The application of risk assessment in animal quarantine in Australia

D.W. WILSON and D.J.D. BANKS *

Summary: This paper describes the ways in which the Australian Quarantine and Inspection Service (AQIS) uses risk assessment and risk management. Taking into account the need to meet both national and international obligations, AQIS has adopted a more systematic and transparent approach to import risk assessment by employing a procedure designed to examine each point along the importation chain at which an animal or animal product might become infected.

The authors discuss the four principal factors influencing the risk involved and the three phases used by AQIS in assessing risk.

Objective data are rarely available in the animal health field and most analyses rely, at least in part, on subjective estimates. The authors outline a way of overcoming this through the use of simulation, whereby probability distributions are used for many steps.


INTRODUCTION

This paper describes how the Australian Quarantine and Inspection Service (AQIS) uses risk assessment and risk management. Taking into account the need to meet both national and international obligations, AQIS has adopted a systematic and transparent approach to import risk assessment. This approach is consistent with the commitment of the Australian Government to quarantine risk assessment, which was set out in the 1988 quarantine policy statement “Australian quarantine – looking to the future” (3). However, a conservative policy is still in place (in line with the national animal health status), reflecting the importance of the livestock industries in the economy of Australia.

INTERNATIONAL FOCUS

Australia enjoys a very favourable animal health status, mainly due to the physical isolation of the country. In more recent times, an increase in the volume of international movements in animals and animal products and more rapid transport systems have heightened the risk of the introduction of unwanted pests and diseases and necessitated a new approach to quarantine. Quarantine philosophy has also been changed by greater attention being paid to the international obligations of a given country in formulating national quarantine laws.

* The Australian Quarantine and Inspection Service, G.P.O. Box 858, Canberra, ACT 2601, Australia.
As a member of the international community and particularly as a major agricultural producer and exporter, Australia is expected to fulfil these obligations, while at the same time protecting the industries which form the backbone of the national economy. An accepted international principle is that all countries have the right to adopt measures which are necessary to protect human, animal and plant health (2). This principle has been incorporated in virtually all multilateral, bilateral and regional treaties and agreements on trade. A further principle is that these measures should only be as stringent (i.e. the extent to which they interfere with trade) as is necessary to achieve disease control objectives. This generally means that total bans on imports cannot be justified if scientifically-based control measures could reasonably be expected to prevent entry of disease.

The new General Agreement on Tariffs and Trade (GATT) Code on “Sanitary and Phytosanitary Measures” (human, animal and plant health) defines principles for handling quarantine measures and settling disputes involving quarantine arrangements between countries.

Principles in this GATT code include the following:
- harmonisation (basing national quarantine measures on agreed international standards)
- equivalence (using a variety of measures equivalent to the international standards and appropriate to the countries concerned, in order to achieve quarantine objectives)
- national treatment (imports are treated no more stringently than domestic produce)
- transparency (an open consultative process for making decisions and settling disputes)
- disease-free zones (acceptance of animals and animal products from disease-free areas of otherwise affected countries).

**APPROACHES TO RISK ASSESSMENT: OLD AND NEW**

Various terms have been coined to distinguish the new approach: “acceptable risk”, “tolerable risk”, “minimal risk”, etc. Although the above terms have come into vogue relatively recently, animal health and quarantine programmes have always been based on risk assessment and risk management. The quarantine officer must first determine whether controls are necessary and then identify those which are best suited to the task. The first step is achieved through assessment of risk and the second through management of risk.

From a quarantine perspective, risk assessment can be considered as the process of identifying and estimating the statistical probabilities, and evaluating the consequences of all risks associated with the importation of an animal or animal product. Risk management is the decision-making process used to identify and implement measures which can be applied before, during or after importation to reduce the risk to an acceptable and manageable level.

In this context, risk assessment and risk management include all procedures used in the development and review of import requirements and the addressing of operational problems (such as the development of position papers, consultation procedures,
the preparation of technical arguments and the notification of decisions. The discussion paper, “The application of risk management in agricultural quarantine import assessment” (1), broadly outlines the procedures followed.

