



Biosafety-Europe:

**What did we achieve and what
could be recommended to the
EU?**

**Kathrin Summermatter, IVI, Switzerland
Jürgen Mertsching, Hannover Medical School, Germany
Consortium members**



Overview project

- Coordinated action, 6th framework, Priority Scientific Support Policies, DG Research
- 4 working packages
- 19 partners from 10 different countries (Austria, Belgium, France, Germany, Netherlands, Norway, Sweden, Switzerland, Czech Republic, UK)
- Official starting point: 1st April 2006
- Ending 2008



Main objectives

- Overview about containment level 3 and 4 facilities in EU
- Definitions for biosafety - biosecurity
- National legislation, guidance, best practices and inspection in biosafety and biosecurity
- Biosafety management (BSO, BSC, risk assessment etc.)

- Safety measures in CL3 and 4 facilities
- Validation of critical compounds
- Practices and procedures in different countries
- Audits – laboratory acquired infections
- Cost – benefit
- Existing training programmes within the different containment facilities

Q1

Q2



Main objectives cont.

- Recommendations on biosafety and biosecurity measures applicable to future policy making and a guide for legislation based on harmonised procedures
 - A provisional training manual defining essential training topics
 - Proposal for initiating training in biosafety and biosecurity
- ⇒ **Close out seminar, 12 November 2008:**
Presentation of recommendations



Results

- **Questionnaire 1:** over 50 questions, response rate >30%, 13 CL4 and over 90 CL3
- **Questionnaire 2** (ongoing activity): CL3 and CL4
- **Networking:** Euronet P4, ENIVD, Epizone, Europa-Bio, Biosafe, Cropbioterror
- **Exchange with stakeholders:** WHO, ECDC, OSHA-Europe,
- **Initiating training workshops:**
 - Czech Republic, Prague
 - Romania, Timisoara
- **Laboratory biosecurity workshop**
- **Working definition for biosafety and biosecurity**



Working Definitions: for laboratory biosafety and laboratory biosecurity

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents, or their accidental release.

Laboratory biosecurity is the physical and administrative measures that secures biological material and information that could cause harm to health or economic loss as a result of malicious release, intentional loss, theft or misappropriation.



Main findings and areas for recommendations

- **Legislation**
- **Biosafety**
- **Laboratory Biosecurity**
- **Training**



Legislation

1. Harmonisation and unification of biosafety and biosecurity subsections

- GMO \Leftrightarrow pathogenic agents
- Human, plant and animal pathogens: no common system for classification, need for risk based approach

2. Harmonisation of the classification of biological agents

- EU list is not up to date
- Missing information for strains
- Need to rapidly up-date lists

3. Persons responsible for biosafety and biosecurity

- Competences and responsibilities need to be defined



Legislation- tentative conclusions

- **Need to determine where harmonisation would make sense and where it would be a benefit**
- **Need to have a uniformed harmonised system for the classification of organisms**
- **Too many key-players and stakeholders on EU and national level (DG-Sanco, DG-Research, DG-JLS etc.)**
- **Too slow.....**



Biosafety

- **Physical containment**
 - Performance specifications not evidence based and not reflected by EU directives
 - Missing framework for animal and plant pathogens
 - Differences between GMO and native organisms
- **Procedural practices**
- **Risk management**
 - Diverse approach
 - Better documented for GMO than for native organisms
 - Lack of evidence to support risk assessment
- **Incident Reporting**
 - No common mechanism to report and to learn from incidents within EU
 - Not enough valuable data



Biosafety- tentative conclusions

- **Requirements for GMO and native organisms should be the same**
- **Evidence based decisions \Leftrightarrow political driven decisions**
- **A common incident reporting system to learn from LAI**
- **Funding for biosafety „research“ should be made available**



Laboratory biosecurity

- **No word for biosecurity and no difference to biosafety in some EU languages (eg. German)**
- **In most countries no specific biosecurity legislation**
- **Awareness for biosecurity differs in research, diagnostics and industry**
- **No biosecurity risk assessment or determination of valuable biological material (threat assessment)**
- **Security aspects in human resources management**
 - Background checks of personnel including maintenance and ICT
 - Insider as biggest threat
- **Transport: sender – receiver**



Laboratory biosecurity – tentative conclusions

- **Differences between laboratory biosecurity and biosafety should be made clear in all languages, need for harmonisation**
- **Need for a minimum standard for laboratory biosecurity including a threat assessment**
- **Need for harmonisation of threat assessment**
- **Transport: solve the biosecurity gap between sender and receiver of high risk biological agents**



Training

- **Training must be seen on several levels**
 - BSOs
 - Scientists
 - Technicians
 - Management
- **Biosecurity training is presently only a minor part of biosafety training course.**
- **Training courses should not be prescriptive but be risk assessment based**
- **High level awareness training required for directors of microbiology laboratories**



Training – tentative conclusions

- **Lack of harmonisation means it is difficult to provide EU wide training. We need biosafety competency-building structures**
- **Expert group linked to European agencies (e.g. ECDC) to develop train the trainer courses, increase expertise and transfer courses throughout the EU**
- **EU should fund biosafety/biosecurity scholarships to develop biosafety professionals throughout the EU**



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BIOSAFETY-EUROPE**

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**Join us to discuss and
exchange your views**

**Break out session A
Biosafety Europe:
Quo vadis?**

Thank you!