RISK ANALYSIS A DECISION SUPPORT TOOL
FOR THE CONTROL AND PREVENTION OF ANIMAL DISEASES

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Summary: Animal health risk analysis is a very useful tool for decision-making. This paper explores the use of risk analysis in animal health and examines the principal constraints faced by veterinary services to effectively apply this tool. A survey was designed to obtain information on the use of risk analysis, training, risk analysis capabilities in OIE Member Countries, and risk communication. Most countries reported the use of risk analysis for animal health related decisions. However, the results of the survey show that training is still needed by the decision-makers, field staff and personal that perform risk analyses. Respondents indicate that the OIE should play a more active role in training as well as in the dissemination of risk analysis results.

1. INTRODUCTION

In April 1994, the Final Act of the Uruguay Round of Multilateral Trade Negotiations of the General Agreement on Tariffs and Trade (GATT) was signed; this led to the creation of the World Trade Organization (WTO) in January 1995. Among the agreements that were included in the treaty that established the WTO is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) which sets out the basic rules for food safety and animal and plant health standards (5).

The main goal of the SPS agreement is to allow for increased trade of agricultural products while recognizing the right of countries to protect human, animal and plant health. The SPS agreement has had a significant influence on the way trade decisions related to agricultural products are made. Its main intent is to avoid the use of sanitary and phytosanitary measures as unjustified barriers to trade. The agreement dictates that all measures must be scientifically based and not unnecessarily restrictive.

¹ USDA: United States Department of Agriculture
APHIS: Animal and Plant Health Inspection Service
VS: Veterinary Services
The key principles included in the agreement are risk analysis, regionalization, harmonization, equivalence and transparency. Both risk analysis and regionalization depend on data generated by animal disease surveillance systems. Epidemiology therefore, is a key element in providing the scientific basis to satisfy international trade requirements. Harmonization, equivalence and transparency are the basis for mutual trust between veterinary services –essential to ensure safe trade (7).

More than ever, veterinary services worldwide are faced with having to fulfill a crucial role in protecting their country’s animal health status, conduct scientifically valid risk analyses and provide sound surveillance information on the occurrence of diseases within their territories. Although all WTO Member Countries are required to comply with the SPS Agreement, a review conducted by the SPS Committee suggested that several countries still faced difficulties in its full implementation (6).

The intent of this paper is to provide a general background on risk analysis and explore how risk analysis is being used among the Office International des Epizooties (OIE) Member Countries. For this purpose a survey was developed and sent to the 158 OIE Member Countries. Ninety-seven countries (61%) responded, these were:

Algeria, Andorra, Angola, Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Belgium, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Burkina Faso, Burundi, Bhutan, Canada, Colombia, Congo, Costa Rica, Côte-d’Ivoire, Croatia, Cyprus, Czech Republic, Denmark, Dominican (Rep.), Ecuador, Egypt, El Salvador, Eritrea, Estonia, Finland, Former Yug. Rep. of Macedonia, France, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, Iceland, Iraq, Iran, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kenya, Kuwait, Laos, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Morocco, Myanmar, Nepal, New Caledonia, New Zealand, Nicaragua, Norway, Oman, Paraguay, Peru, Poland, Qatar, Romania, Saudi Arabia, Singapore, Slovak, Slovenia, South Africa, Spain, Sudan, Sweden, Switzerland, Syria, Taipei China, Tanzania, Thailand, Togo, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Vanuatu, Venezuela, Vietnam and Zimbabwe.

2. THE ROLE OF THE OIE IN THE IMPLEMENTATION OF RISK ANALYSIS

The OIE has a role in helping Member Countries in the implementation of risk analysis capabilities within the official veterinary services.

The SPS Agreement specifically designates the OIE as the organization responsible to develop international standards for animal health and zoonoses. In the case of risk analysis, both the OIE International Animal Health Code (OIE Code) and International Aquatic Animal Health Code each contain an entire section dealing with import risk analysis including the evaluation of Veterinary Services, zoning and regionalization and surveillance and monitoring of animal health (4).

