

**Protocol of the
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and
Animal, Plant and Food Risk Analysis
Network
(APFRAN), Science Division
Canadian Food Inspection Agency**

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Animal Health and Production Risk Analysis Framework

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Introduction

Risk Analysis as Scientific Decision Support

The animal health program historically was a semi-closed system in which the inputs, processes and outputs were relatively autonomous from their environment. The goal of import, for example, was zero-risk, and disease control activities centred around eradication. In the early 1990's a risk assessment group was created to address the pressures of liberalized trade, farming of non-traditional species, the increase in disease intelligence and the need for transparent processes to arrive at decisions which minimize the risks. While refining its risk assessment processes, the Animal, Plant and Food Risk Analysis Network (APFRAN) developed a systematic approach to the entire spectrum of risk analysis activities. The integrity of both risk assessment and management depend upon the validity, transparency and repeatability of the process. APFRAN was also instrumental in formalizing the risk analysis approach adopted by trade bodies and international standards agencies. To date, the expertise developed within APFRAN is applied primarily to import decisions. This structured approach, as well as APFRAN's specialized expertise in economics, statistics and modelling, would benefit non-import decisions. The need for expanding this decision-making application is discussed below.

Subjective Factors Influencing Decision-making

Decision-making is a process of choosing among alternative courses of action for the purpose of attaining a goal or goals. It is viewed as a four-phase process: **intelligence**, **design**, **choice** and **implementation**. For most practical purposes, decision-making and problem solving are viewed as similar processes.

Individual differences in cognitive style can impact on every phase of the decision making process, resulting in less than optimal decisions. For example for **intelligence**, information gathering can range from perceptive, in which the focus is on relationships among data items, to that of a receptive individual who focuses on details. Individual differences in information evaluation can have an impact on the sequence by which data is analysed in the **design**, **choice** and **implementation** phases. Systematic (analytic) individuals pursue a structured, deductive approach. Intuitive (heuristic) individuals use trial-and-error strategies. Other subjective factors influencing the decision-making process include the decision styles (e.g., autocratic versus democratic). Arbitrary inputs may include time allotment, prioritization and whether the decision is made by an individual or group.

Decision-making and risk analysis

The process of risk analysis can be used to provide structure to decisions in which uncertainty is involved. Traditionally a distinction was made between risk, when the probabilities of uncertain outcomes were known, and uncertainty, when they were not. This approach is impractical as rarely are probabilities 'known'. Therefore, risk analysis processes have been adjusted to encompass uncertainty decisions - those decisions which are encountered constantly in the management of any system. The four steps in decision-making outlined above parallel the activities outlined for import risk analysis in these guidelines. The **design** phase of decision-making requires a spectrum of possible tools, depending on the nature of the decision. Among them are modelling, generating alternatives, and scenario development. Similarly, the **choice** phase can consider using algorithms, sensitivity analysis and other mathematical tools to arrive at a clear definition of the **choice**. While APFRAN cannot assume the responsibility of the decision-maker in the process, it can assist in arriving at a more objective, documented and repeatable decision, which can build on future decisions.

Policy

Policy on Import Risk Analysis for Animals and Animal Products

The Animal Health and Production Division (AHPD) of the Canadian Food Inspection Agency (CFIA) is responsible for the decision to prohibit or allow importation of animals, animal germplasm and animal-sourced products. AHPD may establish specific conditions under which importation may proceed, e.g., testing, quarantine, in order to safeguard the Canadian animal health status. This document presents the steps followed in the import risk analysis process for animals and animal products.

1. PROCESS INITIATION

A prospective importer makes an inquiry to a CFIA Operations Officer. If no import permit conditions are currently listed on the Automated Import Reference System (AIRS) that match this request, the Operations Officer will explain the steps described below to the prospective importer.

- a) An application for permit to import must be completed by the prospective importer and the appropriate fee paid.
- b) The Operations Officer determines if an environmental assessment is required.
- c) If an environmental assessment is required, the appropriate fee must be paid in advance by the prospective importer.
- d) The Operations Officer can explain to the applicant the advantage of completing the environmental assessment prior to starting the risk assessment, in the event that the outcome of the environmental assessment is unfavourable. Documentation of this discussion is suggested. The importer can decide if he/she wishes to pursue the environmental assessment and the risk assessment concurrently or to wait first for the results of the environmental assessment.
- e) A risk assessment is required for any importation of a new species, a new product or a commodity from a new country. For the case in which a new species, genus, product or country is considered to present the same risk as that for which a risk assessment has already been completed, only an addendum to the original risk assessment may be required. The import conditions will need to be amended to show all commodities/countries for which it applies.
- f) The prospective importer must submit the fee for a risk assessment.
- g) The Operations Officer forwards the request with all required information to the Program Network Officer who in turn forwards to the AHPD Program Officer who is responsible for development of import protocols or responsible for that particular species.
- h) To indicate the need for a risk assessment, a Request form is completed by the AHPD Program Officer and forwarded to APFRAN. A copy of the Request may also be forwarded to the Director of AHPD. Should the Director have any problems with the request, he/she may communicate with the AHPD Program Officer and APFRAN. The importer may be contacted for further description of and information on the commodity to complete the Request.

i) The completed and approved Request is forwarded to the Animal, Plant and Food Risk Analysis Network (APFRAN) of the Science Division. APFRAN informs the AHPD Program Officer within 3 working days of the anticipated delivery date for the risk assessment based on the date of receipt of the Request and the existing workload. The AHPD Program Officer calculates the time frame to generate the import conditions (usually 10 working days or more depending on the amount of industry consultation) and communicates the anticipated completion date to the submitting Program Network Officer. The Operations Officer relays this information to the prospective importer.

Risk assessments may be done by a AHPD Program Officer under the following conditions:

- C the case is urgent, could not be foreseen and could have serious economic and/or political consequences, and
- C the case is straightforward enough that the officer can free up the time required, and
- C the species to be imported is identified in the Hazard Identification Tables of the Animal Health and Production Risk Analysis Framework and the country of origin is listed in the Country Freedom Recognition Tables, and
- C the risk assessment report will be submitted to APFRAN for approval on an urgent basis (subject to existing workload).

3. HAZARD IDENTIFICATION and RISK ASSESSMENT

APFRAN is responsible for identifying the hazards associated with the importation and conducting the risk assessment for each hazard. The risk assessment process involves collecting evidence and information and consulting with experts nationally and internationally, in particular those experts in the CFIA Centres of Expertise (listed below).

Centre for Animal and Plant Health (CAPH), Charlottetown, Prince Edward Island
Retroviruses

Health of Animals and Food Laboratory (HAFL) St-Hyacinthe, Quebec
Indigenous Porcine Diseases

Animal Disease Research Institute, Nepean, Ontario
Avian Diseases
Brucella
Germplasm (Semen and Embryos)
Mycobacteria
Rabies
Biologics Evaluation Laboratory (BEL)

National Centre for Foreign Animal Diseases (NCFAD), Winnipeg, Manitoba
Foreign Animal Diseases

Health of Animals Laboratory (HAL), Saskatoon, Saskatchewan
Animal Parasitology

Animal Diseases Research Institute (ADRI), Lethbridge, Alberta
Diseases of non-traditional Livestock
Indigenous Bovine and Equine Viral Diseases
Leptospirosis

A draft risk assessment document is prepared and sent for peer review.

4. PEER REVIEW

APFRAN selects the participants for peer review according to the risk assessment. The peer review participants may include scientific experts from the CFIA Centres of Expertise, CFIA field epidemiologists, risk analysts, economists and biostatisticians. The comments received from the participants are incorporated into a revised risk assessment document. The consultative process may be curtailed due to trade-related time constraints.

5. IMPORT PROTOCOL DEVELOPMENT

AHPD develops an import protocol based on the information presented in the risk assessment document. During the process, the CFIA Centres of Expertise may be consulted for scientific advice. Legal Services may be consulted for interpretation and legality of the protocol statements. Problems identified in the risk assessment may be referred back through the previous four (4) steps. The protocol development will take into account the use of standardized General Provision requirements and the more specific health requirements for export from the particular country. These requirements for health must comply with the World Trade Organization Sanitary/Phytosanitary Agreement.

6. IMPORT PROTOCOL

The import protocol for a commodity that has never been imported should receive industry consultation through the Import Advisory Committee (IAC). The protocol would be sent to this group by the AHPD coordinator for comments. The function of the IAC is advisory and not regulatory. The final decision on importation rests with the AHPD. If there are further questions and concerns, APFRAN and/or the Centers of Expertise will be contacted in an effort to mitigate these concerns. The consultative process may be curtailed due to trade-related time constraints.

7. AHD RISK MANAGEMENT DECISION

The final version of the import protocol will receive authorization from the Director or Deputy Director of AHPD. The export certificate for the commodity can be drafted from the protocol in the country of origin. Once this certificate has been accepted by both countries, then import permits can be issued. The AHPD informatics personnel activate these conditions on the Automated Import Reference System and the Area Office issues the import permit.

