

Short Title: Biosecurity risk-assessment

Biosecurity and the role of risk-assessment

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Abstract

Since 1950, World Trade has increased 14-fold. In the same period, the number of biological invasions has increased exponentially. Risk-assessment is seen by many agencies, including the World Trade Organisation, as an objective and scientific way to manage the biological risks associated with international trade and domestic translocation of goods and people. Bio-invasion risk-assessment should serve three bio-security roles: identify bio-invasion hazards (vectors, pathways and invasive species); quantify invasion risks; and identify cost-effective management options by highlighting weak links in the invasion event chain. This paper argues that the framework developed by the Office International des Epizooties for animal imports is the most appropriate way to achieve this. This framework can be improved, however, by incorporating the rigorous hazard identification procedures developed for Quantitative Risk-assessment in complex industrial systems. The paper also suggests that good bio-invasion risk-assessments have clear endpoints, use rigorous inductive/deductive risk-assessment techniques, are hierarchical, make predictions that can be scientifically tested, and include a thorough analysis of uncertainty. These arguments are illustrated using the ballast-water risk assessment developed for the Australian Quarantine and Inspection Service. The paper examines nine other examples of bio-invasion risk-assessment used by various authorities to manage the importation or translocation of plants, animals and ballast-water are assessed. Many of these are qualitative, highly subjective and ignore the multiple-species hazard associated with the pathway or commodity in question. As a result, the assessment is far from objective or scientific and therefore vulnerable to other political or economic imperatives.

Keywords: Bio-invasions, quantified risk-assessment, vectors, pathway analysis

INTRODUCTION

In December 1999 the world's economic ministers met in Seattle, at the third ministerial meeting of the World Trade Organisation (WTO), to develop the latest trade rules for the global world economy. The meeting failed to achieve this, in part because of the unprecedented protests from a variety of interest groups worried about the social, economic and environmental impacts of free trade. Protest that have since been repeated in Melbourne, Australia and Genoa, Italy.

One of the most immediate environmental impacts of trade is biological pollution – the introduction of non-native or “exotic” plants and animals. Since 1950, world trade has increased 14-fold [1]. In the same period the number of biological invasions in terrestrial, freshwater and marine habitats has increased exponentially [2,3]. Biological invasions are one of the most serious ecological problems of the early 21st century – and the trade policies of the new global economy are an unwitting contributor to this problem.

The environmental implications of global trade were recognised, albeit indirectly, at the inception of the General Agreement on Tariffs and Trade (GATT) in 1947. The World Trade Organisation recently re-visited the question of trade and the environment in its fourth special studies report [1]. The report notes that trade threatens biodiversity because of habitat destruction (principally logging) and biological pollution. Curiously it ignores biological pollution in its subsequent deliberations. Furthermore the report does not examine the conflict that arises between global trade agreements and a nation's environmental autonomy – its ability to protect its own native fauna and flora – nor how this conflict is best managed.

Article XX of GATT 1947 allows countries to ignore normal trading rules in order to protect human, animal or plant life or health, provided that such measures do not discriminate

between sources of imports or constitute a disguised restriction on international trade. These provisions have been replaced, at least for bio-security purposes, by the agreement on Sanitary and Phytosanitary Measures (the “SPS Agreement”), negotiated in 1994 at the end of the Uruguay round of multilateral negotiations. The SPS agreement allows countries to enforce measures to prevent the spread of plant-, animal-, or other disease agents, and to prevent or control the spread of pests. These measures, however, must be based on scientific justification or on an “objective” assessment of the risks to human, animal or plant health [4]. In 1997 the International Plant Protection Convention (IPPC) was revised in line with the SPS agreement.

The SPS agreement and the IPPC, however, are just two - albeit prominent - examples of how risk-assessment is being used to manage bio-security issues. Various other policies and agreements also rely on risk-assessment to manage the bio-invasion risk associated with the movement of goods and people, both internationally and domestically. The purpose of this paper is to examine the process of bio-invasion risk-assessment and some of the problems associated with this process. The paper looks at ten examples of bio-invasion risk-assessment, that are, or have been, used to manage the translocation of various commodities, and ends by asking whether bio-invasion risk-assessment, as currently practised, is up to the job.

RISK-ASSESSMENT AND PATHWAY ANALYSIS

Risk-assessment should contribute to pathway analysis and bio-security in three ways: it should identify hazards, quantify risks and help identify management options and strategies.

First steps

Bio-invasion risk-assessment is just one step in a wider process designed to maintain a nation's bio-security. The assessment usually takes place before the commodity in question arrives at the border and is generally applied to the "pathway" (Figure 1). Here pathway refers to the way in which biological pollutants – exotic plants and animals – are translocated within a nation, or delivered to a nation's doorstep.

The risk-assessment is usually predictive (performed before the commodity is expected to arrive) but could also be applied retrospectively (subsequent to an invasion in order to identify the most likely pathway). Before starting a bio-invasion risk-assessment the analyst must decide:

- which framework to adopt – such as the "chain of event" model recommended by the Office Internationale des Epizooties (OIE) [5,6], the United States Environmental Protection Agency (USEPA) framework for ecological risk-assessment [7,8] and an assortment of others (reviewed in [9]);
- which approach to adopt – are there enough relevant data to take a deductive "accident statistic" approach to risk calculation? Will the analysis be inductive and model-based, or a mixture of both?
- which metric to adopt – will the risk-assessment be qualitative, semi-quantitative, fully quantitative or a mixture of some or all of these? and,

- which process to adopt – will panels of experts conduct the risk-assessment or will the risk calculation be automated?

Each of these decisions has a strong bearing on the risk-assessment process. A panel of experts cannot be expected to make daily multiple assessments – these must be automated. Qualitative risk-assessments, however, are not well suited to automation – there is usually too much uncertainty and too many permutations. For example, the United States Department of Agriculture pest risk-assessment process [10] scores seven components of the bio-invasion process as “high”, “medium” or “low”, and allocates one of five uncertainty codes to each score. The total number of permutations in the risk calculation is $(3 \times 5)^7 = 1.7 \times 10^8$ – clearly a difficult procedure to automate.

