A qualitative risk assessment methodology for scientific expert panels

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Summary
Risk assessment can be either quantitative, i.e. providing a numeric estimate of the probability of risk and the magnitude of the consequences, or qualitative, using a descriptive approach.

The French Agency for Food, Environmental and Occupational Health and Safety (ANSES), formerly the French Food Safety Agency (AFSSA), bases its assessments on the opinions of scientific panels, such as the ANSES Animal Health Scientific Panel (AH-SP). Owing to the lack of relevant data and the very short period of time usually allowed to assess animal health risks on particular topics, this panel has been using a qualitative risk method for evaluating animal health risks or crises for the past few years. Some experts have drawn attention to the limitations of this method, such as the need to extend the range of adjectives used for the lower probabilities and to develop a way to assess consequences.

The aim of this paper is to describe the improved method now established by the AH-SP, taking into account the limitations of the first version. The authors describe a new set of levels for probabilities, as well as the items considered when addressing either animal or human health consequences.

Keywords
Introduction

Risk assessment can be either quantitative, i.e. providing a numeric estimate of the probability of the risk and the magnitude of the consequences, or qualitative, that is, using a descriptive approach. Both types are equally valid (17).

One of the missions of the food safety agencies of European Union (EU) Member States is to provide risk managers with sound risk assessments of various aspects of human and animal health. The Agence nationale de sécurité sanitaire (ANSES), formerly the French Food Safety Agency (AFSSA), bases its assessments on the opinions of scientific panels (SP).

Scientific panels must often make their assessments over a very short time period, from a couple of days to a few weeks. Furthermore, most of the data required to fully evaluate the extent of a health issue are generally not available or non-existent. Thus, qualitative risk assessment is often the only relevant tool available for evaluating animal health or animal health crises. Such a qualitative approach has been used for more than ten years in animal health (8, 10, 16).

Since 2002, a qualitative method has been widely used by the scientific experts of what was then the AFSSA Animal Health Scientific Panel (AH-SP) (1, 2, 3, 6). However, some experts have drawn attention to the limitations of the method used, such as the need to extend the range of adjectives used for the lower probabilities and to develop a tool to assess consequences. A specific study has not been completed to document these limitations. However, during previous meetings of the expert panels of the Agency, clarification of this topic was requested. For this reason, a specific working group was set up to discuss and improve this method and, in this article, the authors describe and discuss this new version (4).

Methods

The working group to improve the qualitative method was composed of various experts from different scientific fields (e.g. infectiology, parasitology, laboratory diagnostics, veterinary epidemiology, quantitative risk assessment and risk management). These experts, also the authors of this work, can be identified as follows:

- J.-P. Ganière and B. Toma (infectiology)
- C. Chartier (parasitology)
- A.-M. Hattenberger and J. Guillotin (laboratory diagnostics)
- B. Dufour, F. Moutou and L. Plée (veterinary epidemiology)
- B. Durand, R. Lancelot, C. Saegerman and A. Thébault (quantitative risk assessment)
- D. Boisseleau (risk management).

Future users were also invited to comment on the revised method (first developed through references 1, 2 and 3). Some of the working group members were also members of the original working group (B. Dufour and F. Moutou) that established the first version of the qualitative risk assessment method used within the AH-SP. This method was based principally on the risk assessment method developed by the World Organisation for Animal Health (OIE) (15).

In this method, risk assessment is defined as one of the risk analysis components required to quantify, or qualify, a specific level of risk, through four inter-related steps (Fig. 1):

- release assessment: estimation of the likelihood of a hazard being introduced in a particular zone
- exposure assessment: estimation of the likelihood of susceptible humans or animals being exposed to the hazard
- consequences assessment: describing the results of the release and exposure to the hazard for humans and animals (health and/or economic consequences)
- risk estimation: combining the results of the preceding three steps.

