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Risk analysis and the importation of animals and animal products

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Summary: Importation of animals or animal products cannot take place without some element of risk. Risk analysis is a blend of art and science and is a tool intended to provide decision-makers with an objective, repeatable and defensible assessment of the risks posed by a particular import proposal. Risk analysis comprises risk identification, risk assessment, risk management and risk communication. Examples are presented of risk analysis involving anthrax in green hides, slow virus diseases and sheep embryos, and Office International des Epizooties List A diseases and embryos. The author proposes that, by sharing methodologies, quarantine services should be able to harmonise approaches to the problem of risk analysis.

KEYWORDS: Anthrax – Embryo transfer – List A diseases – Maedi-visna – Quarantine – Risk analysis – Risk assessment – Scrapie.

INTRODUCTION

Risk analysis is a tool intended to provide decision-makers with an objective, repeatable and defensible assessment of the risks posed by a particular import proposal. The process of risk analysis can be made transparent so that interested parties in the importing country or authorities in the exporting country can, if required, be provided with the documented basis on which the proposal is accepted or declined.

When analysing the risks associated with a proposed importation of animals or animal products, it must be remembered that such imports cannot be made without some element of risk. The benefits of the imports often accrue to only a relatively small group of people, usually the entrepreneurs, initial importers and distributors of the new genetic material (1). The risks, on the other hand, are borne by a much broader group which includes all livestock owners whose animals could be infected with an exotic disease agent as well as the general public, who may be expected to bear the cost of containing and eradicating an outbreak of exotic disease. For these reasons, a risk analysis may include a cost/benefit analysis of the proposed importation. The policy of the New Zealand Ministry of Agriculture is that every citizen has the right to import unless the risk to agricultural security precludes importation. Such a policy presupposes that the quarantine service is charged with making judgements about the risks, and therefore the costs which may be imposed on the agricultural community, but does not sit in judgement on what are commercial decisions.

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In determining whether or not to allow a proposed import to proceed, the quarantine service identifies the risks involved, attempts to quantify these risks and then designs a series of safeguards sufficient to reduce the risk to an acceptable level.

ANALYSIS OF RISK

Risk, as it relates to the importation of animals or animal products, is a measure of the probability of the introduction of an exotic disease and the seriousness of such an outcome. **Risk analysis** is a blend of art and science, and comprises **risk identification**, **risk assessment**, **risk management** and **risk communication**.

In any risk analysis, it is important that **risk identification** be carried out adequately. If a particular risk is not identified, steps to reduce this risk cannot be formulated. Many failures of quarantine are attributable to a failure of risk identification rather than of risk assessment or risk management. In evaluating a proposal to import animals or animal products, the first step is to draw up a comprehensive list of all the pathogens which could be associated with the species or commodity under consideration, and then identify the possible routes by which these pathogens could come into contact with susceptible animals in the importing country.

Risk assessment is the process of estimating, as objectively as possible, the probability that an importation would result in the entry of an exotic disease agent and that local livestock would be exposed to the agent. Risk assessment ought to examine the effect of the introduction of an exotic disease. However, very few studies of this nature have been performed anywhere.

Risk management is the process of identifying and implementing measures which can be applied to reduce risk to an acceptable level and documenting the final import decision.

Risk communication is the process by which the results of risk assessment and risk management are communicated to decision-makers and the public. Adequate risk communication is essential in explaining official policies to stakeholders (such as established livestock industry groups) who are often aware of the risks but not the benefits of importations. Risk communication must also be a two-way process, with the concerns of stakeholders being heard by officials and addressed adequately.

Having identified the possible risks posed by a proposed importation, the next stage in risk analysis is an assessment of the risk entailed by an unrestricted importation of the animals or animal products under consideration. Risk assessment takes into account the prevalence of pathogens in the source population, the probability of pathogens surviving in the animal or product during the process of importation, the probability of the pathogen coming into contact with local livestock after importation and the seriousness of such contact.

