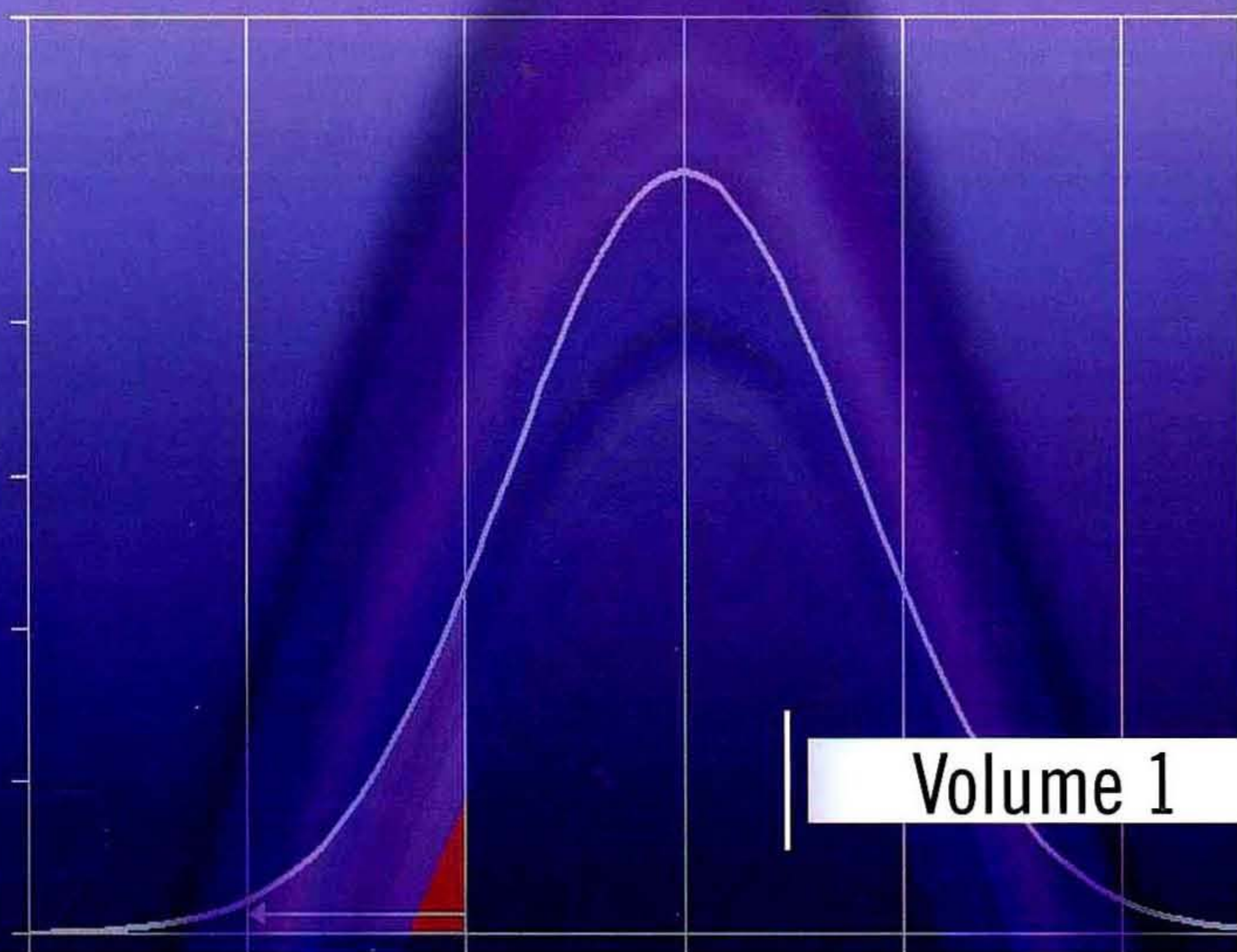


# Handbook on Import Risk Analysis for Animals and Animal Products



Introduction and qualitative risk analysis

Handbook on  
Import Risk Analysis  
for Animals and Animal Products

Volume 1.

*Introduction and qualitative risk  
analysis*

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## Foreword

The importation of animals and their products involves a degree of disease risk to the importing country. This risk may be presented by one or several diseases or pathogenic agents.

The Agreement on the Application of Sanitary and Phytosanitary Measures (referred to in brief as “the SPS Agreement”) of the World Trade Organisation (WTO) allows WTO Member Countries two options in setting sanitary measures to protect against such risks. The SPS Agreement strongly encourages Member Countries to base their sanitary measures on international standards such as the OIE *Terrestrial Animal Health Code* (referred to in brief as “the *Terrestrial Code*”) and the OIE *Aquatic Animal Health Code* (referred to in brief as “the *Aquatic Code*”). In the absence of relevant standards or when Members choose to adopt a higher level of protection than that provided by such standards, science-based risk analysis is essential to determine whether importation in a particular commodity poses a significant risk to human or animal health and, if so, what sanitary measures could be adopted to reduce that risk to an acceptable level. However, the level of protection applied to imports must not be different to that applied to products within the domestic market.

