The application of risk assessment methods in making veterinary public health and animal health decisions

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Summary: The newly emerging discipline of quantitative risk assessment has wide application in the field of veterinary public health and animal health. Regulatory authorities are increasingly faced with public policy decisions that must assess the risks of new technology or practices relative to the potential benefits, thereby establishing a level of acceptable risk.

The elements of risk are a choice of action, a probability of loss and a magnitude of loss. Perceived risk and actual risk are seldom equivalent; adoption of the methodologies used in technological and human health risk assessments will allow veterinary regulators to make better decisions. Determination of levels of acceptable risk are increasingly dependent on quantitative models, and examples are presented for evaluation of different post-mortem meat inspection systems, estimating disease risks associated with animal embryo transfer and formulating national border protection strategies. All models have some degree of subjectivity, and the decisions made by regulators and risk managers should incorporate a wide knowledge of the risk assessment process, as well as the conditions of use that will occur in the real world.


INTRODUCTION

Two major fields of veterinary endeavour are the health of economically important animals and the health of man (34). The maintenance of efficient, progressive and internationally competitive animal production systems increasingly requires regulatory input in terms of evaluating new production technology. Maintaining the health status of domestic animals so that edible products are safe and wholesome is a major component; however, this objective is not always compatible with new technology that changes economics and enhances production. In addition, veterinary regulatory authorities have a major responsibility to ensure that meat inspection programmes for slaughtered animals provide specific standards of safety and wholesomeness. Reassuring consumers with accurate and complete food safety information is emerging as an international priority (39).

In meeting the above objectives, regulatory authorities must address the issue of risk. The newly emerging discipline of risk assessment provides a framework for consistent and orderly decision-making. Formal adoption of this methodology by the veterinary community is, however, in its infancy.

RISK ASSESSMENT

Risk, meaning a danger or hazard, is an integral part of decision-making in the real world. As the ability of an agricultural production system to alter its environment through technological change increases, the need better to quantify the risks inherent in the new technology increases. Decision-making involves a set of actions and outcomes and the characteristics of the associated risks are: a choice of action, a magnitude of loss and a chance of loss (40). Regulatory authorities are increasingly involved in decision-making processes which should assess the risks that may be introduced by new technology, relative to the potential benefits. In addition, they should decide on what is a fair and acceptable risk to the promoters of the new technology, and to the people and the production systems that must bear the risk. The common goal is the reduction of risk, or the minimisation of loss/maximisation of gain (19).

An agricultural system, whether viewed individually or nationally, is first and foremost a business. Druker (16) has summarised the business attitude to risk: "To try and eliminate risk in business enterprise is futile. Risk is inherent to the commitment of present resources to future expectations. The attempt to eliminate risks, even the attempt to minimise them...can only result in that greatest risk of all: rigidity." However, the ability to take risks implies a measure of control over the risk (19); regulating to control risk is meaningless unless the regulation is acceptable and achievable. There may also be conflict between technological estimates of risk and the public perception of the same risk. An "acceptable risk" is a decision problem: a choice is required between different courses of action. Willingness to take a risk is measured by the probabilities placed upon the alternative actions and the judgement as to the possible magnitude of the outcomes, which depends upon the environment in which the actions are taken (19, 33).

The risk assessment process is often multidisciplinary. Technological or engineering risk analysis will estimate the frequency and physical consequences of the undesired event which produces the risk. Health risk analysis will evaluate the human or animal health effects that may result from the physical consequences of the undesired event. An agricultural economist may concentrate on the characteristics of risk and choice under uncertainty, whereas a scientific researcher will primarily be concerned with quantifying risk. The final decision made by the policy-maker will reflect political and social needs as well as the risks (perceived and actual) that are characterised in the risk assessment process.

Defining risk

Risk is the potential for realisation of unwanted negative consequences of an event; risk aversion is action taken to control risk (31). Construction of a decision tree presents decision choices as actions and outcomes. For each action the sum of
probabilities of the outcomes is unity. The probability distribution for a set of known outcomes may be agreed (risk); or it may not be agreed and have unknown outcomes (uncertainty). Reducing uncertainty in a system by gaining more information does not necessarily reduce risk.

The elements of risk (19) are:

- a choice of action (exposure to loss), either voluntary or involuntary;
- a probability (frequency) of loss;
- a magnitude of loss (character, extent and timing), assessments of which are not value-free.

