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Risk analysis and its link with standards of the World Organisation for Animal Health

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Summary
Among the agreements included in the treaty that created the World Trade Organization (WTO) in January 1995 is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) that sets out the basic rules for food safety and animal and plant health standards. The SPS Agreement designates the World Organisation for Animal Health (OIE) as the organisation responsible for developing international standards for animal health and zoonoses. The SPS Agreement requires that the sanitary measures that WTO members apply should be based on science and encourages them to either apply measures based on the OIE standards or, if they choose to adopt a higher level of protection than that provided by these standards, apply measures based on a science-based risk assessment. The OIE also provides a procedural framework for risk analysis for its Member Countries to use. Despite the inevitable challenges that arise in carrying out a risk analysis of the international trade in animals and animal products, the OIE risk analysis framework provides a structured approach that facilitates the identification, assessment, management and communication of these risks.

Keywords
Appropriate level of protection – Risk analysis – Risk assessment – Risk management – SPS Agreement.

Introduction

Under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), members of the World Trade Organization (WTO) are obliged to base their measures on international standards, guidelines and recommendations, where they exist. However, if there is scientific evidence that these standards, guidelines or recommendations do not achieve the level of protection deemed to be appropriate by a country, measures that provide a higher level of protection may be applied. In such circumstances it is important to ensure that the measures do not constitute a disguised restriction on trade, do not result in discrimination between countries where similar conditions exist, and are based on scientific principles, in particular risk assessment techniques developed by the relevant organisation (12).

The SPS Agreement specifically designates the World Organisation for Animal Health (OIE) as the organisation responsible for developing international standards for animal health and zoonoses. In the case of risk analysis, the OIE *Terrestrial Animal Health Code* and *Aquatic Animal Health Code* (*Terrestrial* and *Aquatic Codes*) contain chapters dealing with import risk analysis.

Import risk analysis is not a recent development, as regulatory veterinarians have generally always undertaken some form of analysis prior to approving an importation of animals and animal products. However, the decision-making process has often not been documented and the

rationale used to arrive at a conclusion has not always been shared among the interested parties. While some form of analysis in the animal health field may have been undertaken, it is only since the early 1990s, particularly following the implementation of the SPS Agreement and recognition of the OIE standards within this, that documented methodologies have been developed and a transparent process has emerged (1). The contribution of the *Terrestrial* and *Aquatic Code* chapters on import risk analysis is to provide a structured approach to enable scientifically valid risk analyses to be undertaken.

Risk analysis framework of the OIE Codes

The aim of import risk analysis

The importation of animals and animal products involves a degree of risk of introducing into an importing country pathogens that may spread, become established and lead to adverse biological and economic consequences. The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. Transparency, that is the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions, is essential, because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur. Transparency is also necessary so that the exporting country can be provided with clear reasons for the risk management decision (1).

Risk analysis provides a structured process that is designed to determine what can go wrong, how likely it would be for something to go wrong, how serious it would be if something went wrong and what can be done to reduce the likelihood and/or the seriousness of something going wrong. From an import perspective, risk consists broadly of two components: the likelihood of an event occurring (such as a disease outbreak following the importation of a commodity) and the likelihood of serious consequences arising (including the costs of control and eradication and trade losses) (1, 8, 9).

Risk analysis is a tool that uses data, information and expert opinions from many disciplines and skills, including pathology, microbiology, virology, epidemiology, statistics, probability modelling and economics (1). It needs to be able to deal with incomplete information. It is a blend of critical thinking, deductive reasoning and judgement that requires a good understanding of domestic quarantine law and the SPS Agreement. Obviously, it is unlikely that one person will have all these skills, so ideally the analysis should be undertaken by a project team.

Components of an import risk analysis model

The OIE adopted the Covello-Merkhofer model for risk analysis, which is designed to assess the magnitude of the risk for specified consequences in a given situation (1). In this model, 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 (Fig. 1).

