

Quarantine risk analysis

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Australia's quarantine policy is based on the concept of manageable risk, which is underpinned by quarantine risk analysis, which this article examines with particular reference to recommendations of the 1996 Australian Quarantine Review. Quarantine risk assessment addresses disease concerns associated with any particular proposed import and may also require detailed examination of possible economic and environmental effects. The degree of quantification varies, and more quantitative approaches may be either deterministic or stochastic. Assessments consider both the probability of an event occurring and its consequences, including the direct economic effect of any introduction of an exotic disease.

Although people have always made decisions in the face of uncertainty, risk analysis has been recognised only recently as a formal discipline in its own right. It has developed from an inter-disciplinary background and there is still some confusion in both scientific and popular literature about the precise definition of each of its elements (Krewski and Birkwood 1987; Covello and Merkhofer 1993). Several attempts have been made to develop a standardised nomenclature in, for example, disciplines such as animal health (Hathaway 1991; Ahl *et al.* 1993; Kellar 1993; MacDiarmid 1993; OIE 1994; North 1995), plant health (IPPC 1995; McNamara 1995), food safety (ANZFA 1996; Notermans and Mead 1996) and environmental science (Beer 1996; Beer and Ziolkowski 1996). Some authorities use 'risk management' instead of 'risk analysis' for the overall term (SA/SNZ 1995). Others use 'risk analysis' more narrowly as including elements such as risk identification, assessment and evaluation but excluding risk management and communication. The only difficulty arising from these variations in terminology is that one needs to be conscious of which set of terms is being used in any particular publication or discipline – despite variations in terminology, the basic principles are the same across all disciplines.

For the purposes of this article, risk analysis is used as the overall term to encompass the elements of risk assessment, risk management and risk communication:

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- risk assessment is the process of identifying and estimating the risks associated with an option and evaluating the consequences of taking those risks;
- risk management is the process of identifying, documenting and implementing measures to reduce these risks and their consequences; and
- risk communication is the process of interactive exchange of information and opinions concerning risk between risk analysts and stakeholders.

Many authors have defined risk communication in terms of the process of risk analysts advising stakeholders, such as policy-makers or the general public, of the result of their risk assessment and their proposed risk management strategies. Such a limited approach implies that communication is primarily one-way and occurs only after the risk assessment and management steps have been completed, ignoring the need for two-way communication and consultation throughout the whole process, which is fundamentally iterative in nature. Indeed, the fact that the primary criticism of many risk analyses is often that there has not been effective communication between risk analysts and stakeholders suggests that adoption of such a limited definition of risk communication has been a significant constraint in many analyses.

1. Quarantine risk analysis

Australia has applied risk analysis principles to decisions related to animal and plant quarantine for many years. Although risk analysis principles can be applied to a number of quarantine activities (targeting and evaluating border programs), most recent attention has focused on their application to evaluating requests for access of imports to a country – import risk analysis. Import risk analysis is the primary focus of this article, which examines and expands on the findings of the recent Australian Quarantine Review (hereafter referred to as the ‘Nairn Review’). It should be noted that plant health scientists have tended to use the term ‘pest risk analysis’ for this process, based on their use of the terms ‘pest’ or ‘quarantine pest’ for all organisms of concern (from microbes to vertebrates and weeds).

Despite statements by major reviews of quarantine (Senate 1979; DPIE 1988) and the Australian Quarantine and Inspection Service (AQIS) itself (AQIS 1991; Wilson and Banks 1993), a significant number of individuals and organisations still believe Australia has (or should have) a ‘no risk’ quarantine policy. The expression of this view was sufficiently frequent for the 1996 Senate Report on AQIS to state that it was ‘concerned about the persistence of the view that “no risk” is a viable option for quarantine policy,

despite consistent and unequivocal dismissal of this approach by previous reviews' (Senate 1996, p. xi). Similarly, the Nairn Review concluded that 'the continued perception in some quarters that there ever has been or ever can be a "no risk" quarantine policy for any country – let alone a major agricultural trading nation such as Australia – reflects a fundamental misconception that needs to be corrected in an ongoing awareness campaign' (Nairn, Allen, Inglis and Tanner 1996, p. 83).

