Import risk analysis: the experience of Italy

V. Caporale, A. Giovannini, P. Calistri & A. Conte

Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale', Via Campo Boario, 64100 Teramo, Italy

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Summary
The authors propose a contribution to the possible revision of Chapters 1.4.1. and 1.4.2. of the International Animal Health Code (Code) of the Office International des Epizooties (OIE). In particular, data are presented to illustrate some of the inadequacies of both the rationale and the results of the method for risk assessment reported in the Code. The method suggested by the Code for risk assessment is based on the calculation of the 'probability of the occurrence of at least one outbreak' of a given disease following the importation of a given quantity of either live animals or animal products (unrestricted risk estimate). This is usually undertaken when dealing with rare events. For a country such as Italy, this method may not be particularly useful as the frequency of disease outbreaks is what should be estimated, so as to provide decision makers with appropriate and relevant information.

Practical use of risk information generated by the use of the OIE risk assessment method for swine vesicular disease (SVD) would have encouraged the Chief Veterinary Officer of Italy to prohibit all imports of swine from the Netherlands and Belgium for at least two years in the early 1990s, with the consequent heavy economic losses for both Italy and the exporting countries. On the contrary, the number of actual outbreaks of the disease due to direct imports of swine from Member States of the European Union (EU), which occurred in Italy in 1992, 1993 and 1994 was very low (two to five outbreaks due to direct imports of swine from the Netherlands and one to two from Belgium).

An example of a method for assessing the risks associated with high volumes of trade in commodities is also described. This method is based on the Monte Carlo simulation and provides the information required to evaluate the costs of the strategies compared. The method can be used to predict the number of outbreaks which are likely to occur following importation and enables a comparison to be made of alternative safeguards. This would lead to the selection of the most cost-effective one. The comparison is conducted using risk curves and allows a quantitative evaluation and comparison to be made of various scenarios, varying from an absence of safeguards to combinations of various safeguards.

Keywords

Introduction

The notion of 'risk' is not at all unusual in veterinary medicine. Veterinary services, in particular, were organised and developed in the world mainly to evaluate and manage risks. According to the International Animal Health Code (Code) of the Office International des Epizooties (OIE) (11):

'The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the risks associated with the importation of
animals, animal products, animal genetic material, feedstuffs, biological products, and pathological material. The analysis should be transparent in order that the exporting country may be provided with a clear and documented decision on the conditions imposed for importation, or refusal of importation.

Import risk analysis is preferable to a zero-risk approach because it provides a more objective decision, and enables Veterinary Administrations to discuss any differences in conclusion which may arise concerning potential risks.

Import risk analysis is described in the Code, in Section 1.4, from Chapter 1.4.1. to Chapter 1.4.5. Considerable shortcomings can be found in all existing Chapters.

The authors propose a possible revision of Chapters 1.4.1 and 1.4.2 of the Code. In particular, data will be presented to show some of the inadequacies of both the rationale and the method of risk assessment reported in the Code. An example of a possible alternative method for assessing the risks associated with high volume commodity trade is also described.

**General aspects of risk**

The concept of risk involves both the probability of the occurrence of an adverse event and the magnitude of damage arising from that event. Import situations include safeguards; risk is never zero but can be significantly reduced by adding safeguards (4). Risk, therefore, can be expressed as follows:

\[
\text{Risk} = f(\text{probability}, \text{damage}, \text{safeguards})
\]

Taking into account these basic concepts (4), risk can then be defined, from a quantitative point of view, as a set of triplets:

- what can happen = event \(e_i\)
- likelihood of a given event occurring = likelihood \(p_i\)
- the consequences of a given event occurring = magnitude of the damage \(x_i\).

Therefore, more formally, risk \(R\) is the set of triplets defined as:

\[
R = \{(e_i, p_i, x_i)\}
\]

where:

- \(e_i\) = an event, such as a number of disease outbreaks, occurring under a set of specific conditions or safeguards
- \(p_i\) = the probability of occurrence of that event
- \(x_i\) = the measure of damage of that event (e.g. the cost of that number of disease outbreaks).

