



BIOSAFETY – EUROPE

**Preliminary findings of the survey in Workpackage 2:
Who is working within BSL3 and 4 facilities in Europe and under
which regulatory and operational frameworks?**

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Heidelberg 2007**



Project overview

- **WP1 (Kirsten Leufgen):** Project Management, administrative issues
- **WP2 (Stephen McAdam) :** Project website, inventory of BL3 and 4 facilities in Europe and existing safety/security assurance practices (questionnaire 1)
- **WP3 (Allan Bennett):** Assessment of current biosafety/biosecurity measures and practices (questionnaire 2)
- **WP4 (Stuart Thompson):** Consortium biosafety / biosecurity recommendations for future policy making and training



Rational

- How many BSL3 and BSL4 laboratories exist within Europe?
- What is the scope of their activity and the funding sources?
- What are the national legislations?
- What are the practices and procedures in biosafety and biosecurity within different European countries? Are there any differences?
- What are the costs for biosafety and biosecurity measures?
- What should biosafety and biosecurity training cover?
- Recommendation to the EU

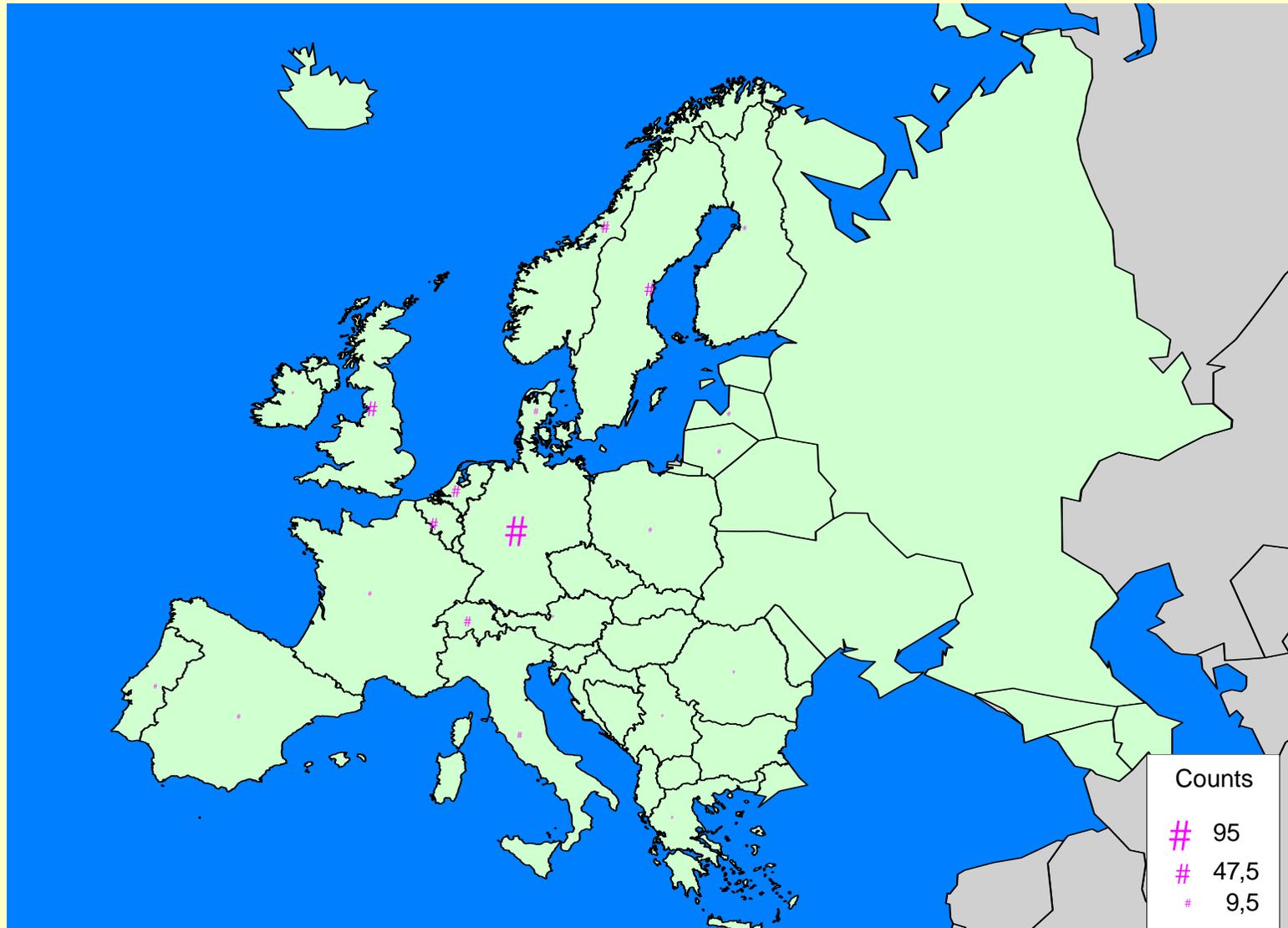


Results WP2 Questionnaire: Introduction

- This presentation will give some brief glimpses into the survey of BSL-3 and BSL-4 high containment laboratories in Europe, performed in Work Package-2 of the Biosafety-Europe project.
- The survey is still running, and the analysis done so far has a very preliminary character.
- The survey was conducted as an online survey, and of the roughly 300 identified laboratory contacts roughly n=90 have responded this far.
- The major disadvantage of the current sample, is not the response percentage, but rather the projects limited success in identifying laboratory contacts in certain parts of Europe

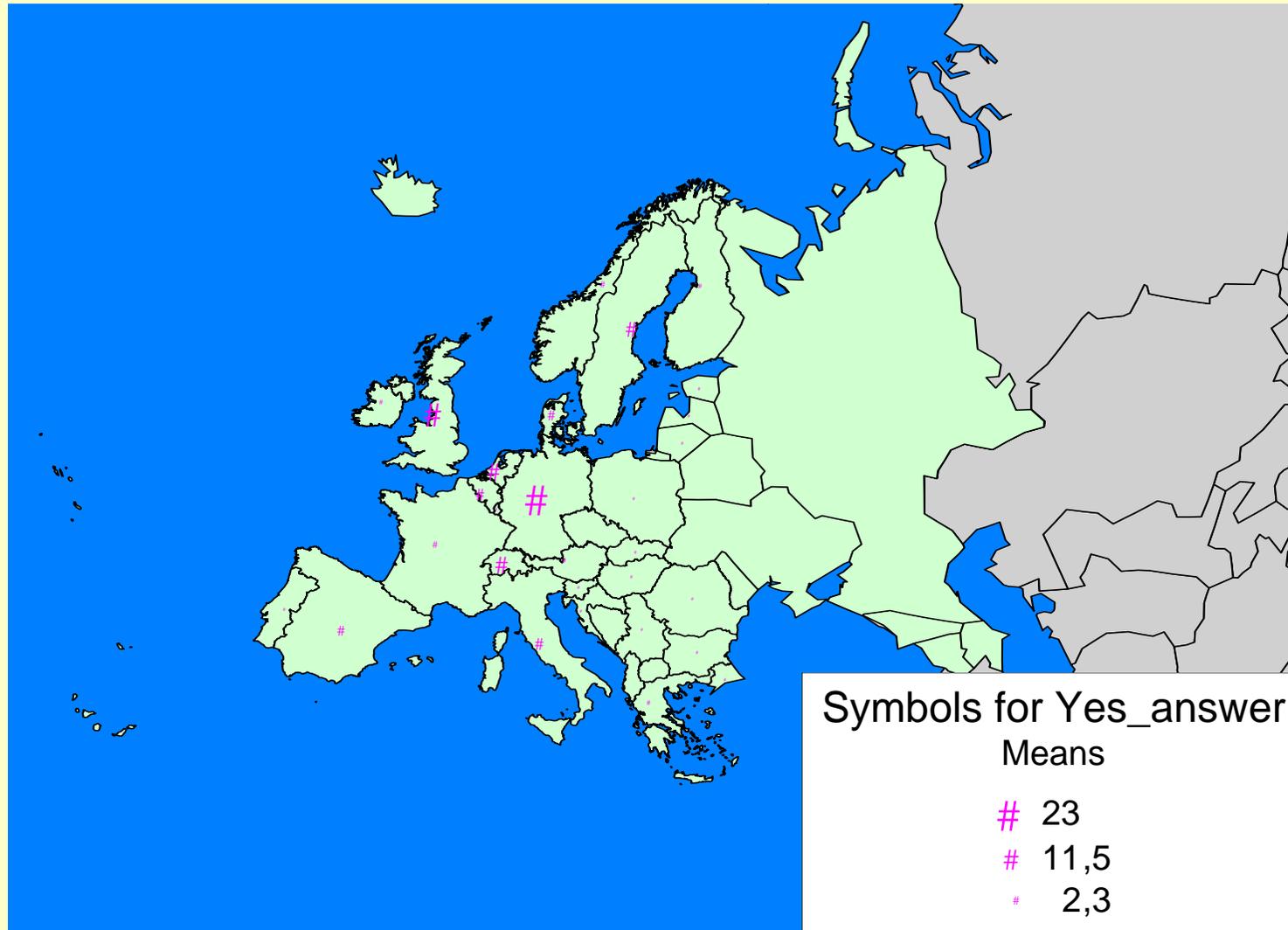


Number of identified laboratory contacts





Number of response (as of February 1st 2007)





Who has responded ?

