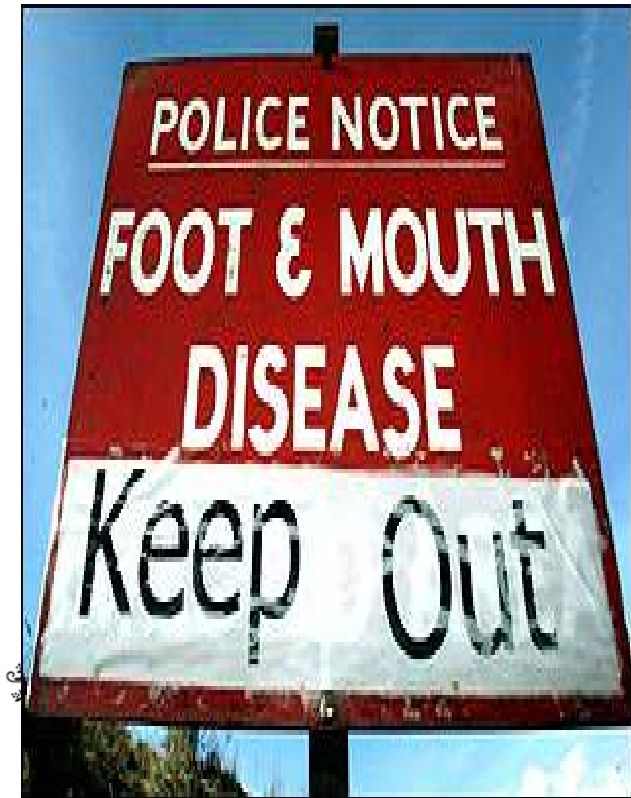


# Biosecurity Risk Analysis in Australia

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# Overview

- Introduction
  - biosecurity risk analysis
  - Biosecurity Australia
- Risk analysis and trade
  - the SPS Agreement
  - the OIE/IPPC framework
- Issues and challenges
- Conclusions



# 'Biosecurity risk analysis'?

- Environment (EIA)
- Human health
  - e.g. FSANZ (using *Codex* framework)
- GMO
  - e.g. GMAC (using UN Convention on Biological Diversity)
- Quarantine
  - exports (to gain market access or on behalf of another country)
  - imports (in response to access requests)
    - IRAs (including 'PRAs')
    - 'policy reviews'
    - advice (operational)



