

BIOSAFETY-EUROPE
Concluding Workshop
Brussels, 13 November 2008

**Assessment of the Cost Effectiveness of
Biosafety and Biosecurity measures**

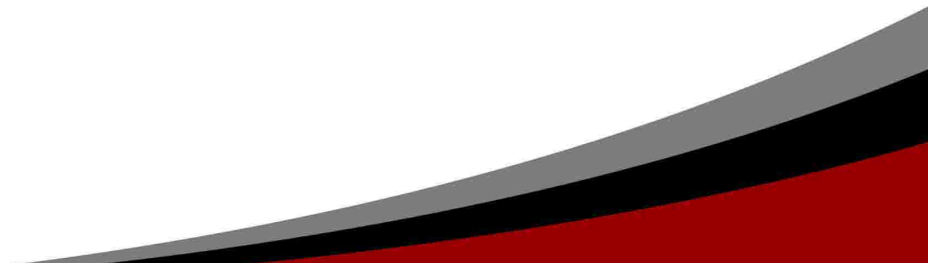
Evelien Kampert



SIXTH FRAMEWORK PROGRAMME

Outline

- Sources of findings
- Breakdown of costs
- Some examples
- Legislation and technical specification
- Cost reduction
- Results and recommendations



Sources of findings

- Questionnaires 1 and 2 (response of about 150 laboratories BSL3 and BSL4)
- German Expert meetings August 2006 and May 2008, Hannover Medical School, Germany
- Biosafety experts of the Consortium



Results of findings

- Questionnaires: comparison of real cost not possible between high containment facilities nor between the different Member States
- Expert meetings in Germany: resulted in percentages of technical installation and construction costs
- Biosafety experts of the Consortium: gave inside information about running costs



Breakdown of costs

Design and Construction phase:

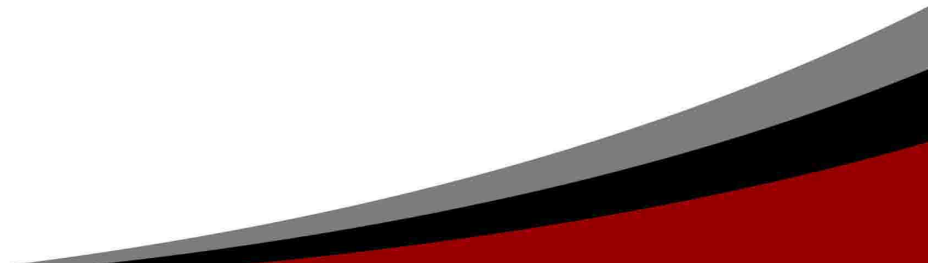
1. **Planning** (program requirement, conceptual design, risk assessment, final design, permits, awarding the contractor)
2. **Construction** (including commissioning /validation)
3. **Putting into service** (biological validation, development of a biosafety and biosecurity management system including manuals and procedures)