Catastrophic risk occurs when the probability of the outcome is extremely low but the magnitude of the possible consequences is great. In animal production systems, such as those in New Zealand that depend on freedom from exotic disease for market access, the introduction of foot and mouth disease virus would be in this category. If there is a high level of uncertainty in probability estimates, the magnitude of loss assumes greater importance in evaluating the total risk (8).

**Quantifying risk**

The decision tree (Fig. 1) uses probability and worth to calculate value (19). Worth may be positive (representing gain) or negative (representing loss). The simplest form of decision analysis uses maximisation of the expected value for each action, i.e. the sum of all the values, as a basis for decision. This is risk-neutral and is often more suitable as a basis for regulatory decisions than maximax (risk-prone) or maximin (risk-averse) criteria (15). However, it should be noted that, with expected value criterion, multiplication of probability and worth can give the same value for risks which have very different characteristics.

![Decision tree](image)

**FIG. 1**

A simple decision tree presenting choices as actions and outcomes
Types of risk have been described by Starr (38):

- real risk, which can only be determined in the future;
- statistical or "actual" risk, calculated from historical data;
- predicted risk, using analytical models structured from past data;
- perceived risk, seen intuitively by individuals and subjective in nature.

Although statistical and predicted risk are regarded as objective measures, they may have subjective elements because of limitations in the quality of data. When appropriate historical data do not exist for technological risk analyses, event tree, fault tree and reliability statistics can be used to evaluate accident sequences to predict the risk of failure (40). These are logic structures and are used to determine the most effective ways of controlling and reducing risk. The event trees give the frequencies of the accident sequences occurring (and construction of risk plots), while the fault trees give the probabilities of system failure. Their ability to include all root causes of failure, including human error, provides a mechanism whereby risk can be controlled by design, quality control and management decisions (40).

The basic statistical method to estimate the average frequency of a risk-causing event involves dividing the number of events in some past time period by the appropriate "exposure time" in that period. If the expected number of events over the time period is less than one, then the expected number can also be used as an approximation for the probability of the event occurring in that time period (40). If the expected number is more than one, the appropriate probability model should be used. If the frequency of an event with a specific consequence is of interest, a plot of frequency versus consequence can be generated by choosing successively larger consequence values and calculating frequencies of events having consequences greater than these values. The precision of the frequency estimates can also be calculated. Estimation of the frequency of events of great magnitude can be achieved by extrapolating from the plot created from less severe events that have occurred in the past.

Statistical methods are inappropriate when very small probabilities are combined with outcomes that are potentially catastrophic; in this case, predictive models and reliability data are used (19, 27). Very complex modelling can ensue and this should include the possibility of human error. Some risks which are identified will be so small that they can be regarded as effectively zero. However, accurate estimation of risk, and outcomes of only limited magnitude, are implicit in effective-zero ratings.

**Risk assessment**

Risk assessment combines the systematic process of risk identification and estimation (quantitative) with a subjective evaluation of the risks (qualitative). Determining acceptable (or accepted) risk is central to the risk assessment process. Whereas experts employ sophisticated methods to analyse risk, the public usually rely on intuitive risk judgements. Perceived risk and actual risk are seldom equivalent and can be a major source of conflict between technological experts and the public. This conflict is often due to a lack of knowledge, and there must be thorough analysis of the risks introduced by new technology so that these can be weighed against the potential benefits. It has been argued by some observers that the apparent pursuit by the American public of a "zero-risk society" threatens the political and economic stability of the country (37).
Risk determination (identification and estimation) is the identification of all possible sources of risk and outcomes and their quantification in terms of probability and magnitude (usually by scientific means). This is often a very expensive process. There may also be considerable subjectivity in identifying the risks and specifying the value of outcomes. In engineering situations, event tree and fault tree analyses are used to identify and quantify all possible sources of failure. Risk estimation establishes the statistical probabilities of all possible outcomes and then determines the consequence values. If statistical probabilities are not available, predicted risk estimates are calculated. Risk comparison procedures may be used if neither of the above is available. Quantification in risk assessment is required to approximate the magnitude of an outcome, set priorities or make comparisons (33).

