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The use of risk analysis to evaluate alternatives to animal destruction

Armando Giovannini

Summary

Risk analysis is a tool for decision-making in the face of uncertainty. It provides numerical estimates of the probabilities and consequences associated with particular scenarios, and may be a valuable technique for comparing different animal disease control strategies and for quantifying their expected effectiveness and the uncertainties of expected results. Within the framework of risk analysis, option evaluation is the process of identifying, selecting and evaluating the efficacy and feasibility of measures in order to reduce the likelihood and/or magnitude of adverse health and economic consequences, including the reduction of mass animal destruction. Examples on the use of option evaluation in the framework of risk analysis in Italy are discussed and include the design of the national bluetongue vaccination programme, modifications in the bluetongue surveillance programme, risk mitigation measures for animal movement in the bluetongue control programme, and evaluation of different testing procedures for brucellosis. A supplementary benefit in all these examples was the significant reduction in the number of animals that had to be destroyed. It is becoming increasingly evident that risk analysis can be a technically sound and socially responsible way to assist decision-making among members of industry, government and the general public. Increasingly, the use of risk analysis supports decision-making in the fields of international trade and health, management of natural disasters, national security, and provides a legitimate alternative to mass animal destruction.

Keywords

Animal disposal, Decision-making, Disease control, Italy, Option evaluation, Risk analysis.

L'uso dell'analisi del rischio per valutare misure di controllo alternative alla distruzione degli animali

Riassunto

L'analisi del rischio è uno strumento utile per il processo decisionale quando ci si trova a dover fronteggiare incertezze. Esso fornisce stime numeriche delle probabilità e delle conseguenze associate a particolari scenari, e può essere utile per comparare differenti strategie di controllo di malattie animali e per quantificarne l'efficacia attesa e le incertezze dei risultati. Nell'ambito dell'analisi del rischio, la valutazione delle opzioni è il processo che permette di identificare, scegliere e valutare l'efficacia e la fattibilità di misure tese a ridurre la probabilità o la gravità di conseguenze economiche e sanitarie indesiderate, ivi compresa la riduzione della distruzione di animali. Vengono considerati e discussi alcuni esempi dell'uso, in Italia, della valutazione delle opzioni nell'ambito del processo di analisi del rischio, fra i quali la definizione del piano nazionale di vaccinazione nei confronti della bluetongue, successive modificazioni del piano di sorveglianza della bluetongue e misure per la mitigazione del rischio legato agli spostamenti di animali ed infine per valutare l'equivalenza di procedure diagnostiche previste per la brucellosi bovina e ovi-caprina. In tutti gli esempi riportati si è avuta una significativa riduzione del numero di animali da distruggere. Sta

Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale', Via Campo Boario, 64100 Teramo, Italy
a.giovannini@izs.it

diventando sempre più evidente che l'analisi del rischio può essere uno strumento tecnicamente valido e socialmente responsabile per coadiuvare il processo decisionale ad opera dell'industria, delle istituzioni governative e del pubblico in generale. Un utilizzo crescente dell'analisi del rischio come supporto al processo decisionale è stato osservato in campi come il commercio internazionale e gli aspetti sanitari collegati, la gestione dei disastri naturali, la sicurezza interna, ed inoltre fornisce dati a sostegno di possibili alternative allo stamping out.

Parole chiave
Analisi del rischio, Controllo delle malattie, Distruzione degli animali, Italia, Processo decisionale, Valutazione delle opzioni.

Introduction

Risk analysis methods were first developed by the nuclear and space industries to assess the likelihood and probability of undesirable events (known as hazards) and were subsequently adopted by the chemical and petrochemical industries. More recently, these methods have been applied to biological systems. In the 1990s, risk analysis was applied to animal health and in particular to food safety (microbiological risk assessment) and import risk analysis (IRA). The Agreement on the Application of the Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO) has encouraged recourse to risk analysis and has resulted in significant improvements in the methodology applied to international trade policies for animals and animal products.

The increased use of import risk analysis after the adoption of the SPS Agreement has led to significant improvements in the methodology of risk analysis as applied to international trade for animals and animal products. It is also apparent that quantitative risk assessment techniques can have a wide range of veterinary applications. Risk analysis, a tool that can be used in decision-making in the face of uncertainty, provides numerical estimates of the probabilities and consequences associated with different scenarios. Risk analysis enables a quantitative evaluation and comparison to be made of various scenarios, ranging from one in which there are no safeguards to combinations of a variety of safeguards. It facilitates the communication of risk and of the consequences to stakeholders and decision-makers, thereby facilitating the selection of the most appropriate safeguards in a transparent fashion by decision-makers (12).

Risk analysis is a valuable technique for comparing different animal disease control strategies and for quantifying expected effectiveness and uncertainties of expected results. Risk analysis has been used in Italy as a decision tool to select the testing strategy for bovine brucellosis (9, 11) and bluetongue surveillance (2, 10) and, in the case of bluetongue, for the design of the vaccination programme (3, 12).

The aim of this paper is to present and discuss the experience of Italy on the use of risk analysis in the evaluation of alternative strategies to disease control or prevention and as an alternative to mass animal destruction

Risk analysis

Components of risk analysis

Risk analysis has been used widely in a number of areas and has resulted in the formulation of a variety of terms and definitions. However, most of the approaches subdivide risk analysis into four components, as follows:

- hazard identification
- risk assessment
- risk management
- risk communication.

Hazard identification means the process of identifying the pathogenic agents which could potentially be responsible for damage to human or animal health.