1.1 International obligations

The Uruguay Round of the General Agreement on Tariffs and Trade culminated in the formation in January 1995 of the World Trade Organization (WTO). The WTO's role and scope are defined in an agreement, of which two annexes have particular relevance to quarantine – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). The SPS Agreement defines the basic rights and obligations of member countries with respect to taking 'sanitary and phytosanitary measures' to protect human, animal or plant life or health. The SPS Agreement defines a number of principles governing sanitary and phytosanitary measures that may affect international trade: basic rights and obligations; harmonisation; equivalence; risk assessment; regionalisation; national treatment; transparency; control, inspection and approval procedures; technical assistance; and special and differential treatment. The TBT Agreement covers food standards such as labelling and nutritional requirements. WTO members are obliged to ensure their quarantine measures are based on an assessment of the risks to human, animal or plant life or health, 'taking into account' risk assessment techniques developed by the relevant international organisations.

For many years, international organisations such as the Office International des Épizooties (OIE) and the International Plant Protection Convention (IPPC) have advocated the use of risk analysis principles in animal and plant quarantine. WTO now recognises these organisations as the custodians of the international standards, guidelines and recommendations for sanitary and phytosanitary aspects of international trade. Australia is a member of WTO and a signatory to its provisions, including the SPS Agreement and the TBT Agreement. Risk assessment and risk management are included in the principle of 'control, inspection and approval procedures' as fundamental to the application of sanitary and phytosanitary measures to international trade. Risk communication is implicit in the SPS Agreement, particularly in relation to its principle of transparency, which obliges members to notify changes of their sanitary or phytosanitary measures. Thus

risk analysis – including risk assessment, risk management and risk communication – is integral to international trade overseen by WTO.

1.2 Principles

The Nairn Review examined the application of risk analysis to animal and plant quarantine. It concluded that a number of fundamental principles should apply to import risk analysis; specifically, that risk analysis should be consultative, scientifically based, transparent, harmonised, and subject to appeal on process. The same principles apply to risk analysis in other disciplines, as reflected in approaches being adopted in areas such as food safety (ANZFA 1996) and environmental sciences (Norton *et al.* 1996). These principles, and current trends associated with them, include:

1.2.1 Consultation

Risk analysis should be conducted in a framework that provides for early and broad consultation with all relevant stakeholders.

1.2.2 Scientific basis

Risk analysis should fundamentally be a scientific process. In particular, risk assessment should be ‘essentially a scientific endeavour based on experimentation and observation’ (ANZFA 1996, p. 2), independent of political considerations. However, it is acknowledged that risk management ‘involves policy decisions based on a balance of scientific, social and economic considerations’ (ANZFA 1996, p. 2). In recognition of this, some countries (including the United States) separate the regulatory application of risk analysis by assigning official responsibility to different agencies for risk assessment (its scientific or technical component) and for risk management (its policy or political component).

1.2.3 Transparency

Risk analysis should be transparent and open. Details of the risk assessment undertaken and any risk management options examined should be readily available for both peer review and public scrutiny.

1.2.4 Consistency and harmonisation

From a regulatory perspective, risk analysis should be consistent with both government policy and international obligations. Risk analysis should take account of international standards, guidelines and recommendations so that it is harmonised as much as possible with international practice. However, a government may in some circumstances elect to use criteria that are more rigorous than international practice, and international agreements may

provide for such a decision. For example, quarantine authorities may use risk management strategies that are more stringent than international standards, guidelines and recommendations where this is scientifically justifiable and consistent with international obligations.

1.2.5 Subject to appeal on process

The process of risk analysis should be subject to appeal to ensure natural justice. The Nairn Review proposed a consultative framework that by improving communication with stakeholders should limit the need for appeal on technical or scientific grounds but permit appeal on process (Nairn *et al.* 1996). Although the Nairn Review proposed establishing AQIS as a statutory authority, the Australian government has decided not to implement this recommendation. However, it will appoint a Board for AQIS that will, *inter alia*, ensure a mechanism for adjudicating on any appeal. The need for appeal through both administrative and judicial approaches was also confirmed in a recent report on the use of risk analysis in a wide range of regulatory agencies in the United States (CRARM 1997).