Risk evaluation is required to complete the risk assessment process. This is essentially subjective and includes interpretation of the significance of risks and levels of acceptable risk (21). Methods classified by Rowe (32) are:

- Risk comparison methods, incorporating known and acceptable risk levels. Historical data, modelling, or perceived risk estimates can be used;
- Cost-effectiveness of risk reduction, considering direct costs and benefits alone. This method attempts to maximise risk reduction given a fixed budget;
- Cost-risk-benefit balancing, weighing all direct and indirect costs against all direct and indirect benefits. Acceptable risk is determined by weighing the benefits against the level of risk presented;
- Combinations of approaches.

Fischhoff (17) adds risk aversion as a method of risk evaluation. A maximum reduction in risk is sought with no consideration of benefits and no comparison with other risks. This may result in a zero-tolerance standard.

It is generally considered that no one method of risk evaluation is valid for all applications. However, the determination of acceptable risk is increasingly dependent on quantitative models which are used to set numerical levels below which an estimated risk is considered acceptable (19). No determination of acceptable risk is valid without consideration of the expected benefit. When human values, e.g. health and safety, are involved, the difference between scientifically evaluated risk and perceived risk may be large and a level of acceptable risk may be difficult to determine. Perceived risk, measured by revealed preference, implied preference or expressed preference methods, will always have large subjective elements; psychometric techniques, however, are available for identifying similarities and differences among different groups (14, 37). People often trade off values rather than costs and benefits (4, 19). In agricultural production systems where economic considerations prevail, acceptable risk may be easier to determine.

A risk assessment is completed by communicating the results to decision-makers and interested parties and proposing effective controls to monitor the selected actions. The decision-making process inevitably involves value judgements, defined by Rowe (31) as technical, social or managerial. The uncertainties and assumptions that may be involved in technical risk estimates are seldom recognised as value judgements, whereas social and managerial value judgements are more readily recognised and accepted.
Risk management is the process whereby a regulatory agency decides what to do about the results of a risk assessment and then implements these decisions. Economic, social and political considerations may result in the setting of priorities and the design of regulations which are suboptimal in scientific and technical terms. With respect to food safety, the agricultural community should recognise that public perceptions shape political reality, whether or not those perceptions are scientifically accurate (11). As a partial response to the difference between perceived risk and actual risk and the problems in resolving this difference, institutional separation of risk assessment and risk management activities has developed as a regulatory principle in the United States (8, 27). Some observers consider this principle not to be easily sustained (33).

Slovic (37) has analysed a number of industrial accidents in which risk has been misjudged. Common faults have been a failure to consider human error and the ways it can affect technical systems, overconfidence in current scientific knowledge and a failure to appreciate how technical systems function as a whole.

**Risk assessment and human health**

Methods of quantitative risk assessment have become most highly developed for the estimation of human health risk (33). Health risk assessment is a specific process used to estimate the likelihood that humans or ecological systems will be affected adversely by a chemical or physical agent under a specific set of conditions (5). Four analytical steps (5, 8) have been described:

- hazard identification: the qualitative indication that a condition/substance may adversely affect human health;
- hazard characterisation: the nature of the adverse effects, including the relationship between the dose of a substance and the likelihood of an adverse effect;
- exposure characterisation: the estimation of the frequency, intensity and duration of human or animal exposure likely to occur before or after application of controls;
- risk characterisation: the quantitative estimation of risk to be used in decision-making by the regulatory agency or risk manager.

Ranking of health risks is not usually a direct process. As an example, possible hazards to humans from a variety of rodent carcinogens can be ranked by an index that relates the potency of each carcinogen in rodents to the likely exposure in humans (2). However, this index cannot be used as a direct estimate of human hazard, as human susceptibility may differ from rodent susceptibility at low dose rates and the general shape of the dose-response relationship (linear, quadratic or threshold) is not known.

Decision analysis is an exercise in building decision-tree models to provide insights into a choice in which outcomes are uncertain and risks are unavoidable (25). Sensitivity analysis can be used to alter repeatedly the values of various assumptions included in the model in order to determine the robustness of the model. For example, if the use of alternative and plausible animal dose-response models results in risk predictions that vary substantially from those derived from the primary model, the risk assessment may not be acceptable. Decision analysis is more frequently being used in the domain of public health and allows policy-makers to examine alternative strategies in an orderly manner; thus, it is likely to have wider application in future risk assessment analyses.
An expert system is a computer programme designed to solve problems as competently as, or more competently than, an expert in a particular domain. Many expert systems reason under uncertainty, and probability theory is one framework in which to develop rule-based programmes (12). Although at present very narrowly focused, expert systems are permanent and accumulative and their knowledge-bases are easily updated. As consultants to human users rather than decision-makers, they may have considerable application as risk assessment tools in the future.