According to the section on risk analysis (Section 1.3. Risk analysis) of the *Terrestrial animal health code* published by the World Organisation for Animal Health (OIE: Office International des Épizooties) (22) that deals with import risk analysis, risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk

assessments may be qualitative or quantitative. Risk management is the process of deciding upon and implementing measures to achieve the appropriate level of protection of a country, whilst at the same time ensuring that negative effects on trade are minimised. Finally, risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis and by which the results of the risk assessment and proposed risk management measures are communicated to decision-makers and interested parties in importing and exporting countries (22). This general description of risk analysis components may be adapted with ease from an import risk analysis framework to many other possible objectives. In particular, the transposition to the evaluation of alternative strategies of disease control or prevention is very simple.

Risk analysis models

The first framework to be developed was the National Academy of Sciences-National Research Council (NAS-NRC) model (17). This model was developed in response to the need to set maximum limits of chemical substances in the environment, food, etc. Risk assessments undertaken using this system were therefore designed to answer the question: 'what is the maximum amount of substance (or pathogen) to which a person can be allowed to be exposed from a particular source?' The framework used in this model is therefore designed as a regulatory tool for setting allowed, acceptable or tolerable levels of contaminants and pathogens in food, and is the system most frequently used by toxicologists (16).

The NAS-NRC system (Fig. 1) divides risk assessment into the following four steps, as detailed below (in this system, hazard identification is included as a part of risk assessment rather than preceding it as is the case in the system described by the OIE).

In the NAS-NRC framework, risk assessment is divided into the following phases:

- hazard identification: the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods
- hazard characterisation: the qualitative and/or quantitative evaluation of the nature of adverse health effects associated with biological, chemical and physical agents which may be present in food (for chemical agents, a dose-response assessment should be performed; for biological or physical agents, a dose-response assessment should be performed if the data can be obtained)

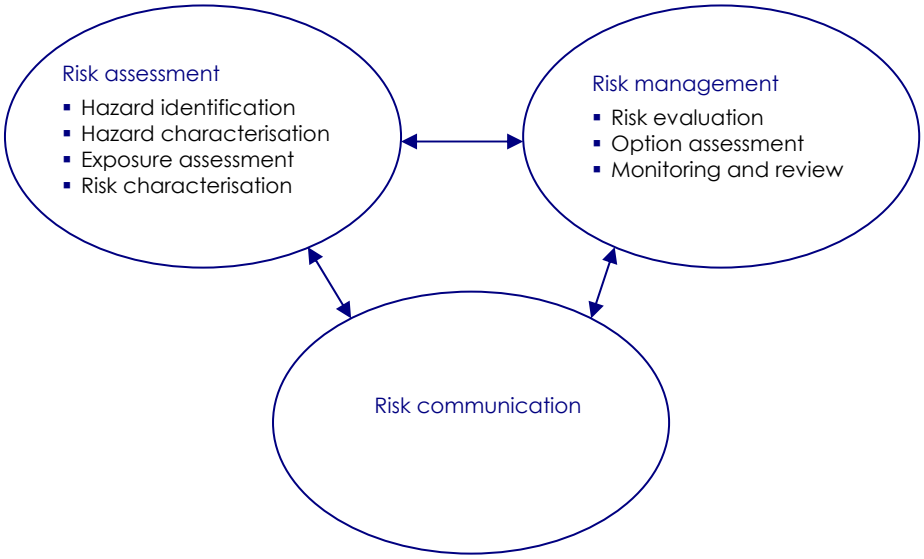

Figure 1
Structure of the risk analysis process of the National Academy of Sciences-National Research Council

- exposure assessment: the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents in food, as well as exposure to other sources if relevant
- risk characterisation: the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population, based on hazard identification, hazard characterisation and exposure assessment.

This scheme may be applied for both qualitative and quantitative risk assessments but is more suitable for a quantitative approach. As already stated, it was originally developed as a regulatory tool for levels of contaminants and pathogens in food.

The components of risk management are as follows:

- risk evaluation: the identification of a food safety problem, establishment of a risk profile and ranking of the hazard for risk assessment and risk management priority
- option assessment: the identification of available management options and selection of the preferred management option, including consideration of an appropriate safety standard (this step includes weighing various health risks along with economic, political and social factors)
- monitoring and review: the assessment of effectiveness of measures taken and a review of risk management and/or assessment as necessary.

A more recently developed framework for risk analysis (Fig. 2) is that developed by Covello and Merkhofer (8). This model is designed to assess the magnitude of risk for specified consequences in a given situation. It can then be used to decide whether the risk is acceptable as it stands, or whether sanitary measures are required to reduce the risk to an acceptable level. Risk assessments using this system are designed to answer the question: 'what is the likelihood of specified consequences (the adverse human health, animal health, economic or environmental effects of interest) occurring as a result of exposure to a particular substance or pathogen that came from a defined release source?' This system is more versatile than the NAS-NRC system and can be applied to various risk questions, making it the system of choice for many risk assessors (16). This is the reason why this approach is used in Italy for the design of vaccination programmes, the re-planning of bluetongue surveillance and the selection of risk mitigation measures to be applied in case of animal movements.

In the Covello and Merkhofer system, risk assessment follows hazard identification, which is considered a separate step and is completed first. This is followed by the four steps of the risk assessment process (release assessment, exposure assessment, consequence assessment and risk estimation). The exposure assessment in the NAS-NRC system includes both the release assessment and exposure assessment components of the Covello and Merkhofer system. The other difference between the two systems is the assessment of consequence, termed 'hazard characterisation' in the NAS-NRC framework and 'consequence assessment' in the Covello and Merkhofer system.