Hazard identification

Hazard identification is an essential step that should be conducted prior to a risk assessment. It involves identifying pathogenic agents that may be associated with an imported commodity and that could potentially produce adverse consequences. As defined in the *Terrestrial Code*, a 'commodity' means 'animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for

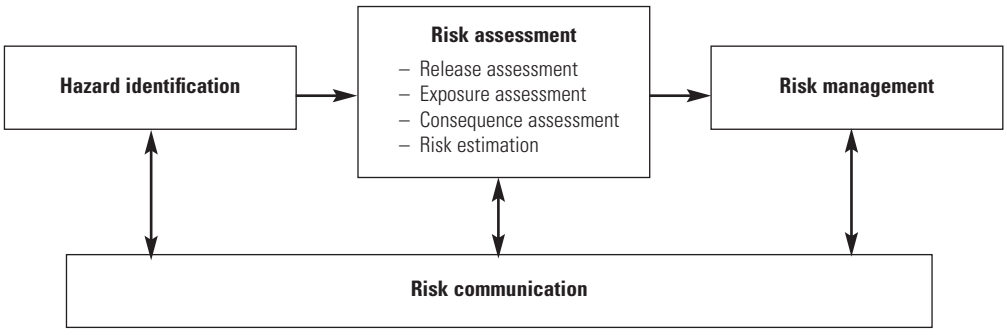

Fig. 1
The four components of risk analysis

agricultural or industrial use, semen, embryos/ova, biological products and pathological material'.

To classify an agent as a hazard, it must be appropriate to the species being imported, or from which the commodity is derived. It must also be present in the exporting country. If it is present in the importing country, it should be subject to control or eradication programmes or be notifiable (Fig. 2). When determining if an agent is likely to be present in the exporting country, an evaluation of the national Veterinary Services, surveillance and control programmes, and zoning and regionalisation systems is important.

Risk assessment

Risk assessment is the process of evaluating the likelihood and biological and economic consequences of the entry, establishment or spread of a hazard within the territory of an importing country. It consists of the following four inter-related steps:

– release assessment: estimating the likelihood of an imported commodity being infected or contaminated with a hazard and describing the biological pathway(s) necessary for that hazard to be introduced into a particular environment

– exposure assessment: describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to a hazard and estimating the likelihood of such exposure occurring

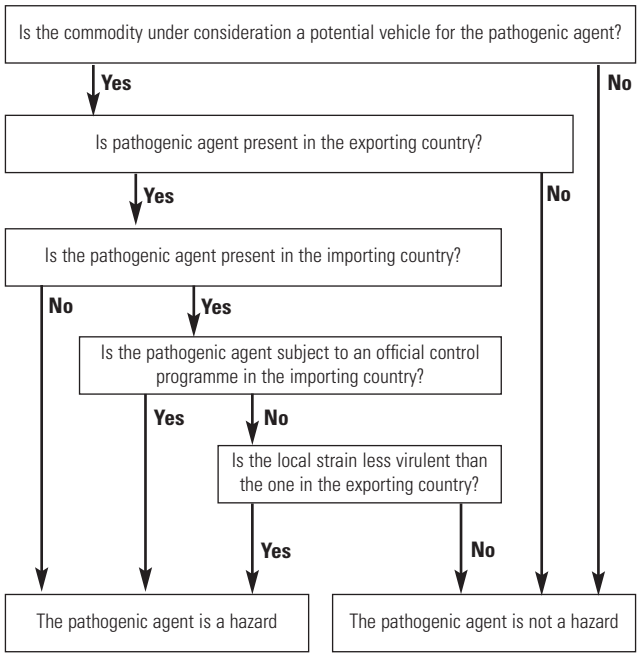

Fig. 2
Steps to determine if a pathogenic agent is a hazard

– consequence assessment: describing the relationship between exposures to a hazard, the potential consequences of those exposures and their likelihood

– risk estimation: combining the results from the release, exposure and consequence assessments to provide a summary estimate of the risks associated with a hazard.

No single method of risk assessment has proven applicable in all situations and different methods may be appropriate in different circumstances. Risks can be estimated by both qualitative and quantitative methods. A qualitative assessment is a reasoned and logical discussion of the relevant commodity factors and the epidemiology of the hazard; the likelihood of its release and exposure and the magnitude of its consequences are expressed using non-numerical terms such as 'high', 'medium', 'low' or 'negligible'. It is suitable for the majority of risk assessments and is, in fact, the most common type of assessment undertaken to support routine decision-making.

