3. STAGE 3: PEST RISK MANAGEMENT

Pest risk management (see Figure 3) to protect the endangered areas should be proportional to the risk identified in the pest risk assessment. In most respects it can be based on the information gathered in the pest risk assessment. Phytosanitary measures should be applied to the minimum area necessary for the effective protection of the endangered area.

3.1 Risk Management Options

A list of options for reducing risks to an acceptable level should be assembled. These options will primarily concern pathways and in particular the conditions for permitting entry of commodities. Examples of the options to consider are:

- inclusion in list of prohibited pests
- phytosanitary inspection and certification prior to export
- definition of requirements to be satisfied before export (e.g. treatment, origin from pest free area, growing season inspection, certification scheme)
- inspection at entry
- treatment at point of entry, inspection station or, if appropriate, at place of destination
- detention in post-entry quarantine
- post-entry measures (restrictions on use of commodity, control measures)
- prohibition of entry of specific commodities from specific origins.

They may also, however, concern ways of reducing the risk of damage, for example, introduction of a biological control agent, or ease of eradication or containment.

3.2 Efficacy and Impact of the Options

The efficacy and impact of the various options in reducing risk to an acceptable level should be evaluated, in terms of the following factors:

- biological effectiveness
- cost/benefit of implementation
- impact on existing regulations
- commercial impact
- social impact
- phytosanitary policy considerations
- time to implement a new regulation
- efficacy of option against other quarantine pests
- environmental impact.

The positive and negative aspects of the options should be specified. While it is recognized that countries according to the sovereignty principle may exercise their sovereign right to utilize phytosanitary measures, countries should also take particular note of the "**Minimal impact**" principle:

> *Phytosanitary measures shall be consistent with the pest risk involved, and shall represent the least restrictive measures available which result in the minimum impediment to the international movement of people, commodities and conveyances.*

Article VI.2(f) of the International Plant Protection Convention makes a similar but less comprehensive provision. Phytosanitary measures recommended should be based on all of the above factors.

In order to determine which options are appropriate, it may be advisable to communicate with interested and affected groups within and outside the PRA area.

3.3 Conclusion for Stage 3

At the end of Stage 3, the appropriate phytosanitary measures concerning the pest or pathway have been decided. Completion of Stage 3 is essential; it is in particular not justified to complete only Stages 1 and 2 and then take phytosanitary measures without proper assessment of risk management options. After implementation of the phytosanitary measures, their effectiveness should be monitored and the risk management options should be reviewed, if necessary.

4. DOCUMENTING THE PRA PROCESS

A PRA should be sufficiently documented so that when a review or a dispute arises, the PRA will clearly state the sources of information and the rationales used in reaching a management decision regarding phytosanitary measures taken or to be taken.

For further information on international standards, guidelines and recommendations concerning phytosanitary measures, and the complete list of current publications, please contact the:

Secretariat of the International Plant Protection Convention

By mail: IPPC Secretariat
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Email: ippc@fao.org

Or visit our WEB site at:

http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/PQ/Default.htm

OIEコード抜粋

GENERAL PROVISIONS

CHAPTER 1.3.1.

GENERAL CONSIDERATIONS

Article 1.3.1.1.

Introduction

The importation of *animals* and animal products involves a degree of disease risk to the *importing country*. This risk may be represented by one or several diseases or infections.

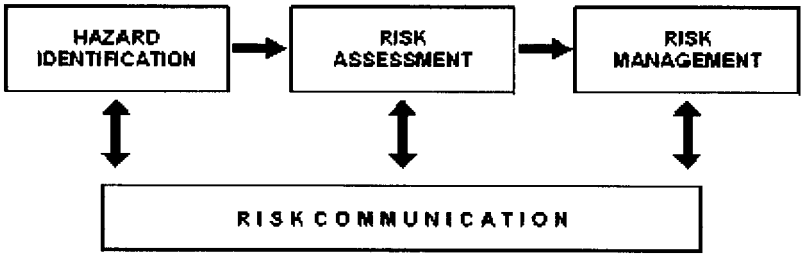
The principal aim of import risk analysis is to provide *importing countries* with an objective and defensible method of assessing the disease risks associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This Chapter alludes to the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO), provides definitions and describes the OIE in-house procedure for settlement of disputes.

Chapter 1.3.2. provides guidelines and principles for conducting transparent, objective and defensible risk analyses for *international trade*. The components of risk analysis described in that Chapter are hazard identification, risk assessment, risk management and risk communication (Figure 1).

Fig. 1. ***The four components of risk analysis***



The risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly for those diseases listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import risk analysis usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning and regionalisation and surveillance systems in place for monitoring of animal health in the *exporting country*. These are described in separate Chapters in this *Terrestrial Code*.

CHAPTER 1.3.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Article 1.3.2.1.

