Veterinaria Italiana, **42** (4), 337-349

Acceptable risk in animal biosecurity import risk analysis: the New Zealand experience

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Summary

The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) provides a framework for managing biosecurity risks in imported agricultural products, under which risk management measures applied to imported goods must be based on a scientific risk assessment. The most important consideration within this framework is the concept of the appropriate level of protection, which member countries are obliged to specify. Practical application of this framework for the importation of animals and animal products has revealed less objectivity than initially envisaged, both for the assessment of risks and for the risk-reduction effect of safeguards. Scientific uncertainty means that there is considerable room for contention between groups in favour of and opposed to a particular import. This environment means that acceptable risk decisions are to a large extent subjective in nature, requiring a participatory approach on a case-by-case basis involving a range of stakeholders.

Keywords

Animals, Animal diseases, Animal products, Biosecurity, Imports, New Zealand, Risk, Sanitary and Phytosanitary Agreement, Trade.

Rischio accettabile in biosicurezza animale, analisi del rischio legato all'importazione: l'esperienza della Nuova Zelanda

Riassunto

L'accordo dell'Organizzazione Mondiale del Commercio sull'Applicazione delle Misure Sanitarie e Fitosanitarie (SPS agreement) rappresenta un sistema integrato per la gestione del rischio in biosicurezza nei prodotti agricoli importati, secondo il quale le misure di gestione del rischio applicate ai prodotti importati devono essere basate su una valutazione scientifica del rischio stesso. La considerazione più importante all'interno di questo sistema è il concetto del livello appropriato di protezione, che gli Stati membri sono obbligati a specificare. L'applicazione pratica di questo modello per l'importazione di animali e prodotti animali ha rivelato una minore obiettività di quella inizialmente prevista, sia nella valutazione del rischio sia nell'effetto di riduzione del rischio delle misure di salvaguardia. L'incertezza scientifica significa che esiste una considerevole competizione tra i gruppi a favore e contro uno specifico prodotto di importazione. Questa situazione indica che le decisioni sul livello di rischio accettabile sono largamente soggettive, in quanto richiedono un approccio partecipativo caso per caso, che coinvolge una serie di protagonisti.

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This is an updated version of a paper published in *Public Sector*, **27** (3), 8-14, September 2004

Parole chiave

Accordo SPS, Animali, Biosicurezza, Commercio, Importazioni, Malattie animali, Nuova Zelanda, Prodotti animali, Rischio.

Introduction

Internationally-agreed methods for the analysis of biosecurity risks associated with imported animals and animal products were developed by the Office International des Épizooties (OIE: World organisation for animal health) soon after the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) was signed in 1994. These methods had their origins in the engineering sciences (3) and, for a number of years, it was generally accepted that quantitative risk analysis could be expected to deliver objective science-based risk analyses, as required under the SPS Agreement, and that this would result in transparent and consistent decision-making (4). However, it has become evident in recent years that there are a number of difficulties inherent in applying these methods to biological systems. This paper discusses why it is difficult or impossible to measure risk and the degree of risk reduction achieved by SPS measures using quantitative risk assessment techniques, as suggested by the SPS Agreement. A companion paper by Murray on the SPS Agreement, trade and risk assessment is included in this journal (6).

Decision-making under the SPS Agreement

The theoretical decision-making framework underpinning the SPS Agreement is shown in Figure 1. At the heart of the framework is the idea that scientific information allows the accurate and

