European BioSafety Assocation

European Bio-Preparedness Seminar

European Commission

July 2006

EBSA

- A not-for-profit organisation
- Founded in June 1996
- Aims:
  - promote biosafety
  - provide a forum for discussion and debate on biosafety and biosecurity issues of concern
  - represent those working in the field of biosafety and associated activities.

Membership

- Individual members
  - approx. 200 members drawn from academic, research, industry, government, consulting and other businesses and organisations.
- Corporate members
  - nearly 30 companies including pharma, “biotech”, architects, transport, consulting …

“Biosafety”

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

Covers all types of intended uses, as well as the prevention and management of accidental pills / releases and potential misuse (“biosecurity”).

EBSA Projects

- Biosafety Europe
- International BioRisk Laboratory Standard
- Biosafety Officer Competence

I. Biosafety-Europe Project

EBSA initiated the project proposal and participates as one of the 19 partners in the consortium

Funded by the European Commission

II. International BioRisk Laboratory Standard

Development of an international biosafety and biosecurity management standard for biological containment laboratories.

Based on WHO Biosafety Manual.

Using CEN Workshop Agreement (CWA) format

- CEN Workshop Agreements (CWAs) are consensus-based specifications, drawn up in an open Workshop environment.
- Internationally recognized standardization platform
- Less expensive than consortia
- Fast agreement

EBSA, ABSA, A-PBA and DNV jointly initiated the project;
proposal seeking EC funding was filed in March 2006.

International BioRisk Laboratory Standard Background

- Wide range of regional / national legislation and guidance documents but…
- No internationally recognised standard for biosafety / biosecurity for laboratories
- WHO interested on such a standard, but no one driving the process
- Need for possibility of formal certification based on a management system, which also addresses
  - facility design and construction

International BioRisk Laboratory Standard
Need for a Standard

- Improve performance through the adoption of recognized good practice
- Ensure safe international exchange and collaboration
- Increase awareness and adoption of management system approaches within the sector
- Provide organizations with a means for internal audit and third party certification
- Provide stakeholders with a standard to be used as a benchmark in setting requirements for facilities

“Management System”

“System used to establish policy, objectives and a plan or programme to achieve those objectives. This includes the organisational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining the organisation’s OH&S policy.”

Source: OHSAS 18001, definitions 3.11

“Laboratory Certification”

- ***Laboratory certification is the systematic examination of all safety features and processes within the laboratory (engineering controls, personal protective equipment and administrative controls).***

- ***Laboratory certification is an on-going quality and safety-assurance activity that should take place on a regular basis.***

- ***WHO Biosafety Manual, 3rd edition.***

International BioRisk Laboratory Standard
Principles of project (1)

- **Management system approach to address biosafety and biosecurity**
- **Based on the WHO Biosafety Manual 3rd Edition & Biosecurity Guideline (Draft 2006)**
- **Focus on biological agents/materials in a laboratory setting**
- **Holistic approach encompassing people, facilities and working procedures**

International BioRisk Laboratory Standard
Principles of project (2)

- **Not intended to replace any national or regional regulatory requirements that may apply**
- **Voluntary**
- **Non-prescriptive - there may be a number of ways in which adequate control measures can be applied**
- **Associated guidance planned to support organisations in identifying how adequate measures can be identified and implemented**

International BioRisk Laboratory Standard Benefits to Organisations

- Smaller organisations struggle to demonstrate safe and responsible management of work with hazardous organisms.
- Certification of compliance with such an internationally recognised standard by an accredited organisation would demonstrate responsible management.
- Adoption of a standard of the proposed type is likely to lead to improved safety performance especially in countries where biorisk management is currently less well-established
- Would help identify potential collaborators/contractors with guarantee of responsible management.

III. European Biosafety Professional Competence

Biosafety Advisor

Biosafety Officer

Biosafety Manager

Biosafety Coordinator

Biosafety Responsible

Biosafety Officer (BSO)
Advisor, Manager, Coordinator

- Not defined in European Directives for
  - contained used of GMOs
  - worker protection from pathogenic agents
- Some countries define the role of the BSO:
  - for GMO activities (e.g., NL)
  - for GMO and pathogens (e.g. BE, CH, DE)
- Some countries provide official training, but no exams (e.g., DE, NL)
- Majority of countries do not define the role

Who is the Biosafety Officer ?