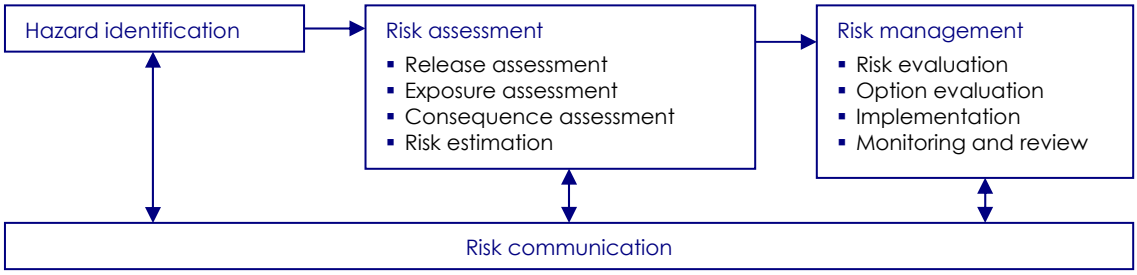

Figure 2
Structure of the Covello and Merkhofer risk analysis process

A third approach in the risk analysis process is that adopted by the International Plant Protection Convention (IPPC). The objectives of a pest risk assessment according to the IPPC are, for a specified area, to identify pests and/or pathways of quarantine concern and evaluate the risk presented, to identify endangered areas and, if appropriate, risk management options.

The steps in the process are similar to those described in the Covello and Merkhofer model, with the main exception being that the IPPC (like NAS-NRC) includes pest categorisation (equivalent to hazard identification) within risk assessment, rather than as a separate procedure.

Risk assessment and option evaluation

One of the components of risk management according to the Covello Merkhofer model is option evaluation. According to the *Terrestrial animal health code* (22), option evaluation is the process of identifying, evaluating the efficacy and feasibility of and selecting measures to reduce the risk associated with an importation in line with the appropriate level of protection of a country. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. The evaluation of the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then the comparison of the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

The option evaluation, therefore, is a bridge activity between the risk assessment and the risk management components of risk analysis. Risk cannot indeed be conceived as an abstraction that does not take into consideration the measures in place to mitigate its effects or risk mitigation measures that could possibly be implemented.

The approach used in Italy to compare a number of different options was based on that described by Kaplan and Garrick (14), according to whom, risk can be considered as a function of the damage caused by a hazard (e.g. a pathogenic agent), its probability of occurrence and the safeguards adopted. In quantitative terms, Kaplan and Garrick (14) express the risk as a set of triplets, as follows:

$$Risk = \{\langle s_i, p_i, x_i \rangle\}$$

where:

s_i = a scenario (such as a number of disease outbreaks); in the definition of the scenario, a set of specific conditions and safeguards under which the scenario occurs is also included

p_i = the probability of occurrence of that scenario

x_i = the measure of damage of that scenario (e.g. the cost of that number of disease outbreaks).

If all possible events are arranged in order of increasing severity of damage ($x_1 \leq x_2 \leq x_3 \leq .. \leq x_n$), a cumulative probability can be calculated of each event and all subsequent events. The graphic representation of this cumulative probability distribution is a risk curve (Fig. 3).

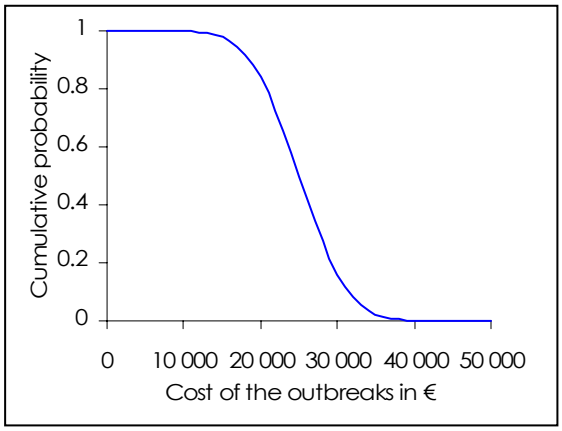

Figure 3
Example of a risk curve

If a set of different risk management options is considered (e.g. of specific conditions and safeguards), the result is a set of risk curves (one for each option) that enables a comparison of the options (Fig. 4). From the risk curves presented in Figure 4, for example, the following evaluation of the three risk management options considered can be made:

- option 3 (red line) is the less effective mitigation option: for any value of the damage, the probability of having that

damage or more is greater for option 3 than for any other option
- options 1 (blue line) and 2 (green line) are both better than option 3, but option 2 is, on average, better than option 1: the probability distribution of option 2 has a median value (the value of the damage corresponding to a cumulative probability of 0.5) of €25 000 instead of €27 000 for option 1.

Option 1 (blue line) has greater variable effectiveness than option 2: 80% of the total cumulative probability distribution is between €18 000 and €31 000 in the case of option 2 (green line) and between €15 000 and €39 000 in the case of option 1 (blue line).

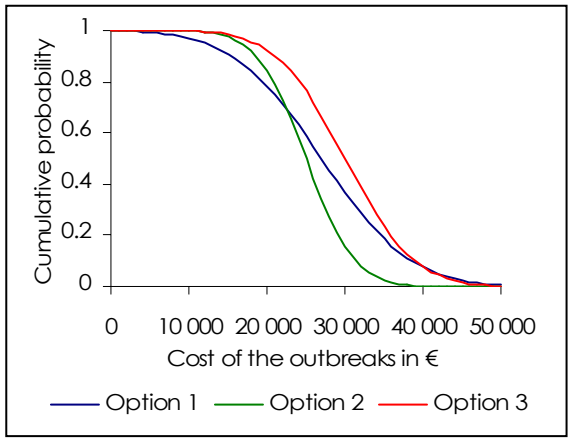

Figure 4
Example of risk curves for three options of risk mitigation

Applications of risk analysis to the evaluation of disease control or prevention strategies

Disease control

The bluetongue vaccination programme in Italy was designed using risk analysis tools (3, 12).