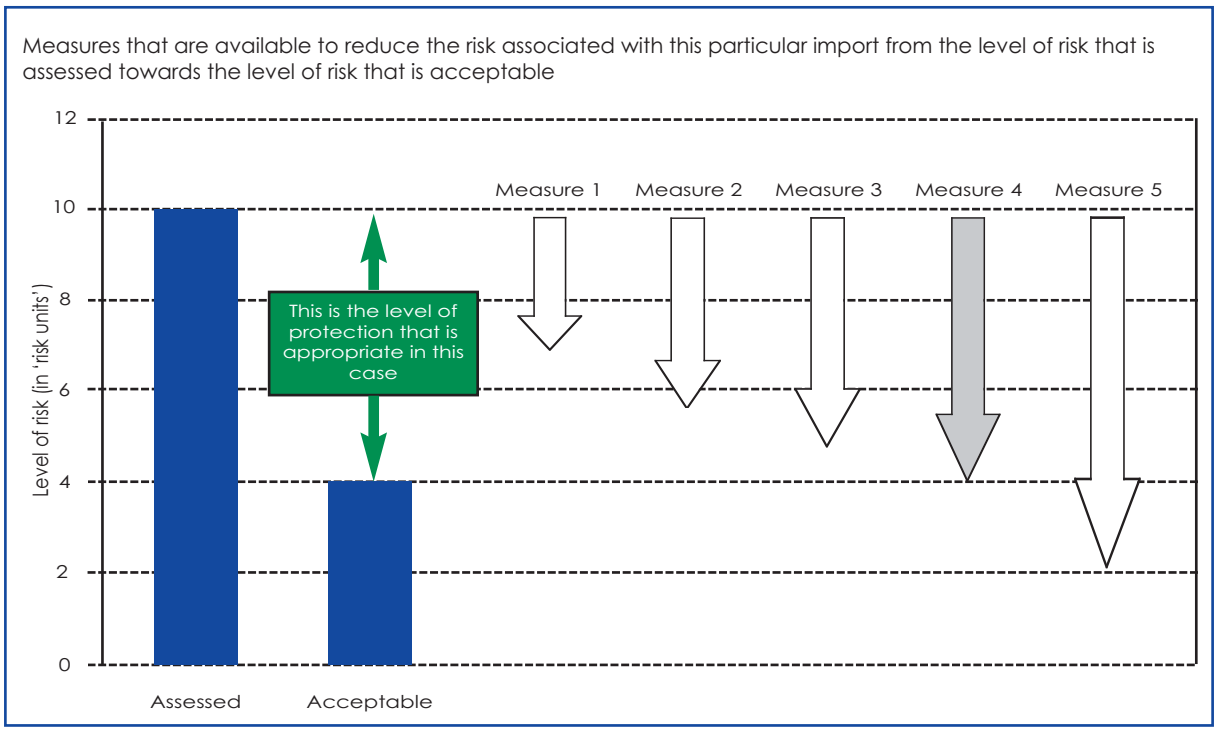

Figure 1
Relationship between assessed risk, acceptable level of risk, appropriate level of protection and sanitary and phytosanitary measures (9)

objective measurement of the biosecurity risk associated with a proposed imported commodity and that a country can compare the assessed risk with a pre-set national acceptable level of biosecurity risk. Further, the framework assumes that the amount of risk reduction achievable through the application of a range of available risk management measures (safeguards) can also be scientifically determined, so that decision-makers can transparently select and apply the measure(s) that deliver the required amount of risk reduction in order to reduce the risk from the assessed level down to (but not below) the national acceptable level. In the hypothetical example shown in Figure 1, measure 4 reduces the risk from its assessed level of 10 risk units to the acceptable level of 4 units, thereby delivering the level of protection that is appropriate in this instance. Thus, the 'acceptable level of risk' and the 'appropriate level of protection' are closely related but fundamentally different concepts, contrary to the observation in the SPS Agreement that many WTO members consider them to be the same. The differences between these two terms are described below.

Notwithstanding the appeal of this theoretical framework, risk analysis practitioners in animal health regulatory agencies throughout the world have struggled to implement these concepts since the SPS Agreement came into force in 1995. A fundamental issue is whether risk really can be measured objectively, and if so, *how*. A clear preference for quantification is signalled by the SPS Agreement; this has been echoed by the SPS Committee and at Appellate Body hearings. The risk as defined in the SPS Agreement comprises two components – the likelihood of an adverse event and its consequences. Risk is expressed as a function of likelihood and consequence, and the SPS Agreement implies that risk is in fact the *product* of those two components. Further, since likelihood is expressed as a probability, which has no units, and since under the SPS Agreement consequence is to be expressed in economic terms, it follows that the units of risk (and acceptable risk, and the risk-reduction effect of safeguards, and the appropriate level of protection) should also be expressed in currency units. Thus, the framework suggests that acceptable risk is about acceptable economic losses to the economies of member countries (perhaps in exchange for the benefits of free trade), while the appropriate level of protection is essentially the level of economic losses *avoided* through the application of safeguards.

The SPS framework applied to animal biosecurity

In the context of animal biosecurity import risk analysis, the adverse event of concern is the inadvertent introduction of exotic diseases when importing animals and animal products, while the consequences of introduction are the likely effects of those diseases if they were introduced. Under OIE guidelines for import risk analysis (8), for any given potential hazard, a risk assessment comprises the following analytical steps:

- release assessment: likelihood of introduction
- exposure assessment: likelihood of establishment and spread
- consequence assessment: economic impacts
- risk estimation: summary of the risk.

