992). The problem was formally documented in Australia in 1973 (Grainger, 1973), having been implicated as the vector for *Crassostrea gigas* introductions to New Zealand some two years earlier (Dinamani, 1971). The scale and potential adverse impacts of ballast water introductions, however, were not fully recognised until the late 1980's, largely through the work of Carlton, Williams, Hallegraef, Hutchings and Pollard. The reader is referred to Jones (1991) for a succinct review of the contribution made by these authors.

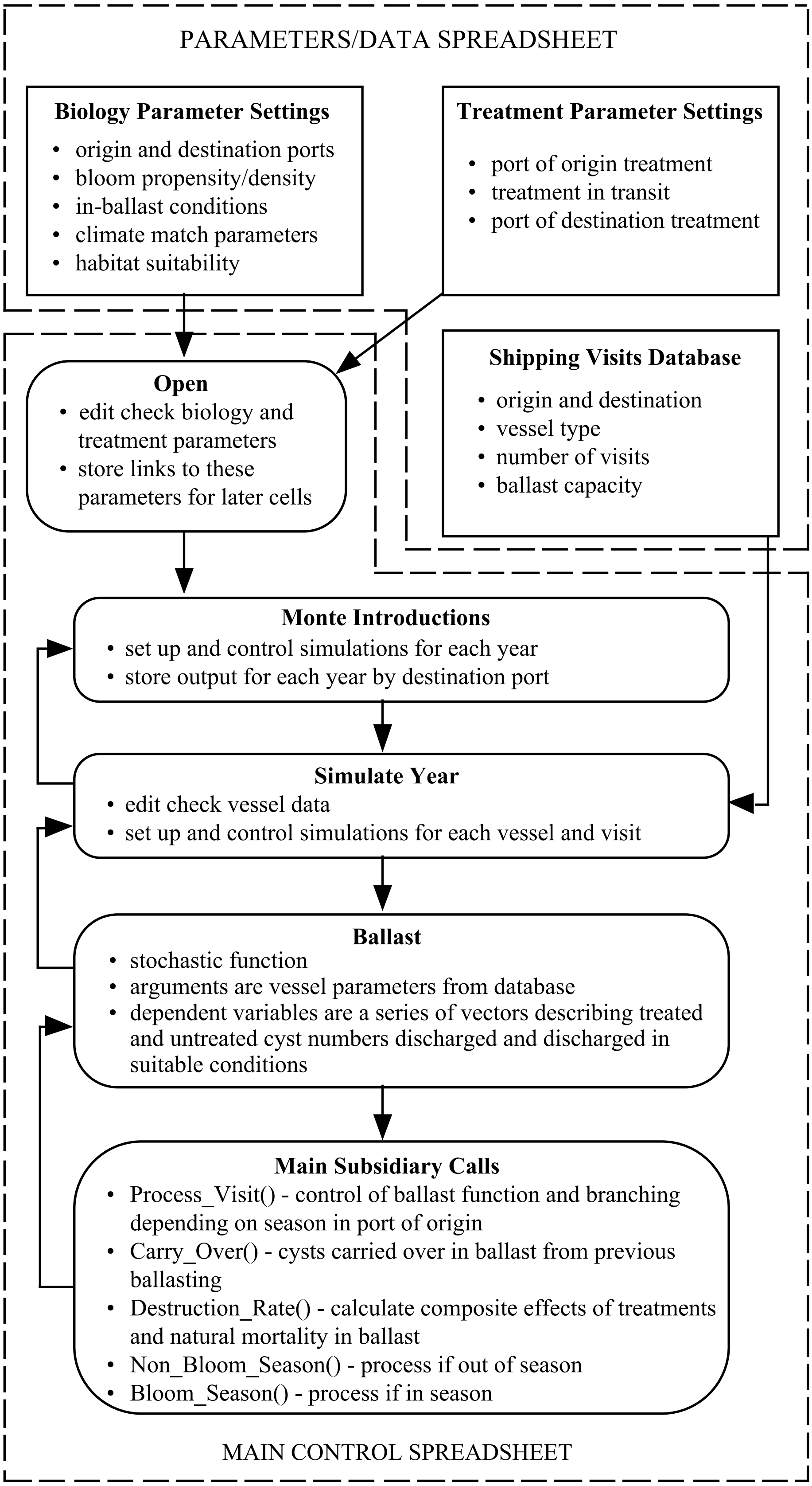
The first attempts at undertaking an assessment of the risks associated with ballast water and sediment discharges are more recent still, and indeed only two examples of assessments of this kind were discovered during this review. These are detailed below in sections 4.1 and 4.2. The paucity of documented ballast water risk assessments suggests that this discipline is still in infancy. As such there is no standardised risk assessment framework or internationally accepted data support system that characterise the much more mature chemical and import risk assessment paradigms.

4.1 Bio-economic risk assessment of the potential introduction of exotic organisms through ship's ballast water

In 1993 the Australian Quarantine and Inspection Service (AQIS) commissioned ACIL Economics and Policy Ltd. to undertake the development of a methodology for assessing the risks associated with the introduction of exotic organisms in ballast water and apply this methodology to toxic dinoflagellates (AQIS, 1994b). The main emphasis of the ACIL study was to assess the cost likelihood function associated with toxic dinoflagellate introductions into Australia's east and south coasts, which were identified as having the greatest concentration of amenities and aquaculture facilities likely to be adversely affected by toxic dinoflagellate blooms. The risk analysis formed the backdrop against which the net benefits of alternative ballast water management strategies could be subsequently evaluated.

The development of the cost likelihood function necessarily required a quantified expression of the frequency of successful toxic dinoflagellate establishment and bloom in the recipient ports identified. A dedicated Excel based model was developed by the study team in response to this. The model (Figure 4.1) was designed to simulate the annual pattern of shipping arrivals in five domestic port groupings (Port Hedland, Hay Point, Newcastle, Sydney/Botany Bay and Hobart/Triabunna) from five different ballast intake regions (Japan, Korea, Other Asia, New Zealand and 'Other'). Vessel visits were further distinguished on the basis of five vessel types (bulk carrier, woodchip, ore carrier, tanker and chemical tanker), whilst introduction risk was assessed in relation to the cysts[10] of four dinoflagellate species (*Gymnodinium catenatum, Alexandrium catenella, A. tamarense,* and *A. minutum*).

[10] Motile life stages of toxic dinoflagellates were considered very unlikely to survive the ballast and de-ballast procedure and therefore only the cysts of these species were carried forward in the assessment.



(Source: AQIS, 1994b)

Figure 4.1 Overview of the ACIL Organism Introduction Model

The modelling approach adopted by the ACIL study team is very similar to that advocated by the OIE, in that both view introduction risk as the end product of a sequence of events to which individual probabilities can be applied[11]. In particular the ACIL study team identified the following key steps in the introduction cycle of dinoflagellate cysts (*pers comm* D. Campbell, ACIL):

1. the number of cysts of each species already present in the ballast tanks at the time the vessel takes on ballast (the cyst 'carry-over');

2. the probability that the vessel departure is during a time of the year when bloom activity is feasible for the port at which ballast is taken on;

3. given that blooming is feasible, the probability that there is a bloom present at the time of taking on ballast;

4. given that there is a bloom, the density of cysts in the water taken on board by the vessel;

5. the natural mortality of cysts during the vessel's voyage;

6. the additional mortality due to the ballast water treatment (if any) used; and,

7. the probability that the cysts are subsequently discharged in a suitable environment.

This sequence of conditional probabilities underlines the introduction simulation at the heart of the ACIL risk assessment. The model incorporates stochastic elements of chance into some of these steps through a simple Bernoulli switch. In the first instance the model assumes that 10% of all vessels potentially carry-over cysts from previous voyages. The simulation therefore runs a Bernoulli trial for each vessel with a 10% chance of success (a success being defined as cyst carry-over). The subsequent number of cysts onboard the vessel is then determined in relation to the vessel type ballast capacity, its discharge efficiency (assumed to be 98% for all vessel categories) and the density of cysts on board (nominally set at 10 per m^3 in the first instance).

Vessel departures from port were assumed to be uniform over the period of a year. Bloom seasons for each port of departure were pre-assigned and a similar Bernoulli switch used to flag vessels ballasting during this season. An identical procedure was then used to identify vessels ballasting during actual bloom events. In the absence of empirical data, the model assumes a log-normal distribution for the cyst density during a bloom with pre-assigned median and 99 percentile[12]. The values assigned to these parameters result in a distribution that is heavily skewed to the right, reflecting the increased likelihood of very high cysts densities during a bloom event. This mixture of discrete and continuous distributions has the effect of assigning a reasonably high probability to the event that there are no cysts present in the water column whilst a vessel is ballasting, but in the (unlikely) event that there is a bloom, cyst numbers could be expected to be very high.

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[11] Refer to Appendix B4 for an excellent illustration of this approach for salmon product imports.

[12] The median and 99 percentile were used because these parameters were considered easier for experts to estimate than the usual mean and variance. A spreadsheet algorithm was then used to translate this to the mean and variance so that standard calls could be made to the distribution during the simulation (*pers comm* D. Campbell, ACIL).

Natural mortality within the ballast tank was modelled as a simple exponential decay function with a fixed species specific half life under oxidated conditions. Allowance was also made for the possibility that cysts could settle into anoxic sediments within the ballast tank thereby extending the duration of the cyst phase. The half life under these anoxic conditions was assumed to be twice that of the oxidated condition, and applied to 5%[13] of all vessel journeys. The effects of three alternative ballast water treatment schemes (ballast exchange, heat and peroxide treatment) were propagated through the analysis by applying a simple multiplier to the exponential decay function describing natural mortality.

Habitat suitability upon discharge was modelled as a function of tidal flushing rate (the percentage of cysts flushed out to sea before settlement), sediment suitability (the probability that the sediment which the cysts settle into is suitable) and time suitability (to allow for other circumstances) within each of the domestic port groupings. Again each of these parameters were assigned fixed values, and Bernoulli trials run with a probability of success equal to this pre-assigned value. The new port environment was deemed suitable in the event that each of the trials registered a success during the simulation.

The assessment drew a number of key conclusions from the model most notably that all the ports received frequent discharges of ballast water contaminated with live cysts mainly from (Korea and Japan) but that there was a dramatic year to year variation in the numbers of cysts discharged, and thus under rare but plausible conditions, extremely high inoculation densities could be achieved. Furthermore the model also predicted that the ports of Queensland and Victoria were the most common recipients of average and extreme inoculation densities, as compared to the Tasmanian ports. The fact that *G. catenatum* populations have been established in Tasmania, via ballast water introductions, as opposed to the ports further North, suggests two alternative hypothesis: either habitat constraints are much stricter for the more northerly ports than is the case for Tasmania, or the habitat constraints are equally severe throughout these ports, requiring large inoculation of cysts, at levels well above ‘average’, and in this sense the Tasmania ports were simply unlucky. The assessment, notes, however that these two elements are not necessarily mutually exclusive and points to the possible role played by the cold, nutrient rich, southern ocean currents that regularly extend into Tasmanian waters and thereby possible relax habitat constraints, but rarely extend further North into Victorian or Queensland waters.

The results of the assessment are interesting not so much for the economic estimates of the cost benefit derived from the ballast water management strategies but rather for the risk assessment approach adopted by the analysts. This is undoubtedly one of the first attempts to treat ballast water introductions as a set of discrete steps to which individual probability statements can be assigned, again underlining the parallels with import risk assessment noted earlier. The approach is commendable and the overall modelling pattern of rare, but large cyst numbers during ballasting events conforms to current understanding of bloom dynamics. The efficacy of the analysis, however, is undoubtedly undermined by the simplistic approach. The details of the model were kept deliberately simple so as not to over engineer an analysis faced with a paucity of empirical evidence (*pers comm* D. Campbell, ACIL), but despite this the assessment maintained very ambitious objectives, resulting in a poor treatment of systematic uncertainty.

[13] This figure was increased to 25% for woodchip vessels because of the high levels of organic matter carried in these vessels.

Perhaps a more appropriate strategy under these circumstances is to try and capture more realism for a simpler set of objectives.

4.2 Ballast water risk assessment: 12 Queensland ports

In June 1995 six of the eight Queensland port authorities commissioned a ballast water risk assessment with the objective of quantifying, as far as possible within the limits of available data, the risk of foreign marine species being introduced to and successfully establishing in Queensland waters (Hayes *et al*, 1996). The risk assessment framework comprises of five stages:

1. the identification of all overseas 'source' ports importing ballast water to the 12 Queensland ports within the scope of the assessment;

2. a characterisation of the ballast water receival environments at each of the Queensland ports (the receival ports);

3. the selection of a sub-sample of overseas source ports for inclusion in a multivariate environmental similarity analysis, and the completion of this analysis in relation to the receival ports;

4. the identification of species at the source ports which could possibly establish in Queensland waters; and,

5. an assessment of establishment risk based on the preceding elements above.

The assessment is a 'first-pass' semi-quantitative analysis of risk (Hilliard and Raaymakers, in prep.) which is largely predicated on the assumption that for non-native species which are repeatedly transferred to the foreign ports, the likelihood of long term survival is proportional to the biophysical similarity between the source port and the target port environment. The analysis does not address the issue of survival during uptake, transportation and discharge[14], but rather assumes that for species which survive these stages, the likelihood of establishment is a function of the frequency of inoculation, the biophysical similarity between ports and the ability of the species concerned to survive the routine seasonal range and extremes of conditions at the target port.

The first stage of the assessment identified a total of 4,953 vessel visits to the twelve Queensland ports between January 1989 and July 1995, arriving from 264 foreign ports and discharging an estimated 123, 093, 226 tonnes of ballast water (Table 4.1)[15]. Of these 264 source ports, 46 were carried forward for inclusion within the multivariate similarity analysis for each of the Queensland ports. The remaining ports were excluded on the grounds that less than 5 vessel visits from these ports occurred during the study period, the port was situated

[14] Furthermore no allowance is made for ballast which is retained on board the vessel between ports, nor for the effect of any ballast exchange procedures.

[15] In this assessment ballast water discharges are estimated on the basis of vessel deadweight ratios alone. In reality the quantity of ballast discharged is intimately linked to cargo (un)loading patterns. The reader is referred to Walters (1996) for examples of the potentially large errors that can occur if this is aspect of the vessel activity is ignored.

beyond the mean winter sea surface 15°C isotherm or because reliable environmental information could not be gathered. The 46 selected ports provided the 12 Queensland ports with an average of 69% of the estimated volume of ballast water discharged during the study period.

The assessment further identified 108 berths within the twelve Queensland ports and 46 overseas ports, for which data regarding 40 environmental variables was collected in addition to mean/median and extreme seasonal temperature, salinity and rainfall values for both summer and winter. A series of multivariate similarity assessments were then undertaken (including hierarchical agglomeration, hybrid ordination and nearest neighbour analysis) in order to rank each of the selected overseas ports in terms of their environmental similarity with each Queensland receival port on a year round and seasonal basis. These rankings were subsequently reduced to four broad scale coefficients of risk with respect to the likelihood of population establishment and the influence of season on successful inoculation.

Table 4.1 Overseas arrivals to Queensland ports between January 1989 and July 1995.

Queensland receival port	Number of arrivals	Estimated total ballast water discharged (t)*	Number of source ports
Hay Point	2,851	91,065,091	190
Weipa	531	8,066,304	114
Abbot Point	434	13,049,010	93
Cape Flattery	180	2,792,502	54
Townsville	224	2,272,949	60
MacKay	185	1,533,611	68
Cairns	178	1,461,578	66
Mourilyan	165	1,259,459	50
Lucinda	109	1,092,138	25
Bundaberg	53	424,070	28
Port Alma	27	72,514	22
Karumba	41	10,000	5
TOTALS	4,953	123,093,226	264

(Source: Hilliard & Raaymakers, in prep.)

* The ballast water discharges were estimated on the basis the specified dead weight tonnage (DWT) of each arrival vessel type, and the average ballast capacity to DWT ratio for each vessel type, as specified in AQIS (1994a).

The final stage of the assessment synthesised all of the preceding information to produce a set of semi-quantitative predictors that indicate which overseas ports during particular seasons represent a high, moderate or low threat to the Queensland ports. These predictors were based on the volume of ballast water received by Queensland from each of the foreign ports, the environmental similarity between the source and receival port, and the known or suspected occurrence at the source port of potentially hazardous species.[16]

The results of the analysis indicated that the majority of overseas visits to the Queensland ports involved bulk carriers, departing from Japanese ports within the Sea of Japan. The assessment notes that these port environments are characterised by relatively cool inshore waters and thus the members of the marine communities in these ports are less likely to establish in more tropical waters of Queensland. More particularly the study suggested that the pathogens and disease organisms of the tropical ports of PNG, Indonesia and the Philippines represented a potential threat to Queensland whilst Singapore posed a high macrobiota risk by virtue of its environmental similarity with a number of the Queensland ports and the presence of the introduced Asian clam *Potamocubula amurensis*.

[16] In this context 'hazardous species' were defined as taxa with life-cycle characteristics, environmental tolerances and/or previous translocation histories that imply a threat.

5 DISCUSSION

Much of the literature on ecological risk assessment is dominated by chemical risk assessment procedures and issues. Indeed it often seems that ecological risk assessment is considered by some authors to be synonymous with the chemical risk assessment paradigm. This is an unfortunate corollary of the historical development of the discipline and the origins of its terminology. Animal import risk assessment has a history as long, if not longer, than that of the chemical risk assessment framework, yet the development and progress in this field seems to have been largely ignored by assessors not directly associated with veterinary science.

The current frameworks espoused for chemical risk assessment are not readily applicable to biological stressors, primarily because biological entities are not governed by the same laws of dispersion and decay that apply to chemical or physical stressors. This difference is fundamental and pervasive, and suggests that at best a single ecological risk assessment framework will only be generally applicable, and at worst will offer no more than a series of key words. A detailed evaluation of the risks associated with biological stressors will in all likelihood require a tailor made framework. Furthermore in light of the very particular complexity associated with biological introductions a number of authors have suggested that a qualitative assessment, involving panels of experts in a delphic approach, is the best that risk assessment for biological stressors can currently hope for. Again, however, this stance takes no account of the quantitative assessments routinely undertaken for animal import risk, and a whole host of other miscellaneous risk assessment techniques.

So how does the OIE framework successfully provide quantitative measures of the risk of disease and parasite transmission through animal product imports, when a number analogous assessments have failed to do so? In answer it is possible to identify a number of components of the framework that facilitate a quantitative expression of risk:

1. it identifies simple and clear endpoints, namely the transmission of specified disease agents;

2. the assessment is able to draw upon an extensive literature and understanding with regard to the epidemiology of the disease agents concerned; and,

3. the maintenance of excellent database of disease outbreaks and occurrences internationally allows the framework to draw heavily on empirical evidence in establishing parameter estimates within the risk models.

These components allow an empirical approach to the assessment of risk that is somewhat akin to the assessment of failure frequency rates in engineering risk assessments. From here it is a relatively simple step to specify likely probability distributions for each parameter within the model and thereby develop a relatively comprehensive assessment of uncertainty within the whole process. One drawback with this and the other import risk assessment frameworks, however, is that no allowance is made for unplanned deviations from the expected course of events associated with the import commodity. It is not difficult in this sense to conceive of unlikely, but still plausible, accident events which effectively short circuit the introduction cycle normally associated with the product in question, and as consequence significantly increase either the likelihood or effects of successful establishment of the disease/parasite agent.

Unfortunately a similar empirical approach cannot be adopted for ballast water introductions until such time as comparable data sets regarding ballast tank assemblages, viable inoculations and successful establishments are collated on an international scale. Whilst some of this data is undoubtedly being collected in a variety guises for individual research aims, there is currently no central collating mechanism or agency which fulfils an equivalent role to the OIE.

A number of alternative quantitative methodologies to assess import or introduction risk are currently being developed on the basis of the attributes of the species in question. Again, however, the efficacy of this approach generally relies on being able to empirically test the methodology against successful invaders or known weed species. Furthermore in many instances these techniques simply serve to highlight the very idiosyncratic nature of introductions which defy a generalised predicative methodology.

Despite the occurrence of these ‘outliers’ these techniques are generally successful and on most occasions would successfully serve as taxonomic hazard analysis methodologies. Furthermore their predictive ability could probably be improved by the application of formal hazard identification techniques similar to those currently used in engineering risk assessment, and to that described by the Royal Commission on Environmental Pollution (1991) for genetically modified organisms. Adopting these types of hazard assessment tools will assist in the identification of low probability (ie unlikely to be covered by the professional experience of the analyst) but plausible risk scenarios, that undoubtedly characterise many of the successful ballast water introductions to date, and which will continue to confound the qualitative risk assessment approaches currently being advocated for introduced species.

The USDA and OIE risk assessment frameworks both provide a useful starting point from which to conceptualise the ballast water introduction risk problem. The former emphasises that introduction risk is a function of the likelihood of establishment and the consequence of establishment, whilst the latter views the successful establishment of a non-indigenous species as the culmination of a series of steps, each of which must be successfully negotiated by the invading species, and to which a probability of success can be assigned. In this sense ballast water risk is very similar to the risk presented by animal product imports and by genetically modified organisms, as envisaged by Alexander (1985) in Table 5.1. The equivalent steps within the ballast water cycle, addressing the risk of inoculation within a suitable habitat, are:

1. the probability of the organism being present in the body of water from which ballast water is drawn at the time of ballasting;

2. the probability of uptake of the organism in the ballasting process;

3. the probability of the organism surviving the ballasting process;

4. the probability of the organism surviving the voyage in the ballast tank;

5. the probability of the organism surviving the de-ballasting process; and,

6. the probability that at the time of de-ballast the recipient port provides a suitable habitat for the introduced population.

At least one assessment of ballast water risk has already been attempted from this perspective (section 4.1) and it is recommended that this approach be maintained for subsequent assessments. In the absence of a detailed database, however, none of the steps in this introduction cycle can be inferred empirically from historical data. As a result a quantitative expression of ballast water risk can only proceed by modelling each of the steps, and by using rigorous hazard identification techniques to establish plausible introduction scenarios. This is particularly important with respect to the probability of suitable habitat. The environment varies in a stochastic manner and thus the constraints imposed by that environment also vary in a stochastic manner. It is essential therefore that the return period associated with a suitable habitat be established in a site specific manner, otherwise the predictions of the assessment are unlikely to accurately reflect the likelihood of successful introduction.