Biosafety / containment level

- **BSL4**
 - 13 respondents from organisations that have laboratories operating at BSL-4 level (one of which also operate a lab at BSL-3 level).
 - Seven work with Class III cabinets
 - Four work with protective suits (plus one with both suits and cabinets)
 - Two responses of "isolator" / "animal isolator"
- **Size of BSL4 – lab**
 - Of the n=8 reporting m² of lab the average size was 320 m², however one very large lab (of 1450 m²) exaggerate the average, the average for the 7 other labs were: 158 m².
 - On average 12 persons working at the BSL4-lab (range of 1-50)
- **BSL3:** 81 respondent working at this containment level



Variations in terms and definitions I/III

Terminology used for biological safety levels:

- CL1, CL2, CL3, CL4
- NBS1 NBS2, NBS3 (Nivell de Bioseguretat (catalan) / Nivel de Bioseguridad (spanish))
- P2, P3, P4
- SAPO 3 / 4 (specific animal pathogens order, UK)
- PC-I, PC-II, PCM-I, PCM-II, PK-I, PK-II (transgenic plants)
- S1, S2, S3
- S1-S4 if GMO, Schutzstufe 1-3 if BioStoffV
- Sicherheitsstufe 1-4
- ML-I, ML-II, ML-III (labs); DM-I, DM-II, DM-III (animals with GMO; Netherlands)
- A1, A2, A3 (animal)



Variations in terms and definitions II/III

Defining Biosafety

- *In our organisation we define biosafety as the prevention of large-scale loss of biological integrity by reducing the risk of different types of contamination.*
- *Biosafety concerns the protection of the environment*
- *At the moment we do not have any written definitions of biosafety*
- *The practical and management measures taken to prevent or minimise harmful exposure of staff and the environment (including the public) to biological agents.*
- *The classification of microorganisms.*
- *Biosafety is to avoid unintentional exposures to pathogens by proper routines and other preventive measures.*



Variations in terms and definitions III/III

Defining Biosecurity

- *To me, biosecurity and biosafety are synonymous*
- *I do not discriminate between biosafety and biosecurity*
- *Biosecurity concern the protection of people*
- *For our organisation biosecurity is related to the more passive concept of biosafety and attempts to ensure that ecologies sustaining either people or animals are maintained.*
- *Biosecurity refers to institutional and personal security measures designed to prevent the loss, theft, misuse or intentional release of pathogens or toxins. (reference made to D.O. Flemming & D.L. Hunt)*
- *The measures implemented (over and above those of biosafety to prevent the loss, theft, misuses, diversion or intentional release of infectious agents into the environment.*
- *Measures taken to prevent intentional malicious exposure of personnel and environment to pathogenic agents.*



Legislative issues

- **Biosafety:**
 - 95% reports to have national legislation that specifically regulates biosafety in relation to the contained use of pathogens, microorganisms or gene modified microorganisms
 - 80% reports that this national legislation is based on EU – Directives, mainly directive: 2000/ 54 / EC, but also 98/81/EC (64%), 90/219/EEC (54%)
- **Biosecurity:**
 - 56% reports to have national legislation that specifically regulates biosecurity (i.e. the security of valuable or sensitive biological materials)

Reference & best practice resources

- European directives are most widely used for reference or best practices (by 75%), followed by WHO LBM (52%), "Other" (37%), BMBL (26%), Health Canada (20%), NIH rDNA (14%).



Conclusion

- Huge task to locate and identify high containment BSL-3 and BSL-4 laboratories across Europe.
- Of the roughly n=90 whom have responded this far Biosafety-Europe project some countries have the lions share of response (in particular Germany), thus quite a few countries is still not really covered.
- The survey is still running, and the analysis done so far has a very preliminary character.
- Open text terms and definitions entered by the n=90 respondents clearly indicates the need for harmonisation and standardisation within Europe in this fields.