Biorisk Management:
Biosafety and Biosecurity

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Biorisk Management

- Valuable Biological Material
- in the "Laboratory"
- in Europe

Valuable Biological Materials (VBM)

- *Biological materials that require administrative oversight, control accountability, and specific protective and monitoring measures to protect*
  - *their economic and historical (archival) value, and/or*
  - *the population from their potential to cause harm*
- *VBM may include:*
  - *pathogens and toxins*
  - *non-pathogenic organisms*
  - *vaccine strains*
  - *foods*
  - *genetically modified organisms (GMOs)*
  - *cell components*
  - *genetic elements*

WHO Biorisk management: Laboratory biosecurity guidance

“Laboratory”

- Broadly defined
- For human, veterinary and agriculture related purposes
- Includes:
  - Clinical and diagnostic facilities
  - Public health laboratories
  - National/regional reference centers
  - Research centers: academic, pharma, agro/environment …
  - Production facilities: vaccines, pharmaceuticals, industrial

International guidance and conventions

WHO guidance

- Laboratory Biosafety Manual, 3rd edition
- Biorisk management: Laboratory biosecurity guidance. 2006

International Conventions

- UN Model Regulations on the Transport of Dangerous Goods
- Cartagena Protocol on Biosafety – transboundary movement of GMOs
- Aarhus Convention – hazard communication and public participation

European regulatory framework

Worker protection

- **Directive 89/391/EEC safety and health of workers at work**
- **Directive 2000/54/EC worker protection from risks from biological agents at work**

Genetically modified organisms

- **Directives 90/219/EEC and 98/81/EC on the contained use of GMOs**

Transboundary movement of GMOs

- **Regulation (EC) No. 1946/2003 on transboundary movements of GMOs**

Dual use

- **Regulations (EC) No. 1334/2000 and No. 1504/2004 on export control of dual use items**

Plant pathogens and protection of the environment

- **Directive 2000/29/EC protective measures against introduction & spread of plant pathogens into the Community**
- **Directive 95/44/EC establishing conditions under which harmful plant pathogens may be used for trial or scientific purposes**

Environmental liability

- **Directive 2004/35/EC**

Waste

- **Directive 94/31/EC on hazardous waste**

Biorisk management: who is responsible?

- The management of an organisation is responsible and accountable for the safe and secure handling of VBM
- Management must ensure the establishment of a biosafety and biosecurity management program appropriate to the nature and scale of the work performed and planned by the organization
- To develop, implement and maintain this program, management may appoint:
  - A biological safety professional
  - An Institutional Biosafety Committee (IBC)

Laboratory Biorisk Management

The management of potential risks to human health animals and/or the environment resulting from activities involving natural or recombinant biological agents and toxins due to

- unintensional exposure or accidental release (biosafety)
- unauthorized access, loss, theft, misuse, diversion or intentional release for malicious purposes (*laboratory biosecurity*)

Biosecurity vs Biosafety Risk Management

- Long list of tasks associated with biosecurity are often presented

- How different are they from biosafety tasks?

Management of risks due to unintensional exposure or accidental release (biosafety)

- Risk assessment:
  - Organism
    - ***Inventory & RG***
  - Facilities & equipment
    - ***Facility design, equipment selection***
  - Procedures & practices:
    - ***Review & approval of new work, new group***
    - ***Waste management***
    - ***Transport - traceability***
    - ***Emergency plans / procedures***
    - ***Facility signage***
- Occupational health - interface with providers
- Training provisions
- Audits

Management of risks due to unauthorized access, theft, misuse …(biosecurity)

- Risk assessment:
  - **Organism**
    - ***Inventory (what) & RG + where & how much, access to them***
  - **Containment**
  - **Facilities design – emphasis on access control**
  - **Equipment selection - security**
  - **Procedures & practices:**
    - ***Review & approval of new work, new group – personnel selection***
    - ***Waste management***
    - ***Transport – traceability – wider range of materials***
    - ***Emergency plans / procedures – plans for worst case scenarios***
    - ***Facility signage – more general information***
- Occupational health - interface with providers
- Training provisions – awareness of potential dual-use
- Audits
- Bioethical and scientific analysis of research

Biosecurity vs Biosafety

- To the BSO most of the tasks associated with biosecurity are everyday responsibilities for biosafety, with a few exceptions:
  - ***Inventory*** ***where & how much, access to them***
  - **Facilities – emphasis on access control**
  - **Equipment - security**
  - ***New work, new group – personnel selection***
  - **Training – including biosecurity, awareness of potential dual-use**
  - ***Facility signage – more general information***
  - ***Emergency – plans for worst case scenarios***
  - ***Bioethical and scientific considerations of research topics***
  - ***Security: physical, staff, transport, material control, information***
- Have we incorporated those biosecurity aspects into our biosafety responsibilities?

European Biosecurity - EBSA's position

- Extensive regulatory framework in place
- Some harmonization needed across countries
- Key to biorisk management (biosafety and biosecurity)
  - A committed management
  - Laboratory biorisk management system
  - Competent biosafety professional with well defined role
- Transport regulations for the protection of public health, animal health and the environment
  - The responsibility of the UN Committee of Experts on Transport of Dangerous Goods
  - Gap analysis
    - GMOs: needs definition clarified & requirements risk-based
    - plant pathogens: not currently addressed, some are dual-use