

# **Risk analysis as a unifying concept in the work of the international “SPS” organisations**

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**“The great nations have always acted like gangsters, and the small nations like prostitutes”**

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# International organisations and instruments

- CAC - food safety
- OIE - animal health and zoonoses
- IPPC - plant health
- CBD – biosafety and invasive alien species
  
- ➔ Ever-increasing work programmes, but limited expertise



# Risk analysis in “biosecurity”

- ⇒ What can go wrong?
- ⇒ How likely is it to go wrong?
- ⇒ How serious would it be if it went wrong?
- ⇒ What can be done to reduce the likelihood of it going wrong?

# Risk analysis

- ➔ Each "biosecurity" sector has different history and usage, but many aspects are common
- ➔ Clear trend at the national level towards institutional approaches that bridge the various sectors
- ➔ Clear incentive at the international level for increased co-operation and harmonisation of approaches between parties responsible for applying different agreements and legal instruments

# Food safety

- ➔ Generic framework for managing risks established
- ➔ “Safety evaluation” (“notional zero risk”) for chemicals, but few quantitative standards for microbes
- ➔ Microbiological RA suffers from lack of data, uncertainty, non-representativeness
- ➔ International consensus on ALOP is difficult
- ➔ Equivalence is a key issue

# Animal health

- ➔ OIE Codes contain provisions on import risk analysis, but basis for zoonoses standards not clear
- ➔ Risk management only addressed in general terms
- ➔ Standards reflect a “broad agreement concerning the likely risks” but linkages not specified
- ➔ Consequence assessments can be direct e.g. production losses, or indirect e.g. potential trade losses

# Plant health

- ⇒ IPPC covers plants, wild plants, risks to environment
- ⇒ Risk estimates for probability of introduction, and economic consequences, but methodologies not described
- ⇒ Non-commercial, social and environmental consequences difficult to quantify in economic terms
- ⇒ Risk management only addressed in general terms, but recognition that some risk of introduction of a quarantine pest always exists

# Biosafety

- ➔ CBD has objectives of conservation of biological diversity, sustainable use, and fair and equitable sharing of benefits from use of GMOs
- ➔ Cartagena Protocol on Biosafety to the CBD applies to trans-boundary movement of GMOs, with less onerous grounds for restricting imports cf. SPS Agreement
- ➔ RA methods and framework for managing risks not well developed

# Invasive alien species

- ➔ CBD also covers the introduction and safe management of invasive alien species and genotypes that threaten ecosystems, habitats or species
- ➔ RA methods and framework for managing risks not developed
- ➔ Burden of proof lies with the proposer



# Exploring the synergies in “biosecurity” risk analysis

- ➔ Rapid development within sectors
- ➔ Experience and progress not necessarily shared between sectors
- ➔ Potential to: improve risk analysis both within and between sectors, provide for consistency in approaches and outputs, and facilitate better uptake and understanding by all stakeholders



# 1. Generic framework for managing risks

- ➔ Reduce the ambiguous use of terminology
- ➔ Develop a generic framework for managing risks
- ➔ Functional separation of RA and risk management
- ➔ Seek to improve collaboration among diverse interests and institutions (particularly public health, agriculture, environment, trade, and their associated stakeholders) to achieve biosecurity in a mutually supportive manner

# Agreed process: Framework for managing risks



- STEP **1** Preliminary risk management activities
- STEP **2** Assessment of risk management options
- STEP **3** Implementation of measures
- STEP **4** Monitoring and review

## 2. Assessment of risks

- ➔ Identify and accept differences in RA, but ensure each sector benefits from the experiences of others
- ➔ Explore different treatment of economic aspects
- ➔ Food safety RA generates estimates that are considerably above unity, whereas animal and plant health RA is often trying to estimate risks that are extremely small fractions

### 3. Decisions on management of risks

- ➔ Costs and benefits need to be evaluated in an understandable and transparent manner
- ➔ Decision-making criteria are arguably best developed for food safety
- ➔ Risk management is only addressed in general terms by OIE, IPPC and the CBD, and criteria and processes for determining ALOP are not well developed



## 4. Precaution

- ➔ Irrespective of international debate, is implicit in most RA and risk management processes
- ➔ SPS Agreement describes a general approach i.e. adopt provisional measures until more complete RA available
- ➔ CBD / Cartagena Protocol provide more latitude: “lack of relevant scientific information and knowledge regarding the extent of the potential adverse effects of a GMO shall not prevent a party from taking a decision on an importation”

## 5. Risk communication

- ⇒ Arguably presents the greatest level of commonality
- ⇒ Addressed by other presenters in this Symposium



# Conclusion

- ➔ Not appropriate to develop "one-size-fits-all" approach
- ➔ Need a "toolbox" that provides sets of principles and guidelines in international and national contexts
- ➔ Traditional focus on regulating individual sectors / systems is shifting to one of ensuring confidence in overall regulatory frameworks at all levels
- ➔ Development of a more unified approach in risk analysis would assist understanding of biosecurity, and the optimisation of scarce resources in developing countries