The working group discussed each of these steps. The various approaches suggested by group members were tested in trials and compared with quantitative methods for animal health risk assessment, when discussing the probability of occurrence and the combination of methods. A list of 15 animal diseases and zoonoses was presented to five experts in risk management, to test and evaluate the scoring scale. The result is shown in Table I. Whatever the example and the scoring scale, the presentation of the flow chart is very important (6).
Intervals were used to express uncertainty in the estimated probabilities (i.e. the level of importing a disease, D, into a country, C, might be considered to lie between two and three on an ordinal scale running from zero to nine).

Probability of occurrence

The probability of occurrence depends on both the probability of release and the probability of exposure. Successive tests and trials helped to establish guidelines for combining these two probabilities to estimate the probability of occurrence. The authors adopted the rationale that the qualitative approach should remain close to quantitative probabilistic approaches. However, to develop an efficient tool, they also tried to ensure that the scale was able to discriminate between the lower risks.

The authors therefore set up trials using quantitative data in a similar manner to the way in which qualitative data is employed. For instance, as $10^{-3} \times 10^{-5} = 10^{-8}$, the combination of the probability of release with the probability of exposure gives a result (probability of occurrence) lower than each of the two original probabilities. The following rules were used for combinations:

- combining a ‘null’ probability with any other level of probability results in a ‘null’ probability of occurrence
- the smallest end result is ‘nearly null’, except when combining a ‘null’ probability with any other probability
- combining two probabilities gives a result no higher than the lowest of the two levels. However, such combinations may, in some cases, result in a level that is lower than the lowest of the two initial levels.

This method generates a results table (Fig. 2), with figures that represent the different levels of the ordinal scale associated with the qualitative words.

### Results

**Assessment of probabilities of release and exposure**

A ten-point scale was suggested, using adjectives for every estimated event (Table II). These ten levels can be used to express the probabilities of exposure and release, either independently or in combination (corresponding to the probability of occurrence). However, given the large number of levels, it proved difficult and not entirely relevant to define each word precisely. It was therefore decided to link the adjectives used for each level with a number on an ordinal scale, between zero and nine, to balance the difficulty of weighing up a list of words. This correspondence is indicated in Table II.

### Table I

**Assessment of consequences in animal health for a number of disease examples**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Health and economic consequences for a farm (0 to 3)</th>
<th>Likelihood of disease spread (0 to 3)</th>
<th>National and international economic consequences (0 to 3)</th>
<th>Assessed consequences in animal health – Total (0 to 9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot and mouth disease (UK, 2001)</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Highly pathogenic avian influenza (France, 2007)</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Bluetongue (Belgium, 2006)</td>
<td>1–2</td>
<td>3</td>
<td>3</td>
<td>7–8</td>
</tr>
<tr>
<td>Bovine brucellosis (France, 2008)</td>
<td>2</td>
<td>2–3</td>
<td>2</td>
<td>6–7</td>
</tr>
<tr>
<td>Bluetongue (France, 2006)</td>
<td>0–1</td>
<td>1–2</td>
<td>3</td>
<td>4–6</td>
</tr>
<tr>
<td>Bovine tuberculosis, Mycobacterium bovis (France, 2008)</td>
<td>0–1</td>
<td>2</td>
<td>1–2</td>
<td>3–5</td>
</tr>
<tr>
<td>Q fever (France, 2008)</td>
<td>2</td>
<td>1–2</td>
<td>0</td>
<td>3–4</td>
</tr>
<tr>
<td>West Nile fever (France, 2008)</td>
<td>1–2</td>
<td>1</td>
<td>0</td>
<td>2–3</td>
</tr>
<tr>
<td>Rabies (France, 2008)</td>
<td>0–1</td>
<td>0–1</td>
<td>0–1</td>
<td>0–3</td>
</tr>
</tbody>
</table>

### Table II

**Ordinal scaling and adjectives used to qualify an estimated probability (of release, exposure or occurrence) and the severity of the consequences**