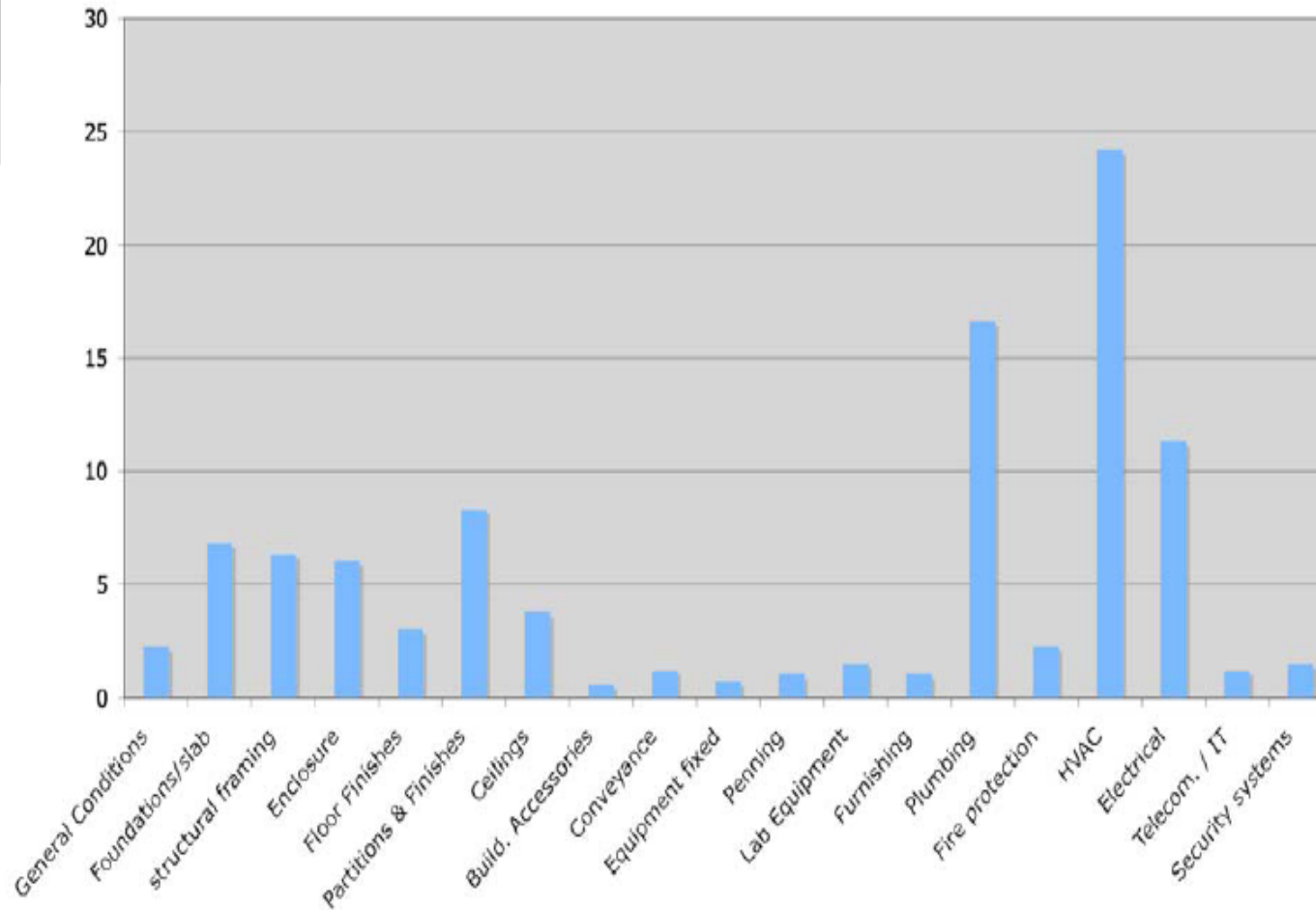
Breakdown of costs / 2

Operational phase:

- Running costs (including preventive and routine maintenance costs)
- Scientific Program costs: beyond the scope of this project