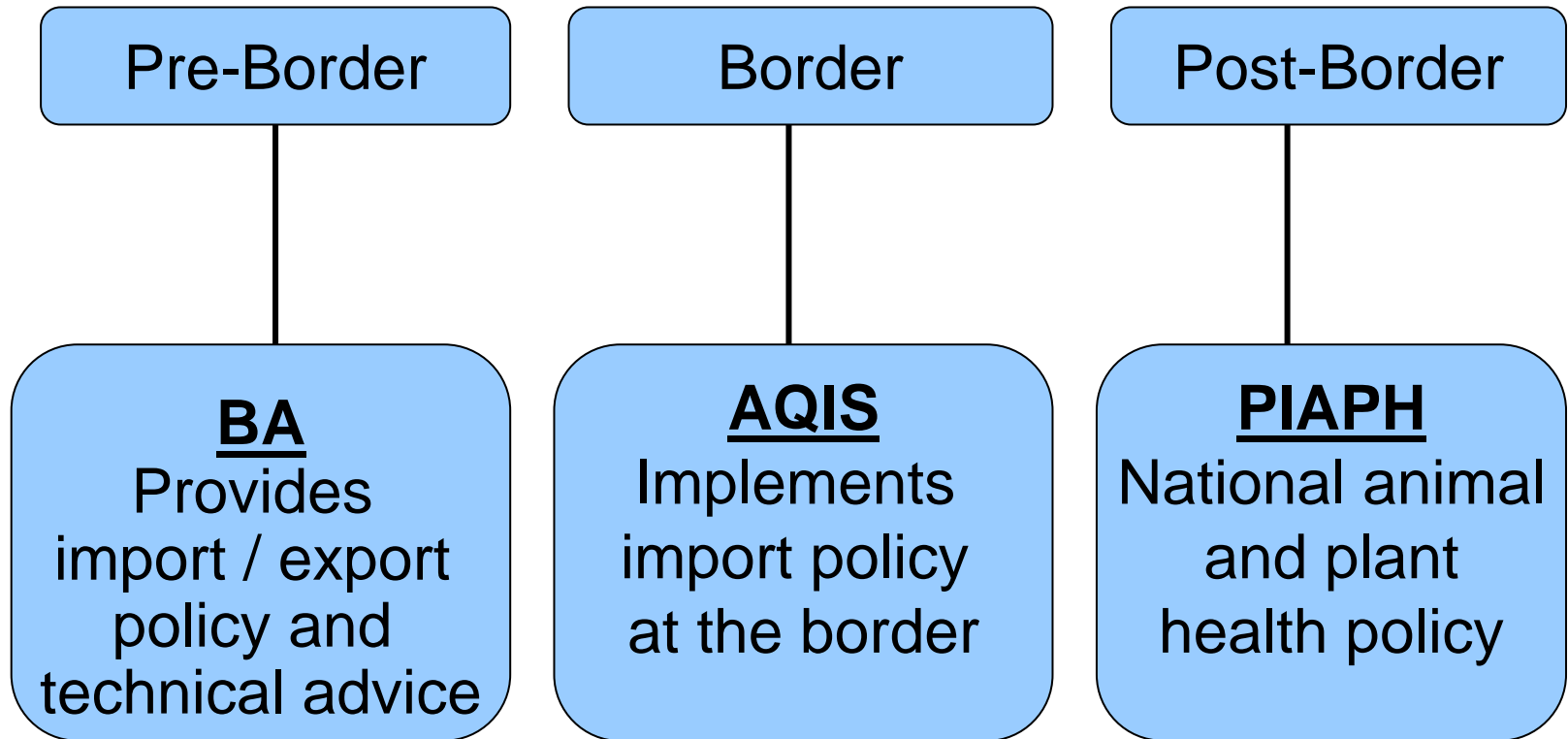
# Biosecurity Australia

- An agency of some 130 people
  - plus externally contracted resources as needed (research, statistical, legal etc.)
- A budget of about \$17 million p.a.
- Structured into three groups:
  - Animal Biosecurity
  - Plant Biosecurity
  - Biosecurity Development and Communications



# Where does BA fit?

## Continuum of Quarantine



# What does BA do?

- Scientific analysis related to trade
  - imports (IRAs, policy reviews)
  - exports (technical market access)
- Technical advice and support
  - imports/exports, health status etc.
- Policy advice
- International standards
- Capacity building (Asia–Pacific)



# How does BA do this?

- Within an international regulatory framework and obligations
- Using sound science to underpin decisions:
  - science, policy, politics
- Under very close scrutiny
  - Australian stakeholders
  - overseas governments and industries
- With some difficulty!



# The Trade Environment

- World Trade Organization (WTO)
  - Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement)
  - Agreement on Technical Barriers to Trade (the TBT Agreement)
- Standards and guidelines
  - World Organization for Animal Health (OIE)
  - Codex Alimentarius Commission
  - International Plant Protection Commission



# The biosecurity environment

- Australia has a unique and valued natural environment, and its animal and plant health status is very good
  - for example, animal health:
    - free of all 15 ‘List A’ diseases (FMD, HPAI etc.)
    - free of other significant diseases (BSE etc.)
- We have something worth protecting
  - perception here is that we have ‘lowered’ biosecurity standards in response to trade pressure
    - despite never having had a ‘zero risk’ approach
    - despite fact that many imports are sought here (e.g. genetic material)



# Risk Analysis

- Risk assessment
  - identifying and estimating the risks associated with an option and evaluating the consequences of taking those risks
- Risk management
  - identifying, documenting and implementing measures to reduce these risks and their consequences
- Risk communication
  - interactive exchange of information and opinions concerning risk between risk analysts and stakeholders



# The SPS Agreement

- Establishes a multilateral framework of rules and disciplines on SPS measures
- Requires SPS measures to be based on scientific principles
- Requires WTO members to base their SPS measures on risk assessment
- Recognises right of WTO Members to take SPS measures necessary for the protection of human, animal and plant life or health
- Seeks to minimise negative effects of SPS measures on trade



- Article 2.1: gives right to take measures to protect human/animal/plant life or health
- Article 2.2: measures must be:
  - only to extent necessary to protect
  - based on scientific principles
  - not maintained without scientific evidence (except if 5.7 applies)
- Article 3.3: can maintain a measure that results in a higher level of health protection than relevant international standards if:
  - there is a scientific justification
  - determined by assessment of a level of protection in accordance with paras 1 to 8 of Article 5



- Article 5.1: measures must be based on assessment:
  - appropriate to the circumstances
  - that takes into account techniques developed by the relevant international organisations
- Article 5.4: the appropriate level of protection (ALOP) should take into account the objective of minimising trade effects
- Article 5.6: measures must be no more trade-restrictive than required to achieve the ALOP
  - taking into account technical and economic feasibility



- Article 5.7: where relevant scientific information is insufficient:
  - can adopt provisional measures based on available information
  - but Members must seek the information needed for a more objective assessment
  - must review the measure within 'a reasonable period'