If all possible events are arranged in order of increasing severity of damage \(x_1 \leq x_2 \leq x_3 \leq \ldots \leq x_N\), a cumulative probability of each event and all events worse than that event can be calculated \((p_n)\). A risk curve is a graphical representation of such a cumulative probability (Fig. 1). In Figure 1, the number of outbreaks (i.e. the event) can be used as an expression of the damage, because of the correlation between the number of outbreaks and the overall cost of these outbreaks.

Risk, therefore, is considered as a function of probability and damage \((x_i, p_i)\). It follows that risk cannot be described by a single number, but rather by one or more curves (4).

**Shortcomings in the rationale of the method proposed in the International Animal Health Code**

The Code chapter on import risk analysis, based on the calculation of a so-called 'unrestricted risk' as defined by Morley (7), does not consider either damage or safeguards. This is an abstraction that has little relevance to either the real world or to risk analysis as defined in specialised literature. Since the unrestricted risk estimate (URE) considers neither damage nor safeguards, it appears no more than an imprecise method of calculating and expressing country-wide prevalence. The URE ignores the fact that diseases, except those transmitted by vectors, cluster within herds or flocks.

Discussing risk while ignoring safeguards is not realistic. Nevertheless, calculation of risk in the absence of safeguards provides a useful baseline for the comparison of the possible scenarios.
A further shortcoming in the method proposed in the Code is the improper use of subjective information. Whatever risk analysis technique is chosen, a certain degree of subjectivity is always present; however, the source of the data and the reason for the choice of a particular value, should always be explicit and scientifically documented.

When data are either unavailable or scanty, quantitative risk inferences made by transforming qualitative data into numbers cannot be justified. In relation to the OIE standard forms of disease reporting, a report of disease occurrence of +++ should not be translated into a quantitative statement such as 'the prevalence is 0.75'. In such cases, careful use of expert opinion may be justified in order to determine a distribution for variables such as prevalence. When quantitative information is unavailable, only a qualitative risk assessment should be carried out.

Risk analysis procedures should be fair and formulated in such a way as to avoid unnecessary disputes.

The use of results of the evaluation of veterinary services is another improper use of subjectivity in risk analysis. The objective of the evaluation is not to be able to state, for example, that the veterinary services of a given country only rate 0.8 on the assessment scale for a veterinary services, so any prevalence estimate reported needs to be multiplied by 2.3. This would be neither logical, valid nor fair. The evaluation of veterinary services is beyond the scope of this paper and has been discussed in another paper (9), where a method is suggested to generate the information needed for an objective estimate of the degree of under-reporting.

The risk assessment method suggested by the International Animal Health Code

The sole method suggested by the Code of the OIE for risk assessment is based on the calculation of the URE (7). This is the probability of the occurrence of at least one outbreak of a given disease following the importation of a given quantity of either live animals or animal products. If this probability is lower than a given threshold ($S_1$), importation is permitted without any restriction, if the probability is higher than a second threshold ($S_2 > S_1$), importation is not permitted. Finally, if the probability lies between the values $S_1$ and $S_2$, importation is allowed only if safeguard measures are adopted.

The suggested method is, in fact, a very simplistic way of calculating risk which only takes into account the single scenario in which no safeguard measures are adopted. Furthermore, only the probability is considered and not the damage.

The URE is an exponential function of the number of units imported. In other words, as the number of imported units increases, the risk rises very rapidly to the point of overcoming the $S_2$ threshold, even in the case of a very low infection/disease prevalence in the exporting country. In Figure 2, the variation of URE as a function of the number of outbreaks occurring in the exporting country is reported, while in Figure 3 the same variation is calculated as a function of the number of animals imported.

![Fig. 2](image1)

**Variation in unrestricted risk estimate as a function of the number of outbreaks in the exporting country**

In the example reported in Figures 2 and 3, foot and mouth disease (FMD) is considered. The exporting country examined has a population of 10,000,000 cattle and an average herd size of ten animals. Parameters suggested by Morley for FMD were used (7). However, similar curves could be generated in the case of any other disease or infection.

