

Risk analysis: assessment, management and communication

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Summary

Import risk analysis is now a well-established discipline which aims to assist Veterinary Services to answer the following questions: 'What can go wrong?', 'How likely is it to go wrong?', 'What would be the consequences of it going wrong?' and 'What can be done to reduce either the likelihood or the consequences of it going wrong?'. Risk communication is that part of the overall process which, among other things, helps the decision-maker to determine whether a particular risk is acceptable or not. Good risk assessment and communication are dependent on clear formulation of the question to be answered. Scenario trees and influence diagrams are very useful tools in assessing and communicating risk. The authors outline the import risk analysis procedures adopted by the Veterinary Services of one Member Country of the OIE (World organisation for animal health).

Keywords

Acceptable risk – Appropriate level of protection – Influence diagram – New Zealand – Risk analysis – Risk assessment – Risk communication – Scenario tree.

Introduction

Although risk analysis, as a formal discipline, has been adopted only relatively recently by those working in the animal health field (6), important peer-reviewed texts are already available to assist the newcomer (10, 17, 18).

Risk analysis is a tool intended to provide decision-makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action (6). Risk analysis is intended to answer the following questions:

- What can go wrong?
- How likely is it to go wrong?
- What would be the consequences of it going wrong?
- What can be done to reduce either the likelihood or the consequences of it going wrong?

In the terminology adopted by the OIE (World organisation for animal health) (14), the first of these steps (What can go

wrong?) is called 'hazard identification'. Because the *International Animal Health Code* (the *Code*) is focused on trade, hazard identification is defined as 'the process of identifying any pathogenic agents which could potentially be introduced in the commodity considered for importation'. However, risk analysis is equally applicable to other areas of decision-making, such as those affecting disease surveillance or control programmes, and so hazard identification is merely the step of identifying what it is that might go wrong in whatever activity is being considered.

The steps which answer the questions 'How likely is it to go wrong?' and 'What would be the consequences of it going wrong?' are together known as 'risk assessment'. The *Code* (14), with its focus on trade, defines this as 'the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a hazard within the territory of an importing country'. However, the same assessment processes would apply when considering the likelihood of, for example, a particular disease escaping detection under different surveillance strategies.

Risk assessment may be qualitative, in which case the likelihood of the outcome, or the magnitude of the consequences, is expressed in terms such as 'high', 'medium' or 'low', or it may be quantitative. In quantitative risk assessments the likelihood is expressed in terms such as 'one disease introduction in 100 years of trade' or 'failure to correctly identify one diseased herd out of 100'.

Both qualitative and quantitative approaches to risk assessment are valid and, in fact, every risk assessment must first be conducted qualitatively (19). Only if further insight is required is it necessary to attempt to quantify the risk. Indeed, as North (12) suggests, quantitative '...risk analysis is best used to develop insights, and not to develop numerical results which might mistakenly be considered to be highly precise. The discipline of numerical calculation can help to sharpen thinking about risks involving high levels of complexity and uncertainty, and thereby enable conclusions to be drawn which could not have been reached solely on the basis of qualitative reasoning.'

The process of formulating and implementing measures designed to reduce the likelihood of the unwanted event occurring, or the magnitude of its consequences, is called 'risk management'.

Risk analysis is an important tool to aid decision-making. If one has a choice between, for example, two surveillance programmes, risk analysis can help the decision-maker to choose between a highly sensitive but expensive test and a less sensitive but cheaper test (8). In this case, the response to 'What can go wrong?' is that the surveillance programme might fail to detect an infected herd. 'How likely is it to go wrong?' and 'What would be the consequences?' are answered by the risk assessment.

However, the main reason that workers in the animal health field have adopted risk analysis is because of the incentives provided by the establishment of the World Trade Organization (WTO) and the promulgation of the Agreement on the Application of Sanitary and Phytosanitary Measures, the 'SPS Agreement' (20). This agreement obliges WTO members to remove barriers to trade unless there is a risk to human, animal or plant health. The agreement further specifies that such a risk must be demonstrated through the process of risk analysis.

Historically, significant diseases of humans and livestock have been spread internationally by trade (1). Indeed, international trade in animals or animal products cannot be conducted without some element of risk, but, in the past, this possibility has frequently been used to shield local industries from competition. Since the establishment of the WTO, risk analysis has become the basis for attempting to assess whether a particular trade in fact poses a significant risk to human or animal health and, if so, what measures can be adopted to reduce that risk to an acceptable level. That is, risk analysis is a discipline to facilitate international trade while, at the same

time, protecting human and animal health in the importing country. Risk analysis is a tool to help determine which animal products can enter a country, and under what conditions.

An import risk analysis is, in effect, a type of map (7). When a hazard (a biological agent) has been identified in the exporting country, the release and exposure assessments (14) attempt to model the various pathways by which that hazard could travel from infected animals in one country into susceptible animals in the importing country (3, 9, 17).

How should risk analysis be conducted?

In 1999 the OIE Working Group on Informatics and Epidemiology (the Working Group) (13) drafted advice on the way in which Veterinary Services should conduct risk analysis.