Table 5.1 The probability of a deleterious effect from a genetically engineered organism is the product of six factors

Probability	Event
P_1	RELEASE - will the genetic engineered organism escape ?
P_2	SURVIVAL - will it survive in the natural environment ?
P_3	MULTIPLICATION - will it proliferate ?
P_4	DISSEMINATION - will it be dispersed to distant sites ?
P_5	TRANSFER - will its genetic information be transferred to other species ?
P_6	HARM - will the engineered organism be harmful ?
$P = P_1 \times P_2 \times P_3 \times P_4 \times P_5 \times P_6$	

(Source: Alexander, 1985)

The ballast water risk assessments completed to date emphasise the fact that confident expressions of introduction risk cannot proceed in the absence of species and site specific information. The species perspective on the suitability of new port environments seems particularly pertinent in this regard. Analysis of environmental similarity between port environments, such as that recently completed by Hilliard and Raaymakers (1997), can provide a hazard profile for international trade. This cannot, however, be translated into a risk assessment without some reference to the biorequirements of the species concerned and the time at which these are met (if at all) in the new port environment. Obviously this necessitates that the scope of the assessment is determined in relation to a pre-defined set of species. This set can be defined in a number of ways, for example the set of species present in a given port, or a set of target pest species. It is perhaps important that this set is kept to a manageable number during the early stages of development of ballast water introduction risk assessments.

Methodologically it is also important that the assessment is able to develop as more data becomes available. Quantitative risk assessment is an iterative process that improves as more empirical evidence is fed into the analysis. Bayes theorem provides a unified statistical framework for updating estimates of uncertainty in light of new information and is already being advocated by many authors for fishery risk assessments. The adoption of the Bayesian statistical paradigm as the methodological core of a ballast water risk assessment is theoretically attractive. The development of such an approach in practice warrants further investigation.

6 CONCLUSIONS AND RECOMMENDATIONS

The purpose of this review has been to provide a comprehensive assessment of the current state of the art as regards ecological risk assessment, in particular as it currently provides for biological stressors. Much of what has traditionally been considered as ecological risk assessment has been solely concerned with chemical pollutants, and indeed the terminology and frameworks which have been developed for the discipline as a whole demonstrate a clear emphasis on chemical stressors. This has undoubtedly caused difficulty as assessors attempt to extend these frameworks to biological pollutants.

As a result of this historical background, very few risk assessments of an explicitly biological nature have been completed within the ecological risk assessment paradigm as commonly understood by most practitioners. This is not to say that biological risk assessments have not been completed, but rather they were not recognised (or certainly not labelled) as such by those undertaking them. As a result this literature review was forced to look outside the realms of what is traditionally considered to be 'ecological risk assessment' in order to find examples of risk assessments for non-indigenous introductions.

The extension of this review outside the realms of the risk assessment paradigm currently being advocated by institutions such as the United States Environmental Protection Agency, has been particularly fruitful. There is a view, currently held by many within the field of ecological risk assessment, that risk assessments for biological stressors cannot be quantitative. But outwith the chemical risk assessment discipline we can point to numerous examples of successfully implemented, quantitative risk assessments, involving biological entities. It may be argued that these assessments do not qualify as ecological risk assessments, but these arguments would surely be semantic.

A number of conclusions can be drawn then, from the current state of the art as regards ecological risk assessment for biological stressors:

1. it is unduly pessimistic to believe that the best that assessments of non-indigenous species introductions can hope to achieve are qualitative expressions of risk. Furthermore such qualitative expressions are unlikely to satisfy the requirements of environmental managers seeking to allocate risk reduction resources in the most cost efficient manner. In particular the implementation of a decision support system for ballast water management strategies, aimed at providing the most cost efficient risk reduction measures, necessarily requires a quantified metric of invasion or establishment likelihood against which the efficacy of alternative management strategies can be gauged. Without such a metric the risk assessment framework is unlikely to serve as any more than a screening tool for invasion hazard;

2. the determination of simple and measurable, at least in principal, endpoints is critical to the successful development of any quantitative risk assessment methodology. Fortunately for ballast water introductions two suitable candidates can be identified in this regard: the likelihood of inoculation into a suitable habitat and the likelihood of establishment. The former is undoubtedly less ambitious than the latter, and for species which *a priori* are considered to be undesirable, could provide a suitable metric for decision makers. Adverse environmental or economic impact is clearly a more desirable metric but this requires the undoubtedly more complex analysis of non-native establishment and effect;

3. systematic hazard identification techniques are currently available that could be applied in order to identify the potential adverse impacts of non-indigenous organisms and assist in taxonomic hazard analysis, particularly with respect to elucidating the plausible but low probability risk scenarios that often characterise alien species introductions. To date the application of these techniques has only been explored in relation to the release of genetically modified organisms and not to non-native species more generally. The similarity between these entities, however, at least from a risk assessment perspective, suggests that these techniques could be successfully extended to identify the hazards associated with non-native introductions;

4. the unified framework currently advocated by the USEPA for ecological risk assessment is difficult to apply to non-indigenous species. An arguably more appropriate framework, which views the risk of introduction as the culmination of a long chain of events, has been applied to import risk analysis for many decades. This framework, together with the Quantitative Risk Assessment paradigm, which emphasises that risk is a function of the frequency and consequences of undesired events, appears to provide a more suitable basis from which to tailor a specific risk assessment framework for ballast water introductions;

5. in the first instance the absence of a comprehensive and centrally collated database regarding species assemblages found under specific ballasting conditions and the frequency of successful establishment, requires that the ballast water risk assessment framework be inductive and model based. The development of such a database is, however, essential if confidence in the results of the framework is to be eventually established. Groundtruthing procedures should therefore form an important part of any ballast water introduction framework;

6. invasion success is a function of both species specific and site specific attributes. Any assessment of invasion risk must therefore adopt a species and site specific perspective and is unlikely to be successful in the absence of detailed information at both the species and site specific levels. The development of bio-rules for the species concerned could provide a means by which a quantitative expression of invasion success is possible. Again the identification of these rules pre-supposes an in depth knowledge of the life-history and bio-requirements of the species concerned. As a result the data requirements for a quantitative assessment for invasion risk will undoubtedly be onerous; and,

7. Bayes theory provides a unified statistical approach that could allow for a coherent and rigorous updating of estimates of ballast water risks as information is gathered. This approach has been adopted within other areas of ecological risk assessment, notably fishery risk assessment, but its application to non-native introductions is yet to be tested.

In light of these conclusions this review makes the following recommendations:

1. a tailor made risk assessment framework for ballast water introductions should be developed in a manner analogous to the import risk assessment framework, but which seeks to emulate the quantitative risk assessment paradigm and employ the hazard identification techniques more commonly associated with this paradigm;

2. the framework should make provision for groundtruthing procedures against which the predictions, or prior distribution assumptions, of the risk assessment can be tested,

modified and strengthened in light of empirical evidence. The Bayesian paradigm should be investigated in this regard with a view to its adoption as the framework's preferred statistical approach;

3. the risk assessment should proceed in a species and site specific manner and seek to develop an in depth understanding the life-history of species *a priori* considered a hazard, expressed through a series of bio-rules for these species; and,

4. a general search for data requirement overlaps with other organisations, both nationally and internationally, should proceed in conjunction with the risk assessment framework to identify means of sharing the data burdens of the assessment framework

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APPENDIX A1: Toxic chemical release inventory risk screening guide

Under section 313 of the 1986 Emergency Planning and Community Right to Know Act, certain businesses within the United States must submit annual reports to the United States Environmental Protection Agency, for certain specified toxic chemicals manufactured, imported, processed or used at the facility (USEPA, 1989). These facilities must account for their total aggregate releases to the environment for each notified chemical. These aggregate data are referred to as the Toxic Chemical Release Inventory (TRI).

The Act requires that releases to air, water, land and in wastes transferred outside of the site are reported, for both routine releases (point and fugitive) and accidental releases. Each year the USEPA receives thousands of toxic chemical release inventory reporting forms. This information must be screened and prioritised. The risk screening guide is intended to serve as a framework for the initial analysis of TRI data. The system uses general risk assessment principles and results in a qualitative (high, medium, low) expression of risk. The assessment provides risk based priorities for follow up investigation of TRI facilities and chemicals within geographic areas of interest. The guide is not used for making final decisions or absolute judgements about the risk associated with a particular facility.

The risk screening procedure has three elements: toxicological potency assessment, exposure evaluation and risk characterisation. During the toxicological potency assessment experimental studies involving test organisms and/or epidemiological studies are reviewed to determine if a chemical can cause health or environmental effects and how these effects are exhibited, and to characterise the dose-response relationship. Ecological effects of concern include toxicity, persistence, bio-accumulation and any other ecologically significant adverse effect, (for example on species growth or survival). Various EPA estimates of toxicological potency are utilised as standard references during this procedure, notably:

1. Reportable Quantities (RQ). A reportable quantity is assigned to a chemical on the basis of intrinsic physical and toxicological properties. There are five levels of RQ, 1, 10, 100, 1,000 and 5,000 pounds. The quantity does not provide a definitive indication of how hazardous a chemical will be at its reportable level but rather indicates the relative potential to cause toxicological effects at a given exposure level;

2. Threshold Planning Quantities. Like reportable quantities, threshold planning quantities are a relative toxicological ranking system but which take into account the tendency of a chemical to become airborne as well as their toxicity; and,

3. Aquatic Water Quality Criteria (AWQC) values. These are the EPA's estimates of the ambient concentration of chemical in surface waters that will not cause adverse effects to aquatic organisms.

The exposure assessment undertaken in the evaluation qualitatively considers the plausible exposure pathways and potential environmental levels of the chemical(s) concerned. These are determined as a function of site-specific data including location of release, characteristics of population of interest (human or ecological), geographic distance to population, physical transport characteristics, and chemical-specific data such as environmental transformation characteristics, quantity of release and rates of release. The requisite data for this type of analysis is collected by requiring facility personnel to complete standardised data sheets for each environmental medium.

The exposure evaluation defines inner and outer zones. Populations within the inner zone are considered to be in a plausible exposure pathway if they are in contact with the medium into which the chemical is released. The outer zones are areas that contain specific populations of interest that are likely to be exposed. The process provides suggested inner zones for each medium (for example 1 mile for air, 4 miles downstream for flowing surface water).

Data from the completed facility worksheets for each medium are used to assess exposure pathways, potential environmental levels and toxicological potency to identify ‘high’, ‘moderate’ or ‘low’ priority risk scenarios. The completion of facility worksheets is assisted by a set of standard forms and guidance notes on completion.

The objective of the risk screening procedure is to identify high priority routes of potential exposure, hazardous facilities, chemical releases and/or data gaps for follow-up activities prior to a more comprehensive risk assessment, if deemed necessary. When assessing the type and extent of follow-up activities, the agency may consider non-risk factors such as legal requirements, the level of public concern, control technologies and economics. For example if a facility is already using best available technology (BAT) it may not be able to reduce release levels further without trade-offs.

APPENDIX A2: Environmental hazard and risk assessment under the United States Toxic Substances Control Act 1976

The United States Toxic Substances Control Act (TSCA) 1976 provides for the regulation of industrial chemicals that are deemed to present an unreasonable risk towards human health or the environment (Nabholz, 1991). The risk assessment framework specified in the act consists of the integration of the hazard assessment for the chemical with an exposure assessment. The results of the risk assessment are *inter alia* used to apply the following regulatory controls:

1. control pending additional testing;

2. direct control; or

3. no control.

The results of the risk assessment as well as economic and relative risk factors (the costs and benefits of the new chemical, the cost of additional testing, the relative hazards as compared to substitutes, etc.) are considering when deciding whether the chemical presents an ‘unreasonable’ risk.

The TSCA makes a clear distinction between new and existing chemicals. Under section 5 of the Act, manufacturers of new chemicals are required to provide a pre-manufacture notice which includes information on the physio-chemical nature of the substance, anticipated production volumes and use, and proper disposal procedures. This information is reviewed by the USEPA and if the chemical is determined to be of low concern, and its anticipated production volume is less than 100,000kg per annum, then it is exempted from the risk assessment requirements of the remainder of the Act. If, however, there is concern over the potential toxicity of the substance, or it has significant anticipated production volume then it passes onto the hazard assessment proper.

The hazard assessment commences by identifying all of the known effects of the chemical towards organisms in the environment. Toxicity data for the chemical generally consist of effective concentrations which indicate the type and severity of effect at various concentrations for specific test organisms. The collection of all of the effective concentrations for a substances is known as its Hazard Profile.

The hazard profile may consist of measured toxicity data or Quantitative Structure Activity Relationships (QSAR’s). For new chemicals the hazard profile will typically be limited to acute fish/invertebrate toxicity and chronic algal toxicity data. For existing chemicals, however, the existing toxicity database is usually much more extensive and the hazard profile is regularly able to specify acute and chronic values for fish, invertebrate, benthic, macro-algal and bacterial species, including information on growth and reproduction effects.

Once the Hazard Profile has been developed a Concern Concentration (CC) is determined. The CC represents that concentration of a substance which if exceeded in the environment may cause a risk. If the CC is not exceeded it is assumed that the environmental risk is too low to warrant regulatory action. CC’s for chronic risk are calculated by applying one of four assessment factors (1, 10, 100, 1000) to the effective concentrations in the hazard profile. The assessment factor is chosen on the basis of the amount and quality of the data available to the hazard profile and reflects the uncertainty associated with that data.

The objective of the environmental exposure assessment is to predict the expected environmental concentrations of the substance due to its production, processing use and disposal. Chemical releases of the substance are estimated from a separate and dedicated engineering analysis which identifies release quantities over the life cycle of the substance. Most of the releases regulated under the TSCA are to streams or rivers, having first undergone some form of waste water treatment. For the purposes of the exposure assessment therefore the daily amount of chemical released after treatment (kgd^{-1}), is instantaneously mixed with the daily amount of water in the stream (ld^{-1}), to give a predicted environmental concentration (PEC) in micrograms per litre. The assessment is conservative in that after mixing with the stream no losses are estimated and a constant PEC is assumed, thereby resulting in a worst case exposure estimate.

Two alternative methods are used during the exposure assessment. The first, the percentile stream flow method, calculates two PEC's, one for low flow and one for mean flow conditions. The second approach, the probability dilution method, predicts how many days per year the CC is exceeded using all the daily streamflows for the whole year.

In this manner up to 18 PEC's may be calculated (10 to 90% percentiles for low and mean flow conditions), and potentially more if releases will occur from multiple sites. Streamflow data used in the exposure assessment are obtained from the United States Geological Survey.

The risk calculation is made on the basis of a single quotient, by comparing the PEC with the CC's in the hazard profile. This comparison allows the nature and extent of the risk to be investigated. For example whilst the PEC may be below the CC for acute toxic effects on fish, it may exceed the CC for chronic effects on fry or algae indicating a potential long term risk at this particular stage of the organism's life cycle. Alternatively the CC may only be exceeded where the PEC is calculated under low flow conditions, etc.

This approach is extended using the probability dilution method in so much that risk can be expressed as the number of days on which a CC is exceeded. For example if an acute 4–day LC_{50} is exceeded on 4 days or more then the risk of acute toxicity (ie. killing >50% of exposed organisms) is indicated. The greater the number of days the CC is exceeded, the greater the risk.

APPENDIX A3: The United Kingdom Department of Environment substance selection scheme

The European Commission Dangerous Substances Directive (76/464/EEC) requires member states to eliminate pollution by List I substances and reduce pollution by List II substances. Since the Directive was adopted the commission has identified 129 potential List I chemicals but as of 1995 only 17 of these had been confirmed in status as List I and regulated accordingly.

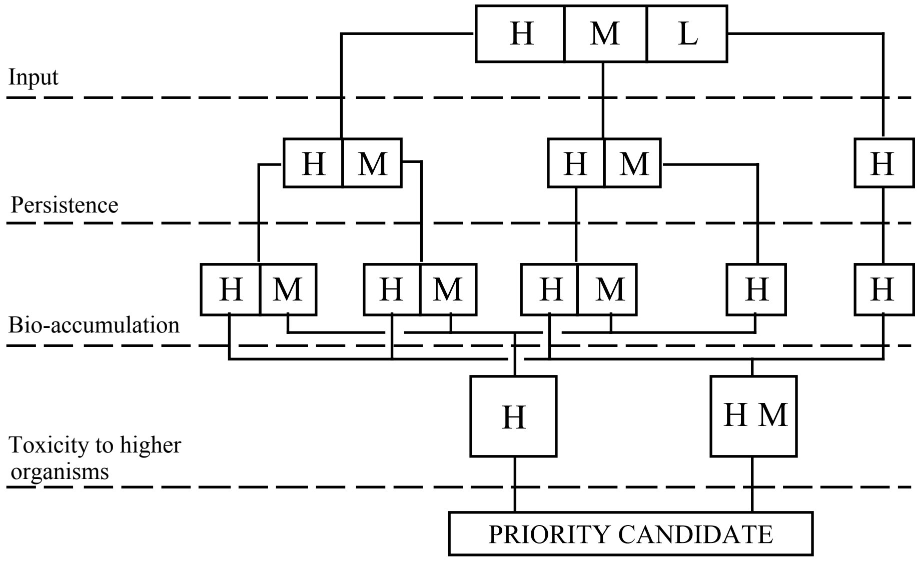
In the absence of systematic and generally accepted criteria for deciding which of the remaining 112 chemicals should be considered as List I substances, the UK Department of Environment has developed a substance selection scheme which provides a set of decision rules to identify those substances that should be considered for priority action. The scheme works on the premise that the combination of the chemical's properties along with its prevalence in the aquatic environment should form the basis of the hazard assessment (Byrne, 1988).

The scheme distinguishes three risk scenarios; the short and long term, and food chain. The short term scenario refers to acute toxic effects whilst the long term refers to chronic effects. Both of these are a function of the release rates into the environment and the substance's persistence. The food chain scenario refers to toxicity problems in higher organisms due to bioaccumulation. The data requirements for the scheme are thus acute and chronic toxicity, persistence, bioaccumulation and concentration potential, and toxicity to higher organisms.

The scheme uses decision trees for each of the risk scenarios described above. The system considers the substance's likely input to the environment together with the relevant criteria for the tree. For example the food chain risk decision tree (Figure A3.1) considers input, persistence, bioaccumulation and toxicity to higher organisms. The chemical is scored as high, medium or low against each criteria, with some branches of the tree leading to a priority candidate selection.

The subdivisions of high, medium and low used in the decision trees for the chemical properties are summarised in Table A3.1. A similar approach is adopted for assigning input rankings based on the annual production of the chemical within the United Kingdom in lieu of accurate environmental exposure predictions.

Substances which are on the border line of being priority action candidates are identified by undertaking a sensitivity analysis in which the results obtained by running the selection scheme utilising slightly different numerical trigger values for toxicity, persistence, etc. are compared. Sensitivity analysis undertaken in this manner by the Department of the Environment for the 129 potential List I substances, varying the numerical triggers by factors of 5 and 10, resulted in a change of status for only 10-15% of the chemicals, suggesting that the scheme is fairly robust (Bryne, 1988).



(Source: Byrne, 1988)

Figure A3.1 The United Kingdom Department of Environment food chain risk decision tree.

Table A3.1 Numerical trigger values for chemical property rankings in the substance selection scheme

	Numerical value				
Propert Y rank	**Acute toxicity (LC_{50} mg/l)**	**Chronic toxicity (EC_{50} mg/l)**	**Persistence half-life (days)**	**Bio-accumulation & concentration factor**	**Toxicity to higher organisms (LD_{50} rat (oral) mg/kg)**
high	≤1.0	≤ 0.01	≥ 100	≥ 1,000	≤ 50
medium	> 1.0 - < 100	> 0.01 - < 1	> 10 - < 100	999 - 101	> 50 - < 500
low	≥ 100	≥ 1	≤ 10	≤ 100	≥ 500

(Source: Byrne, 1988)

APPENDIX A4: EC Commission regulation 1488/94/EEC

Commission regulation 1488/94/EEC (OJ L 161/3 29.07.94), which entered into force on the 29 August 1994, requires that an environmental risk assessment be carried out for each substance appearing on the ‘priority list’ in accordance with regulation 793/93/EEC. Regulation 793/93/EEC deals with the evaluation and control of ‘existing substances’, in other words the tens of thousands of chemicals marketed in the EC before 1981, which were not covered by Directive 79/831/EEC, which requires a similar environmental risk assessment for ‘new substances’[17] (Commission regulation No. 1488/94). The risk assessment requires the following steps be carried out for all three environmental compartments (air, water and soil):

1. hazard identification;
2. dose (concentration) – response (effect) assessment;
3. exposure assessment; and,
4. risk characterisation.

In addition to the three environmental compartments, non compartment specific effects which are relevant to the food chain and the microbiological activity of sewage treatment systems are also considered. On the basis of the risk characterisation results one of the following conclusions are drawn:

1. there is a need for further information and/or testing;
2. there is at present no need for the above and no need for risk reduction measures beyond those already applied; or,
3. there is need for limiting the risks, implementing controls under Council Directive 76/769/EEC.

The risk assessment commences with a hazard identification stage, undertaken on the basis of information required of the manufacturer or importer of the substance. This includes *inter alia* information on the pathways and anticipated environmental fate of the substance, together with acute and chronic ecotoxicity data, and carcinogenity, mutagenity and/or toxic effect on reproduction. The assessor is further empowered to demand more information if that initially supplied by the manufacturer is not sufficient. Ecotoxicity is usually measured in relation to fish, daphnia, algae, bacteria, and terrestrial and soil dwelling organisms, however, less stringent data requirements exist for substances imported or produced in quantities of less than 1000 tonnes per annum.