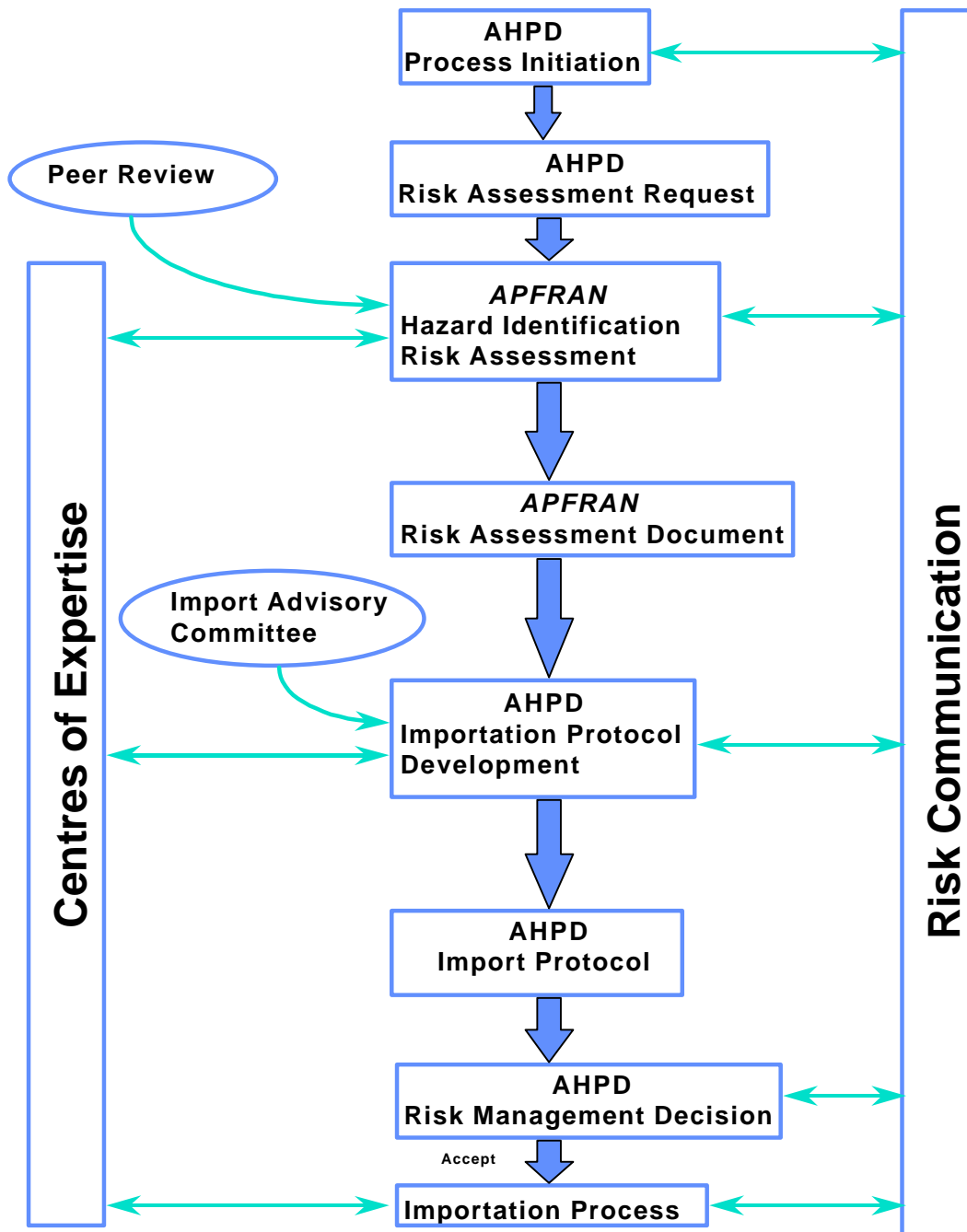
8. IMPORTATION PROCESS

The importation may then proceed in compliance with the Health of Animals Act and Regulations. Changes to the import protocol and therefore the export certificate may be necessary due to problems encountered with certification during the importation or due to changing trade barriers.

9. RISK COMMUNICATION

Risk communication takes place throughout the risk analysis process. Risk communication with stakeholders and other interested parties is principally the responsibility of AHPD, however, risk communication should be carried out by all parties involved in the risk assessment when appropriate.

Import Risk Analysis Process for Animals and Animal Products



Policy on Import Risk Analysis for Veterinary Biologics

The process for risk analysis related to veterinary biologics is presented in this document. Risk analysis of veterinary biologics is carried out by Program Officers in the Veterinary Biologics Section (VBS) of the Animal Health and Production Division (AHPD) in the Canadian Food Inspection Agency (CFIA).

The risk analysis process begins when a submission is received for the licensing of a veterinary biologic. During a preliminary screen of the submission, a risk characterization is made and the product is classified as a Type 1 or Type 2 product. A Type 1 biologic contains inactivated components and a Type 2 biologic contains live or recombinant components.

A risk assessment may be requested when:

1. the components of a Type 1 biologic are from a country other than the U.S.A. or there is uncertainty concerning the disease status of the country of origin,
2. it is needed to support a policy or regulatory change for a "class" of products (e.g., swine vaccine for pseudorabies) where the change may introduce an undefined risk, or an identified potential risk.
3. the product is a type 2 biologic with live components or components which have a genetic modification resulting in altered pathogenesis, and
4. other circumstances leading to uncertainty about a component of animal origin.

The decision as to whether the risk assessment request proceeds to the Animal, Plant and Food Risk Analysis Network (APFRAN) is made by the Associate Director, VBS.

The hazard identification and risk assessment steps are similar those described in the import risk analysis process for animals and animal products.

Risk management activities for veterinary biologics include: defining label indications and instructions, quality assurance through serial release testing, monitoring of adverse reactions, production facility inspections and other compliance activities.

Risk communication is carried out throughout the review process. Risk assessment and environmental assessment documents are tools which help Program Officers carry out risk communication. Specific risk communication packages may be developed to best meet the needs of particular groups, for example, livestock owners, veterinarians, or pet owners.

Policy on Risk Analysis for Domestic and Export Activities

The need for risk analysis of a domestic or export related issue can be identified by an Operations Officer through the Program Network Officer or a Program Officer in the Canadian Food Inspection Agency (CFIA). The decision of whether the risk analysis request proceeds to the Animal, Plant and Food Risk Analysis Network (APFRAN) is made by a Program Officer of the Animal Health & Production Division of the CFIA.

The nature of export or domestic issues requiring risk analysis is diverse. Export issues often involve illustrating to importing countries the Canadian disease status based on current surveillance and/or control programs and the safety of the commodities sourced from domestic livestock. Domestic issues may involve evaluating the effect of the presence and/or movement of potentially diseased animals within Canada, assessing changes in disease control programs and activities and evaluating programs that regulate animal feed medication.

The risk assessment steps are similar to those for import risk analysis for animals and animal products.

Methodology

Risk Analysis Terminology

Acceptable risk: a management decision with regard to the permissibility of a hazard; a decision made (in the risk assessment process) about the safety of a regulatory decision or the acceptability of a hazardous event. This is a subjective decision about issues around which there may be substantial disagreement. To say that a hazard is acceptable, admissible, allowable, or permissible appears to trivialize the concerns of a client community. For good risk communication to occur, it is best not to use the phrase "acceptable risk" or any of its variants (Ahl and others 1993).

Agent: a vector or organism of concern which causes a disease or other hazard to an agricultural commodity or resource (Ahl and others 1993).

Benefit-cost analysis: an economic method for assessing the benefits and costs of achieving alternative health based standards with different levels of health protection (The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

Carrier: a person or animal that harbours an agent, serves as a potential source of infection yet shows no clinical disease (Last 1988). An incubatory carrier is the designation given to persons or animals during the incubation period of a disease and convalescent carrier implies infection persisting during the recovery period. This carrier state may occur throughout the disease course following infection.

Commodity: animals, animal products, animal genetic material, feedstuffs, biological products and pathological material (OIE International Animal Health Code 1998)

Comparative risk analysis: the process of comparing and ranking various types of risks to identify priorities and influence resource allocations (The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

Cost-effectiveness analysis: an economic method to identify the least costly way to achieve a particular health protection goal (The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

Covello-Merkhofer model: a risk assessment model consisting of four interrelated but conceptually distinct steps (Covello and Merkhofer 1993).

1. Release assessment: consists of describing the potential of a risk source to release or otherwise introduce risk agents into an environment accessible to animal and human populations. Release assessments typically include (a) a description of the types, amounts, timing, and probabilities of the release of risk agents, and (b) a description of how these attributes might change as a result of various actions or events. Release assessment is the process of developing a description of the relevant characteristics of the risk source that establishes its potential for creating harm by releasing or otherwise introducing risk agents into portions of the environment accessible to animals and humans.

2. Exposure assessment: consists of describing the relevant conditions and characteristics of animal and human exposures to risk agents produced or released by a given risk source. Exposure assessments typically would include (a) a description of the intensity, timing, frequency, and duration of exposure, (b) routes of exposure (e.g., ingestion, inhalation, or insect bite, and (c) the number, species and characteristics of populations that might be exposed. The exposure assessment is the process of developing a description of the relevant conditions and characteristics of animal and human exposures to risk agents produced or released by a specified source of risk

3. Consequence assessment: consists of describing the relationship between specified exposures to a risk agent and the economic consequences of those exposures. Consequence assessments typically include a specification of the impact on health in the animal and human populations sustained under given exposure scenarios. In other words, the consequence assessment is the process of developing a description of the relationship between the specified exposures to a risk agent and the health and other consequences to animals and humans exposed.

4. Risk estimation: consists of integrating the results from release assessment, exposure assessment, and consequence assessment to produce quantitative measures of health and environmental risks. These measures typically include (a) estimated numbers of people experiencing health impacts of various severities over time, (b) measures indicating the nature and magnitude of adverse consequences to the natural environment, and (c) probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates.

Data: facts, information organized for analysis or used as the basis for a decision (Ahl and others 1993).

Database: a collection of relevant data and information arranged for ease of use and speed of retrieval, as by a computer (Ahl and others 1993; Covello and Merkhofer 1993).

Disease-Free: used historically to refer to a country, area or region which met a given set of criteria. The implication was that any animal or animal commodity originating in this area or region presented no hazard to an importing country from a particular agent or organism. Scientifically, it is not possible to prove the absence of an agent. The term disease-free really means that the agent, if it was present, occurred at an extremely low prevalence. This however, is not the same thing as absence. Thus, the risk associated with the importation of commodities from such an area would be negligible, tolerable, de minimis, presenting no significant risk (Ahl and others 1993)

Documentation: providing references for data, information sources and analytical procedures.

Economic analysis: an analysis in monetary values of the costs and benefits of various actions to protect health or the environment (The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

Evidence-based: evidence-based decision-making or risk assessment refers to basing the decisions or risk assessment on facts, information and data (Kaplan 1997).

Exotic or foreign: situated outside an area; born in or belonging to, or characteristic of some other area. That which is not known to occur in a given area or region (Ahl and others 1993).

Expert information approach: a means of eliciting the relevant information and experience from experts on some parameter or input in a risk assessment (Kaplan 1992).

Geographic Information System (GIS): computer-based systems for storing, retrieving, manipulating, analyzing, displaying and mapping data. It is used as a tool for planning, decision-making, and risk analysis (Ahl and others 1993).