As a range of different skills is required to perform the different components of a risk analysis adequately, the Group recommended that a team approach be adopted. An animal health import risk analysis requires the expertise of the epidemiologist, with his or her understanding of the patterns of disease. Depending on the commodity being considered, the analysis may also require the specialised skills of virologists, microbiologists and parasitologists. In some instances it may be necessary to seek advice from experts as diverse as climatologists, entomologists, wildlife experts, industry technologists, statisticians and economists. It is unlikely that all this expertise can be incorporated into a single risk analysis unit, even in the most developed countries. It follows then, that each major risk analysis should be treated as a project, and people with the necessary skills should be integrated into the project team as appropriate. In the opinion of the Working Group (13), members of the team do not need to be located at the same site.

Hazard identification

The first step in the risk analysis process described by the OIE is hazard identification (14). This is the process of identifying which pathogenic agents could be introduced by the commodity being considered for importation. This process requires a good knowledge of animal diseases, patterns of disease and the properties of the pathogenic agents concerned.

Specifically, knowledge of the current animal disease status of the exporting country is required. Information of this kind is available from the OIE, the national Veterinary Services of that country and other sources.

Access to a range of reliable sources of information is essential and amongst such sources are libraries, the World Wide Web and a network of specialist contacts.

Risk assessment

According to the *Code* (14), this phase of the risk analysis consists of four steps:

- release assessment
- exposure assessment
- consequence assessment
- risk estimation.

The Working Group (13) advised that the release and exposure assessments require the skills of a veterinary epidemiologist. When assessing the risks posed by vector-borne diseases, there may be a need for the participation of entomologists, parasitologists and climatologists. Consequence assessment requires the skills of a veterinary epidemiologist and, in some cases, an economist.

Where quantitative assessments are undertaken, the epidemiologist needs to have access to the appropriate computer skills and, perhaps, specialist mathematical skills. The skills of the biometrician may also be needed.

Risk management

The international standards of the OIE are the preferred choice of disease control measures for risk management (14). However, there may be occasions when the analysis leads to the conclusion that the measures outlined in the *Code* are insufficient to meet the appropriate level of protection for the importing country. In these circumstances, other measures may be formulated. In such instances, the Working Group (13) advised that the process of managing risks to an acceptable level will also require the expertise of a veterinary epidemiologist. In addition, he or she will need specialist input from diagnostic laboratory staff, quarantine staff and commodity processing experts. The expertise of an economist may also be helpful in determining the relative cost-effectiveness of proposed measures.

Risk communication

Risk communication is the process by which information and opinions on hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries. It is a multi-dimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout (14). In general, it is the attention paid to communication that most influences the success of a risk

assessment, as well as the determination and acceptance of the most appropriate risk management strategy (19).

Acceptable risk

The risk communication process is essential in assisting the decision-maker to deal with one of the most difficult problems encountered during the risk analysis process; namely, determining what constitutes an 'acceptable risk'. The *Code* is not able to provide guidance on this matter, confining its definition of acceptable risk to the 'risk level judged by Member Countries to be compatible with the protection of animal and public health within their country' (14).

Determining whether a risk is acceptable or not is not always difficult. For example, in situations where the decision must be made between different disease surveillance strategies, or between different control programmes, there may be little controversy. It may be relatively easy to show the benefits as well as the risks associated with the different options. When comparing the risk of different surveillance options failing to detect brucellosis in extensively managed cattle herds, MacDiarmid and Hellström (8) were able to show that one strategy cost 40% less than the existing one, with a very small risk of missing an infected herd. As there was little controversy surrounding the issue, with all interested parties recognising the desirability of reducing costs, it was relatively easy to secure acceptance of the small risk taken in adopting the cheaper option. Issues surrounding trade are seldom as straightforward.

In decisions involving importation, it may be difficult to gain agreement on what constitutes an acceptable risk, even in situations where risk can be quantified relatively objectively. As the risks and benefits of any decision are seldom borne equally by all the interested parties (or 'stakeholders'), what is acceptable to one group may not be acceptable to another (6).

In risk communication, the stakeholders consulted may be domestic only, or may include the Veterinary Administration of the country from which the proposed importation is to occur. The range of groups considered to be stakeholders (including consumers) and the mechanism for consultation may vary between countries (13).

Whereas the *Code* (14) refers to acceptable risk, the SPS Agreement (20) uses the term 'appropriate level of protection' (ALOP). These two terms are often used interchangeably, as if they were synonyms. However, on closer examination, it appears that these two terms may be quite different (15, 16).

At a country level, the acceptable level of risk can be seen as the highest level of risk that a country is prepared to tolerate from agricultural imports, and the objective of risk management is to apply protective measures to reduce risk to the acceptable level. The amount of risk reduction achieved by the risk management