In some circumstances it may be desirable to undertake a quantitative analysis, for example, to gain further insights into a particular problem, to identify critical steps or to compare the effect of sanitary measures. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication.

Although a quantitative analysis involves numbers, it is not necessarily more objective, nor are the results necessarily more 'precise' than a qualitative analysis. Choosing an appropriate model structure, the pathways to include or exclude, the level of aggregation or disaggregation, the actual values used for each input variable and the type of distribution applied to them, all involves a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is subjective.

Since both qualitative and quantitative analyses are inevitably subjective to a certain extent, how can the degree of objectivity be demonstrated? The solution lies, not in the method chosen, but in ensuring that the analysis is transparent. All the information, data, assumptions, uncertainties, methods and results must be comprehensively documented and the conclusions must be supported by a reasoned and logical discussion. The analysis should be fully referenced and subjected to peer review.

Even though all risk analyses include a degree of subjectivity, many people find numbers seductive and

reassuring, and some analysts use so-called 'semi-quantitative' methods in the mistaken view that they are somehow more 'objective' than strictly qualitative techniques; the same could be said of quantitative analyses. However, a number of significant problems may arise from adopting a semi-quantitative approach in an import risk analysis. The approach is sometimes employed as a means of combining various qualitative estimates, by assigning numbers to them, to produce a summary measure or to prioritise risks. The numbers may be in the form of probability ranges or scores, which may be weighted before being combined by addition, multiplication, etc. The numbers, ranges, weights and methods of combination chosen are usually quite arbitrary and need careful justification to ensure transparency. It should be recognised that numbers assigned to categories cannot be manipulated mathematically and statistically. It is impossible to assign precise numbers unless a quantitative assessment has already been carried out. Semi-quantitative assessments often give a misleading impression of objectivity and precision and may not adequately reflect relativities, which can lead to inconsistent outcomes. Assigning numbers to subjective estimates does not result in a more objective assessment, particularly when the numbers chosen and their method of combination are arbitrary. Semi-quantitative methods will rarely offer any advantage over a well-researched, transparent, peer-reviewed qualitative assessment.

As stated in the *Terrestrial* and *Aquatic Codes*, a risk assessment provides a structured approach for assessing equivalence amongst different sanitary measures. As well as providing an indication of the overall risk estimate it facilitates a comparison of the relative impact of proposed measures on the risks associated with particular steps in the importation pathway (8, 9).

Risk management

Risk management is the process of deciding upon and implementing measures to achieve the level of protection considered to be appropriate by an importing country, while at the same time ensuring that negative effects on trade are minimised. The objective is to manage disease risks to the extent necessary by ensuring a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and a country's desire to import goods and fulfil its obligations under international trade agreements.

It is not acceptable merely to identify a range of measures that might reduce the risks. There must be a reasoned relationship between the measures chosen and the risk assessment so that the results of the risk assessment support the measure(s).

Where there is significant uncertainty, a precautionary approach may be adopted. However, the measures selected must nevertheless be based on a risk assessment that takes account of the available scientific information. In these circumstances, the measures should be reviewed as soon as additional information becomes available. It is not acceptable to simply conclude that, because there is significant uncertainty, measures will be based on a precautionary approach. The rationale for selecting measures must be made apparent.

Risk communication

Risk communication is a two-stage process. Firstly, information and opinions regarding hazards and risk are gathered from potentially affected and interested parties during a risk analysis. Secondly, the results of the risk assessment and proposed risk management measures are communicated to decision-makers and stakeholders in both importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

Link between risk analysis and OIE standards

The SPS Agreement stipulates that the measures applied to protect human and animal health should be based on international standards. The SPS Agreement specifically designates the OIE as the organisation responsible for developing international standards for animal health and zoonoses. The *Terrestrial* and *Aquatic Codes*, in addition to the procedural framework for import risk analysis that has already been discussed, prescribe sanitary measures applicable to the international trade in animals and animal products for each of the diseases on the OIE list of notifiable diseases.