Hazard: an agent that can cause adverse effects (e.g. an organism that is a necessary cause of an animal disease). A hazard is an element or event that poses potential harm; an adverse event or adverse outcome. A hazard is identified by describing what might go wrong and how that might happen (Ahl and others 1993). Covello and Merkhofer (1993) defined hazard as a (potential) source of risk that does not necessarily produce risk. A hazard produces risk only if an exposure pathway exists and if exposures create that possibility of adverse consequences. Hazard identification is the process of identifying new agents in sources of risk. Risk sources may release risk agents to the air, soil, surface water, or groundwater. The risk agents released may be either chemical, physical, biological, or forms of energy.

Hazard identification: the process of identifying the biological agents which could potentially be introduced with a commodity or activity and for which pathways exist for exposure of the agents to susceptible animals and man.

Hosts (Last 1988; Thrusfield 1995)

- a) Host - a person, animal, bird or arthropod that is can become infected with and give sustenance to an agent.
- b) Primary (natural) host - a person or animal that maintains an infection, for example, hog cholera in swine.
- c) Secondary host - a species that is additionally involved in maintaining the infection but not the principal source of infection, for example, Aujeszký's disease in cattle.
- d) Definitive host - a term reserved for parasitic infections to describe a person or animal in which the agent undergoes sexual reproduction, for example, *Taenia saginata* infection of man.
- e) Intermediate host - a term reserved for parasitic infections to describe a person or animal in which the agent develops only to a larval stage or asexual state, for example, *Cysticercus bovis* in cattle.

Implementation: to put into effect the risk management decision.

Information: knowledge derived from study, analysis, or experience; in computer science usage, data that can be coded for processing by a computer or similar device (Ahl and others 1993).

Information system: a system concerned with the gathering, manipulation, classification, storage and retrieval of data and information contained in databases. The computer is the organizing element (Ahl and others 1993).

Latent infection: a persisting infection within the host without clinical disease and often without demonstrable presence of the agent in blood, secretions or excretions (Last 1988). There is a balance between the host and replication of the agent for what can be a considerably long time (Thrusfield 1995), for example, African swine fever virus and hog cholera latent infections in swine following recovery.

Model: A representation of an activity or process in mathematical form in which an equation is used to stimulate the behaviour of the component events, states of nature, risk management actions and biological processes under study.

Model Inputs: represent the components of a model. Terms that are often used interchangeably with model inputs in risk analyses are the words 'inputs,' 'variables,' 'factors,' or 'parameters'. Use of the latter term 'parameter' may lead to confusion with its use in experimental statistics. There the term parameter represents the numerical descriptive measure that characterizes a population, for example the population mean (m), the population standard deviation (s) and the binomial proportion p . The slope and intercept are parameters of a least squares univariate regression model. The term parameter is used in spreadsheet computer software to represent the arguments of a mathematical or statistical function and the parameters of a probability distribution such as the shape parameters of the beta distribution or the parameters of a normal distribution, the mean and standard deviation. The word 'variable' is best defined as a characteristic that changes or varies over time and/or for different individuals or objects under consideration.

Monitor and review: to observe, audit and review the events or consequences following

the risk management decision. It may include periodic or continuous surveillance or testing to determine the characteristics of the risk source or the health status of animal and human populations (Covello and Merkhofer 1998).

Native: grown, produced, or originating in a particular area; inborn, natural, indigenous (Ahl and others 1993).

Negligible risk: (also known as **tolerable risk, de minimis risk**) a mutually agreed upon measure or risk so low that all parties agree to accept risk at or below this level under most circumstances (Ahl and others 1993).

Option Evaluation: the process of appraising, weighing and comparing outcomes of risk management options (Covello and Merkhofer 1998). The identification of the option and selecting the option after its evaluation are included in the definition of option evaluation for the purposes of this Framework document.

Organism: any active, infective, propagative or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, viruses, viroids, or any entity characterized as affecting living organisms. It is an entity whose reproduction is ultimately based on nucleic acids (Ahl and others 1993).

Pathway: any means and/or route by which an agent can move or be moved from one place to another (Ahl and others 1993). An exposure pathway is the means by which risk agents are transmitted (Covello and Merkhofer 1993), e.g., the scenarios by which an animal or human population is exposed to a biological agent.

Peer Review: Evaluation of the accuracy or validity of technical data, observations and interpretation by qualified experts in an organized group process (The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

Quantitative definition of risk: Kaplan (1981) defined risk quantitatively as a complete set of triplets $R = \{<s_i, l_i, x_i>\}_c$. This definition answers three questions:

What can go wrong? (s_i)

How likely is that to happen? (l_i)

If it does happen, what are the consequences? (x_i)

To visualize this set of triplets Kaplan (1981) included a simple table, as follows:

Scenario	Likelihood	Damage
s_1	l_1	x_1
s_2	l_2	x_2
s_3	l_3	x_3
.	.	.
.	.	.
.	.	.
s_n	l_n	x_n

The scenarios (s_i) answer the first question, they describe what can go wrong. The second column gives the likelihood, l_i , of each scenario and the third gives a measure, or measures, of the damage x_i attendant to each scenario. If the table is complete in that it includes all possible scenarios, then the complete set of triplets is achieved. The damage index (x_i) may be a multidimensional quantity such as a vector in which the vector components represent animal deaths, human infection, wildlife infection, environmental contamination, etc. The damage may be time-dependent, uncertain or both uncertain and time-dependent.

Risk: the likelihood of the occurrence and the magnitude of the consequences of an adverse event; a measure of the probability of harm and the severity of impact of a hazard. Objective measurement and scientific repeatability are hallmarks of risk. In risk studies, it is common especially in oral communication to use "risk" synonymously with the likelihood (probability or frequency) of occurrence of a hazardous event. In such instances, the magnitude of the event is assumed to be significant (Ahl and others 1993).

Risk analysis: the process that includes risk assessment, risk management and risk communication.

Risk assessment: the process of identifying a hazard and estimating the risk presented by that hazard. It is the process of identifying a hazard and evaluating the risk of a specific hazard, either in absolute or relative terms. It includes estimates of uncertainty in process, and is an objective, repeatable, scientific process. Quantitative risk assessment characterizes the risk in numerical representations (Ahl and others 1993).

Risk Assessment Document: a report of the evidence, methodology, results and recommendations of a risk assessment to ensure a transparent risk assessment process.

Risk communication: the open exchange of information and opinion, leading to a better understanding of risk and risk related decisions; the processes 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 tool to provide a forum for interchange with all concerned about the nature of hazards, the risk assessment and how the risks should be managed; a tool to assure unambiguous interchange of information among those affected by the outcome of risk assessment activities (Ahl and others 1993).

Risk Evaluation: the process of interpreting risks, including determining levels of risk acceptable to individuals, groups or society as a whole (Covello and Merkhofer 1993). The risk management aspect concerned with the initial decision to request a risk assessment is included in this definition.

Risk management: the process of identifying, evaluating, selecting and implementing alternatives for mitigating risk. It is the pragmatic decision-making process concerned with regulating the risk. As a decision process, it is involved in evaluating options to diminish or control present and predicted hazards to the biological and/or fiscal health of agricultural commodities. The decisions made may result in preventive or restorative actions. Risk managers make implicit judgements about the safety of particular courses of action (Ahl and others 1993).

Risk reduction options or mitigation measures: any action or actions which reduces the risk of an agent to cause harm (to domestic livestock); they may be applied to any commodity. Examples include quarantine, diagnostic testing, inspections, restricted use, processing, sentinel monitoring, etc (Ahl and others 1993).

Safety: the degree to which risks are judged acceptable; a subjective decision of the acceptability of a risk. In the literature, it is generally used when discussing safety for human health. What one individual views as safe, another may view as presenting unacceptable risk. In a regulatory context, managers make decisions about, for example, an importation based on their evaluation of the safety of the action for the health of the national herd (Ahl and others 1993).

Sanitary measure: measures used for risk reduction which are appropriate for particular diseases such as are described in each chapter of the *International Animal Health Code*.

Tolerable Risk: a management decision with regard to the acceptability of risk.

Transmission of infection (Last 1988; Martin and others 1987)

A. Direct transmission - the direct transfer of an agent of disease to a receptive host. This may be by direct physical contact (e.g., trichomoniasis- venereally, rabies - by biting), contact with infected excretions and secretions (e.g., leptospirosis - in urine), transplacentally (e.g., bovine viral diarrhoea), or by respiratory droplet spread (e.g., contagious bovine pleuro pneumonia).

Air-borne - direct transmission of an agent of disease via inhalation of particles, consisting wholly or partially of agent, which have been transferred through the air and frequently over long distances (e.g., foot and mouth disease and Aujeszky's disease in swine).

B. Indirect transmission

a) vehicle-borne - mechanical transfer of an agent to a receptive host via contaminated materials such as bedding, (e.g., foot and mouth disease), surgical instruments (e.g., anaplasmosis, enzootic bovine leucosis), or feed (e.g., classical swine fever/hog cholera). The agent may or may not have multiplied or developed in or on the vehicle.

b) vector-borne - two types

1) Mechanical - carriage of an agent on the exterior or in the proboscis of an arthropod or by passage of the agent through its gastrointestinal tract. No multiplication or development of the agent is required (e.g., equine infectious anemia).

2) Biological - carriage of an agent by a vector (arthropod) in which an agent undergoes either a necessary part of its life cycle or multiplication before transmission (e.g., babesiosis and theileriasis).

Transparency: implies clearly written, readily understandable, well-organized, annotated, and available in a timely fashion to involved persons.

Uncertainty: the lack of precision in the model input which is due to measurement or estimation error or to deficiencies in the model or scenario.

Variability: a real-world complexity in which the value of an input is not the same for each case due to a natural heterogeneity or diversity in a well-characterized population. The variable has some non-trivial distribution, for example, the variable of the carcass weight of six month old pigs.

Vector: an organism which can carry and transmit disease (Ahl and others 1993).

Zero risk: in the past this has been used to mean a management decision to eliminate the hazard or not allow its introduction, independent of the likelihood and impact (Ahl and others 1993).