The assessment proceeds by comparing a predicted environmental concentration (PEC) with a predicted no effect concentration (PNEC). The former are established on the basis of either measured environmental data or model predictions entailing:

[17] Directive 79/831 amended the Dangerous Substances Directive such that member states were required to carry out an environmental risk assessment on new chemical substances. The principles for this risk assessment are stipulated in Directive 93/667/EEC and are essentially identical to those above for existing substances. In particular if the PEC/PNEC ratio is <1 then the substance is deemed of no immediate concern and need not be considered again until such time as the quantities marketed in the EC exceeds 1000 tonnes.

1. analysis of all potential emission sources and identification of maximum release;
2. identification of receiving environmental compartments;
3. estimation of the quantities released to particular environmental compartments and of elimination and dilution processes; and,
4. estimation of the distribution and degradation of the substance as a function of time and space, leading to the calculation of PEC_{local} and $PEC_{regional}$.

PEC_{local} refers to the anticipated concentrations around a particular source, whilst $PEC_{regional}$ refers to the concentrations from point and diffuse sources over the wider region of concern. In this manner the $PEC_{regional}$ takes into account the further distribution and fate of the chemical upon release and also provides a background concentration to be incorporated into the calculation of the PEC_{local}. Media specific PEC_{local} algorithms are specified within the assessment framework in order to estimate the anticipated concentrations of a substance around a particular point source, with the environmental conditions in the area around the source assuming average standard conditions. For example the calculation of the PEC for aquatic media (which also assumes that all chemical substances pass through a waste water treatment plant prior to discharge to the environment) is as follows:

$$PEC_{(local),(aquatic)} = \frac{C_{eff}}{\left(1 + K_{p(susp)} \cdot C_{susp}\right) . D}$$

where: C_{eff} = concentration of the substance in the waste water treatment plant effluent

$K_{p(susp)}$ = suspended matter water adsorption coefficient

C_{susp} = concentration of suspended matter in the water column

D = dilution factor

The calculation of $PEC_{regional}$ is made by multi-media fate models, whereby a chemical released into the model is distributed between the various environmental compartments according to the properties of both the chemical and the model environment. The parameters representing the latter are based on a standardised European regional environment.

Predicted No Effect Concentrations (PNEC's) are calculated by dividing the lowest $L(E)C_{50}$ or No Observed Effect Concentration (NOEC) value for the chemical, with an appropriate assessment factor. The assessment factors applied reflect the degree of uncertainty in extrapolating from laboratory test data on a limited number of species, to the environment and are usually orders of magnitude. Having derived the PEC and PNEC values for each environmental media, a risk characterisation is performed by comparing the ratio of the two in a simple risk quotient. If the risk quotient is less than 1 then the assessment framework requires no further information and/or testing, and stipulates no risk reduction measures. If the ratio is greater than 1, then the assessor is required to decide on the need for further information/testing or risk reduction measures taking into account other relevant factors such as bioaccumulation potential, shape of the toxicity/time curve, mutagenity, etc.

APPENDIX A5: Chemical hazard assessment and risk management (CHARM) model[18]

The Chemical Hazard Assessment and Risk Management (CHARM) model, is a tool to support the environmental evaluation of the use and discharge of drilling and production chemicals on offshore oil and gas platforms (Schobben *et al*, 1994). The model again utilises the risk quotient approach and has been developed in response to agreement within both the Oslo and Paris Commissions, and the third North Sea Ministerial Conference (held in the Hague in 1990), on the need to harmonise the regulation of chemicals used offshore.

The CHARM model entails a four stage risk assessment procedure consisting of:

1. pre-screening;
2. hazard assessment;
3. risk analysis; and
4. risk management.

Prior to the hazard assessment chemicals are pre-screened for persistency and bio-accumulation; properties which are not generally well accounted for in the PEC/NEC approach. Chemicals which exhibit these properties are excluded from the risk assessment process and in principal their use offshore will not be permitted.

The hazard assessment component of the model distinguishes three PEC/NEC quotients:

$$Q_{pelagic} = PEC_{water} / NEC_{aquatic\ biota}$$

$$Q_{benthic} = PEC_{sediment} / NEC_{aquatic\ benthic\ biota}$$

$$Q_{foodchain} = PEC_{biota} / NEC_{birds,\ mammals}$$

The calculation of the predicted environmental concentration is made on the basis of simple algorithms for each group. A number of simplifying assumptions regarding indicative North Sea parameters are made to allow a generic assessment. For example the $PEC_{sediment}$ is calculated as follows:

$$PEC_{sediment} = P_{ow} . f_{oc} . C$$

where: f_{oc} = organic carbon content of sediment, provisionally set at 0.01 representing an average North sea sediment with 1% organic carbon content

P_{ow} = octanol-water partition coefficient

C = equilibrium concentration of chemical in water

[18] The CHARM model is yet to be finalised, the information provided here is taken from the Phase 1 project report

The PEC for water is determined at a short distance from the platform (tentatively 500m), the PEC for sediment and for biota are given for the environmental sphere of a platform in an oil and gas field (tentatively set at 10 km^2).

In this manner the hazard assessment is considered to represent a worst-case scenario concerning the PEC for a ‘standard platform’ in a ‘standard reference environment’. These standard conditions were defined on the basis of a survey of actual North Sea platforms and operating conditions. The technique does, however, allow scope for using site specific environmental parameters if these are available.

No effect concentrations for the model are derived from laboratory measured No Observed Effect Concentration’s (NOEC’s) with assessment factors applied to reflect the quality and quantity of data available to the assessment, and the subsequent uncertainty in extrapolating from the laboratory to the environment. If NOEC information is unavailable the model utilises chronic effective concentrations (EC_{50}) with higher assessment factors.

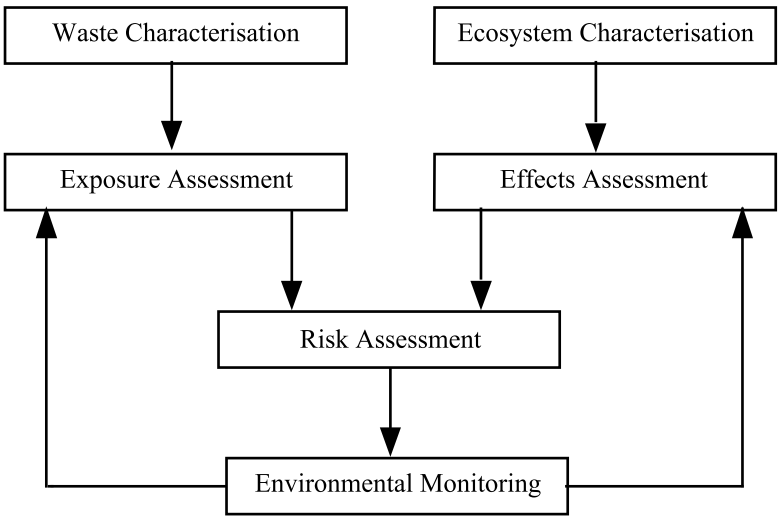
Risk analysis within the CHARM model is simply made on the basis of the Hazard Quotient (the PEC/NEC ratio). The analysis assumes that risks for each of the functional groups (pelagic, benthic and foodchain) are interdependent, the overall risk to the environment is simply defined as the highest Hazard Quotient.

The final component of CHARM considers risk management options and provisions for target setting, comparison of alternative chemicals and cost benefit evaluation related to the use of alternative chemicals or water treatment systems. Risk reduction achieved through either of the latter is plotted against the cost of implementation to define the most cost efficient means to meet targets. For example hazard quotients for each individual chemical used by a platform are added to test the risk reduction associated with a change of water treatment system or the use of alternatives. The costs of these mitigative measures are then plotted against the reduction in the Hazard Quotient to define the most cost efficient solution.

APPENDIX A6: Marine ecological risk assessment at Naval Construction Battalion Centre

Munns *et al* (1991) describe an extremely thorough source driven retrospective risk assessment undertaken at the Naval Construction Battalion Center, located at Allen harbour in Narragansett Bay. In 1984 Allen Harbour was closed to shellfishing due to concerns over possible contamination arising from two adjacent waste disposal sites, Allen harbour landfill and Calf Pasture Point, utilised by the US Navy between 1945 and 1972. The assessment was conducted as part of the remedial investigation required by the Comprehensive Environmental Response, Compensations and Liability Act (CERCLA) 1980.

The risk assessment framework utilised in the study (Figure A6.1) was originally developed by the Environmental Research Laboratory, Narragansett, to investigate the effects of sewage sludge disposal at sea (refer to Appendix D2) being modified slightly for this purpose. In particular since the assessment is retrospective, the emphasis within the model was an *a posteriori* quantification of the effects that have (or have not) occurred as a result of chemicals emanating from the waste disposal sites.



(Source: Munns *et al*, 1991)

Figure A6.1 The ERLN ecological risk assessment framework.

The waste characterisation part of the assessment involved identifying the various chemical substances emanating from the waste disposal sites. This involved taking samples of the water flowing from seeps on the face of the landfill and of the sediments surrounding these seeps. Samples of groundwater from test wells and a single test pit were also utilised in this context. This data was grouped with further information regarding the materials that had been disposed of at the sites in order to identify the variety and quantities of pollutants that might be transported into Allen harbour and nearby Narragansett Bay.

The exposure assessment determined the spatial distribution of contaminants in the harbour and the bay through extensive field sampling; samples of inter-tidal and sub-tidal sediment within

Allen harbour were collected, together with sediment samples from several stations within the Bay. Water column samples were also taken from within and outside the harbour for chemical and bacterial analysis. Finally native bivalves, including quahogs (*Mercenaria, mercenaria*), soft shell clams (*Mya arenaria*), oysters (*Crassostrea virginica*) and an infaunal polychaete (*Nephtys incisa*) were collected from the harbour and analysed for contaminant residues in their body tissues. These organisms exhibit a range of ecological lifestyles and therefore provided information on a number of different exposure pathways.

The ecological effects of contaminants within the harbour were investigated in three ways:

1. native bivalves were sampled *in situ* to assess population abundance, individual condition and histopathological effects;
2. cages containing the blue mussel *Mytilus edulis*, were deployed within the harbour and at control stations to assess the affects of water quality on physiological condition and growth, using the Scope For Growth (SFG) approach; and,
3. the toxicity of the sediment and water samples collected from the harbour and Narragansett Bay were investigated using three types of laboratory toxicity tests – acute toxicity to the amphipod *Amplesica abdita*, sea urchin fertilisation and development, and biomarker tests.

The results of the assessment did not indicate any environmental problems which were unique to Allen harbour and thus clearly attributable to the proximity of the waste disposal sites. The most prominent ecological problems were associated with water quality, with the mussels deployed in the harbour consistently exhibiting reduced physiological condition relative to those exposed at other stations within Narragansett Bay. This, however, could reflect the effects of the boating activity in the harbour.

The sediment samples collected from the harbour were not acutely toxic to *Ampelisca*, but did have an adverse effect on the early life stage processes of the sea urchins and the biomarkers. The interpretation of these results was further confounded by the general lack of effects at higher levels of biological organisation; the study did not observe any significant difference between the health of bivalve populations in the harbour and those in the Bay.

In this context it is interesting to note that study also utilised the results of the pollutant field measurements to quantify environmental risk using the toxicity quotient approach. Two relatively conservative sediment benchmarks were employed in the analysis, the first representing the lower 10 percentile of all concentrations of an individual contaminant observed over a range of studies to cause a biological effect, and the second representing the level of individual chemicals above which statistically significant biological effects are always expected to occur (this statistic was derived from extensive field surveys in the Puget Sound, Washington region). The water column benchmark used was the USEPA's chronic Water Quality Criteria for marine waters (although few of the contaminants detected within the harbour have specified marine criteria).

The results of this approach were very sensitive to the choice of benchmark. In this context the study notes that the first benchmark statistic did not account for factors which mitigated the responses of ecological systems to particular contaminants and thus the second (field observed) benchmark was more appropriate. On this basis, and using mean environmental concentrations in the numerator of the quotient, the assessment concluded that there was a moderate degree of risk (quotient values between 0.1 and 0.9) to benthic communities from the pesticides, poly chlorinated biphenyls (PCB's) poly aromatic hydrocarbons, and selected metal contaminants detected in the harbour. By contrast, based on the small number of appropriate WQC available to the analysis, the risks associated with water column contaminants was minimal – clearly not in accordance with the *Mytilus* SFG results. Again, in both instances, there was no clear association between this risk and the navy waste disposal sites.

APPENDIX A7: Ecological risk assessment case study: impacts to aquatic receptors at a former mining site

Another good example of a source driven, retrospective risk assessment is provided by Hattemer-Frey *et al* (1995). The assessment was undertaken as part of a baseline risk assessment for remedial investigation of a former metals mining site in Kansas, United States, again pursuant to CERCLA requirements. The purpose of the assessment was to investigate the community and population level effects on fish occupying streams and ponds on the site that were exposed to lead and zinc mining related contamination. The assessment utilises fish species as a sentinel for the wider aquatic environments on the site and only uses surface water information, arguing that adverse effects on invertebrates or periphyton, the prey base for such fish, would be recognisable at this higher tropic level.

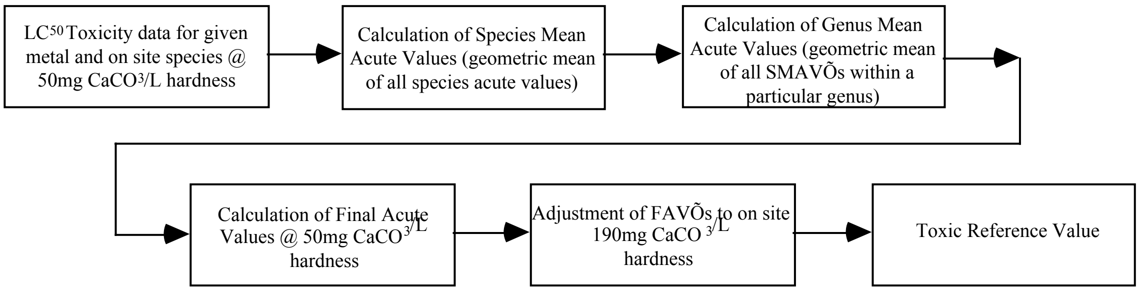
Ecological effects at the former mining site were assessed using three complimentary approaches:

1. toxicity quotient approach in which measured concentrations of metals in the site's surface waters were compared to Ambient Water Quality Criteria (AWQC) derived specifically for the site;
2. a semi-quantitative comparative biological survey of the site; and,
3. a qualitative consideration of other factors that may affect the bio-availability and toxicity of site related metals.

The assessment commenced with surface water and biota (wholebody fish) sampling at the site and stream habitat assessments (in accordance with EPA rapid bio-assessment protocols), undertaken over the period of one year. All samples were taken under low flow conditions on the understanding that pollutant concentrations within surface water bodies would be at their highest under these conditions. Stream segments were also evaluated to assess fish community composition and health as measured by species diversity, size or age class distribution, and condition factors. The preliminary analysis suggested that whilst the overall quality of the stream habitats was rated poor to fair, the condition factor for species occupying these habitats was generally good.

Metals detected in the on-site streams were classified as Chemicals of Potential Concern (COPC's) if the mean concentration of the metal in question was significantly greater (at the 95% confidence level) than the mean concentration in off-site baseline waters unaffected by mining contaminants, as determined by a one tailed student's t-test. Baseline data for ponds was not available and thus all metals detected in the on-site ponds were classified as COPC's. The metal pollutants classified in this manner included cadmium, lead, zinc, mercury, and nickel.

Toxicity quotients for these metals were derived by comparing Exposure Concentrations (EC's) in the water bodies to site specific AWQC's. These site specific reference values were utilised in favour of federal or state values to reflect the relatively hard water at the site (increasing water hardness decreases the toxicity of most metals) and to properly reflect the response of species found at the site, rather then the response of other more sensitive species used in the state wide reference value. The manner in which the site specific AWQC's were derived is summarised in Figure A7.1. Only toxicological data for warm water species potentially occurring in intermittent streams of south-eastern Kansas was used in the derivation of Species and Genus Mean Acute Values (GMAV's).



(Source: Hattemer-Frey *et al*, 1995)

Figure A7.1 Site specific toxicity reference value calculations for a former metals mining site risk assessment

The assessment used the four lowest GMAV's (representing the most sensitive genera) to calculate the site specific Final Acute Value (FAV). These were subsequently adjusted for water hardness using standard techniques, with the exception of the FAV for mercury (because water hardness has no influence on the toxicity of mercury). The FAV was adjusted to a Final Chronic Value (FCV) by dividing the FAV by its geometric mean acute-to-chronic ratio. The latter are provided as a standard tool by the United States Environmental Protection Agency for given metals for species for which both acute and chronic test data are available. (An alternative approach was used for cadmium due to very wide bounds in the acute-to-chronic ratio of different species – 0.9 for chinook salmon, 434 for flagfish).

The resulting toxicity quotients for zinc and cadmium were consistently greater than 1 in most of the surface water bodies sampled at the site, suggesting that exposure to cadmium and zinc was likely to cause both chronic and adverse effects in fish populations at the site. The authors note, however, that a toxicity quotient greater than 1 does not necessarily mean that exposure to metal levels in the site's surface waters is significant enough to cause population effects. Indeed the results of the toxicological analysis largely disagreed with the results of the biological site survey which observed a variety of good condition fish species in naturally reproducing populations on the site. In discussion, the authors highlight a number of factors which may account for the inconsistency between observational field data and the laboratory toxicity quotients, including:

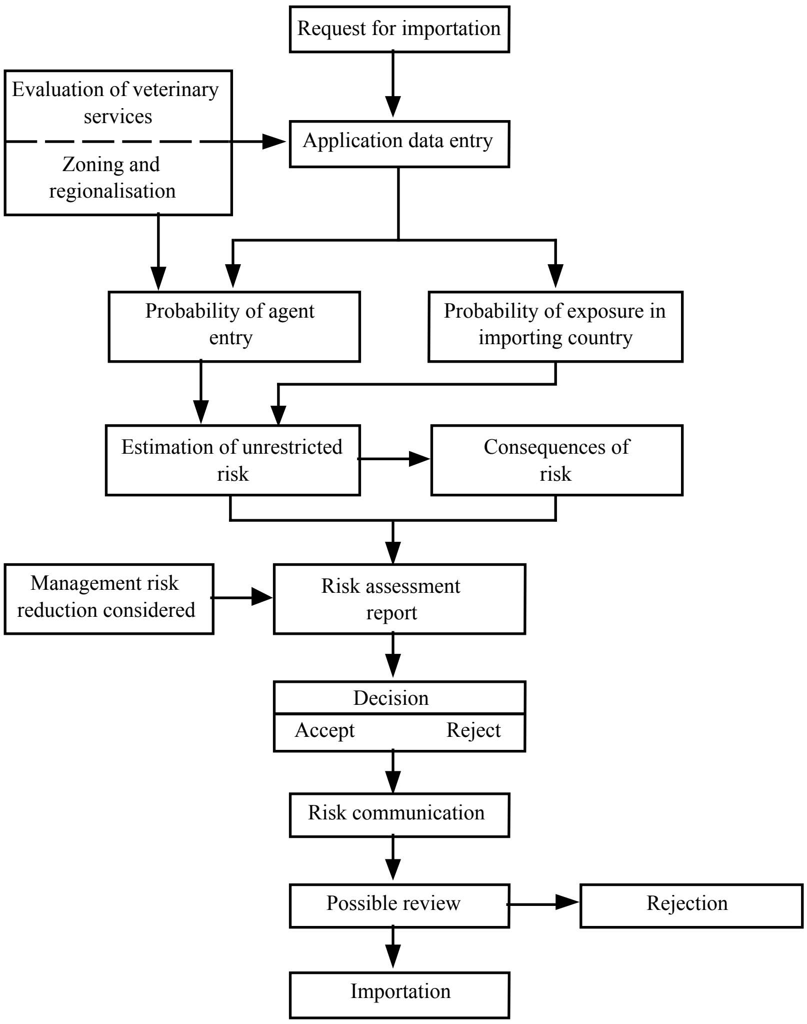
- metal speciation;
- high alkalinity and hardness;
- acclimatisation to elevated metals in the environment; and,
- evolutionary tolerance.

The latter mitigating factors were deemed particularly significant in light of evidence gathered in the field survey that suggested that certain biota which are known to be relatively sensitive to cadmium and zinc, and which could reasonably have been expected to occur in the surface waters of the site, were absent.

APPENDIX B1: International Animal Health Code – import risk analysis

The stated aim of the OIE's risk analysis framework (OIE, 1996) is to provide importing countries with an objective and defensible method of assessing the disease risks associated with animal and animal product imports, and thereby provide exporting countries clear reasons for any subsequent import restrictions.

The framework advocated by the OIE forms section 1.4 of the International Animal Health Code; mammals, birds and bees, and is illustrated in Figure B1.1 below. The framework is generic and individual countries are required to design and adopt their own methodologies based around it.



(Source: OIE, 1996)

Figure B1.1 The OIE's import risk analysis process

The unrestricted risk estimate refers to the risk associated with the importation of the commodity in its usual form (ie in the absence of the implementation of any import risk management measures). The unrestricted risk estimate is considered the product of two probabilities; the probability of agent entry and the probability of exposure of susceptible species in the importing country. The former represents the probability that at least one animal import unit is infected with the agent of concern. Therefore, due to the multiplicity of disease agents that may be associated with the import commodity, it may be necessary to carry out multiple risk estimates for each disease potentially associated with the animal product.

The quantitative risk algorithm advocated by the OIE can be summarised as follows:

Unrestricted risk estimate = P(agent entry) x P(exposure in the importing country)

P(agent entry) = 1 - (1 - country factor x commodity factor)$^{\text{No. of animal import units}}$

The country factor is an estimate of the prevalence of the disease in the exporting country and for List A diseases (and some List B diseases), is a function of the number of outbreaks that have occurred in the exporting country in the last 12 months, the average herd size, the average duration of the disease and the number of animals in the population (refer to Appendix B2 for further details). For the majority of List B diseases, for which quantitative outbreak data is usually unavailable, a prevalence is simply assigned to the disease on the basis of its reported occurrence in the country (exceptional, low sporadic, enzootic or high).