Identify hazards

Hazard identification is the critical step in risk-assessment – hazards that are not identified are not assessed so risk is underestimated. Biosecurity hazards can be broadly classified into three groups: vectors, pathways and species. In most situations one or more of these is known a priori – usually the vector (e.g. salmon imports, shipping, live bait). The pathway(s) associated with the vector and the species hazard is usually more difficult to identify.

In the first instance, multiple pathways are often associated with single vectors both pre- and post-border (Figure 1). Shipping is the principle vector responsible for transmitting marine pests around the world. The main pathways of this vector are ballast-water and hull fouling [11-14], but there at least nineteen possible (pre-border) pathways on a typical ship [15]. Similarly, the Australian import risk analysis for non-viable salmonids [16] identifies at least seven possible (post-border) pathways for contaminated salmon (Figure 2).

Secondly, most risk-assessments define only those pathways associated with the planned event-chain for the commodity concerned. Accidents during the event chain may introduce new pathways or change the significance of the usual ones. The situation is made still more complicated if multiple species are associated with a vector and/or pathway. Bio-security hazard assessment must therefore identify the complete vector/pathway/species set. In effect the hazard assessment must define the ‘mechanics’ of the invasion process – which species might invade and exactly how they could do this.

Leaving aside the problem of the species for the moment, there are several techniques for predicting how they could invade. These techniques are, broadly, deductive or inductive. Deductive techniques simply record what has happened in the past and are usually implemented through:

- a checklist; or,
- unstructured brainstorming.

Deductive hazard-identification appears to be the norm for bio-security risk-assessment. The techniques are simple and easy to implement, but may mislead the analyst into believing, without confirmation, that all hazards have been identified. Deductive techniques, by their very nature, will capture only those events that lie within the professional experience of the assessor(s). Alternatively, inductive techniques could include:

- logic tree analysis – fault tree and event trees
- hazard and operability studies or HAZOP [17]; and,

- failure modes and effects analysis [18].

These techniques were originally developed in an industrial context, usually as the first step in a quantitative risk-assessment, and have been successfully used for many decades. They are successful because they are logical, rigorous and systematic, and make no prior assumptions about the likelihood of hazardous scenarios. They are therefore an excellent way to identify plausible, but improbable, events that may be overlooked by deductive approaches because they are not within the analyst's professional experience. It is rare, however, to see these techniques used in a bio-invasion or ecological risk context. A notable exception is GENHAZ – a HAZOP analysis for genetically modified organisms [19], and the fault-tree analysis developed for AQIS's ballast-water risk-assessment [20].

Quantify risks

Risk is a function of the likelihood and consequences of undesired events. In a bio-security context the undesired event is biological pollution. The second role of bio-invasion risk-assessment is, therefore, to quantify the likelihood and consequences of biological pollution. Quantitative risk-assessments for biological stressors, however, are notoriously difficult [21, 22] so most assessments address these issues qualitatively (see below). Analysts usually reject quantitative techniques because the problem is too complex or because reliable data too few.

It would be unduly pessimistic, however, to believe that qualitative risk estimates are the best that bio-invasion analysts can hope to achieve. Bio-invasion pathways usually involve several steps – infection, entry, survival, establishment and/or dispersal, and impacts. The uncertainty associated with each step increases from left to right, ie from infection to impacts.

Quantitative probabilistic techniques become increasingly inappropriate as one moves from

low to high uncertainty [23]. It may not be necessary, however, to quantify all of the steps in the invasion sequence. For species that are *a priori* pests, with a well-documented impact history, quantified estimates of inoculation (ie all those steps up to and including survival in the recipient area) may be sufficient from a risk manager's perspective. Alternatively the analyst could adopt quantitative methods as far as possible, and only use qualitative approaches for higher order events such as establishment and dispersal.

Quantitative risk-assessment techniques can (again) be broadly classified as deductive or inductive. Deductive techniques use an “accident-statistic” or frequentist approach to calculate probability. For example Cohen and Carlton [24] report interceptions of the Chinese mitten crab *Eriocheir sinensis* at San Francisco airport (hand-carried by disembarking airplane passengers). It is possible to establish the probability of entry via this pathway by comparing these figures with total passenger numbers over an equivalent period. These figures will help predict future arrival rates so long as the conditions under which they were collected (e.g. flight patterns, market price of the crabs) remain broadly the same.

The alternative inductive approach models some or all of the steps in the invasion chain. These models can range from simple point estimates – such as the efficacy of evisceration on reducing the risk of importing contaminated salmon [25] to complex ecosystem models – such as that used to investigate the impacts of *Mnemiopsis leidyi* in the Black Sea [26]. Variability is usually propagated through these models by describing statistical distributions for important model parameters and using Monte Carlo simulation techniques to sample from these distributions [27, 28].

Quantitative risk estimates have the following advantages:

- they allow proper, probabilistic expressions of variability;
- they quickly identify what is unknown - by just “doing it” the assessor(s) is forced to think very hard about what is and isn’t known about the bio-invasion process;
- they are well suited to an iterative assessment cycle - calculate risk, collect data, ground-truth predictions, refine models, and re-calculate risk;
- they are amenable to the scientific method; and,
- they can be used to compare alternative management strategies through a risk-benefit analysis.

Quantitative assessments are amenable to scientific scrutiny because their predictions are testable – for example the predicted number of infected animal units per import tonne can be tested through routine sampling. Indeed continual monitoring, surveillance and ground-truthing should be an essential component of any ecological risk-assessment, quantitative or otherwise. Quantitative risk estimates, however, are not necessarily “objective”. Subjective probability-elicitation techniques are (and should remain) an important tool in the risk analyst’s toolbox [29]. Furthermore important subjective judgements are involved in all quantitative risk-assessments – all probability-based inferences rely on a statistical model, but the choice of model is largely subjective. Even the simplest hypothesis test involves fundamentally subjective choices about the design and duration of the experiment [30]. The strength of quantitative risk-assessment, as in science, lies not in its objectivity but rather in the way it exposes subjective input.

Managing risk

Bio-security ultimately aims to eliminate and contain (or slow the spread of) established pests, and to slow the rate of new invasions. In its third role, bio-invasion risk-assessment is a management tool to assist this process. In this role the risk-assessment should:

- help identify weak links in the invasion chain;
- identify where further data collection would improve the risk assessment;
- identify the management options with the greatest benefit/cost ratio; and,
- quantify the probability of the management strategy failing, perhaps as part of a formal management strategy evaluation [31].