1.2.6 Subject to periodic external review

Within any organisation, the risk analysis process and associated decisions should be subject to periodic external review. Such external review is consistent with the principles of transparency and harmonisation, and with overseas experience with the use of risk analysis in regulatory decision-making. The recent review of risk analysis in the United States regulatory agencies (CRARM 1997) concluded that there is a need for greater use of external peer review of regulatory decisions that are based on risk analysis.

Other areas where significant changes are occurring and starting to affect risk analysis include risk perception and risk communication. Over the past decade there has been a significant increase in studies on risk perception, including individual, group and societal judgement of the nature and magnitude of various types of risk. There is increasing recognition that risk communication is an essential element of risk assessment and risk management, and not just a final step in which results of an assessment and recommendations for risk management are advised or promulgated. However, there is also an increasing recognition of the need to present the results of risk assessments in ways that are clear and understandable to different stakeholders. Many people, whether involved in a particular risk assessment as members of the general public or as decision-makers, are neither interested in nor able to understand complex or detailed assessments, particularly if presented in statistical terminology (a 95 per cent confidence of a risk being between 1 in 4.6×10^{14} and 1 in 5.2×10^{15} per year). Visual presentation of such information is far more effective, and assessments and

management options are increasingly being summarised in graphs, diagrams, maps and user-friendly computer programs that allow people to see the effect of varying different input parameters. For issues that are geographically based, such systems can draw on powerful visual presentation tools such as geographic information systems as an aid to understanding assessments and facilitating decision-making under uncertainty (cf. the National Resource Information Centre's decision support system for selecting a national radioactive waste repository, Veitch and Caughley 1993).

2. Proposed process for import risk analysis

The Nairn Review was asked to examine the current import risk analysis process used by AQIS (AQIS 1991) and considered many submissions that commented on various aspects this process. The review proposed a process for import risk analysis that it argued should provide greater consultation and ownership, while continuing to meet Australia's international obligations. The major differences between the process proposed and current AQIS practice are in the duration, timing and amount of consultation and its provision of an appeal mechanism. The proposed process provides a transparent framework for import risk analysis that the Nairn Review acknowledged may require finetuning to take account of experience with its application.

2.1 Consultation and a partnership approach

Many submissions to the Nairn Review stressed that early consultation and use of a partnership approach to import risk analysis would address many of their concerns. A major theme of the review was that quarantine is a shared responsibility best met through a partnership approach involving governments, industry and the general public. The Nairn Review argued that early consultation with key stakeholders will help to obtain consensus on priorities, the need for detailed risk analysis, the timetable and deadlines, the scope of the risk analysis and the methods it should employ, and that the risk management required to ensure the proposed import would not jeopardise Australia's animal and plant health status nor have a negative effect on its natural environment (Nairn *et al.* 1996, p. 91).

2.2 Initial advice on import access requests

The Nairn Review recommended that when AQIS receives an import access request, it should immediately advise registered stakeholders (which are key industry groups that it proposes AQIS identify) and the general public that

an application has been received. This advice should include the use of electronic media such as the Internet and the Worldwide Web. Individuals and organisations that are not registered stakeholders but have an interest in any particular request can then follow its progress or arrange to participate more fully through one of the relevant registered stakeholders.

Under the proposed process, AQIS would then undertake a preliminary evaluation of the request to determine whether or not it should be considered by in-house risk analysis or would require a more detailed risk analysis with broader external consultation. AQIS would advise relevant registered stakeholders of its preliminary evaluation on each import request, nominate its preferred process for undertaking the risk analysis, and request that stakeholders indicate a priority for considering the request. AQIS would ask the relevant registered stakeholders to endorse its preferred process. If a majority of stakeholders agrees with the preferred process nominated by AQIS, then AQIS would initiate the risk analysis after its Board determines the priority of the request. The Nairn Review identified several criteria that should be considered in determining the priority given to an import access, including the extent to which Australia is likely to benefit from the proposed import, the source of the import access request, the quality of the application and supporting documentation, and the time the application has been before the Board (Nairn *et al.* 1996, pp. 93–5).