The commodity factor is an estimate of the probability of the agent of concern being in the commodity at the time of import or, where diagnostic testing is applied to the commodity prior to import, the probability that a disease agent is present given a negative test result. The commodity factor is a function of the species represented by the animal import unit, the survival rate of the agent concerned, the sensitivity of any diagnostic test and the effects of any associated processing procedures on the viability of the disease agent (again refer to Appendix B2 for further details).

With the exception of embryos, ovum or semen, the number of animal import units simply represents the expected number of animals that have contributed to each kilogram of the total importation. Because of the their intended use, embryos and semen units are considered as one animal import unit.

The probability of exposure in the importing country is intended to represent the likelihood that a diseased commodity is exposed to animal or human populations within the importing country, coupled with the likelihood of agent transmission, infection and subsequent manifestation of the disease. The probability of exposure is clearly influenced by a wide range of factors including the intended use of the commodity, intermediate hosts and vectors, transmission mode of the disease and the animal and human demographic characteristics in the importing country. The risk assessment framework advocates that importing states should identify the chain of events required in order for exposure to occur. In undertaking this, the assessment should identify the most likely exposure and transmission scenario and estimate each event probability accordingly. By using the most likely exposure route the assessment is considered to identify the highest unrestricted risk estimate and therefore need not elaborate any other possible exposure scenarios.

The health code goes on to consider a number of related topics including risk management and zoning and regionalisation in exporting countries. The latter is of particular relevance to the assessment framework in so much that is allows for the designation of disease free zones, surveillance zones, buffer zones and infected zones within exporting nations.

APPENDIX B2: A model for the assessment of the animal disease risks associated with the importation of animals and animal products

The generic risk assessment framework advocated by the Office International des Epizooties provides little in the way of quantitative details, and indeed leaves individual exporting nations to develop their own risk assessment models around the framework. A more detailed exposition of the way in which each of the elements of the OIE framework may actually be computed is provided by Morley (1993), who provides a standardised format for animal health risk assessment together with a number of important data items for the component parts of the assessment.

The basic OIE risk assessment algorithm remains unchanged:

$$URE = (PAE) \times (PDE)$$
$$PAE = 1 - (1 - CF1 \times CF2)^{nAIU's}$$

where: URE = unrestricted risk estimate

PAE = probability of agent entry

PDE = probability of domestic exposure

CF1 = country factor

CF2 = commodity factor

AIU = animal import units.

For List A diseases (which have compulsory outbreak notification requirements) the risk assessment model proceeds in the following manner. The prevalence of disease in the exporting country (CF1) is determined as a product of the number of reported outbreaks in the previous 12 months (as notified in the OIE publication *World Animal Health)*, the average herd size and the average duration of infection over the denominator of the number of animals in the nation's population.

The average herd size is estimated by dividing the appropriate livestock population in the nation by the number of herds, both of which are reported annually to the OIE and listed in *World Animal Health*. The average duration of infection (ADI) is estimated in the following manner:

$$ADI = \left[(IP + DC) \times (CFR)\right] + \left[(IP + DC) \times (1 - CFR) \times (1 - LIS)\right] + \left[(LP) \times (LIS)\right]$$

where: IP = the duration of the incubation period

DC = duration of the disease course over all forms

CFR = the case fatality rate

LIS = the proportion of surviving animals which become latently infected

LP = the duration of latent infection.

The author notes that each of these parameters should properly be described by a probability distribution and suggests the use of the uniform distribution, thereby requiring maximum and minimum values estimates for each parameter. Point estimates are used in the absence of this information. The paper then goes on to supply the ADI for a number of animal diseases.

For List B diseases the assessment of the country factor is much more difficult because these disease are not generally notifiable under OIE regulations and thus in the majority of cases only a nominal measure of prevalence within exporting states is available. In the absence of a formalised reporting procedure, the assessment generates a single numerical measure of prevalence, which is correlated to the OIE's reported disease occurrence using scientific abstracts related to disease outbreaks published in *Animal Disease Occurrence* (an annual annotated bibliography of the Centre for Agriculture and Biosciences International). The author provides a number of decision rules for the selection of abstracts, primarily requiring the abstract to contain prevalence information from studies involving the test of at least 100 animals. This information is used to generate values for the low and high assignations. Points between these two values (quartiles) are then correlated to low sporadic and enzootic. Again the paper provides reference values for a number of animal diseases.

The commodity factor (CF2) is an estimate of the probability of the agent being present at the time of importation. Clearly this is dependant on a number of factors such as the age of the animal, the species, the epidemiology of the disease, the product processing and so forth. Unlike the country factor, however, no general algorithm is available for the commodity factor (this is perhaps unsurprising given its species and agent specific nature). In this respect the assessment requires that the assessor place a value on the commodity factor in light of any relevant information in the literature concerning transmission and agent survival. For example the author suggests that where processing of a product effectively eliminates the disease agent, an extremely small probability value, such as 1×10^{-8} should be used. Alternatively where there is little influence on the disease agent a conservative value of 1.0 can be used.

Similar difficulties are encountered with estimating the probability of domestic exposure (PDE) which represents the likelihood that a diseased commodity is exposed to animals or humans in the importing country and that agent transmission, infection and disease occur. The author notes that with the importation of live animals the PDE is usually considered as absolute (1.00), whilst for processed animal products and diseases which require direct transmission, or transmission by vectors, the PDE approaches zero. Again the assessment framework requires the assessor to consider all the potential transmission modes and make a best estimate on the basis of all relevant information.

The framework does, however, allow for an alternative deductive approach to estimating the PDE, on the basis of historical importation statistics and recorded outbreaks of disease in human or animal populations. For example if no incidence of trichenellosis (a human disease associated with contaminated pork consumption) was reported in a nation, in a given year, that had imported 4 million pork AIU's (equivalent to 20 million frozen carcasses) that year, of which approximately 160,000 were infected with trichenellosis (based on an enzootic prevalence correlation of 4×10^{-2}), then the mean frequency of exposure can be estimated using the mean of the beta distribution:

$$\mu = \frac{x+1}{n+2}$$

where: x = number of reported disease incidents = 0

n = number of infected AIU's = 160,000

In this manner the mean frequency of exposure is estimated as 6.3×10^{-6} per annum.

APPENDIX B3: Risk of introducing anthrax by importing green hides

MacDiarmid (1993) provides a number of examples of quantitative assessments of the risk of transmitting diseases with imports of animals and animal products from states where the disease in question is prevalent, to states where the disease is not. The examples are typical import risk assessment procedures whereby the risk analysis views the transmission of infectious agents through imports as the climatic conclusion to a complex sequence of events (Kellar, 1993).

The particular example illustrated below assesses the risk of introducing anthrax to New Zealand through the importation of green hides from Australia, and is based on a similar methodology originally developed in Australia to assess the risk of introducing transmissible gastroenteritis of swine in pig meat (MacDiarmid, 1993).

The annual probability of anthrax introduction via the medium of unprocessed hides is a function of the total number of hides imported annually, the probability (p) that a hide contains anthrax spores and the number of occasions (n) on which susceptible animals, in the importing state, are exposed to contact with those spores.

The risk assessment proceeds in the following manner:

$$p = i.s.e$$

where: i = the probability that an Australian animal was infected with anthrax at the time of slaughter

s = the proportion of spores surviving pre-export handling

e = the proportion of green Australian hides among all raw stock processed in New Zealand

Values for these variables are assigned on the basis of empirical evidence and/or simple subjective estimates. For example the average number of officially confirmed cases of anthrax in Australia between 1970 and 1981 was 19 per year, the maximum expected incidence was calculated at 40 cases per year, whilst total slaughtering of cattle and sheep over the period 1989-1990 were approximately 40.23 million. The value of i was therefore estimated at $40/(40.23 \times 10^6) = 9.94 \times 10^{-7}$.

The pre-export survival rate of anthrax spores is estimated to be 0.9 (the spores are considered extremely resistant to adverse environmental conditions), whilst the proportion of Australian green hides among all the skins processed in New Zealand is estimated to be 0.068 (920,000 Australian hides imported on average each year compared to an average total of 13.5 million hides processed annually in new Zealand).

Therefore p is estimated as:

$$0.068 \times 0.9 \times 9.94 \times 10^{-7} = 6.1 \times 10^{-8}$$

The number of occasions per year on which susceptible animals are exposed to contact with anthrax spores is calculated as follows:

$$n = g.t.v.f$$

where: g = the number of officially approved tanneries in New Zealand (23)

t = the proportion of g operating with a risk of contaminating pasture by waste water during flood periods (0.2)

v = the average number of days per year on which flooding occurs on pastures downstream of tanneries (25)

f = the probability of processing contaminated material during flood periods (0.11)

Therefore n is estimated as:

$$23 \times 0.2 \times 25 \times 0.11 = 12.65$$

No allowance is made for the probability of livestock encountering anthrax spores on contaminated pasture (assumed to be 1.0), and thus the probability of introducing anthrax in any one year is:

$$T = p.n = 12.65 \times 6.1 \times 10^{-8} = 7.72 \times 10^{-7}.$$

(Note; the number of occasions on which contact with spores causes infection actually follows a binomial distribution such that the chance of at least one infection is given by $T = 1 - (1 - p)^n$, but when T is small this approximates to $T = p.n$)

APPENDIX B4: The risk of introducing exotic diseases of fish into New Zealand through the importation of ocean-caught Pacific salmon from Canada

This assessment, MacDiarmid (1994), was undertaken to assess the risk of salmonid disease introduction to New Zealand, accompanying the import of eviscerated frozen fillets of wild, ocean caught Pacific salmon from Canada, and is again typical of the risk assessment approach adopted for import risk analysis. The assessment commences with a qualitative review of salmonid disease, concluding that of the 22 diseases most commonly associated with Pacific salmon, furunculosis (a septicaemic disease caused by the bacterium *Aeromonas salmonicida)* is the most likely disease to be associated with the import product (due to the possible intramuscular location of the causative agent) and is therefore the most appropriate sentinel disease organisms with which to conduct a quantitative risk assessment.

The quantitative risk assessment is again based on the premise that the import risk is the culmination of a long chain of events starting with the incidence of the disease in the Pacific ocean stock, and ending with the likelihood of diseased scraps of product (or commodities associated with that) entering suitable environments and infecting local salmonid stocks. The approach is largely empirical but differs significantly from that adopted in B3 in that triangular distributions are fitted to each of the variables in the import chain, allowing for some expression of uncertainty in the final risk estimate. Monte Carlo (Latin Hypercube) sampling of values within each of these distributions, for 5000 iterations of the model, allows the calculation of the cumulative probability of infection to be addressed.

Table B4.1 illustrates the manner in which the number of diseased fish imported per tonne of product (D) is estimated, together with the values of the triangular distribution indexing parameters fitted to each of the assessment variables.

The indexing values utilised for each of the variables above are established on the basis of empirical evidence, where available, and qualitative estimates where not. For example, sea surveys of 600 wild Pacific salmon by the Canadian Department of Fisheries and Oceans did not detect *A. salmonicida*, suggesting 99% confidence limits for prevalence of 0.00 to 0.88%. Similar surveys of 19,000 spawning fish, however, reported furunculosis legions in 0.047% of the fish examined. The author notes that the extreme stress imposed on the fish during fresh water migration and spawning results in the recrudescence of any latent infection, and spread of infection amongst crowded stressed individuals. This latter figure is thus considered an over-estimate of the actual prevalence of furunculosis in Pacific salmon at sea (indeed no incidents of this disease has been reported in the fish caught at sea), and the index values for the triangular distribution were allocated accordingly. By contrast little in the way of empirical evidence is available for the efficacy of washing (R4) as a risk reduction agent. Under these circumstances the author simply postulates a conservative underestimate of the maximum risk reduction factor (30%).

The assessment then goes on to consider the likelihood of *A. salmonicida* associated with these contaminated imports entering local environments and infecting local salmonid populations with furunculosis. Three possible pathways are identified for *A. salmonicida* entry into local salmonid environments; poor disposal of fillet scraps, kitchen waste water and poor disposal fillet wrapping paper. Table B4.2 summarises the approach adopted for scraps contaminating freshwater.

Table B4.1 Input variables and algorithm used to estimate probability of importing *A. salmonicida* contaminated salmon product.

	Triangular distribution parameters		
	Minimum	Most likely	Maximum
Proportion of diseased fish in stock (P)	0.00*	0.02	0.06
Evisceration of fish reduces risk to (R2)	(1– 0.80)*	(1– 0.95)	(1– 0.99)
Inspection & grading reduces risk to (R3)	(1– 0.10)*	(1– 0.50)	(1– 0.70)
Washing reduces risk to (R4)	(1– 0.00)	(1– 0.05)	(1– 0.30)
Mean weight of ocean caught salmon in kg (K)	1.50	2.50	5.00
Proportion remaining after evisceration (F)	0.65	0.71	0.73
No. fish represented/tonne (N)	N = 1000/(F x K)		
No. of diseased fish/tonne	P x N		
No. of diseased fish imported (D)	D = P x N x R2 x R3 x R4		
Results (after 5000 iterations of model)	8×10^{-5}	0.6	4.5

(Source: MacDiarmid, 1994)

* An increase in prevalence of infection leads to an increase in likelihood of clinical disease, this in turn was considered to lead to a higher probability that infected fish will be rejected during initial processing. The model allows for this dependency between variables P and R3 by increasing R3 as P increases by a factor of 0.4. Similarly increasing prevalence was considered to reduce the efficacy of evisceration as a risk reducing measure, thus the model decreases R2 by a factor of 0.4 as P increases.

Again the assessment variables are estimated on the basis of empirical evidence where available. For example, disposal proportions P2 and P3 are based on the results of a survey conducted by the New Zealand Ministry of Agriculture and Fisheries (MAF), into the way households dispose of fruit wastes. Where there is no empirical basis upon which to base these values, for example the probability of infecting a water body, then conservative estimates are employed. The analysis is undertaken for fresh, estuarine and salt water environments for all three regions of New Zealand, and concludes that the expected probability of scraps serving as the vehicle by which *A. salmonicida* is introduced into a susceptible salmonid is 1.7×10^{-10}, rising to a maximum of 3.5×10^{-9}.

Table B4.2 Input variables and algorithm used to estimate probability of scraps introducing furunculosis to freshwater

	Triangular distribution parameters		
	Minimum	Most likely	Maximum
Proportion disposed of as uncooked scraps (P1)	0.1	0.17	0.34
Proportion not incinerated (P2)	0.95	0.98	1.0
Proportion not buried (P3)	1×10^{-4}	0.001	0.005
Contaminate freshwater? (R6)	0.001	0.01	0.05
Proportion of fishery in region 1* (Sp)r1	0.25	0.25	0.25
Infect susceptible host when present? (R7)	1×10^{-5}	1×10^{-4}	0.01
Infect susceptible host in region 1*	(Sp x R7)r1		
Infection introduced into freshwater, (S1)r1	(S1) = (D x P1 x P2 x P3 x R6 x R7 x Sp)r1		

(Source: MacDiarmid, 1994)

* Unlike the example provided in B3, this assessment makes some allowance for the spatial distribution of risk in the importing nation. New Zealand is divided into three regions. The volume of salmon imports into each of these regions is assumed to be proportional to the human population. Similar estimates are made for the proportion of the total salmonid (farmed and wild) population in each of these regions. In this manner the author notes that there are virtually no salmonid fisheries in the region with the highest human population (ie the region consuming the greatest amount of imported salmon products), underlining the fact that the import risk is spatially distributed.

APPENDIX B5: FAO guidelines for pest risk analysis

Part 1 of the International Standards for Phytosanitary Measures (FAO, 1996), drawn up in compliance with the International Plant Protection Convention (IPPC) 1951, describes the process of risk analysis for plant pests for the purpose of assisting National Plant Protection Organisations prepare phytosanitary regulations.

The Pest Risk Analysis (PRA) consists of three stages; initiation, assessment and management. The initiation of a PRA is triggered either by the identification of a new pathway, usually an imported commodity, that may allow the introduction of a plant pest, or by the identification of a new pest. The latter may occur in a number of ways, for example where a species is intercepted for the first time in an imported commodity or where a species is reported as being more damaging than previously thought in an area other than its native range. If the initiation is triggered by the identification of a new pathway then the assessment requires that potential pest species, which are likely to be associated with that pathway, are listed and then subjected to the second assessment stage.

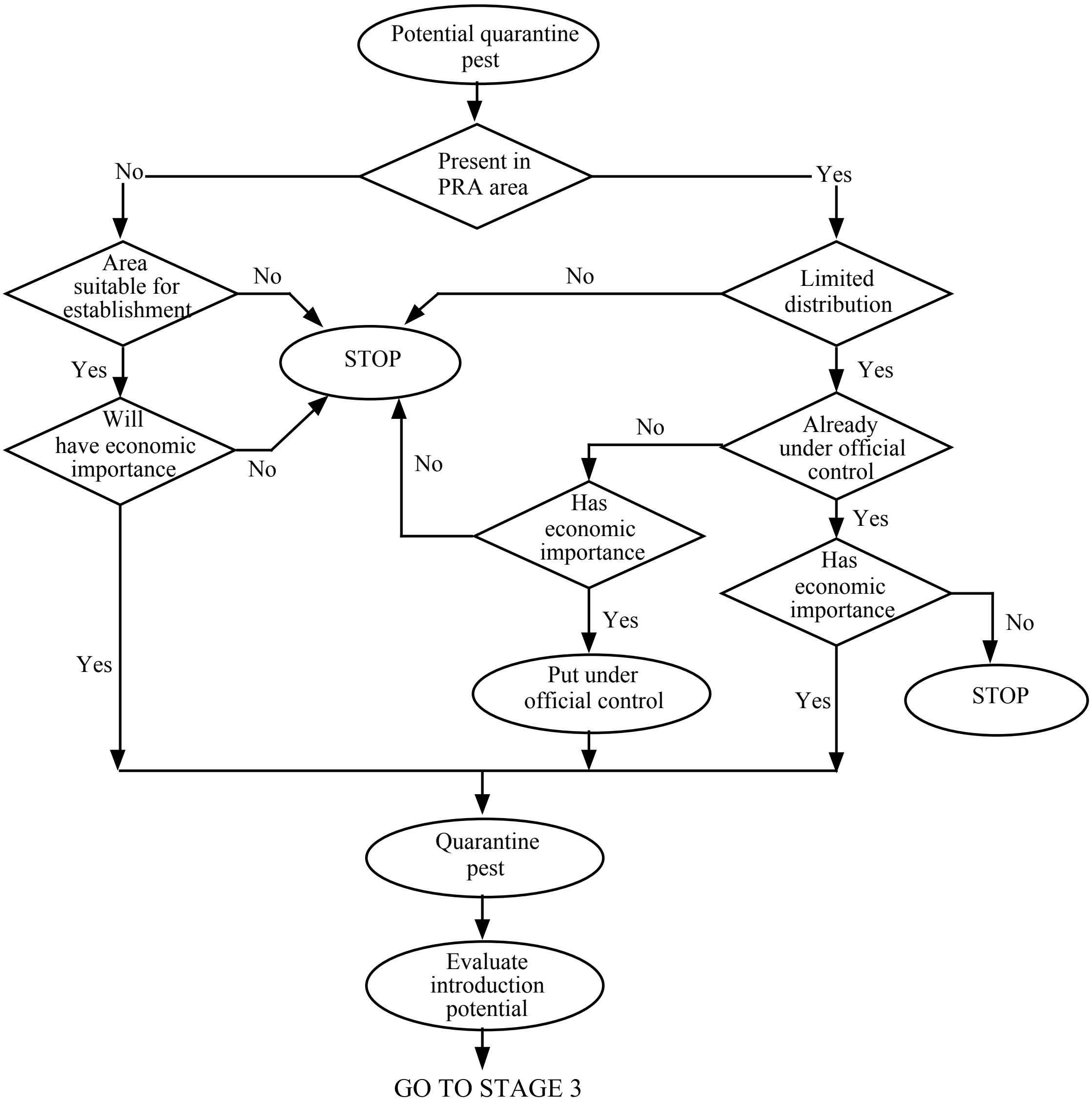
Stage 2 of the assessment considers each species short listed for assessment, and examines, for each, whether the criteria for quarantine pest status are satisfied; namely that the species is not already present, or not widely distributed, in the area of concern (the PRA area), is not currently controlled, and has the potential for establishment and subsequent adverse economic impact, (refer to figure B5.1).

In undertaking the assessment the PRA is to consider all aspects of each pest individually and in particular gather information about its geographical distribution, biology and potential economic impacts in the receiving environment. The framework then advocates that expert judgement be used to assess the establishment, spread and economic importance potential of the species concerned. The final stage of the assessment considers the introduction potential of the pest, which is a function of the pathway concerned, and the frequency and quantity of pests associated with that.

If the pest satisfies the assessment criteria, and is thereby categorised as a quarantine pest, the assessor is required to review the information collated during the assessment stage and decide whether the pest has sufficient economic importance and introduction potential (ie sufficient risk) for phytosanitary measures to be justified. If so the assessment proceeds to the third and final stage (risk management), if not the PRA stops at this point.

The framework requires that pest risk management options implemented to protect the PRA area should be proportional to the risk identified in stage 2, and should be applied to the minimum area necessary for effective protection. Possible management options suggested include:

1. inclusion in a list of prohibited pests;
2. phytosanitary inspection and certification prior to export;
3. inspection and/or treatment at entry;
4. definition of requirements to be satisfied before export; and
5. prohibition of entry of specific commodities from specific origins.