VETERINARY PUBLIC HEALTH

Although health risk assessment procedures are now well-established, there has been little application in the domain of veterinary public health. There is, however, considerable opportunity to adapt this methodology to a major field of veterinary endeavour: the design and application of modern meat inspection programmes. These have markedly different priorities from those that evolved at the turn of the century, when animal husbandry was poor and infectious disease was common. Production animals now have a much higher health status and large, homogeneous lines of livestock are presented for slaughter. Parallel with visible abnormalities, control of unseen microbiological contamination and residues is now recognised as being of major importance, and a number of regulatory agencies are addressing the problem of inappropriate distribution of inspection resources (10, 22, 28).

A risk assessment model using a risk comparison approach has been developed in New Zealand to evaluate the scientific validity of different post-mortem meat inspection procedures for a particular class of livestock slaughtered in a specific geographical region. Health risk assessment methodology has been adapted to meet the specific needs of the veterinary public health application (22, 23). As risk in meat hygiene includes public health, animal health and aesthetic hazards, all such conditions which could cause grossly identifiable changes in the tissues of interest must be considered in the hazard identification. In the case of hazards in meat detectable by post-mortem inspection procedures, dose/response relationships are an untested and inappropriate way of characterising risk. Therefore, all conditions that can be detected by post-mortem procedures are considered to constitute some level of risk if they are present in the final product; this is the most severe hazard characterisation possible. In practical terms, this requires detailed recording of all abnormalities in descriptive categories that reflect on-line decision-making.

The exposure characterisation is drawn from the performance attributes of the screening test (sensitivity and specificity); these determine the non-detection rates in passed tissues and the level of wastage associated with particular procedures. Statistically defined exposure characterisations allow quantitative risk characterisations for different procedures. However, it should be noted that statistically significant differences in performance attributes do not alone dictate the superiority of one inspection procedure over another. This comes from the full risk characterisation and from all the objectives of the total inspection programme (24). Separate, as well as combined, risk assessments for public health and aesthetic hazards should be undertaken. These allow independent analysis of public health, animal health and aesthetic risks and are of obvious importance when a target tissue is not retained for human consumption. Localised abnormalities with no indicator function have no relevance in the evaluation of different procedures.
A quantitative risk assessment for alternative post-mortem meat inspection procedures for the spleen of lambs slaughtered in New Zealand using a negative-matching design (23) illustrates the risk assessment approach. It is noteworthy that New Zealand is free of all the International Office of Epizootics List A diseases and that lambs are free of the 25 "foreign" diseases ranked by the United States Department of Agriculture as being economically important. Important principles incorporated in the methodology include:

- use of a predictive model, as no historical statistical data is available for risk assessments;
- testing of the model in a commercial processing environment, so that operator error and whole-programme interactions can be included;
- an extensive random sampling programme, so that the results from the model are representative of the real world;
- a sample size of 30,000 units so that there is a 95% probability of including any hazard that exists at a prevalence of 1:10,000 or more;
- a risk evaluation that considers the worst possible outcome included in the confidence interval, rather than the mean outcome;
- a risk evaluation that places maximum importance on the quantitative aspects of the exposure characterisation rather than on the qualitative aspects of ranking hazards according to some subjective scale.

The results are summarised in Table I. A consideration of individual abnormalities (unpublished data) detected by different post-mortem inspection procedures reveals that:

- All cases of concurrent pathological involvement of the spleen and other tissues were detected by visual examination alone;
- The spleen did not provide any assistance in reaching a disposition for other viscera and/or the carcass when there were concurrent pathological conditions. Thus, the spleen had no indicator function that would contribute to a risk evaluation of different inspection procedures;
- The addition of palpation to the visual inspection process resulted in a decrease in the non-detection rate for all abnormalities of 1.11 per 1,000 spleens that would be passed for human consumption. The best possible case using 95% confidence intervals would be a decrease of 1.49 per 1,000. The small increase in performance with the addition of palpation was related almost exclusively to trivial aesthetic defects (fibrous tags and trauma);

- When abnormalities of possible public health importance alone were considered, the addition of palpation decreased the non-detection rate in the best possible case by 0.01 per 1,000 spleens that would pass inspection. This decrease related to infarcts alone: abnormalities of very questionable importance with respect to constituting a possible hazard to human health.