This type of equation is fundamental for those situations where the estimate of the probability of at least one event is required. This is usually undertaken when dealing with rare events. For a country such as Italy, this equation may not be
particularly useful since the variable which needs to be estimated is the frequency of disease outbreaks.

It should be stressed that in any given country, at any given moment, the possibility of at least one unidentified infection/disease outbreak cannot be excluded. For the FMD example above, in the case of a single unidentified outbreak in the exporting country, the importation of only 100 animals would result in a very low URE of $2.4 \times 10^{-5}$. Taking into consideration the number of cattle imported into Italy each year (for example, 1 million cattle are imported every year from France), the value of URE will increase dramatically to approximately 0.2.

### Application of the International Animal Health Code risk analysis methodology to Italy

An import risk analysis was carried out using actual data on the number of animals imported into Italy, using the method described in the Code, to test whether the shortcomings discussed above have any practical consequences.

Any application of risk assessment methods to the situation in Italy must take into account the fact that Italy is largely deficient in animal proteins in general and in those of bovine origin in particular. The country must therefore import large quantities of animals and animal products each year. This type of situation is common amongst other Member States of the European Union (EU). Greece, Portugal and Spain, for example, have a ratio of bovine animals to people that is even less favourable than Italy.

The number of animals imported into Italy each year is very large and does not vary greatly from year to year. Total variation in the number of animals imported from other countries of the EU between 1990 and 1991 was 8.2%, while that from countries in the rest of the world was −14.6% from 1993 to 1994. Variations of this magnitude have no practical influence on the URE calculations.

Imports of live animals from other countries of the EU in 1991 and from the rest of the world in 1994, are reported in Tables I and II. The monetary value of imported animals and animal products in 1991 was equivalent to US$7,364 million (5).

The URE for swine vesicular disease (SVD) and classical swine fever originating in Belgium, Germany and the Netherlands was calculated according to the method indicated by the OIE (3, 8) for the years 1990-1993. The URE was also calculated for contagious bovine pleuropneumonia (CBPP). Table III provides the basis for the calculation of URE, together with results.

### Table I

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Lots</th>
<th>Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equine</td>
<td>2,848</td>
<td>22,907</td>
</tr>
<tr>
<td>Bovine</td>
<td>30,739</td>
<td>1,441,244</td>
</tr>
<tr>
<td>Caprine</td>
<td>403</td>
<td>28,592</td>
</tr>
<tr>
<td>Ovine</td>
<td>1,565</td>
<td>719,827</td>
</tr>
<tr>
<td>Swine</td>
<td>8,869</td>
<td>1,524,446</td>
</tr>
<tr>
<td>Rabbit</td>
<td>40</td>
<td>18,070</td>
</tr>
<tr>
<td>Poultry</td>
<td>766</td>
<td>11,161,437</td>
</tr>
</tbody>
</table>

Source: Animo (animal movement) Information system (2)

### Table II

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Lots</th>
<th>Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equine</td>
<td>470</td>
<td>6,880</td>
</tr>
<tr>
<td>Bovine</td>
<td>1,605</td>
<td>38,944</td>
</tr>
<tr>
<td>Ovine-caprine</td>
<td>48</td>
<td>30,886</td>
</tr>
<tr>
<td>Swine</td>
<td>2</td>
<td>470</td>
</tr>
<tr>
<td>Poultry</td>
<td>23</td>
<td>189,052</td>
</tr>
</tbody>
</table>

Source: Shift (system for health control of imports from third countries) Information system (3)

The results of the URE calculation for SVD can be compared to the number of actual outbreaks of the disease which occurred in Italy in 1992, 1993 and 1994, which were due to swine imports from Member Countries of the EU without merging with the domestic swine population (Table IV).

The data seem to indicate the undetected occurrence of SVD infection in the Netherlands and Belgium in 1991 and in the Netherlands in 1993.

The method described in the OIE Code does not appear to be very useful for decision-making, at least when high volumes of trade are considered. In fact, because of the large quantities imported into Italy, the importation of any disease present in the exporting country is almost certain, unless safeguards are applied.