The weak link in an invasion chain is the step with lowest probability of success.

Management strategies aimed at barring or slowing this step are likely to return good cost benefit. In this context it is important to emphasise that, even if risk-assessment fails to eliminate biological invasions (which it inevitably will do), slowing the rate of invasions or spread of an established pest has considerable value [32].

TEN EXAMPLES OF BIO-INVASION RISK ASSESSMENT

Table I summarises ten examples of bio-invasion risk-assessments that are used by various regulatory agencies to manage imports or translocations of one kind or another. Most bio-invasion risk-assessments are based on, or mirror, the OIE's "chain of events" framework. This framework views bio-invasion 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. The overall probability of success - ie invasion – is the product of the probabilities assigned to each step in the event chain.

The OIE framework is simple, effective and approaches bio-invasions from the perspective of the invading species. The framework's efficacy can be improved, however, by incorporating basic tenets of the Quantitative Risk-assessment (QRA) paradigm. The QRA paradigm consists of five steps: hazard identification, frequency assessment, consequence assessment, risk calculation and uncertainty analysis. It was originally developed for complex industrial systems, but its techniques can be applied equally well to complex ecological systems.

For example, Australia's policy for translocating live aquatic organisms [33] is largely based on the OIE framework but also borrows from the QRA paradigm - distinguishing between the frequency of undesired events and their consequences. The policy addresses three events in the bio-invasion chain: escape/release, survival and establishment. The assessment is qualitative, at least in the first instance, and asks questions to determine the likelihood of escape or release. The assessment then considers the consequences of release. The next set of questions determines the likelihood of survival followed by the consequences of survival, and finally the likelihood and consequences of establishment. The question sequence emphasises that the consequences at one step in the bio-invasion event chain (which species escape, at which life-stages, how many individuals, when and where) are intimately linked to the

likelihood of success at the next step (will these individuals survive), which in turn determines the consequences at the next step, and so forth.

With one exception, all of the bio-invasion models summarised in Table I are species-specific, meaning that each is applied on a species-by-species basis. The one exception is the Queensland Ports Corporation ballast-water risk-assessment [34]. This is based on the environmental similarity between the donor and recipient ports, as measured by 40 environmental variables. Carlton *et al* [15] develop a similar, but much simpler, approach based purely on comparing the salinity of ballast-water to that of the recipient port.

Bio-invasion risk-assessments based on environmental comparison avoid the question; “which species will be the next invader?” They are therefore well suited to a translocated habitat or environment containing a multitude of species (eg ballast-water, the soil of a pot plant, consignment of Siberian timber, etc.). This approach assumes that the likelihood of invasion is directly proportional to the biophysical similarity between donor and recipient environments. As a first step in the risk-assessment process this is a useful approach, but as a stand-alone assessment it is seriously flawed. Notwithstanding the difficulties of measuring biophysical similarity, this approach is virtually impossible to improve empirically [35] and is not conservative for species with broader environmental tolerances than their current range. The water hyacinth, *Eichhornia crassipes*, is a spectacular example of the inability of environmental-matching to predict the future range of an invading exotic [36].

Seven out of the ten assessments summarised in Table I calculate risk with the aid of an expert assessor or panel review. Three of these assessments are qualitative – in each case the assessor(s) must answer a series of questions about the species concerned and its ability to survive and reproduce in the recipient environment. The other four are mixed

qualitative/semi-quantitative – the assessor assigns scores to a similar series of questions.

Qualitative and semi-quantitative assessments are attractive because they are flexible – they can be applied when data are scarce, and are easily modified to the particular circumstances of the assessment. Risk-assessment, however, is all about uncertainty – indeed this is what distinguishes it from environmental impact assessment. Uncertainty in a risk-assessment takes many forms [37 – 39], the most important being variability (a characteristic's true heterogeneity) and epistemic (our incomplete knowledge of the system in question).

Qualitative and semi-quantitative risk-assessments do not address either of these very well.

Three approaches are typically adopted:

- uncertainty is not formally addressed in the assessment procedure – a high-risk status is (presumably) assigned to the species or commodity if there is insufficient information to allow a reasonable assessment, but this is entirely at the discretion of the assessor(s). Examples include Australia's translocation policy and the Schedule 6 assessment procedure (Table I);
- the assessment is inherently conservative – a high-risk status is automatically assigned to the species or commodity unless there is sufficient information (as judged by the assessor) to indicate a low invasion risk. Examples include the expert system for screening alien plants in the South African fynbos [40] and the AQIS weed risk-assessment [41]; or,
- the assessment includes a qualitative or semi-quantitative description of uncertainty – the assessor(s) describe, score or rank their level of uncertainty with each question, which is then accounted for in the final risk calculation. Examples include the review

and decision model for introductions of aquatic organisms [42] and the generic aquatic-organisms risk analysis review process [10].

Clearly none of these approaches is “risk-assessment in the sense of explicitly characterising the probability of populations or communities [of organisms] becoming impaired” [43].

Furthermore the assessments are scarcely “objective” and are difficult to justify scientifically because they do not (usually) make testable predictions. The AQIS weed risk-assessment is possibly an exception; the procedure was empirically tested against 370 known invasive weeds in Australia. The assessment’s decision boundaries (accept/evaluate/reject) were then manipulated to ensure all serious weeds were rejected, while the number of further evaluations and useful plants rejected were minimised. Although not a scientific hypothesis test, it does introduce some empirical rigour that is usually lacking in qualitative/semi-quantitative assessments.

Three out of the four quantitative or semi-quantitative assessments summarised in Table I automate the risk calculation. Of these the New Zealand import health risk analysis [44] and the AQIS ballast-water risk-assessment [45, 46] are the most sophisticated. The former uses a mixture of deductive and inductive techniques to quantify the risk of introducing *Aeromonas salmonicida* into New Zealand with salmon imports. Figure 3 summarises the risk-assessment procedure, illustrating the OIE chain of event model, and the analysis conducted at each step of the event chain. Figure 4 summarises the AQIS ballast-water risk-assessment, which again emulates the OIE framework. The assessment is entirely inductive, however, because the lack of data on species assemblages in specific ballasting conditions, or on the frequency of successful inoculation or establishment, does not allow a deductive approach.