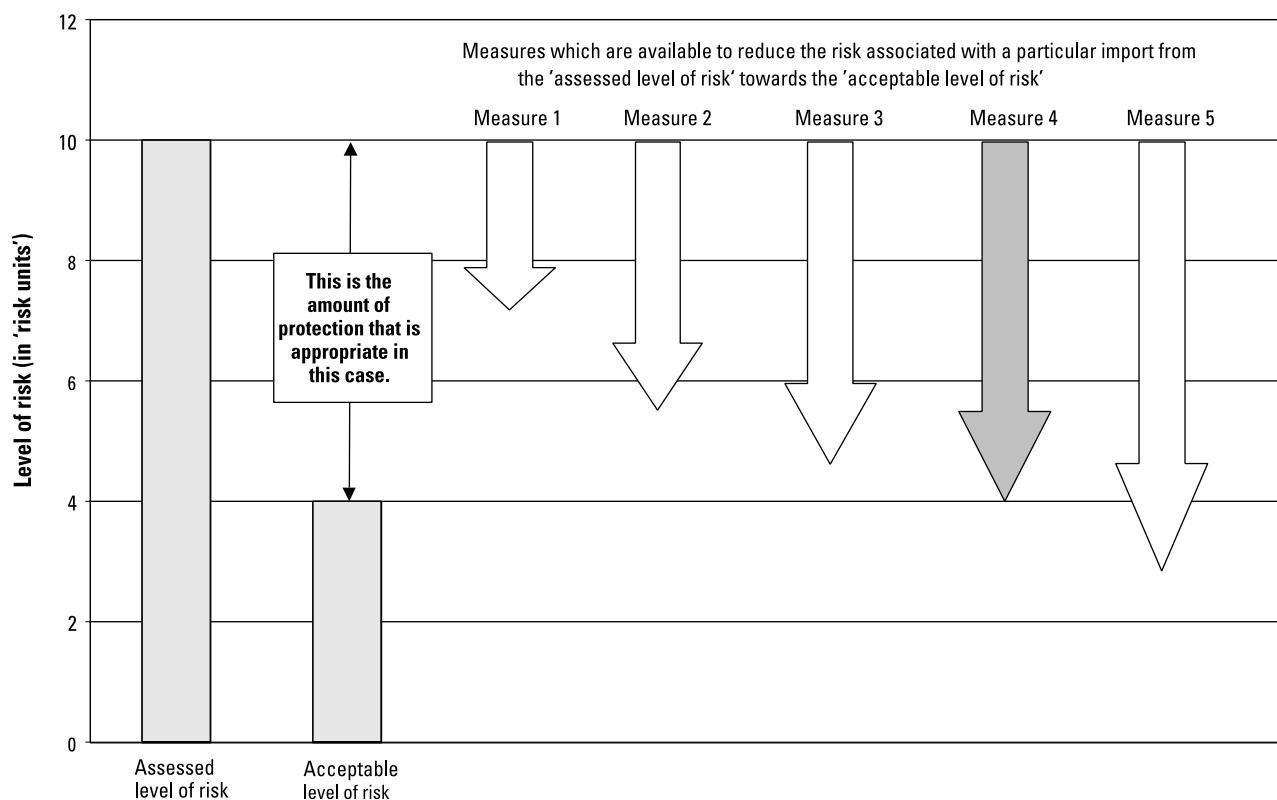


Fig. 1
The relationship between the acceptable level of risk and the appropriate level of protection, and the way in which risk management measures can reduce an assessed level of risk to an acceptable level (15)

measures applied in any particular instance may be thought of as the level of protection that is appropriate in that case. While it is possible to imagine the acceptable level of risk as being fixed for a country, the level of protection that is appropriate will vary from instance to instance, depending on the level of assessed risk in each case. Thus, a low level of protection may be appropriate when a high risk is acceptable or when the assessed risk is not much higher than the acceptable level, while a high level of protection may be necessary (i.e. appropriate) when the level of acceptable risk is very low (15, 16).

The concept of acceptable risk is clearly crucial for decision-making according to this framework, as it is the benchmark against which the other two components (the assessed risk, and the amount of reduction achievable by risk management measures) are measured. The relationship between these three ideas is illustrated in the hypothetical example shown in Figure 1.

In this example, the authors assume that it is possible to measure risk in some form of hypothetical 'risk unit', and that it is known in advance how much risk reduction can be achieved by each of the five risk management measures which are available. Figure 1 shows that the assessed level of risk is higher than the acceptable level of risk (which is known in

advance), and it is evident that measures 1, 2 and 3 are unable to reduce the risk to the acceptable level, while measure 5 would reduce it too far, which would restrict trade unnecessarily. However, measure 4 can be expected to reduce the risk from the *assessed* level to the *acceptable* level. Therefore, measure 4 would deliver the *level of protection* that is *appropriate* in this instance, in other words, the ALOP (15, 16).

These three vital components must be measurable on the same scale if the framework is to be useful for decision-making, so that it is possible to deduce what the hypothetical 'risk units' in Figure 1 might be. A number of articles of the SPS Agreement suggest that risk should, preferably, be expressed quantitatively, and that risk is a function of likelihood and consequence, a relationship that has been expressed elsewhere (2) as:

$$\text{Risk} = f(\text{likelihood}, \text{consequence}).$$

Furthermore, the consequences of an adverse event should be measurable in economic terms, implying that risk is *the product* of likelihood and consequence. Thus, when likelihood is expressed as a probability and consequence is expressed in monetary units, it follows that risk itself (in addition to acceptable risk, and the appropriate level of protection) should also be expressed in monetary units. Thus, these hypothetical

'risk units' are also, in fact, monetary units. In other words, the above framework envisages that the risks associated with trade are measurable in economic terms; that is, in terms of the cost of the expected damage to plant, animal, and human health. The acceptable risk would be the acceptable loss for the country concerned; the effect of the risk management measures would be the level of losses that could be avoided by their adoption; and the ALOP would be the loss actually avoided by applying the chosen risk management measures (15).

Another problem in deciding what constitutes an acceptable risk is that the risk increases with the volume of any particular commodity imported (14). This is intuitive, as most people accept that the more tickets they buy in a lottery, the more likely they are to win. However, in international trade, this fact may cause problems, as importing countries want assurance that the trade is 'safe', regardless of its size or duration.