Introduction

An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

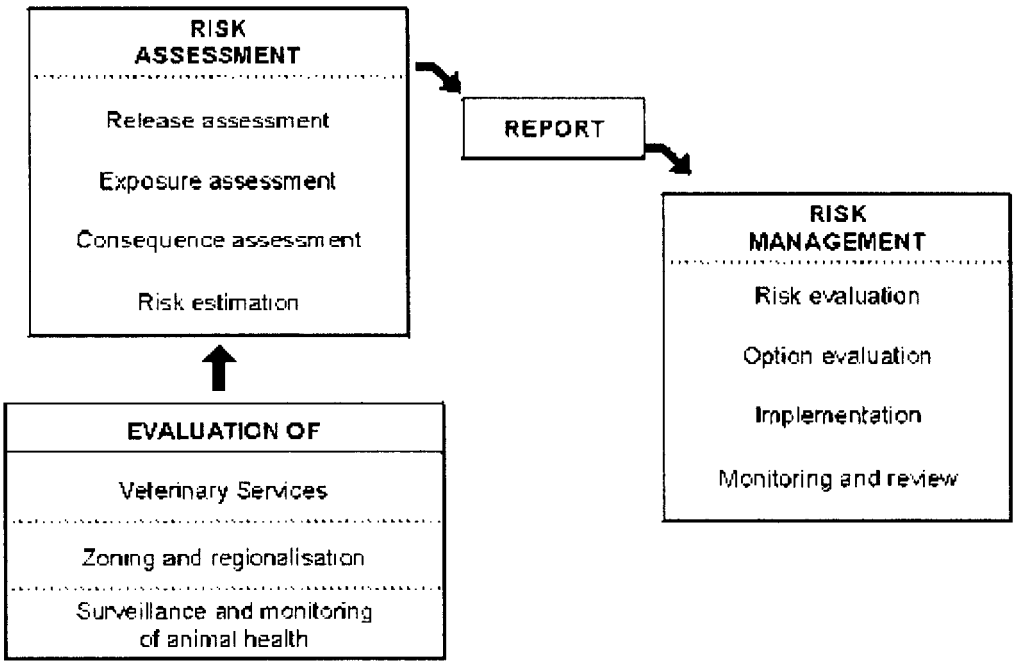
Hazard identification is an essential step which must be conducted before the risk assessment.

The risk assessment process consists of four interrelated steps. These steps clarify the stages of the risk assessment, describing them in terms of the events necessary for the identified potential risk(s)

to occur, and facilitate understanding and evaluation of the outputs. The product is the risk assessment report which is used in risk communication and risk management.

The relationships between risk assessment and risk management processes are outlined in Figure 1.

Fig. 1. ***The relationship between risk assessment and risk management processes***



Article 1.3.2.2.

Hazard identification

The hazard identification involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a *commodity*.

The potential hazards identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each potential hazard is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as potential hazards or not. The risk assessment may be concluded if hazard identification fails to identify potential hazards associated with the importation.

The evaluation of the *Veterinary Services*, surveillance and control programmes and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in this *Terrestrial Code*, thus eliminating the need for a risk assessment.

Article 1.3.2.3.

Principles of risk assessment

1. Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Risk assessment must be able to accommodate the variety of animal *commodities*, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.
2. Both qualitative and quantitative risk assessment methods are valid.
3. The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
5. Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.
6. Risk increases with increasing volume of *commodity* imported.
7. The risk assessment should be amenable to updating when additional information becomes available.

Article 1.3.2.4.

Risk assessment steps

1. Release assessment

   Release assessment consists 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 of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the 'release' of each of the potential hazards (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a. Biological factors
   - species, age and breed of animals
   - agent predilection sites
   - vaccination, testing, treatment and quarantine.

b. Country factors
   - incidence/prevalence
   - evaluation of *Veterinary Services*, surveillance and control programmes and zoning systems of the *exporting country*.

c. Commodity factors
   - quantity of commodity to be imported
   - ease of contamination
   - effect of processing
   - effect of storage and transport.

If the release assessment demonstrates no significant risk, the risk assessment conclude.

2. Exposure assessment

Exposure assessment consists 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 (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a. Biological factors
   - properties of the agent.

b. Country factors
   - presence of potential vectors
   - human and animal demographics
   - customs and cultural practices
   - geographical and environmental characteristics.

c. Commodity factors
   - quantity of commodity to be imported
   - intended use of the imported animals or products
   - disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. Consequence assessment

Consequence assessment consists 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 potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

a. Direct consequences
   - animal infection, disease, and production losses
   - public health consequences.

b. Indirect consequences
   - surveillance and control costs
   - compensation costs
   - potential trade losses
   - adverse consequences to the environment.

4. Risk estimation

Risk estimation consists 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. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

Article 1.3.2.5.

Principles of risk management

1. Risk management is the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
2. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.

Article 1.3.2.6.

Risk management components

1. Risk evaluation - the process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.
2. 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.
3. Implementation - the process of following through with the risk management decision and ensuring that the risk management measures are in place.
4. Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

Article 1.3.2.7.

Principles of risk communication

1. Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the *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.
2. A risk communication strategy should be put in place at the start of each risk analysis.
3. The communication of risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4. The principal participants in risk communication include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.
6. Peer review is a component of risk communication in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FBT 05/5/4**

May 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Fifth Session

Chiba, Japan, 19-23 September 2005

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS FOR FOODS DERIVED FROM BIOTECHNOLOGY

1. The 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology with the understanding that its final report should be submitted to Commission in 2009. It adopted the Terms of Reference of the Task Force (ALINORM04/27/41 APPENDIX VIII).

2. The Commission agreed that a Circular Letter be issued to solicit specific proposals for new work and to define priorities and that comments received would be distributed as a working document for the consideration by the first session of the Task Force (ALINORM 04/27/41, para 89).

3. In pursuant to this decision by the Commission, the Circular Letter 2005/2-FBT was issued in February 2005 to solicit proposals for new work.

4. This document includes comments submitted by Argentina, Australia, Brazil, Canada, Iran, Japan, Mexico, New Zealand, United States of America, Venezuela, 49th Parallel Biotechnology Consortium, Biotechnology Industry Organization (BIO), Consumers International (CI). Project Documents for the items proposed as new work were also attached as Annexes to this document.