There is a substantial body of information on the survival of pathogens in many animal products (in meat, for example [10]) and, theoretically, each of the other factors should be amenable to being quantified in a similar objective and scientific fashion. In reality, it is often not possible to quantify these factors adequately at present. Much risk assessment is ultimately based on guesswork and is thus potentially controversial and open to challenge from either domestic interest groups or overseas trading partners.

Risk management, on the other hand, is usually able to be quantified more objectively. For instance, there should be very little debate over the sensitivity of a particular serological test, or the efficacy of a particular embryo washing regimen for a specific pathogen on embryos of a given species.

An example can be provided by a serological test which has a sensitivity of 0.95 when applied to animals infected with a particular disease agent. The probability of missing a single infected individual is 0.05. However, the predictive value of a diagnostic test is also a function of the prevalence of infection in the population under test. The probability that an animal which yields negative results in a given test is actually infected is calculated as follows (11):

$$P(I|N) = \frac{p(1-s)}{p(1-s) + (1-p)e} \quad \text{[Equation 1]}$$

where $P(I|N)$ = probability of an animal which has given negative results in the test actually being infected; p = true prevalence; e = specificity of the test; and s = test sensitivity.

In matters of quarantine, the exclusion of animals giving "false positive" results is seldom of major concern; therefore it will be assumed, for the purposes of this discussion, that specificity (e) = 1. With a test of sensitivity (s) = 0.95, the probability of a given test-negative animal actually being infected varies with prevalence (p) as illustrated in Table I. It can be seen that as the prevalence of infection in the source population increases, the probability of a given test-negative animal being infected also increases.

TABLE I

Probability that an animal which gives negative results in disease testing is actually infected with the disease agent, given a test sensitivity of 0.95 and a specificity of 1

Prevalence	Probability (I N)
0.01	5.05×10^{-4}
0.05	2.62×10^{-3}
0.1	5.52×10^{-3}
0.2	1.23×10^{-2}

Probability (I|N): probability of an infected animal (I) given a negative result (N)

Similarly, at any given prevalence, the probability of including a test-negative infected animal in an importation increases with the number of animals in the group to be imported. The probability of including even one test-negative infected animal (c) in a group of n animals can be calculated thus (11):

$$\text{probability } (c \geq 1|N) = 1 - \left\{ \frac{(1-p)e}{(1-p)e + p(1-s)} \right\}^n \quad \text{[Equation 2].}$$

The effect of increasing the size of the group destined for import is illustrated in Table II.

TABLE II

Probability that an animal which gives negative results in disease testing and is actually infected with the disease agent will be included in a group destined for import (disease prevalence = 0.01, test sensitivity = 0.95, test specificity = 1, entire group tested)

No. of animals in group	Reactor animal only excluded: Probability ($c \geq 1 N$)	Single reactor disqualifies group: Probability of no test positives
100	4.92×10^{-2}	5.00×10^{-2}
200	9.61×10^{-2}	2.50×10^{-3}
300	1.41×10^{-1}	1.25×10^{-4}
400	1.83×10^{-1}	6.25×10^{-6}
500	2.23×10^{-1}	3.13×10^{-7}

Probability ($c \geq 1|N$): probability of a number of infected but test-negative animals (c) being equal to or greater than 1, given a negative test result (N)

With some diseases, a policy decision may be taken that a positive test result will disqualify only the individual animal which reacted positively to the test. The risks involved in adopting such a policy are illustrated by the above examples (Tables I and II). However, with some other diseases (often Office International des Epizooties [OIE] List A diseases), it may be decided that a positive test result in any one animal will disqualify the entire group intended for importation. In such cases, the probability of disqualifying an infected group increases as disease prevalence and/or the size of the group increases. The probability of a given test failing to detect at least one test-positive animal in an infected group (B), thus identifying the group as infected, can be calculated as follows (8):

$$B = (1 - (t/n)^{pn}) \quad \text{[Equation 3]}$$

where t is the number of animals from the group which are tested.