Seeking to expand the knowledge base and the use of risk analysis, the OIE has published two volumes of the Scientific and Technical Review dedicated to this topic (Vol. 12 (3), 1993 and Vol. 16 (1), 1997). In addition, the OIE Director General convened an Ad hoc group to draft an “Import Risk Analysis Handbook” expected to be published in 2002.

In 1998, recognizing the growing importance of risk analysis and the need to implement effective surveillance systems to detect animal diseases the OIE International Committee approved the USDA-APHIS-VS Centers for Epidemiology and Animal Health (CEAH) as the OIE Collaborating Center in Animal Disease Surveillance Systems and Risk Analysis. The Collaborating Center has four primary objectives:

1) Review, evaluate and adapt methodologies and approaches to enhance animal disease surveillance systems and the risk analysis process,

2) Promote the harmonization of methods applied in disease surveillance and risk analysis,

3) Provide technical cooperation to OIE Member Countries on an Ad hoc basis in areas related to animal disease surveillance systems and risk analysis, and

4) Establish a critical mass of trained individuals in OIE Member Countries to improve the quality of animal disease surveillance and risk analysis.

Risk analysis a decision support tool for the control and prevention of animal diseases
The OIE Collaborating Center in Animal Disease Surveillance Systems and Risk Analysis in cooperation with the OIE Regional Representations, other Collaborating Centers as well as various other organizations, has conducted several training sessions on risk analysis in Latin America, Asia, Africa and Eastern Europe.

In 1999, the OIE Regional Commission for the Americas created an Ad hoc Group with the mandate to interpret the Risk Analysis Chapter in the OIE Code, train in risk analysis methods, develop practical guidelines for risk analysis, provide methodological guidance for risk analysis studies and offer methodological reviews of risk analyses submitted for consideration. This Group met several times and has created a website containing information related to its work (http://www.aphis.usda.gov/oieamericas/oieindex.htm).

3. RISK ANALYSIS – GENERAL PRINCIPLES

All countries involved in international trade have always assessed the risk involved in allowing imports of animals and animal products. However, the decision-making process often has not been documented and the rationale used to arrive to a conclusion has not always been shared among the interested parties (the ‘black box’ approach). The contribution of the OIE Code chapter on risk analysis is to provide a structured approach to conduct scientifically valid risk analysis.

The SPS agreement states that sanitary and phytosanitary measures and risk assessments should be based on international standards that, in the case of animal health, are contained in OIE’s International Animal Health Code.

According to the OIE Code, risk analysis is a process comprising various phases (4):

- **Hazard identification** – identifies the pathogenic agents that could potentially produce adverse consequences associated with the importation of a commodity.

- **Risk assessment** – evaluates the likelihood of entry, establishment or spread of a disease according to the sanitary or phytosanitary measures which might be applied, and the associated potential biological and economic consequences. This part of the process consists of four steps:
  - **Release assessment** – describes the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability of that complete process occurring
  - **Exposure assessment** – describes the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring
  - **Consequence assessment** – describes the relationship between specified exposures to a biological agent and the consequences of those exposures.
  - **Risk estimation** - integrates the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the identified hazards

- **Risk management** – contrasts the risk assessment results with the country’s appropriate level of protection and identifies any additional measures necessary to reduce the risk to acceptable level.

- **Risk communication** – establishes a multidimensional and iterative process involving all interested parties in a risk analysis. Risk communication should ideally begin at the start of the risk analysis process and continue throughout.

Risk analyses can be quantitative, providing a numeric estimate of the probability and the magnitude of the consequences, or qualitative – using a descriptive approach. Although quantitative assessments provide more detailed information, both types of assessments are equally valid and can withstand scrutiny if challenged, provided they are based on good quality data and address all the defined stages of the process.
A common perception is that if an importing country applies the risk-mitigation recommendations of the OIE Code, a risk analysis is not necessary. While it is true that an in-depth risk analysis may not be necessary, the establishment of import requirements involves at least a partial application of the risk analysis process. Part of the complexity in developing import requirements is that for each commodity multiple hazards can be identified, while the Code provides recommendations on an individual disease basis. Risk analysis in its simplest form provides a framework to establish a link between the hazards identified for the specific commodity, the sanitary status of the exporting and importing countries and the recommendations of the Code.