If AQIS and relevant registered stakeholders cannot agree on the preferred risk analysis process, it should meet with them to try to obtain consensus. If agreement is still not forthcoming, then the matter would be referred to the Board, which will determine the process to be followed. In all cases, AQIS would advise the applicant and relevant registered stakeholders of the outcome of its consultation on whether the request will be considered by in-house or detailed risk analysis.

2.3 Determining the type of risk analysis

A relatively small number of import risk analyses gain public and media attention because they are complex and controversial. However, it should be emphasised that the vast majority of import access requests are routine and should be addressed by AQIS by a process of in-house risk analysis. The Nairn Review stressed that the in-house risk analysis process is not in any way less scientific than the detailed risk analysis by scientific experts from within and outside AQIS – it is just less complex because of any of a number of reasons that determine whether an import access request can be readily approved or rejected on sound scientific grounds. For example, requests that could be readily approved include those for import of a commodity from a source with a similar health status to that of a source already approved for

imports of the same commodity. Alternatively, there may be reasons that would enable an in-house assessment to determine that an import access request can be readily rejected on sound scientific grounds. For example, such reasons would include requests that involve possible or likely contamination with an agent of a disease of concern known to be unable to be removed or inactivated by the application of current risk management strategies.

For in-house import risk analysis under the process proposed by the Nairn Review, AQIS would establish an in-house risk analysis team (IRAT) that, once the priority for considering an import access request has been determined, would develop a timetable, decide the risk analysis method to be used, and seek whatever external advice and consultation it deems necessary. This consultation would normally include discussion with the applicant and relevant registered stakeholders while proceeding with the risk analysis. It would also include the routine release of a discussion paper supporting the draft decision and (where an application is approved) the draft protocol governing the proposed import.

Under the process proposed by the Nairn Review, AQIS would coordinate and chair a Risk Analysis Panel (RAP) for those import access requests that do not fit the criteria for an in-house risk analysis by AQIS and require a more detailed risk analysis by scientific experts from within and outside AQIS. Each RAP would comprise a core of two government members with experience and expertise in quarantine risk analysis plus one to three external members with scientific expertise relevant to the import access request under consideration. 'Members would be selected because of their scientific expertise, and not as representatives of any particular organisation, sector or industry. They would ensure that each detailed risk analysis considers the best available and most current scientific knowledge. Their involvement should also help to ensure improved consultation, transparency and independence – and thus ultimately greater ownership of the process itself and the RAP's final decision' (Nairn *et al.* 1996, p. 99).

Under the proposed process, AQIS and relevant registered stakeholders would reach consensus on the membership of each RAP. If, after consultation, AQIS and relevant registered stakeholders cannot agree on membership of the RAP, the matter would be referred to the Board, which would determine the panel's membership. Each RAP would estimate the time needed to undertake its risk analysis, identify key stages in the analysis, and seek agreement with relevant registered stakeholders on its proposed timetable and deadlines. Each RAP would also determine and agree on the scope of the risk analysis, including identification of the pests and diseases of concern to be considered, the scope of the scientific assessment required, the need for and scope of any other assessment

required (economic, environmental, etc.), and the analytical methods to be used. Each RAP would prepare a preliminary evaluation as an issues paper that would also propose when and how the RAP will consult further with relevant registered stakeholders during the risk analysis and include appropriate dates or deadlines for consultation. Consultation would include circulation of the issues paper to relevant registered stakeholders for comment and agreement on the proposed approach. The RAP would endeavour to obtain agreement of relevant key registered stakeholders on the proposed scope, methods and timetable before proceeding with its detailed risk analysis. If agreement cannot be reached after consultation, the RAP would meet with relevant registered stakeholders to try to obtain consensus. If agreement is still not forthcoming, the RAP would refer the matter to the Board for its decision.

2.4 Use of expert Working Parties for risk assessment

The Nairn Review proposed that, where necessary, a RAP would appoint or contract expert Working Parties to complete specific components of a detailed risk analysis. RAP Working Parties would be chaired, convened and managed by an appropriate expert from outside AQIS. Each Working Party would include at least one member from AQIS and, where appropriate, include industry experts. RAP Working Parties would comprise appropriate experts – particularly in science for Scientific Working Parties conducting detailed risk assessments and considering risk management options, and in economics for Economics Working Parties examining the potential economic loss due to the introduction or establishment of any pests or diseases of concern. In some cases, a RAP may also identify a need to assign and contract Working Parties to examine other areas.