The difference in risk between the two policies is illustrated in Table II. It can be seen that where the presence of a single reactor animal disqualifies the entire group destined for export, rather than the reactor animal alone, the risk of an infected animal being imported is significantly reduced.

Whether a positive result in a particular test disqualifies only the affected individual or the whole importation, the risks of importing unwanted disease can be further reduced by imposing a series of safeguards. When a series of safeguards is applied to an importation, it may be relatively easy to quantify the amount by which the risk is reduced, even if consensus on the magnitude of the initial, unrestricted risk cannot be attained.

At this point, it is appropriate to look at some examples of risk analysis.

RISK OF INTRODUCING ANTHRAX BY IMPORTING GREEN HIDES

In reviewing the conditions governing the importation of hides and skins into New Zealand, Harkness (7) outlined an approach to assessing the risk of introducing anthrax

through the importation of green hides from Australia. The method used was based on a system which was developed in Australia to assess the risk of introducing transmissible gastroenteritis of swine in pig meat, and which was outlined in a recent New Zealand publication (10).

PROBABILITY OF ANTHRAX INTRODUCTION

The annual probability (T) of anthrax introduction via the medium of unprocessed hides is related to the probability (p) that a hide contains anthrax spores and to the number of occasions (n) on which susceptible animals are exposed to contact with those spores. The number of occasions on which contact with spores causes infection follows a binomial distribution, so that the chance of introduction of infection is as follows:

$$T = 1 - (1 - p)^n$$

However, when T is small (e.g. less than 0.001) the above expression approximates to the following:

$$T = pn$$

which simplifies the interpretation of the estimate of T .

This is the basis of the present estimates.

Probability of presence of anthrax spores

The following assumption is also made:

$$p = ise$$

where:

- i is the probability that an Australian animal was infected with anthrax at the time of slaughter

(The average number of officially confirmed cases of anthrax between 1970 and 1981 was 19 per year [range 9-42] and, without reference to the continuing decline in case numbers over many years, the maximum expected incidence was calculated at 40 cases per year. Total slaughterings of sheep and cattle in Australia in 1989-1990 were approximately 40.23 million, a figure which has been stable since 1980-1981 [range 37.2-42.3 million]. The value of i was therefore estimated at $40 \div 40.23 \text{ million} = 0.00000994$ or 9.94×10^{-7} .)

- s is the proportion of spore infectivity surviving pre-export handling

(Since the spores of the anthrax bacillus are extremely resistant to adverse environmental conditions and survival rates are considered to be very high, s was estimated at 90% [range 75-95%]; $s = 0.9$.)

- e is the proportion of green Australian hides among all rawstock processed in New Zealand

(Approximately 38.4 million sheep and 3.1 million cattle are slaughtered in New Zealand annually, an estimated 31% of hides and skins produced in New Zealand are processed in the country, amounting to 13.5 million pieces annually. The estimated annual import volume of green skins from Australia is 0.92 million [range 0.90-1.40 million]. Thus e was estimated at $0.92 \text{ million} \div 13.5 \text{ million} = 0.068$.)

Therefore p was estimated as:

$$0.068 \times 0.9 \times 0.00000994 = 0.00000061 \text{ or } 6.1 \times 10^{-8}$$

Exposure of susceptible animals

The number of occasions per year on which susceptible animals are exposed to contact with anthrax spores was calculated as follows:

$$n = gtvf$$

where:

- g is the number of officially approved tanneries in New Zealand

($g = 23$; Ministry of Agriculture and Fisheries records.)

- t is the proportion of approved tanneries operating with a risk of contaminating pasture by wastewater during flood periods

(No satisfactory information was available when the assessment was made. Waste drainage is controlled by local authorities under the appropriate legislation. The estimated proportion presenting risk was 10-20%, therefore t was assumed = 0.2.)

- v is the average number of days per year on which flooding occurs on pasture downstream of tanneries

(estimated range was 20-30 days per annum, so $v = 25$.)