The assessment was conducted by answering the following questions:
- What is the likelihood of bluetongue spreading from areas of southern Italy that were infected in 2000 (Calabria) without a vaccination programme?
- What are the effects of vaccinating either sheep and goats or sheep, goats and cattle against bluetongue in the regions involved, on the spread of the disease and on the eradication of bluetongue from Italy?

The adoption of a stamping-out strategy was not considered in this assessment because it was well known that this strategy was ineffective in the case of vector-borne infections. From 1998 to the implementation of Directive 2000/75/EC in Europe in 2000, well over 200 000 sheep died or were culled, but the disease continued (7). European legislation in force at that time to control bluetongue required the slaughter of all susceptible animals in an outbreak with the possible extension of such measures to neighbouring farms suspected of exposure (5). Throughout that series of outbreaks, affected countries attempted to control and eradicate the virus by traditional disease control measures but sadly this did not halt disease spread. Vector control is theoretically a cornerstone for vector-borne diseases. However, in the case of bluetonuge, vector control programmes had not provided satisfactory results in the past, due to the particular biology of *Culicoides* and to the variety of species involved, characterised by different biology and ecological niches. Therefore, alternative vaccination strategies were compared and a 'do-nothing' approach was also studied.

The overall risk assessment was conducted on a qualitative basis by evaluating the likelihood of each event occurring, while some specific problems were also analysed on a quantitative basis using computer models.

The methods used to answer the second question will be the focus of this section of the article.

Qualitative and quantitative risk assessments were conducted to determine the probability of halting the circulation and spread of virus.

Qualitative assessment

The manufacturer of the vaccine claimed a level of protection of 99.4% (P. Hunter, Onderstepoort Biological Products, personal communication) based on the following ratio:

$$\frac{\{\text{Total score of clinical signs in vaccinated and challenged animals}\}}{\{\text{Total score of clinical signs in non-vaccinated and challenged animals}\}} = 99.4\%.$$

This ratio measures the effectiveness of the vaccine in reducing economic losses due to mortality and lower production caused by the disease. Reduction of economic losses, however, was not the only possible purpose of bluetongue vaccination in Italy. By creating a bluetongue-resistant population belt, it also aimed at lowering the probability of spread of infection and at reducing virus circulation by interrupting the virus transmission cycle (12).

In the presence of bluetongue virus infection, animal movements cease as international standards prohibit the movement of susceptible animals from areas in which the virus is circulating. According to Directive 2000/75/EC, a protection zone of 100 km in radius and a surveillance zone of 50 km around the protection zone must be established around any farm on which a bluetongue outbreak has occurred or virus circulation has been confirmed (7). All animal movements from the protection zone to the surveillance or free zone and from the surveillance to the free zone are strictly forbidden. The application of Directive 2000/75/EC in 2001 caused a severe upset in animal movements in over one third of Italy. The cattle and ovine industries in Italy are characterised by a high degree of animal movement. Most of the slaughterhouses and the fattening units for veal calves and beef cattle are situated in the northern regions, while in the centre and south of the country, the sheep industry is mostly based on long-range seasonal nomadism (transhumance) which has been practised since pre-Roman times. It soon became apparent that a movement ban from all southern regions and the principal islands to northern Italy would disrupt production cycles of both species (3). A control policy based on the vaccination of the majority of the susceptible ruminant population would induce population immunity levels that would significantly reduce the area in which the virus was circulating. Moreover, as immunised animals are resistant to wild virus infection, they are thus unable to carry infection into free areas (3).

Data available on the effectiveness of bluetongue vaccines relate mainly to protection against clinical disease, rather than to the effects on intensity and duration of viraemia, which are required to evaluate the extent to which spread of infection is likely to be reduced in vaccinated animals.

According to data on controls performed by the bluetongue vaccine producer from 1995 to 1999, none of 60 sheep vaccinated and challenged with virulent virus presented fever after challenge. Since it has been demonstrated that fever is consistently present in post-infection viraemia, the absence of fever suggests an ability of the vaccine to prevent viraemia following challenge with virulent virus. However, quantitative data on this issue in the available literature were very scanty in 2001. They involved only one vaccine that was less effective than that used in Italy which reduced the duration of viraemia after challenge with wild virus to 5.8% of the average duration observed in unvaccinated sheep (19).

Sheep, goats and cattle are the only important hosts that play a role in maintaining the disease. Once recovered, sheep, goats and cattle are clear of the virus and are immune to infections by the same serotype for at least one year (21). This means that a significant reduction in the duration of viraemia should significantly reduce the chances of the vector becoming infected and spreading infection.

Therefore, a quantitative assessment was performed to quantify the effects of vaccination on a population basis.

Quantitative assessment

The assessment was based on a simulation model that took the following scenarios into consideration:

- absence of (any form of) vaccination in susceptible populations
- vaccination of fractions (75-85%) of the sheep and goat populations
- vaccination of fractions (75-85%) of domesticated susceptible populations (sheep, goats and cattle).

The range of vaccination coverage considered by the model (75-85%) is the range most frequently attained by effective mass animal vaccination campaigns.

For each scenario, the probability of infection spread was estimated by simulating the number of secondary cases expected one month after the onset of 1, 10, 50, 100 and 200 primary cases (animals already infected before commencing the vaccination campaign or infected animals introduced into the area). The risk curves resulting from the simulation of the various scenarios are given in Figures 5, 6, 7 and 8.