Likelihood of release and exposure

Release assessment estimates the likelihood of the hazard being present in the imported commodity and quantitative risk assessments usually model this as a binomial process, where each unit of the imported commodity is considered to have a constant probability of carrying the disease agent. The likelihood of at least one imported unit being infected increases according to the size of shipment,

so the likelihood of release is directly proportional to the volume of trade. However, predicting the volume of trade may be difficult, particularly for trade in a completely new commodity, which is often when import risk analyses are required. Theoretical approaches for estimating the likely volume of trade have been proposed using partial equilibrium models (11), but their application has been limited by the absence of the necessary supply and demand curves.

A closely related issue is the choice of the actual unit of trade, *n*, which for quantitative modelling needs to be selected under the assumption of independence of the imported units that underlies the binomial distribution. When the trade of interest is live animals, then the unit of trade is usually the individual animal, and the group of interest is a defined population for which surveillance has established a prevalence *p* for the disease agent. Therefore, in order to calculate the risk, the first data requirement is for surveillance of all potential hazards in the population from which the imported animals will be taken, and there are issues concerning the availability and quality of such data. Animal disease surveillance capabilities vary considerably between countries, particularly in relation to the national and regional animal disease surveillance programmes that are in place and the accuracy of diagnostic tests. The likelihood of an imported animal being infected can be estimated only if reliable surveillance data exists.

For live animals, the second step of the risk assessment is the likelihood of exposure of susceptible species in the importing country to the organism, if it is introduced. This step is also relatively straightforward. Since imported animals are very likely to come into direct contact with other animals, the likelihood of exposure can reasonably be assumed to be high for most of the infectious diseases that are the focus of an import risk analysis.

Considerable efforts have been made to quantitatively model the likelihood of introduction and the establishment of diseases through the importation of live animals. The results of such models have been applied in designing risk management measures in pre-export or post-arrival quarantine (5). This has been particularly effective for diseases where the objective is risk minimisation and where time in quarantine is the most important factor influencing risk (e.g. scrapie in sheep). But even in this situation, computational limitations imposed by the software that is most widely used in risk modelling, means that for most importations it is not possible to evaluate the binomial for the likely number of introductions [x = (n,p)]. Thus, quantitative risk analyses usually consider the likelihood of any (one or more) introductions occurring $[1–(1–p)^n]$, a somewhat more esoteric concept, and one that presents significant problems in terms of communicating the results of the risk analysis.

On 1 January 1995, the WTO replaced the General Agreement on Tariffs and Trade (GATT), which had been in existence since 1947, as the organisation overseeing the multilateral trading system. The 128 governments that had signed GATT by the end of 1994 were officially known as 'GATT contracting parties'. Upon signing the new WTO agreements (which include the updated GATT, known as GATT 1994), they officially became known as 'WTO members'. This brought new emphasis to risk analysis requirements. Risk analyses on live animals have become less common over the past decade, as international trade has increased in animal genetic material (semen, embryos, hatching eggs). Furthermore, the growth in world trade that has resulted from GATT has resulted in an increase in the range of animal products being traded. The manufacture of these products may involve a range of physical and chemical processes and, in this context, the question

for quantifying the likelihood of release becomes 'what is the likelihood that a certain quantity of a given animal product will carry a critical amount of the pathogen of concern?' At the same time, the question of exposure assessment also becomes more complicated. For example, 'what would be the pathway by which susceptible animals in the importing country would be exposed to this product, and what is the likelihood, per unit of trade, that infection will result in the exposed animals?' A range of complexities emerge with this shift in focus, particularly as there may be a number of theoretical exposure pathways. To explore this complexity, scenario trees are often constructed for both the release and exposure assessments and, for quantitative modelling, probabilities are assigned to each branch. Multiplying the branch probabilities gives an overall probability for the event in question, for example, the likelihood that a virus will be introduced in a certain quantity of product and will result in infections in susceptible animals. Monte Carlo simulation enables the likelihood to be modelled on an iterative basis and the likelihoods of release and exposure are frequently presented as probability distributions or confidence levels. A number of problems are encountered in implementing the above approach. First, the required data are seldom available to fully complete the scenario trees, as research to address the questions that risk analysts ask has seldom been performed. The more detailed the model, the more likely this is to be an issue, and in practice the analyst usually must make assumptions that are based on the limited available scientific information.