Regardless of the volume of the traded commodity, the Code methodology has a number of other limitations. For example, the calculation of the Country Factor, which is an estimate of the prevalence of the disease in the exporting country, has a number of fundamental problems, as follows:

a) the fact that diseases generally tend to cluster within herds is ignored

b) one reported disease outbreak is assumed to involve only one herd or flock

c) no account is taken of the duration or extent of an outbreak, the range of susceptible species involved and the
Table III
Unrestricted risk estimate calculation according to the risk assessment method of the Office International des Epizooties for swine vesicular disease, classical swine fever and contagious bovine pleuropneumonia

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of outbreaks</th>
<th>Population (a)</th>
<th>No. of herds (a)</th>
<th>NAIUs (b)</th>
<th>URE for the year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Swine vesicular disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Netherlands</td>
<td>0</td>
<td>15</td>
<td>0</td>
<td>13,565,974</td>
<td>29,211</td>
</tr>
<tr>
<td>Belgium</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>6,290,586</td>
<td>23,345</td>
</tr>
<tr>
<td>Spain</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>17,044,484</td>
<td>174,832</td>
</tr>
<tr>
<td><strong>Classical swine fever</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>118</td>
<td>5</td>
<td>0</td>
<td>24,764,081</td>
<td>242,165</td>
</tr>
<tr>
<td><strong>Contagious bovine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pleuropneumonia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>One undetected outbreak</td>
<td>19,600,000</td>
<td>270,000</td>
<td>1,086,480</td>
<td>0.734</td>
</tr>
</tbody>
</table>

URE: unrestricted risk estimate
NAIUs: number of animal import units
(a) Source: Office International des Epizooties (10)
(b) Average between 1990 and 1991; Source: Italian Ministry of Health (Italian Veterinary Border Inspection Posts information network)

The use of risk curves for evaluating safeguards

As the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization is embraced by more countries, the volume of animals and animal products traded internationally is likely to increase substantially. With large volumes of trade, the focus for decision makers changes from discerning the likelihood of the occurrence of at least one disease outbreak to estimating the probable frequency of disease outbreaks. To provide decision makers with a useful support tool, risk assessment techniques should be developed which are capable of predicting the likely number of outbreaks associated with specific sets of safeguards. These methods should, where possible, be based upon actual data to evaluate the risk on the basis of 'real life' experiences. Some attempts have already been made in this direction (6).

Risk curves as described by Kaplan and Garrick could be one such method (4). This approach allows a quantitative evaluation and comparison of various scenarios varying from no safeguards to combinations of various safeguards. The method facilitates the communication of the risks and their consequences to stakeholders and decision makers and enables the decision makers to choose appropriate safeguards in a more transparent fashion.

Ovine-caprine brucellosis has been chosen as an example of the application of risk curves incorporating the following scenarios:
- scenario 1: no serological testing of imported animals (i.e. no safeguards)
- scenario 2: serological testing of 1% of imported lots
- scenario 3: serological testing of a sample of imported lots to detect, with 95% probability, the presence of infection, if present in at least 5% of imported lots
- scenario 4: serological testing of a sample of animals from all imported lots to detect, with 95% probability, the presence of infection, if present in at least 5% of animals in the lot
- scenario 5: serological testing of all animals in all imported lots.

In scenarios 2, 3 and 4, animals are sampled within each lot to detect infection if present in at least 5% of the animals in each lot with a confidence of 95%. The choice of 5% prevalence is an example of a possible strategy aimed at reducing the number of tests while still maintaining a certain level of confidence in detecting disease.

For all five scenarios, the same parameters were used, derived from actual ovine-caprine imports from France in the years 1990 and 1991. The number of imported lots was 833 and the number of animals in the imported lots was based on a triangular distribution with the following parameters:
- minimum: 20 head
- most probable: 98 head
- maximum: 150 head.