The Nairn Review anticipated that RAP Working Parties would usually be chaired by an appropriate professional officer from one of the specialist Groups within the Commonwealth Department of Primary Industries and Energy. Thus a specialist scientist from the Bureau of Resource Sciences would normally chair each RAP Scientific Working Party, and a specialist economist from the Australian Bureau of Agricultural and Resource Economics would normally chair each RAP Economics Working Party. The Nairn Review noted that having expert Working Parties chaired and managed by agencies external to AQIS should further ensure that each RAP's work is, and is seen to be, quite independent and scientifically based and 'should also help to allay fears expressed in some quarters that AQIS has in the past faced a conflict of interest by being "judge, jury and executioner" on import access requests' (Nairn *et al.* 1996, p. 101).

2.5 Determining the level of risk

Under the process proposed by the Nairn Review, each IRAT or RAP would assess risks associated with the import access request referred to it, and examine appropriate risk management strategies that might be used to reduce the level of risk. Where such strategies are available to reduce the level of risk of introducing exotic pests or pathogens of concern to a manageable level, the IRAT or RAP would decide to permit the proposed import, subject to the risk management strategies it determines are appropriate.

In some cases, a RAP Working Party may determine that there are significant gaps in information that need to be filled by further research before it can make a scientifically based decision on a particular import access request. This conclusion would be conveyed to the relevant RAP, with recommendations that specify the gaps and define the research needed to fill them. The RAP would then consider contracting and funding necessary research – or encouraging other research providers or the applicant to fund such research – to fill the gaps identified. The RAP should also advise the applicant and relevant key registered stakeholders that the risk analysis is ‘on hold’ because of the information gaps identified, of the action it has taken or recommends be taken to fill these gaps, and of the proposed revised timetable for considering the import access request.

Quarantine decisions can have effects on areas considerably removed from the scientific or technical aspects of maintaining a country’s animal or plant health status. The Nairn Review thus stressed that

If a RAP considers that an appropriate risk management strategy can be applied to an import access request, it should advise the Department of Primary Industries and Energy, which would then be responsible for determining if approval is likely to have a significant effect on an Australian industry. The Department would also be responsible for identifying any structural adjustment measures that might be required, and liaising with other agencies such as the Department of Foreign Affairs and Trade concerning any international considerations that might arise from approving the request. Conversely, if a RAP considers that an appropriate risk management strategy cannot be applied to an import access request, it would advise the Department of Primary Industries and Energy, which would be responsible for liaising with other agencies such as the Department of Foreign Affairs and Trade concerning any international implications that might arise from not approving the request.

(Nairn *et al.* 1996, p. 103)

3. Methods for risk assessment

The fundamental steps in risk assessment are the identification of the risks or hazards of concern, the assignment of a probability of the occurrence of each risk, and the estimation of the consequences resulting from the occurrence of each risk. There are several published reviews of methods used in import risk assessment – including Kellar (1993), MacDiarmid (1993) and OIE (1994) for animal health; Moreau (1995), Osborne, McElvaine, Ahl and Glosser (1995) and Silva, Samagh and Morley (1995) for veterinary biologicals; and IPPC (1995) and McNamara (1995) for plant health. Reviews are available on trends in both animal and plant import risk assessment in the United States (Chang, Miller, Ahl and McElvaine 1994) and Canada (APHD 1994; Bossé *et al.* 1996), and on the incorporation of economic studies into import risk assessment (Dijkhuizen, Huirne and Jalvingh 1995; Dijkhuizen, Horst and Jalvingh 1996). However, most information on methods used in import risk assessment is gleaned by examining examples of specific assessments, whether primarily qualitative (Cassidy, Freier, Corso and Forsythe 1996 on risks associated with private quarantine facilities for horses), semi-quantitative (APHIS 1991 and CEAH 1996 on the risks of bovine spongiform encephalopathy in the United States) or quantitative (Beckett, Morris and MacDiarmid 1996, on risks associated with imports of porcine semen). There is also a significant and expanding literature on modelling the probable spread and effect of incursions of diseases, based on climatic factors (the use of the CLIMEX program to predict the likely range of introduced insect pests) or epidemiological spread (Markov chain or state-transition models of the spread of pathogens in susceptible populations).

