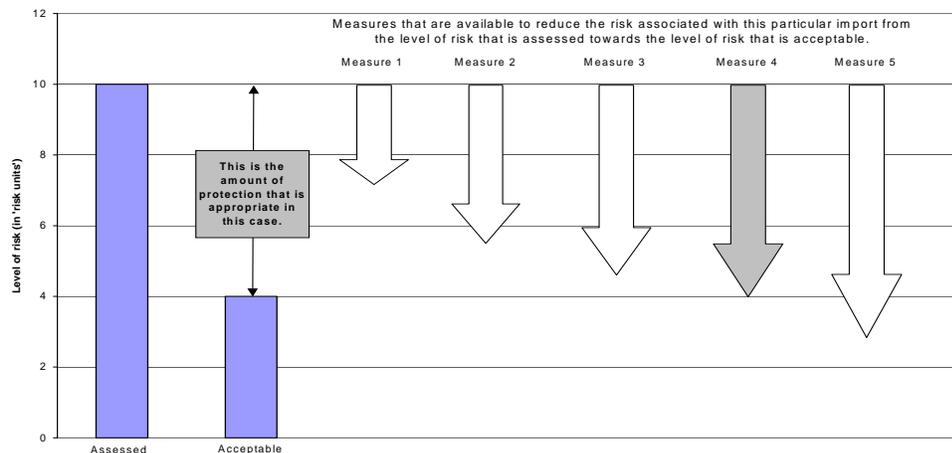


The limits to quantification in import risk analysis. H.J. Pharo, Biosecurity Authority, Ministry of Agriculture and Forestry, PO Box 2526 Wellington, New Zealand.

In the early 1990s it appeared that quantitative risk analysis would answer the call for objective science-based risk analyses, delivering decisions that were transparent and consistent. However, in the decade since these ideas first emerged in veterinary epidemiology, a number of constraints on what is possible have become evident – in particular, difficulties estimating the likelihood of an adverse event, and difficulties predicting consequences of such an event. This paper covers assessment of likelihood; a separate paper at this symposium addresses consequence assessment.

This theoretical decision-making framework underpinning the SPS agreement is shown in Figure 1. At the heart of the framework is the idea that it is possible to measure risk accurately and objectively, based on science, and that a country can determine its acceptable level of risk. Further, it is assumed that the amount of risk reduction achievable by the application of a range of safeguards can be determined, so that decision-makers can objectively select and apply the measure(s) that deliver the required amount of risk reduction to reduce the risk from the assessed level down to (but not below) the national acceptable level. For example, measure 4 in Figure 1 reduces the risk from its assessed level of 10 units to the acceptable level of 4 units, thereby delivering the level of protection that is appropriate.

Figure 1. The relationship between assessed risk, acceptable level of risk, the appropriate level of protection, and SPS measures.



Notwithstanding the appeal of this theoretical framework, a number of critical questions have concerned WTO member countries since the SPS agreement came into force in 1995. Foremost among these is *how* to measure risk. A clear preference for quantification is signalled by the SPS Agreement, and has been echoed by the SPS Committee and at Appellate Body hearings. This is perhaps not surprising in view of the prevailing construct of risk – it is commonly expressed as a function of likelihood and consequence, and the SPS agreement implies that risk is in fact their product. Since likelihood is expressed as a probability while consequence is expressed in monetary terms, it follows that the units of risk (and acceptable risk, and the effect of

safeguards, and the appropriate level of protection) should also be expressed in currency units, suggesting that acceptable risk is all about acceptable economic losses to the national economy. So how accurately can the likelihood of an adverse event be assessed?