With this in mind, the first step of the process is to perform a thorough hazard identification identifying all the pathogens that could be associated with the commodity and are present in the exporting country. The OIE is the main source for official information on disease occurrence in its Member Countries. Updated information can be obtained through Handistatus II and the Weekly Disease Information Reports. Excellent reviews on the hazards associated with meat products, poultry and most domestic species have been produced (1, 2, 3).

The SPS agreement allows the application of sanitary measures only if measures achieving a similar level of protection are applied internally under an official program in the importing country or if the disease is exotic. Therefore, once a list of hazards is established it has to be contrasted with the diseases that are exotic or are under official control programs in the country to determine the validity of the application of sanitary measures (Figure 1).

The next step of the process is to verify that the recommended measures in the OIE Code satisfy the importing country’s appropriate level of protection. Although the application of the measures contained in the Code is the preferred option, the SPS agreement recognizes the right for countries to adopt more stringent measures provided they are based on a scientifically valid risk assessment (5).

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Is disease exotic to importing country?

Yes
  Requires scientific demonstration

No
  Is disease under official control?

Yes
  Are equivalent SPS measures required internally?

No
  Are countries with equivalent health status treated equally? (non discrimination)

Yes
  Legitimate SPS measure

No
  Invalid SPS measure

Are SPS measures based on international standards (OIE Code) or on a scientifically valid risk assessment?

Yes

No
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Figure 1 – Criteria for the validity of sanitary measures (Zepeda et al. 2001) (7)
4. SURVEY RESULTS

The survey was designed to obtain information on how risk analysis is being used among OIE Member Countries focusing on four broad areas:

- Use of risk analysis
- Training
- Risk analysis capabilities
- Communication

*Use of risk analysis*

Eighty percent of countries indicated the regular use of risk analysis for decision-making. Import-export decisions and in-country decision-making were the most frequent uses of risk analysis (79% and 66% respectively). Nineteen countries (20%) indicated that they do not use risk analysis or perform an incomplete non-methodological risk assessment, the main reason cited was lack of knowledge and training.

The overwhelming majority of countries (75%) that do apply risk analysis utilize a qualitative/descriptive approach. Three factors affect the choice of a qualitative/descriptive approach over a quantitative approach, in order of importance these are: the type and quality of data, the time required to conduct more detailed assessments and lack of training.

A complete risk assessment consists of four sequential steps: hazard identification, release, exposure and consequence assessments. The survey shows that most countries (64%) carry out the entire process up to the consequence assessment level, while 16% only carry out hazard identification, 10% arrive at the release assessment level and 10% carry out the process up to the exposure assessment level.

While most countries (82%) reported that risk analysis was a very useful tool for decision-making, lack of training and resources were the two main reasons for not conducting risk analyses on a regular basis.

*Training*

Most countries (74%) have received training in risk analysis. Universities, private consultants, OIE Collaborating Centers and other organizations have provided training. Most of the training received (59%) covered both qualitative and quantitative risk analysis methods. The main reason cited for not having received training were lack of funding (44%), lack of awareness (24%) and lack of availability (23%).

The type of participants in training sessions were mostly field personnel (52%), decision-makers (14%), risk analysts (17%) and seventeen percent were participants with other backgrounds and responsibilities. When asked on the effectiveness of training the majority of respondents (57%) felt that although the training provided was a good introduction to general concepts, more in depth training was needed. Only 18 countries (19%) felt that participants were able to conduct risk analysis after training.

Ninety-six percent of respondents thought that the OIE should play a more active role in training through its Collaborating Centers.

*Risk analysis capabilities*

Only 20 countries (21%) reported having a dedicated risk analysis unit. In the countries that did not have a specific risk analysis unit, the responsibilities were generally allocated in the epidemiology and disease surveillance unit (47%) and the import-export unit (31%).

An interesting finding of the survey was that over half of the countries (51%) hired external consultants to perform risk assessments.
Risk analysis is a multidisciplinary effort; according to the survey the professionals involved in risk analysis were veterinary epidemiologists (37%), veterinarians (35%), statisticians (15%), agricultural economists (6%) and other backgrounds (7%).