- f is the probability of processing contaminated material during flood periods

(calculated as average number of days of flooding divided by days worked, approximately $25 \div 235$. Therefore $f = 0.11$.)

Therefore n was estimated as $23 \times 0.2 \times 25 \times 0.11 = 12.65$.

The calculations therefore suggest that the probability of introducing anthrax in any one year is:

$$T = 0.00000061 \times 12.65 \\ = 0.000000923 \text{ or } 7.72 \times 10^{-7}$$

(i.e. less than one in a million).

The risk is likely to be even lower when one considers that the probability of livestock encountering the anthrax organism on any contaminated pasture is less than 1 and that pre- and post-mortem inspection at Australian abattoirs is highly effective in preventing anthrax cases being processed for their hides.

The weakness of a deterministic model such as this is that it does not give the decision-maker any indication of the **uncertainty** of the risk estimate. As most of the variables are only estimates of what is most likely, the "real" risk estimate will be shrouded in uncertainty. A simulation model, using a computer software programme such as @Risk (Palisade Corporation, Newfield, New York, United States of America [USA]) allows each of the variables to be represented as a range of values and then, by a series of iterative calculations, presents the final risk estimate as a probability distribution. An example of the type of graphic representation of risk produced by @Risk is shown in Figure 1. This example was generated by @Risk from a spreadsheet model which was based, with minor modifications, on the anthrax risk assessment described above.

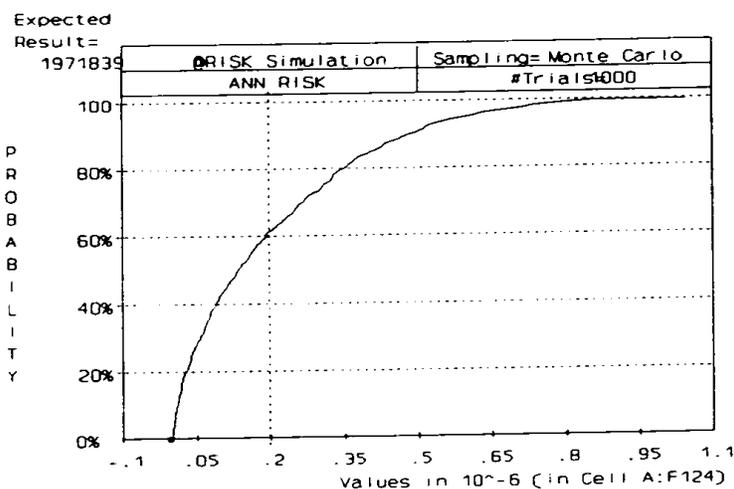


FIG. 1

A representation using the computer software package @Risk (Palisade Corporation, Newfield, New York, USA) of the cumulative risk of introducing anthrax in green hides from Australia (see text for assumptions)

In the example shown there is a 99% probability that the annual risk is less than 0.8 per million

Even when the question of uncertainty has been addressed, the risk assessment is not complete. A **sensitivity analysis** must be carried out. This involves replacing each variable with a single, most likely value and then increasing each variable in turn by a factor of ten to identify the most critical variables. By identifying the steps in the assessment which have the greatest effect on the final risk estimate, attention can be focused on obtaining better information or designing risk reduction measures.

REDUCING THE RISK OF INTRODUCING MAEDI-VISNA

Maedi-visna and the closely-related ovine progressive pneumonia are retrovirus infections of sheep which are present in many, if not most, sheep-rearing countries. A series of safeguards can be imposed to ensure that these retrovirus infections are not introduced with the importation of new sheep bloodlines (9).

In common with other retrovirus infections, maedi-visna has a prolonged period between infection and seroconversion. Seroconversion may take many months. However, the serological tests available have relatively high sensitivity and are reasonably reliable in animals over twelve months of age. It is likely that up to 5% of infected sheep fail to seroconvert.