(Source: FAO, 1996)

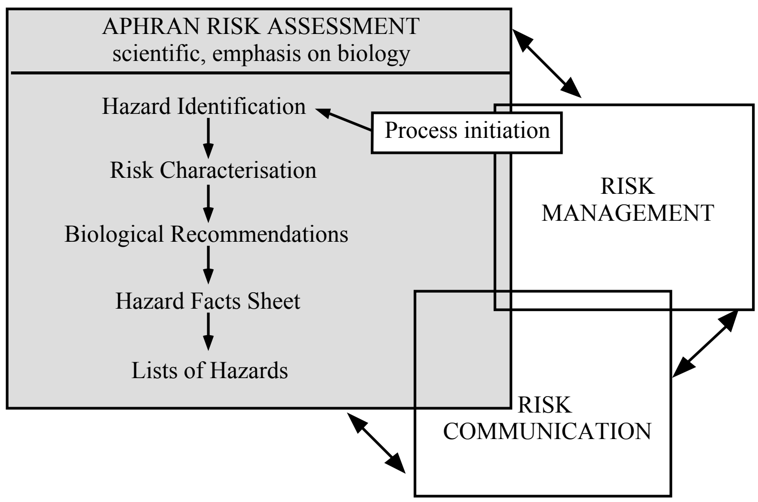
Figure B5.1 The FAO's plant pest risk assessment framework

In all instances, however, the framework requires that phytosanitary measures be implemented with the 'minimum impediment' to the international movement of commodities, in accordance with Article VI.2(f) of the International Plant Protection Convention, 1951.

The detailed implementation of the framework and assessment of pest risk is left to the discretion of individual nation states. The reader is referred to appendix B8 for an example of the manner in which the framework is implemented for controlling plant imports in to Australia.

APPENDIX B6 Risk assessment models of the animal and plant health risk assessment network

A general model[19] for animal and plant risk assessment, as used by the Animal and Plant Health Risk Assessment Network (APHRAN), a research branch of the Canadian Animal and Plant Health Directorate, is described in Agriculture & Agri-Food Canada (1994). This risk assessment model agrees generally with those of the FAO and the OIE described above. A schematic diagram of the general risk assessment model is shown in Figure B6.1 below.



(Source: Agriculture & Agri-Food Canada, 1994)

Figure B6.1 APHRAN general risk assessment model

The risk assessment process commences when a request is made to conduct a risk analysis for a specific hazard (new pest or pathogen) or a new commodity. Such requests are accompanied by a commodity profile and a preliminary risk profile, which simply serve as a mechanism to collate initial information. The latter in particular provides details of the values that are placed at risk, the persons who are the primary producers and beneficiaries of the risk, and those whose interests are placed at risk (the risk bearers).

Hazards (plant pests, animal pathogens or food-borne pathogens) associated with the commodity are identified but only those that have a potentially significant negative impact on human, plant or animal health, are not present or widely distributed, or subject to official control in Canada, are carried through to the next stages of the assessment.

The risk characterisation stage consists of assessing the probability of hazard establishment and the potential impact of the hazard. The former is expressed as a function of the likelihood of the hazard's entry into Canada, the availability of suitable habitats and susceptible hosts, and the subsequent potential for spread. The potential impact of the hazard is expressed as a function of

[19] Specific models for plant and animal health risk assessment, and food safety risk assessment are available. These are identical to the general model described except in wording.

its effect upon the health of its host, its anticipated economic impact and its potential environmental impact.

The assessment methodology advocates the use of detailed quantitative mathematical models to estimate the probability of Canada experiencing the adverse effects of a specific pest introduction. The framework acknowledges, however, that in most instances the requisite data for a quantitative analysis will be unavailable and requires, as a minimum, that each of the impact elements above are qualitatively rated as high, medium, low or negligible, and provides specific definitions for each of these. For example for plant pests the follows definitions of environmental impact are utilised:

Rating = negligible: there is no potential to degrade the environment or otherwise alter ecosystems by affecting species composition or reducing longevity or competitiveness of wild hosts.

Rating = low: there is limited potential impact on environment, slightly reducing wild host longevity, competitiveness, recreation or aesthetics.

Rating = medium: there is potential to cause moderate environmental impact with change in ecological balance, affecting several attributes of the ecosystem, as well as moderate recreation or aesthetics impacts.

Rating = high: there is potential to cause major damage to the environment with significant losses to plant ecosystems and subsequent physical environmental degradation.

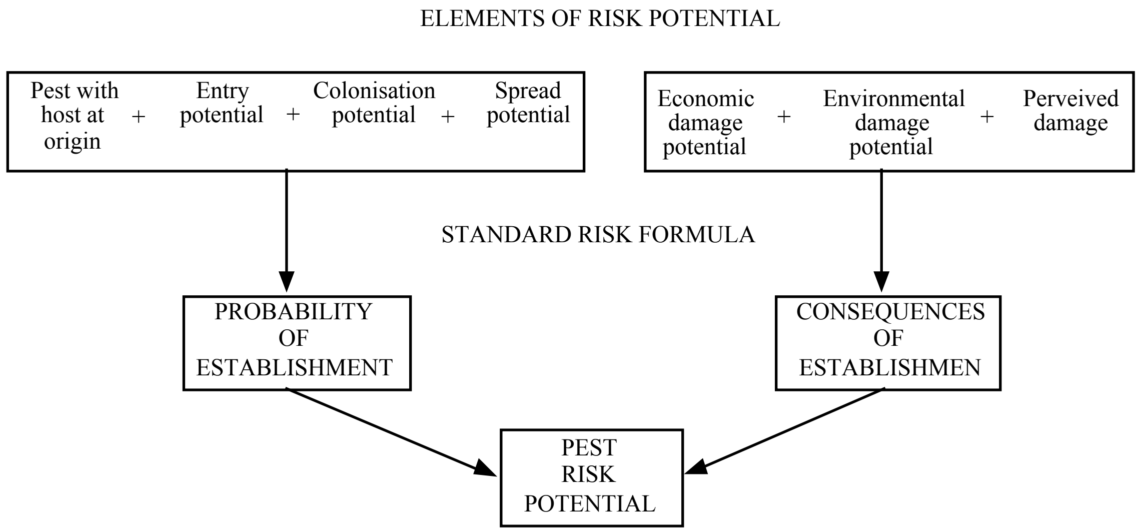
The individual ratings are then used to provide an overall risk rating of negligible, low, medium or high, together with a discussion of the sources and magnitude of uncertainty, assumptions used, data restrictions and the existence of supporting or contradicting evidence. This information is then used to suggest biological recommendations which are carried through to a separate risk management stage.

All data and information collated by the assessment process is systematically summarised in hazard fact sheets, which are used to support the assessment, and are available for future reference.

The risk assessment framework concludes with a broad classification of hazards into high, medium, low or negligible, in order to assist in identifying those hazards that require immediate attention and those that should receive lower priority.

APPENDIX B7: Pest risk assessment of the importation of *Pinus radiata, Nothofagus dombeyi* and *Laurelia philippiana* logs from Chile

The risk assessment paradigm adopted by the USDA's Animal and Plant Health Inspection Service (Orr, 1993) to assess the risk of introducing pest insects and pathogens to the United States with the import of *Pinus radiata*, *Nothofagus domeyi* and *Laurelia philippiana* logs from Chile, is similar to that of the Quantitative Risk Assessment paradigm in so much that risk is expressed as a function of the probability of establishment of the introduced pest and the consequences of establishment, as illustrated in Figure B7.1



(Source: Orr, 1993)

Figure B7.1 APHIS pest risk assessment paradigm.

In a similar approach to that adopted by MacDiarmid (1996), this assessment commences with a qualitative assessment of the insects and micro-organisms known to be associated with Monterey pine plantations in Chile, and only goes on to consider those species which are not known in the US and are considered as a potential pest of US resources, or species which, although already present in the US, are sufficiently genetically different (or more virulent) to warrant concern. The assessment acknowledges that for many species of insects and micro-organisms there is simply insufficient information to make such a judgement, and only those species for which adequate information is available are included within the assessment, relying on the mitigation measures developed from the assessment to be equally effective to those unknown organisms which inhabit the same niche on the imported logs.

Those species which satisfy the criteria above are carried through to the Individual Pest Risk Assessment Process (IPRA). In this process each of the seven specific IPRA elements (ie pest with host at origin, entry potential, colonisation potential, spread potential, economic damage potential, environmental damage potential and perceived damage potential) is assigned a risk value (high, moderate or low) based on the available biological information and subjective judgement of the assessor. The assessment provides no definition or measurement scale for these ranking's, and indeed stresses that none can be provided because the value of the elements contained under probability of establishment are not independent of the rating of the consequences of establishment. In addition, each specific element of the risk assessment is allocated one of five certainty codes from very certain (vc), through to very uncertain (vu). The seven risk values allocated in each IPRA are then combined into a final Pest Risk Potential (PRP) by completing the following steps:

1. determine the probability of establishment. The overall risk rating for probability of establishment acquires the same rank as the single element with the lowest risk rating;
2. determine the consequences of establishment. The overall consequences are designated on the basis of the three individual risk element ranks, as illustrated in Table B7.1
3. determine the pest risk potential. The PRP is ascertained for each species considered on the basis of the pest risk associated with the probability of establishment and the consequences of establishment, as illustrated in Table B7.2

Results of the assessment are then used to formulate mitigation procedures, if deemed necessary, to reduce the risk of introduction and establishment of foreign pests.

Table B7.1 APHIS method for ascertaining consequences of establishment for specific pests.

Economic damage potential	Environmental damage potential	Perceived damage potential	Consequences of establishment
high	low, moderate or high	low, moderate or high	= high
low, moderate, high	high	low, moderate or high	= high
moderate	moderate	low, moderate or high	= moderate
moderate	low	low, moderate or high	= moderate
low	moderate	low, moderate or high	= moderate
low	low	moderate or high	= moderate
low	low	low	= low

(Source: Orr, 1993)

Table B7.2 APHIS method for ascertaining pest risk potential for a specific organism.

Probability of establishment	Consequences of establishment	Pest Risk Potential
high	high	= high
moderate	high	= high
low	high	= moderate/low*
high	moderate	= high
moderate	moderate	= moderate
low	moderate	= moderate/low*
high	low	= moderate
moderate	low	= moderate
low	low	= low

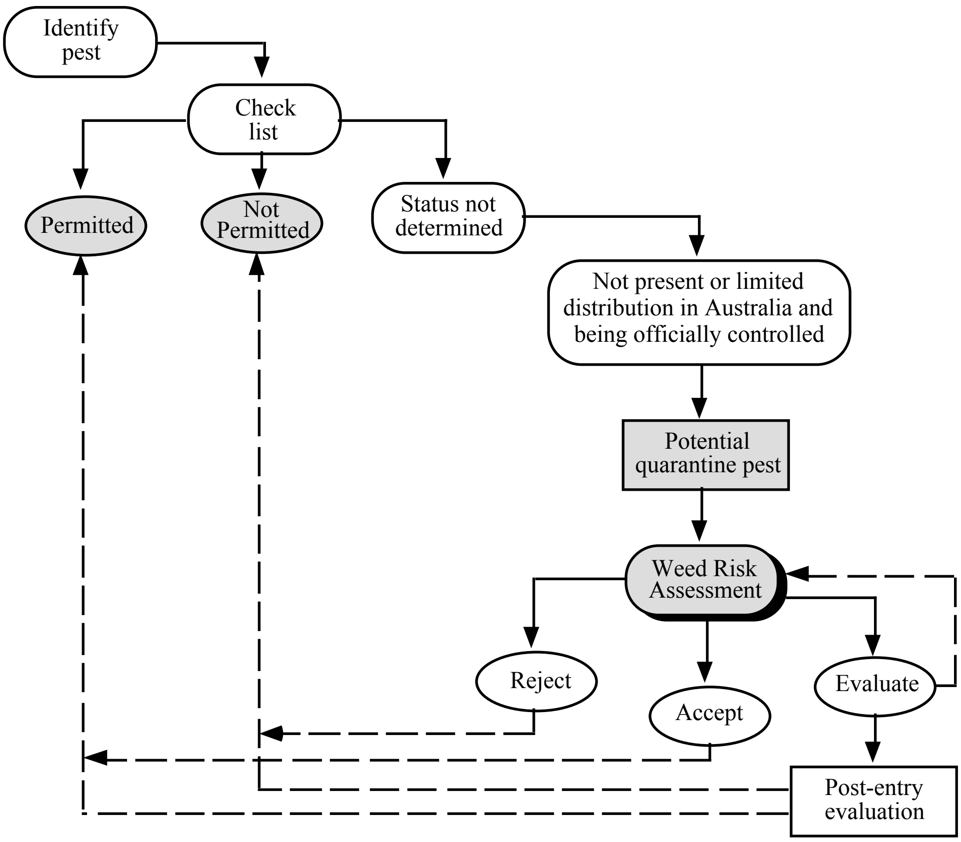
(Source: Orr, 1993)

* If two or more of the single elements that determine the probability of establishment are low, pest risk potential is considered low, rather than moderate for this assessment.

APPENDIX B8: Determining the weed potential of new plant introductions to Australia

Pheloung (1995) provides details of a weed risk assessment that forms part of a wider screening and approval process for the introduction of new plant species into Australia. This screening system corresponds to the first two stages of the FAO pest risk analysis (refer to Appendix B5).

The screening system has three tiers, the first determines whether the plant is a registered quarantine pest by reference to AQIS schedules of prohibited species. If the status of the plant is undetermined, and it is not present (or of limited distribution) in Australia, and is subject to official control, then it is deemed a potential quarantine pest and passes on to the second tier, the Weed Risk Assessment (WRA), as illustrated in Figure B8.1.



(Source: Pheloung, 1995)

Figure B8.1 Flow chart for screening plant introductions to Australia

The Weed Risk Assessment (WRA) itself comprises of a set of 49 questions on the biogeography, biology/ecology and undesirable attributes of the species concerned. The answers required by the assessment are almost entirely of the form ‘yes’, ‘no’ or ‘do not know’. The system generates a numerical score on the basis of the answers provided by the assessor which is positively correlated to weediness. This score is then used to allocate the plant to one of three possible recommendations; reject, accept or evaluate.

The WRA system requires that a minimum number of questions be answered from each of the following three main sections:

1. **Biogeography.** The documented distribution, climate preferences and weediness in other parts of the world. This information is also used to predict a potential distribution in Australia using available prediction systems (such as Climex™). If data is unavailable then it is assumed that the species will readily grow unassisted in Australia;

2. **Undesirable attributes**. The species is interrogated for noxious and invasive characteristics such as toxicity, recognised host of pests and pathogens, allelopathic, resistance to herbicides, re-growth from mutilation, long lived propagules, etc; and,

3. **Biology/ecology**. The reproductive nature and dispersal potential is investigated. For example an aquatic plant, that reproduces by vegetative fragmentation, producing buoyant propagules would score highly in the system.

In most cases the system allocates one point for a 'yes', and deducts one point for a 'no'. An answer of 'do not know' returns a score of zero. Furthermore the assessment of potential distribution, based on climate matching, is used to weight the responses to four questions on weed status in other parts of the world. A good climate match increases the value of a yes response to these questions.

The third and final tier of the assessment is post entry evaluation in the form of field studies to examine more directly weed potential (and to verify potential benefits). This third tier is only entered into if the WRA returns a value that indicates further evaluation is required. This further evaluation can also include re-running the WRA using updated information or undertaking an economic cost/benefit analysis.

Importantly, the allocation of the decision rules (accept, reject, evaluate) to overall score intervals was calibrated by running the risk assessment for 370 plant species representing known weeds and useful species from agricultural, environmental and other sectors. The resulting range of scores for non-weeds overlapped the range of scores for serious weeds, demonstrating that it is impossible to define a critical value which would successfully reject all serious weeds whilst accepting all useful species. By setting the decision scores thresholds at 0 (accept/evaluate) and 7 (evaluate/reject) the system successfully rejected all serious weeds, rejected less than 10% of the useful plants and minimised the number of species requiring further evaluation to approximately 29%.

APPENDIX B9: Expert system for screening potentially invasive alien plants in South African fynbos

The South African fynbos is a nutrient poor environment which is periodically subject to intense fire, and thereby exerts very particular environmental stresses on the trees and shrubs that inhabit it. These stresses represent barriers to potentially invasive species which have been identified and categorised in the expert system described by Tucker & Richardson (1995), which forms the basis of an invasion risk assessment framework.

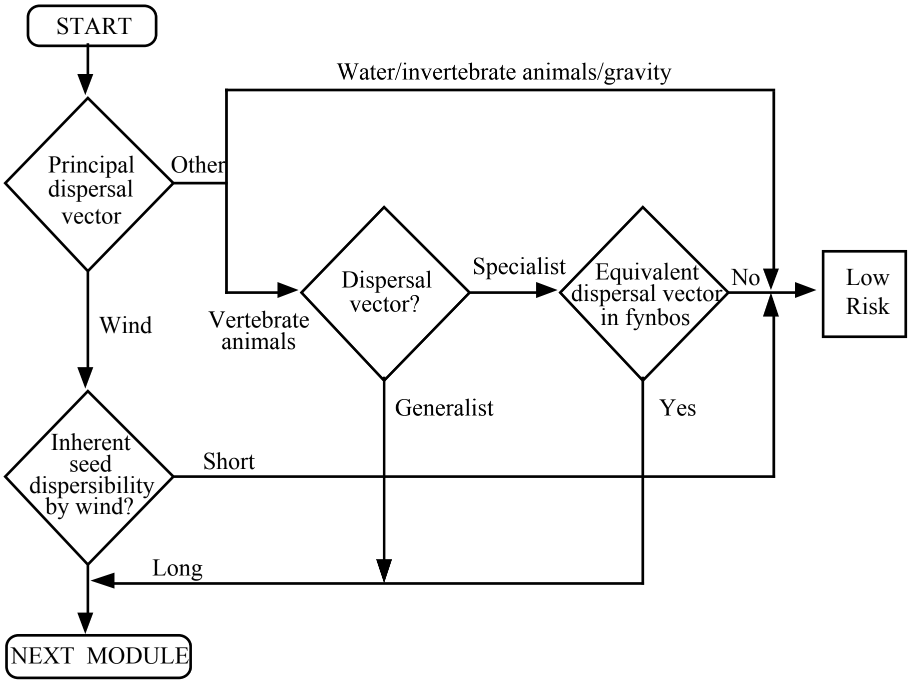
The risk assessment system is an extension of the work by Richardson *et al* (1990) who collated data on the attributes required for maximum recruitment from 60 *Pinus* taxa. From these 6 attributes (short juvenile period, fire tolerance, seed crop variability, degree of serotiny, seed mass and seed wing size) were chosen as the principal determinants of survival and proliferation in the fynbos. Correspondence analysis, on the basis of these attributes, was then used to identify five functional groups for the whole pine genus that are consequently distinguished primarily by their potential for colonisation and establishment in fire prone environments.

This analysis formed the basis of a subsequent risk assessment framework centred around the invasion barriers and windows within the fynbos environment, notably the low rainfall and nutrient conditions and the periodic fire disturbance, as compared to the species attributes required to flourish under these conditions and exploit the disturbed habitats. The risk assessment requires an assessor familiar with the ecology of the alien in question to answer 24 questions which are grouped into six modules regarding:

1. broad scale environmental conditions in the species' native range;
2. population characteristics and habitat specialisation;
3. seed dispersal mechanisms;
4. seed production mechanisms;
5. likely seed predation patterns in the fynbos; and,
6. life history adaptations to fynbos fire conditions.

Each of these questions are nested within an expert system which maintains the decision rules within the assessment framework for the allocation of the species to low or high risk categories. Figure B9.1 illustrates the approach and decision rules for the queries pertaining to seed dispersal mechanisms (question 11 to 14 in the assessment framework).

The assessment framework is designed to be inherently conservative; a species is automatically assigned a high risk status unless there is sufficient information (as evidenced by the assessors response to the questions) to indicate that it has a low likelihood of successfully invading the fynbos environment. In particular if the assessor responds 'unknown' to a question then that question is not taken into account and control is transferred to the next module on the route to 'high risk status'. Thus absence of information does not bias the results of the assessment towards a low risk status.



(Source: Tucker & Richardson, 1995)

Figure B9.1 Queries and decision rules pertaining to seed dispersal utilised in the fynbos invasion risk assessment system.

Some of the questions within the system require a detailed knowledge of the life history attributes of the species being assessed and the characteristics of its home environment. Indeed in many instances the system requires more than a simple yes no reply to the question. For example in the first module (broad scale environmental conditions) the typical fire return period (in years) within the species native range is required to be input, together with the annual rainfall (in mm). Similarly the species juvenile period and seed bank longevity must be entered in years during the latter modules.

The risk assessment system was tested against 14 established alien species within the fynbos and successfully identified all but three of these species as high risk. Two of these species are dispersed by water and are therefore restricted to riparian habitats within the fynbos whose invasion determinants are quite distinct from those of the fynbos more generally. The third species performance was better than predicted by the system due to opportunistic mutualism with the introduced grey squirrel which disperses its seeds. The authors highlight this as an example of the idiosyncrasies that often underline plant invasions and thereby confound risk assessment.

APPENDIX C1 Environmental risk management of introduced aquatic organisms in aquaculture

Kohler (1992) provides a framework for assessing the risk associated with the introduction of cultured aquatic organisms. The analysis begins by assessing the organism's potential for escape from containment and the likelihood of it establishing self sustaining populations in the wild. These attributes are assessed using an 'Index of Colonisation'; $C = (E).(A)$, where E is escape potential and A is acclimatisation potential. E is considered a function of the culture system, its location in relation to natural water bodies and the consignment form of the cultured product. The assessment requires that each of these elements be ranked on a numerical scale ranging from 0.0 (lowest risk) to 1.0 (highest risk) as follows:

$$E = \frac{(e_1 + e_2 + e_3)}{3}$$

where: e_1 = culture system:

a. closed indoor research = 0.1
b. closed indoor commercial = 0.5
c. outdoor culture = 1.0

e_2 = adjacency to natural waters:

a. near = 1.0
b. intermediate distance = 0.2 – 0.9
c. distant = 0.1

e_3 = consignment form:

a. live = 1.0
b. processed = 0.0

The author emphasises that the values given to the sub-elements of E (as well as the values assigned to the sub-elements below) are subjective, and that the specific values utilised need not be those illustrated here provided that they are based on the perceived relative risk. The second aspect of colonisation potential is acclimatisation potential (A), and this is indexed in a similar manner:

$$A = \frac{(a_1 + a_2 + a_3)}{3}$$

where: a_1 = niche/habitat match:

a. temperature
b. salinity
c. community structure
d. spawning/nursery suitability
e. etc.

a_2 = reproductive potential:

a. fecundity

b. single versus multiple spawn
c. parental care

a_3 = Dispersal potential:
a. sedentary
b. migratory
c. pelagic early life stages

These sub-elements are designed to reflect the ecological relationship of the non-native organism to its new environment, and are again scored from 0.0 to 1.0. In this case, however, the values assigned to a_1, a_2 and a_3 are the means of the scores of the appropriate sub-elements.