The risk assessment process determined that routine inspection of the spleen of lambs slaughtered in New Zealand is not necessary if the tissue is not retained for human consumption; if the spleen is retained, inspection should be limited to visual
### TABLE I

**Performance characteristics for different inspection methods for the detection of abnormalities in the spleen of lambs**

<table>
<thead>
<tr>
<th>Inspection method</th>
<th>True prevalence (%)</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>NDR</th>
<th>Wastage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>+</td>
<td>255</td>
<td>11</td>
<td>266</td>
<td></td>
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<tr>
<td></td>
<td>-</td>
<td>44</td>
<td>30,519</td>
<td>30,563</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>a</td>
<td>b</td>
<td>0.97</td>
<td>± 0.28</td>
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<tr>
<td></td>
<td></td>
<td>c</td>
<td>d</td>
<td>± 4.02</td>
<td>± 0.02</td>
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<tr>
<td></td>
<td>+</td>
<td>289</td>
<td>13</td>
<td>302</td>
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<td></td>
<td>-</td>
<td>10</td>
<td>30,517</td>
<td>30,527</td>
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<tr>
<td></td>
<td>+</td>
<td>85.28</td>
<td>99.96</td>
<td>1.44</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>± 0.02</td>
<td>± 0.43</td>
<td>± 0.21</td>
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<tr>
<td></td>
<td></td>
<td>µ</td>
<td>µ</td>
<td></td>
<td></td>
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<tr>
<td>Visual examination plus palpation</td>
<td></td>
<td>0.94</td>
<td>96.66</td>
<td>99.97</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>+</td>
<td>302</td>
<td>1</td>
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<td>10</td>
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<td>+</td>
<td>96.66</td>
<td>99.97</td>
<td>0.33</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>± 0.01</td>
<td>± 0.20</td>
<td>± 0.22</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity = $\frac{a}{a + c}$  
Specificity = $\frac{d}{b + d}$  
NDR = Non detection rate per 1,000 spleens that pass inspection  
Wastage = false positive rate per 1,000 spleens that pass inspection
examination alone. The risk assessment of inspection procedures for the spleen of lambs, described above, is part of a major research project investigating the validity of all post-mortem inspection procedures for the viscera and carcass of lambs (23).

The practical aspects of applying a sufficiently rigorous risk assessment model to compare different post-mortem inspection procedures are somewhat daunting. The cost is high, extensive field trials are necessary and industry co-operation is essential. If a risk assessment process indicates that specific inspection procedures applied to a defined class of livestock are unjustified and wasteful, however, cost-effective changes in allocation of processing and inspection resources can be made. Unseen contamination of meat with enteric pathogens has emerged as the dominant cause of meat-borne zoonoses, and reallocation of resources within meat inspection programmes is required to combat this hazard (7, 28, 36). To ensure equivalence for meat products that are marketed outside the country of origin, international agreement is needed on the methods that should be used to determine the scientific basis of each programme.

Veterinary aspects of food safety, other than post-mortem meat inspection programmes, include administering regulations to prevent such adulterants as pesticides and animal drugs from entering the food chain. These substances reduce the cost of producing food; however, quantitative risk assessments are often necessary to determine what level of residues are acceptable in the final product. The risks to human health depend on how toxic the substance is, the level of residue in a particular product and the amount of that product likely to be eaten by an individual consumer. Most toxicologists and food scientists, however, consider that microbiological contaminants are a much more significant hazard than chemical residues (30).

The National Academy of Sciences in the United States has reported that current meat inspection programmes for poultry are misdirected in that they do not focus on the prevention of microbiological and chemical contamination (7). A major review based on risk assessment methodology is recommended, although sampling regimes to detect violative levels in food derived from animals faces major cost constraints. At current testing levels, any hazard that exists at a prevalence of less than 1:100 in the target population is likely to go undetected. The low intensity of surveillance programmes administered by veterinary regulatory agencies obviously has a marked effect on risk assessments of hazards in food. All hazards can never be eliminated, but whether or not the consumer is prepared to fund much more expensive surveillance programmes to bring about a reduction in risk is a matter for public policy debate.