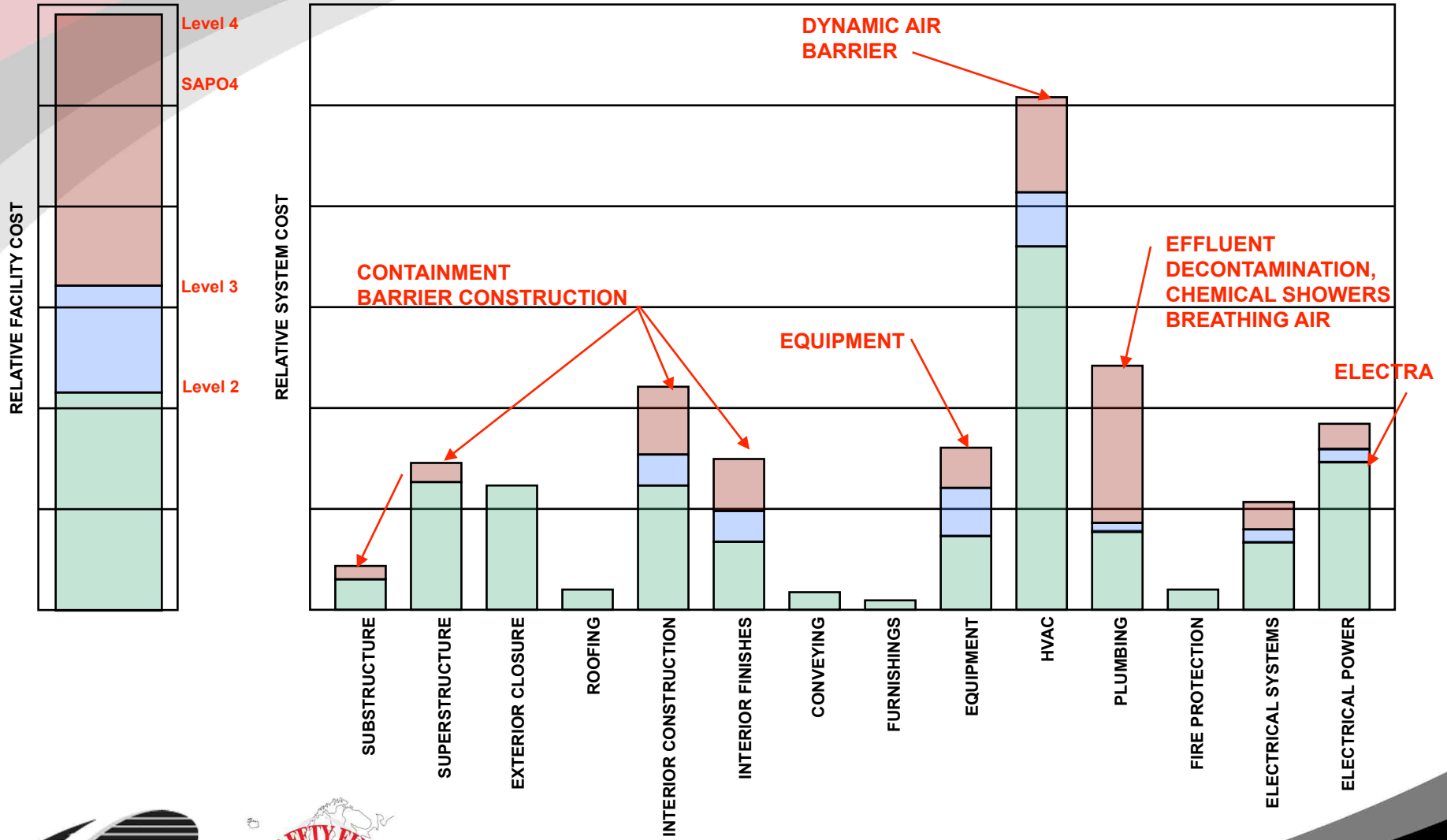
Construction Cost Breakdown in %



Construction cost breakdown of a large animal facility (BSL3 Ag), P. Mani, P. Langevin, 2006