Studies on the transmission of maedi-visna virus by embryo transfer have not yet been published. However, a very small study with the closely-related virus of caprine arthritis encephalitis failed to demonstrate transmission of infection. A large number of studies have shown that another retrovirus, enzootic bovine leukosis (EBL) virus, is not transmitted along with embryo transfers and, as the maedi-visna virus and EBL virus are both almost entirely cell-associated, it is valid to assume that the risk of transmitting maedi-visna virus is similarly remote.

In this general discussion, it will be assumed that the initial risk $P(I)$ is unknown, i.e. $P(I) = X$.

The first safeguard (S_1) is a serological test (enzyme-linked immunosorbent assay [ELISA]) for evidence of maedi-visna infection in the donor ewe. The probability that this test will detect infection in animals over 12 months of age is taken as 0.95; therefore $S_1 = 0.05$ and:

$$P(\text{I}|\text{donor ELISA negative}) \times P(I) = 0.05X.$$

The second safeguard (S_2) is embryo transfer. By analogy with EBL (see above), for which over 2,000 embryo transfers from infected donors have been made without transmitting infection, it is 95% certain that embryo transfers will not transmit the disease in more than 0.26% of transfers (4). Therefore, $S_2 = 0.0026$ and:

$$P(\text{transmission via embryo transfer} | \text{donor ELISA negative}) \times P(I) = 0.00013X.$$

(A simplification has been made in the calculations at this point. It is usual that each donor produces a number of embryos, several of which may develop into lambs. Should a donor be infected with maedi-visna, the likelihood of disease transmission increases with an increase in number of offspring. However, the more infected offspring which are born in quarantine, the greater the probability of at least one of these offspring seroconverting before the termination of quarantine.)

The third safeguard (S_3) against introducing maedi-visna would be to hold the lambs produced from the embryo transfers in quarantine and test them serologically when they are more than two years old. The probability of infected sheep seroconverting in two years is greater than 0.9. Therefore, $S_3 = 0.1$ and:

$$P(\text{offspring ELISA negative at 2 years of age} | \text{donor ELISA negative} \cap \text{transmission via embryo transfer}) \times P(I) = 0.000013X.$$

It can be seen that even if the prevalence of maedi-visna is high in the donor flock, the risk of introducing the disease is very slight and depends on which of the two policies referred to above is adopted. If one disqualifies only those offspring which seroconvert, but permits seronegative flock mates to be released from quarantine, the risk of introducing maedi-visna would be less than 1 in 100,000 sheep, even if 50% of the donor flock were infected. The risk would be significantly less if a single seropositive offspring disqualified the entire group.

LIST A DISEASES AND EMBRYO TRANSFERS

Many countries operate a quarantine policy of excluding an entire importation if any individual within the consignment gives a positive result in a test for one of the OIE List A diseases.

By taking into account factors such as sensitivity of the diagnostic test on the herd or flock of origin and on embryo-derived progeny, and the probability of the disease being transferred along with the embryo, an estimation can be made of the risk of allowing an infected but test-negative embryo-derived import to leave a quarantine programme.

Equation 3, which is based on the hypergeometric distribution, modified to take into account test sensitivity, can be rearranged (8) to calculate the minimum prevalence of true infection (p) which must be present in a herd for a given test to identify at least one test-positive animal with a nominated confidence level equal to $(1 - \beta_m)$:

$$p = \log \beta_m / n \log (1 - ts/n) \quad [\text{Equation 4}].$$

In other words, if the test procedure detects no test-positive animals in a sample of size t from a herd/flock of size n , then at confidence level $(1 - \beta_m)$, it can be said that the herd/flock is free of infection or has a prevalence less than p (8).

Table III shows how one may calculate the risk of a particular List A disease entering a country through an importation based on an embryo transfer programme and a policy of a single test-positive animal disqualifying the entire shipment.

Values for size of herd/flock, test sensitivity, number of donors, average number of offspring per donor and probability of transmitting disease by embryo transfer are all hypothetical in this example (Table III).