**ANIMAL HEALTH**

Risk assessment in qualitative terms has long been a feature of national decisions on border surveillance and quarantine, despite a dearth of quantitative risk assessments pertaining to the animal health decisions made by veterinary regulatory authorities. Descriptive analyses are common: national prevention and eradication policies to prevent the establishment of screw-worm fly (*Chrysomya bezziana*) in Australia provide a good example (3). The possible means of entry, necessary surveillance systems and methods of eradication if border controls are breached are balanced against the cost of establishment to individual producers and to the nation. The
evaluation of policy options included very high benefit/cost ratios for most regulatory actions. Descriptive analyses also are often used to assess potential risks and formulate appropriate responses to national disease control problems, both potential (26) and realised (9).

Border protection

Regulatory agencies have traditionally tended towards risk-averse policies rather than risk balancing when considering border protection. Formal risk quantification processes will gradually change this approach as a newer philosophy embraces minimisation of loss/maximisation of gain. In addition, a non-specified or non-quantified risk of introduction of a disease agent can no longer be hoisted as a non-tariff trade barrier in a free-trading world.

The current controversy over importation of Canadian pork into Australia (Cornwall to MacDiarmid, personal communication) provides an example of some of the problems that veterinary regulators have in utilising quantitative risk assessment data assembled in a newly emerging scientific field. The probability of infection of Australian pigs with transmissible gastroenteritis virus if importation of Canadian pork was accepted as public policy was estimated by different analysts to be within a range of 1 in 3.3 million to 1 in 15,000 per year. Uncertainty in estimates of the prevalence of infection in the Canadian slaughter population, the prevalence of pigs incubating the virus at slaughter and the risk of transmission by feeding imported, uncooked pork scraps to pigs all contributed to this marked variation. The absence of quantitative data on the likely economic gains of importation versus loss to individual producers and the nation if transmissible gastroenteritis virus was introduced and became established further reduced the utility of the above risk estimates. No detailed sensitivity analyses were available to test if the procedures were sufficiently robust.

Animal embryo exchange

Animal embryos are rapidly becoming an important international exchange medium for improvement in the germ plasm of domestic animals, and public policy that incorporates the advantages of the embryo with safe import strategies are veterinary responsibilities. The regulator must know the potential benefits, the risks, who the clients are and what tools are available to control those risks (1). In addition to the proponent of the particular trade, clients include the general public, the international animal health community and the national livestock producer. There is a very uneven distribution of risks and benefits among these client groups, as well as a wide-ranging opportunity to apply the risk assessment process when deciding public policy. Germ plasm cannot be transported internationally without some risk of simultaneously transporting an exotic agent (41) and there needs to be a formal evaluation of acceptable risk. A consideration of the distribution of risk and expected benefits among different client groups is central to this evaluation. Unless substantial increases in productivity or genetic diversification can be identified, zero-risk public policy is likely to be the outcome of the risk assessment.

New Zealand is free of all exotic diseases of sheep; there is, however, considerable pressure from the agricultural community to increase the genetic diversity of the national flock. MacDiarmid (personal communication) has applied a mathematical model to assess the probable number of seronegative sheep infected with maedi virus
which might escape an embryo importation programme, allowing embryos to be collected from seronegative donors in an infected flock in the country of origin. Estimates included in the model are:

- the prevalence of maedi infection in the flock of origin is 20%;
- the number of animals in the flock of origin is 400;
- the sensitivity of the serological test on donors is 95%;
- the sensitivity of the test on recipients and/or offspring is 95%;
- the number of donors (test negative) is 100;
- the number of recipients implanted per donor is 4;
- the probability of infection per infected transfer is 0.01;
- the success rate from embryo transfer is 50%.

The recipients are slaughtered in quarantine after they have weaned their offspring. The probability of a test-negative infected offspring being released into the national flock per importation using the model is 1:166,000. A formal risk evaluation and establishment of a level of acceptable risk would include sensitivity analysis to test the effect of different ranges of assumptions included in the model, and detailed benefit/cost analysis for different client groups.