The above terms have also been used by critics to distinguish between the new approach and the old, so-called “nil risk” or “zero risk” concept of quarantine. There is no such thing as “nil risk” in quarantine in the real world. The very conservative import policies previously applied in Australia were often called “nil risk” by primary industry organisations which tend to be protectionist by nature. However, in the 1970s and 1980s, the demand for new genetic material increased, particularly from countries from which imports had previously been prohibited. This pressure has continued with progress in technology (embryo transfer technology and new diagnostic techniques) and the increase in the international movement of people and animal material. The extent of the increase in the international movement of animals and genetic material can be gauged by the fact that, in 1980, Australia had eight agreed import protocols, while there are now over 120 such protocols for live animals, genetic material and animal products.

The imposition of a ban on imports does not constitute a “nil risk” policy, especially in the face of demand for new genetic material and the consequent high level of smuggling which may occur. In almost all cases, smuggling poses a higher disease risk than controlled imports.

**SOURCES OF INFORMATION USED BY AQIS**

The risk assessment process is greatly assisted by accurate knowledge of the relevant risk factors, including the following:

- the diseases of concern and the prevalence of these diseases in the species for export and any closely related species in the exporting country and surrounding areas
- the epidemiology of the diseases of concern
- the effectiveness of the disease surveillance and monitoring systems in the exporting zone/country and the powers of the veterinary administration over the movement of animals and animal diseases
- the sensitivity and specificity of diagnostic tests
- any effect of product processing on risks of disease introduction.

AQIS uses several databases to make the information essential for risk assessment readily available. These are described below.

**Country disease status database**

Information on animal disease statistics, the current disease outbreak situation, animal population, veterinary infrastructure, disease control and import policies, and the disease situation in neighbouring countries is compiled for each exporting country. Some of the data come from the OIE publications *World Animal Health* and *Disease Information* and the FAO-OIE-WHO publication *Animal Health Yearbook*.

While it is vital that OIE data should be the basis of risk assessments, the animal disease information supplied to the OIE by Member Countries is still inadequate. This
information is qualitative, vague and incomplete, and it is difficult to obtain accurate data, even from developed countries, for diseases other than List A diseases.

**Disease database**

The disease database contains information on all OIE Lists A and B diseases and covers host susceptibilities, modes of transmission and disease characteristics.

**Pathogen inactivation database**

This contains data on agent survival and inactivation by pH changes, temperature, chemicals, storage, etc., for all OIE List A and some List B pathogens.

For animal products, AQIS has gathered as much data as possible on standard industry manufacturing processes and has assessed the risks posed by each process.

**OIE codes**

The OIE International Animal Health Code Commission has developed codes which establish recommended quarantine procedures for the international movement of animals, genetic material, animal products and animal-derived biologicals. The OIE Standards Commission has developed standards for diagnostic tests which support the *International Animal Health Code* (4). The diagnostic techniques set a standard for international trade.

**METHODS OF ASSESSMENT OF DISEASE RISK**

AQIS employs a step-by-step procedure designed to examine each point along the chain of importation at which the animal or product might become infected. The underlying philosophy is that the process is structured and objective. This method shows the assumptions made when estimating the probabilities of various events which might lead to an outbreak and how these probability values were calculated.

The four principal factors influencing the risk are as follows:

- zone/country factors (i.e. diseases present in the animal population of the zone/country of export)
- commodity factors (i.e. diseases present in the animal or product)
- risk reduction factors (i.e. methods of reducing risk, e.g. product treatment, animal testing or quarantine)
- probability of domestic exposure (i.e. risk of pathogens from the imported animal or product reaching susceptible animal populations in the importing country).