Risk Assessment Request

From:

Date submitted:

History, background and rationale of the request:

Description of commodity or activity to be assessed:

Volume, quantity and frequency of commodity or activity:

Time-frames associated with commodity or activity:

Risk Assessment on	July 1, 2009
RISK ASSESSMENT REQUEST	
From:	
Date submitted:	
<hr/>	
History, background and rationale of the request:	
Description of commodity or activity to be assessed:	
Volume, quantity and frequency of commodity or activity:	
Time-frames associated with commodity or activity:	

Risk Assessment on	July 1, 2009
HAZARD IDENTIFICATION	
Hazard	OIE List
<hr/>	
VIRUSES	
RICKETTSIAS	
BACTERIA	
FUNGI	
PROTOZOA	
PARASITES	
OTHER	
REFERENCES	
COMMENTS	

Risk Assessment on	July 1, 2009
RELEASE ASSESSMENT	
HAZARD:	

Risk Assessment on	July 1, 2009
EXPOSURE ASSESSMENT	
HAZARD:	

Risk Assessment on	July 1, 2009
CONSEQUENCE ASSESSMENT	
HAZARD:	

Risk Assessment on	July 1, 2009
RISK ESTIMATION	
HAZARD:	

Risk Assessment on	July 1, 2009
REFERENCES	
HAZARD:	

Import Risk Analysis Process

INTRODUCTION

The process of import risk analysis begins following a request for importation of a commodity, whether the importation is to consist of single or multiple consignments or is to be on a continuous basis. It starts with a risk management decision to conduct a risk assessment for the importation in question. The history and background, a full description of the commodity, and the volume, quantity, frequency and time-frames of the proposed importation are all documented. In the case of veterinary biologics, the production outlines may be required.

The risk assessment process consists of hazard identification and four interrelated assessment 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 document which is used in further risk communication and risk management.

The relationships between hazard identification, risk assessment, risk management and risk communication in import risk analysis are outlined in Figure 1.

HAZARD IDENTIFICATION

Animals and Animal Products (See Appendix 1: Animal Health Hazards Associated with Imported Live Animals, and Appendix 2: Animal Health Hazards Associated with Imported Animal Products)

Hazard identification is a categorization step, identifying biological agents dichotomously as potential hazards or not. The risk assessment is concluded if hazard identification fails to identify potential hazards associated with the importation. The criteria employed for identifying hazards for imported animals and animal products are listed below:

- ! The identification of hazards for the importation of animals and animal products must be in accordance with the Sanitary Phytosanitary Agreement of the World Trade Organization.
- ! The hazard identification involves identifying the biological agents exotic to Canada (including foreign strains, serovars, serotypes, species, or sub-species) or represent biological agents of diseases for which national control and eradication programs are in-place and 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 are present in the exporting country in that species or other susceptible species.
- ! A disease agent is only a hazard for that commodity if the agent can infect or contaminate the commodity, can survive any treatment and transportation, and potentially be exposed to a susceptible host (primary or secondary) resulting in adverse consequences.
- ! The Office international des épizooties (OIE) list of diseases called List A and List B and the Food and Agriculture Organization (FAO) List C represent the principal lists of diseases (biological agents) for conducting hazard identification for the importation of animals and animal products.

- ! The hazard list may include those vector-borne diseases for which there exists no known competent vector in Canada. The potential adverse consequences would result from and be limited to disease in the imported animals themselves.
- ! With respect to animal products, the disease agents must be able to survive any processing methods, the time-interval between harvesting/processing and importation, and then be exposed to a susceptible host. This combination of processing, mode of transmission, and exposure to target host or hosts greatly reduces the list of hazards associated with animal product importation.
- ! Exposure of a susceptible host to a hazard in an imported product would occur through the oral route. The deliberate feeding of product in swill or as uncooked scraps to swine, or as scraps either deliberately fed to, or foraged by, dogs, results in these two species being the major target hosts exposed to hazards. The use of imported feather, meat, bone and blood meal as a dietary supplement (as a mineral lick or as part of a compounded feed) or in fertilizer exposes additional target hosts.
- ! The hazards identified for feather, meat, blood and bone meals reflect the likelihood of recontamination of these products with raw material following rendering at temperatures that may be more than sufficient to inactivate many animal pathogens.
- ! The evaluation of the veterinary services, surveillance programmes and zoning and regionalisation systems may be important inputs for hazard identification with respect to the presence of a biological agent infecting an animal population in the exporting country.
- ! Animals and animal products being imported into internationally recognized zones in Canada which are free of specific diseases (biological agents) would necessitate that these disease agents be considered as hazards.

Germplasm (See Appendix 3: Animal Health Hazards Associated with Imported Germplasm)

Embryos

The International Embryo Transfer Society (IETS) has developed recommendations in its Manual (third edition 1998) in order to mitigate the disease risks associated with the transfer of embryos produced both in-vivo and in-vitro. The procedures detailed in Recommendations for the Sanitary Handling of Embryos in Chapter III of the IETS Manual are internationally recognised and followed, and hazards which have been shown to be reliably removed or inactivated by adherence to these procedures are not considered as animal health hazards. The IETS classifies pathogens into four categories according to the risk of transmission:

Category 1	risk of transmission negligible provided embryos are properly handled
Category 2	risk is negligible but status being verified by further work
Category 3	preliminary evidence is that the risk is negligible, but further work required
Category 4	preliminary work in progress

Diseases listed in Categories 1 and 2 are not considered as animal health hazards. The Research Subcommittee of the IETS Import/Export Committee reviews current research

periodically and the categorisation may change as a result.

Trypsin treatment

Washing of embryos with trypsin has been shown to be effective in removing or inactivating certain viruses which appear refractory to the standard washing procedures. These pathogens are retained as hazards as a reminder to specify trypsin treatment, which represents a *modification* of the standard protocol.

In-Vitro Fertilized Embryos

Differences in the zona pellucida invalidate the treatment of risk presented by IVF-derived embryos as equivalent to that presented by in-vivo fertilized embryos. (e.g., efficiency of trypsin treatment in eliminating pathogens from IVF embryos has not been demonstrated, therefore its use would be empirical). For this reason IVF embryos are treated as a separate category.

Micro-Manipulated Embryos

Provided micro-manipulated (e.g., sexed, cloned) embryos are in-vivo derived and treated using standard washing procedures prior to manipulation, they may be regarded as equivalent to non-manipulated embryos.

Semen

Agents inactivated or removed from semen by internationally recognised collection, processing and storage methods (which detail dilution procedures (extension) and addition of antibiotics in order to mitigate the associated risk of transmission of disease) are not considered as animal health hazards.

Semen and embryos for import into special health status populations, such as artificial insemination centres, may result in additional hazards being identified. Responsibility for requesting health assurances mitigating these additional risks must rest with the management of the facility in question.

Veterinary Biologics

The production of veterinary biological products involves processes which are subject to variability and source materials which, by their nature, provide good substrates for the growth of microbiological contaminants. A large number of different hazardous agents may potentially be associated with imported veterinary biologics, dependent upon the particular product under consideration.

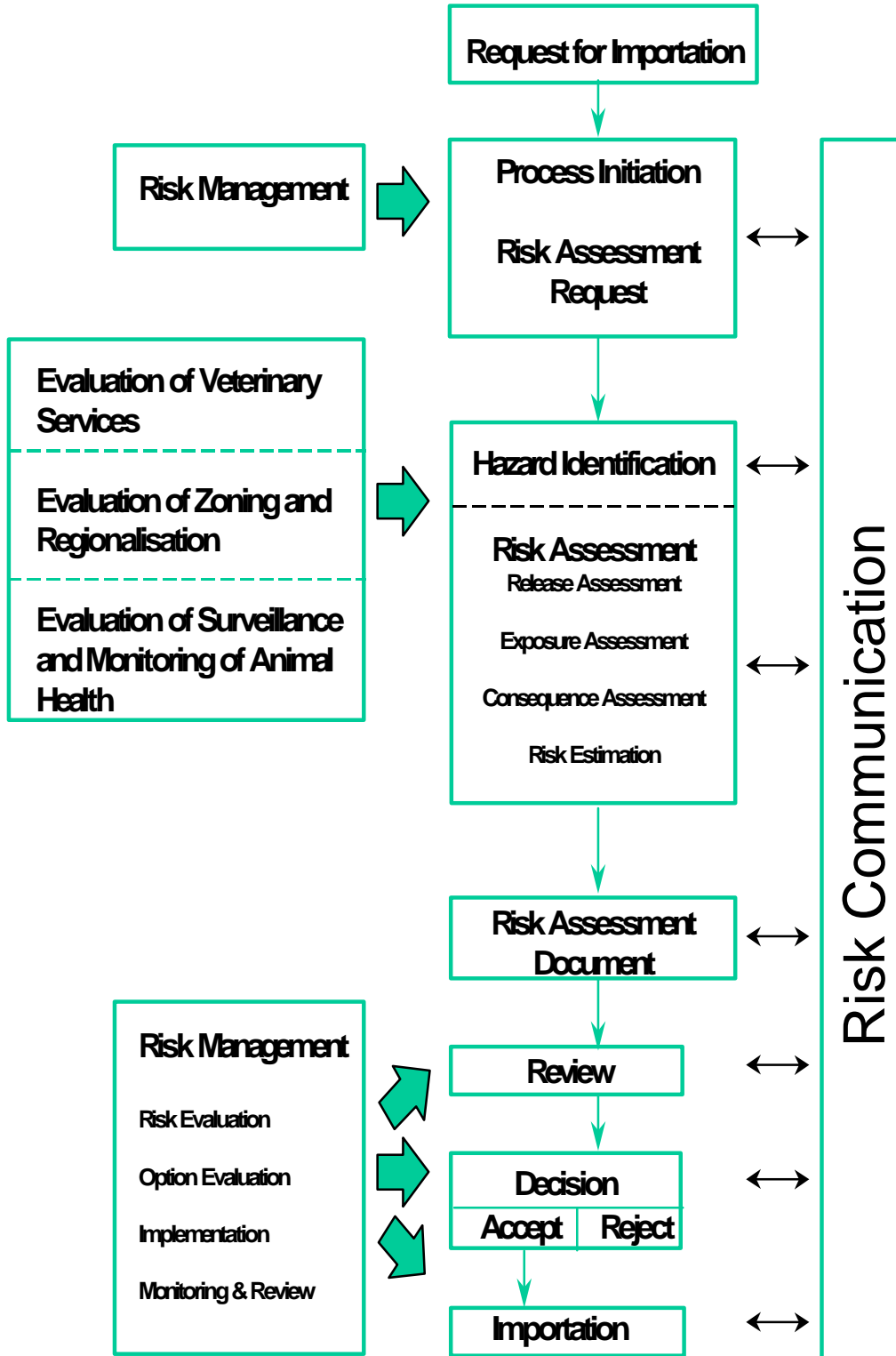
Consideration of the country, region or zone of origin of each component of the veterinary biologic is of great importance, particularly regarding non-traditional disease agents such as prions which are unlikely to be inactivated or removed by the manufacturing process. The components which present the most risk are those substances of animal origin which are used to supplement media in which the agent undergoes amplification. Other components which may introduce a hazardous agent include substances of animal origin used in diluent, master seed strains (that is, live bacteria, viruses or parasites), specific-pathogen-free (SPF) eggs used for amplification of agents used in live vaccines, cell substrates upon which pathogens are grown, and water.