Risk analysis is a tool intended to provide decision-makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action. In this regard, the principal aim of import risk analysis, a relatively new and evolving discipline, is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals and their products.

The proposal for an import risk analysis handbook arose during a 1998 meeting of the OIE Working Group on Informatics and Epidemiology. The Istituto Zooprofilattico Sperimentale dell’Abruzzo e del Molise ‘G. Caporale’ at Teramo (an OIE Collaborating Centre for Epidemiology and the Organisation of Veterinary Services in Developing Countries) offered to convene an OIE *ad hoc* Group to draft such a handbook. With the support of this Institute, this *ad hoc* Group of international experts has developed a comprehensive treatise on the subject.

Volume 1 of this handbook introduces the concepts of import risk analysis and discusses qualitative risk analysis while Volume 2 (which will be published later) addresses quantitative risk analysis. The key issues in the discipline are explained within the frameworks provided by the WTO SPS Agreement and the chapters in both *Codes* on risk analysis.

I believe that the handbook will provide practical guidance to Veterinary Services confronted with the need to analyse the risks posed by imports, to ensure that stakeholders, risk analysts and decision-makers can be confident that the disease risks posed have been identified and can be managed effectively. The handbook will also be useful as a training aid to address the critical need for capacity building in this discipline.

I would like to thank the experts from the *ad hoc* Group (all actively involved in conducting risk analyses) for their contributions to this excellent handbook. In particular, my sincere thanks go to Dr Stuart MacDiarmid who has spent many hours editing both volumes to ensure that the final product will be accessible to veterinarians worldwide.

Dr Bernard Vallat  
Director General, OIE

## Definitions

The following definitions are taken from the OIE *Terrestrial Animal Health Code*.

**Acceptable risk:** Risk level judged by OIE Member Countries to be compatible with the protection of animal and public health within their country.

**Code:** The *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code* of the OIE.

**Commodity:** *Animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material.*

**Consequence assessment:** The process of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the consequences of a given exposure and estimates the probability of them occurring.

**Exposure assessment:** The process of describing 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, either qualitatively or quantitatively.

**Hazard:** Any pathogenic agent that could produce adverse consequences on the importation of a *commodity*.

**Hazard identification:** The process of identifying the pathogenic agents which could potentially be introduced in the *commodity* considered for importation.

**Implementation:** The process of following through with the risk management decision and ensuring that the risk management measures are in place.

**Importing country:** A country that is the final destination to which *commodities* are sent.

**International veterinary certificate:** A certificate, issued in conformity with the provisions of Chapter 1.2.2. of the *Code*, describing the animal health and/or public health requirements which are fulfilled by the exported *commodities*.

**Monitoring and review:** The ongoing process by which the risk management measures are audited to ensure that they are achieving the results intended.

**Option evaluation:** The process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the Member Country's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing 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.

**Qualitative risk assessment:** An assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.



- Quantitative risk assessment:** An assessment where the outputs of the risk assessment are expressed numerically.
- Release assessment:** The process of describing the biological pathway(s) necessary for an importation activity to ‘release’ (that is, introduce) pathogenic agents into a particular environment, and estimating the probability, either qualitatively or quantitatively, of that complete process occurring<sup>1</sup>.
- Risk:** The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the *importing country* during a specified time period.
- Risk analysis:** The process composed of hazard identification, risk assessment, risk management and risk communication.
- Risk assessment:** The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an *importing country* (see Articles 1.3.2.3. and 1.3.2.4.).
- Risk communication:** Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties (see Article 1.3.2.7.).
- Risk estimation:** The process of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset.
- Risk evaluation:** The process of comparing the risk estimated in the risk assessment with the Member Country’s appropriate level of protection.
- Risk management:** The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (see Articles 1.3.2.5. and 1.3.2.6.).
- Sanitary measure:** Measures such as those described in each Chapter of the *Code* which are used for risk reduction and are appropriate for particular diseases.
- Sensitivity analysis:** The process of examining the impact of the variation in individual model inputs on the model outputs in a quantitative risk assessment.
- Transparency:** Comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.
- Uncertainty:** The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.
- Variability:** A real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.
- Veterinary Administration:** The governmental Veterinary Service having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application.

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<sup>1</sup> The terms ‘likelihood’ and ‘probability’ may be used interchangeably. There is a tendency to use the term ‘probability’ when referring to quantified risk, and ‘likelihood’ when risk has been assessed qualitatively. However, either term is correct

**Veterinary Authority:** A Veterinary Service, under the authority of the *Veterinary Administration*, which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or supervision of the issuing of *international veterinary certificates* in that area.

**Veterinary Services:** The Veterinary Services comprise the *Veterinary Administration* and all the *Veterinary Authorities*.

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