REDUCING THE RISK OF INTRODUCING SCRAPIE

Other than cases of scrapie in imported sheep in 1952-1954 and 1976-1977, New Zealand has remained free of the disease. Apart from some importations from Australia, which is also scrapie-free, the release from quarantine of Scandinavian-origin sheep in late 1990 was the first infusion of new genetic material into the New Zealand sheep population in over 40 years.

The Scandinavian imports were from countries which are free of scrapie (Denmark and Finland). However, interest has been expressed in importing bloodlines from countries where scrapie is present, and the New Zealand Ministry of Agriculture and Fisheries has proposed an importation strategy based on embryo transfer, bioassay of donor animal lymph node material inoculated into young goats, and a period of quarantine for the embryo-derived offspring. This chain of safeguards is seen as providing adequate assurances against the introduction of scrapie (9).

An assessment of the risk of introducing scrapie in a hypothetical importation programme is outlined in Table IV. For discussion purposes, the prevalence of scrapie within the donor flock is assumed to be 0.1. This is a hypothetical answer to the question "At what prevalence could scrapie be present in the flock and still escape detection?" Hypothetical values for the number of donors in the programme and the average number of offspring per donor are used as examples.

The first safeguard addressed in Table IV is embryo transfer. While some studies have indicated that transfer of washed embryos is unlikely to transmit scrapie (2, 5), a recent study has demonstrated transmission of scrapie in some transfers of unwashed embryos (6). Embryo transfer must be viewed as a risk-reducing measure, rather than an absolute barrier to the introduction of scrapie. For the purposes of this discussion, the probability of transmitting the disease along with embryo transfer is taken as 0.2.

TABLE III

Risk of a disease being introduced by an embryo transfer programme with a policy whereby a single embryo giving positive results in testing for the disease disqualifies the entire shipment

Assumptions: Negative test on herd/flock of origin	
Embryos imported	
Offspring quarantined	
Recipients slaughtered	
Single case disqualifies entire import	
Size of herd/flock of origin (N) =	300
Number tested (t) =	300
Sensitivity of test in herd/flock (s) =	0.9
Nominated confidence level =	0.95
Therefore probability of test failing to detect at least one positive animal in an infected group (B) =	0.05
Maximum prevalence (p) to escape detection = $\log_8/N \log(1-ts/N)$ =	0.0043
Number of donors (n) =	50
Average number of offspring per donor (m) =	4
Probability of transmitting disease by embryo transfer =	0.01
Sensitivity of test on progeny =	0.9
Proportion of donors which are infected (pD) =	0.0043
Proportion of donors which are not infected (qD) =	0.9957
Proportion of progeny from infected donors which are infected (pE) =	0.01
Proportion of progeny from infected donors which are not infected (qE) =	0.99
Proportion of infected progeny which test positive (pC) =	0.90
Proportion of infected progeny which test negative (qC) =	0.10
Probability of 0 infected animals among progeny = $\{qD+pD[qE]^m\}^n$ =	0.9915
Probability of 1 or more infected animals among progeny = $1-\{qD+pD[qE]^m\}^n$ =	0.0085
Probability of 0 reactors among progeny = $\{qD+pD[qE+pE(qC)]^m\}^n$ =	0.9923
Probability of 1 or more reactors among progeny = $1-\{qD+pD[qE+pE(qC)]^m\}^n$ =	0.0077
Probability of 0 infected animals in group of animals giving negative test results = $\{qD+pD[qE]^m\} / \{qD+pD[qE+pE(qC)]^m\}^n$ =	0.9992
Probability of 1 or more infected animals in group of animals giving negative test results = $1-\{qD+pD[qE]^m\} / \{qD+pD[qE+pE(qC)]^m\}^n$ =	0.0008

TABLE IV

Risk of scrapie being introduced by an embryo transfer programme incorporating bioassay on donor ewes