Good manufacturing practice (GMP) is particularly important in reducing the hazards associated with veterinary biologics by attempting to eliminate defective environmental conditions which could allow contamination of the biologic during the production process. This is most likely during the so-called "open stages", prior to sealing of the product into sterile vials or ampoules. These stages include formulation (where adjuvants, stabilisers and preservatives are added), filling, and freezing. Inadequate inactivation of any immunogen and cross-contamination with other products manufactured at the facility are also risks. The "closed stages" of production include the labelling and storage of the biologic - incorrect identification at this stage will cause inappropriate use of the product later.

In conclusion, the hazard identification for imported veterinary biologics evaluates:

- vaccine microorganism or immunogen and its source
- country or zone of production facility
- other biological agents in vaccine facility and their source
- animal origin reagents and their source (e.g.. fetal bovine serum, bovine serum albumin, media containing peptones and protein hydrolysates of bovine origin)
- cell substrates (cell lines, primary cells, SPF eggs) and their source
- process (e.g., culture, concentration, harvest, separation, blending).

Figure 1
Import Risk Analysis Process



RISK ASSESSMENT STEPS

1. RELEASE ASSESSMENT

Release assessment consists of describing and quantifying the potential of a risk source to release or otherwise introduce biological agents into an environment accessible to animal and human populations. The risk source is represented by the importation activity that can introduce a biological agent into an importing country. The release assessment typically describes the types, amounts, timing, and probabilities of the release of biological agents, and how these attributes might change as a result of various actions, events or measures. Some of the inputs that may be required in the release assessment are:

- incidence or prevalence
- incidence/prevalence in adjoining zones or countries
- evaluation of the veterinary services, surveillance programmes and zoning and regionalisation systems of the exporting country
- species, age and breed of animals
- agent predilection sites
- ease of agent contamination
- effect of processing and inactivation procedures such as freezing, heat treatment, maturation, fumigation, salting, desiccation, pasteurization, steam heat, storage, chemical and mechanical treatment, and acidification
- effect of additives or treatments
- animal health certification policy and practice
- vaccination policy and practice
- effect of diagnostic testing
- effect of therapeutic treatment
- effect of quarantine (pre- and post-embarkation, with or without sentinel animals)
- effect of slaughter inspection (ante- and post-mortem)
- effect of deboning of carcasses
- effect of removal of lymphatic and central nervous system tissues from carcasses
- effect of temperature and duration of storage and transit

For the importation of veterinary biologics the following inputs in the release assessment may be included:

- effect of dilutions in vaccine production (e.g., growth and maintenance media, standardisation, stabiliser)
- effect of agent amplification in vaccine production
- testing of vaccine lots
- effect of inactivation in vaccine production (e.g., irradiation, chemical)
- effect of attenuation on vaccinal immunogen
- effect of separation, concentration, lyophilization and reconstitution in vaccine production

2. EXPOSURE ASSESSMENT

Exposure assessment consists of describing and quantifying the relevant conditions and characteristics of animal and human exposures to biological agents produced or released by a given risk source. The exposure assessment typically describes the amount, timing,

frequency, duration of exposure, routes of exposure (e.g., ingestion, inhalation, or insect bite), and the number, species and characteristics of the animal and human populations that might be exposed. Some of the inputs that may be required in the exposure assessment are:

- the presence of potential vectors
- the nature and properties of the agent
- the inherent nature and intended use of the release source
- routes of exposure, modes of transmission and portals of entry
- primary, secondary and intermediate hosts of the agent
- human and animal demographics
- customs and cultural practices
- compliance with human and animal health legislation
- disposal practices for unused commodity or contaminated material
- geographical and environmental characteristics.

For the importation of veterinary biologics the following inputs in the exposure assessment may be included:

- quantity (e.g., doses imported)
- dose volume
- routes of administration
- target and non-target species
- infection threshold
- immunocompromised subpopulations, animals and humans
- environmental and host persistence.

3. CONSEQUENCE ASSESSMENT

Consequence assessment consists of describing and quantifying the relationship between specified exposures to a biological agent and the economic consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences. The consequence assessment typically includes a specification of the impact on health in the animal and human populations sustained under given exposure scenarios. The consequences may include:

- animal losses from deaths and removal and slaughter/destruction
- production losses including abortions and infertility
- loss of gene pool
- losses from trade embargoes
- losses from domestic animal movement restrictions
- losses in domestic marketability
- control and eradication costs
- monitoring, surveillance, laboratory testing and trace back costs
- quarantine and isolation costs
- compensation costs
- cleaning and disinfection costs
- treatment costs

- vaccination costs
- human illness and deaths
- treatment and hospitalization costs for human illness
- 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 quantitative measures of health and environmental risks. The final outputs of this process are estimates of the magnitudes of possible adverse health or environmental consequences, including a characterization of the probabilities, uncertainties, or degree of confidence associated with these estimates. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome. A qualitative risk assessment is thus a summation of the findings of the release, exposure and consequence assessments.

For quantitative assessments, the final outputs may include:

- estimated numbers of herds, flocks, animals or people experiencing health impacts of various severities 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

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. This is exemplified by the variety of animal commodities, the multiple hazards that may be identified with an importation and hence, the different disease epidemiologies, detection and surveillance systems, exposure scenarios and types and amounts of data.
2. Both qualitative and quantitative risk assessments have merit.
3. An organizational arrangement that separates risk assessment from risk management decision-making is encouraged to ensure that the risk assessments are not influenced to fit prior regulatory conclusions.
4. 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 information elicitation.

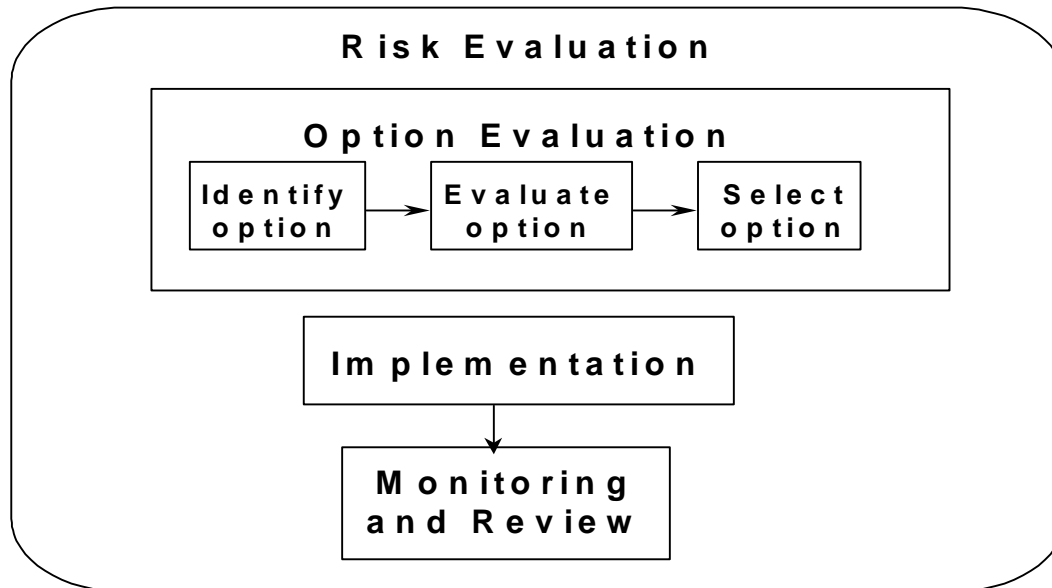
5. Consistency and transparency in risk assessments should be encouraged in order to ensure fairness and rationality, comparison of risks and ease of understanding by all the interested parties. Consistency may be limited to similar commodities and depend on the types and amount of data available. Improvement in risk assessment methods should supersede consistency.
6. Risk assessments should illustrate the uncertainty in the risk estimation output.
7. Generally the risk estimates increase with increasing volume or quantity of commodity imported.
8. The risk assessment should be amenable to updating when additional information becomes available.

RISK MANAGEMENT

While risk management comprises a number of measures, not all will necessarily be included in every risk analysis. The elements of risk management (see Figure 2) include:

1. Risk evaluation - the aspect of risk management concerned initially with the decision to request a risk assessment and secondly, interpreting, comparing, judging the significance of and deciding the tolerability of the risk as estimated in a risk assessment document.
2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting sanitary measures, in addition to those that may have been considered in the initial risk assessment, in order to reduce the risk associated with an importation. The efficacy is the degree to which an option reduces the likelihood and magnitude of adverse biological and economic consequences. Evaluating the efficacy is an iterative process that involves incorporation into the initial risk assessment which is then re-evaluated to determine the degree of risk reduction. 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 on acceptance or refusal of the importation and ensuring that the risk management measures are in-place for either decision.
4. Monitoring and review - the ongoing process to observe the importation and conduct a review, if necessary, of the risk assessment, the sanitary measures and the risk management decision.

Figure 2
Risk Management



PRINCIPLES OF RISK MANAGEMENT

1. The risk management decision on importation should be based on the probability of adverse health effects on animals or humans; that is the health-associated outputs of the risk assessment. These health associated outputs may (and probably will) in their turn have economic consequences, which will then also be included as risk assessment outputs. All risk management decisions should be in accordance with the *Sanitary and Phytosanitary Agreement* of the WTO.
2. The international standards of the OIE, as prescribed in the *Code*, should represent 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.