- A full time person with training in biological sciences …
- A researcher that also fulfills the requirements mandated by the regulations …
- A clinical laboratory manager …
- A senior technician …

Are these people qualified for their job?

Who is concerned about BSO competence and why …

- National/International authorities – assurance that materials will be safely managed
- Workers – assurance of proper guidance and working environment
- Employer - liability
- Institutions when collaborating– assurance that materials will be safely managed
- EBSA
- National organisations/networks, e.g., UK, BE

European Biosafety Professional Project

- Who appoints the BSO?
- To whom does the BSO report?
- What are the BSO's responsibilities?
- What are the BSO's competencies?
  - for general laboratories (levels 1 and 2)
  - for activities of containment level 3
  - for activities using animals or plants or insects
  - for large scale production
  - for gene therapy
  - ….
- Curriculum for training

Biosafety Officer (BSO)

- Is instrumental in the development and implementation of the *biosafety policy* of the organization in accordance to national and international rules, regulations and best practices

- Is appointed by senior management
- Reports to the responsible senior manager
- Must maintain an independent position
- Is the competent person
- Is the point of contact for biosafety - internally and externally

- Should have a close liaison with Health Safety and Environment management and other safety-related groups within the organisation (Occupational Health …)

Tasks of the BSO
to ensure a biosafety management program

- **Risk assessment and risk management**
- **Records**
- **Occupational health provisions and interface with others responsible**
- **Waste management**
- **Emergency plans / procedures**
- **Ensure the security of biological agents**
- **Notifications and permits**
- **Interact with relevant authorities**
- **Provide guidance on codes, standards and best practices**
- **Maintain an up-to-date biosafety program that considers the changes in national and international rules and regulations as well as scientific advances in the field**
- **Develop and provide training**
- **Review / audit biosafety management systems, practices and procedures**
- **Advice on facility design and safety equipment, commissioning and validation**
- **Review and approval of program work (new research, new group …)**

How to define a “Professional”

An individual recognized as possessing specific knowledge of a particular discipline.

Who possesses

- **recognized academic preparation,**
- **has related work experience,**
- **has mastered and applies a recognized body of knowledge in his/her field.**

The professional

- **adheres to a code of professional conduct,**
- **is acknowledged by his/her peers as a professional,**
- **typically will hold a certificate or license recognizing his/her stature.**

Skills of the BSO

- Theoretical knowledge
- Practical experience
- Knowledge of resources – where to find information

depth depends on work environment

Work environments

Biological agents in the laboratory (levels 1, 2, 3)	**GMO (levels 1, 2 or 3)**	**Large scale production**
Animal (levels 1, 2 or 3)	**Plant (levels 1, 2 or 3)**	**Facility/Engineering**
Parasites	**Arthropods**	
Clinical	**Gene therapy**	

Skills of the BSO

- **Law / Standards**
  - **Worker protection, GMO, environment, transport …**
- **Biologicals agents aspects**
  - **isolation, manipulation and propagation of pathogenic microorganisms,**
  - **hazards & risk groups,**
  - **infection control,**
  - **risk assessment …**
- **Technical aspects**
  - **principles of containment, facility design, and practices to prevent occupational infections or release of the organisms to the environment,**
  - **disinfection, sterilization,**
  - **waste …**
- **Biosafety management**
  - **program management;**
  - **developing and conducting training programs**
  - **(Risk) communication / public perception …**

Next steps …

- Best practices document
- Define a curriculum
- Draw outline of courses
  - Develop EBSA courses
  - Training provider courses

Biosafety Europe Project

- Evaluation of courses – system of course certification

- Accreditation program for
  - “Registered Biosafety Professional”
  - “Certified Biosafety Professional”

- Accredited by whom? EC, MS, EBSA …

Transport of Biological Material

Address the transport of **all** biological materials under UN Model Regulations using a risk-based approach

- Infectious agents
- Biological substances category B (diagnostic specimens, clinical specimens …)
- GMOs
- Quarantine organisms and plant pathogens
- Biological products
- Biological waste