The second stage of the assessment considers the potential impact an introduced species might have should it escape to the wild. In a manner similar to that above an 'Index of Impact' is defined I = (V).(T), where V is the vulnerability of the receiving system and T is the threat potential of the introduced species. The former is expressed as:

$$V = \frac{(v_1 + v_2)}{2}$$

where: v_1 = biotic factors:
a. species diversity
b. predator/prey relationships
c. endangered or rare species
d. etc.

v_2 = abiotic factors:
a. fertility
b. structural complexity
c. anthropogenic disturbance

The threat potential is expressed:

$$T = \frac{(t_1 + t_2 + t_3 + t_4 + t_5)}{5}$$

where: t_1 = habitat alteration;
t_2 = trophic alteration;
t_3 = spatial alteration ;
t_4 = gene pool deterioration; and,
t_5 = disease introduction.

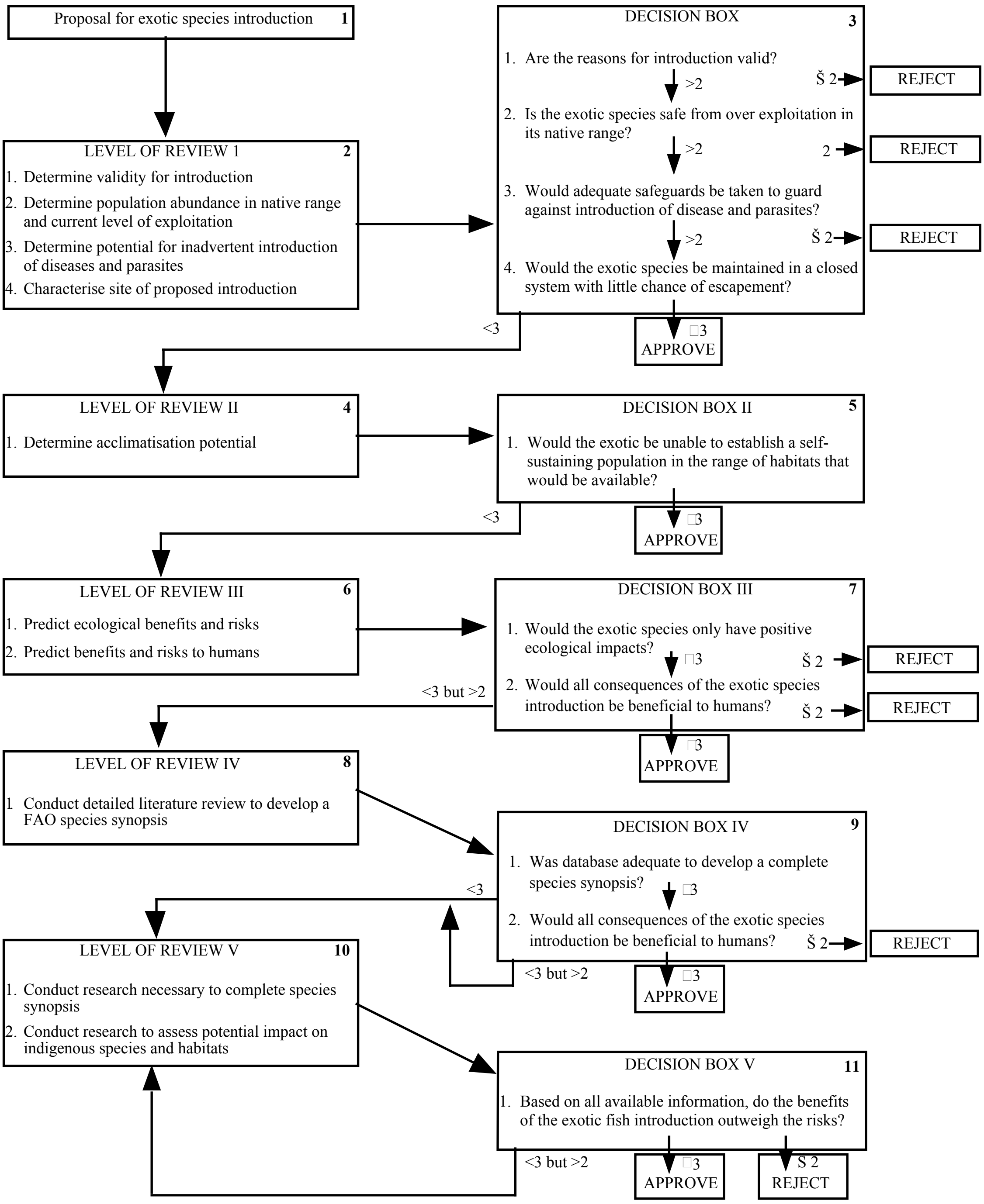
Again V is assigned a number between 0.0 and 1.0 depending on the assessors subjective perception of the vulnerability of the receiving environment in relation to invasibility, whilst the individual sub-elements of T can be scored between 0.0 and 1.0 to provide an overall scoring for T. The environmental risk that a non-native species poses is then assessed by simply combining the Index of Colonisation and the Index of Risk:

$$R = \frac{[(E)(A) + (V)(T)]}{2}$$

Again R will vary between 1.0 and 0.0 and thus provides a unit scale over which the relative risk of different introductions, or the relative risk reduction achieved by different management strategies, can be gauged.

APPENDIX C2: Review and decision model for evaluating proposed introductions of aquatic organisms

Figure C2.1 illustrates the review and decision model proposed by Kohler (1984) for evaluating the proposed introductions of aquatic organisms.



(Source: Kohler, 1992)

Figure C2.1 Review and decision model for introductions of aquatic organisms

The review and decision model was proposed as part of a wider protocol concerning introduced aquatic organisms that required the establishment of an evaluation board or committee, the promulgation of a formal proposal for each proposed introduction, the evaluation of the proposed introduction employing A review and decision model (illustrated in Figure C2.1), standards for research facilities conducting preliminary studies, necessary permits and disease free certifications and written reports on outcomes of introductions submitted to the evaluation board and local natural resource agency(s).

Thus it was envisaged that the model would be employed by an evaluation board or panel of experts. Each member of the board would utilise a questionnaire (refer to Table C2.1) for appraisal of the introduction. Mean scores taken from this questionnaire are those utilised at the decision points in the model.

Table C2.1 Questionnaire for appraisal of introductions of aquatic organisms used in conjunction with the review and decision model.

	Response					
Question	**No**	**Unlikely**	**Possibly**	**Probably**	**Yes**	**Unsure**
1. Is the need valid and are no native species available that could serve the stated need?	1	2	3	4	5	x
2. Is the organism safe from over exploitation in its native range?	1	2	3	4	5	x
3. Are safeguards adequate to guard against importation of disease/parasites?	1	2	3	4	5	x
4. Would the introduction be limited to closed systems?	1	2	3	4	5	x
5. Would the organism be unable to establish a self-sustaining population in the range of habitats that would be available?	1	2	3	4	5	x
6. Would the organism have mostly positive ecological impacts?	1	2	3	4	5	x
7. Would most consequences of the introduction be beneficial to humans?	1	2	3	4	5	x
8. Is data base adequate to develop a complete species synopsis?	1	2	3	4	5	x
9. Does data base indicate desirability for introduction?	1	2	3	4	5	x
10. Based on all available information do the benefits of the introduction outweigh the risks?	1	2	3	4	5	x

(Source: Kohler, 1992)

APPENDIX C3: Generic nonindigenous aquatic organisms risk analysis review process[20]

The purpose of this review process is to provide a standard, comprehensive and practical framework with which to evaluate the risk of introducing non-indigenous organisms into a new environment (Orr, 1995). The process was designed to meet the requirements of the US Aquatic Nuisance Prevention and Control Act (1990) and to be flexible enough to accommodate a variety of approaches to exotic organism risk assessment depending on the availability of resources and information. The approach provided by the author, as detailed below, can be considered as the generic minimum required by the assessment procedure.

The risk assessment methodology is a modified version of the pest risk assessment process employed by the USDA's Animal and Plant Health Inspection Service, and indeed the basic paradigm is identical to that employed for plant pests (refer to Figure B7.1). The process is triggered by a request for the opening of a new pathway which might harbour non-indigenous aquatic organisms (for example aquatic species imports) or the identification of an existing pathway which be of significant risk (for example the ballast discharges of vessels arriving from a particular location). The risk assessment again commences with a qualitative review of the organisms that are associated with the pathway, from which organisms of concern are selected for further evaluation (on the same grounds as those used by APHIS for plant pest assessment).

Once the list of the organisms of concern has been collated for a particular pathway, an estimate of risk is made at three levels. At the first an estimate of risk is made for each of the seven 'elements of risk potential' identified in the risk assessment paradigm (Figure B7.1). This process is identical to that utilised by APHIS in that each of the four establishment elements are scored as high, medium or low, (and the overall probability of establishment is assigned the lowest value allocated to any of the individual elements). The consequence of establishment is determined on the basis of the combinations of the high, medium or low allocations to the three consequence elements as illustrated in Table B7.1.

The second level combines the seven risk element estimates into an Organism Pest Potential (ORP) which represents the overall risk of the organism being assessed. This is achieved in a similar, but not identical, way to the plant pest risk assessment approach, as illustrated in Table C3.1

The third and final stage links the various ORP's into a Pathway Risk Potential (PRP) which represents the combined risk associated with the pathway, as illustrated in Table C3.2.

In this manner the PRP reflects the highest ranking ORP, with the possible exception of instances where the number of medium risk organisms reaches a level deemed to warrant sufficient concern such that the pathway be rated high. The number 5 used in the table is arbitrary.

[20] The information provided below is drawn from a draft document of the proposed risk review process.

Table C3.1 Determining the Organism Risk Potential under the generic non-indigenous aquatic organism risk review process

Probability of establishment	Consequences of establishment	Organism Risk Potential
high	high	= high
moderate	high	= high
low	high	= moderate
high	moderate	= high
moderate	moderate	= moderate
low	moderate	= moderate
high	low	= moderate
moderate	low	= moderate
low	low	= low

(Source: Orr, 1995)

Table C3.2 Determining the Pathway Risk Potential under the generic non-indigenous aquatic organism risk review process

Organism Risk Potential		Pathway Risk Potential
Rating	Number	Rating
high	1 or more	high
medium	5 or more	high
medium	>0 but <5	medium
low	all	low

(Source: Orr, 1995)

The author again emphasises that the high, medium or low ratings applied to the individual elements of the risk components cannot be defined or measured because the value of the elements under ‘probability of establishment’ are not independent of the rating of ‘consequence of establishment’, (although the reasoning behind this is not entirely clear). By contrast the ratings of high, medium and low used in the ORP and PRP ratings can be specified, and the author offers the following definitions:

Low = acceptable risk; organism(s) of little concern (does not justify mitigation)

Medium = unacceptable risk; organism(s) of moderate concern (mitigation is justified)

High = unacceptable risk; organism(s) of major concern (mitigation justified).

The assessment methodology also advocates the use of standard organism risk assessment forms, requiring the assessor to complete each section (together with a simple expression of their uncertainty) and thereby undertake the risk review process. Other information required of the assessor in this manner includes details of the life-cycle, distribution and natural history of the organism concerned and pathway being considered.

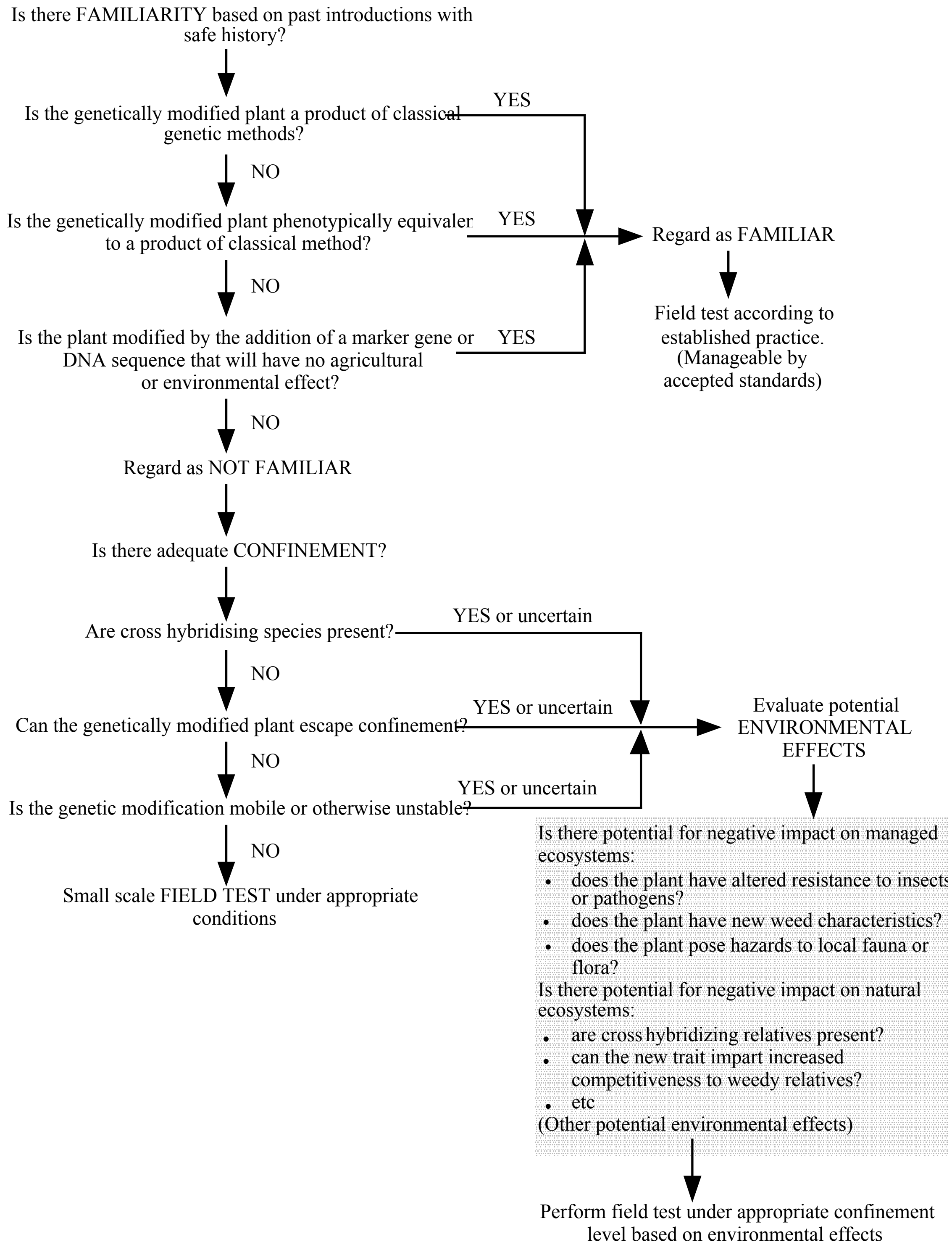
APPENDIX C4: NRC risk assessment framework for genetically modified plants and micro-organisms

Three criteria underpin the National Research Council's framework for the assessing the safety of genetically modified plants and micro-organisms intended for field testing (NRC, 1989); familiarity with the history of introductions similar to that proposed; control over the spread and persistence of the micro-organism or plant (as well as exchange of genetic material with indigenous flora); and, environmental effects including potential adverse effects associated with the introduction. These criteria essentially represent decision components around which the risk assessment framework is built, as illustrated in Figure C4.1.[21]

The assessment framework for genetically modified plants is relatively simple, reflecting the assertion that the majority of genetic modifications that have been undertaken, or anticipated, are similar to those that have been produced with classical techniques, thus entailing no new are inherently different hazards. On this basis situations that are familiar, and considered safe by virtue of past experience, are immediately classified as manageable by accepted standards (MAS). If, however, the engineered plant is considered as sufficiently different from previous introductions, the assessor is required to assess the likelihood that the plant will escape from the confines of the field test and exchange genetic material with wild plant species. If confinement is difficult or uncertain then the potential environmental effects are investigated, again through a series of questions. Note that the example set provided in Figure C4.1 is for illustrative purposes and is not considered to be comprehensive. If potential negative environmental effects are indicated in this manner then the assessor is directed to consider more stringent confinement mechanisms. It is interesting to note that there is a clear presumption in favour of permitting the field research with genetically modified plants. What is under scrutiny are the confinement strategies that may be required of the field trial not the desirability of the trial itself.

The assessment framework for micro-organisms is essentially the same as that described above, although couched in more appropriate terminology. Again if the genetically engineered micro-organism does not satisfy the familiarity criteria it is evaluated with respect to the ability to control its persistence and dissemination in the natural environment, and its potential for significant adverse effects.

[21] Figure C4.1 shows the risk assessment framework for genetically modified plants, the framework for genetically modified micro-organisms is essentially identical although a number of the questions are framed in more appropriate terms.

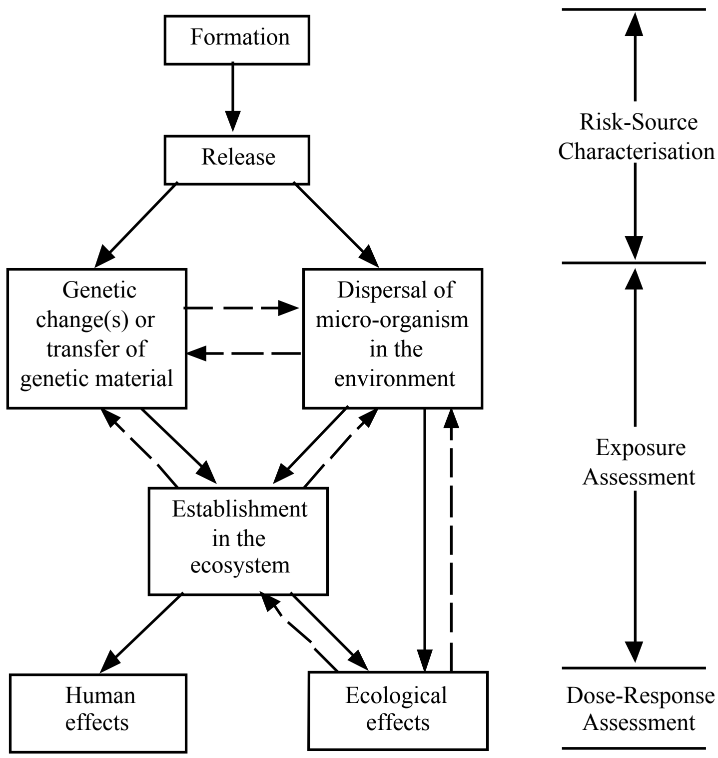


(Source: NRC, 1989)

Figure C4.1 NRC framework for assessing the risks associated with the release of genetically modified plants in field trials

APPENDIX C5: The OTA risk assessment framework for environmental introductions

Fiksel & Covello (1985) describe a risk assessment framework, developed by the Office of Technology and Assessment (OTA), to assess the risks associated with release of Genetically Modified Micro-organisms into the environment. The model requires that five stages be considered in the risk assessment, and as shown in Figure C5.1, these correspond roughly with the central stages of the chemical risk assessment paradigm.



(Source: Fiksel & Covello, 1985)

Figure C5.1 The OTA risk assessment framework for addressing the risks associated with the release of genetically modified micro-organisms

The five step procedure thus requires the assessor to address the following issues:

1. the creation of the genetically altered micro-organism through deliberate or accidental means;

2. the deliberate release or accidental escape of some or all of these micro-organisms into the environment;

3. the subsequent multiplication, genetic reconstruction, growth, transport, modification and die off of these micro-organisms in the environment, including possible transfer of genetic material to other micro-organisms;

4. the establishment of the organisms within an ecosystem niche, including possible colonisation of human or other biotic hosts; and,

5. the subsequent occurrence of human or ecological effects due to the interaction of the organism with some host or environmental factor.

The framework, however, provides little additional guidance as to how each of these steps might be accomplished. In this context the authors suggest that the first two stages can be adequately addressed using fault tree, event tree or simulation analysis, suggesting therefore that these stages are roughly equivalent to the hazard identification stage of the QRA paradigm or the risk source characterisation stage of the toxicological risk assessment paradigm, (refer to Appendix C8 for an example in this context). Similarly it is suggested that the last stage, human and ecological effects, corresponds to the dose-response assessment stage of this paradigm and can thus utilise conventional epidemiological or toxicological methods, although it is noted that the development of techniques for ecological effects assessment is not as well advanced as that for human effects due to the complexity of ecological systems which usually prevents the direct application of toxicological methods.