RISK COMMUNICATION

Risk communication represents the interactive exchange of information on risk among risk assessors, risk managers and other interested parties. It begins when a risk analysis is requested and continues after the implementation of the decision on the importation acceptance or refusal.

PRINCIPLES OF RISK COMMUNICATION

1. The communication of risk should be an open, interactive and transparent exchange of information that may continue after the decision on importation.
2. The principal recipients of 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.
3. Peer review should represent a component of risk communication in order to obtain scientific and analytic critique and to ensure the validity of the scientific data, methods and assumptions.
4. The uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.

DISEASE STATUS EVALUATION OF COUNTRIES/REGIONS/ZONES

OBJECTIVE

To comply with World Trade Organization (WTO) requirements, a scientific, transparent and consistent process to evaluate countries/regions/zones for disease status was developed.

APPROACH

The disease status evaluation of countries, regions or zones is conducted case by case, for OIE Lists A, B and C and other diseases identified as animal health hazards associated with the importation of animals or animal products and by-products. The criteria employed for country, region, or zone disease status evaluation varies depending on different factors (e.g., epidemiology of the disease, geographical or physical barriers, surveillance, etc.).

Knowledge of the veterinary infrastructure is critical for the evaluation of disease status and past trade experience is an important criterion. The competency of the veterinary infrastructure of new trading partners is evaluated as a first step for disease status recognition.

For the most part, countries evaluated tend to be trading partners which were previously assessed for certain OIE (Office international des épizooties) List A diseases. Their capability to maintain good veterinary services is not reviewed in general, only specifically in the event of new outbreaks of OIE List A diseases.

If countries are not reporting to the OIE or if the level of trade with Canada is very limited in recent years, the veterinary infrastructure is assessed before official recognition for any diseases.

The sources of information used are:

- Animal health hazard lists developed by the Animal, Plant and Food Risk Analysis Network (APFRAN) - Animal Health
- OIE publications: World Animal Health, Disease Information and Monthly Reports
- OIE Website www.oie.int
- Official United States Department of Agriculture (USDA) lists of countries recognized free of diseases (includes OIE List A diseases only)

5 areas are defined:

- **EUROPE: 18 countries - ASIA: 1 country**
- **AMERICAS: 11 countries- CARIBBEAN: 14 countries**
- **OCEANIA: 2 countries**

For each area, tables are completed in spreadsheets:

- One table for all OIE List A diseases
- One table per species for all diseases defined as animal health hazards for importation of live animals or animal products and by-products (includes OIE List A, B, and C and other diseases)
- Species included are: cattle, sheep, goats, horses, pigs, poultry, lagomorph, bees,

cervidae, camelidae and ratites.

PRINCIPLES FOR OIE LIST A DISEASES

The OIE List A disease status of countries not officially recognized free by Canada is assessed unless one of the following applies, in which case official freedom recognition is granted without further assessment:

- The USDA has evaluated the disease status of the country and recognized it officially free of the disease
- The disease is not present in the continent where the country is located
- The disease is a vector-borne disease and the vector is not present in the country.

PRINCIPLES FOR DISEASES OTHER THAN OIE LIST A DISEASES

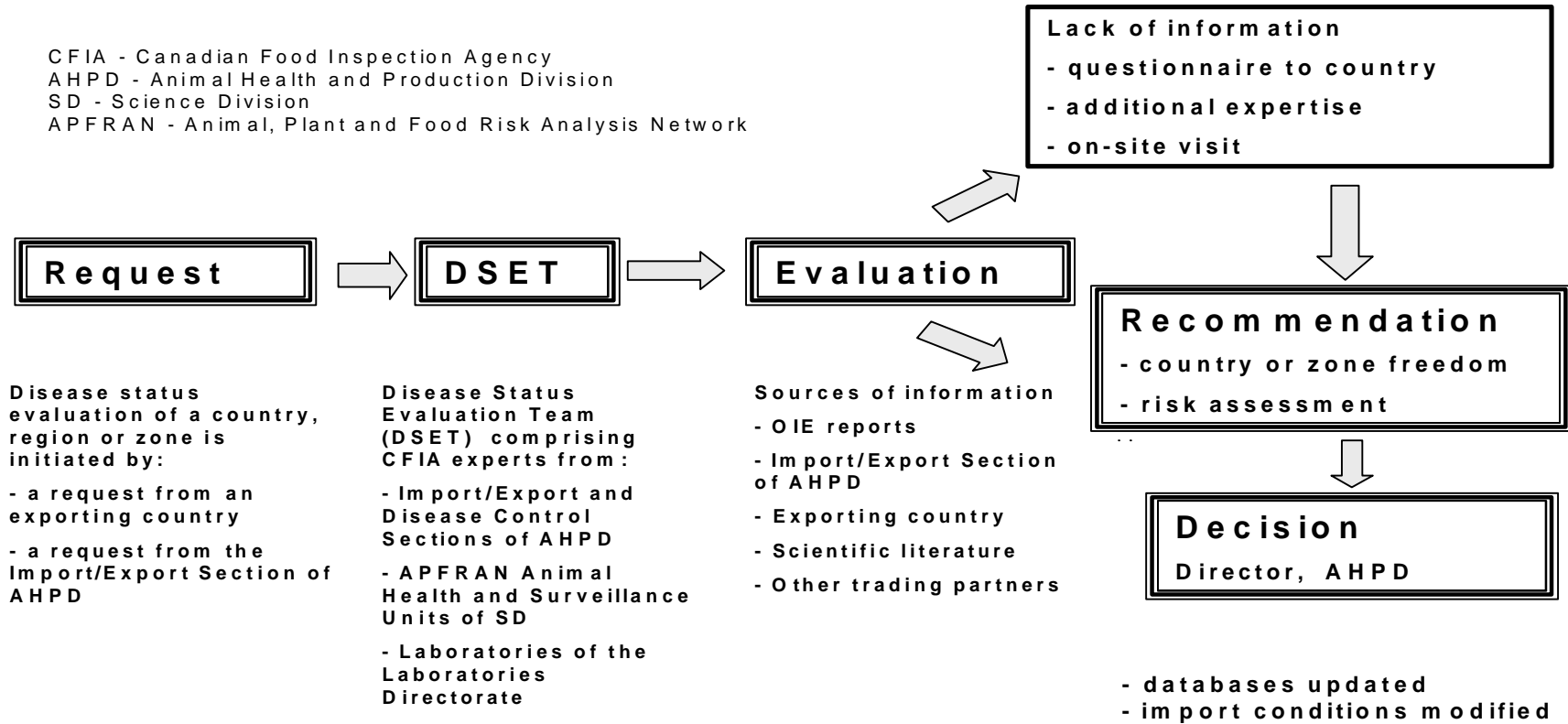
If one of the two conditions below apply, no further assessment is needed.

- The disease is not present in the continent where the country is located
- The disease is a vector-borne disease and the vector is not present in the country.

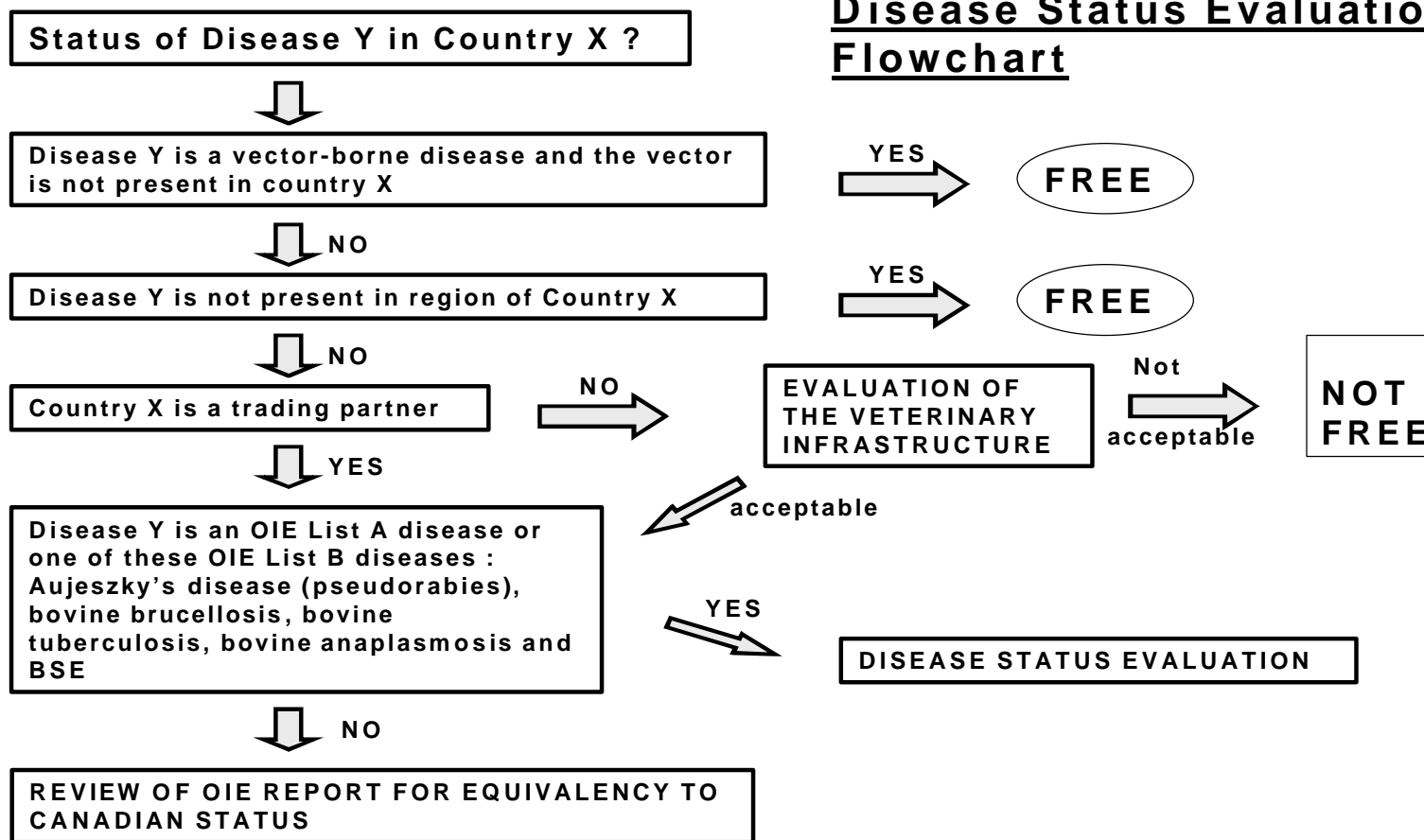
If none of the previous conditions apply, the determination of the equivalency status will be based on OIE reports since the country is a trading partner that is already officially recognized free of certain OIE List A diseases. If the disease status and control measures are equivalent to Canada's, equivalency is granted without further assessment. If differences exist however, further information is requested from the country to determine equivalency.