Assumptions: Embryos imported	
Offspring quarantined	
Recipients slaughtered	
Lymph nodes from donors bioassayed in goats	
Single case in quarantine disqualifies entire programme	
Putative prevalence of scrapie in donor flock (p) =	0.1
Number of donors (n) =	50
Average number of offspring per donor (m) =	1
Probability of transmitting scrapie by embryo transfer =	0.20
Length of quarantine in years =	5
Probability of scrapie manifesting during this period =	0.76
Number of donor ewes per pool for bioassay (e) =	3
Number of sentinel goats inoculated per pool (g) =	3
Probability of transmitting scrapie via bioassay (t) =	0.80
Probability that scrapie will manifest during bioassay period (d) =	0.90 *
Probability of at least one of e donors being infected = $1-(1-p)^e$ = x =	0.2710
Probability that none of the g goats inoculated manifests scrapie = $(1-t)^g$ = y =	0.0220
Probability that at least one donor is infected but escapes detection = $xy/(1+xy-x)$ = z =	0.0081
Posterior probability p' approximates to z/e =	0.0027
Therefore proportion of donors which could be infected (pD) =	0.0027
Proportion of donors which are not infected (qD) =	0.9973
Proportion of progeny from infected donors which are infected (pE) =	0.2
Proportion of progeny from infected donors which are not infected (qE) =	0.8
Proportion of infected animals with clinical signs (pC) =	0.76
Proportion of infected animals without clinical signs (qC) =	0.24
Probability of 0 infected animals among progeny = $\{qD+pD[qE]^m\}^n$ =	0.9734
Probability of 1 or more infected animals among progeny = $1-\{qD+pD[qE]^m\}^n$ =	0.0266
Probability of 0 clinical cases among progeny = $\{qD+pD[qE+pE(qC)]^m\}^n$ =	0.9797
Probability of 1 or more clinical cases among progeny = $1-\{qD+pD[qE+pE(qC)]^m\}^n$ =	0.0203
Probability of 0 infected animals in clinically-negative group = $\{qD+pD[qE]^m\} / \{qD+pD[qE+pE(qC)]^m\}^n$ =	0.9935
Probability of 1 or more infected animals in clinically-negative group = $1-\{qD+pD[qE]^m\} / \{qD+pD[qE+pE(qC)]^m\}^n$ =	0.0065

* equivalent to sensitivity of test

The second safeguard is a five-year quarantine period for the embryo-derived offspring. Information from a number of sources indicates that at least 76% of sheep with scrapie exhibit signs of the disease before five years of age (3, 12, 13). This figure is used in Table IV to calculate the proportion of infected animals (0.24) which would not show clinical signs of disease within a five-year quarantine period.

The third safeguard in the scrapie quarantine programme is a bioassay using young goats inoculated intracerebrally and intraperitoneally with a 10% homogenate of mesenteric lymph nodes collected from the embryo donor sheep. If scrapie agent is present in the embryo donors, the probability of transmitting the disease to a sentinel goat is 0.80 and the probability of the goat exhibiting clinical scrapie during the observation period is 0.90 (9). These values appear in Table IV.

Tissue samples from a number of donor ewes are pooled for the bioassay. In Table IV, a figure of three donors per pool is used. In the past, New Zealand programmes have used this figure and three sentinel goats have been inoculated with homogenate from each tissue pool.

In Table IV, the number of donors per pool, the number of sentinels per pool, the probability of transmitting scrapie by this method and the probability of the sentinel goats manifesting scrapie are used to calculate a posterior probability for the prevalence in the donor flock. In the example used, if no sentinel exhibits signs of scrapie, it is estimated that the probability of the donors being infected would not have exceeded 0.0027.

This value is then used in a fashion similar to the way in which the maximum prevalence estimate in Table III was used. By performing a similar series of calculations, a final estimate is obtained for the probability that one or more infected offspring will be present in a clinically normal group at the end of the quarantine and bioassay observation period.

As in the example of anthrax in green hides, the risk assessment calculations in Tables III and IV must be subjected to sensitivity analysis before decisions are made on the basis of the results. The use of the programme @Risk will also be helpful in addressing the uncertainty surrounding each variable and hence the final risk estimate.