Importantly the authors note that it is in the intermediate stages of the risk assessment framework, roughly equivalent to the exposure assessment of the chemical risk assessment model, that the biggest differences with the traditional ecological risk assessment paradigm occur, primarily because:

1. several complex feedback loops can exist between an organism and its environment, for example once established a genetically modified micro-organism can potentially alter the environment in ways that promote its further proliferation, thereby inducing a chain of secondary effects. Thus for ecological risk assessment of micro-organisms, the proliferation, establishment and ecological effects stages cannot be as easily disaggregated as the source, fate and transport, and effects assessment might be in a chemical risk assessment; and,

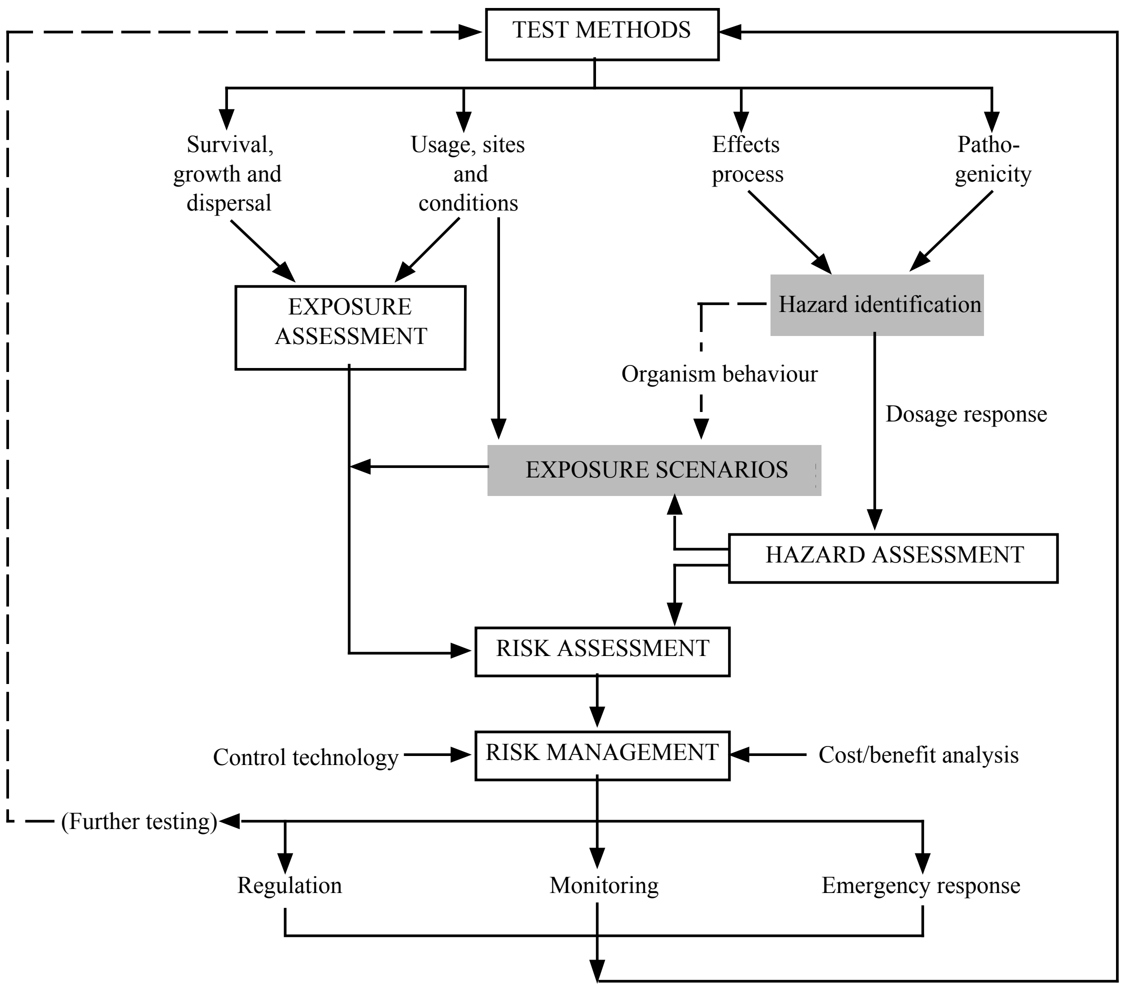
2. biotic stressors are not restrained by the physio-chemical laws of dispersion and decay that usually govern chemical and physical stressors in the environment. Risk assessment techniques and approaches designed to address the exposure of endpoints within the environment to these types of stressors are unlikely to be successfully adapted for genetically modified micro-organisms.

As a consequence the concept of ‘exposure’ as commonly understood and applied in traditional ecological risk assessment models is not adequate for the purposes of GMO risk assessment approaches.

It is interesting to note that the authors conclude that the complexity of the natural environment and its interactions with biological entities currently precludes the application of quantitative probabilistic risk assessment techniques. It is implied, however, that with sufficient data regarding the micro-organism, the risk assessment could attempt to attain the status of ‘consequence analysis with confidence bounds’ in which a deterministic consequence analysis is performed under various assumptions, thus providing confidence bounds to bracket the best estimate of consequences (Fiksel & Covello, 1985).

APPENDIX C6: Risk assessment for release of biotechnology products

Strauss (1991), provides a schematic representation of a risk assessment framework developed by researchers at Cornell University and the Institute for Comparative and Environmental Toxicology, in a study of the potential impacts of environmental releases of biotechnology products (Figure C6.1).



(Source: Strauss, 1991)

Figure C6.1 Risk assessment framework for the release of biotechnology products

The assessment framework data requirements are further stipulated as follows:

1. details of how the organism is released, including the locale, rate, and form of release;

2. survival characteristics of the introduced organisms, including the range of physiological and nutritional stresses tolerated;

3. growth and propagation of the organism and its genetic material, including physiological and nutritional requirements, and interaction with other organisms;

4. dispersive ability of the organism; and,

5. characteristics of the interaction and activities of the introduced organism with other components of the natural environment.

The original research group went on to consider critical exposure pathways between the source of the introduction, initial die-away, transport, survival, establishment and the site of any realised environmental impact, identifying factors that mitigated against exposure (adverse environmental conditions giving rise to starvation, competition, predation, etc) and factors that enhanced exposure (intrinsic organisms properties such as adaptiveness, competitiveness, resistance, etc).

A number of methods were also recommended to test the survival and growth of GMO’s under a range of environmental conditions, with primary productivity, growth, respiration, secondary productivity (growth and reproduction of consumers), and nutrient fluxes being the best candidates for ecological test method development and application in biotechnology risk assessment. Again, however, little detail accompanies the framework with to regard to the manner in which each of the components of the risk assessment should be undertaken or even approached.

APPENDIX C7: Assessing the risks of invasion for genetically engineered plants

An alternative risk assessment approach to that advocated by the National Research Council is offered by Parker & Kareiva (1996). The authors suggest that whilst species traits may give some indication of a plants capacity for invasion, in its simplest form successful establishment can only arise if the invading population is able to sustain a positive growth rate. The most appropriate measure of invasion risk is therefore the finite rate of increase (λ). The risk assessment framework developed by these authors accordingly focuses on the finite rate of increase of plants and is illustrated by assessing the invasion risk of genetically engineered plant strains in relation to the parent lines from which they were derived.

The assessment methodology uses greenhouse studies to estimate an individual plant's mean finite rate of increase expressed as;

$$\lambda = P(gs) \times F_{adult} \times S$$

where: P(gs) = germination/survivorship probability

F_{adult} = total number of flowers of the adult plant

S = number of seeds per fruit of particular plant in question.

Significance difference between transgenic and parental finite rate of increase was then investigated using a one tailed student's t test.

In discussion, the authors note that for genetic modifications that do not alter biotic stress traits, greenhouse risk assessments (based on finite rates of increase) will be conservative, tending to overestimate the invasiveness of GEO's. This is largely due to the fact that plant performance, as measured by rates of population increase, are anticipated to be much higher in a greenhouse as compared to the field. Furthermore because the greenhouse environment minimises stochastic variation in environmental conditions, enhanced fitness capabilities within transgenics as compared to parent lines are likely to be more prominently expressed. The authors acknowledge, however, that greenhouse studies are less useful to examine the effects of genetic modifications that alter a biological stress response, such as drought or frost response.

The approach is interesting, however, as it represents one of the first attempts to provide a quantitative metric of invasion ability, for genetically modified organisms, based on the characteristics of the organism in question; in this instance the total number of flowers and seeds per fruit of the plant.

APPENDIC C8: GENHAZ; a system for critically evaluating genetically modified organism hazards

GENHAZ is a hazard identification and assessment methodology that employs Hazard and Operability (HAZOP) procedures, more commonly associated with chemical process industry, to identify the potential hazards and uncertainties associated with the release of Genetically Modified Organisms into the environment (Royal Commission on Environmental Pollution, 1991). The procedure was designed principally for experimental releases of plants and micro-organisms, but is clearly applicable to the release of other types of genetically modified organisms, or indeed to introductions of non-indigenous species more generally.

HAZOP is an approach by which a multi-discipline team of assessors, familiar with the process in question, are encouraged to systematically use their experience and imagination to identify potential hazard scenarios in complex industrial systems. The procedure takes as its starting point the line, flow and control diagrams that represent the intended operating system of the plant. The technique then systematically works through each item of plant, for example a pipe leading from a feed vessel to a reactor, and applies guide words such as more, less, other than, etc. to focus attention on possible deviations from the planned intention. Each application of the guide word usually generates a number of potential deviations from intent, from which possible causes and consequences are identified and recorded.

The approach is successful because it is systematic and also because it makes no prior assumptions as to the potential likelihood of hazard scenarios and is therefore and excellent means to identify plausible, but low probability, events that may ordinarily be overlooked simply because they do no form part of the assessors established operating experience. The GENHAZ framework has four main elements (Figure C8.1):

1. a series of questions about the proposed release, presented in the form of a questionnaire, the answers to which provide the statement of intent to be examined by the methodology;

2. two elements used to structure and to focus the use of the questionnaire, namely the components of the genetically modified system and a further set of seven stages describing the construction and release of the genetically modified organism;

3. the procedure for following a GENHAZ study; and,

4. a set of guide words which aid the interrogation by the team of the design intention of the proposed release.

The components of the genetically modified system comprise the construct (for example the nucleic acid from a gene donor), the recipient or host into which the construct is to be made, and the intended product, which is the genetically modified organism itself. The GENHAZ guide words are applied to each of these construction stages.

The seven release stages are concerned with the preparation of the construct for release (MAKE or SELECT), the actual process of introduction (RELEASE), the events following the release during which the GMO either establishes itself or fails to do so (ESTABLISH), the subsequent population growth, spread and reproduction (POPULATION), the potential for unintended transfer of DNA material (GENETIC TRANSFER), the monitoring of the progress of the introduction (MONITOR) and finally the clean up plans or contingency plans in the event of a premature termination of the release (TERMINATE AND CLEAN UP).

Design Intention	GENHAZ Questionnaire's answers		
Component of the genetically modified system	CONSTRUCT	RECIPIENT	PRODUCT
Stages of the release	MAKE or SELECT RELEASE ESTABLISH POPULATION GENETIC TRANSFER MONITOR TERMINATION/CLEAN-UP		
GENHAZ procedure	INTENTION CAUSE	DEVIATION ACTION	CONSEQUENCE
Guide words	NO/NOT AS WELL AS WHERE ELSE	MORE PART OF	LESS OTHER THAN WHEN ELSE

(Source: Royal Commission on Environmental Pollution, 1991)

Figure C8.1 The main elements of the GENHAZ framework

The questionnaire is similarly structured around the three construction components and the seven release components to ensure a comprehensive description of the intent of the modification and introduction. These statements of intent are accompanied by a narrative description of the release proposal and form the main database for the GENHAZ assessment. The guide words are applied to each of the assessors answers in the questionnaire in order to suggest ways in which deviations from the intended course of events may occur.

The successful completion of a HAZOP assessment requires the application of a multi-discipline team of scientists and engineers familiar with the system in question. GENHAZ similarly requires a team of ecologists, geneticists and representatives from the laboratory where the actual construction of the modified organism is to take place.

APPENDIX C9: Decision support protocol used to assess the advisability of allowing the importation of alien aquatic animals into southern Africa

De Moor and Bruton (1993) describe a decision support protocol designed to assess the invasion risk associated with the import of non-native aquatic species for aquaculture and aquarium purposes. The protocol is loosely based on a similar approach advocated by Kohler and Stanley (refer to Appendix C2) and requires that the assessor address a number of key issues regarding the candidate species and target environment. The protocol is sub-divided into five stages (Figure C9.1) commencing with three 'pruning' questions, followed by a series of questions regarding the species' ability to survive and invade the target environment and the potential for subsequent adverse environmental impacts. In the event that there is insufficient information to complete the protocol the importation is to be banned.

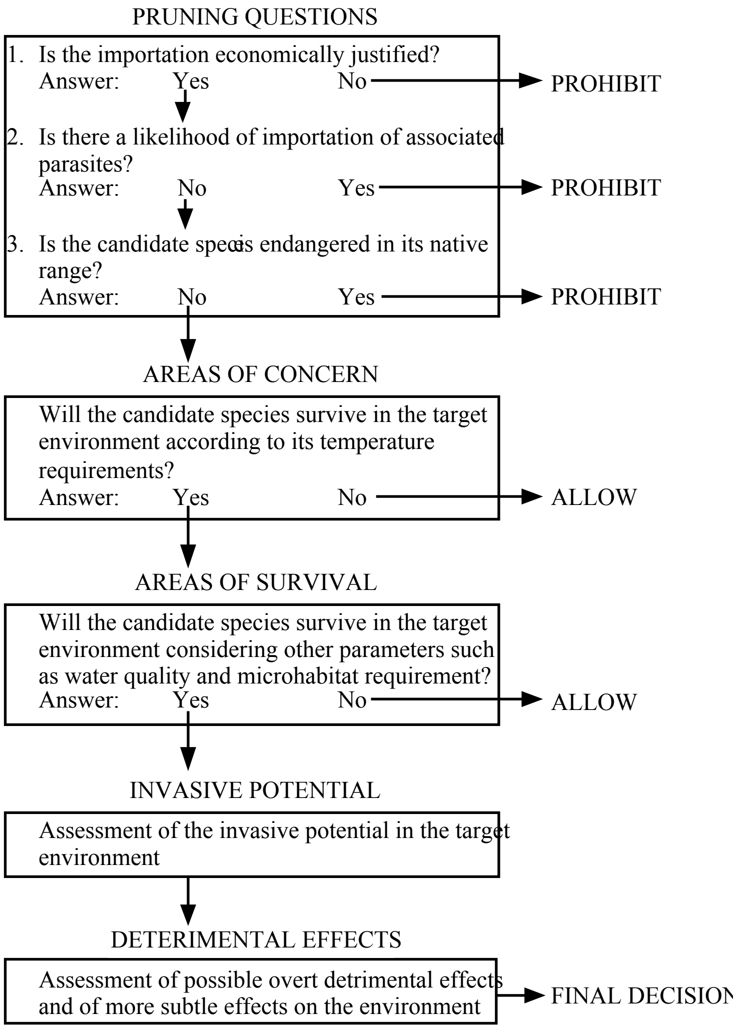
If the species concerned harbours parasites or is endangered in its native range, or if the importation is not economically justified, then it is immediately rejected at the pruning stage. In the first instance the ability of the species to survive in the target environment is assessed against the temperature tolerances of all its life stages in relation to the temperature regime in the target environment. The most important parameters are seen as the expected annual extremes in water temperatures (January mean monthly maxima and July mean monthly maxima) in the target environment. Where this information is difficult to obtain, it may be inferred from the presence or absence of temperature sensitive organisms such as Trout (*Oncorhynchus mykiss*) or bilharzia vector snails.

The survival likelihood is then further assessed in relation to the physio-chemical water conditions at the target site, the species' trophic status and its habitat requirements. The former requires that measurements of pH, nitrate-nitrite ratios, total dissolved solids, total phosphates and turbidity be taken at the site, together with a calculation of Chutter's Biotic Index which is considered as an effective index of water quality integrating across parameters such as dissolved oxygen and BOD through-out time.

The species potential to invade is assessed in relation to the following criteria:

1. mobility – ability to move rapidly and colonise new areas;
2. hardy – tolerant of a wide range of adverse water quality conditions;
3. aggressive – in its interaction with other species;
4. trophic tolerance – exhibiting a high degree of trophic plasticity;
5. size – significantly larger than any closely related species;
6. special ability to cross normal environmental barriers (such as air breathing or high salt tolerance); and,
7. life history – ability to cross between altricial and precocial life styles depending on conditions.

If the species exhibits more than one of these characteristics then it is considered invasive. If it exhibits more than four it is classified as highly invasive. The potential to invade is also assessed in relation to the environmental resistance at the target site, expressed in terms of the presence of predators, the level of disturbance by man and degree of pollution (as measured by Chutter's biotic index).



(Source: de Moor & Bruton, 1993)

Figure C9.1 Decision support protocol for the assessment of invasion risk associated with the importation of alien aquatic animals into southern Africa.

Finally the assessor is required to consider the potential 'detrimental' or 'disastrous' effects that may follow the invasion of the target site by the species concerned. The former are defined as predation/parasitism, habitat alteration or competition effects, whilst the latter are defined as harm to man (or his livestock), serious economic damage through habitat alteration or the spread of disease. If on completion of the protocol questionnaire the assessor arrives at the final decision stage, the species is to be allocated to one of two categories; case 1, the candidate species is likely to survive and invade the target environment; or, case 2, the species would not survive the annual temperature regimes in the target environment but there is a possibility that it could gain access to a connected area where there is potential for concern. The risk management strategies to be adopted in each of these are then determined in relation to the expected environmental impacts of the species concerned.

APPENDIX D1: A watershed level ecological risk assessment methodology

An excellent example of an effects driven retrospective risk assessment (ie an assessment that results from the observation of apparent effects in the field that require explanation) is provided in Hession *et al* (1996). The assessment is concerned with the water quality of Wister Lake on the Poteau River in Okalahoma. The lake was originally identified as having water quality problems in 1974, but whilst a number of pollutant sources were identified as possible suspects, the relative importance and distribution of these sources was largely uninvestigated. The risk assessment endpoint selected for the study was the trophic state of the lake. The corresponding measurement endpoint being chlorophyll a concentration (that can be subsequently related back to trophic state or eutrophication).

The study commences with the hypothesis that certain land-use practices in the lake's watershed have resulted in excessive phosphorous loadings, thereby accelerating eutrophication within the lake itself. The assessment utilises a nutrient loading and lake response model, EUTROMOD, to estimate annual phosphorous loadings from the water shed (exposure assessment) and resulting lake trophic state (effects assessment). The former was simulated for ten separate sub-watersheds around the lake using information on point and non-point phosphorous sources, annual precipitation rates, soil loss and surface run-off estimates. Lake response was predicted from a set of non-linear regression equations:

$$\log_{10}(CHLA) = 2.0 + 0.51\log_{10}(P) + 0.23\log_{10}(\tau) - 0.35\log_{10}(z)$$

where: CHLA = annual median in-lake chlorophyll a concentration (µg/l)

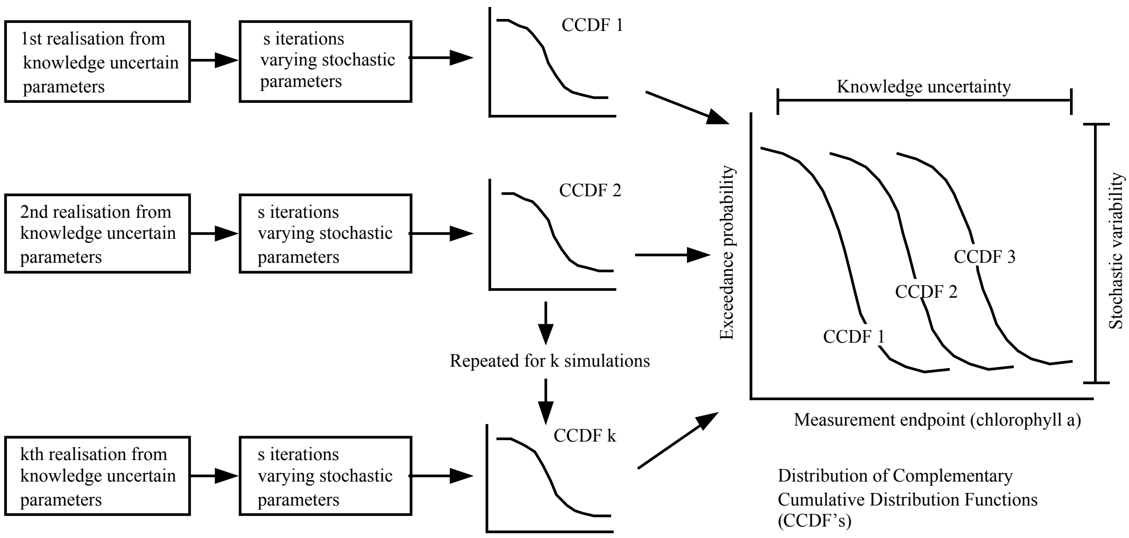
P = annual median estimated in-lake phosphorous concentrations (mg/l)

τ = hydraulic residence time (years)

z = average lake depth

Other data requirements included climate parameters (precipitation and lake evaporation rates), watershed characteristics (land-use, soil type and topography) and lake morphometry (surface area and mean depth). The assessment model treats each land-use within each sub-watershed as an homogenous unit and requires individual inputs for each land use type for many of the parameters above. A Geographic Information System (GIS) was utilised to collate the resulting data inputs.

The assessment addresses the issue of parameter value uncertainty and stochastic variability using a two phase Monte Carlo procedure (refer to Figure D1.1) with Latin hypercube sampling to ensure full coverage across the range of each variable probability distribution. The range of 17 of the model parameters was assigned subjectively, largely on the basis of quoted literature values, whilst the corresponding probability distributions were simply assumed to be either triangular or uniform (depending on the availability of supporting data). The analysis also allowed for stochastic temporal variability in annual weather conditions, as described by annual precipitation rates and rainfall erosivity, by fitting log-normal probability distributions to each of these parameters on the basis of roughly 30 years of weather data from within the lake watershed and Okalahoma respectively. No allowance was made, however, for spatial stochastity in these parameters.



(Source: Hession *et al*, 1996)

Figure D1.1 Two phase Monte Carlo uncertainty analysis employed in the Lake Wister water- shed risk assessment.

This two phase Monte Carlo procedure was performed with 200 simulations, sampling from the 17 variable parameters (knowledge uncertainty), with each simulation consisting of 50 iterations, sampling from the temporally variable climate parameters (stochastic uncertainty). The 50 stochastic output results for each simulation were statistically aggregated to describe complementary cumulative distributions functions (CCDF's). The resulting curves describing the simulations were further simplified by identifying the 5^{th}, 50^{th} and 95^{th} percentile curves from across the 200 CCDF's output.

The allocation of a lake to a trophic status on the basis of chlorophyll a concentrations is itself subject to considerable uncertainty. At a given chlorophyll a concentration a given lake can have different probabilities of being classified as oligotrophic, mesotrophic, etc. On this basis, and using the median CCDF, the authors conclude that Lake Wister has a negligible chance of being oligotrophic, a 3% chance of being mesotrophic, a 61% chance of being eutrophic and a 36% chance of being hypertrophic.