Ballast-water example

The AQIS ballast-water risk-assessment is based on the OIE framework - ballast-mediated invasions are viewed as a sequential chain of events (Figure 4). The risk-assessment, a central component of the ballast water Decision Support System implemented by the Australian Quarantine and Inspection Service on the 1st July 2001, was designed to deliver species- and vessel-specific risk estimates, on a per vessel-visit basis. For this reason the assessment had to be automated.

The assessment uses a relatively low-order endpoint – survival in the recipient port – to maintain a reasonable bound on uncertainty, and defines ballast-water risk as

$$\text{Risk}_{\text{species}} = p(\omega) \cdot p(\phi) \cdot p(\psi) \cdot p(v) \quad ,$$

where $p(\omega)$ is the probability that the donor port is contaminated with the species in question, $p(\phi)$ the probability that the vessel becomes infected with this species, $p(\psi)$ the probability that the species survives the vessel's journey, and $p(v)$ the probability that the species will subsequently survive in the recipient port.

The assessment is inductive, modeling each step in the invasion chain via discrete modules.

The assessment is also hierarchical, allowing increasingly accurate risk estimates to be made when more data are made available to the analysis.

Identify hazards

The ballast-water risk-assessment borrows two hazard identification techniques from the QRA paradigm: fault-tree analysis and HAZOP analysis. Fault trees identify the chain of events that lead to hazardous occurrences – in this instance vessel infection. Hazard and Operability analysis (HAZOP) uses guide words to test the effects of deviations in the process of intent –

in this case port-based processes (environmental and anthropogenic) that might invalidate the predictive algorithms in the assessment.

Figure 5 illustrates the start of the fault-tree analysis completed for the risk-assessment (refer to [20] for the complete tree). The analysis helped identify 10 vessel-infection scenarios, which are mutually exclusive for the life-stages of most species (ie each life-stage falls into one or other of the infection scenarios). The infection scenarios are defined by the habitat of the life-stage (water column, soft/hard substrate or epiphyte) and its infection characteristics (planktonic, tychoplanktonic², neustonic, vertical migrator and floating detached) (Table II).

The HAZOP analysis is designed to highlight environmental and anthropogenic activity in a port (donor and recipient) that may not be captured by the risk-assessment models. Bio-invasion processes are very time-dependent. Carlton [47] makes this point well, listing six scenarios that can change an unsuccessful process to a successful invasion, including environmental changes in existing donor regions and recipient regions (eg donor and recipient ports) and dispersal vector changes. A fault-tree analysis, however, does not capture time-dependent variables very well. A more creative and open-ended approach, such as HAZOP, could help here. Table III, for example, shows the start of a possible HAZOP analysis for port-based processes. By applying guide words such as “more”, “less”, “none”, etc. to the main environmental variables, such as temperature and salinity, the analysis forces the assessor to consider whether deviations from the “typical” conditions could occur, and/or the extent to which these deviations are adequately described by existing data sets. This approach, however, is yet to be tested on an actual port.

² Meaning false plankton – organisms that ordinarily reside on or in hard or soft substrate but get swept up into the water column by tidal currents, waves, ship’s propellers, etc.

In the AQIS ballast water risk assessment the species hazard is defined a priori – the risk-assessment is applied to a target list of species that are known to be marine pests in their native or introduced range. The assessment is currently limited to these species. It can, however, be applied to any species provided certain data requirements are met. The assessment does not, however, identify potential pests amongst the many hundreds of species that are daily transported around the world in ballast-water, and does not therefore calculate the risk of introduction for these species.

Quantify risks

The ballast-water risk-assessment attempts to quantify four steps in the bio-invasion process, up to and including survival in the recipient port (Figure 4). The probability of donor port infection is based on the results of port surveys and the attendant probability of Type II error – ie the species is not detected by a survey but is in fact present [46]. The infection status of ports that have not been surveyed is inferred from the infection status of the bioregion in which the port is located, and the native and/or introduced range of the species concerned.

The ballast-water infection scenarios identified in Table II are used to model the probability of vessel-infection with any life-stages of the species concerned. The framework is hierarchical. In the first instance it uses simple models for each step of the invasion process and maintains conservative assumptions if anyone of the steps cannot be quantified. For example it assumes that the probability of vessel infection is “1” if the requisite data is unavailable. More sophisticated models are used when more data becomes available. In this way several levels or tiers of assessment can be made, each progressively more accurate with increasing data.

A Bayesian journey-survival model is used to quantify the analyst’s uncertainty about the species’ life expectancy in the ballast-tank, and hence the probability that the species will

survive the journey [29]. Figure 6, for example, shows the posterior distribution function for the life expectancy of the larval life-stages of *Asterias amurensis* based on samples taken onboard the *MV Iron Sturt* during voyages in south east Australia (CSIRO, unpublished data). The probability of journey survival $p(\psi)$ is given by the probability that the species life expectancy equals or exceeds the vessel's journey duration (days).

Finally the probability of survival in the recipient port is calculated by comparing kernel density estimates or extreme-value distributions of temperature and/or salinity in the recipient port with the temperature and/or salinity tolerance of the species concerned. Figure 7, for example, shows the kernel density estimates for maximum sea-surface temperature in Hobart and Sydney in January 1994. A kernel density is a non-parametric estimate of a probability distribution function – in this instance the probability of sea surface temperature – and can be used to provide a direct estimate of survival probability $p(\nu)$. The kernel densities shown in Figure 7 were constructed using the Epanechnikov kernel and an “automatic” bandwidth (see [46] for further details).

Managing risk

Of 32 ballast-water and sediment management options, only one - ballast-water exchange - is widely practised by the shipping industry [15]. If alternative management strategies are practised in the future, then it is unlikely that anyone option would be the most appropriate for all vessels on all routes. Future management options might be adopted in one of two ways:

- on a bio-region to bio-region basis – for example all ballast translocated between bio-regions North-South of the equator, or on the Western/Eastern margins of continents, that are environmental similar but biologically distinct, might be more stringently controlled; or,

- on a vessel-, tank- and species-specific basis – for example some of the ballast translocated on a domestic voyage might be controlled to avoid the further spread of an established marine pest.