Impact of Systems on Containment Facility Cost



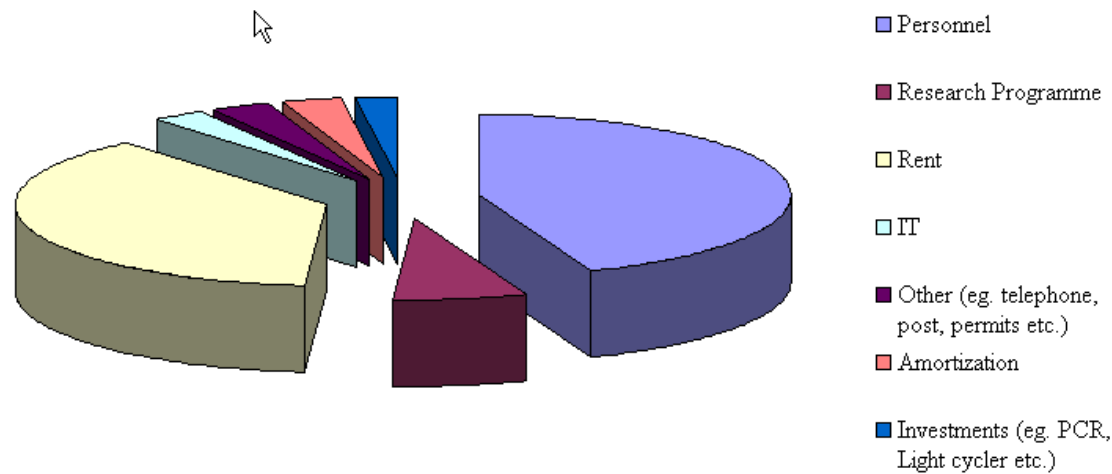
Example of the cost breakdown of a containment level 3 + 4 laboratory in W-Europe:

Design	8 %
Risk assessments, Validation Master plan	2 %
Permits	1 %
Advisory costs	5 %
Construction costs	46 %
Technical installations + inventory	20 %
Security costs	6 %
Management	12 %
Running costs / per year including rent excluding scientific program	12 %



Breakdown of running costs of a high containment large animal facility

Personnel	44 %
Research program	8 %
Rent including energy	37 %
IT	2.7 %
Other (eg. administrative)	3 %
Amortization of equipment	3 %
Investments (eg. light cycler, ELISA etc.)	2.3 %



Relevant legislation

- **2000/54/EC** Protection of workers from risks related to exposure to biological agents at work

ANNEX V

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

- **98/81/EC** contained use of Genetically Modified Micro-organisms



Containment measures (2000/54/EC)	BSL 3	BSL 4
1. The workplace is to be separated from any other activities in the same building	Recommended	Yes
2. Input air and extract air to the workplace are to be filtered using (HEPA) or likewise	Yes, on extract air	Yes, on input / extract air
3. Access is to be restricted to nominated workers only	Yes	Yes, via airlock
4. The workplace is to be sealable to permit disinfection	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	Recommended	Yes
7. Efficient vector control, for example rodents and insects	Yes	Yes

