

GOVERNANCE ISSUES: Regulatory challenges and trade implications

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THE DUAL USE 'DILEMMA'

ANY technology, including biotechnology, can be applied with intention of:

- Generating economic/social/ environmental **benefits**
- Causing **harm**

BIO SAFETY VERSUS BIOSECURITY

BIO SAFETY

Protection of
human health and safety
and the environment

BIOSECURITY

Controlling access
to sensitive:

- materials
- facilities
- information



CHALLENGE 1 - TRIGGERS

- **PROCESS** (technology used)
 - Keeping definitions up to date
 - Detectability
- **PRODUCT** (impact on receiving environment)
 - Technology agnostic
 - Exemptions based on experience with use



CHALLENGE 2 - SCOPE

- Balance between precautionary and promotional
- Risks versus Benefits (potential for compromise)
- Approach has to be decided in context of governance (ie policy not regulatory)

TRADE IMPLICATIONS

Trade = imports/exports across national boundaries

- Living organisms are constrained by geographical boundaries
- Inconsistent regulatory decision making can led to uncertainty and blockages

INTERNATIONAL AGREEMENTS (1)

- **Cartagena Protocol on Biosafety** – precautionary approach for dealings with biotechnology products and advance informed agreement for transboundary movement
- **World Trade Organisation Agreements** – promotional - require biosafety measures to be based on science (SPS) + right to implement standards aimed at biosafety AND biosecurity (TBT)

INTERNATIONAL AGREEMENTS (2)

- **Biological and Toxin Weapons Convention**
 - prohibits the development, production, stockpiling and transfer of biological weapons , or the means of their delivery
 - provides a mechanism for international cooperation regarding dual use in context of research oversight
- Only apply to signatories and implementation at national level

ACHIEVING COMPLIANCE

- Regulation is KEY governance tool available to governments
- Australia, for example, has enacted legislation to establish regulatory schemes for:
 - Genetically Modified Organisms
 - Security Sensitive Biological Agents
 - Export Controls for Defence and Dual Use Goods
- Effective implementation and trust relies upon cooperation and trust being established with stakeholders ('social licence to operate')

BUT REGULATION IS NOT THE ONLY TOOL OF GOVERNANCE