The AQIS ballast-water risk-assessment allows management options to be directed at specific vessel- or route-hazards, and also identifies where best to break the event chain. For example a simple demonstration project [46] illustrates that with species that have resistant diapause life-stages (such as the cysts of *Gymnodinium catenatum*) appreciable risk reductions can only be achieved by avoiding vessel infection. In this case the management strategies applied at the donor port are likely to provide the best cost-benefit ratio. Alternatively, with species that have relatively delicate larval life-stages (such as *Asterias amurensis*) appreciable risk reductions can be achieved by enhancing the natural mortality that occurs in the ballast tank, particularly on long journeys. In this instance management strategies applied en-route might prove the most cost-efficient.

DISCUSSION

Bio-security risk-assessment faces at least three important problems: the “which species” problem; the “fire-fight” problem; and the problems associated with a lack of data.

Which species

While environmental-match assessments are a useful measure of bio-invasion hazard, effective bio-invasion risk-assessment must be species-specific [35]. For pathways that can deliver multiple species this raises two questions:

- which species might be on the path at any given time; and,
- on which species should the analyst conduct the risk-assessment?

The easiest way to identify the species on a path is to wait, observe and record what happens. This is simple, rigorous and effective, but hardly proactive or precautionary. Invasion biologists have traditionally listed the characteristics of successful invaders (those species that make it to the end of the bio-invasion event sequence - see for example [48, 49]). Recording the species that are present at each step of the bio-invasion event sequence (not just the end), and listing their biological characteristics relative to the characteristics of the pathway, would undoubtedly shed some more light on this problem. The analyst could gain further predictive insights by also exploring the invasion “mechanics” of a particular pathway, using the hazard analysis tools discussed above. Taken together, these approaches would help identify what types of species are likely to be present in a given pathway and why.

The next question is which species to conduct the risk-assessment on. The risk analysis guidelines published by the OIE [6] give no guidance here. Some authors suggest that the risk-assessment need only be conducted on the species that is most likely to be introduced, reasoning that if the risk is negligible for this species, then the overall risk is negligible [25]. In practice, however, this approach is likely to be quickly rejected by stakeholders opposed to the pathway.

The FAO guidelines for pest risk analysis [50] state that all pests that are likely to follow a pathway should be listed, but only “quarantine pests” should be subject to a detailed risk-assessment. Quarantine pests are defined as a pest of potential economic importance to an area, and either not yet present there, or present but not widely distributed (and subject to official control). AQIS apply the following criteria to distinguish quarantine pests from pests – a species (disease agent in this context) is only considered in the risk-assessment if:

1. it is infectious; and,

2. a) exotic to Australia, or
 - b) present in Australia but subject to official control; and
3. a) OIE listed and/or
 - b) would be expected to cause significant harm in Australia [16].

If there are a large number of species that satisfy these criteria, then they are usually prioritised in some fashion. The AQIS salmon-import risk-assessment, for example, considers only the disease agents of salmon with a Humphrey score greater than 21 (with a few exceptions). The Humphrey Score is the sum of the individual scores allocated by the analyst to the pathogenic significance, potential for international spread, potential for entry and establishment in Australia, socio-economic and ecological consequences, and difficulty of control or eradication, of each disease agent [51].

The FAO guidelines clearly envisage risk-assessments for multiple species. In practice, analysts may have difficulty in deciding whether a species is a quarantine pest; for example, they may not know whether the species is exotic or endemic (see lack of data below). But the fundamental problem with this approach is that qualitative (and semi-quantitative) risk-assessments cannot provide overall measures of pathway risk for multiple species. If the probability of success at each step in the bio-invasion event chain is independent (in a statistical sense) from species to species, then the overall pathway risk is given by

$$\text{Risk}_{\text{pathway}} = 1 - \prod_{i=1}^n [1 - \text{Risk}_{\text{species } i}] ,$$

which is approximately equal to

$$\text{Risk}_{\text{pathway}} = \sum_{i=1}^n \text{Risk}_{\text{species } i}$$

for species $i = 1$ to n when the species risk is small. But how does one sum qualitative or semi-quantitative expressions of species risk in a meaningful way? How many “negligible risks” sum to a “moderate risk”? This question cannot be answered in a qualitative fashion and therefore is usually ignored in most bio-invasion risk-assessments.

The United States Department of Agriculture adopt an interesting approach to the problem. The import risk-assessment for Monterey pine from Chile [52] recognises that basic biological information is unavailable for many of the insect and fungi associated with the Chilean timber. However, by developing a detailed risk-assessment for pests that inhabit each of the timber’s niches (the bark surface, the inner bark, the sapwood and the heartwood), the analysts hoped to develop effective mitigation measures that would eliminate the known pests and the unknown organisms that inhabit the same niche. In effect, the analysts advocate a guild or functional group approach to risk-assessment, which may help with the “which species” problem.

A guild is a group of species that exploit the same resource in a similar way [53]. Guild theory suggests that species that utilise the same resource have similar diets, are found in similar habitats and behave in a similar manner. The theory has been advocated as a useful tool for environmental impact assessment – actions that affect one member of a guild should affect all members similarly [54], and as a means of defining exposure in (chemical) ecological risk-assessment [55].

A functional group is similar to, but broader than, a guild. A functional group is made up of species categorised by body plan (anatomical and morphological), behaviour or life history,

whereas a guild is defined purely on the basis of resource use. Functional group ecology has been used to understand and predict how terrestrial plants disperse, establish and persist [56], to categorise the response of marine algae to disturbance [57] and to define the dynamics of freshwater streams [58]. As a risk-assessment tool, however, this approach does not appear to have been explored much.

A risk analyst might use functional groups or guilds in two roles - to identify the types of organisms that might occur in a pathway, and to manage these organisms. Table II, for example, identifies ballast-water infection scenarios based largely on the habitat and behaviour of the life-stage concerned. Species that share these habitat and behavioural characteristics will infect vessels in a similar way. One might therefore expect similar infection probabilities for all species within the functional group. Thus the analyst might define functional groups on the basis of the infection characteristics of a species – how does a species join a pathway and where in that pathway does it reside. From here the analyst might define management strategies aimed at preventing a functional group from either joining the pathway or remaining viable within it, as suggested in the import risk-assessment for Monterey pine.