**Communication**

Risk communication is an essential part of the risk analysis process. However, only thirty countries (25%) indicated they routinely publish risk assessments while an overwhelming seventy-five percent of countries did not. The official gazette or its equivalent was the most frequent means of dissemination (47%) followed by electronic means through a website (28%) and other means (25%).

Risk analyses cannot be conducted in isolation, with this in mind studies should ideally be subjected to an independent peer review. The results of the survey show that most countries (56%) submit their analyses to peer review which is conducted mostly internally within the veterinary service (75%) and only occasionally submitted to external reviewers (25%).

Ninety-three percent of respondents believe that the OIE should develop a role in making the results of risk analyses available.

**CONCLUSIONS**

The survey results show that risk analysis is considered as a very important tool in decision-making within veterinary services. Although quantitative risk assessments provide more in-depth information, the fact that most countries choose a qualitative approach to risk analysis shows that the process is not required to be quantitative or overly complex, this view in shared by most countries even those that have pioneered the use of quantitative risk assessments.

Good risk assessments, either qualitative or quantitative, depend on good quality data. The choice of a qualitative approach over a quantitative one due to the scarcity and lack of quality of data will not provide a sound basis for decision-making. Veterinary services must be able to provide accurate information on the occurrence of animal diseases within their territories and other factors that play a role in risk assessment.

A complete risk analysis has to be thorough, scientifically based and address all the steps of the process. An area that has not been addressed as thoroughly as the other areas of the process is consequence assessment. Recognizing this, the OIE Collaborating Center for Animal Disease Surveillance Systems and Risk Analysis convened in 2001 an international meeting to delineate the minimum scope that should be addressed in consequence assessments and agree on the basic approach that should be followed. Consequences should consider both biological and economic considerations including losses in international trade.

To ensure proper application of risk analysis decision-makers, risk analysts and field personnel need to be trained. However, risk analysis training must be adjusted to cover the expectations and needs of different audiences. The OIE Collaborating Center in Animal Disease Surveillance Systems and Risk Analysis has developed a training strategy with several courses and seminars specifically designed for each level.

Dedicated risk analysis units are not a requirement within a veterinary service. The finding that close to eighty percent of countries do not have a specific unit to deal with risk analysis supports this statement. Satisfactory risk analysis capabilities can be developed within the epidemiology and disease surveillance unit and the import-export unit. Furthermore, many countries contract-out the development of risk analysis studies with external consultants. This approach can yield acceptable results as long as proper guidance is given on the context of the study and the epidemiological coherence of the process.

Risk communication is a multidirectional effort involving all interested parties in the decision-making process; it is the cornerstone to achieve the transparency required by the SPS Agreement. However, this is the area of the risk analysis process that has received the least attention. The survey suggests that the OIE should take a more active role in disseminating the results of risk analyses. Recognizing that the OIE should remain neutral, an option for consideration could be to publish risk analyses to demonstrate approaches and methods and eliminate all references to individual countries and any other information that may be considered sensitive.
Animal health risk analysis is a continuously evolving field. As such, peer review of methods and approaches will help improve the quality of risk analysis internationally. At present, risk analysis studies are mostly reviewed internally within the veterinary services, there is an opportunity to broaden the scope of reviewers recognizing the multidisciplinary nature of the process.

Veterinary Services worldwide have always assessed risk even though these assessments have not always followed a structured methodology. The increase in trade worldwide implies a potential increase in the risk of introduction of diseases, it is therefore essential to establish mechanisms that allow commercial exchanges and at the same time safeguard the animal health status of the countries involved. Risk analysis is a tool for decision-making that provides, by means of a logically structured and consistent process, information on the risk of introduction of animal diseases through trade in animals and animal products.

Many countries have taken significant steps in the development and application of risk analysis. Others however, still require assistance to strengthen their risk analysis capabilities. Article 9 of the SPS Agreement considers the provision of technical assistance through the appropriate international organizations. It is therefore the role of the OIE to provide such technical assistance through its Collaborating Centers and Member Countries willing to share their expertise in the field.

REFERENCES