As discussed above, an important element of hazard identification is to determine whether or not a pathogenic agent is likely to be present in the exporting country. To this end, the OIE provides a number of relevant standards which cover the evaluation of Veterinary Services, notification of disease occurrences, zoning and compartmentalisation, and surveillance.

Risk-mitigation recommendations for OIE-listed diseases

The *Terrestrial* and *Aquatic Codes* provide risk-mitigation recommendations for each listed disease according to the status of the exporting country. If an importing country

applies the measures recommended in the *Code*, it is not obliged to undertake a risk analysis, at least not for the purpose of international trade. In such cases, it would conduct a simple form of risk analysis, one which consists of identifying the hazards associated with the commodity of interest, describing the sanitary status of both the exporting and importing countries and listing the measures recommended in the *Codes*. However, if there is scientific evidence that these measures do not achieve a country's appropriate level of protection, measures that provide a higher level of protection may be applied. In such cases, however, a risk analysis must be undertaken that transparently documents the supporting scientific evidence and rationale for adopting such measures.

Evaluating Veterinary Services

An evaluation of the capacity and competence of the Veterinary Services of a country is an important element in the risk analysis process. It underpins the importing country's confidence in the quality and reliability of disease data and claimed disease status of the exporting country, as well as the effectiveness of its disease control and eradication programmes. The *Terrestrial Code* has a section devoted to the definition of quality and the evaluation of Veterinary Services (Section 3 – Quality of Veterinary Services [10]). Any Member Country wishing to obtain official OIE recognition of their animal health status (in relation to rinderpest, foot and mouth disease, bovine spongiform encephalopathy or contagious bovine pleuropneumonia) must first show that their Veterinary Services comply with the provisions of this Section.

The OIE has developed a Tool for Evaluating the Performance of Veterinary Services (OIE PVS Tool) and by 1 October 2010, PVS evaluations had been completed in 96 countries (11). The Tool is designed to assist Veterinary Services to:

– establish their current level of performance

– identify gaps and weaknesses in their ability to comply with OIE standards

– form a shared vision with stakeholders, including the private sector

– establish priorities and carry out strategic initiatives.

Notification of disease occurrences

Risk assessments, whether qualitative or quantitative, are dependent on reliable data. Since the OIE provides official information on disease occurrence within the territory of its Member Countries, it is an important resource for the hazard identification step. Up-to-date information can be easily obtained from the OIE World Animal Health Information Database, as well as from its Weekly Disease Information Reports.

Zoning and compartmentalisation

Chapters 4.3. and 4.4. of the *Terrestrial Code* provide an outline of the general considerations and principles for defining a zone or compartment (4, 5). Zoning is a procedure aimed at establishing and maintaining a clearly defined part of a country that contains an animal subpopulation with a distinct health status with respect to a specific disease. Compartmentalisation, on the other hand, focuses on an animal subpopulation residing in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease. Supporting evidence of the effectiveness of the measures implemented to establish and maintain the health status of a zone or compartment is a critical input into a risk assessment.

Animal health surveillance

In general, surveillance is a tool aimed at determining the presence or absence of a particular disease, its distribution and the efficacy of control and eradication measures. As a result, it provides an invaluable source of information for a risk analysis. The *Terrestrial* and *Aquatic Code* chapters on animal health surveillance and the chapters covering specific diseases, such as foot and mouth disease and classical swine fever, provide practical guidance on the type of information that a surveillance system should generate, as well as recommendations to assess the quality of those surveillance systems (2, 3, 6, 7).

Implementation and use of import risk analysis

A survey of the application of risk analysis in decision-making for importation of animals and animal products was undertaken in 2001 (13). Of the 97 OIE Member Countries that responded to the survey, 80% indicated that they regularly undertook a risk analysis. The majority adopted a qualitative rather than a quantitative approach based on a consideration of the type and quality of data available, the time required to conduct more detailed quantitative assessments and a lack of training in quantitative techniques.