<table>
<thead>
<tr>
<th>Ordinal scaling</th>
<th>Adjectives used</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Null</td>
</tr>
<tr>
<td>1</td>
<td>Nearly null</td>
</tr>
<tr>
<td>2</td>
<td>Minute</td>
</tr>
<tr>
<td>3</td>
<td>Extremely low</td>
</tr>
<tr>
<td>4</td>
<td>Very low</td>
</tr>
<tr>
<td>5</td>
<td>Low</td>
</tr>
<tr>
<td>6</td>
<td>Not very high</td>
</tr>
<tr>
<td>7</td>
<td>Quite high</td>
</tr>
<tr>
<td>8</td>
<td>High</td>
</tr>
<tr>
<td>9</td>
<td>Very high</td>
</tr>
</tbody>
</table>

Intervals were used to express uncertainty in the estimated probabilities (i.e. the level of importing a disease, D, into a country, C, might be considered to lie between two and three on an ordinal scale running from zero to nine).
Assessment of consequences

Risk is defined as a product of the probability of occurrence of a particular event and the consequences of this event occurring. The assessment of consequences is therefore another key step in the risk assessment method.

Only health (animal or human) and the resulting economic consequences were addressed, in a scientific approach to assessing consequences for animal or human populations. The authors did not consider political consequences.

Scores of between zero and three, as shown in Table III, were assigned to the items considered, to give a global qualitative assessment of consequences for human or animal health. Given this choice, the result is easily changed into qualitative outputs or scoring, following the ordinal scale. This makes calculating the following combinations, with a qualitative or ordinal score for the probability of occurrence, much easier.

For animal health, the authors considered the following items (Box 1):

– health and economic consequences for a particular holding; these include the micro-economic consequences (direct or indirect) of disease on a single farm. They depend on the existing control measures available;

– the spread of the disease between herds; in this step, the type of outbreak (e.g. sporadic, anazootic, enzooptic, epizooptic, panzooptic) is considered;

– national and international economic consequences of the disease (for the animal health industry in a particular country, for example). These are the macro-economic consequences of the disease (e.g. on trade in animals and their by-products), and include quality impairment, exclusion from particular markets and the costs of implementing control measures at the national level. These consequences may be influenced by the size of the animal population affected and the economic value of the breeding and/or farming sector involved.

Two items were considered particularly relevant for assessing the consequences for human health (Box 1):

– consequences at the individual level
– consequences at the community level.
Consequences at the individual level

It is important to consider the ‘gravity of the condition’ in the person or animal concerned. This item comprises the health consequences of the disease for an individual (intensity, gravity, morbidity, mortality, etc.), together with the costs entailed (e.g. the need for prolonged treatment, the duration of sick leave, the effects on productivity at work, etc.). A quantitative tool is already available for such assessments: the Disability-Adjusted Life Years scale (DALYs), used for ranking foodborne diseases at a national level in the Netherlands (7). This tool takes into account disease severity, the effects of the condition on life expectancy and the duration of symptoms (9, 11).

Consequences at the community level

The ‘spreading abilities’ of the disease are one of the two most important factors when assessing the consequences of the disease at a community level. The causal agent of the disease may be transmitted between humans or from a single animal case to a large number of people (e.g. trichinellosis) (5).

On the other hand, it is also important to ‘consider the overall cost of the disease’ to public health administrations. This cost is the sum of all costs resulting from the disease (duration of sick leave, consequences in other sectors of the industry, disease control tools available).

Some examples of such an assessment are shown in Table I.

As described for the assessment of probability, uncertainty can be expressed as an interval for a particular item (for instance, 2 - 3, as shown in Table I).

The consequences are then assessed as the sum of the scores for all the items, for animals or humans, giving a value between zero and nine. The final score for animal or human consequences can then be translated into adjectives, as shown in Table II.

Risk estimation

According to the OIE Terrestrial Animal Health Code (15), risk (R) can be defined as a combination of the probability (p) of an adverse event occurring and the consequences (c) of such an occurrence, giving:

\[ R = p \times c \]

The final step in risk assessment is therefore to combine the qualitative estimated probability of occurrence with the qualitative estimated consequences for either humans or animals.