Risk analyses on animal products involve a question that is not encountered in analyses for live animals, such as what quantity of the organism is of concern, and how this is to be measured. Unfortunately, for advocates of quantitative analysis, the infectious dose for most agents is not well defined, as this involves many factors including the immune system of the host, the environment and management system in which the animals are raised and the variation in the micro-structure of the organism itself, which can determine how it interacts with the host tissues. Although there are some quantitative measures for agent concentration, such as colony-forming units (cfu) for bacteria or 'infectious dose fifty' (ID_{50}) for viruses, the use of such terms requires a detailed understanding of what they are designed to measure. For example, infectivity of a virus of chickens might be expressed in terms of 'chicken infectious dose fifty' (CID_{50}), which is the amount of virus that will on average cause infection in 50% of the chickens (usually birds at one day of age that have not been exposed to any pathogens and so can be considered immunologically naive) to which it is administered. Unfortunately, however, the details start to get quite complex, since CID_{50} may be expressed in terms of 'tissue culture infectious dose fifty' ($TCID_{50}$) or 'egg infectious dose fifty' (EID_{50}), depending on which viruses can be coaxed to grow in what medium in the laboratory. For most viruses, infectious dose is poorly researched. Moreover, since these various ID_{50}s are the medians of unknown probability distributions, their use in infectious disease models implicitly includes the assumption that there is a certain (low) probability that even a single virus particle is able to initiate an infection if exposed to an animal. This has major implications for decision-makers who must determine what constitutes a negligible risk.

When attempting to model the likelihood of release in processed bulk commodities, such as animal feeds, the analyst encounters further complications. Here, the choice of the unit of trade, n, can be somewhat arbitrary, and the probability of introduction per unit of trade, p, is rarely available

for various units of trade. With these bulk commodities, the assumption of independence referred to earlier is very unlikely to hold true, as infectivity is probably clustered in some way within the shipment.

A further issue in considering processed animal products is that there is considerable variation in the manufacturing processes used (physical or chemical processes for specific time periods) and the effect of these processes on contaminating pathogens of concern is rarely known, except for a narrow range of bacteria that are of human food safety concern. Where inactivation information is available, the relationship is usually complex and non-linear, and for some organisms, for example foot and mouth disease (FMD) (2), there may be resistant fractions of the agent, the infectious nature of which is incompletely understood.

In the absence of any historical information on how exotic agents might be expected to behave if introduced, a number of hypothetical exposure pathways may be suggested. However, the framing of these 'likely exposure scenarios' can be somewhat speculative, particularly when considering exposure pathways for endangered native fauna. Such speculation almost inevitably leads to the consideration of worst-case scenarios which might be quite reasonable in some situations, for particularly high-impact diseases, such as FMD, but there may be less justification for their use for other diseases.

Consequences of introduction and establishment

Release and exposure assessments give an estimate of the likelihood of one or more adverse events resulting from an import, and it follows that the consequences of interest are those of one or more primary adverse events. The SPS Agreement lists a number of direct and indirect economic effects to consider when assessing the consequences of import risks, namely: those arising from lost production, mortality, disease control and lost sales. The extent of these will depend not only on how a particular disease behaves epidemiologically within a certain environment, but also on the effects of national and international market reaction on the economy of the country concerned. Despite the appeal of using this approach, there are severe difficulties associated with predicting these effects.

As mentioned earlier, current standard risk modelling software is unable to calculate the number of events expected over a certain period of time, so the likelihood of *any* introductions is usually calculated instead. In that case, the consequences that need to be considered are those following any introductions. This raises an important issue for diseases that do not threaten international markets, since there is clearly a great difference in local control costs between one and one million adverse events. Moreover, the number of primary outbreaks arising directly from introducing the organisms in the imported commodity may be relatively few when compared to secondary outbreaks as a result of spread by various mechanisms.

For each primary adverse event, there might be a range of possible consequences, depending on how and where the organism is introduced, which species in what ecological zone is infected first, the degree and speed of spread from the point of initial introduction and how long it is present prior to detection (assuming that detection will prompt the initiation of control efforts). Thus, the consequences of an introduction may be framed in terms of three questions, as follows:

a) What are the various possible scenarios as a result of the introduction?
b) How likely is each possible scenario?
c) What would be the consequences (costs) of each scenario?