# OIE/IPPC risk analysis framework

## Hazard identification

- Identify diseases of concern in country that wants to export to us
- Assess country's vet/plant health services and knowledge of health status

## Risk assessment

- Release: describe pathways for entry
- Exposure: describe pathways for contacting importing country's animals and establishment/spread
- Consequence: effects if agent(s) of concern were to establish/spread here
- Risk estimation:  
likelihood x consequences





## Risk management

- identify and document measures to reduce these risks to meet ALOP (if possible)

## Risk communication

- occurs throughout process
- comments sought on:
  - scope, method, panel membership
  - hazard identification
  - draft IRA
  - final IRA



# Final recommendation

- to Director of Quarantine: makes decision
- to AQIS: implements decision
  - develop detailed protocols with each applicant country
- to BA: for ongoing monitoring and review
  - advise DoQ and AQIS to modify or suspend imports if situation changes (e.g. disease occurs overseas; new diagnostic test; new processing method ...)



# Evaluating unrestricted risk

<b>Likelihood of entry and exposure</b>	<i>High</i>	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	<i>Moderate</i>	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	<i>Low</i>	Negligible risk	Negligible risk	Very low risk	Low risk	High risk	Extreme risk
	<i>V. Low</i>	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
	<i>E. Low</i>	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
	<i>Negligible</i>	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		<i>Negligible impact</i>	<i>Very low impact</i>	<i>Low impact</i>	<i>Moderate impact</i>	<i>High impact</i>	<i>Extreme impact</i>
<b>Consequences of entry and exposure</b>							

**= ALOP**



# Issues and challenges

- May be a lack of relevant data
  - how detailed should assessment be?
  - validation and lack of a 'gold standard'?
- May be a limited number of risk management options
- Recognising and assessing potential consequences
  - national, regional and local effects
  - information gaps
  - measuring and valuing public health and environmental consequences



- **Distributional aspects**
  - who benefits?
  - who bears consequences?
  - compensation/adjustment?
- **What is an 'acceptable' level of risk?**
  - depends who you are!
  - how to define 'appropriate level of protection' (ALOP)?
  - use/abuse of '(pre)caution'
  - consensus by consultation
- **How to handle disputes**
  - nationally
  - internationally



- Quantification
  - qualitative (e.g. low, moderate, high)
  - semi-quantitative (numerical scale or probability ranges)
  - quantitative (quantitative data points and/or probability distributions)
  - deterministic or stochastic
- Outrage
  - Sandman's equation:  $\text{Risk} = \text{Hazard} + \text{Outrage}$
  - outrage is as real, measurable, and as much a part of risk as hazard
  - in general, we do better at managing hazard than outrage





- Trust

- acceptance of risks depends on confidence in risk management, and this depends on trust
  - e.g. medical vs industrial uses of radiation or chemicals)
- trust is fragile and in the absence of trust, science (including risk assessment) only feeds distrust by uncovering more ‘bad news’

- Science in policy-making

- post-normal science (Funtowicz and Ravetz)
- trans-science (Weinberg)
- focus on ‘expertise’ rather than ‘science’ (Collins and Evans, Carolan)



# Two 'languages' of risk

<b>'Expert'</b>	<b>Public</b>
scientific	intuitive
stochastic	yes or no
acceptable risk	safety
changing (new information)	static (is it or isn't it safe...)
comparative	absolute/discrete
population average	personal effects
a death is a death	it matters how we die

Powell and Leiss (1997)



**Australian Government**  
**Biosecurity Australia**

# STEEP

- Social
- Technical/scientific
- Economic
- Environmental
- Policy/political

– Not just ‘T’!



# Conclusions

- The RA process provides a framework that is:
  - science-based, but multidisciplinary
  - transparent and consultative
  - consistent with government policy and international obligations
  - harmonised with international standards
- Biosecurity RA (especially IRA):
  - is often complex
  - requires good tools and judgement
  - is often (by its nature) controversial



# Further information

Biosecurity Australia

[www.daff.gov.au/BiosecurityAustralia](http://www.daff.gov.au/BiosecurityAustralia)

Biosecurity Australia (2003) *Import Risk Analysis Handbook*

[Handbook](http://www.affa.gov.au/content/publications.cfm?ObjectID=D667DCE6-A412-4673-A6B49B7579CF4AD7)<http://www.affa.gov.au/content/publications.cfm?ObjectID=D667DCE6-A412-4673-A6B49B7579CF4AD7>

Nairn, M. E., Allen, P.G., Inglis, A.R. and Tanner, C. (1996) *Australian Quarantine: a shared responsibility.*

<http://www.affa.gov.au/content/output.cfm?ObjectID=60E73514-8A9C-44A3-8395E08F7E8CABC4&contType=outputs>



Australian Government

Biosecurity Australia