This model has also been used to estimate the probability of scrapie agent escaping from the four-and-a-half-year-old New Zealand scrapie quarantine programme. In this case, embryos have only been imported from countries believed to be scrapie-free; however, it is estimated that the agent could be present in such countries at a prevalence of 0.5%. Experimental research indicates that transmission of the scrapie agent by embryo transfer has a probability level of up to 10%. As there is no pre-clinical test for scrapie, detection must rely on expression of the disease during a long period of quarantine. This probability is 0.72 for a four-and-a-half-year-old animal. The model estimates that the probability of an infected sheep failing to manifest clinical disease before release at this time is 1:7142.

Acree and Beal (1) provide an example of a mathematical model to estimate an acceptable order of risk for importation of germ plasm. This calculates a benefit/cost ratio by considering:

\[ ni: \text{expected number of import units; } \]
\[ ns: \text{estimated number of import units that may be smuggled into the country in the absence of a legitimate statute; } \]
\[ pDI: \text{probability that one unit will introduce the disease agent and will become established in the importing country; } \]
\[ qDi: \text{probability that one unit will not contain the agent; } \]
\[ pDs: \text{probability that one smuggled unit will introduce the agent; } \]
\[ qDs: \text{probability that one smuggled unit will not introduce the agent; } \]
\[ YB: \text{yield benefit; } \]
\[ PB: \text{genetic diversity benefit; } \]
\[ DC: \text{estimated total cost resulting from the introduction and establishment of the agent. } \]
These workers consider that the cost/benefit ratio of their model should be 100 or more, given uncertainties in the estimates, and the fact that benefits are long-term whereas the costs induced by introduction of an undesirable disease agent would be incurred short-term. The maximum probability of disease introduction per import unit is calculated by setting the cost/benefit ratio as a constant. Identifying and isolating import units that meet an acceptable maximum probability of disease introduction (e.g. 1 per million) is then a matter of stepwise application of preventative medical tools.

As embryo transfer can never be totally risk-free, every effort should be made to gain accurate probability estimates of the risk associated with each step in the preventative medical technology. The performance attributes of serological and bacteriological tests used to ascertain freedom from exposure to the disease agent in the donor dams need to be precisely defined. Quarantine periods to ensure that no animal is incubating the disease agent may still contain an element of residual risk. Repeated washing of embryos sequentially dilutes the concentration of loosely attached virus particles on the zona pellucida, but this process does not guarantee freedom from the virus (35). Unfortunately, there is little current research data upon which to base probability estimates of the aforementioned risks; fortunately, there are few intracellular disease agents that have the biological characteristics necessary to create a risk in embryo transfer. That is to say, those:

- found in the reproductive or circulatory systems;
- able to contaminate or infect the embryo;
- remaining in association with the embryo without causing obvious damage;
- retaining sufficient invasiveness throughout the transfer process to infect the recipient or the subsequent offspring (1).

**Animal health management**

Risk assessment in animal health can also be reduced to a site-specific level. There is an increasing interest in the health management approach to the delivery of veterinary services rather than a focus on individual animals. The economic consequences of veterinary intervention in herd health programmes depend on risk attributes as well as on the expected value of the intervention. Decisions must therefore consider both the possible outcomes and the attitude of producers to risk. Risk can be defined as the variance in expected returns; computer simulation modelling can be used for the efficient selection of veterinary interventions based on both expected value and risk. This is essentially a risk assessment process and has been shown to be a useful economic tool in veterinary intervention in dairy herds (18).

**CONCLUSION**

Flexibility is essential in risk assessment methodology, and new scientific and technological information should be capable of incorporation in the process as it becomes available. The subjectivity bias in raw data is a major source of variation in risk estimates and every attempt should be made to improve the quality of
information that is available. Similarly, regulatory agencies should be allowed a degree of flexibility in the way they implement statutes (39).

Decision-makers should recognise that all risk estimates conducted by scientific and technological experts have a degree of subjectivity, and that the decisions they make should include a knowledge of the real world and the likely conditions of use that will occur. Gough (19) has summarised different international approaches to decision-making on public policy. In general terms, the United States, Japan and some European countries use the adversary approach which, though slow and expensive, is perceived as credible by the public who are given access to the process. In Britain and Holland, the authoritative approach vests most of the decision-making power in the "experts", who negotiate directly with industry. Although efficient, this is not open to public scrutiny; a final decision may therefore lack public credibility. A consensus approach, incorporating consultation and compromise, appears to be a better alternative.