In applying risk analysis to international trade in animals and animal products, there are many challenges, such as the availability of data for input variables in the release, exposure and consequence assessments. Data are not always available either in assessing the effect of risk management measures. Decisions on the management of animal and zoonotic disease risks associated with

international trade are obviously made in the face of varying degrees of uncertainty. Despite the challenges arising in conducting risk analyses, their use is still recommended, as they provide a structured approach that facilitates the identification, assessment, management and communication of risks. By ensuring that the analysis is transparent and subjected to peer review, stakeholders and trading partners can be assured that an objective analysis has been undertaken and that the sanitary measures adopted are appropriate.

Conclusion

It is important to take steps to further promote the application of risk analysis to international trade of animals and animal products. Efforts should be made to improve the availability and quality of surveillance data and to enhance research that produces data on the efficacy of manufacturing methods of animal products and dose–response effects of animal pathogens. Given that the incubation period of most potential diseases is shorter than the time it takes for animals and animal products to reach importing countries, the role of import risk analysis has become increasingly important. The OIE plays a central role in setting standards and recommendations as well as coordinating research for the collection and production of supporting data.

L'analyse du risque et son articulation avec les normes de l'Organisation mondiale de la santé animale

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Résumé

Parmi les accords constitutifs du traité qui a donné naissance à l'Organisation mondiale du commerce (OMC) en janvier 1995, figure l'Accord sur l'Application des mesures sanitaires et phytosanitaires (accord SPS), qui définit les règles fondamentales régissant la sécurité sanitaire des aliments ainsi que les normes zoosanitaires et phytosanitaires. Aux termes de l'Accord SPS, l'Organisation mondiale de la santé animale (OIE) est l'organisation chargée d'élaborer les normes internationales en matière de santé animale et de zoonoses. L'Accord SPS stipule que les mesures sanitaires appliquées par les pays membres de l'OMC doivent être fondées scientifiquement et préconise l'application de mesures fondées sur les normes de l'OIE ; si les pays choisissent d'instaurer un niveau de protection supérieur à celui garanti par ces normes, les mesures appliquées doivent être basées sur une appréciation du risque fondée sur la science. L'OIE a également élaboré pour les besoins de ses Membres un cadre de référence opérationnel pour la conduite de l'analyse du risque. Malgré les difficultés qui surgissent inévitablement lors de la réalisation d'une analyse des risques liés aux échanges internationaux d'animaux et de produits d'origine animale, la procédure d'analyse du risque mise en place par l'OIE fournit une méthode structurée qui facilite l'identification, l'appréciation et la gestion des risques ainsi que les opérations de communication relatives au risque.

Mots-clés

Accord SPS – Analyse du risque – Appréciation du risque – Gestion du risque – Niveau approprié de protection.

El análisis del riesgo y su vinculación con las normas de la Organización Mundial de Sanidad Animal

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Resumen
Entre los acuerdos incluidos en el tratado por el que en enero de 1995 se creaba la Organización Mundial del Comercio (OMC) figura el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias (Acuerdo MSF), que fija las reglas básicas en materia de inocuidad de los alimentos y de normas zoo y fitosanitarias. En el Acuerdo MSF se designa a la Organización Mundial de Sanidad Animal (OIE) como organismo responsable de elaborar normas internacionales en materia de sanidad animal y zoonosis. En él también se exige a los miembros de la OMC que apliquen medidas sanitarias científicamente fundamentadas, y se los alienta a aplicar las normas de la OIE o bien, si optan por un nivel de protección superior al que éstas ofrecen, a instituir medidas basadas en una determinación científica del riesgo. La OIE ofrece también a sus Países Miembros un protocolo de referencia para el análisis del riesgo. Pese a las inevitables dificultades que surgen al aplicar tal análisis al comercio internacional de animales y productos de origen animal, el sistema de referencia de la OIE para el análisis del riesgo ofrece un planteamiento estructurado que facilita la identificación, determinación, gestión y comunicación de este conjunto de riesgos.

Palabras clave
Acuerdo MSF – Análisis del riesgo – Determinación del riesgo – Gestión del riesgo – Nivel adecuado de protección.

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