Three phases in assessing risk can be identified:

- identifying the chain(s) of events (steps) necessary for a disease to become established
- assigning point probabilities to each step (the component probabilities are multiplied where a step involves several components which constitute a risk only when they come together [e.g. there is contact with an animal and this animal is infected]; otherwise, probabilities tend to be additive)
- identifying the points of greatest sensitivity in an importation chain (i.e. points at which pathogens of concern might enter the chain, and points at which contamination might be reduced or eliminated from the product or detected in the animal); this enables maximum attention to be directed at these points.
The ultimate restricted cumulative risk estimate is the risk ascribed to the importation of an animal or animal product, taking into account measures which may be taken to manage the risk. By using a range of values for the steps, the cumulative risk might be quoted as falling within a given range, with a known level of confidence.

In the past, quantitative risk assessments have been carried out largely by manually analysing standard probability estimates. The various steps in the chain of events which might lead to an outbreak were described and a probability value was then assigned to each step. The final risk estimate was then calculated from the component parts.

This method can be refined by incorporating the analysis into a computer spreadsheet model. The only difference between the two is that spreadsheet models calculate probability estimates automatically; this is particularly valuable in assessments with many individual steps. Similarly, in situations where risks can arise from several different sources or through more than one pathway, spreadsheet modelling simplifies the task of calculating cumulative probabilities. Spreadsheet models have particular value if individual probability estimates require frequent changes (in the light of new scientific evidence or due to differing opinions regarding the risks of occurrence of a particular event or step).

In an ideal situation, the risk of introduction of an unwanted disease through a particular importation could be accurately determined using objective data generated by surveys and research. The probability of infection of an animal or animal product would be known at all potential infection points and the final cumulative risk could be calculated from the individual probabilities.

Such complete data are rarely available in the animal health field and most analyses rely, at least in part, on subjective estimates based on extrapolations of available information. Analyses of the levels of risk have to be performed on the basis of the best available data. Surveys may not have been conducted, or the source of risk may not easily lend itself to objective analysis.

One way of overcoming this lack of concrete data is through the use of simulation, whereby a probability distribution is used rather than a single probability value for each step which requires a subjective estimate. The distribution may be uniform between maximum and minimum limits or may follow a curve (e.g. normal or triangular distributions). The model is then run over a large number of iterations (e.g. 10,000), using a commercial simulation package (@Risk, Palisade Corporation, Newfield, New York, United States of America) within the spreadsheet, which results in a distribution of final risk estimates rather than a single value. The distribution is calculated from the various combinations of individual step probabilities selected during the run, which (over a large number of iterations) represents virtually all possible outcomes.

The advantage of this method is that rather than being presented with a single estimate of the risk involved with a particular action, the decision-maker has access to a distribution which describes a range of possible values and their likelihood of occurrence. This gives a better understanding of the risk being taken. For example, in addition to the mean risk value, it is possible to show the likely spread or variation in this value, either graphically or using percentiles. The main statistics of interest are the mean and the 5% and 95% percentiles.

Sensitivity testing of the model can also assist by identifying those steps which have a major influence on the overall risk estimate. While it may not be possible or
cost-effective to implement risk reduction measures at all stages in importation, this
technique identifies areas where such measures would have the greatest effect. The
model is run using the “likely” values estimated earlier and the cumulative risk estimate
is noted. The first step risk in the model is then increased tenfold and the cumulative
risk estimate is re-calculated. The first step risk is then returned to its original value, and
the second step increased tenfold and so on. When all step risks have been evaluated,
their effects on the cumulative risk estimate are compared.

Sensitivity testing will have identified the critical points where controls would
significantly reduce the overall risk. The model can then be used to show the effect of
implementing these controls. For example, the cumulative risk estimate for a product
imported without controls might be 1 in 10,000. The controls which are identified as
being practical to impose (and which would be included in the import requirements) are
inserted into the model, which is then re-run. The effectiveness of these controls can then
be demonstrated in the model by reducing the step risk at the point of application of the
control to a figure appropriate to the perceived effectiveness of the control which, in this
example, might result in a shift of the cumulative risk estimate to 1 in 100,000.