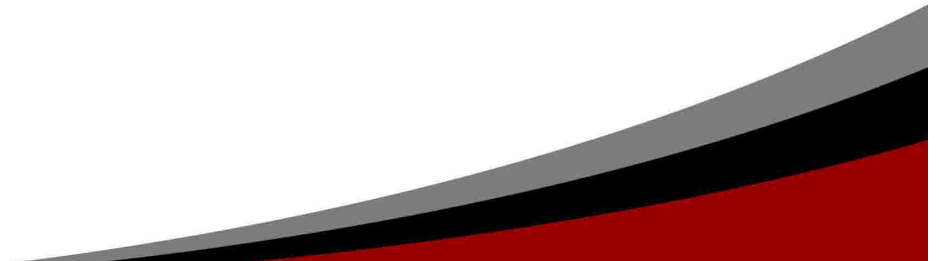


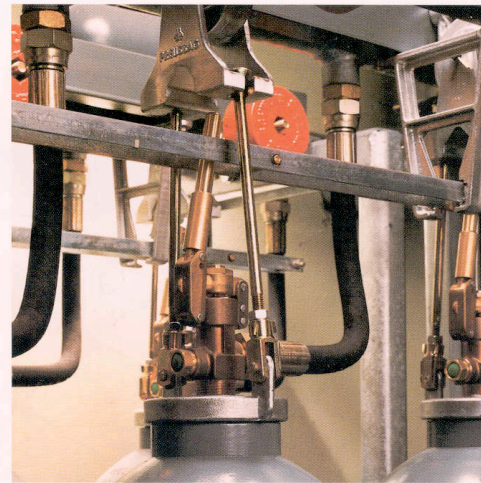
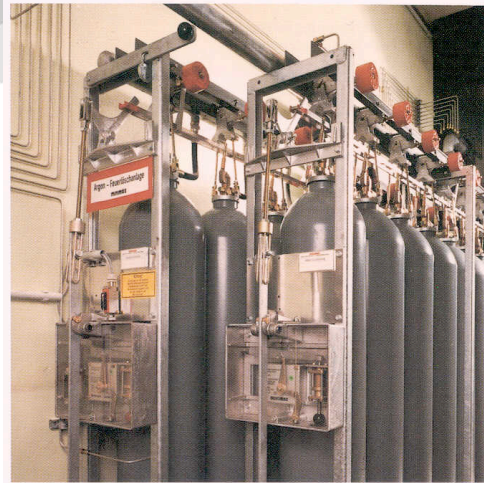
Containment measures	BSL3	BSL4
8. Surfaces impervious to water and easy to clean	Yes, for bench and floor	Yes, bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes, secure storage
11. An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Yes
12. A laboratory is to contain own equipment	Recommended	Yes
13. Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment	Yes, for airborne inf.	Yes
14. Incinerator for disposal of animal carcasses	Yes (available)	Yes



Point of interest:

- Based on the route of infection (even for agents within a single risk-group) different containment measures are required (airborne, blood borne, etc.)
- Type of handling requires different containment measures (laboratory, animal work, large scale)





High Containment Systems to develop

- HVAC (redundancy, gas tightness, etc)
- Filtration control (e.g. HEPA efficiency testing, plumbing vent filters)
- Effluent and waste treatment
- Decontamination (shower, fumigation)
- Breathing air
- Fire extinguishing
- Security systems
- Structural / architectural components (e.g. finishes, doors, walls regarding leak proof and resistance to disinfectant)



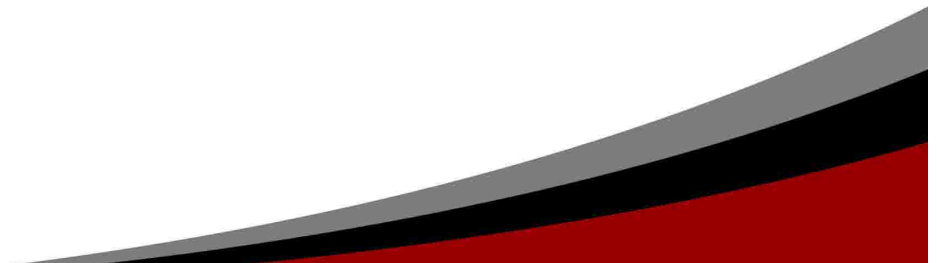
Cost reduction through optimization of the planning phase requires:

- Participation of Biosafety and Biosecurity experts in design team
- Risk assessment to assess all biosafety and biosecurity related elements prior to completing the final design
- Flexible, modular construction method to avoid later reengineering



Cost reduction through optimization of the construction phase requires:

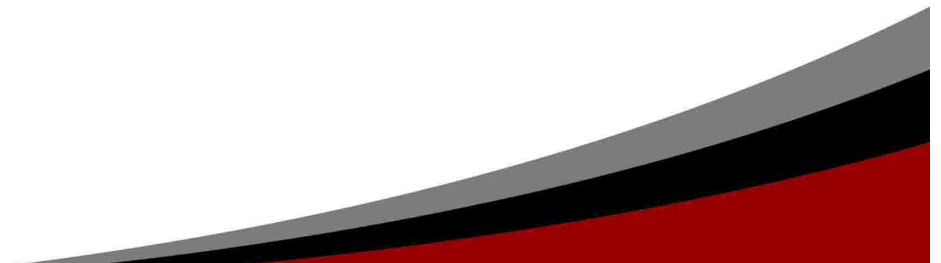
- Selection contractors with approved bio-containment experience
- Design review by competent authorities and containment experts to avoid major failures
- Commissioning/Validation of all biosafety and biosecurity related elements starting day 1 of the construction



No cost reduction

for

- Putting into service phase (biological validation)
- Operational phase (dedicated personnel, maintenance, electricity, etc.)