Disease Status Evaluation Steps

CFIA - Canadian Food Inspection Agency
AHPD - Animal Health and Production Division
SD - Science Division
APFRAN - Animal, Plant and Food Risk Analysis Network



Disease Status Evaluation Flowchart



CRITERIA FOR DISEASE STATUS EVALUATION OF A COUNTRY/REGION/ZONE

1. DISEASES OF CONCERN

The criteria for disease status evaluation of a country, region or a zone are applied to:

1. Foot-and-mouth disease
2. Vesicular stomatitis
3. Swine vesicular disease
4. Rinderpest
5. Peste des petits ruminants
6. Contagious bovine pleuropneumonia
7. Lumpy skin disease
8. Rift Valley fever
9. Bluetongue
10. Sheep pox and goat pox
11. African horse sickness
12. African swine fever
13. Classical swine fever (hog cholera)
14. Highly pathogenic avian influenza (fowl plague)
15. Newcastle disease
16. Aujeszky's disease (pseudorabies)
17. Bovine brucellosis
18. Bovine tuberculosis
19. Bovine anaplasmosis
20. Bovine spongiform encephalopathy

2. REPORT OF CASES

The disease must be compulsorily notifiable in the country, region or zone. No cases have been reported for a minimal period and a waiting period is required to regain freedom status after occurrence of the disease and appropriate cleaning/disinfection measures are completed.

OIE Standards for Minimal Periods With No Cases

D I S E A S E O F C O N C E R N	Minimal period with no case to GAIN disease free status		Minimal period with no case to REGAIN disease free status	
	STAMPING O U T	N O S T A M P I N G O U T	STAMPING O U T	N O S T A M P I N G O U T
FMD - <i>country</i>	12 months and no vaccination during that period	-	3 months	-
- <i>zone</i>	2 years and no vaccination for 12 months	-	3 months	-
VESICULAR STOMATITIS - <i>country</i>	-	2 years	-	-
- <i>zone</i>	-	idem	-	-
SWINE VESICULAR DISEASE - <i>country</i>	9 months	2 years	60 days for an infected zone	12 months for an infected zone
- <i>zone</i>	idem	idem	idem	idem
RINDERPEST - <i>country</i>	6 months	3 years	21 days for an infected zone	6 months for an infected zone
- <i>zone</i>	3 years	idem	30 days	6 months
PESTE DES PETITS RUMINANTS - <i>country</i>	6 months	3 years	21 days for an infected zone	6 months for an infected zone
- <i>zone</i>	idem	idem	idem	idem

D I S E A S E O F CONCERN	Minimal period with no case to GAIN disease free status		Minimal period with no case to REGAIN disease free status	
	STAMPING OUT	N O STAMPING OUT	STAMPING OUT	N O STAMPING OUT
CONTAGIOUS BOVINE PLEUROPNEUMONIA <i>- country</i> <i>- zone</i>	12 months for provisional freedom, no vaccination for 2 years 2 years for freedom from CBPP idem	3 years for provisional freedom, vaccination stopped 5 years for freedom from clinical CBPP, no vaccination for 2 years 7 years for freedom from CBPP, no vaccination for 4 years idem	2 years for freedom from CBPP idem	2 years for freedom from CBPP idem
LUMPY SKIN DISEASE <i>- country</i> <i>- zone</i>	- -	3 years idem	- -	- -
RIFT VALLEY FEVER <i>- country</i> <i>- zone</i>	- -	3 years idem	- -	- -
BLUETONGUE <i>- country</i> <i>- zone</i>	- -	2 years, no vaccination for 12 months idem	- -	- -
SHEEP POX AND GOAT POX <i>- country</i> <i>- zone</i>	6 months idem	3 years idem	21 days for an infected zone idem	6 months for an infected zone idem

DISEASE OF CONCERN	Minimal period with no case to GAIN disease free status		Minimal period with no case to REGAIN disease free status	
	STAMPING OUT	NO STAMPING OUT	STAMPING OUT	NO STAMPING OUT
AFRICAN HORSE SICKNESS - <i>country</i> - <i>zone</i>	2 years, no vaccination for 12 months idem	- -	2 years for an infected zone, no vaccination for 12 months idem	- -
AFRICAN SWINE FEVER - <i>country</i> - <i>zone</i>	12 months 12 months	3 years 3 years	12 months for an infected zone 12 months	3 years 3 years
CLASSICAL SWINE FEVER - <i>country</i> - <i>zone</i>	6 months or 1 year if vaccination is practised idem	2 years idem	40 days for an infected zone idem	6 months idem
HIGHLY PATHOGENIC AVIAN INFLUENZA - <i>country</i> - <i>zone</i>	6 months idem	3 years idem	21 days for an infected zone idem	6 months idem
NEWCASTLE DISEASE - <i>country</i> - <i>zone</i>	6 months (vaccination or not) idem	3 years idem	21 days for an infected zone idem	6 months idem

DISEASE OF CONCERN	Minimal period with no case to GAIN disease free status		Minimal period with no case to REGAIN disease free status	
	STAMPING OUT	NO STAMPING OUT	STAMPING OUT	NO STAMPING OUT
AUJESZKY'S DISEASE (PSEUDORABIES) - <i>country</i>	95% confidence level that the prevalence is less than 0.02%	-	95% confidence level that the prevalence is less than 0.02%	-
- <i>zone</i>	idem	-	idem	-
BOVINE BRUCELLOSIS - <i>country</i>	no reactors for 5 years	-	-	-
- <i>zone</i>	idem	-	-	-
BOVINE TUBERCULOSIS - <i>country</i>	99.9% of the cattle in tuberculosis-free herds for at least 6 years	-	-	-
- <i>zone</i>	idem	-	-	-
BOVINE ANAPLASMOSIS - <i>country</i>	no cases for 2 years (95% confidence level that the prevalence is less than 0.02%)	-	-	-
- <i>zone</i>	idem	-	-	-
BSE - <i>country</i>	6 years	-	6 years	-
- <i>zone</i>	-	-	-	-

- = no OIE standard specified
Idem = identical to that immediately above

3. VETERINARY INFRASTRUCTURE

Organization and structure of veterinary services of the country, region or zone are known.

- 3.1 Organigrams
- 3.2 Animal health budget
- 3.3 Number of veterinarians per sector
- 3.4 Legislation - regulatory measures for the prevention and control of the disease
- 3.5 Monitoring and audit programs
- 3.6 Livestock populations (recent census)
- 3.7 Industries profile (animal identification, marketing, movement patterns, feed and slaughter industries, biological and pharmaceutical industries)
- 3.8 Training and educational programs

4. LABORATORY SUPPORT

Laboratory support is adequate.

- 4.1 Level of containment
- 4.2 Diagnostic methods (protocols)
- 4.3 Transport of samples
- 4.4 Expertise of people

5. SURVEILLANCE MEASURES

The country, region or zone being evaluated must demonstrate that an effective system of surveillance is in place for early investigation of clinical disease, detection of the agent and reporting disease incidence and prevalence.

- 5.1 Scientifically-based surveys
- 5.2 Routine sampling and testing of animals
- 5.3 Organized sentinel program, if appropriate
- 5.4 Banking of biological specimens for retrospective studies, if needed
- 5.5 For zoning, a surveillance zone or physical or geographical barriers separate the free zone from the rest of the country and animal health measures effectively prevent the introduction of disease

6. IMPORT POLICIES

Import policies should be equivalent to Canadian import policies or not represent an unacceptable risk of introducing the disease into the country, region or zone.

7. CONTROL MEASURES

Control measures are in place to prevent spread of the disease if reintroduced into the country, region or zone.

- 7.1 The country, region or zone must have a record of regular and prompt animal disease reporting
- 7.2 An emergency plan is in place
- 7.3 An eradication program is in place
- 7.4 Traceback capabilities are adequate
- 7.5 Garbage (swill) feeding practices are controlled
- 7.6 There is a compensation program

8. VACCINATION PRACTISES

Vaccination policies are reviewed for equivalency with Canadian policies.

QUESTIONNAIRE INSTRUMENTS FOR THE DISEASE STATUS EVALUATION OF A COUNTRY/REGION/ZONE

The disease(s) to be evaluated is(are) _____

The country/region/zone to be evaluated is(are) _____

Instructions: Please provide detailed answers (English or French translation required) to these questions.

REPORT OF CASES

Describe the last outbreak in the area evaluated (date, number of cases, species, age of animal infected, source of infection, eradication procedures).

VETERINARY INFRASTRUCTURE

A. Organization and Structure of Veterinary Services

1. National Veterinary Services
Please provide an organogram (or organizational chart), which includes numbers, positions, and number of vacancies, and describe the role of veterinarians in establishing national and state animal health policy.
2. Sub-national Veterinary Services
Do the above listed states have a full-time state veterinary service?
Please provide organograms, which include numbers and positions.
3. Other providers of Veterinary Services
Describe linkage with other providers of veterinary services.

B. Human and Material Resources

1. Total number of veterinarians who are graduates from internationally-recognized veterinary schools registered in the WHO/FAO World Directory of Veterinary Schools (national and subnational).
2. Number of full-time government veterinarians (national and subnational).
3. Number of part-time government veterinarians (national and subnational).
4. Number of private veterinarians authorized to perform official veterinary functions. Please provide a list of accredited veterinarians per function.

5. Animal Health

Number of veterinarians whose practices are associated principally with farm livestock sector, list by geographical area (show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export, and other functions, as applicable).

