GOVERNANCE ISSUES: Regulatory challenges and trade implications

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WSSF 27 Sept 2018 – Engaging Key Stakeholders in Addressing Biosecurity

THE DUAL USE 'DILEMMA'

ANY technology, including biotechnology, can be applied with <u>intention</u> of:

Generating economic/social/ environmental benefits

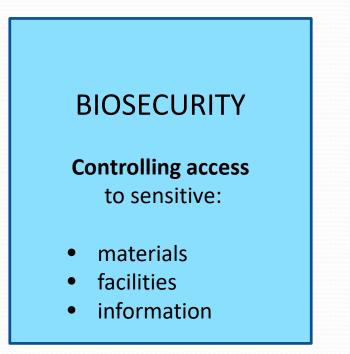
Causing harm

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BIOSAFETY VERSUS BIOSECURITY

BIOSAFETY

Protection of human health and safety and the environment



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 <u>governance</u> (ie policy not regulatory)

TRADE IMPLICATIONS

Trade = imports/exports across <u>national</u> boundaries

- Living organisms are constrained by <u>geographical</u> 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 <u>KEY</u> 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