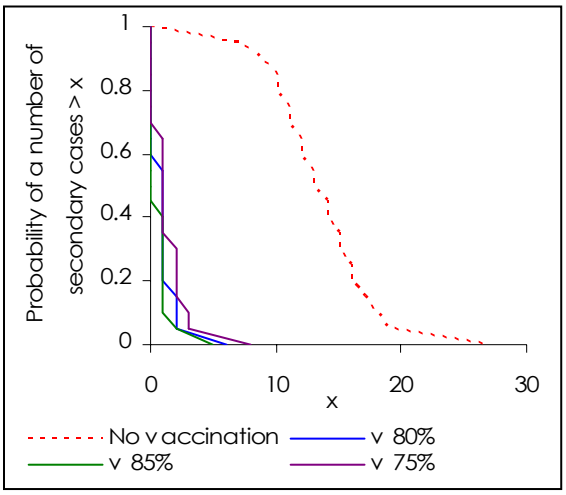

Figure 5
Number of secondary cases expected from a single primary case (vaccination of cattle, sheep and goats)

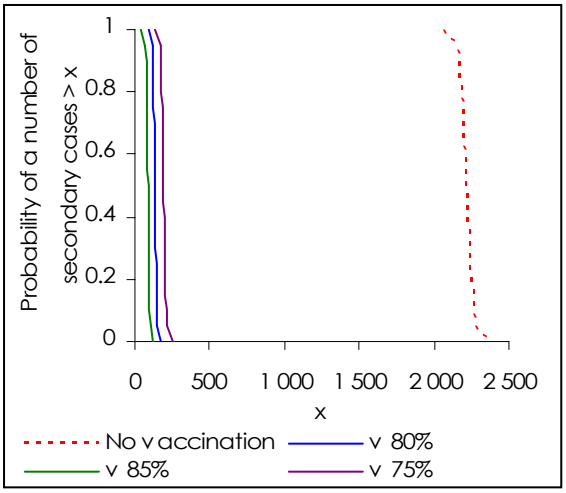

Figure 6
Number of secondary cases expected from 200 primary cases (vaccination of cattle, sheep and goats)

Figures 5 and 6 show that if at least 80% of the cattle, sheep and goat populations are vaccinated effectively, the probability of a number of secondary cases greater than or equal to primary cases (endemic infection) is always very low, regardless of the number of primary cases that trigger transmission. As a consequence, there is a high probability of observing a decrease in the number of cases over time (and therefore the elimination of infection in the population) when herd immunity involves at least 80% of the susceptible population. On the other hand, if herd immunity involves only 75% of the population, the probability of eliminating infection is lower (30% in the event of a single primary case and 35% in the event of 200 primary cases).

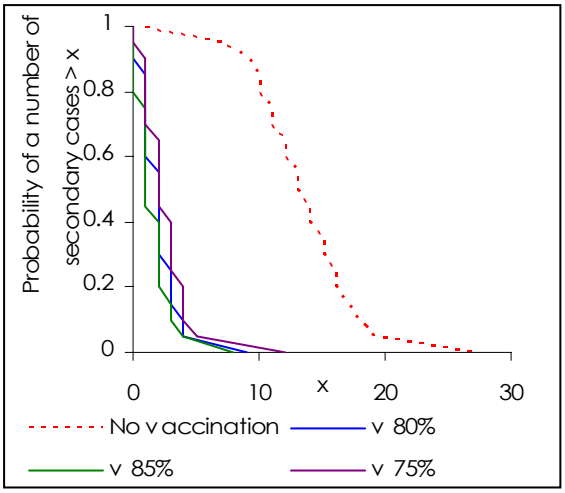

Figure 7
Number of secondary cases expected from a single primary case (vaccination of sheep and goats only)

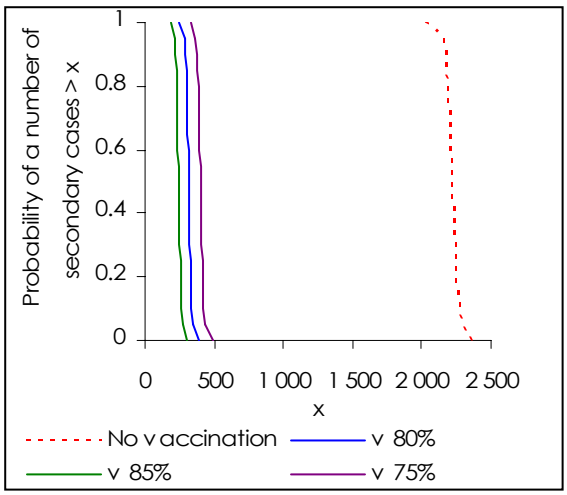

Figure 8
Number of secondary cases expected from 200 primary cases (vaccination of sheep and goats only)

Figures 7 and 8 illustrate those scenarios in which only the sheep and goat populations are vaccinated. In these scenarios, the probability of a number of secondary cases that are greater than or equal to the number of primary cases (endemic infection) is always higher than after vaccination of all ruminants. Moreover, in the case of vaccination of sheep and goats alone and even in the case of 85% immunisation of the eligible population, the probability of a number of secondary cases exceeding the primary cases is 40% when infection is triggered by a single primary case. This probability increases with the number of primary cases, up to over 65% when infection is started by 200 infected animals (12).

In May 2001, the Italian Ministry of Health decided to vaccinate all domestic ruminants (15). No vaccination was performed in Italy until the winter of 2001/2002. Results obtained from the 2002 vaccination campaign were consistent with the predictions of the model. To provide adequate protection, the model predicted that at least 80% of susceptible livestock needed to be immunised if vaccination was to be effective. Two regions achieved at least 80% vaccination (Sardinia and Tuscany). In 2002, only 24 sheep in six flocks in Sardinia showed signs of bluetongue, compared with 239 178 diseased sheep in 6 090 flocks the previous year. In Tuscany, no clinical case of bluetongue was detected in sheep in 2002, compared to 693 diseased sheep in 158 flocks in 2001. No southern region, apart from the province of Trapani (Sicily), vaccinated over 60% of the susceptible populations. In these regions, bluetongue infection spread actively in 2002, with 2 344 sheep in 314 flocks showing signs of disease, compared with 10 360 animals in 497 flocks the previous year. Serological test results on sentinel animals confirmed clinical surveillance findings.