An initial step in import risk analysis is to determine which diseases in the country of origin of a proposed import do not occur in the importing country and are of sufficient concern to warrant exclusion. Import risk analysis basically establishes a scenario tree or outline of the pathway or pathways of entry and establishment of unwanted diseases that might be associated with a proposed import. In qualitative approaches, emphasis focuses on the key points in the pathway where risk management factors can be applied to eliminate (by heat treatment of a product) or reduce (by vaccinating or testing live animals) the risk of importing diseases of concern. In semi-quantitative approaches, numerical values (the prevalence of the disease of concern) are applied at each point for which data are available. In fully quantitative approaches, such data are applied at all points of the pathway of entry and establishment.

3.1 Quantification

In many disciplines, there has been a marked trend towards the use of more quantitative methods of risk assessment over the past decade. In engineering

and related disciplines, fully quantitative assessments are feasible and widely undertaken. However, for most risk assessments in natural resource issues there are – and are likely to continue to be – data gaps that preclude a fully quantitative approach. In such disciplines, fully quantitative risk analyses are the exception rather than the norm. It is only in relatively simple cases that reliable quantitative data are available for all steps in an import risk assessment (for all points in the potential pathway or pathways of entry and establishment of a potential disease of concern). In addition, in complex situations with multiple possible scenarios that each have only an extremely small probability of occurrence (as is often the case in import risk assessments), the mathematics of fully quantitative assessment is problematic and not yet well defined. Such situations are assessable only by qualitative or semi-quantitative approaches even if good data are available for all points in a scenario tree. From a practical perspective, it should also be appreciated that even when they are possible, more quantitative approaches are extremely resource-intensive, requiring skilled staff, large amounts of data, sophisticated computing resources and a large investment of time. Thus although quantitative approaches to risk analysis have some application in evaluating selected import access requests, semi-quantitative and qualitative approaches are more appropriate for the vast majority of import risk analyses.

With the trend to increasing use of quantitative approaches to risk assessment, there has been a tendency to consider that more quantitative approaches are necessarily ‘better’ or ‘more scientific’ than less quantitative approaches. However, quantitative risk assessment has also been criticised recently for a perceived lack of objectivity (Breyer 1993; Pollack 1996) resulting from the use of expert judgments that allegedly reflect not only scientific knowledge but also factors such as ‘policy values and cultural values’. Some commentators have expressed concern that scientific judgment involved in risk assessment is not as objective as may be purported, and that quantitative estimates have a large variability and uncertainty, particularly when applied to environmental problems. For example, one study of various estimates of the potential carcinogenicity of a particular chemical showed that quantitative assessments could vary by as much as eight orders of magnitude, a variation characterised as ‘clearly a dubious basis for issuing permits, setting clean-up levels, and setting standards’ (Ginsburg 1993). There is concern that scientific and policy judgments involved may damage the credibility and objectivity of risk analysis, particularly its more quantitative approaches (Cox and Gooday 1995). However, explicit and clear acknowledgment and discussion of assumptions and data used in risk assessment should minimise any concerns about the lack of objectivity and permit more careful consideration of the need to obtain better data where necessary.

The Nairn Review was asked specifically to make recommendations on 'revisions to the quarantine risk assessment process, including the potential for greater use of quantitative methods of assessment'. Comment was sought on risk assessment methods through submissions and public hearings. In addition, the review paid particular attention to current practice and trends in risk assessment methods used in other countries, especially in Canada, New Zealand and the United States. The Nairn Review concluded that import risk assessment should use the method most appropriate to the import access request being considered, with each assessment group (IRAT or RAP) determining which method is most appropriate for each import access request. It concluded that 'the perception held in some quarters that quantitative approaches are inherently "better" or "more scientific" than qualitative approaches is misguided – a poor quantitative risk assessment (one using poor data or using inappropriate quantitative techniques) can be quite misleading and far less scientific than a good semi-quantitative or qualitative assessment' (Nairn *et al.* 1996, p. 106).