**STEPS OR FACTORS IN THE IMPORTATION CHAIN**

These factors or steps can be placed into the cells of a spreadsheet to enable
calculations of the risk for each step and substep and the final cumulative risk estimate
to be made.

**FACTORS FOR LIVE ANIMALS**

**Exporting country factors**

The factors influencing the risk associated with the exporting zone/country/region
are as follows:

a) Disease prevalence in the zone/country/region and surrounding areas:
   - from OIE reports and literature (objective? how reliable?)
   - from informal information
   - specific surveys
   - regionalisation of disease

b) Vector presence and efficiency – seasonal variation

c) Import policies

d) Assessment of Veterinary Services:
   - diagnostic capabilities
   - border security
   - confidence in certification provided.

The variables affecting the risk associated with an animal prior to export are as
follows:

a) Disease prevalence in species and breed (notifiable? official disease control
programme?)
b) Disease characteristics:
   - methods of spread
   - clinical signs
   - carrier state? reservoir species?

c) Effectiveness of pre-export quarantine or similar isolation procedure:
   - use of sentinel animals
   - effectiveness of supervision

d) Effectiveness of disease testing:
   - number and sequence of tests
   - sensitivity and specificity of tests
   - diagnostic capability of exporting country
   - herd testing vs individual testing

e) Pathogen treatment effectiveness.

The level of risk during transportation can vary due to the following parameters:
   - inadequate disinfection of aircraft/vessel
   - route taken
   - infection by animal, human or equipment source.

All these factors can be combined to show the cumulative risk of an infected animal entering the importing country.

Importing country factors

The risk associated with an infected animal being released from post-arrival quarantine or a similar isolation procedure is influenced by the following factors:
   - disease characteristics (as above)
   - effectiveness of disease testing (as above)
   - effectiveness of pathogen treatment.

The following factors affect the risk that a susceptible local animal will become infected and cause an outbreak in the importing country:
   - vector presence and efficiency
   - host susceptibility
   - end use of imported animal
   - husbandry practices.

The infection chain must be completed for an outbreak to occur.

FACTORS FOR ANIMAL PRODUCTS

Exporting country factors

The factors influencing the risk associated with the exporting zone/country/region are as follows:

a) Disease prevalence in the zone/country/region and surrounding areas:
   - from OIE reports and literature (objective? how reliable?)
   - from informal information
b) Vector presence and efficiency – seasonal variation

c) Import policies

d) Assessment of Veterinary Services:
   - diagnostic capabilities
   - border security
   - confidence in certification provided.

The variables affecting the risk of a pathogen being present in a product from an infected donor are as follows:

a) Disease prevalence in species and breed (notifiable? official disease control programme?)

b) Disease characteristics:
   - methods of spread
   - predilection sites
   - clinical signs (carrier state in donor?)

c) Effectiveness of disease testing of donor and/or product (if any):
   - number and sequence of tests
   - sensitivity and specificity of tests
   - diagnostic capability of exporting country

d) Pathogen treatment effectiveness (if any).

The factors which influence the risk of a disease agent surviving specified processing are as follows:

- pH changes (e.g. post-mortem changes in meat)
- temperature (e.g. retort pouches, ultra-high temperature [UHT] treated milk)
- chemical additives (e.g. B propriolactone, salt)
- post-processing contamination
- plant approval and registration:
  - risk of cross-contamination
  - incorrect or nil processing.

The risk of an agent surviving storage and transport is influenced by the following factors:

- maintenance temperature (e.g. freezing to kill Trichinella spp.)
- maturing of product (e.g. cheese)
- possible contamination during storage or transport.

All these factors can be combined to show the cumulative risk of a contaminated product arriving in the importing country.

