Risk assessment in international trade
The SPS agreement and the international standard setting organizations

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Seminar on Risk Assessment procedures in SPS issues: the EU versus the USA approaches
The Agreement on the Application of Sanitary and Phytosanitary Measures ("the SPS Agreement") sets out the basic rules for food safety and animal and plant health requirements.
All countries maintain measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants.

And at the same time that unnecessary health and safety regulations are not used as an excuse to protect domestic producers from foreign competition?
Why have an SPS Agreement?

Because sanitary and phytosanitary measures can so effectively restrict trade, WTO member governments want to have clear rules on how they can be used.

The SPS Agreement is designed to set out clearer, more detailed rights and obligations for food safety and animal and plant health measures which affect trade.

Countries are permitted to impose only those requirements needed to protect health which are based on scientific principles.
The SPS Agreement explicitly permits governments to choose their own standards. But regulations must be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal or plant life or health.

They should not unjustifiably discriminate between countries where similar conditions exist.
Adapting to conditions:

Due to differences in climate, existing pests or diseases, or food safety conditions, it is not always appropriate to impose the same sanitary and phytosanitary requirements on food, animal or plant products coming from different countries. This is taken into account in the SPS Agreement.

Governments should also recognize pest and disease-free areas which may not correspond to political boundaries, and adapt their requirements so that they are appropriate for products from these areas, an approach known as “regionalization.”
The SPS Agreement makes sanitary and phytosanitary measures more transparent.

Governments are required to notify each other, through the WTO Secretariat, of any new or changed sanitary and phytosanitary requirements which affect trade.

Each WTO member must also set up offices (called “Enquiry Points”) to respond to requests for more information on new or existing SPS measures.

This information is now readily available in a comprehensive online database, the SPS Information Management System (http://spsims.wto.org).
SPS Committee

A special committee has been established within the WTO as a forum for member governments to exchange information on all aspects of the SPS Agreement’s implementation.

If a legal dispute arises on a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.
In 2001, the heads of the FAO, OIE, WHO, WTO and the World Bank agreed to work together to improve technical assistance in SPS. This led to the creation of the Standards and Trade Development Facility (STDF), which serves to raise awareness of the importance of compliance with international SPS standards and coordinates the provision of SPS-related technical assistance. More information, including eligibility criteria and application forms, is available on the STDF website (www.standardsfacility.org).
Role of the International Organizations

- for food safety, the joint FAO/WHO Codex Alimentarius Commission (Codex);

- for animal health, the World Organisation for Animal Health (previously known as the Office International des Epizooties - OIE);

- and for plant health, the International Plant Protection Convention (IPPC), based in FAO.
Specific role of the OIE

One of the main aim of OIE is to ensure the sanitary safety of international trade in live animals and their products. This is achieved by providing standards, guidelines and recommendations on the health measures to be used by the competent authorities of importing and exporting countries to prevent the introduction and spread of pathogens while avoiding unjustified trade barriers. The standards are laid out in the Codes and Manuals for terrestrial and aquatic animals.
Member Country obligations

See the OIE document “International trade: Rights and Obligations of OIE Members”: http://www.oie.int

- Notification obligations:
  Terrestrial Code: Notification of diseases and epidemiological information which is necessary to minimise the spread of important animal diseases and to assist in achieving better worldwide control of these diseases”.

- Countries shall also provide information on the measures taken to prevent the spread of diseases e.g. quarantine measures, controls on the movement of animals, animal products...that could be responsible for disease transmission (including vectors, where applicable).
General obligations

- The animal health situation in the exporting country, any transit country, and the importing country should be considered before determining the import health measures required for trade.

- To maximise harmonisation of the sanitary aspects of international trade, Members should base their import health measures on OIE standards;

- Certification requirements should be exact and concise, and should clearly reflect the agreed positions of the trading partners.
Importing country obligations
Import health measures should reflect the national level of protection for animal and public health and should not be more restrictive than the measures for the same pathogens/diseases in that importing country.

Exporting country obligations
- Be prepared to supply to the importing country information relevant to the safety of the traded commodity
- Establish inspection and certification procedures for certifying officials, with appropriate controls.
Import Risk Analysis/Risk Assessment/Risk Evaluation: What for?

- To provide importing countries a method of assessing the disease risk associated with importation of animals and animal products.

- To provide exporting countries clear reasons for the imposition of import conditions or refusal to import.