3.2 Deterministic and stochastic approaches

Semi-quantitative or quantitative approaches to risk assessment can be either deterministic or stochastic. The deterministic approach assigns a single number (an amount or a probability) to each point in a scenario tree so that assessment leads to a single value, ignoring the fact that variation is an integral component in all natural systems. In contrast, the stochastic approach assigns each point a value that takes account of variation – it uses a parameter defined as a probability distribution for each point. For example, in considering disease risks associated with an import access request, a risk assessment using a deterministic approach might assign a value of 10 per cent for the prevalence of a particular disease in the population of origin. In contrast, a stochastic approach might assign this a value determined by a normal distribution with a mean of 10 per cent and a standard deviation of perhaps 2 per cent, thus approximating the real range of values encountered in the population.

The stochastic approach uses computer simulation, which is now available in a range of software packages that can be run on desk-top computers (@RISK, Palisade Corporation). Such simulations lead not to a single value for the overall assessment but to a range of values defined as a probability density distribution. For example, a deterministic analysis might conclude that the risk of introducing a particular disease with an imported product is 1 in 15 700 000 per tonne per year. A stochastic analysis of the same pathway might lead to a result of a 95 per cent confidence that the risk is between 1

in 14 000 000 and 1 in 17 000 000 per tonne per year. A stochastic approach provides a more realistic estimate than does deterministic analysis because it takes account of natural variation.

3.3 Sensitivity analysis

Simple scenario trees can be analysed in a semi-quantitative or quantitative manner even where there are some gaps in data. For example, an extreme value may be assumed for data at a particular point (that the prevalence of infection in the population of origin is 100 per cent) for missing data points and the simulation run. One can also use expert opinion to provide a 'best guess' of the value for a particular data point (using the Delphi technique). Other approaches that are likely to be used increasingly include applications from new computing developments (fuzzy logic or agent-based modelling) to help fill data gaps. Such approaches enable the analyst to conduct sensitivity analyses to determine whether or not the particular parameter for which data are not available has a major impact on the overall risk. Such analysis often shows that there are only a few critical points in the pathway that have a significant effect on the overall probability, and if good data are available for these points, the analyst can be confident that the assessment is robust. However, if good data are not available for these critical points, the analyst can report that robust quantitative risk analysis is not possible until further information is available to fill these gaps. Risk analysts reaching this conclusion might encourage research providers to commission or conduct appropriate research to fill the gaps identified, use a less quantitative approach, or focus on appropriate risk management options to reduce the risk.

3.4 Manageable risk

In many risk analyses, the level of risk that a decision-maker, stakeholder or society as a whole is prepared to accept has been the subject of much debate. Some authorities advocate attempts to determine a level of 'acceptable risk', often by comparing the risk of a particular decision option with risks taken in other areas (e.g. comparing the apparent risk of death from ingesting a residue with the average risk of death from other causes such as aeroplane or automobile accidents). Others have argued that with appropriate consultation, a team undertaking a risk assessment should assess risks associated with a particular risk analysis and examine appropriate risk management strategies that might be used to reduce the level of risk to one that is 'manageable'. For example, the Nairn Review concluded that for quarantine risk analysis the pertinent concept is one of 'manageable risk' – not 'no risk' (which is unachievable) or even so-called 'acceptable' or

'minimum' risk. It acknowledged that a certain amount of judgment is implicit in this concept, but developed a proposed process that it believes ensures that stakeholders are fully involved in determining who should participate in making this judgment. Consistency of application of the concept of manageable risk will be achieved by reference to existing Australian policies and procedures, by reference to relevant international standards, guidelines and recommendations, and through the contribution of experienced risk analysts (Nairn *et al.* 1996).

3.5 The precautionary principle

In some cases, a risk analysis may determine that there are significant gaps in information that need to be filled by further research before a scientifically based decision can be made on a particular issue. Analysis might also lead to recommendations that specify the gaps and define the research needed to fill them. For example, a number of submissions to the Nairn Review argued that where there is significant uncertainty or where there are significant gaps in knowledge needed to conduct risk assessment, quarantine authorities should take a conservative approach. Some submissions went further and advocated adoption of the precautionary principle (or a variant of it) in cases they deemed involved significant uncertainty, probable delayed identification or reporting of incursions, or inadequate or no means of containing, controlling or eradicating incursions.