Importing country factors

The factors influencing the risk associated with contaminated products being released into the importing country include the following:

- whether the product is fully processed.
The variables affecting the risk that a susceptible local animal will come into contact with a contaminated imported product, become infected and cause an outbreak in the importing country are as follows:

- disease characteristics
- vector presence and efficiency
- host susceptibility
- end-user restrictions to reduce risk
- husbandry practices.

The infection chain must be completed for an outbreak to occur.

Various mechanisms exist to reduce the risk associated with the import of animal products. These include the following:

1. a requirement for processing certificates from the veterinary authorities of the exporting country to accompany each consignment
2. the use of designated processing plants which have been previously inspected and approved
3. the use of internationally-recognised manufacturing processes, e.g. F\(_0\)\(_3\) (heating at 121°C for 3 min)
4. random sampling of product on arrival for:
   - manufacturing defects (not strictly of animal quarantine concern but a good indication of adherence to good manufacturing practices)
   - the presence of pathogens (time-consuming and costly; justifiable only for pathogens of major concern or for particular processing plants or products which have previously caused problems)
5. restrictions on end-use/end-user (according to the requirements listed on the import permit):
   - import for use in an approved establishment only
   - import for specific use only
   - permit for single import only vs an unlimited permit.

All these mechanisms are used by AQIS, depending on the assessed risk.

**IMPORT PROTOCOL DEVELOPMENT AND REVIEW**

Australia is now following the form of certificate recommended in the OIE *International Animal Health Code* (4). Australia also incorporates the control measures for the major diseases (OIE Lists A and B) set out in the *Code* and the tests listed in the OIE *Manual of standards for diagnostic tests and vaccines* (5). The use of internationally recognised procedures helps to standardise risk assessments.

Protocols for live animals and animal products are based on templates which define each step of the process using standardised paragraphs. The strategy for each disease expressed in the template would be used for all imports of species or the products of species susceptible to the disease from countries with similar disease status and control measures.
Steps in the development and/or review of import requirements include the following:

a) Research is conducted into disease risk using factors or steps in the importation chain.

b) An objective risk assessment paper is prepared and perhaps a draft protocol from research.

c) Initial consultation takes place with industry and scientific bodies (Commonwealth Scientific and Industrial Research Organisation; State Departments of Agriculture; Australian Nature Conservation Authority; Australian Veterinary Association; national organisations of rural industries which are potentially affected) and the general public. In consultation, it is made clear that only disease risk aspects of the proposal will be addressed – trade and protection issues are dealt with in other areas of Government. Consultation is also conducted through circulated papers and public/industry meetings with a clearly defined period for discussion and comment. Many industry organisations now have technical committees to address import/export issues, which meet regularly with AQIS.

d) Technical comments on the first risk assessment paper are examined, and a subsequent paper prepared. If the proposal receives solid support on disease risk grounds, the subsequent paper would document the entire risk assessment process. However, if the proposal receives solid opposition on disease risk grounds, the basis for the opposition would be researched and, if found valid, the proposal would be refused. If technical comments are broadly based and the proposal is important or controversial, a second paper would be prepared (incorporating comments received and research arising from those comments) for further consultation.

e) Discussions are held with potential exporting countries as early as possible during the consultation process.

f) Those concerned are notified of the outcome of the quarantine risk assessment.

The entire process must be well documented.

To a large extent, AQIS uses combined industry/government working parties to examine new proposals and to monitor existing policies and programmes. Such working parties are formed when AQIS does not have the necessary expertise in-house or when it is deemed advisable for the risk assessment to be performed independently of AQIS. Working parties are supposed to be based on “skills” rather than being “representative” (i.e. membership is based on the skills of the nominee rather than the fact that he or she may represent a sector of the Government or industry). In this way, discussions are more objective and outcomes more technically based.

Industry is now, justifiably, more involved in the quarantine decision-making process, and therefore has the responsibility to be objective and to separate the issues into those which relate to disease risk and those which do not (trade, subsidies and tariffs). This is true whether or not a specific working party is formed, and applies equally well during the normal consultative process.