Quantitative risk assessments in specific human health situations are commonly criticised for overestimating risk, engendering unjustified public concern and leading to excessive control (33). Unduly conservative models and science policy judgements are often blamed and the public is often unaware that maximum tolerances rather than actual margins are used. Similarly, other regulatory decisions are challenged as being insufficiently protective, the scientific basis of the risk assessment process being inadequate to address all sources of risk. These contradictory criticisms usually reflect technical problems and, in this sense, the scientific community has the opportunity to improve its methods of quantitative risk assessment. However, the increasing use of risk assessment processes in public policy decisions inevitably confronts all sectors of the community with the fact that their economic, political and public health status contains elements of risk. Communicating risk by regulatory agencies has thus become an essential part of the risk assessment process (13, 20, 33).

In the past decade, risk quantification has challenged much of the conventional wisdom about the safety of technology and the efficacy of particular interventions and policy options (14). As sophisticated and innovative technologies move closer to commercial applications in the domain of veterinary endeavour, risk assessment procedures must keep pace with the technological state of the art. Risk assessment in public policy decision-making is probably most advanced in the United States where Federal Regulations require that risk research defines risk, considers its effects, identifies target populations and provides some form of cost/benefit analysis (6, 29). Rowe (31) makes a pragmatic observation: "It is evident that no single method or process works in all situations. It may well be that the process of risk assessment itself is more important than the method or particular approach used. The visibility of the process and the explicit attention given to all aspects of assessment may be the only underlying paradigm."

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L'APPLICATION DES MÉTHODES D'ÉVALUATION DES RISQUES À LA PRISE DE DÉCISION EN MATIÈRE DE SANTÉ PUBLIQUE VÉTÉRINAIRE ET DE SANTÉ ANIMALE. - S.C. Hathaway.

Résumé: Cette nouvelle discipline qu'est l'évaluation quantitative des risques trouve de larges applications dans le domaine de la santé publique vétérinaire et de la santé animale. Les autorités doivent de plus en plus souvent prendre des décisions qui impliquent une évaluation des risques des technologies ou des pratiques nouvelles par rapport aux avantages potentiels, c'est-à-dire exigeant une définition du niveau de risque acceptable.

Le choix entre les actions possibles, les probabilités de perte et l'ampleur de la perte constituent les éléments du risque. Risque perçu et risque réel sont rarement équivalents ; le recours à des méthodes d'évaluation des risques technologiques et sanitaires permettra aux autorités vétérinaires de prendre de meilleures décisions. La détermination du niveau de risque acceptable dépend de plus en plus de modèles quantitatifs. Des exemples d'évaluation de différents systèmes d'inspection de la viande sont présentés dans cet article, accompagnés d'une estimation des risques sanitaires liés aux transferts d'embryons et d'une formulation des stratégies de protection des frontières nationales. Tous les modèles ont une certaine subjectivité et les décisions prises par les autorités et les gestionnaires de risques doivent reposer sur une large connaissance du processus d'évaluation des risques et des conditions d'utilisation réelles.


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Resumen: Esta nueva disciplina que es la evaluación cuantitativa de riesgos tiene amplias aplicaciones en el campo de la salud pública veterinaria y la sanidad animal. Es cada vez más frecuente que las autoridades tengan que tomar decisiones oficiales que suponen una evaluación de riesgos de tecnologías o prácticas nuevas respecto a las ventajas potenciales, es decir que requieren una definición del nivel de riesgos aceptable.

La elección entre las posibles acciones, las probabilidades de pérdida y la magnitud de esta pérdida constituyen los elementos del riesgo. El riesgo percibido y el riesgo real son raramente equivalentes y la utilización de técnicas de evaluación de los riesgos tecnológicos y sanitarios permitirá a las autoridades veterinarias tomar mejores decisiones. La determinación de un nivel de riesgos aceptable depende cada vez más de modelos cuantitativos. El artículo presenta ejemplos de evaluación de diferentes sistemas de inspección de la carne, con una estimación de los riesgos sanitarios relacionados con las transferencias de embriones y una formulación de las estrategias de protección de las fronteras nacionales. Todos los modelos incluyen cierto grado de subjetividad y las decisiones tomadas por las autoridades y los administradores de riesgos deben reposar en un profundo conocimiento del proceso de evaluación de estos últimos y las condiciones reales de utilización.
REFERENCES