One example, which demonstrates the effects of import volume on the level of risk, examined the risk of introducing infectious bursal disease (IBD) virus through trade in poultry meat (9). Under the assumptions of the quantitative Monte Carlo simulation model, if boneless chicken meat products from a particular country were imported into New Zealand, even in relatively small volumes, the risk of introducing a virulent field strain or a 'hot' or 'intermediate' vaccine strain of IBD virus into backyard poultry would be high. Indeed, the probability of IBD introduction and establishment approaches 0.34 if as small an amount as 0.1% of the chicken carcass equivalents consumed in New Zealand were imported. With greater volumes of imports, the risk increased (Table I).

Table I
Summary of the results from using the Monte Carlo simulation model for a quantitative assessment of the risk of introducing infectious bursal disease virus into New Zealand through imported boneless chicken meat products

Volume of current consumption	Mean result	95th percentile result
0.1%	0.15	0.34
1.0%	0.68	0.98
10.0%	0.96	1

Source: (9)

Constructing a risk assessment model

Regardless of whether one is developing a qualitative or quantitative risk assessment model, there are a number of important steps that must be worked through in a systematic manner (17, 18). The greatest challenges, however, are those presented by a quantitative risk assessment (10). The most

common approach to quantitative risk assessment is through Monte Carlo simulation modelling, using spreadsheet and computer software, such as @Risk (18, 19). However, whether one plans to conduct a qualitative or quantitative assessment, there are two crucial first steps in developing a risk assessment model (10), as follows:

- state the question to be answered clearly and explicitly
- draw a scenario tree.

From the outset, it is essential to have a clear understanding of the precise terms of the question to be answered, regardless of whether one is planning a qualitative or quantitative risk assessment. The process of defining the question is known as 'scoping the outcome' and, if the outcome is poorly scoped, problems will arise in interpreting and communicating the results (10).

When considering likelihood, the units of the numerator and denominator must be stated explicitly. For example, the numerator may be expressed as the probability of one event, several events or, more commonly, of at least one event. The denominator may be expressed per imported animal, per tonne of meat, per consignment, or per year, etc. The way in which risk is expressed has an important effect on how a model is developed and how the results are interpreted and communicated (10).

A question might be asked: 'What is the likelihood of introducing foot and mouth disease (FMD) with bovine embryos?' The imprecise phrasing of this question makes it impossible to identify clearly the exact outcome of interest. For instance, is the decision-maker interested in the probability per embryo, per donor, per recipient, per consignment, per month or per year? Is he or she interested in the probability that the embryos will pass all the tests, despite there being at least one embryo contaminated with FMD virus: $P(all \cdot | D^* \geq 1)$? Or is the decision-maker interested in the probability that at least one embryo is contaminated with FMD virus, despite all the embryos having passed the tests and been accepted for importation: $P(D^* \geq 1 | all \cdot T)$? The latter scenario considers all the embryos, whether they are likely to be from infected donors or not, while the former scenario considers only embryos from infected donors.

Murray (10) offers an example of a clear and explicit question:

What is the probability of at least one outbreak of FMD in [an importing country] each year if it is anticipated that between one and two thousand bovine embryos, that comply with the sanitary measures outlined in the Code, are imported annually from a country where FMD is endemic?

Whether one is planning a qualitative or quantitative risk assessment, a graphical depiction of the biological pathways provides a useful conceptual framework. It assists in showing,

in a simple and transparent manner, the range and types of pathways considered for qualitative assessments and is an essential step if a quantitative model is to be developed. Scenario trees are the most appropriate and effective way of depicting biological pathways (10, 19). They provide a useful ‘mind map’ or visual representation to:

- identify pathways and variables
- identify information requirements
- ensure a logical chain of events in space and time
- provide a framework for the development of a mathematical model
- ensure the appropriate estimate is calculated
- assist with communicating the model structure
- clarify ideas and understanding of the problem.

A scenario tree starts with an initiating event, such as the selection of animals from a herd which is potentially infected. The tree then goes on to outline the various pathways, such as accepting animals that test negative for the presence of the disease agent (17), that lead to different outcomes, such as the occurrence of an outbreak of the disease (10). Examples of scenario trees are presented in Figures 2, 3 and 4.

Another approach to depicting a model graphically is the influence diagram, which shows how different variables interact with one another. An example of an influence diagram appears in Figure 5.

An example of risk analysis procedures

The New Zealand Ministry of Agriculture and Forestry (MAF) has been conducting import risk analyses for many years (4, 5). Over that time, MAF has formalised its procedures to ensure that all import risk analyses meet the New Zealand requirements for consultation and scientific rigour (11). Although the authors would not propose that these MAF procedures are universally applicable, the overall framework may contain elements which are useful to other Veterinary Services. For that reason, current procedures for conducting risk analyses in New Zealand are outlined below. These procedures may sometimes be modified according to the nature of the commodity under consideration or in the light of experience. For example, it may be decided that the analysis does not warrant the establishment of a team to oversee a particular project. After consultation with the other appropriate government departments (see below), it may be decided that monitoring can be maintained by less formal means.