The functional group or guild approach is probably less useful, however, when it comes to quantifying the likelihood or consequences of invasion. The probability of invasion is intimately linked to very specific species/life-stage characteristics. Subsuming these characteristics within a higher ecological unit (functional group or guild) may not allow quantitative expressions of invasion probability, but should at least identify effective risk-mitigation strategies.

Lack of data

Good data are fundamental to bio-invasion risk-assessment. Invasion success is a function of species, pathway and site attributes. Any assessment of bio-invasion risk, particularly quantitative, is unlikely to be successful in the absence of detailed information on each of these attributes.

Species information is particularly problematic in this regard. Cummins [58] noted that so long as the species is the fundamental ecological unit, the perpetually incomplete state of our taxonomic knowledge would constitute a major constraint for the development of ecological theory. Twenty-six years later, incomplete bio-systematic data still remains a major constraint for bio-invasion risk-assessment. The problem is particularly acute for microbial species such as bacteria, fungi and viruses. For example, less than 10% of the native Australian mycoflora have been identified and described [59]. A functional group or guild approach might help here, but the probability of invasion success, and its consequences, remains fundamentally a species-specific problem. Bio-systematic research is still, therefore, an important component of a good bio-security strategy (Figure 1).

To some extent the analyst can handle data availability, or the lack of it, through a hierarchical or tiered risk-assessment framework. The lower tiers of a risk-assessment should be protective (risk averse) and use conservative assumptions; the higher tiers should not be accessed unless certain data requirements are met, as in the ballast-water risk-assessment described above. This approach allows a progressively more “accurate” assessment of risk as more data become available to the analyst, thereby embodying the precautionary principle [60]. A hierarchical risk-assessment penalises data gaps, but provides risk-reduction rewards for additional data collection costs. This should provide an incentive for the proponent of the

activity or import in question to shoulder this cost and supply the requisite data – a sort of “polluter pays” principle.

It is apposite to note here that Article 5.7 of the SPS agreement allows members to adopt provisional sanitary measures on the basis of available information if the scientific evidence is insufficient. Members must, however, obtain the necessary information for a more “objective assessment of risk” within a reasonable period of time. In practice, trade sanctions imposed on the basis of a low-tier conservative risk-assessment are likely to be quickly challenged within the WTO as being unscientific. Furthermore, it is not entirely clear from the wording of the SPS agreement who should pay to obtain the necessary information.

De facto fire fighting

Risk-assessment, as with any management strategy, will not completely eliminate biological invasions – species will continue to slip through the net. Environmental managers will inevitably find themselves “fighting fires” – having to deal with exotic species within their national boundaries. The solution here is to fight spot-fires – manage the invasion as early as possible. Border surveillance, rapid-response and pre-defined eradication/containment strategies are therefore critical to successful bio-security – a fact long recognised by veterinary science. For example, in Australia, the procedures, management structures and job descriptions in the event of a terrestrial or aquatic animal disease emergency are already well established within AUSVETPLAN [61] and AQUAVETPLAN [62] respectively. An emergency marine pest plan is currently being drafted along similar lines.

It is also important to carefully record which species slip through the net, how and why. This information will eventually form the empirical databases that allow deductive approaches to risk-assessment (and should provide important clues to the functional group analysis

discussed above). Again, veterinary science provides a precedent; for example the *World Animal Health* database, maintained by the OIE, contains information on the number of herds and average herd size of cattle, etc, in nations around the world, together with reported outbreaks of certain notifiable diseases. This type of information is an essential component of the quantitative import risk-assessments for animals and animal products [5].

SUMMARY

A good bio-invasion risk-assessment will have the following characteristics:

- clear endpoints and well-defined boundaries that are sufficiently relevant from a policy perspective, but simple enough to minimise uncertainty in the overall risk estimate;
- rigorous inductive and deductive risk/hazard assessment techniques , particularly as applied to hazard identification;
- hierarchical or tiered structure to allow increasingly accurate risk estimates as more information becomes available;
- make predictions through-out the bio-invasion process that can be scientifically tested; and,
- include a good analysis of variability and epistemic uncertainty.

It appears, however, from a limited review of the literature, that few bio-invasion risk-assessments exhibit all (or indeed any) of these characteristics. A large number of bio-

invasion risk-assessments are qualitative, often because there are insufficient data to conduct a quantitative assessment. These assessments usually have the following characteristics:

- they are subjective;
- they do not tackle uncertainty or tackle it poorly;
- they cannot address multiple risk sources; and
- they do not make predictions that can be scientifically tested.

As a result, these assessments are easy to challenge and are therefore vulnerable to other political or economic imperatives. In the Canadian salmon case, Australia's ban on salmon imports was deemed unjustified on the basis of the available scientific evidence [63]. The qualitative risk-assessment that subsequently allowed salmon imports [16], however, is no more "objective" or scientific than the qualitative assessment [64] that originally supported the ban, and does not appear to contain any substantially new evidence. It appears the decision to allow Canadian salmon imports into Australia was based on economic or political imperatives rather than on an assessment of the biological risk. Although the quantitative assessment conducted by New Zealand [44] may have influenced this decision.

Qualitative assessments *per se* are not bad, but often they are not sufficiently rigorous or scientific to stand up to the economic and political realities of the global world economy. Quantitative risk-assessments are generally more robust, but concomitantly much more difficult to perform – particularly in data-scarce situations. If relevant data truly is scarce, however, one wonders how any risk-assessment, qualitative or otherwise, can be seen as objective and scientific. In other words for some pathways and commodities, bio-invasion

risk-assessment, as a discipline, is not sufficiently mature for the role that, for example, the WTO demands of it. There are two solutions to this problem – manage biological pollution in another way or invest in the science of bio-invasion risk-assessment.

With respect to the latter solution, there are a number of useful avenues that might be explored, notably:

- develop the deductive science – surveillance, monitoring and reporting of species at all stages of the bio-invasion process should be made part of the iterative cycle of bio-invasion risk-assessment;
- develop the inductive science – quantitative models that make scientifically testable predictions should be encouraged, together with rigorous hazard identification techniques such as those developed for complex industrial systems;
- individual nations should share species and environmental data in databases that can be accessed internationally, specifically for the purpose of assisting quantitative bio-invasion risk-assessment;
- bio-systematic research should continue to be funded as an important component of any bio-security strategy; and,
- rapid-response strategies should be developed to deal with the inevitable incursions of pests.