The precautionary principle has been defined in various ways but may be simply seen as the principle of adopting a conservative approach when the relevant information needed to make an informed decision is limited – the greater the uncertainty, the more conservative should be the decision. Provided due account is taken of the need for judgment in any decision, the principle is not necessarily inconsistent with the principles of risk analysis. Quarantine provides a good example of the valid application of the precautionary principle. The SPS Agreement specifically states that 'in cases where relevant scientific information is insufficient' member countries of the WTO may provisionally adopt 'sanitary or phytosanitary measures on the basis of available pertinent information'. However, the SPS Agreement sees the adoption of conservative measures as only provisional, and states that if adopted on the basis of gaps in information, member countries 'shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time'. Thus Australia's international obligations preclude the ongoing or indefinite use of the precautionary principle as grounds for not taking a decision on any import access request (Nairn *et al.* 1996).

4. The need for a multidisciplinary approach

Risk assessment (particularly using more quantitative approaches) is an extremely demanding, complex and resource-intensive process. In the natural resource issues generally (including quarantine), it involves consideration of scientific and economic factors, often requiring the use of multidisciplinary teams. The tasks may be split among different teams, typically with one group working on scientific risk assessment and feeding its results into another group working on economic assessment for the same risk analysis. There is also a trend towards greater consideration and inclusion of environmental concerns in risk analyses of natural resource issues, particularly to ensure sustainability of the natural resource base, and this trend was reflected in the number of submissions the Nairn Review received that commented on the need for more rigorous environmental assessment in import risk analysis. Indeed, in complex import risk analyses, risk assessment teams may need to include specialists with skills in disciplines such as communications, mathematics, statistics, computer modelling, ecology and environmental science in addition to those in risk analysis, animal or plant health, and economics.

One of the challenges for risk assessment in natural resources generally is to improve the match between the outputs of scientific assessment and the inputs needed for economic assessment. For example, health risk assessments often measure risks in terms of a biological indicator (the percentage increase in lung function) rather than in using measures that might be appropriate as the starting-point for an economic assessment (the number of days a person is ill). The recent review of risk analysis in United States regulatory agencies (CRARM 1997) concluded that there is a need for far greater collaboration between scientists and economists involved in risk assessment to minimise inconsistencies in their approaches to risk assessment and management. There is undoubtedly both a need and an opportunity for similar improvement in collaboration between scientists and economists involved in import risk analysis in Australia.

Although there have been several cost-benefit analyses of Australia's quarantine, with the most recent being that of Hinchy and Fisher (1991), there have been relatively few formal published economic risk assessments of specific quarantine import access requests. In Australia, those that have been completed tend to be for long-standing and high profile requests to import products. Examples include apples (Hinchy and Low 1990), salmon meat (McKelvie 1991; McKelvie *et al.* 1994) and poultry meat (Hafi *et al.* 1994). It can be expected that future import access requests for other agricultural products will require detailed risk analysis using a consultative approach similar to that proposed by the Nairn Review. Some of these will require

detailed scientific risk assessments, which will tend to use more quantitative approaches, if only to provide a basic sensitivity analysis and comparison of the effect of different risk management options. Many will also require detailed economic assessment of the potential effects of approval of import access requests – whether the specific cost of the potential introduction and establishment of an exotic disease (for inclusion in the import risk analysis) or of more general economic effects on prices and markets (for consideration in possible industry adjustment measures or other policy options). Some future import access requests will also require detailed environmental risk assessment, and there is a role for economists to work with scientists to develop better standards and methods for such assessment.

The trend of using more quantitative approaches in risk analysis will undoubtedly continue. In practice, the benefit of more quantitative approaches is not in attempting to quantify precisely the actual level of risk associated with a particular decision. The main benefit of more quantitative approaches is the ability to compare risks between different options and to examine the effect of different management strategies. If the analyses are structured in accordance with the principles noted earlier in this article, the data, data gaps, assumptions and scenario tree used will be transparent and available for peer review and amendment as further information becomes available. By following these principles, risk analysis will provide more robust and better presented information to help decision-makers make the best possible decisions with the information available.

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