6. Veterinary Public Health

Number of veterinarians employed in food inspection, list by commodity.

7. Number of technical assistants employed by the Veterinary Services:

- involved with farm livestock
- involved with food inspection

8. Total budgetary allocations to the Veterinary Services for the current previous fiscal years

9. Summary of the forms of communication systems available to the veterinary services, on a nation-wide and local area basis.

10. Summary of the numbers and distribution of official administrative centres of the veterinary services (national and subnational) in the country.

C. Legislation

1. Animal health and veterinary public health

Information is requested, to verify the legal mandate to regulate AH and VPH issues on national and regional basis with specific reference to:

- animal and veterinary public health controls at national and regional (state) frontiers,
- control of endemic diseases of livestock,
- emergency powers for control of exotic disease outbreaks,
- compensation provisions for animal owners that are affected by disease control measures, and
- registration and use of veterinary pharmaceutical products, including vaccines.

A copy of current enabling legislation for federal animal health activities is requested (English or French translation required).

D. Monitoring and Audit Programs

1. Descriptive summary of any compliance unit that monitors the work of the Veterinary Services

2. Copies of official annual reports of the national and subnational Veterinary Services
3. Copies of reports of official reviews of the function or role of the Veterinary Services, which have been conducted within the last three years.

E. LIVESTOCK POPULATION

1. Date of most recent census of animal population of susceptible species of the disease evaluated
2. Most recent census statistics for national herd by state/province - number of animals, number of herds/flocks.
 - 2.1 National herd
 - commercial operations
 - small land operations
 - 2.2 Zone/region herd
 - commercial operations
 - small land operations
3. Most recent annual statistics for animals marketed and animals slaughtered by state/province - number of animals.
 - 3.1 Markets
 - 3.2 Abattoirs
 - federal
 - state/provincial

LABORATORY SUPPORT

1. Elaborate on the diagnostic laboratory infrastructure (descriptive summary of the organizational structure and role of the government veterinary laboratory service, particularly its relevance to field veterinary services).
2. What level of containment is required for diagnostic laboratories?
3. What specimen collections are routinely collected for diagnosis and how are they transported?
4. What diagnostic methods are used?
5. What reference laboratories are used to confirm diagnosis of the disease?
6. List the number of samples (and sample types) received for the disease diagnosis from (i) the zone/region, and (ii) nationally, for the last three years. Provide results.
7. What internal and external quality assurance program do you use?

8. Do private laboratories receive samples for testing? If so, describe accreditation process and reporting of results.
9. What kind of training have the diagnostic personnel had regarding the specific disease agents of concern?

SURVEILLANCE MEASURES

1. Describe standard surveillance procedures for the disease evaluated (i) in zone/region evaluated, and (ii) in the adjacent areas. (Disease agents tested for, number of samples submitted annually for the last 3 years, and results).
2. If a serological screening for antibodies was to be conducted in the zone/region/country by accredited veterinarians, describe the method used and the statistical data obtained.
3. Is reporting of sick animals to state or national veterinary services mandatory? Explain procedure.
4. Describe the reporting method to the National Veterinary Services.
5. Describe the reporting method of suspicious and/or confirmed diagnoses to other countries. If the zone/region/country was recognized a free area, what process would be used to notify trading partners of an outbreak?
6. Are quarantines imposed on premises with suspicious cases, pending final diagnosis?
7. Describe the animal identification system in use for swine.
8. What geographic and environmental characteristics of the exporting region may influence the prevalence of the pest of disease agent?

IMPORT POLICIES

For zoning and regionalisation requests, compare the national policy/program to that of the zone/region.

1. From what countries or parts of countries do you allow the importation of susceptible species?
2. Is importation of susceptible animals, meat and products into the zone/region from other areas of your country permitted? If so, please list the areas and the commodities imported.
3. Has your country recognized parts of countries to be free from the disease? If so, which ones and on what basis?

4. Identify major classes of animal products being imported and source countries.
5. Describe your import policies with regard to disease status of the exporting country.
6. Describe the program with specific reference to inspection procedures at international air and marine ports, and interstate airports.
7. What are the control measures for the entry of imported animals and animal products (certification, inspection, quarantine, tests...)? Provide examples of relevant documents and verification process used.
8. Provide statistics on border inspection activities along the border between the zone/region and neighbouring areas, including the number of commercial importations inspected, the number of vehicles inspected, and the quantity of animals and animal products seized by your inspectors, with emphasis on the zone/region points of entry.
9. Describe the import program for veterinary biologics, and provide details on swine vaccine importations (quantity, country of origin).
10. Describe any policies/program relative to the disposal of food wastes from arriving international aircraft and ships.
11. What are the patterns of livestock movements within the zone/region/country evaluated?
12. How are the animals transported and handled during market transactions?
13. For each relevant hazard, is the pest or disease agent known to exist, or has it existed previously, in any region adjacent to the zone/region/country evaluated? If yes, at what prevalence? If no, when was the most recent diagnosis?
14. Are there any relevant factors about the adjacent regions that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)?
15. To what degree is the region separated from regions of higher risk through physical or other barriers?

CONTROL MEASURES

1. If an outbreak should occur in the area, what control procedures would be used? How do they compare with the National eradication program?
 - a. Are the procedures different for infected herds vs exposed herds?
 - b. Do they include total depopulation with burial, burning, or rendering of infected herds?

- c. Would slaughter with carcass salvage at abattoir be permitted (salvage of apparently healthy animals from infected herds or exposed herds)?
 - d. Can you describe the compensation program funded by producer organizations?
2. Does your country permit the feeding of commercial garbage to swine? If so, what restrictions are imposed? Number of garbage (swill) feeding operations?
3. What restrictions are placed on the movement of domestic livestock exposed to communicable diseases?
4. How are investigations, which determine the source of infection, routinely practiced?
5. Are quarantines placed on premises and/or areas where disease outbreak is suspected? If so, define quarantine.
6. Describe normal animal movement/marketing patterns from swine breeding units to the abattoir, including use of auction markets, assembly yards, etc.
7. What are the controls on the movement of animals and animal products during a disease outbreak?
8. After depopulation of an area that was infected, what methods are used to detect and prevent the introduction of infection through repopulation?
9. Is the administration of serum permitted? If so, under what conditions? Who may administer?
10. Is the use of BVD vaccine permitted for swine? (*For request on Classical swine fever, only*)
11. What is the process for gathering information on disease outbreaks? (electronics, otherwise).

*Please provide examples of documentation used in disease control activities.

VACCINATION PRACTICES

1. When was a vaccine last officially or legally used in the area? How do you ensure it is no longer being used?
2. Where are the laboratories that currently produce vaccine located?
3. What type of controls are applied in the laboratories?
4. In what areas is vaccination for the disease permitted? Number of doses of vaccine used annually? How are vaccinated animals identified? Provide examples of certification and tag used.

**QUESTIONNAIRE INSTRUMENT FOR THE EVALUATION OF THE
BOVINE SPONGIFORM ENCEPHALOPATHY DISEASE STATUS OF
A COUNTRY/REGION/ZONE**

QUESTIONNAIRE

RISK ANALYSIS

1. Was a risk analysis conducted to assess BSE risk factors in your country? If so, please supply a copy of the document.

(It is not necessary to answer the following questions if the information is provided in the risk analysis document)

LEGISLATIVE AUTHORITY

1. Are there animal health legislations in place relative to BSE ? If so identify, describe and give dates of introduction.

RUMINANT POPULATIONS

1. Can you describe your cattle, sheep and goat populations?
- number of animals per species
- system of identification, and capacities of tracing animals

ANIMAL TRADE

1. Can you describe your BSE importation policies regarding live ruminants and embryos of cattle, sheep and goats as well as the geographical origin of these importation from 1988 to present.
2. What is the use of imported animals and embryos (fattening, breeding, milk production. etc.)?
3. What are the mechanisms used by slaughterhouses to identify animals and their origin?
4. If cattle and bovine embryos were imported from BSE infected countries describe how the animals are monitored or controlled for BSE and what restrictions are imposed at slaughter.

ANIMAL FEED

1. Is your country producing mammalian derived meat and bone meal (MBM)? If so, describe its use per species and husbandry system?
2. Have you imported mammalian and/or ruminant derived MBM? If yes,

list totals imported by country of origin and date of importation from 1987 until present.

3. Were there any restrictions imposed on these importations?

MEAT AND BONE MEAL BANS

1. What is the nature of any ban (when introduced, full description including species involved)?
2. Can you provide details on the implementation, auditing and compliance/breaches statistics?
3. How do you ensure that there is no cross-contamination between banned feed and other feed?

SPECIFIC BOVINE OFFALS (SBO) AND SPECIFIED RISK MATERIAL (SRM) BANS

1. Is there any ban in place (when introduced, full description including species, tissues and ages of material used)?
2. Can you provide details on the implementation, auditing and compliance/breaches statistics?
3. Have you imported bovine offals since 1988? If so, from where? Describe restrictions and end use.

SURVEILLANCE OF TSE WITH PARTICULAR REFERENCE TO BSE AND SCRAPIE

1. What is the incidence of laboratory confirmed cases of BSE and scrapie? Have other TSEs (excluding CJD) been diagnosed in your country? Please supply details.
2. What are the age distribution, geographical distribution and countries of origin of cases?
3. What is your clinical definition of BSE suspect including age?
4. What is the incidence of suspect cases in which BSE could not be excluded clinically?
5. Describe surveillance methods, programs, reporting procedures and record keeping of clinical cases of BSE and scrapie.
6. Describe training and educational efforts for awareness of farmers, veterinarians control services and authorities.
7. What are the incentives for reporting cases (e.g. compensation)?

8. What are your procedures of laboratory confirmation and recording of suspect cases of BSE and scrapie? (Supply copies of standard operating procedures (SOPs)).

RENDERING AND FEED PROCESSING

1. Can you describe all rendering and feed processing systems used?
2. Can you describe the type of material used?
3. How do you ensure that during processing, transport and storage cross-contamination of feed with MBM containing mammalian or ruminant material will not occur?

BSE OR SCRAPIE RELATED CULLING

1. Describe all culling related to BSE and scrapie, targets of culling and animals involved.

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