When conducting import risk analyses on animals or animal products, the current practice of MAF (11) is to take the following steps:

- a) establish a project team in accordance with Biosecurity Council policy
- invite representatives from other departments with biosecurity accountabilities (the Ministry of Health, Department of Conservation, Ministry of Fisheries) and the New Zealand Food Safety Authority to participate

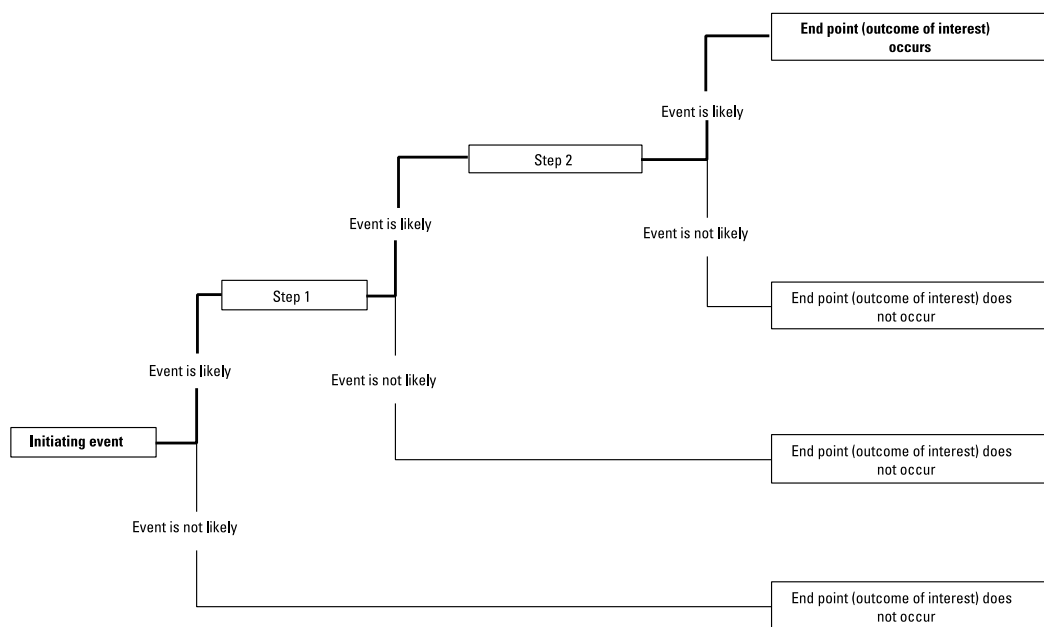


Fig. 2
Framework for a scenario tree (10)

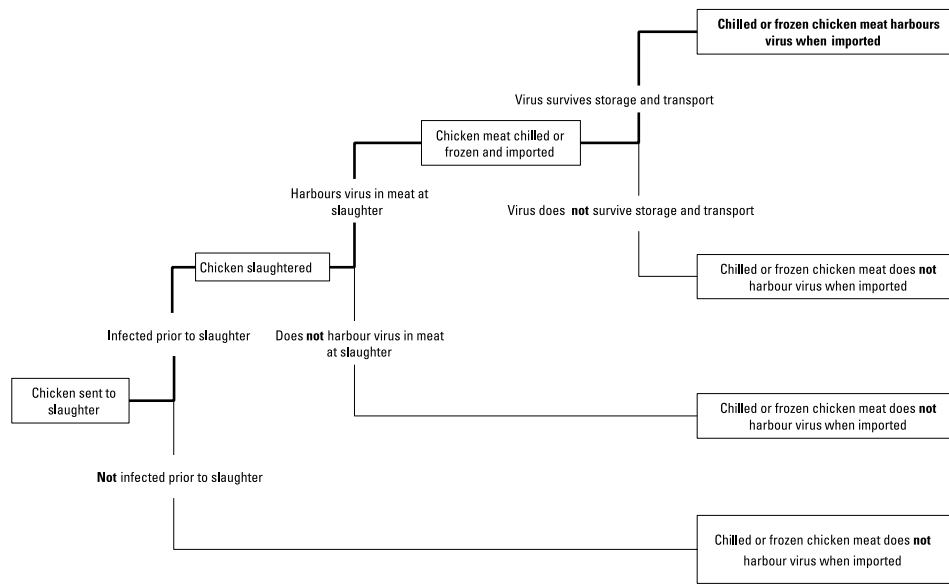
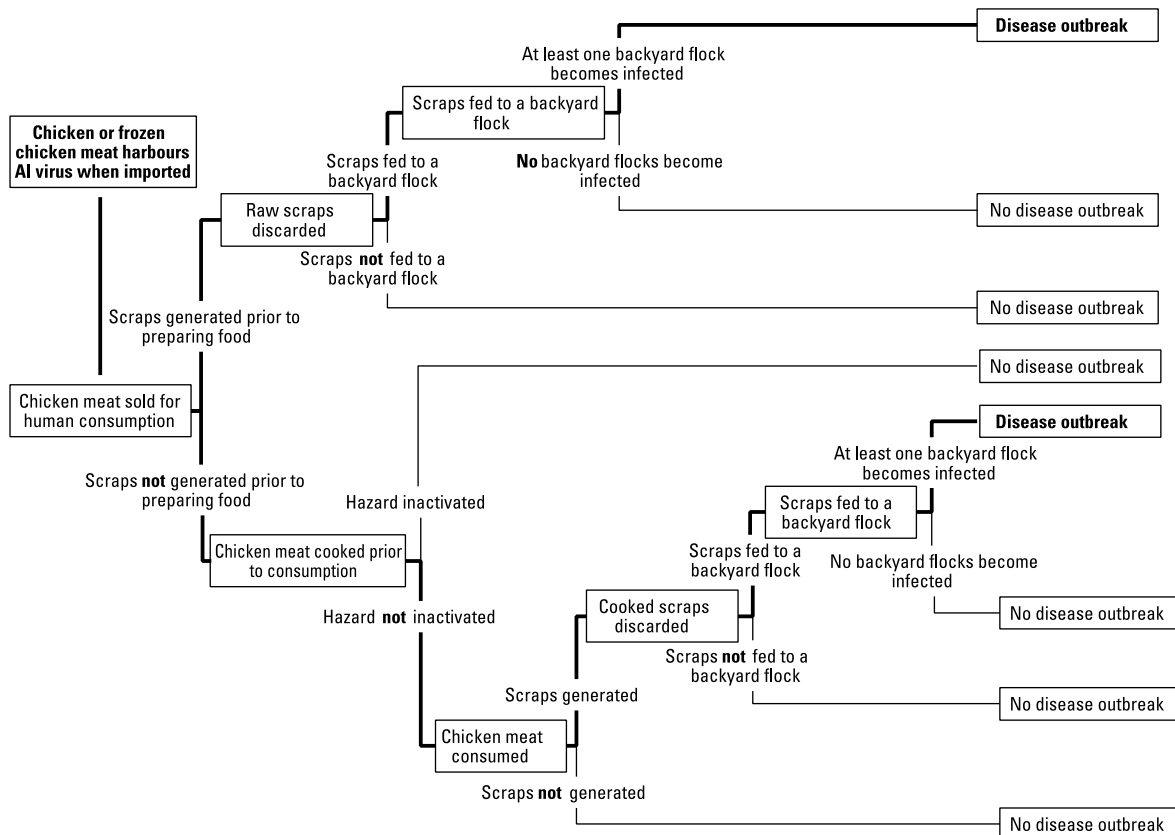


