

BIOSAFETY-EUROPE
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BIOSAFETY

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SIXTH FRAMEWORK PROGRAMME

What do we mean by Biosafety

- Facilities
- Equipment
- Practices
- Procedures
- To reduce/prevent risk of exposure of workers and environment to dangerous pathogens

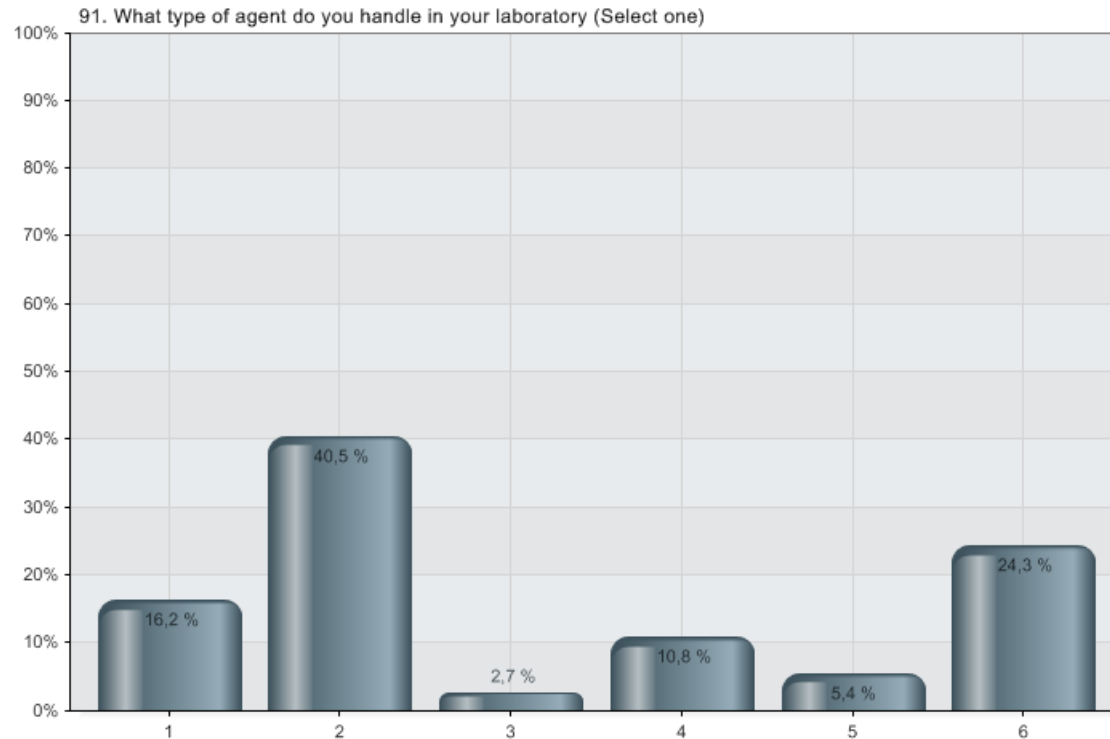


NO Standard BL3 laboratory

- **Biosafety practices and procedures should depend on the following factors:**
- **Agent**
 - Pathogenicity, Host range
 - Stability, Transmission route
 - Endemicity
- **Activity**
 - Volume, titre
 - Aerosolisation risk, animal infection



Respondents to Questionnaire



1	blood borne
2	Aerosol transmitted
3	Prion
4	Potential RG3 diagnostic samples
5	Agents transmitted through ingestion
6	Animal pathogens



Findings (1)

- In many countries the regulatory framework for GMMs is more strongly enforced than that for biological agents in general.
- Containment level 3 laboratories throughout the EU are not of a comparable standard.












Findings (2)

- Different terminologies for "containment level (CL)" are used within the member states. But in practice, most laboratories refer to the WHO term "biosafety level (BSL)".



Biosafety Nomenclature

- A1, A2, A2Q, A3, A4
-  ABSL-2, ABSL-3, ABSL-4
-  ACDP-1, ACDP-2, ACDP-3, ACDP-4
-  BA2, BA3, BL1, BL2, BL2+, BL3
-  BSL2, BSL2+, BSL3, BSL3**, BSL4
-  BSL-PRION, BSL-FMD, BSL3Ag, BSL3Agr, BSL-4VET
-  CL-1, CL-2, CL-3, CL-3+ , CL4
-  DEFRA-1, DEFRA-2, DEFRA-3, DEFRA-4
-  DM-I, DM-II, DM-III
-  G1, G2, G2Q, G3, G4
- HR1, HR2, HR3
- L1, L2, L2Q, L3, L3**, L4, L4VET
- LS1, LS2, LS3, LS4
- ML-I, ML-II, ML-III
- NBS3
- P2, P3, P4, P4D
- PC-I, PC-II,
- PCM-I, PCM-II,
- PK-I, PK-II, PKM-I , PL
- SAPO ¾, Stufe2 -4, S1, S2, S3, S3**, S4



Findings (3)

- There is no harmonized system for the reporting of laboratory incidents and accidents. Northern European countries reported higher number of laboratory acquired infections than other parts of Europe, which in part may reflect differences in the implementation on the laboratory level of national legislation.



Findings (4)

- Less than half of the laboratories surveyed report being subject to oversight by a biosafety committee.
- Those with biosafety responsibilities often hold functional roles that may be in conflict with strict biosafety considerations.



Lack of EU Biosafety Guidance

- There is a lack of Europe-wide harmonized practical guidance (best practices) on how to implement the European Directives on biological agents and GMMs. A few EU Member States have developed their own national guidance on the basis of the directives. In other cases these gaps are filled by US Government publications (e.g. Biosafety in Microbiological and Biomedical Laboratories (BMBL)), the WHO Biosafety Manual and Canadian guidelines.



Conclusions (1)

- EC legislation (biological agents and GMO) only constitutes minimum requirements and therefore is in some instances not specific enough to ensure harmonization of the implementation on the national level.
- The EU Directive 2000/54/EC has not been substantially updated since 1997.
- Enforcement on the national level of legislation is not equal for biological agents and GMOs.



Conclusions (2)

- Terminologies are used differently in different Member States and between organizations which makes communication and scientific exchange difficult.
- There is a varying interpretation of the EU legislation between Member States down to the laboratory level, even when EU legislation is implemented on the national level.



Conclusions (2)

- The varying interpretation of the EU Directives seemingly gives room for different approaches to biosafety and laboratory biosecurity.
- The use of different terminologies and the varying interpretation of biosafety and laboratory biosecurity throughout Europe may make the exchange of scientists between Member States difficult.



Recommendations for EC Authorities

- To merge or at least harmonize Directives 2000/54/EC and 98/81/EC as the same control measures, based on risk assessment, can be applied to both biological agents and GMMs.
- To regularly update the classification list of micro-organisms and technical measures according to current scientific knowledge (Annex III and V).



Recommendations (2)

- To require national authorities to collect and report data on laboratory acquired infections. These data should then be compiled on a European level and reported.
- To require organizations handling biological agents and toxins and GMMs to ensure competent biosafety advice commensurate to the risk through e.g. an organizational biosafety committee, a biosafety professional.



Recommendations (3)

- To develop a consistent terminology for biosafety levels (BSL) for biosafety levels (BSL). The WHO terminology (BSL) could serve as the basis.
- To develop an EU –wide, evidence-based guidance on biosafety practices and procedures.



Why Harmonise?