Data from the Balearic Islands and Corsica also appear to support the projections made by the model. Although only sheep were vaccinated in both areas, in the Balearic Islands the sheep population greatly outnumbered cattle and the total number of vaccinated animals was close to 80% of the total susceptible population (cattle, sheep and goats). In contrast, less than 70% of the total population of sheep and goats were vaccinated in Corsica. According to expectations based on predictions, the disease now seems to have disappeared from the Balearic Islands, while a new epidemic occurred in Corsica in 2001. No case of disease was detected in Corsica in 2002 after a second vaccination campaign.

Testing strategies

The risk analysis approach used to determine the bluetongue control strategy was also used for subsequent alterations to the surveillance programme (2) and to animal movement restrictions (10).

Bluetongue surveillance

The effects of changes to the surveillance programme were evaluated using a Montecarlo model that simulated the number of sentinel seroconversions expected in specific field conditions of an infected region of Italy (2). Scenarios of variable numbers of sentinel groups or variable numbers of sentinels within each group were compared.

The simulation model that was developed predicted a significant reduction in the effectiveness of the system when the number of sentinel herds tested decreased. However, the variation in the number of animals tested within each sentinel herd did not significantly reduce the accuracy of the system. The simulation study indicated that the number of sentinel animals within herds could be reduced by one third without a significant reduction in the effectiveness of the system. The simulation model described was designed and validated using data derived from the Italian serological surveillance programme. Results, therefore, are applicable to the situation in Italy and cannot be extrapolated to others. However, the mathematical approach used in the model could prove useful in developing simulation models in other countries (2).

Bovine brucellosis

In accordance with Council Directive 97/12/EC, a cattle herd can be classified as 'officially brucellosis free herd' and maintain its status, based on a number of different testing

procedures that are officially considered as equivalent by the European Union (EU) legislation (6). It is incumbent on the member country to select the testing protocol (s). Procedures provided by the directive for herd qualification are as follows:

- two serological tests (based on the serum agglutination test [SAT], Rose Bengal test [RBT], complement fixation test [CFT], enzyme-linked immunosorbent assay [ELISA], buffered *Brucella* antigen test, plasma ring test or plasma agglutination test) of the entire herd, at an interval of more than three months and less than twelve months (procedure A)
- three milk ring tests (MRT) at quarterly intervals, followed by a serological test at least six weeks later (procedure B).

Testing procedures for the maintenance of qualification are as follows:

- three milk ring tests performed at intervals of at least three months (procedure C)
- three milk-ELISA tests performed at intervals of at least three months (procedure D)
- two serological tests as listed above, conducted at an interval of at least three months and not more than six months (procedure A)

The only procedure applied in Italy at the time was procedure A, based on RBT as the screening test and CFT as the confirmatory test. Due to the simplicity and low costs of the MRT and milk-ELISA, an evaluation of their equivalence with serological tests was conducted to include milk testing in the national eradication programme (11).

The evaluation was performed using a Montecarlo simulation model. Different scenarios were considered using the above testing procedures, a range of field-derived values for the husbandry and fertility parameters and observed values for the within-herd prevalence of infection.

The result of the simulation of the various scenarios was expressed in terms of the probability of detecting an infected herd (Fig. 9) and in terms of the cost of the application of the various procedures to the cattle population involved (Fig. 10), given the cost of testing and surplus testing for the confirmation of positive results (true- and false-positives) obtained in milk testing. This assessment enabled the decision-makers in Italy to define the rules for the application of milk testing in the eradication of brucellosis. The MRT which is of lower sensitivity than individual serology in all of the testing procedures and scenarios considered (Fig. 9), was not included in the programme. On the contrary, the milk-ELISA that was at least as sensitive as individual serology (Fig. 9) and

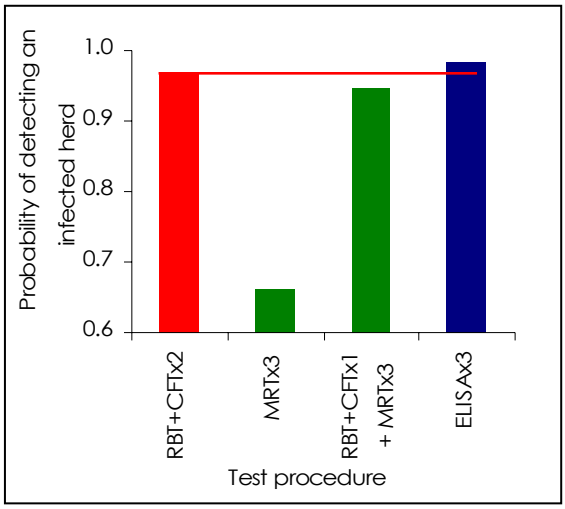

Figure 9
Results of simulations of herd testing for bovine brucellosis
Testing of infected herds with optimal husbandry and fertility parameters