Fig. 3
Scenario tree for a release assessment

This example evaluates the risk of introducing a virus through imports of chilled or frozen chicken meat



AI: avian influenza

Fig. 4
Scenario tree for an exposure assessment

This example evaluates the risk of exposing backyard chickens to avian influenza through imports of chicken or frozen chicken meat

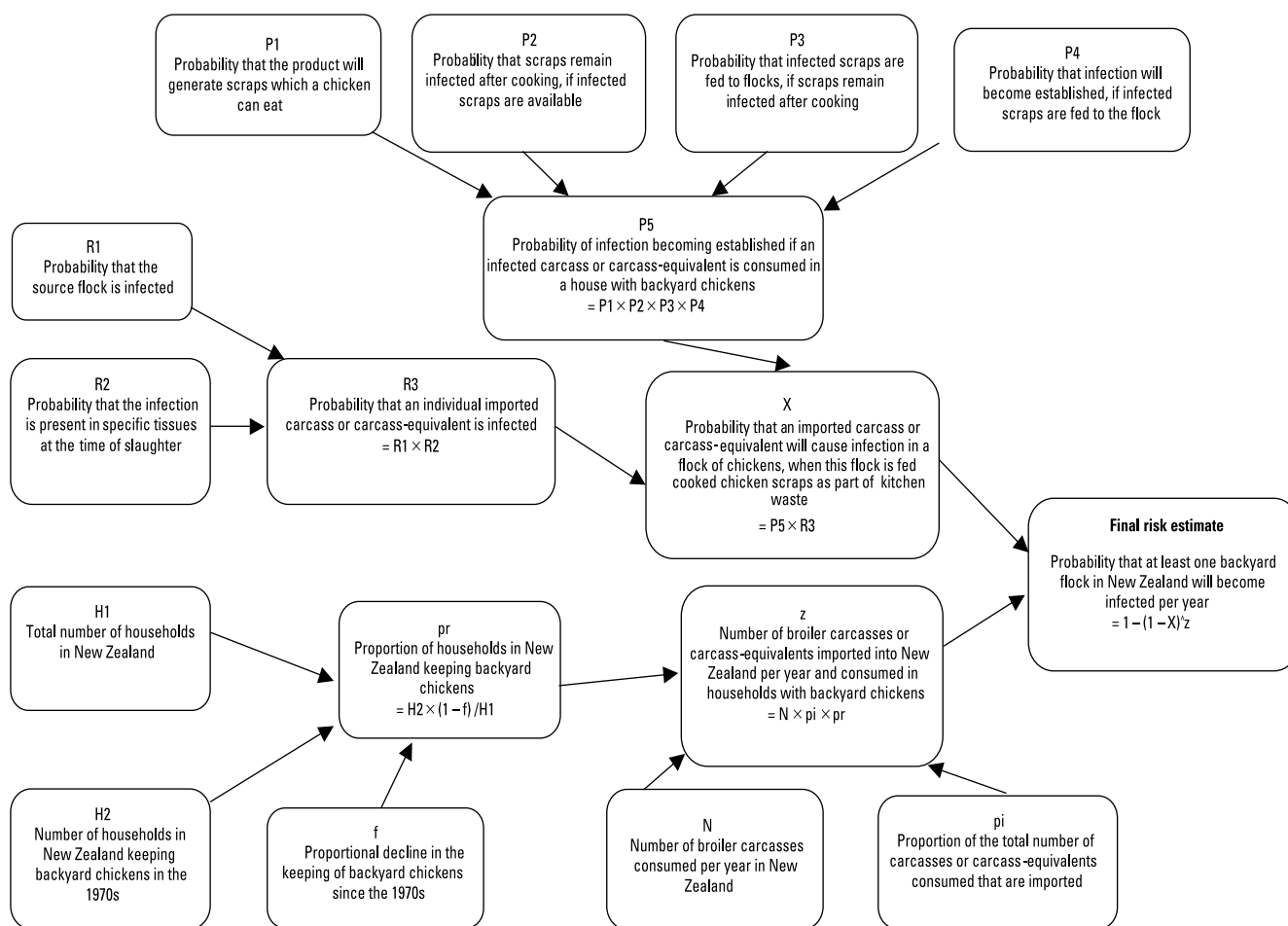


Fig. 5
An influence diagram modelling the risk of introducing infectious bursal disease virus in imported chicken meat and its establishment in backyard poultry flocks in New Zealand (9)