The experts agreed that consequences could decrease or increase the weighting of the probability of occurrence in risk assessment. If the assessed consequences are considered to be minor, then the estimated risk should be lowered for a given estimated probability of occurrence. If the consequences are considered more serious, then the estimated risk should be increased for a given probability of occurrence, even for low probabilities of occurrence.

Three guidelines were then developed to take into account this effect of the consequences on the final assessed risk:

- consequence scores from one to three (‘nearly null’, ‘minute’ or ‘extremely low’) should lower the estimated risk for a given probability of occurrence
- consequence scores from four to six (‘very low’, ‘low’ and ‘not so high’) do not modify the estimated risk for a given probability of occurrence
- consequence scores from seven to nine (‘quite high’, ‘high’ and ‘extremely high’) should increase the estimated risk for a given probability of occurrence.

Figure 3 shows the results of combining consequences and probabilities.

Discussion

The method described allows expert panels to combine the probabilities of occurrence and consequences, in either animal or human health, to obtain an ordered magnitude of an estimated risk.
Assessment of release and exposure probabilities

Other qualitative scales were studied and discussed by the scientific members of the AFSSA working group (1, 2, 3). Particular attention was paid to the adjectives used to qualify release and exposure probabilities, consequences and assessed risk, in terms of whether the same words should be used for each of the components of the risk assessment process. The experts were cautious not to use words like ‘moderate’ or ‘medium’ to push the assessors to take a position on the level of each probability. Nevertheless, other words could have been chosen and levels like ‘very low’, ‘low’ and ‘not very high’ do represent a medium risk. Actually, today, because of the difficulty of gaining universal agreement on precise definitions of the words, the ordinal scale is used more and more often and is preferred by the expert panel.

There were various reasons for favouring the use of the same scale for probabilities, consequences and risk:

– all the adjectives used in this method are simple and easy to understand and can be applied to every aspect of the risk assessment procedure. It is therefore possible to say that the severity of a consequence is high, just as it is possible to talk about a high probability or risk;
– the use of the same adjectives makes it easier for future users to apply this method;
– the method for combining probabilities, consequences and risks is easier to apply if the same adjectives are used in all three cases. The use of three different sets of adjectives for the same ordinal level would have made it more difficult to understand the results.

Probability of occurrence

Figure 2, which presents the results of combining the probabilities of release and exposure, has been simplified to show one result per box, rather than the expected variability in the result. There is therefore only one result for each combination in this table.

To combine the intervals (representing the uncertainty), the lowest values of each estimation must be combined so as to define the lower limit of the result. Combining the highest values of each interval will give its upper limit.

The result of combining two qualitative probabilities must be interpreted with care, because there are uncertainties about the exact levels of the probabilities considered and the way in which the table was established, i.e. in the same way as for quantitative methods.

Risk estimation

The method used to create Fig. 3, combining probabilities and consequences to allow conclusions to be drawn about estimated risk, is simple but arbitrary. It requires thorough testing with various scenarios and examples. As described for the assessment of consequences and probabilities, this step makes it possible to take uncertainty into account through the use of intervals. In addition, any uncertainty (or, on the contrary, the level of knowledge) must be highlighted to those managing the risk (13).

Reproducibility and repeatability of the method proposed above

Some characteristics of the proposed method enable it to be relatively easily reproduced and repeated by different expert groups:

– a single and easy-to-understand list of adjectives describing the levels
– logical rules for combining two probabilities (the result of the combination of two probabilities cannot be higher than the lower of the two initial probabilities)
– a short list of items for the rapid assessment of global consequences
– simple rules for combining probabilities and consequences to obtain the estimated risk.

The members of the working group are fully aware of the subjectivity involved in the method.

Conclusion

The method proposed by the AFSSA working group must be able to be adapted to new situations and new data sets. It remains highly dependent on the subjective views of the experts using the model, but can be used to organise knowledge and facts, so as to address the questions posed by risk managers more accurately. Murray (12) pointed out that, ‘regardless of which method is adopted it is important to appreciate that risk assessment inevitably includes a degree of subjectivity’.