- To ensure stakeholders and decision makers that the risks posed by import goods are identified and managed effectively.
Global approach resulting in:

- A risk level being defined: as a result of the risk assessment

- Measures to control the risk being defined and implemented: risk management
Risk analysis is used for

- Import: trade based, identification of hazards, sanitary measures for risk management
- Any other situation where decision is made to manage uncertainty:
  - Planning for new disease outbreaks: identify major risks, assess the risk, better understand possible entry points, detect and respond through preparedness planning...
  - Zoning: preparedness planning, targeted surveillance
  - Endemic disease: RA to help decisions on surveillance, control and eradication
Reasons to undertake risk analysis

- Import of a new commodity or from a new country
- Occurrence of a new disease in a neighbouring country or a country which export goods to your country
- Occurrence of a new disease in your country
- A change in the pattern or severity of an endemic disease
- Occurrence of a new vector which can transmit a disease
- Decision to design a surveillance or a control or eradication programme
Risk analysis for policy and decision making

- To prepare contingency plans
- To strengthen quarantines and border controls
- To better target surveillance
- To strengthen diagnostic capabilities
- For training and awareness for veterinary staff and other stakeholders
Roles of veterinary services

- **Goals:**
  - Improving the livelihoods of farmers
  - Ensuring that food is safe for consumers
  - Promoting trade

- **Throught:**
  - Preventing occurrence of new diseases: prevent incursion, detection, response
  - Decreasing the impact of diseases: control, eradication
Using a range of technical tools

- Surveillance
- Management of the information
- Laboratory diagnostic
- Risk analysis
- Quarantine, zoning
- Contingency planning
- Epidemiology investigation
- Implementation of control programmes
- Economic analysis
- Extension
Setting health measures

SPS Agreement gives WTO members two options:

To base health measures on the international (OIE, Codex) standards (preferable)
or:
To conduct a scientific risk analysis
  • where there is no relevant standard, or
  • when a Member chooses to adopt a higher level of protection than that provided by the OIE standards.

Setting health measures always involves risk analysis, in some form.
Measures may be a combination of the OIE standards and additional measures acceptable to the importing country and its trading partners.
Components of Animal Health Risk analysis

- The initiation phase: hazard identification
- Risk assessment: estimation of the risk associated with the hazard to enter, establish, spread and cause damage to livestock and the environment
- Risk management: measures to reduce the risk
- Risk communication: communication with stakeholders throughout the risk analysis process
Risk Analysis

Hazard Identification → Risk Assessment → Risk Management

Risk Communication
Risk Assessment

Entry (Release) Assessment

Exposure Assessment

Consequence Assessment

(Probability of the Hazard Occurring)

Risk Estimation

Risk Evaluation (Part of Risk Management)
The elements of risk management

Source: Canadian Food Inspection Agency (2005)
OIE Code and handbooks

 CHAPTER 2.1.

 Import risk analysis

 OIE Handbook on Import Risk Analysis for Animals and Animal Products

 Framework for risk analysis, based on OIE standards and epidemiological rules
Identify the hazard(s)

Identify the Code recommendations on trade for the disease(s) under consideration:

For listed diseases there are chapters in the Code:
On the host species and commodities traded.
Listing ‘safe commodities’ for which an importing country should not impose measures, regardless of the status of the source country for that disease.
Recommending measures for safe trade in other commodities, taking into account:
• the nature of the commodity (live animal, genetic material, product for human consumption or other use)
• the health status of the country (or zone) from which the commodity is imported
• the intended purpose (eg dairy products as human food vs. for feeding to calves).
Determine measures

- **Option 1:** Adopt the OIE recommendations (strongly recommended).
- **Option 2:** Where the *Code* does not make recommendations for a particular commodity, it means that OIE experts have not yet developed relevant health measures. In this case, conduct a scientific risk analysis.
- **Option 3:** If the OIE recommendations do not meet the importing country’s accepted level of risk: conduct a scientific risk analysis risk.

Draft an import health certificate
OIE standards, guidelines and recommendations address:

- Trade safety
- Animal and human health
- Animal productions
- Food security, poverty alleviation
- Income generation
A mandate far wider than when the OIE was created

To prevent the spread of animal diseases throughout the world (1924)

To improve animal health worldwide (4th Strat. Plan 2006-2010)

FIFTH STRATEGIC PLAN 2011 - 2015

Improve animal health, veterinary public health, animal welfare, and consolidate the animal’s role worldwide
First, continuing to consolidate major objectives of the 4th Strategic Plan

- Transparency of world animal disease situation (including zoonoses)
- Collect and publish veterinary scientific information, notably animal disease prevention and control methods
- Sanitary safety of international trade in animals and their products under the mandate given by the WTO
Reinforcing priority missions of the Fifth Strategic Plan 2011-2015

**Food security:**
- Food security (from quantitative and qualitative perspective) is a key public health concern
- Healthy animals guarantee food security and food safety

**Food safety:**
- Need for a global supply of safe food
- The Veterinary Services must play a key role in protecting consumers

Developing international standards on animal welfare
Animal health is a key component of animal welfare
OIE Standard setting process

- Specialized Commissions:
  Scientific Commission for Animal Diseases, Code Com., Biological Standards Com., Aquatic animals Com.

- Ad Hoc Groups: FMD Vaccine Quality, FMS Status, PPR, PRRS, Brucellosis, CSF, RVF, Epidemiology, Trade in animal products, Antimicrobial resistance...

- Working Groups: Wildlife, Food safety...
Proposed Standards sent to all OIE Delegates

Comments from all OIE Delegates
Consultation of major partners
Second round of discussions with Commissions...