A number of issues arise when attempting to implement the above approach. Even for agents that are known to have a narrow host range, the size of the disease outbreak that might occur following its introduction is likely to be difficult to predict. The key unknown factors are how quickly and by what route a particular agent would spread if it were introduced, how quickly it would be detected and, therefore, how many locations would be affected and in what areas. History will not be of much help, as most of the agents of primary concern are exotic and have always been so. Consequently, the only historical information available relates to other countries, which may be very different in many ways.

Therefore, in practice, it is again necessary for analysts to make assumptions on the likely size of the initial outbreak. Assumptions surrounding scenario prediction are frequently little more than personal beliefs, and even if such beliefs are held by 'experts' they carry unknown biases. A good example of how difficult it is to predict the extent of a future outbreak comes from a retrospective assessment of the outbreak of FMD in the United Kingdom in 2001. By the time it was detected, the disease had become widespread due to large-scale movements of infected sheep. This particular strain of FMD virus produced almost no clinical signs in these infected sheep. It is unlikely that an analyst considering this situation in 2000 could have predicted the influence of the so-called 'bed and breakfast sheep', an indirect result of European Union (EU) subsidies to sheep farmers.

The 'bed and breakfast sheep' anecdote is based on what the visiting New Zealand veterinarians learned by word of mouth while they were assisting the British veterinary authorities to manage the UK FMD outbreak of 2001, and it illustrates how difficult it can be to predict the extent of a future outbreak. The circumstances that prompted these sheep movements had not been present in the UK at the time of the previous outbreak 30 years before. In the interim, Britain had joined the EU and, under the Common Agricultural Policy of the EU, many farming sectors had become dependent on subsidies. One such subsidy was a per head subsidy on breeding sheep, which meant that once a year a British farmer could expect a visit from an EU official who would estimate the size of his sheep flock in order to calculate the subsidy. Although, under EU rules, the subsidy was only payable for sheep that had been owned by that farmer for at least 12 months, in practice it was impossible for the duration of ownership to be verified; therefore, farmers had an incentive to increase their flock size at the time of the head count. Since it is clearly impossible to conduct a national sheep census on a single day, there would need to be some form of scheduling by EU officials, which allowed farmers to buy extra animals shortly before the visit. The way to do this, without leaving a paper trail, was to visit the sale yards and to negotiate the purchase 'in the car park', as opposed to purchasing in the sale itself. Thus, large numbers of sheep, commonly referred to as 'bed and breakfast sheep', were constantly moving around Britain, almost like a wave, just in front of the EU officials. Moreover, since concerns arose a few years earlier that sheep might be harbouring bovine spongiform encephalopathy (BSE or 'mad cow disease') which would masquerade as scrapie, farmers were reluctant to buy animals over a certain age. To verify that the sheep about to be purchased were not above the desired age, the potential purchaser would estimate their age by inspecting their teeth. Since the highest concentration of FMD virus is present in the saliva of infected animals, this would have allowed the virus to be transmitted very rapidly to a large number of animals.

Even if the number of outbreaks can be predicted, the consequences per outbreak are likely to vary considerably. The consequence is relatively easy

to predict and accurate if there is 100% mortality or culling, but the consequence of any other less severe outcome depends on a number of local factors. Losses of sales depend on the reaction of markets, which is becoming notoriously difficult to predict as consumer concerns regarding food safety have never been greater. For some diseases, lost sales may simply be related to lower production on individually affected farms, while for others, the market reaction may spread from local to international concerns. For national economies that rely to any significant degree on the export of animal products, the real or imagined fear of an extreme international market reaction may drive national decision-making about a number of disease agents. A good recent example was the diagnosis of the first case of BSE in Canada in 2003. Within days of the announcement, Canada's beef exports practically ground to a halt; the resulting losses to the Canadian economy were estimated at about US$11 million per day. A similar situation arose on Christmas Eve of the same year when the USA reported its first case of BSE; the Japanese market for US beef collapsed overnight. It is slightly ironic that one of the reasons that the losses suffered by the US cattle industry were so high was that the US was one of the first countries to shut its doors to Canadian beef exports earlier that year. This reinforced the perception in international markets that there was indeed a risk in importing beef from a country that had reported a single BSE case, a perception that was not supported either by international expert opinion or international standards.