The following assumptions were made:

a) the sensitivity of the complement fixation test, used for serological testing, has been reported to be 97% (8)

b) ovine-caprine brucellosis prevalence in animals in the exporting country is 0.1%; each lot represents a random sample of the population of origin

c) in each infected lot only one infected animal is present. This assumption is a good approximation in the case of a 0.1% population prevalence and a lot size of between 20 and 150. This also allows considerable simplification of calculations

d) a positive result to serological testing of a single animal results in refusal of the entire lot

e) each undetected but infected lot generates only one outbreak. This is consistent with the assumption of a single infected animal in each infected lot. Transportation time is such that brucellosis is extremely unlikely to spread within lots.

The model structure and calculations performed to generate risk curves are reported in Figure 4 (1).

For each of the five scenarios, a Monte Carlo simulation was undertaken using 1,000 iteration. The results are reported in Figure 5.

An example of the model realisation using @RISK©, for the simulation of the import of 833 lots is reported in Figure 6.
Number of infected animals in the lot = RiskBinomial\(n, p\)

where 'n' is the number of animals in the lot and 'p' is the prevalence of brucellosis in the source population.

- Is the lot tested? (1 = yes; 0 = no) = IF(RiskUniform(0,1)<Round\((1-0.05^*\frac{1}{(0.05^*n-1)/2})\)*\(10-0.05^*10-1)/2),0/10,1;0)

where the proportion of lots tested is compared to a random number generated from a RiskUniform distribution to determine if the lot is tested.

- Number of animals tested in each lot = Round\((1-0.05^*\frac{1}{(n*0.05)})*(n-(0.05*n-l)/2);0)*C

where 'n' is the number of animals in the lot and 'C' is the result of the formula 'is the lot tested?' which acts as a flag to either return a value of zero for untested lots or the actual number of animals tested by applying the formula for 'c' in Figure 4.

- Number of animals that are infected and tested = IF(B*D>0;RiskHypergeo\(D;B;A);0)

where 'D' is the number of animals tested, 'B' is the number of infected animals in the lot, 'A' is the number of animals in the lot.

- Number of positive animals = IF(E>0;RiskBinomial\(E;0.9667);0)

where 'E' is the number of animals in the lot that are infected and tested and 0.9667 is the sensitivity of the test.

- Is the lot infected? (1 = yes; 0 = no) = IF(And(B>0;F=0);1;0)

where 'B' is the number of infected animals in the lot and 'F' is the number of test positive animals in the lot.

The sum of the last column 'G', provides the total number of infected lots imported.

Figure 6 reports the differences among the different scenarios summarised below:

- Scenario 1: is the lot infected? (1 = yes; 0 = no) = IF(B>0;1;0)

where 'B' is the number of infected animals in the lot.

- Scenario 2: is the lot tested? (1 = yes; 0 = no) = IF(RiskUniform(0,1)<0.01;1;0)

where the proportion of lots tested is compared to a random number generated from a RiskUniform distribution to determine if the lot is tested.

- Scenario 4: is the lot tested? = 1.

- Scenario 5: is the lot tested? = 1.

- Number of tested animals = A

where 'A' is the number of animals in the lot.

- Number of infected and tested animals = B

where 'B' is the number of infected animals in the lot.

The actual model was realised using VisualBasic©. Whilst the model could be run using @RISK®, VisualBasic© was more rapid as several thousand input distributions were required for each scenario to model 833 lots.

The average number of animals to be tested in each of the 5 scenarios would be as follows:

- scenario 1 = 0 tested animals
- scenario 2 = 349 tested animals
- scenario 3 = 2,356 tested animals
- scenario 4 = 34,770 tested animals
- scenario 5 = 74,415 tested animals.

The average number of outbreaks that can be expected due to the import of 833 lots, according to the various safeguard strategies, would be as follows:

- scenario 1 = 70.66 outbreaks
- scenario 2 = 70.34 outbreaks
- scenario 3 = 68.54 outbreaks
- scenario 4 = 38.42 outbreaks
- scenario 5 = 2.40 outbreaks.