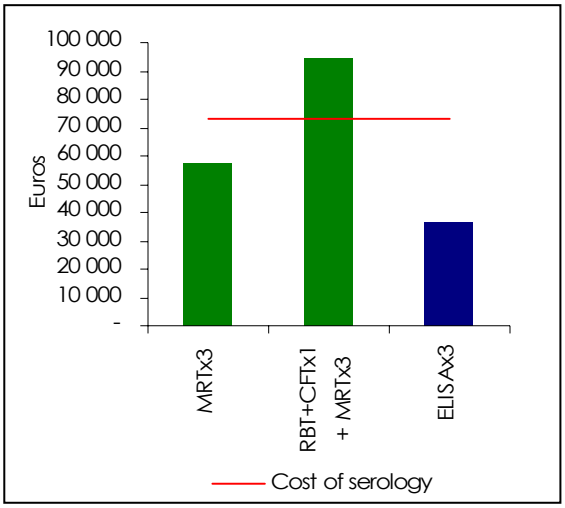

Figure 10
Results of simulations of herd testing for bovine brucellosis
Cost of the various options in euros

more economical than serology (Fig. 10), was adopted for the maintenance of qualification of herds in officially free regions.

Sheep and goat brucellosis

Council Directive 91/68/EEC (4) that lists animal health conditions governing intra-community trade in sheep and goats is the strategic basis for the control of ovine and caprine brucellosis in the EU. This strategy aims at achieving officially brucellosis (*B. melitensis*)-free (OBF) status in all EU holdings and territories.

In the case of OBF ovine or caprine holdings which are not situated in a part of the territory which is recognised as OBF, the holding may retain its OBF status if a representative number of sheep and goats over six months of age are monitored annually and give negative results.

The representative sample to be tested for each holding consists of the following:

- all non-castrated males over six months old
- all animals introduced onto the holding since the previous test
- 25% of females that have reached the age of reproduction (sexually mature) or are in milk, with a minimum of 50 per holding – except on holdings where there are less than 50 such females, in which case all females must be tested.

However, testing only a limited number of animals poses a risk of not detecting infection (if present) in an OBF holding, thereby reducing the efficacy of any brucellosis control plan. A risk assessment was performed to evaluate the extent to which the procedure fixed by Directive 91/68/EEC was able to detect infection (if present) in a given holding and to evaluate whether or not this procedure can be accepted as a safe basis for declaring a holding to be brucellosis-free (9). The evaluation was made using statistical analyses and a simulation model based on field data from a study area in southern Italy. The results of the simulation model indicated that when using the Directive's sampling procedure in observed field conditions and in flocks of over 50 animals, brucellosis infection would have a 45% probability of being missed. Due to the lower within-herd prevalence of infection observed in large flocks, the performance of the sampling procedure proposed by Directive 91/68/EEC was particularly poor in large flocks (Fig. 11). It would be advisable, therefore, to modify the EU legislation to improve the sampling criteria for the maintenance of OBF status. The authors suggested that a statistically based sampling method be employed instead of the fixed percentage method currently in use and that entire flocks be tested in areas of very low prevalence of infection.

Other decision-making problems

Bluetongue and animal movements

Amendments to the rules governing animal movements were also based in part on the results of a Montecarlo simulation model (10). The need for these changes was that since August 2000, animal trade between infected and free areas had come to a complete standstill. Long-term standstills lead to significant economic losses and negative social consequences which are sometimes greater than those due to the disease. As farmers did not receive compensation, the standstill measures could not be enforced indefinitely. In the meanwhile, a vaccination campaign was initiated in the infected regions of Italy. In 2002, the goal of vaccinating over 80% of susceptible domestic ruminant populations, set by the Ministry of Health, was reached in some regions (Abruzzo, Sardinia and Tuscany). The vaccination campaign successfully reduced clinical disease. In Sardinia, the number of clinical outbreaks declined from 6 090 in the 2001-2002 epidemic to 10 outbreaks in 2002-2003. In Tuscany, after 158 outbreaks in the 2001-2002 epidemic, the clinical disease disappeared altogether. Therefore, risk associated with animal movements from those regions was likely to be lower after vaccination than it was when standstill restrictions were imposed, and conditioned by the immunity levels induced by vaccination of susceptible animal populations. A simulation model was developed to assess the expected number of viraemic animals introduced into free areas from infected areas. The mathematical structure of the model was the same as that used to evaluate the vaccination strategy (12). Three scenarios were considered, describing