There are precedents in each of these areas, particularly in the databases and emergency response strategies of veterinary science. The challenge is to develop these areas in a

systematic and coordinated fashion for all commodities and processes where risk-assessment is used to manage biological pollution.

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Table II Ballast-water infection scenarios used to model vessel-infection in the AQIS ballast-water risk-assessment

| | PLANKTONIC | TYCHO- PLANKTONIC | NEUSTONIC | VERTICAL MIGRATOR | FLOATING DETACHED |
|-----------------|------------|----------------------|-----------|----------------------|----------------------|
| WATER COLUMN | | | | | |
| SOFT | | | | | |
| HARD | | | | | |
| EPIPHYTE | | | | | |

Table III Example of a HAZOP analysis for port-based processes

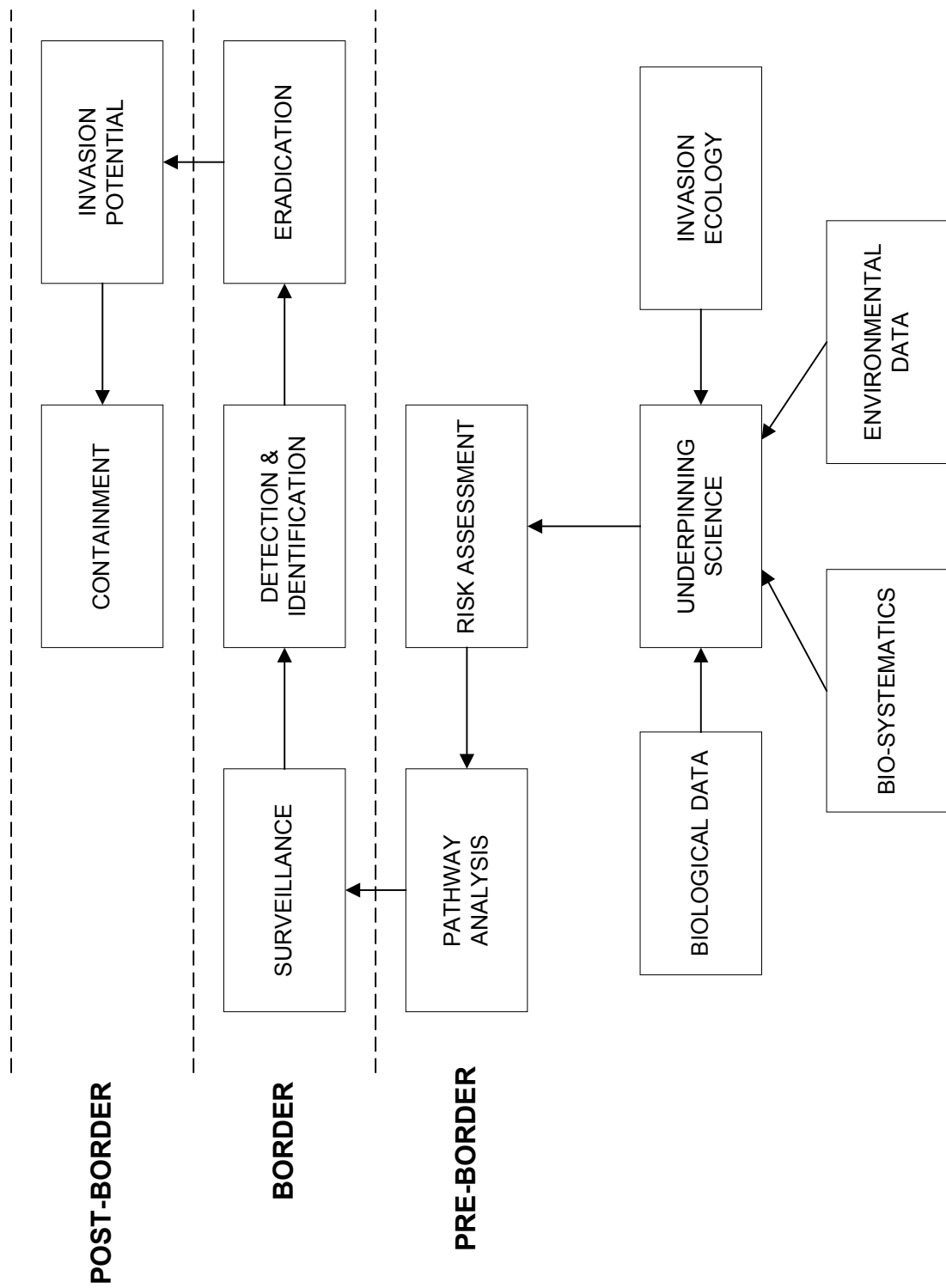
| GUIDE WORD | DEVIATION | POSSIBLE CAUSE | CONSEQUENCE & SIGNIFICANCE ASSESSMENT |
|------------|---|---|--|
| None | Salinity – no freshwater | Drought | Consider likelihood and effects of drought conditions on port environment in relation to species tolerance for salinity, temperature, etc. and port circulation patterns |
| More of | Temperature – increased | Simply a warm year | Test derivation of EV distribution for SST – time-series length relative to other meteorological records, presence of trend |
| | | Localised warming, eg industrial outfall | Check for presence of industrial outfalls at temperatures significantly higher than ambient |
| | | Localised warming due to lagoon effect | Check for presence of partially enclosed habitats with restricted water circulation |
| | Oxygen – increased | Reduction in detritus input | Check for evidence of reduction in detritus loads and variation in oxygen minima at the freshwater-brackish water interface, relative to species tolerance |
| Less of | Salinity - reduced | Increased freshwater input into areas of restricted circulation | Check for presence of partially enclosed habitats with restricted circulation and freshwater input, together with extremes in freshwater discharge history |
| | | Stratified flow regime within estuary | Check for evidence of salt wedge and freshwater lens, variation in relation to freshwater input, and the extent to which this is captured in port data |
| As well as | Bed shear stress - increase | Sympathetic effect of extreme tidal current and wind induced shear stress | Hypothesise potential maximum shear bed stress conditions (and likely return period) on basis of sympathetic extremes of tide and wind, highlighting likelihood distribution in time |
| | Target species presence – altered behaviour | Predation avoidance responses between target species | Consider any evidence for behavioural interactions between target species and implications for vessel infection models – eg altered vertical migration patterns |
| Where else | Salinity – altered circulation | Flood events change pattern of freshwater sources | Consider likelihood of new freshwater (or storm drain) inputs into port environment and likely significance with respect to circulation and salinity/temperature regime |
| | Target species – altered distribution | Settlement or colonisation of new areas in port | Consider availability of existing and new habitats within port and potential implications for pest distribution |
| When else | Altered reproductive season | Species hypothetical niche is broader than realised niche | Consider any evidence for species reproductive season extending either side of documented season in native or introduced range |