The issues may be divided into the following groups:

a) disease risk
   - biological factors
   - economic effects of disease entry resulting from the decision:
     - present risk vs change in risk
     - major diseases only
b) economic effects of the trade resulting from the decision. It is not in the charter of AQIS to examine these effects, which are for assessment by other areas of Government.

All the above may be taken into account by the decision-makers (i.e. the AQIS assessment that the proposal presented insignificant disease risk, from a quarantine viewpoint, may be only one of the factors taken into account when the decision is made).

**QUANTITATIVE RISK ASSESSMENT**

The move to a more quantitative risk assessment system has not been without problems, which have included attempts to define “acceptable”, “tolerable”, “unacceptable”, etc. risks.

The terms “acceptable” and “tolerable” can have many definitions and the acceptability of a risk will vary, particularly when the group which serves to benefit from the import is different from the group at risk (by possible disease entry) from the import. Many imports of animal products (e.g. meat) fall into this category and this has led to the attempted calculation of cost/benefit ratios for some proposals. Generally, these have not been satisfactory, due to both the lack of objective data and the lack of agreement on “acceptable” ratios. However, a level of acceptable risk cannot be determined without consideration of the expected benefit.

AQIS considered adopting risk figures used in civil engineering: the most acceptable risks appeared to be in the area of 1:10,000, but there was doubt that this figure was applicable to animal diseases. In addition, AQIS found it difficult to propose that the same acceptable risk figure should apply to foot and mouth disease (FMD) as to bovine leucosis, for example, or Johne's disease. While the risk of importing FMD with an animal or an animal product could be reduced to a very low level fairly easily, the effects of an FMD outbreak in Australia would be catastrophic. On the other hand, the chances of importing *M. paratuberculosis* with cattle could be moderate, but the effects of such an import would not be as severe.

In recent major risk assessments conducted by AQIS (on the import of milk products from FMD-affected countries and on the import of salmon meat), quantitative risk figures have not been allocated to the assessments. AQIS does not yet feel that any such figures can be justified. AQIS is, however, still taking a “risk conservative” stance, in line with Government policy (i.e. that if there is insufficient data to assess the risk accurately, a conservative decision must be taken).

The national and international standardisation of risk assessment methodology is far more important than agreement on any so-called “acceptable” figure which could and should vary from country to country depending on pathogen, disease status, the need for import and the industries affected.

It must be emphasised that quantitative risk assessment does not tell the decision-maker what decision to make: it does not provide a substitute for survey or research data and does not remove the need for sound epidemiological knowledge. Quantitative risk assessment is used solely to assist, and not to control, the decision-making process.


Les quatre principaux facteurs de risque concernés et les trois étapes de la procédure d’évaluation des risques utilisée par l’AQIS font l’objet de la discussion.

On dispose rarement, en santé animale, de données objectives ; la plupart des analyses se fondent donc, au moins en partie, sur des estimations subjectives. Les auteurs indiquent comment résoudre ce problème en recourant à la simulation, ainsi qu’à la méthode des probabilités appliquée à différents stades.


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Resumen: Los autores describen las modalidades de aplicación de la evaluación de riesgos y de la gestión de riesgos en el Servicio australiano de cuarentena e inspección (Australian Quarantine and Inspection Service: AQIS). Con el fin de satisfacer las exigencias nacionales e internacionales, el AQIS ha adoptado un método de evaluación de riesgos relacionados con la importación particularmente sistemático y transparente, que remite a todas las etapas del proceso de importación en que un animal o un producto de origen animal puede ser infectado.

Son objeto de la exposición los cuatro principales factores de riesgo del caso y las tres etapas del método de evaluación de riesgos utilizado por el AQIS.

No es frecuente contar con datos objetivos, en sanidad animal; la mayoría de los análisis se suelen basar, al menos en parte, en estimaciones subjetivas. Los autores proponen resolver este problema mediante la simulación y valiéndose del cálculo de probabilidades aplicado en distintos momentos.


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REFERENCES