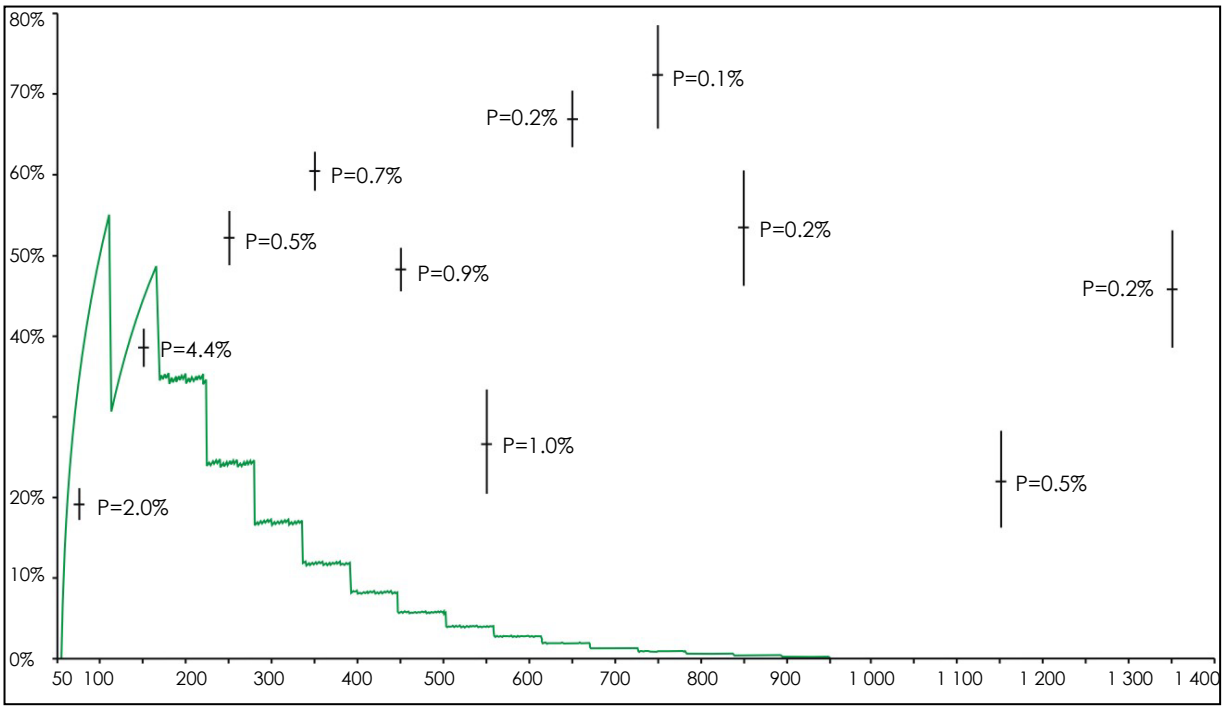

Figure 11
Theoretical probability (green line) of missing the flock infection in the event of 1.79% within-flock prevalence and results of simulation with 95% confidence interval subdivided by flock size class

different types of territory that were selected as paradigmatic examples, as follows:

- scenario A, a territory in which over 80% of the total animal population has been vaccinated and the incidence of infection in previous years was high
- scenario B, a territory in which about 50% of the total animal population has been vaccinated
- scenario C, a territory in which a negligible fraction of the total population has been vaccinated.

The expected number of viraemic ruminants among animals from areas subjected to movement restrictions varies according to the vaccination level of the population in the area of origin. When less than 80% of the domestic ruminant population in the area of origin is vaccinated, the risk of a number of viraemic cattle capable of causing bluetongue virus spread to free areas is not negligible, even if other risk mitigation measures are applied. On the contrary, when over 80% of the domestic ruminant population in the area of origin is vaccinated, the risk of spreading infection through animal movements to free areas is significantly lower. The results of the risk assessment were taken into account by the Italian General Directorate of Veterinary Services which modified national veterinary legislation on movement bans from restricted zones (10).

Conclusions and future challenges

In the last 30 years, there have been two striking accomplishments in the risk and decision sciences. Firstly, theoretical and technical advances have led to powerful and sophisticated methods for the quantitative analysis of risk. Secondly, an increasingly coherent and influential body of empirical research has shed light on how cognitive and emotional processes interact to give rise to decisions and judgments of risk. As a result, the last few decades have witnessed an explosion of innovative empirical, theoretical and analytic methods and tools for analysing risks and for making decisions in conditions of uncertainty (18).

It is becoming increasingly evident that risk analysis can be a technically sound and socially responsible way of assisting decision-

makers from industry, government and the general public (1). Increasing recourse to risk analysis as a support to decision-making has been observed in the fields of international trade and health, management of natural disasters and even national security in response to the 9/11 attack (18). On the contrary, very few examples are available on the use of risk analysis in the animal health sector to compare different surveillance and/or control strategies for animal disease and to quantify expected effectiveness and uncertainties of expected results. Besides the examples described in this paper, only a few attempts have been made to optimise disease surveillance and control programmes. These include the risk-based optimisation of the Danish *Salmonella* programme in pork (13) and dairy cattle (20).

Despite its limited use in support of decision-making in animal disease control, risk analysis is often superior to other techniques that are used extensively to date, such as the classic cost-benefit analysis.

Usually, the traditional cost-benefit analysis is based on the most probable values for the variables involved, with no consideration of either uncertainty or variability. Quantitative risk assessment, on the contrary, not only provides outputs expressed in terms of possible levels of damage (that can be expressed in financial terms) but also gives the probability distribution of those damage levels. In other words, the uncertainty and the variability are also taken into consideration. The importance of variability is clearly shown in Figure 4.

Furthermore, in the case of risk analysis, the institution of a communication channel involving the principal stakeholders is a necessity from the beginning of the process. Risk communication consists of information exchanges between parties on the nature of the risk and the measures taken to control this risk. This is a fundamental responsibility for public authorities when managing public health risks. This can only function correctly if risk assessments and risk management decisions are transparent and public. The history and evolution of the bovine spongiform encephalopathy crisis in Europe made it abundantly clear that all steps of policy-making need to be taken in a transparent manner. There is no unique or defined level of acceptable risk that is applicable to all situations, but the acceptable risk (consequently, the level and intensity of controls applied) is a societal or political judgment. A further complication is that, in the case of animal disease control at least, the benefits of a control strategy (e.g. stamping out a foot and mouth disease outbreak) may be advantageous to relatively few citizens, such as the entrepreneurs who export to free countries. The costs of eradication (compensation to farmers), on the other hand, may be borne by many, including the livestock industry, the public and taxpayers, who might be expected to bear the cost of eradicating a disease. This may mean that a control strategy which is welcomed by a group of entrepreneurs may be quite unacceptable to the livestock industries and general taxpayers. Without transparency, stakeholders will neither be able to follow the development of the policy decisions taken, nor fully appreciate the consequences which they may bring. Transparency will result in the necessary public scrutiny and ensure democratic control and accountability. Finally, it can be concluded that the use of risk analysis in the design of animal disease control strategies, as amply demonstrated in the examples described in this paper, can be a powerful tool for providing alternatives to the mass destruction of animals associated with stamping out.

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