b) establish a working group to conduct the risk analysis

– invite representatives from the other departments with biosecurity accountabilities to participate when appropriate

c) define, in precise terms, the question to be answered i.e. ‘scope the outcome’

– define precisely the nature and source(s) of the commodity/commodities

d) conduct the preliminary hazard identification

e) identify interested parties or ‘stakeholders’

f) inform stakeholders of the project and seek their comment on the preliminary hazard identification

– send letters to probable stakeholders identified by the project team and the working group

– publish an announcement in the six-weekly MAF publication, *Biosecurity*

g) conduct the risk analysis according to the OIE *International Animal Health Code* guidelines (14)

h) subject the risk analysis to internal scientific review

i) subject the analysis to external scientific review

j) ensure that the working group considers the critiques of the reviewers carefully

– adopt all criticisms and suggestions from reviewers unless there are compelling reasons not to do so

– if a criticism or suggestion is rejected, document the reason for rejection

k) publish the revised risk analysis for stakeholder scrutiny

l) analyse the resulting submissions

– collate and compile the submissions from the stakeholders into a single document

– document the MAF response to each submission

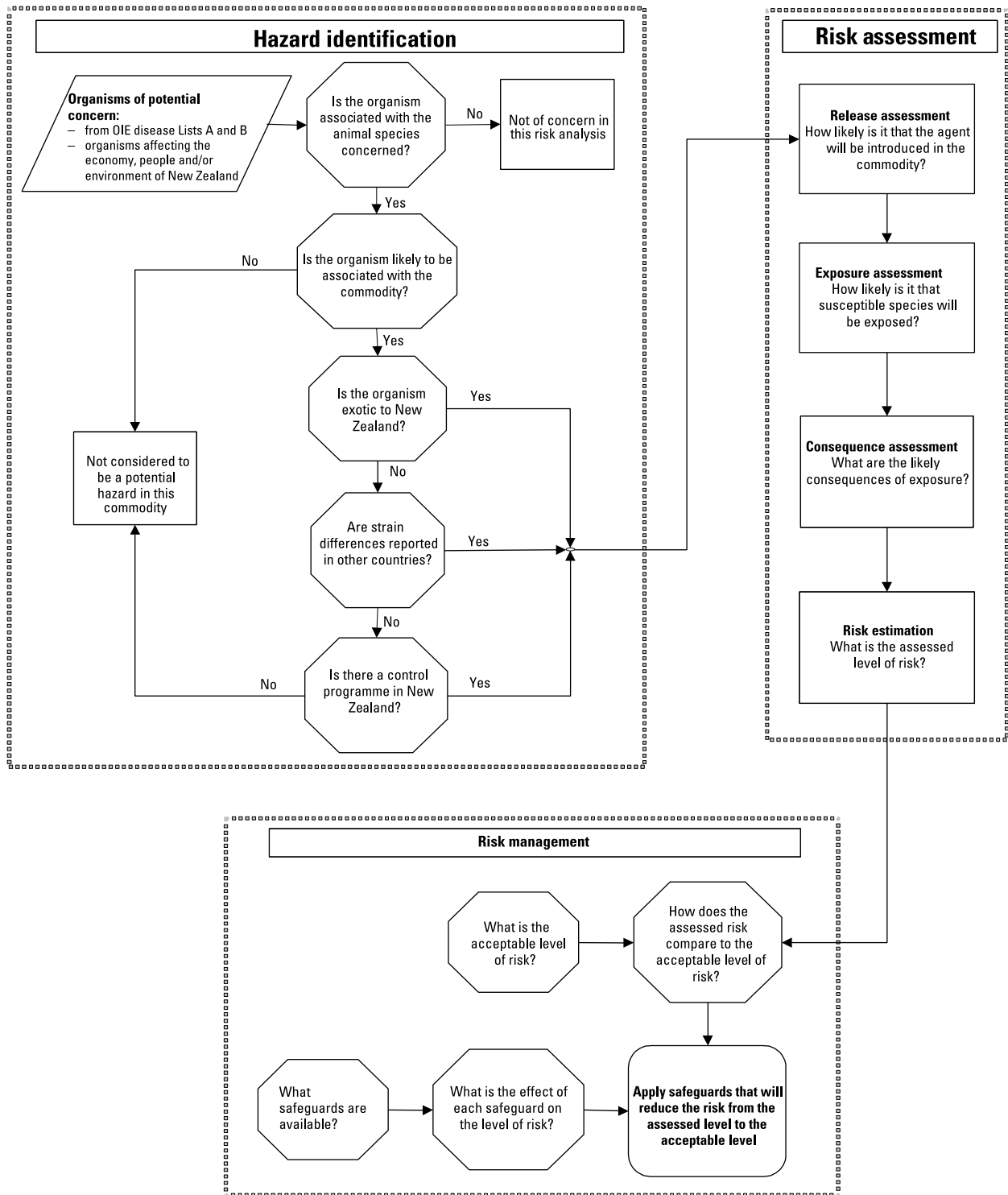


Fig. 6
Decision framework demonstrating how import risk analyses are performed in New Zealand