General Session May
Adoption: vote of all Delegates during the World Assembly
Proposed Standards sent to all OIE Delegates

Transparency

New texts for Conflict of Interest and Confidentiality

Top down and bottom up process
Democratic process
Aquatic Animal Health Code

2011 Fourteenth Edition
OIE Tools

- HQs Departments:
  Scientific & Technical,
  Animal Health Information,
  International Trade,
  Regional Activities

- Expertise
The OIE’s scientific Network

OIE Reference Centers
225 laboratories, 111 diseases/topics in 37 countries

40 Collaborating Centres
38 topics in 21 countries
Disease information

The OIE Early Warning System

OIE Headquarters

Warning (within 24 hours) in the OIE official languages

Country at risk

Infected country

OIE Members
Other International Organizations

OIE Info Distribution List
OIE Web Site

National Veterinary Services
Preventive action

National Veterinary Services
Preventive action

World Animal Health Information Database

WAHIS
- Immediate notifications & follow-up reports
- Semestral reports
- Annual report

WAHID

SAMBA 1996-2004

HandiStatus II 1996-2004

OIE-info distribution list: Alert messages and RSS feeds

WAHID Interface

World Animal Health publication
Global Early Warning System (GLEWS)

DISEASE TRACKING
DATA ANALYSIS
DISEASE INTELLIGENCE

Fundamental activities
for targeted surveillance, prediction,
awareness and reporting to OIE

And then for the appropriate response: choice
of tools, methods and strategies
Permanent institutional cooperation

FAO - Food and Agriculture Organization
WHO - World Health Organization
CODEX ALIMENTARIUS - International Food Standards
WTO - World Trade Organization
IPPC - International Plant Protection Convention
World Bank
CABI - CAB International
ILRI - International Livestock Research Institute

And cooperation with Regional public organisations and private sector bodies
(more than 50 agreements)
International Cooperation

FAO - OIE GF TADS

Global Framework for the Progressive Control of Transboundary Animal Diseases
Underlying principles

- Scientific advances to be translated in the Code
- Standards OIE to be used by importing/exporting countries
- Quality of Veterinary Services to implement and certify
- Risk based approaches, Risk analysis
- Regional/international approaches
Underlying principles

- Multisectoral approaches
- Private Public Parternership
- Other factors than sciences to be addressed:
  
  Consumer perception
  
  Economical and political pressure
Challenges for the normative Organizations

- Globalization/increase of exchanges
- Food security and poverty alleviation
- Emergence and bioterrorism
- Wildlife
- Reduction of Veterinary Services budgets
- Commodity trade/commodity based
- Heterogeneous education levels: evaluation, core curriculum
Additional new challenges for the normative Organizations

- Additional conditions/consumer perception: animal welfare, residues
- Political pressure
- Direct bilateral agreements between importing and exporting countries
- Private standards
- Increasing role of the private industry

Good management practices...

Sciences-based and risk-based approaches to be maintained
Interface between Risk Assessors and Risk managers

Risk Management:
- Process of identifying, selecting and implementing measures that can be applied to reduce or avoid the level of risk associated with the particular hazard(s) being considered.

- Managing risk to achieve an Appropriate Level Of Protection (ALOP: term being used in the SPS agreement. Can be also named « acceptable level of risk »)
- Ensure an appropriate balance between minimizing the likelihood of disease incursions and their consequences and the desire to import commodities while fulfilling the international obligations under trade agreements

- The ALOP should be justified and achievable

- There is no zero risk: a zero risk approach cannot be used by the stakeholders to ask for a total import ban.
- There is no unique and well define level of acceptable risk applicable to all countries and all commodities. Each country can choose its own Appropriate Level Of Protection (ALOP) which is a societal and political judgement

- ALOP to be decided before any decision regarding import and implementation of risk management measures
- There are possible conflicts of interest between a private importer and the rest of livestock industry stakeholders and general public (taxpayers who will bear the cost of eradicating an introduced disease):
  
  e.g. import of less expensive goods with subsequent economic competition with other stakeholders  
  
  e.g. import of superior genetic stock with benefits for the importing entrepreneur only
Within this context, it is indispensable that the risk assessor and the risk manager be in close interaction but at the same time that their respective roles are clearly defined.

- E.g. is the risk assessor responsible to estimate the risk only, or also to propose a range of management options, or to recommend some of them?

- In principle Risk Assessment and Risk Management processes should be separate since RA is a technical science-based process while RM incorporates value judgments
Conclusions

- WTO Members should meet the WTO SPS rules, i.e., use of international standards and risk analysis.
- Health measures for animals and products should be based on OIE standards, where these exist, or risk analysis, taking into account all relevant OIE guidance.
- Information on the disease status of exporting countries is available in WAHID (and should be validated with the Veterinary Authority).
The credibility of the Veterinary Services (VS) in providing information on the country’s disease situation, reporting to the OIE and issuing reliable veterinary health certification, is paramount.

The OIE encourages Members to follow the PVS Pathway to improve compliance with OIE standards for efficient VS.
However, these guidelines in themselves cannot provide full protection against disease incursion and spread.

National and farm level biosecurity precautions are essential adjuncts to OIE standards. All stakeholders must play their part to the full to ensure that biosecurity measures are effective in preventing disease occurrence and spread.
Thank you for your attention