Main results (1)

Finding:

Existing legislation on containment (biological agents and GMMs) doesn't give guidance to an appropriate and safe design

Result:

Different interpretations of the current requirements are possible which can lead to inappropriate approaches

Recommendation:

Update of legislation or development of a technical guidance to support safety and harmonisation of the containment of BSL3 and BSL4 laboratories in Europe



Main results (2)

Finding:

For high containment facilities several containment issues are still under development (leak-tightness of the lab, fire extinguishing, waste treatment, etc.)

Result:

Lack of data and pressure of public perception leads to expensive overkill of physical containment measures

Recommendation:

Support of the EC for funding research to establish evidence based technical solutions



Main results (3)

Finding:

Running costs of high containment facilities are extremely high (energy, maintenance, dedicated personnel)

Result:

The running costs rapidly exceed the investment costs

Recommendation:

Long term funding for programs should be guaranteed before starting the planning of a high containment facility



Recommendations (1):

Research

- Technical measures have to be specified based on the evidence of risk.

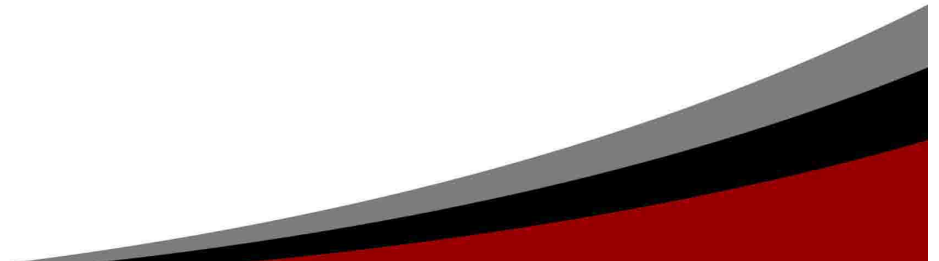
Therefore funding is needed to support applied research on biosafety and biosecurity measures to gain knowledge on the effectiveness and efficiency of containment- and control-measures.



Recommendations (2):

Defining minimal standards

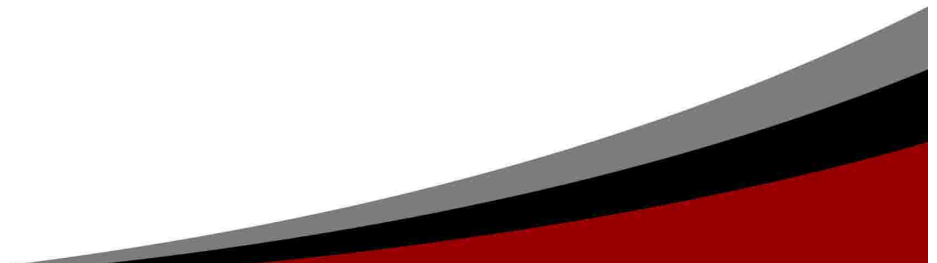
- The EC should facilitate an international risk-discussion forum in order to define minimal safety standards. By defining uniform European minimal safety requirements, costs could be minimized.



Recommendations (3):

Platform to exchange technical information

- A Europe-wide platform for exchange of practical knowledge and experience on biosafety and biosecurity should be established and supported by the EC. Participants could include biosafety professionals from high containment facilities (human and veterinary) as well as biosafety and biosecurity legislators.



Thank you for your attention