While the extreme market reaction to these isolated cases of BSE may have been difficult to anticipate, it is easier to predict the market reaction to highly infectious diseases such as FMD. Even a single case of FMD in New Zealand would result in immediate closure of most international markets for exports of livestock and livestock products, which the Reserve Bank of New Zealand has estimated would result in economic losses of more than US$4 billion in the first year; about 4% of gross domestic product. For many other diseases, however, the international trade losses would be substantially lower, and since some livestock sectors in New Zealand are not significantly export-oriented (e.g. the pig and poultry industries), diseases in these sectors would have only local consequences, which would require estimates of mortality, reduced production, control and surveillance costs, etc. A range of scenarios could be developed to allow the valuation of such losses, but assigning probabilities to the likelihood of their occurrence would again require assumptions to be made.

Assessing potential public health implications of incursions presents special difficulties, often in relation to uncertainty as to whether humans may be affected or not. This is not an issue for recognised zoonoses (i.e. animal disease agents that are known to infect humans, such as rabies), but it can be a significant problem in cases where the zoonotic potential of a particular agent is feared but unknown. A case in point was the consideration of approving the release of rabbit haemorrhagic disease in New Zealand, as a bio-control agent in 1997. A significant issue in the decision not to approve the import and release of this organism was the concern that the virus might cause disease in humans, perhaps by viral mutation at some time in the future (7).

Similar issues are associated with uncertainty when assessing environmental consequences of introduced specific exotic pathogens (or free-living pest species) on the New Zealand environment and on endangered native fauna in particular. For example, when considering proposed importations of cage birds and poultry or poultry products, the potential effects of an introduced exotic agent on native birds must be considered. Limited disease surveillance has been undertaken on native bird populations

in New Zealand; consequently, there is little information on what organisms are present in these species. Moreover, the susceptibility of these unique native bird species to specific exotic agents is unknown (10). There has been widespread concern about the potential effects of Newcastle disease and avian influenza viruses, as various strains of these viruses have been found in a very wide range of bird species in many countries. However, recent studies suggest that the majority of these strains are unlikely to produce disease in birds other than poultry (1). Even in the recent avian influenza pandemic in Asia, the effects on species other than poultry were relatively sporadic and limited, and apparently resulted primarily from spill-over from infected poultry units rather than from transmission between non-poultry species. However, since the necessary scientific investigations have not been conducted to determine the effect of these viruses on native birds, it is assumed that native birds are fully susceptible and precautions are taken to prevent their introduction. This is in effect an assumption of a worst-case scenario.

Although the introduction of free-living pests (e.g. exotic mammals, insects, snakes, lizards) is more likely to be associated with imports of plants or non-animate items than with imports of animals and animal products, assessing the consequences of their introduction presents particular difficulties that are worthy of discussion here. For a free-living organism to become an environmental pest it must first be invasive, but the degree of invasiveness in a particular ecosystem is uncertain even if a particular species has a known track record of invasiveness elsewhere. For example, if one were to consider the environmental risks facing a country that was considering importing live brushtail possums (*Trichosurus vulpecula*) from New Zealand, then the experience of invasiveness in the New Zealand environment would not necessarily indicate likely invasiveness in another country. While the degree of invasiveness of these animals in their native Australia would be negligible, in other countries it might be expected to be closer to the New Zealand experience, where the possum was very invasive. Similar issues face import regulatory authorities when considering the likely impact of various animals found in or on shipping containers. In practice, there is little choice other than to assume that invasiveness is possible, perhaps over an unknown timeframe. Similar issues of 'information deficits' arise when considering free-living species, such as marine organisms and freshwater fish.

A number of issues exist in relation to the valuation of impacts, and these are also recognised as important issues in benefit-cost analysis, particularly for non-market effects. These include issues of fairness, such as who has standing, how to include preferences of future generations, and what discount rate to use for future costs. Implicit in using current market prices for valuing effects is that there will be no large change in the future relative to other market prices. However, market relationships can change in calculating the costs incurred by animal diseases, as has been spectacularly demonstrated in the case of scrapie in sheep. In the 1970s, economists in the then Ministry of Agriculture and Fisheries research division justified the decision to import high-scrapie-risk sheep from Britain on the basis that the benefits to the economy that the new breeds would deliver would far exceed the costs, even if scrapie were inadvertently introduced with those animals. However, although the potential impact of scrapie might have been considered insignificant in the 1970s, recent concerns in Europe that sheep showing clinical signs of scrapie might in fact be harbouring BSE would mean that the consequences of scrapie would have to be assessed considerably higher today. This sort of major market shift is impossible to predict.