APPENDIX D2: An ecological risk assessment framework for examining the impacts of oceanic disposal

An interesting example of a population based ecological risk assessment is provided by Munns *et al* (1989). The assessment investigates the impact of sewage sludge disposal at the 106 Mile Deepwater Municipal Sludge Dump Site, located off the Northeast coast of the United States. The assessment uses quasi-extinction, modelled with data from two near shore copepod species, as a surrogate endpoint for the effects on offshore species in the vicinity of the dumpsite.

The risk assessment framework is interesting for the way in which it mixes both chemical risk assessment and population modelling techniques. Time averaged sewage sludge concentrations in the well-mixed upper water column around the dump site are modelled under two exposure scenarios, the first representing current sludge disposal rates and the second representing an arbitrarily much higher rate which increases sludge concentrations around the site 100 fold. Details of the dispersion model used to predict environmental concentrations (PEC's), however, are not provided. Stochasticity in dispersion processes was mimicked by allowing sludge concentrations within isopleths predicted by the model to vary as a log-normal variable, with mean equal to the model's predicted concentration (without stochasticity) and variance equal to 1 to 10 times the mean. In this manner the sludge concentrations around the dump-site were divided into six zones (ranging from 1.0 x 10^3 to 1 x 10^2 µg/l), whilst exposure concentrations were derived by Monte Carlo sampling within these zones from the specified probability distributions.

Population dynamics of the species in the vicinity of the dumpsite were represented by a series of difference equations describing the population size (n) of m age classes at time t:

$$
\begin{aligned}
&n(0,t) = \sum n(x,t-1) f_x \\
&n(1,t) = n(0,t-1) P_1 \\
&n(2,t) = n(1,t-1) P_2 \\
&\textit{etc.}
\end{aligned}
$$

where: f_x = fecundity of female in age class x

P = the probability of survival of females from age class x-1 to x.

In matrix notation this system of linear equations can be represented as:

$$
\begin{array}{ccccc}
\mathbf{n}(t-1) & & \mathbf{M} & & \mathbf{n}(t) \\
\begin{bmatrix} n_0 \\ n_1 \\ n_2 \\ . \\ n_m \end{bmatrix} & . & \begin{bmatrix} f_o & f_1 & f_2 & . & f_m \\ 0 & P_0 & 0 & 0 & 0 \\ 0 & 0 & P_1 & 0 & 0 \\ . & . & . & . & . \\ 0 & 0 & 0 & 0 & P_{m-1} \end{bmatrix} & = & \begin{bmatrix} n_o \\ n_1 \\ n_2 \\ . \\ n_m \end{bmatrix}
\end{array}
$$

The matrix notation can thus describe total population size and the distribution of individual age class sizes through time. Furthermore the matrix equation can be solved for its characteristic root λ which represents the geometric rate of population increase. The requisite life history data for offshore zooplankton species is generally unavailable hence the assessment utilises the near shore copepod *Eurytemora affinis,* for which age specific fecundity and survivorship data is available, as a surrogate for closely related offshore species.

The dose-response relationships used in the analysis were extrapolated from toxicant response relationships described in the literature for another species, in a three step method: an empirically derived mortality rate quoted for *Eurytemora herdmanii* exposed to Kepone ($y = 1.84 + 0.00007 \exp(0.423x)$) was normalised against the 96 hr LC_{50} of Kepone. Sewage sludge PEC's derived from the dispersion simulation were then normalised against the 96 hr LC_{50} of a worst case sludge reported for *Eurytemora herdmanii,* and mortality rates in the model extrapolated using the empirical regression relationship. The assumption here being that Kepone and sewage sludge act on mortality in *Eurytemora* in a similar fashion.

Sewage sludge effects on fecundity were simulated in a similar fashion but took two forms. The first describing age specific fecundity impact and the second describing effects on age of first reproduction. The first index utilised an empirical description of fecundity impact on exposure to Kepone ($y = -11.29x + 277.9$), in conjunction with quoted age specific fecundity reductions on exposure to sewage sludge, normalised against the appropriate LC_{50} concentrations. Changes in the age of first reproduction of *Eurytemora* were regressed against Kepone concentration ($y = 0.319x + 12.15$) and then adjusted in response to normalised sewage sludge concentration.

Simulation of zooplankton exposure to the sewage sludge at the site was achieved by advecting the hypothetical population through the centre of the dumpsite in the long axis of the sewage plume, thereby maximising sludge exposure. Duration within each of the sludge zones was based on a 30 day advection time from the centre of the site to entrainment in the Gulf Stream, resulting in a total of 2.86 days in zone 1 (highest concentration of sewage sludge), 3.00 days in zone 2, 11.47 days in zone 3, 13.72 days in zone 4, 0.57 days in zone 5 and 0.57 days in zone 6 (lowest concentration of sludge). Total exposure therefore occurred over a total of 32.2 days allowing for upstream areas of sewage sludge encountered prior to reaching the centre of the dump site.

The population model was used to estimate λ at hourly intervals thereby allowing for variation in exposure on a daily basis. The demographic data used in the model, however, were specified on a one day interval and thus the hourly λ's were discounted by a factor of 1/24, and then aggregated as a product to describe a zone specific growth rate (δ) resulting from exposure within each zone. One hundred hypothetical populations were run through this simulation for each of the 10 levels of environmental stochasticity (variance to mean ratio in the log-normal distribution of the PEC). At the end of each iteration a resulting δ was calculated to describe the impact on the population of passive advection through the entire region of sewage sludge contamination. A resultant λ was also estimated as the geometric mean of the zone specific δ's to summarise the total the daily geometric growth rate realised by the population over the 32.2 day period. This statistic was used to project population size subsequent to passage through the sewage plume. The resulting population size was compared to pre-defined critical population sizes (N_c); all populations below N_c were deemed to have become quasi-extinct.

The results of the analysis demonstrated in a quantitative manner how the risk of quasi-extinction to populations that respond similarly to *Eurytemora herdmanii* increased with increasing environmental stochasticity and critical population size.

APPENDIX D3: An object orientated model for ecological risk assessment on a great blue heron colony

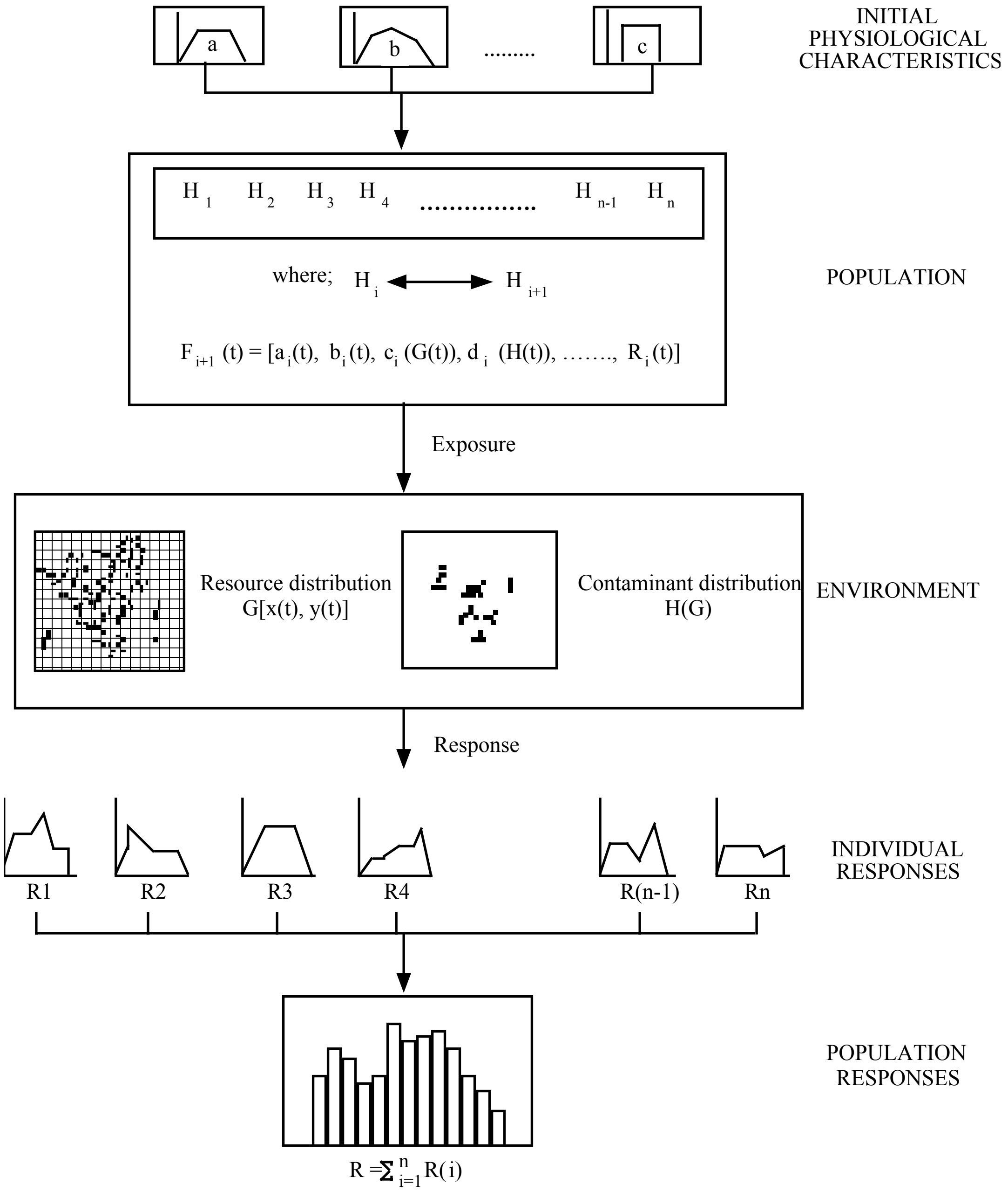
An interesting example of a predictive object orientated approach to ecological risk assessment is provided by Matsinos *et al* (1994). Again the risk assessment framework utilises a mixture of traditional toxicological approaches and population modelling. Rather than adopt a population wide perspective (such as that in Appendix D2), the assessment simulates a breeding colony of Great Blue Herons (*Ardea herodias*) as an assemblage of interacting individuals, thereby using an individual-orientated approach to assess the overall effects on the population following PCB contamination of the colony's habitat.

The basic risk assessment framework is illustrated in Figure D3.1, and comprises of the following sub-components:

1. an explicit landscape sub-model surrounding the colony representing a 10 km by 10 km area sub-divided into 25,600 cells, each containing information on elevation and water depth. The latter is allowed to vary to reflect rainfall patterns in the area;
2. a resource sub-model which controls the availability of fish in each cell. Herons can form flocks in each cell and thereby deplete its resources, however, fish are not permitted to disperse from one cell to another, empty cells are simply replenished after 2 to 3 days simulation;
3. a contamination profile of the landscape that assigns PCB concentrations to each cell on the basis of sample information collected at the Heron colony. Accurate estimates for all 25, 600 cells were not feasible and thus each cell was allocated a PCB concentration randomly drawn from a uniform distribution (0.03 – 0.08 ppm);
4. behavioural sub-models for both adult birds and nestlings consisting of more than 200 probabilistic and deterministic rules describing food searching strategies, foraging efficiency of adults, feeding of nestlings, energetics based on food consumption, the ways in which adults interact with their mates (during nest attendance, egg incubation, etc.) and other conspecifics (when to initiate a nest, how to join a flock, etc.); and,
5. a bio-accumulation sub-model for the uptake and body burden of PCBs in both adult birds and nestlings (due to piscivory), incorporating behavioural effects of PCBs on adult birds based on a simple dose-response relationship.

The success or failure of the colony is ultimately linked to the ability of adult birds to successfully forage and bring back adequate food to their nestlings during a critical period between the hatching of the eggs and fledging of the young herons. The model assumes that if the nestling does not receive enough food (estimated to be 14 kg of fish throughout the nesting period) at regular intervals then it does not fledge successfully. Importantly the model allows the assessment to investigate both the direct effects of PCB contamination (direct lethal effects in both adult and juvenile birds) but also the more subtle indirect effects (reduction of adult foraging efficiency) which may be more significant in terms of the assessment endpoint (the success of the colony).

The model simulation was run using 50 breeding pairs of Herons. In the first instance the model was run without including behavioural effects. The results suggested that no lethal concentrations accumulated in adult birds. Note that in the toxicological risk assessment paradigm this would be equivalent to saying that the toxicity quotient for acute toxic effect is less than one, indicating no effect.



(Source: Matsinos *et al*, 1994)

Figure D3.1 Object orientated risk assessment model for a Great Blue Heron colony

In the second instance the model was run with a simulated effect of PCB on foraging behaviour based on a linear dose response relationship resulting in a decrease in foraging efficiency at accumulated PCB levels in excess of 60 ppm. The results of this simulation clearly demonstrated the emergence of sub-lethal indirect effects that eventually cause colony failure because the nestlings are not fed adequately.

APPENDIX D4: Use of risk analysis to assess fishery management strategies: a case study using orange roughy on the Chatham Rise, New Zealand

Francis (1992) provides an excellent example of a quantified ecological risk assessment which addresses the likelihood of collapse of an Orange Roughy (*Hoplostethus atlanticus)* fishery subject to alternative fishing management strategies, expressed in terms of Total Allowable Catch (TAC), set from one year to the next.

In the methodology risk is expressed as the probability that the fishery would collapse within 5 years, where collapse was defined as the point at which the fishable biomass at the beginning of the fishing season falls to less than two-thirds of the TAC set for that season. The assessment centres around a deterministic, age-structured population model with the following parameters:

1. age of entry into the fishery (ie the age at which the fish are physically large enough to be captured);

2. the number of individuals recruited to the adult population from the larval phase;

3. total instantaneous mortality, expressed as function of natural and fishing mortality;

4. the fishable biomass, summed over von Bertalanffy's relationships describing the mean length of fish of a given age and the mean weight at that length; and,

5. the annual catch recorded from the fishery.

The risk assessment essentially consists of two Monte Carlo simulations. The first generates a probability distribution for the fishable virgin biomass (the biomass at the commencement of the fishery), whilst the second samples from this distribution for repeated iterations of the fishery model under alternative management strategies (ie different TAC's) and tracks the number of instances when the fishery is deemed to have collapsed.

Values of the virgin fishable biomass are obtainable from catch data recorded since the fishery officially opened in 1978 and trawl surveys. In particular maximum likelihood methods can be used to determine a point estimate for the most likely virgin biomass, $B\hat{}_0$, and the catchability constant q^ (relating the trawl survey indices to the absolute biomass), given historical catch and survey data. The statistical assumptions used in this were that each trawl survey biomass index, O_i, is normally distributed with expected value q times the true biomass, B_i, and that all biomass indices have the same coefficient of variation, c.

Uncertainty in the estimation of the fishery biomass through the use of survey trawls and in the parameters of the model used to generate the biomass history, requires that the virgin biomass (B_0) be properly represented through a probability distribution. The risk assessment, simulates such a distribution in the following manner:

1. choose a trial value for B_0;

2. run the fishery model with this value and generate a biomass history;

3. generate a simulated trawl survey index history assuming that the indices are normally distributed with mean value equal to corresponding value in the biomass history, and with coefficient of variation c;

4. calculate the maximum likelihood estimate $B\hat{}_{0sim}$ from the simulated trawl indices;

5. repeat steps 3 and 4 one hundred times and calculate the proportion p of the $B\hat{}_{0sim}$ that are greater than $B\hat{}_0$;

6. repeat steps 1 to 5 for a range of trial B_0 values; and,

7. graph p against the trial B_0 values and draw a smooth line through the points.

The line that results from step 7 is the estimated cumulative distribution function for B_0. In other words the height of the curve above any of the trial values of B_0 is an estimate of the probability that the true value of B_0 is less than this value. The derivative of the cumulative distribution function then gives the probability density function for B_0.

The author notes that the determination of the virgin biomass distribution function in this manner, only reflects error and uncertainty in the trawl survey biomass indices. In order to evaluate the effects of uncertainty in the population model parameters a sensitivity analysis was conducted to identify which of the model's parameters had the greatest influence on its results. The sensitivity analysis suggested that the greatest uncertainty in the model results was attributable to the variation in the value of natural mortality employed.

The risk analysis continues through a second Monte Carlo simulation as follows:

1. randomly choose a value of the virgin biomass B_0 from the probability distribution described above;

2. run the population model with this value up to the present using catch data to simulate fishing mortality, but holding the recruitment parameter constant from one year to the next;

3. continue the simulation 5 years into the 'future' allowing the recruitment value to vary as log-normal variable, setting the 'catch' for that anyone year to 1.3 times the value of the TAC selected for that year (to allow for overrun in the catch) or the catch obtained from applying a fishing mortality value of F = 1, whichever was the lesser; and,

4. repeat steps 1 to 3,200 times, estimating the probability of collapse as the proportion of these 200 runs in which the fishery collapses.

The results of the analysis demonstrate that the risk of collapse is strongly dependant on both the rate with which the TAC is reduced from one year to the next and the assumed overrun in the catch. Changes in the natural mortality rate (M), however, has relatively little effect on the risk of collapse as compared to the influence of this parameter in the original population model.

APPENDIX D5: Fisheries decision analysis: the Bayesian approach

A powerful yet potentially controversial example of Bayesian statistical inference within fisheries decision analysis is described by Hilborn *et al* (1994)[22]. The approach utilises Bayes theorem to express uncertainty associated with alternative hypotheses (in this context the value of an important parameter within the fisheries model) and the effect this has on the outcome of different management strategies (namely different quotas set for the fishery).

The authors detail a simple deterministic age structured population model for a New Zealand hoki fishery which commenced in 1972. The model requires the determination of recruitment at virgin biomass (R*), a parameter that describes the steepness of the Beverton-Holt stock recruitment curve (z), weight of fish by sex and age ($w_{s,\,a}$), vulnerability of the fish to the gear by sex and age ($v_{s,\,a}$), fecundity of female fish by age (e_a) and natural mortality rates by sex and age ($s_{s,\,a}$). With these parameters the model commences by specifying the virgin unfished stock size in 1971 (which is proportional to the value chosen for R*), running the model algorithms simulating one year in the fishery, subtracting the first year's observed catch in 1972 and updating the predicted biomass for 1972. This process is then continued on an annual basis to cover the entire catch history of the fishery. The simulation generates a predicted population age structure for each year of the fishery which can be quickly summed across cohorts to determine the predicted vulnerable biomass for any given year (V_y).

Additional information is available to the assessor at this point in the form of trawl survey data which provide values for the observed vulnerable biomass in the year that the survey was undertaken (O_y). In this example the authors assumed that the trawl surveys of the hoki stock (undertaken in 1984, 1989 and 1990) provide an absolute measure of abundance. They also assume that the observed index is lognormally distributed about the true abundance, for which the predicted vulnerable biomass is substituted, such that

$$O_y = V_y \exp(x_y) \qquad\qquad x \approx N(0, \sigma_x),$$

where σ_x is the standard deviation of the observation process. The deviation between the observed and predicted vulnerable biomass is

$$d_y = \log(O_y) - \log(V_y),$$

and the likelihood function[23] for the observed vulnerable biomass in any one year (y) is:

$$L(O_y / R^*) = \frac{1}{\sigma_x \sqrt{2\pi}} \exp\left(\frac{-d_y^2}{2\sigma_x^2}\right).$$

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[22] Strictly speaking this is not an example of a risk assessment, but rather of decision assessment. The step to risk assessment would be a relatively simple one, however, once an appropriate endpoint had been selected. It is included within this review because it provides a clear description of the Bayesian approach to risk assessment.

[23] When a mathematical equation, used to describe a probability distribution function, is instead regarded as a function of one or more parameters of the distribution function for a fixed value of the variate, it is termed a likelihood function.

Since the trawl survey observations from one year to the next are independent, the likelihood for all years taken together is simply

$$L(O/R^*) = \prod_y L(O_y / R^*) \quad .$$

In the discrete case, Bayes theorem states

$$pr(H_i / Data) = \frac{pr(Data / H_i) pr(H_i)}{\sum_{j=1}^{n} pr(Data / H_j) pr(H_j)} \quad ,$$

where pr(Data/H_i) is the probability of the data given the discrete hypothesis i, and pr(H_i) is the prior probability of hypothesis i. In this context the alternative hypotheses are the different discrete levels of R* and the probability of the data given the hypothesis is simply the likelihood L(O/R*). Much of the utility of the bayesian approach to fisheries decision assessment (and risk assessment) comes from the ability to explicitly allow for uncertainty in one or more parameters within the assessment methodology. In this example the authors adopted a simple deterministic approach for illustrative purposes, fixing all values within the population model except for R*. In the absence of any prior information regarding R*, the authors assume that all hypotheses (discrete values for R*) have equal probability and therefore propose a discrete uniform prior distribution; R* = U(500 000, 2 000 000) tonnes.[24] Since virgin stock size is proportional to R* the assumption of a uniform prior for R* is equivalent to a uniform prior for the virgin stock size.

The authors go on to illustrate the advantages of the Bayesian approach be evaluating the consequences of different management strategies (future quotas) across different possible states of nature (R*). The model was run for each year up to and including 2001, subtracting different fishing quota's from the previous year's predicted vulnerable biomass. The results were portrayed in terms of the ratio of the predicted biomass in 2001 to the virgin stock size for each discrete value of the posterior distribution function of R*, allowing the determination of the expected value of each of the quota policies. The authors conclude by suggesting that one of the key advantages of the bayesian approach is that additional complexity can be readily incorporated into the assessment by:

1. allowing other parameters within the model such as fecundity, mortality, etc. to vary in a Monte Carlo type simulation; and,
2. specifying prior distributions for these parameters and then running a higher dimension Bayesian analysis.

[24] Much of the controversy surrounding the application of bayesian techniques arises in relation to the form of the prior distribution. It is common in circumstances where the assessor claim no prior information to assume a uniform distribution, but if there is truly no prior information on what basis are the bounds of the distribution specified?