"ACCEPTABLE" RISK

Even in situations where the risk from unrestricted entry can be quantified objectively and little controversy surrounds the calculation of the extent to which safeguards reduce this risk, it may be difficult to reach agreement on what constitutes an **acceptable** risk. A figure which denotes an acceptable business risk to the entrepreneur may be quite unacceptable to the representatives of the established livestock industries.

In addition, risk is proportional to the volume of imports. The effect which the size of an importation has on risk is mentioned above. It can be seen that where a policy of excluding only reactor animals is practised, risk increases in proportion to either the size of a shipment or the number of shipments.

On the other hand, while a policy of excluding an entire shipment on the basis of even a single reactor results in a reduced risk with larger shipments, an importer could protect his or her investment by splitting a large importation into several smaller

shipments. While this would reduce the financial risk taken by the importer, it would increase the risk of exposing the importing country to exotic disease.

The discipline of risk analysis, as applied to the importation of animals and animal products, is still in the initial stages of development. Risk can be calculated per animal, per shipment or on an annual basis. It will be some time before general agreement can be reached regarding what constitutes "acceptable" risk. However, by sharing methodologies, quarantine services should be able to harmonise approaches to the problem of risk analysis and obtain mutual understanding of different individual concerns, even when significant disagreement remains over the acceptable level of risk.

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L'ANALYSE DES RISQUES LIÉS À L'IMPORTATION D'ANIMAUX ET DE PRODUITS D'ORIGINE ANIMALE. - S.C. MacDiarmid.

Résumé : L'importation d'animaux ou de produits d'origine animale comporte nécessairement un certain risque. Alliant l'art et la science, l'analyse des risques constitue pour les décideurs une méthode objective, reproductible et justifiée d'évaluation des risques liés à un projet d'importation donné. L'analyse des risques comprend l'identification des risques, l'évaluation des risques, la gestion des risques et les échanges d'informations concernant les risques. L'auteur donne des exemples d'analyse des risques appliquée au charbon bactérien pour les peaux vertes, aux maladies à virus lents pour les embryons d'ovins, ainsi qu'aux maladies de la Liste A de l'Office international des épizooties pour les embryons en général. En combinant leurs méthodes, les services de quarantaine devraient pouvoir, selon l'auteur, harmoniser leurs approches du problème de l'analyse des risques.

MOTS-CLÉS : Analyse des risques - Charbon bactérien - Evaluation des risques - Maedi-visna - Maladies de la Liste A - Quarantaine - Transfert d'embryons - Tremblante.

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ANÁLISIS DE RIESGOS E IMPORTACIÓN DE ANIMALES Y DE PRODUCTOS DE ORIGEN ANIMAL. - S.C. MacDiarmid.

Resumen: La importación de animales o de productos de origen animal comporta ciertos factores de riesgo. Arte y ciencia, el análisis de riesgos constituye para las autoridades responsables un método objetivo, reproducible y justificado para evaluar los riesgos que puede representar un proyecto de importación determinado. El análisis de riesgos comprende los siguientes aspectos: identificación de riesgos, evaluación de riesgos, gestión de riesgos e intercambio de información sobre los riesgos. El autor da ejemplos de análisis de riesgos aplicados al carbunco bacteridiano para las pieles verdes, a las enfermedades causadas por virus lentos para los embriones de ovinos, así como también a las enfermedades de la Lista A de la Oficina internacional de epizootias para los embriones en general. Si comparten las metodologías utilizadas, concluye el autor, los servicios de cuarentena de los distintos países deberían poder armonizar las soluciones al problema del análisis de riesgos.

PALABRAS CLAVE: Análisis de riesgos - Carbunco bacteridiano - Cuarentena - Enfermedades de la Lista A - Evaluación de riesgos - Maedi-visna - Prurigo lumbar - Transferencia de embriones.

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