The use of this qualitative method makes it possible to ensure that the risk assessment steps are as transparent, reproducible and comprehensible to non-experts as possible. The discussion of the results by groups of scientists (experts in different fields of study) decreases the risk of subjectivity due to personal experience and opinion, by confronting different viewpoints. Collective assessments are indeed necessary to take into account interdisciplinary points of view (14) and avoid conflicts of interest if treated by only one risk assessor.
A key factor in any assessment is an understanding of risk estimation, ensuring that the required conditions are met, so that conclusions can be drawn on the levels of probability, consequences and risks. Any group of experts using such methods must:

– describe in detail all the steps and pieces of information used to assess the levels of probabilities and consequences; a flow chart may be useful;

– express the results of the assessment of probabilities and consequences so that they can be understood by risk managers (i.e. the probability is considered to be ‘nearly null’ at a level of one, on a scale running from zero to nine);

– draw conclusions about the estimated risk, when possible;

– remember that assessment results depend heavily on the time frame, the period and the level of scientific knowledge available;

– remember that a lack of data and the need for further scientific evidence should be highlighted when necessary. Uncertainty due to a lack of data should be clearly identified at all steps in the assessment, and taken into account by the use of intervals between levels.

Further testing and validation of this method through various examples and scenarios are still required. In fact, this method is nowadays routinely used by ANSES experts in its working groups for the animal health panels. For instance, it was the methodology used to evaluate the risk of introduction of Rift Valley fever virus into the French territories of the Indian Ocean (Mayotte and Reunion Islands).

Une méthodologie d’évaluation qualitative du risque destinée aux comités scientifiques d’experts


Résumé
Une évaluation du risque peut être quantitative, c’est-à-dire fournir une estimation chiffrée de la probabilité de survenue d’un risque et de l’ordre de grandeur de ses conséquences, ou qualitative, c’est-à-dire procéder de manière descriptive.

L’Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail (Anses) (anciennement l’Afssa : Agence française de sécurité sanitaire des aliments) réalise ses évaluations en se basant sur les avis de comités d’experts spécialisés tels que le comité pour la santé animale. En raison de l’insuffisance des informations disponibles et des délais généralement très courts impartis à l’évaluation des risques sanitaires particuliers en santé animale, ce comité a recours depuis plusieurs années à une méthode d’évaluation qualitative du risque pour évaluer les risques et les crises liés à la santé animale. Certains experts ont attiré l’attention sur les limites de cette méthode et souligné la nécessité d’enrichir les qualifications utilisées pour rendre compte des probabilities les plus faibles, et de mettre au point une procédure permettant d’évaluer les conséquences.
Método de determinación cualitativa del riesgo para comisiones científicas


Resumen
La determinación del riesgo puede ser cuantitativa (cuando ofrece una estimación numérica de la probabilidad del riesgo y la magnitud de las consecuencias) o cualitativa (en cuyo caso se traduce en parámetros descriptivos).

El organismo francés de seguridad sanitaria de los alimentos, el medio ambiente y el trabajo (ANSES, antiguamente AFSSA) basa sus evaluaciones en los dictámenes de comisiones científicas, como la Comisión científica de sanidad animal del ANSES. Debido a la falta de datos pertinentes y al escaso tiempo del que suele disponer para valorar los riesgos zoonóticos ligados a determinados temas, de unos años a esta parte dicha comisión ha venido utilizando un método cualitativo para valorar crisis o riesgos zoonóticos. Algunos expertos han subrayado las limitaciones de que adolece este método, por ejemplo la necesidad de ampliar el repertorio de adjetivos utilizados para las probabilidades más bajas y de encontrar un modo de valorar las posibles consecuencias.

Los autores, tras describir el método perfeccionado que ha instituido la Comisión teniendo en cuenta las limitaciones de la primera versión, pasan revista a un nuevo conjunto de niveles de probabilidad y a las cuestiones que se tienen en cuenta al examinar las consecuencias para la salud humana o animal.

Palabras clave
References