The issues inherent in valuing non-market effects

are frequently seen in public submissions on risk analyses that involve potential environmental effects in New Zealand. These non-market values are difficult to evaluate as it is hard to determine the monetary impact of an import on the environment.

Valuing human life, which would be necessary for a quantitative assessment of the impact of zoonotic diseases, presents intractable difficulties. The economic tools proposed for doing this (e.g. willingness to pay, or the present value of a person's lifetime production as measured by earnings) are based on wealth or income of the victim and this implicitly encourages saving the lives of the wealthy and imposing risks on the poor. If animal welfare ever finds its way into the SPS risk analysis framework, it can be expected to present further problems, including difficulties of measuring welfare, as well as valuating issues due to differences between cultures and world views.

Suggestions have been made for the broader use of economics in acceptable risk decision-making, based on the principles of welfare economics. The major theoretical objection to this is the distribution of costs and benefits either between countries (a country benefits from trade while another faces risk), within countries (a region or sector benefits, while all bear the risk) or within sectors (few cattle farmers benefit directly by allowing imports of live animals, but all bear the risk). Moreover, considerations of 'average' and 'net' benefits are of little practical value, as they rest on an assumption of mobility of resources which has limits not only at the country level, but also between particular sectors within a country.

Risk management

Risk management is the process of selecting and implementing risk reduction measures (safeguards) to manage risks in the imported commodity. The decision-making framework of the SPS Agreement implies that the degree of risk reduction achievable by the available safeguards must be measurable. Safeguards are usually intended to reduce the likelihood of introduction of exotic diseases to a level that is considered acceptable (5), and for the purposes of this discussion, safeguards are grouped into tests and treatments. In each import situation, the decision that must be made is what level of safeguard(s) is adequate to reduce an import risk from its assessed level to a level that is acceptable to the importing country. In some cases where the degree of risk reduction cannot be achieved by testing or treating the imports, the only possible option may be to prohibit a certain import from countries with a specific disease.

Internationally recognised diagnostic tests for animal diseases of trade concern are available for live animals and genetic material. These tests can be applied to the herds or flocks of origin, but the degree to which a test reduces the risk depends on the nature of the test and how it is applied. Diagnostic sensitivity and specificity are known within certain limits for validated tests, and sampling protocols can be designed to allow the calculation of the likelihood of detecting a disease in a population of a certain size assuming a certain prevalence. As discussed earlier, these concepts may be used in quantitative risk assessment models to estimate the likelihood of introduction with a range of safeguards in place. The output of such models is typically a probability distribution showing confidence of detection under different sampling intensities, and with different assumptions about test sensitivity and disease prevalence. The rigor of testing required is directly related to the degree of risk reduction that is sought by the decision-maker.

Diagnostic tests may be applied to animals prior to export, either in the herd of origin or in pre-export quarantine, or after export, in post-arrival

quarantine. The justification for requiring quarantine may be to prevent exposure in the period immediately prior to export (e.g. vector-borne viruses), or to increase the test sensitivity by ensuring that a certain period has lapsed following the last possible exposure (e.g. scrapie in imported live sheep). Quantifying changed test sensitivities under these conditions may not be possible, however.

Visual inspection is the test that is most commonly applied for the detection of 'hitch-hiker pests' on imports of inanimate goods, such as used vehicles and sea containers. These include free-living organisms, such as ants and spiders, which are assumed to have the potential to become established in a country from a very small incursion. The decision-maker is tasked with determining what level of visual inspection is appropriate (and at what cost) to provide adequate assurance that the likelihood of undetected hitch-hiker pests remaining on the goods after inspection is low enough. Quantifying the sensitivity of visual inspection is probably not possible under most practical situations, but it may be considered necessary to apply certain treatments to such goods in addition to testing by visual inspection. The most commonly applied treatment is chemical fumigation, the efficacy of which is often relatively well understood for a variety of specific hitch-hiker pests. However, quantifying the overall level of risk reduction achieved by such combinations of measures is rarely attempted.

A range of treatments may be applied to the animals or animal products to reduce the likelihood of introduction of exotic disease organisms in imports. One such safeguard is the vaccination of live animals. The efficacy of vaccination can vary considerably, depending both on the nature of the disease agent, the nature of the particular vaccine and the vaccination protocol used. Opposite ends of the spectrum in terms of the level of protection achieved by vaccination may be rabies in dogs versus influenza in horses. Whereas rabies virus is stable and highly immunogenic and considerable research has been invested over many years in devising vaccination protocols to deliver a high degree of protection in vaccinated animals, equine influenza virus is less immunogenic and prone to mutations which means that the level of protection achieved in vaccinated animals is considerably lower. Similarly, safeguards recommended for live animals may include treatment with antibacterials or parasiticides, and quantifying the likelihood of introduction of disease agents in such treated animals requires careful consideration of the appropriate scientific literature. In each situation, the decision-maker must determine how effective the chosen treatment regime needs to be in order to achieve an acceptable risk.