Under OIE guidelines, the first risk assessment step concerns the likelihood of the potential hazard being present in the imported commodity. Quantitative modelling usually involves the binomial process, where each unit of the imported commodity is considered to have a constant probability of carrying the disease agent. Clearly the more units that are imported, the higher the likelihood that one of them will be diseased, so the risk is directly proportional to the volume of trade. However, predicting the volume of trade is not easy, particularly when the trade in question is new, as is often the case when import risk analyses are required. Theoretical approaches for estimating the likely volume of trade have been proposed using partial equilibrium models, 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 unit of trade, which needs to be selected keeping in mind 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 . In this case the second step of the risk assessment—the likelihood of exposure of the organism to susceptible species in the importing country if introduced—is relatively straightforward, as for most infectious diseases that are the focus of import risk analyses, the likelihood exposure can reasonably be assumed to be high. Here, exposure is usually considered possible by direct contact with other animals, so its likelihood is a probability of 1.0. For trade in live animals, the problems facing risk analysts are primarily the availability and quality of surveillance information from which to derive prevalence levels, and the accuracy of diagnostic tests. There is little argument about the unit of trade, and risk management is relatively straightforward by the application of standard measures such as pre-export or post-arrival quarantine and testing of samples of animals.

Considerable efforts have gone into the development of sampling approaches for these situations, which have been applied to great advantage in post-arrival quarantine situations where the objective is risk minimisation and where time in quarantine is the most important dependent variable in the risk equation (e.g. scrapie in sheep). Nevertheless, computational limitations imposed by standard software used in risk modelling means that it is not possible to evaluate the binomial $x = (n,p)$ and we are limited to the even more esoteric construction of $1-(1-p)^n$, with a corresponding loss of transparency and increase in difficulty of risk communication.

However, over the past decade risk analyses on live animals have become less common as the international trade focus has tended to move to imports of genetic material (including hatching eggs) and a vast range of animal products that have been subjected to a bewildering array of physical and chemical processes. Thus, the question regarding likelihood of release becomes 'what is the likelihood that a particular quantity of this particular animal product will carry a particular amount of the organism of concern?' The question asked in the exposure assessment is 'what would be the exposure pathway by which this product would be transmitted to

susceptible animals, and what is the likelihood per unit of trade of infection arising in the exposed animal?'. A range of complexities emerge with this shift in focus, which may be compounded by there being a number of theoretical exposure pathways. In this situation, scenario trees are commonly constructed for both the release and exposure assessments, and probabilities are assigned to each branch. However, the more reductionist the model, the less likely it is that values for the probabilities required for the tree will be available, and the greater the reliance on assumptions.

Multiplying the branch probabilities gives an overall probability (a joint probability) for the event in question—for example, the likelihood that a virus will be introduced in a certain quantity of product and will be exposed to susceptible animals. But a fundamental question quickly arises – how much of the organism are we concerned about, and how is this to be measured? While we perhaps need not concern ourselves with levels that are below an infectious dose or with quantities of imported smaller than a certain size likely to be involved in exposure, such considerations raise more problems than they solve. Infectious dose for most agents is not straightforward, involving many factors, including the immune system, environment, management etc. Although there are some quantitative measures for agent concentration (cfu, ID₅₀), their use involves a range of assumptions e.g. CID₅₀ is usually expressed in terms in terms of TCID₅₀ or EID₅₀. Moreover, since these various ID₅₀'s are the medians of unknown probability distributions, their use in modelling infectious dose tends to rest on 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 is unlikely to be the case for most organisms, although it may be close to the truth for prions.

Complications arise when attempting to model the likelihood of release in processed bulk commodities such animal feeds. Here, the choice of the unit of trade, *n*, can be somewhat arbitrary, notwithstanding its importance on the final risk estimate. Further, the commodity may have been subjected to various physical or chemical processes for various times, and data is rarely available to develop the necessary inactivation curves, which are usually not simple linear relationships and frequently involve residual resistant fractions of the agent whose infectiousness is incompletely understood.

In the absence of any historical information on how exotic agents might be expected to behave if introduced, multiple exposure pathways may be suggested, but the framing of these 'likely exposure scenarios' is to some extent a process of professional speculation that inevitably leads to the consideration of worst case scenarios, perhaps understandably so for some 'high impact' diseases such as FMD, but with less justification for some other diseases.

In conclusion, even for relatively simple 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. The relationship of the model results to reality cannot be known, as validation is clearly impossible. Moreover, public discussion of such analyses is practically impossible, particularly when the result is a remote probability (e.g. 10⁻⁴ per year). Thus, although acceptable risk decisions are clearly political decisions, analysts are forced to act as *de-facto* decision-makers.

Reference

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