– send a copy of the compiled submissions and responses to every stakeholder who has made a submission and to anyone else who has requested a copy

m) modify the conclusions of the risk analysis as necessary on the basis of any technical submissions made by the stakeholders

n) develop an import health standard from the risk analysis and from any revised recommendations resulting from the consideration of stakeholder submissions (in MAF, this is the responsibility of the International Animal Trade Section)

A decision framework describing how import risk analyses are performed in New Zealand is shown in Figure 6.

Conclusion

Risk analysis is a structured process designed to help decision-makers answer the questions: 'What can go wrong?', 'How likely is it to go wrong?', 'What would be the consequences of it going wrong?' and 'What can be done to reduce either the likelihood or the consequences of it going wrong?'. While risk analysis strives for objectivity, essential data are often lacking. Therefore, assumptions are unavoidable (19) and, in the interests of transparency, these must be stated explicitly and justified.

A number of factors make consequence assessment particularly difficult. This is because predicting the consequences of disease introduction and establishment requires assumptions to be made about the rate of spread of the disease, the overall size of an outbreak, and the effectiveness of control measures. In practice, this step is seldom performed in import risk analyses (19), since the OIE List of A and B diseases (14) represents

international consensus on which diseases warrant the application of risk management measures.

Even the most objective and transparent risk analysis may not be able to satisfy all stakeholders on the issue of acceptability of risk. Since the risks and benefits which arise from any decision are seldom uniformly distributed in society, what is acceptable to one group of stakeholders may not be acceptable to another. This seems to be particularly the case when there is uncertainty about the effects of a particular disease agent on the natural environment. Furthermore, in the case of trade in animal commodities, factors other than actual disease risks may lie behind opposition to imports. Thus, decisions about acceptable risk are essentially political decisions.

While risk analysis is valuable in *all* decision-making in the face of uncertainty, the major impetus to its use in the area of animal health is due to the requirements of international trade. For this reason, the emphasis in the existing literature is on its application to decision-making on the importation of animals and animal products.

The skills and processes required for conducting risk analysis are more important than the structure in which the process is performed. Without the appropriate skills and processes, no structure can ensure good risk analysis. Where the skills and processes are adequately defined, structures are less relevant and there are a number of ways in which the requirements of good risk analysis can be met.

L'analyse des risques : évaluation, gestion et communication

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Résumé

L'analyse des risques à l'importation possède désormais ses lettres de noblesse. Cette discipline vise à fournir des éléments de réponse aux interrogations des Services vétérinaires, par exemple « Qu'est-ce qui peut mal se passer ? », « Quelles sont les probabilités d'un incident malheureux ? », « Quelles en seraient les conséquences ? », « Quelles mesures contribueraient à réduire les probabilités d'un tel incident ou à limiter son impact ? ». La communication relative au risque est la composante du processus global qui, entre autres choses, permet aux décideurs de déterminer l'acceptabilité d'un risque. De la clarté de la formulation de la question dépendra la qualité de l'évaluation du risque et de la communication relative au risque. Les arbres à scénario et les diagrammes d'influence sont de précieux instruments dans l'appréciation du risque et la communication relative au risque. Les auteurs examinent succinctement les procédures d'analyse des risques à l'importation mises en place par les Services vétérinaires d'un Pays Membre de l'OIE (Organisation mondiale de la santé animale).

Mots-clés

Analyse des risques – Arbre à scénario – Communication relative au risque – Évaluation des risques – Niveau adéquat de protection – Nouvelle-Zélande – Risque acceptable – Schéma d'influence.



Análisis del riesgo: determinación, gestión y comunicación

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Resumen

A estas alturas, el análisis del riesgo ligado a las importaciones es una disciplina sólida, cuyo objetivo es el de ayudar a los Servicios Veterinarios a dar respuesta a los siguientes interrogantes: '¿Qué puede ir mal?'; '¿cuán probable es que vaya mal?'; '¿qué consecuencias tendría que fuera mal?'; y '¿cómo reducir la probabilidad de que vaya mal o mitigar los posibles efectos negativos?'. La comunicación sobre el riesgo es la fase del proceso que sirve, entre otras cosas, para ayudar a los responsables públicos a decidir si determinado riesgo es aceptable o no. La bondad de un proceso de determinación y comunicación del riesgo depende de la formulación correcta y clara del interrogante al que debe darse respuesta. A la hora de determinar y comunicar el riesgo, los árboles de hipótesis y los diagramas de influencias constituyen sendos instrumentos de gran utilidad. Los autores describen con cierto detalle los protocolos de análisis del riesgo ligado a las importaciones que aplican los Servicios Veterinarios de un País Miembro de la OIE (Organización mundial de sanidad animal).

Palabras clave

Análisis del riesgo – Árbol de hipótesis – Comunicación sobre el riesgo – Determinación del riesgo – Diagrama de influencias – Nivel adecuado de protección – Nueva Zelanda – Riesgo aceptable.



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