For imported animal products, in addition to requiring testing of the animals of origin, risk management measures may include required time/temperature treatment steps for different products, on the basis of agent inactivation models that are based on specific scientific research. However, it is common for various stakeholder groups to strongly disagree on what constitutes an acceptable risk. Even in the relatively uncommon situation when research has been conducted on the time/temperature treatments required to achieve different levels of risk reduction in a particular product, there is no completely objective way to determine what level of risk reduction is required to render the imported product safe. Although treatment to achieve a million-fold reduction (a 6D or 99.9999% reduction) in the concentration of organisms is commonly applied in human food safety, the interests of different groups usually determine the risk positions taken and opponents of specific imports commonly argue that no risk in imported commodities is acceptable. Comprehensive quantitative analysis

is rarely possible due to inadequate scientific information in many areas, and conducting further research cannot be guaranteed to resolve all areas of uncertainty. Rather, new information often results in moving the attention of opponents to the decision from one area of uncertainty to another. Once a decision has been taken that a particular set of measures are justified and necessary to manage a particular import risk, a final consideration is the implementation of the measures. For pre-export testing and treatments, assurance that the measures have been applied in accordance with agreed standards is a matter that must be certified by an appropriate authority in the exporting country.

Discussion

Risk acceptability is an enigmatic concept and differences of opinion exist at many levels in society as to how much protection or precaution is appropriate under different circumstances. If the concept of risk implied under the SPS Agreement really does mean that risk should be measured in monetary units, then acceptable risk can perhaps best be viewed as the level of economic losses that can be tolerated at a national level in exchange for a country reaping the benefits of international trade. Individual acceptance of that framework is dependent on perceptions of the fairness of distribution of the benefits of trade and it is therefore easy to see why psychologists studying risk have argued strongly that acceptable risk decisions are essentially subjective in nature (12).

A key principle of the SPS Agreement is that risk management measures should be applied only to the extent necessary to achieve the appropriate level of protection (ALOP) for a country. This paper has argued that the measurement of risk and the degree of risk reduction achieved by SPS measures is not possible in the precise and objective way that appears to have been anticipated by the non-technical drafters of the Agreement. This may explain why none of the WTO member countries have managed to elucidate a national acceptable risk or appropriate level of protection sufficiently clearly that it can be applied as envisaged in this rationalist framework.

In practice, judgements on the significance of risks identified in imported animals or their products are almost always made in the first instance by the risk analysts themselves. To ensure transparent decision-making, it is essential that risk analyses clearly document and justify all assumptions made, and include processes of internal and external peer review of analyses before finalisation, followed by public consultation, to ensure that a variety of views are taken into account by those determining which safeguards are appropriate in particular instances. Many practical challenges exist in meeting the SPS requirement that measures are applied consistently and only to the extent necessary, and the expectation under the SPS agreement that this would all be possible by quantitative methods is far from what is achievable in reality. The replacement of quantitative methods with qualitative risk assessment is discussed further by Murray in this journal (6).

There are many difficulties involved with the application of the rationalist framework of the engineers to biosecurity risk analysis and quantitative risk analysis is far from the precise method that appears to have been envisaged by the architects of the SPS Agreement. Even for relatively simple risk models, the requirement for data quickly outstrips what is available and a large number of assumptions are required. Such modelling can be extremely time-consuming and the complexity that arises from reductionism makes peer review difficult. Validation of biosecurity models is clearly impossible and public views on what constitutes an acceptable risk are highly

influenced by world views, particularly those relating to the morality of globalisation and the distribution of the benefits of free trade. Thus, although acceptable risk decisions are clearly subjective decisions, the nature of the risks mean that scientific experts have no choice but to act as *de facto* decision-makers. Public perception of the trustworthiness of scientists is no doubt one of the more important determinants of the acceptability of this arrangement.

Acknowledgements

The contributions of Biosecurity New Zealand colleagues Stuart MacDiarmid, Katie Owen, Toni Tana and Sandy Toy are acknowledged.

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