From a financial perspective, any safeguard strategy is advantageous when the cost of an outbreak exceeds the cost of the extra serological tests required to detect infected lots. In the ovine-caprine brucellosis example, for each outbreak avoided, the increased number of serological tests required can be calculated as follows:

\[
\Delta T = \frac{T_i - T_{i-1}}{O_{i-1} - O_i}
\]

where:

\(\Delta T\) = increased number of serological tests

\(T_i\) = average number of serological tests performed under scenario \(i\)

\(T_{i-1}\) = average number of serological tests performed under scenario \(i - 1\)

\(O_i\) = average number of outbreaks expected under scenario \(i\)

\(O_{i-1}\) = average number of outbreaks expected under scenario \(i - 1\).
<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No. of animals in the lot</td>
<td>No. of infected animals in the lot</td>
<td>Is the lot tested? Scenario 3</td>
</tr>
<tr>
<td>2</td>
<td>=Round(RiskTriang(20;98;150);0)</td>
<td>=RiskBinomial(A2;0.001)</td>
<td>=IF(RiskUniform(0;1)&lt;Round((1-0.05*(1/633)<em>0.05))/(833-(0.05</em>10-1)/2);0)/833;1:0)</td>
</tr>
<tr>
<td>3</td>
<td>=Round(RiskTriang(20;98;150);0)</td>
<td>=RiskBinomial(A3;0.001)</td>
<td>=IF(RiskUniform(0;1)&lt;Round((1-0.05*(1/633)<em>0.05))/(833-(0.05</em>10-1)/2);0)/833;1:0)</td>
</tr>
</tbody>
</table>

834 =Round(RiskTriang(20;98;150);0) =RiskBinomial(A834;0.001) =IF(RiskUniform(0;1)<Round((1-0.05*(1/633)*0.05))/(833-(0.05*10-1)/2);0)/833;1:0)

835 Total no. of animals Total no. of infected animals Total no. of tested lots. Scenario 3

836 =Sum(A2:A834) =Sum(B2:B834) =Sum(C2:C834)

<table>
<thead>
<tr>
<th></th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No. of tested animals. Scenario 3</td>
<td>No. of infected and tested animals.</td>
<td>No. of positive animals. Scenario 3</td>
<td>Is the lot infected? Scenario 3</td>
</tr>
<tr>
<td>2</td>
<td>=Round((1-0.05*(1/(A2*0.05)))<em>A2-(0.05</em>A2-1)/2);0)</td>
<td>=RiskBinomial(D2;B2;A2)</td>
<td>=IF(E2&lt;0;RiskBinomial(E2;0.9667);0)</td>
<td>=IF(And($B2&gt;0;F2=0);1;0)</td>
</tr>
<tr>
<td>3</td>
<td>=Round((1-0.05*(1/(A3*0.05)))<em>A3-(0.05</em>A3-1)/2);0)</td>
<td>=RiskBinomial(D3;B3;A3)</td>
<td>=IF(E3&lt;0;RiskBinomial(E3;0.9667);0)</td>
<td>=IF(And($B3&gt;0;F3=0);1;0)</td>
</tr>
</tbody>
</table>

834 =Round((1-0.05*(1/(A834*0.05)))*A834-(0.05*A834-1)/2);0) =RiskBinomial(D834;B834;A834)

835 Total no. of tested animals. Scenario 3 Total no. of infected and tested animals Total no. of positive animals. Scenario 3 Total no. of infected lots imported. Scenario 3

836 =Sum(D2:D834) =Sum(E2:E834) =Sum(F2:F834) =Sum(G2:G834)

### Differences for scenario 1

<table>
<thead>
<tr>
<th></th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No. of infected lots imported</td>
</tr>
<tr>
<td>2</td>
<td>=IF($B2&gt;0;1;0)</td>
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### Differences for scenario 2

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<tbody>
<tr>
<td>1</td>
<td>No. of tested lots</td>
</tr>
<tr>
<td>2</td>
<td>=IF(RiskUniform(0;1)&lt;0.01;1;0)</td>
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### Differences for scenario 4

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<td>No. of tested lots</td>
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<td>2</td>
<td>=1</td>
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### Differences for scenario 5

