BIOSAFETY-EUROPE

Final Considerations

Coordination, harmonisation and exchange of biosafety and biosecurity practices within a pan-European network

We acknowledge funding through the 6th Framework Programme of the European Commission.

Project Number: SSPE-CT.2005-022626
Project Full Title: Co-ordination, harmonization and exchange of biosafety and biosecurity practices within a pan-European network
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INTRODUCTION

Research on and diagnosis of highly pathogenic organisms in containment level 3 and 4 laboratories are very important for human public health since they provide opportunities for the development of vaccines and novel therapeutics as well as diagnostic methods to control epidemics. However, they also represent a risk to the population in case those organisms may spread in the environment due to a laboratory accident, poor containment, poor laboratory practices or intentional removal and subsequent release (terrorist attack). Therefore, adequate technical and physical containment measures and best biosafety and biosecurity practices must be implemented in those facilities to prevent accidental or intentional release of dangerous pathogens.

BIOSAFETY-EUROPE is a coordination action funded through the 6th Framework Programme of the European Commission (EC), which aims to explore harmonization and exchange of biosafety and biosecurity practices within a pan-European network. The consortium comprises 18 partners from10 European countries representing industry, academia and government agencies. The project started in April 2006.

BIOSAFETY-EUROPE has established a European multidisciplinary consortium containing expertise in biosafety and biosecurity, in risk containment procedures and in the corresponding legal frameworks in Member States with the aim of exchanging and implementing best biosafety and biosecurity measures.

Detailed information was gathered on European legislation on biosafety and biosecurity, on practices and procedures and on technical and physical measures of European containment level 3 and 4 facilities. Regular input, networking and exchange with various expert groups and stakeholders throughout the project duration were a very valuable tool to continually improve the out-put of the project.

In order to strengthen and support the Member States' efforts, policy recommendations have been formulated on "Legislation (biosafety and biosecurity)", on "Cost-effectiveness" and on "Training". The recommendations will be presented to the relevant EC authority(s).

> **Laboratory biosafety** embraces facilities, equipment, practices and procedures deemed to reduce or prevent the risk of exposure of workers and environment to dangerous pathogens.

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

> A **biosafety professional** is a competent person who has a relevant qualification in the field of life sciences and additional working experience in (micro-)biological laboratories.

1. BIOSAFETY

Findings

National biosafety practices and regulations (derived from EU Directives 2000/54/EC and 98/81/EC) varied from country to country. In many countries the regulatory framework for genetically modified organisms (GMMs) was more strongly enforced than that for biological agents in general. Facilities and practices in containment level 3 laboratories throughout the EU are not of a comparable standard and a large range of different terminologies for "containment level (CL)" were used within the Member States. Many laboratories referred to the WHO term 'biosafety level (BSL)'. It is concluded that EU Directives 2000/54/EC and 98/81/EC require revision and updating to reflect the current state-of-the-art including continuous review of the classification list of microorganisms and a definition of harmonized best practices.

No harmonized system for the reporting of laboratory incidents and accidents was found. Northern European countries reported higher number of laboratory-acquired infections than other parts of Europe, which in part may reflect reporting differences.

Less than half of the laboratories were subject to oversight by a biosafety committee. Moreover, biosafety responsibilities appear often to be attributed to staff in management positions with functional roles that could be in conflict with strict biosafety considerations.

EC legislation (biological agents and GMMs) is often not specific enough to ensure harmonization of the implementation on the national level. There is a lack of European-wide harmonized practical guidance on how to implement the European Directives on biological agents and GMMs. A few EU Member States had developed their own national guidance based on these Directives. In other cases these gaps are filled by US (e.g. BMBL) and Canadian guidelines. The varying interpretation of the EU Directives gives room for different approaches to biosafety and laboratory biosecurity. This and differences in terminology make the exchange of scientists between member states problematic.

Recommendations

BIOSAFETY-EUROPE recommends the relevant EC authority(s)

1.
To merge or at least harmonize the 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 .

2.
To regularly update the classification list of microorganisms and the technical measures according to current scientific knowledge (Directive 2000/54/EC).

3.
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.

4.
To require organizations handling biological agents and toxins to ensure competent advice commensurate to the risks through e.g. an organizational biosafety committee, a biosafety professional.

5.
To develop a consistent terminology for biosafety levels (BSL). The WHO terminology (BSL) could serve as the basis.

6.
To develop an EU–wide, evidence-based guidance on biosafety practices and procedures.

2. BIOSECURITY

Findings

Laboratory biosecurity is a relatively new concept that is still developing and there is currently little consensus across Europe as to what biosecurity means, even within the laboratory environment. BIOSAFETY-EUROPE has used the term "Laboratory Biosecurity" to describe protection against, control of, and accountability for biological material and information within laboratories, in order to prevent their loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release. No EU level legislation exists that has been specifically developed to address the protection of biological agents in the laboratory from loss or willful misuse. However due to the many synergies between biosafety and biosecurity, the EU Directives developed to protect workers from exposure to biological agents or GMMs address most of the issues related to laboratory biosecurity. Only a limited number of Member States have introduced special laboratory biosecurity legislation. Many facilities do implement some biosecurity controls but these are often not based on risk assessment and are often focused on physical security. Less attention is focused on information security or organizational security issues, despite the fact that internal threats from individuals with authorized access to the laboratory must be recognized.