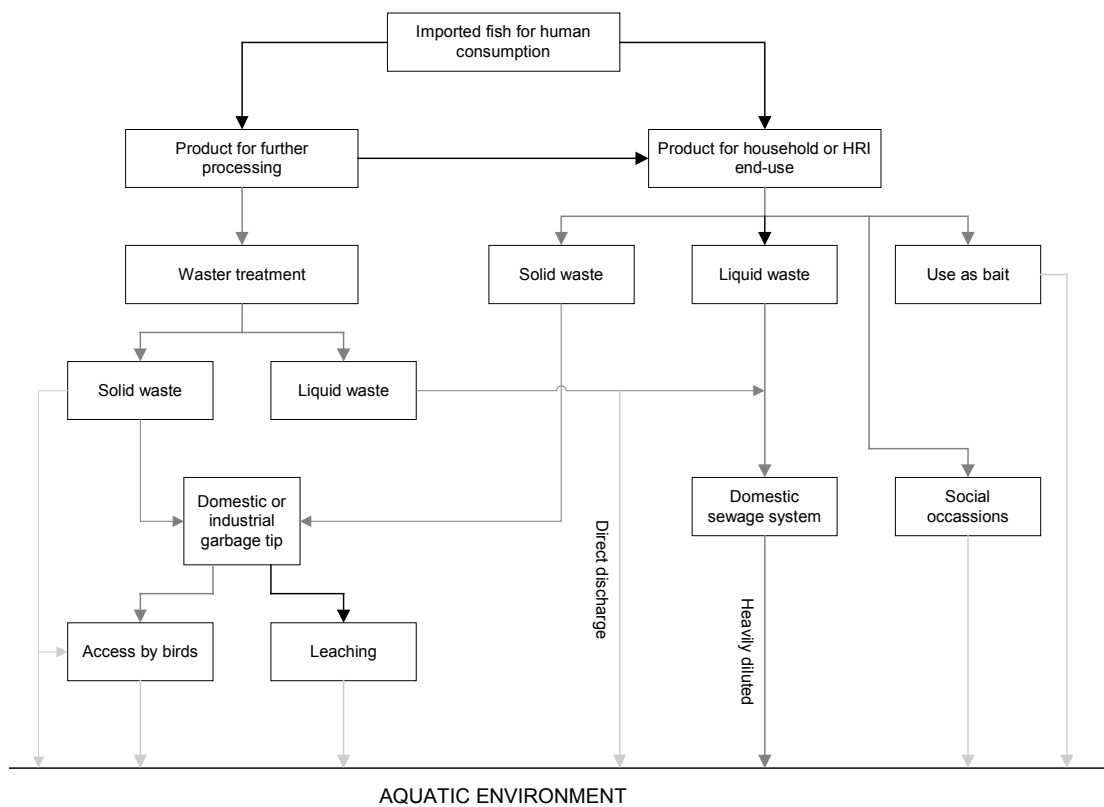
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- Figure 1 An example of a bio-security strategy. Risk-assessment, supported by bio-systematic research and biological and environmental data, is an important pre-border component of this strategy, and
- Figure 2 Contaminated salmon exposure pathways (post-border) identified in the Canadian salmon import risk-assessment conducted by Australia.
- Figure 3 A summary of the New Zealand salmon import risk-assessment framework showing the analyses at each step of the bio-invasion event chain.
- Figure 4 A summary of the AQIS ballast-water risk-assessment framework showing the analyses at each step of the bio-invasion event chain.
- Figure 5 Start of the ballast-water fault tree analysis developed for the AQIS ballast-water risk-assessment. The fault tree was used to identify discrete vessel infection scenarios determined by the habitat and behavioural characteristics of the species concerned.
- Figure 6 The posterior distribution function for the life expectancy of the larval life-stages of *Asterias amurensis*. The distribution function is used by a demonstration project of the AQIS ballast-water risk-assessment to model journey survival. It is based on a non-informative prior distribution (that assumes a constant daily rate of mortality) and the results of four surveys on board the *MV Iron Sturt*. The surveys recorded larval life-stages of *Asterias* as dead after two journeys of 12 days and

one journey of 33 days. The last survey recorded larvae alive after a journey of 16 days.

Figure 7 Kernel density estimates of maximum sea-surface temperature in Hobart and Sydney in January 1994. Probability density estimates such as these are used by a demonstration project of the AQIS ballast-water risk-assessment to calculate the probability that the species concerned will survive if discharged into a port.





KEY

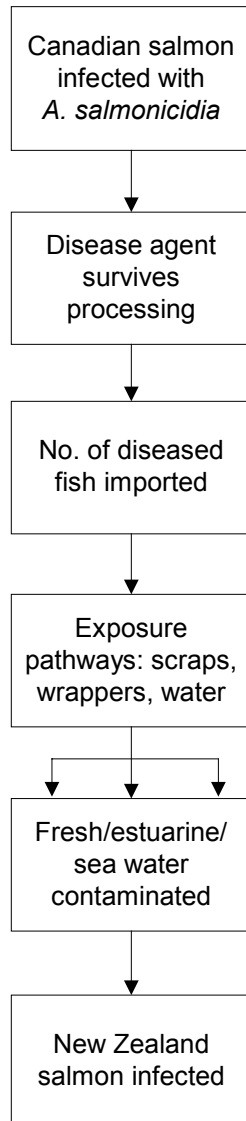
Probable pathway

Less significant

Exceptional



MODEL



ANALYSIS