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<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No. of tested lots</td>
<td>No. of tested animals</td>
<td>No. of infected and tested animals</td>
</tr>
<tr>
<td>2</td>
<td>=1</td>
<td>=A2</td>
<td>=B2</td>
</tr>
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Fig. 6
Calculation basis for the definition of risk curves for ovine-caprine brucellosis using @RISK®
The results are as follows:
- scenario 2 compared to scenario 1: 1,057 serological tests
- scenario 3 compared to scenario 2: 1,121 serological tests
- scenario 4 compared to scenario 3: 1,076 serological tests
- scenario 5 compared to scenario 4: 1,100 serological tests
- scenario 5 compared to scenario 1: 1,090 serological tests.

Given a cost of approximately €1 for a complement fixation test, scenario 5 is the most advantageous scenario when the cost of one outbreak exceeds €1,000.

Conclusions

The analysis and management of risk is a traditional part of veterinary medicine. The new international trade policy for animals and animal products adopted following the SPS Agreement, requires significant changes. Veterinary services involved in this type of activity have traditionally assessed risks qualitatively, but quantitative methods are becoming increasingly important. As with traditional qualitative techniques, quantitative methods should be fully documented, follow a logical process and be based on scientific principles; this should ensure transparency, thus eliminating, as far as possible, inconsistencies in decision making and the application of safeguards.

An important component of risk analysis is quantitative risk assessment. This is a predictive technique which provides numerical estimates of the probabilities and consequences associated with particular scenarios. The risk curves which can be obtained using this technique are an extremely valuable tool. They allow a quantitative evaluation and comparison of various scenarios ranging from absence of safeguards to combinations of various safeguards. Risk curves facilitate the communication of risks and the consequences of these risks to stakeholders and decision makers, allowing decision makers to choose appropriate safeguards in a much more transparent fashion.

The method of risk analysis outlined in the current edition of the Code of the OIE has several shortcomings. When applied to large volumes of commodity trade, the method is essentially inapplicable as the inevitable prediction is that diseases will be introduced unless safeguards are applied. The method has a limited application as a decision tool as no measure of the likely consequences is included (for example, the expected number of outbreaks) and no evaluation of the various safeguard options is attempted. The URE provides an imprecise method of calculating and expressing country-wide prevalence, for example estimating prevalence using subjective disease status reports and modifying such estimates in accordance with further subjective assessments of the veterinary service of the country in question.

In conclusion, a revision of the OIE Code chapter on import risk analysis is required urgently. The revision should consider that risk cannot be described as either 'acceptable' or 'unacceptable' in isolation, but only in relation to the costs and benefits associated with various risk management options. In practice, risk and risk analysis are always part of the decision-making process, in the endeavour to achieve the optimum mix of cost, benefit and risk (4). Risk curves provide an extremely valuable tool for decision makers where large quantities of trade occur.

As the acceptance of risk is a decision-making process that involves economic, social and political considerations, the expression 'acceptable risk' is best avoided; rather the expression 'accepted risk' should be used. The accepted level of risk should be clearly defined and documented.

The revision should note that factual data, sourced from disease surveillance and monitoring systems are widely available in the animal health arena, and recommend that such data be incorporated into risk assessments.

Acknowledgements

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Analyse des risques à l’importation : l’expérience italienne

