

## Principles and methods of risk analysis<sup>1</sup>

*Princípios e métodos de análise de risco*

**Vitor Salvador Picão Gonçalves**

Professor Adjunto, Faculdade de Agronomia e Medicina Veterinária, Universidade de Brasília, Brasília, DF, Brasil

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires World Trade Organization (WTO) members to base their sanitary measures on international standards, guidelines and recommendations, which should be defined by the World Organization for Animal Health (OIE), as regards animal health and zoonoses. Countries may choose to adopt a higher level of protection than that indicated by those standards if there is scientific justification or if the level of protection provided by the prescribed measures does not meet the Appropriate Level of Protection (ALOP) of the importing country. In such cases, WTO members ought to base sanitary measures on risk analyses and should adopt a consistent approach to risk management. In order to prevent this to become a tool to set disguised barriers to trade, the OIE developed guidelines for import risk analysis in animal health.

In this context, risk has two components: the likelihood of a disease entering and spreading in the importing country and its impact on animal and human health, the environment and the economy. According to the OIE system, the risk analysis process consists of four components: hazard identification; risk assessment; risk management; and risk communication. The aim is to assist the decision maker by answering the following questions: (1) what can go wrong? (2) How likely is it to go wrong? (3) What are the consequences of it going wrong? (4) What can be done to reduce the likelihood and/or the consequences of it going wrong?

In order to conduct a risk analysis it is necessary to take into account the available relevant scientific data, the processes and animal production methods, the relevant inspection, sampling and testing methods, the prevalence of specific diseases, the existence of disease-free areas or compartments and of areas of low prevalence, the existence of eradication and control programmes and the credibility of the veterinary services, as well as the relevant ecological conditions. Moreover, economic issues ought to be included, such as the likely damage in terms of production losses, cost of control and eradication and the relative cost-effectiveness of alternative approaches to risk mitigation.

Very often, the hazard is identified beforehand (e.g. the risk of importing bovine semen contaminated with *Brucella abortus*) and risk analysts proceed directly to the risk assessment phase. This is broken down in four steps: (1) release assessment; (2) exposure assessment; (3) consequence assessment; and (4) risk estimation. No single method of risk assessment is applicable to all situations.

Qualitative assessments are logical and structured discussions of the likelihood that a given hazard can present a risk to the importing country and the magnitude of its consequences. Scenario trees can be used to depict the relevant factors and render the logic more clear. Results are expressed in non-numerical terms, such as negligible, low, medium or high. It is still the most common method applied for routine trade decisions.

Quantitative assessments use mathematical models to develop pathways, which are expressed numerically. The simplest form of quantitative assessment is deterministic, where both the inputs and outputs are expressed as single numbers or point estimates. For more complex models, a probabilistic method is preferred, commonly known as Monte-Carlo simulation. For example, if one is trying to assess the probability of transmitting a given infection by embryo transfer, a probabilistic model could deal with both variability and uncertainty, for example by estimating probabilities of the herd of origin being infected and setting confidence intervals for the sensitivity and specificity of diagnostic tests. The model is run many times and the results of each scenario, also called trials or iterations, are combined to produce a probability distribution of possible model outcomes. Quantitative models tend to yield more in-depth analysis but the results are not always more precise than with qualitative assessments, as they depend heavily on reliable data. The choice of an appropriate model structure is prone to a certain degree of subjectivity and because data are often lacking, models need to incorporate expert opinion, which tends to be subjective.

In summary, risk analysis is now a common tool used by decision makers to establish sanitary measures, notably in international trade. The OIE developed guidelines that should be followed by WTO member countries. The choice of methods (e.g. quantitative vs qualitative) depends on the nature of the problem and the amount of data made available to analysts. In all cases, the result should improve the quality of trade decisions, by rendering them more objective and science-based.

<sup>1</sup>Palestra apresentada no XVII Congresso Brasileiro de Reprodução Animal, 31 de maio a 02 de junho de 2007, Curitiba, PR.