Recommendations

BIOSAFETY-EUROPE recommends the relevant EC authority(s)

1. To develop and promote consensus based definitions of laboratory biosafety and laboratory biosecurity.

2. To introduce risk-related laboratory biosecurity assessments alongside biosafety into already existing biosafety legislation.

3. To develop methodology and guidance for biosecurity risk assessment. This risk assessment should address a wider area than just physical security i.e. information and organizational security, as a basis for specific biosecurity measures.

4. To require organizations handling biological agents, toxins and GMMs to have an up-to-date inventory. The level of detail of control should be based on risk.

5. To ensure that new biosecurity measures do not hinder the exchange of scientific personnel, data and knowledge.

3. COST EFFECTIVENESS

Findings

Lack of data and pressure of public perception leads sometimes to unnecessarily complicated and overly expensive physical containment measures. Many practices are based on what has worked in the past even though they have never been validated by detailed studies.
Political and societal pressure sometimes drives the requirements to go beyond what is strictly necessary.
Cost-effectiveness analyses are not performed routinely in the field of biosafety and biosecurity.
Technical guidance in the existing legislation is mostly unspecific, not state-of-the-art and not evidence-based, so that time-consuming and cost-intensive individual solutions have to be worked out.
Continuous, qualified and independent monitoring of construction is indispensable to ensure that no safety problems will occur in the long run due to construction errors. Biosafety and biosecurity are a continuous task for dedicated personnel.
Running costs for high containment facilities are extremely high (e.g. energy, maintenance) and are often underestimated. Therefore long term funding for scientific programs and other operations as well as running costs need to be guaranteed before starting the planning of a high containment facilities.
The collective expertise of the biosafety community is a valuable resource that can make an important contribution in this area and for briefing lay administrators and politicians on biosafety matters.

Recommendations

BIOSAFETY-EUROPE recommends the relevant EC authority(s)

1.
To fund applied research on biosafety and biosecurity in order to gain more in depth knowledge on evidence based controls which could lead to the development of improved containment measures and procedures that are both efficient and costeffective. To encourage the inclusion of applied biosafety aspects into future research project applications.

2.
To initiate and support a Europe-wide platform for exchange of knowledge and experience on biosafety and laboratory procedures and practices. Participants may include biosafety professionals from high containment facilities (human and veterinary) as well as biosafety and biosecurity legislators.

3.
To encourage a discussion on how best to achieve biosafety minimum standards in a cost-efficient way.

4. TRAINING

BIOSAFETY-EUROPE has identified training needs for biosafety and biosecurity within European countries by means of questionnaires and workshops. As there is no general agreement about the best practices in biosafety and biosecurity in Europe and the international community and the legislative environment are not harmonized, training cannot be prescriptive. It is therefore not useful to provide a detailed training manual applicable in all situations.

Using the "Train-the-Trainer" concept, experienced biosafety professionals could train groups of experienced trainers about the scientific principles on which safety decisions are based and implemented and on the key concepts to be included in biosafety courses. Persons who have received this training will then become course providers in their own part of Europe. Rather than repeating what they have just learned, they will need to adapt and apply the essential scientific principles to find safe solutions to nation-specific legislative and regulatory requirements in the context of the prevalent mindsets in individual Member States. Successful instructors must include motivation and empathy and not be limited to knowledge transfer.

Findings

Regular training at different levels and on different topics is crucial to establish good biosafety and biosecurity procedures, build competency, and create a 'biosafety culture' in universities, companies and institutions. To achieve high standards across Europe, material suitable for training to an agreed standard should be produced and distributed to each Member State.

Recommendations

BIOSAFETY-EUROPE recommends the relevant EC authority(s)

1. To bring experts in biosafety and biosecurity training together, taking account of training experiences (e.g. European Biosafety Association and other professional networks) the European Commission should initiate meetings.

2. To increase expertise and to promote courses throughout the EC, a European-wide expert group linked to European agencies (e.g. ECDC, EFSA, OSHA) should be funded to develop Train-the-Trainer courses.

3. To fund biosafety/biosecurity scholarships to educate and train biosafety professionals throughout the EC (e.g. Marie Curie mobility instruments).

4. To define the requirements for competency of biosafety/biosecurity professionals in the legislation.

5. To provide a high standard of off-site training on state-of-the-art devices and techniques by European Competence Centres on biosafety/biosecurity training.

6. To use the training manual, produced by this project (D34) to serve as an outline for an EU-wide biosafety training curriculum.

7. To extend the principles set out here to other territories with which they have scientific interchange such as International collaboration partner countries (ICPC).

The BIOSAFETY-EUROPE Partners

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SIXTH FRAMEWORK PROGRAMME