V. Caporale, A. Giovannini, P. Calistri & A. Conte

Résumé
Les auteurs proposent leur contribution à une éventuelle révision des chapitres 1.4.1 et 1.4.2 du Code zoosanitaire international de l’Office international des épidizooties (OIE). Ils font notamment ressortir, exemples à l’appui, certaines insuffisances aussi bien dans les principes de base que dans les résultats de la méthode d’évaluation des risques figurant dans le Code. La méthode d’évaluation des risques proposée par le Code se fonde sur le calcul de la « probabilité d’apparition d’au moins un foyer » d’une maladie donnée suite à l’importation d’un nombre donné d’animaux ou de produits d’origine animale (estimation des risques non réduits). Cette méthode est d’ordinaire appliquée lorsqu’il s’agit d’événements rares. Pour un pays comme l’Italie, cette méthode n’est peut-être pas particulièrement indiquée dans la mesure où c’est la fréquence des foyers de maladie qui doit être estimée pour fournir aux décideurs des informations appropriées et pertinentes. Le recours à l’information obtenue sur les risques d’introduction de la maladie vésiculeuse du porc tels que déterminés par la méthode d’évaluation de l’OIE aurait incité la Direction des Services vétérinaires italiens à interdire toute importation de porcs en provenance des Pays-Bas et de la Belgique pendant au moins deux ans au début des années 1990, avec les lourdes pertes économiques que cela aurait entraîné pour l’Italie comme pour les pays exportateurs. Or, le nombre de foyers réels de maladie liés à l’importation directe de porcins de pays membres de l’Union européenne et survenus en Italie de 1992 à 1994, a été très faible (deux à cinq cas dus à l’importation directe de porcs des Pays-Bas et un ou deux cas liés à l’importation de porcs belges).

Les auteurs donnent également un exemple de la méthode d’évaluation des risques associés à d’importants volumes d’échanges de marchandises. Cette méthode, qui se fonde sur la simulation de Monte Carlo, fournit les informations nécessaires à l’évaluation des coûts des stratégies comparées. Cette méthode peut servir à prévoir le nombre de foyers probables après importation et à mener une étude comparée des mesures alternatives de sécurité, en vue de sélectionner celle qui offre le meilleur rapport coût-efficacité. L’analyse, effectuée à l’aide de courbes de risque, permet de procéder à une évaluation quantitative et à une comparaison entre divers scénarios, allant de l’absence totale de mesures de sécurité à la combinaison de plusieurs de ces mesures.

Mots-clés
Análisis de riesgos ligados a la importación: la experiencia italiana

V. Caporale, A. Giovannini, P. Calistri & A. Conte

Resumen
Los autores proponen una contribución a la revisión eventual de los capítulos 1.4.1. y 1.4.2. del Código Zoosanitario Internacional (el Código) de la Oficina Internacional de Epizootias (OIE), con una serie de datos que ilustran algunas de las incoherencias que presentan tanto el concepto como el método de evaluación de riesgos expuestos en el Código. Dicho método se basa en el cálculo de la "probabilidad de que se produzca por lo menos un brote" de determinada enfermedad tras la importación de determinada cantidad de animales vivos o productos de origen animal (estimación del riesgo no reducido). Tal suele ser el procedimiento empleado en el caso de sucesos infrecuentes. Semejante método reviste escasa utilidad para un país como Italia, donde lo que habría que estimar para ofrecer a los responsables públicos información adecuada y pertinente sería más bien la frecuencia de brotes de enfermedad. Si a principios de los años 1990 se hubiera llevado a la práctica el método propuesto por la OIE para evaluar el riesgo de enfermedad vesicular porcina, la información resultante habría inducido al Jefe de los Servicios Veterinarios de Italia a prohibir toda importación de cerdos procedentes de los Países Bajos o Bélgica durante por lo menos dos años, lo que hubiera supuesto graves pérdidas económicas tanto para Italia como para los países exportadores. En cambio, el número real de brotes de esa enfermedad que se declararon en Italia en 1992, 1993 o 1994 a resultas de la importación directa de cerdos desde algún Estado Miembro de la Unión Europea fue muy bajo (de dos a cinco brotes por importación directa desde los Países Bajos y uno o dos episodios en el caso de Bélgica). Los autores también describen un ejemplo de método para evaluar los riesgos ligados a intercambios comerciales de gran envergadura. Dicho método se basa en la simulación de Montecarlo y proporciona la información necesaria para evaluar los costes de las distintas estrategias evaluadas. El método puede usarse para predecir el número más probable de brotes que resultarán de una importación, comparar distintas alternativas de prevención y elegir la que presente mejor relación coste/beneficio. La comparación, que se realiza mediante curvas de riesgo, permite evaluar y comparar cuantitativamente distintas situaciones hipotéticas, desde la falta absoluta de medidas preventivas hasta diversas combinaciones de tales medidas.

Palabras clave

References


