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Methods

Biosafety-Europe: Recommendations for the harmonisation of biosafety and laboratory biosecurity practices in Europe on the basis of a comparative approach

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

Biosafety-Europe is a project funded through the 6th Framework which aimed to explore harmonization and exchange of biosafety and laboratory biosecurity practices within a pan-European network. The consortium consisted of 18 partners from 10 European countries from industry, universities and government agencies with expertise in biosafety and laboratory biosecurity, in containment technology and in the corresponding legal frameworks. The project started in April 2006 and ended in November 2009.
Detailed information was gathered on European legislation in biosafety and laboratory biosecurity, on practices and procedures and on technical and physical measures of different European containment level 3 and 4 facilities. Regular input, networking and exchange with various expert groups and stakeholders throughout the project were a very valuable tool to continually improve the out-put of the project.
Based on those findings and in order to strengthen and support the Member States efforts, policy recommendations have been formulated on "Legislation (biosafety and laboratory biosecurity)", on "Cost-effectiveness" and on "Training". In the following, the main findings and recommendations are presented.

Biosafety

It was found that 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 microorganisms (GMM) was more strongly enforced than that for biological agents in general. It was found that facilities and practices in containment level 3 laboratories throughout the EU are not of a comparable standard and that a large range of different terminologies for "containment level (CL)" were used within the Member States. 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 the definition of harmonized best practices.

Laboratories referred to the WHO term 'biosafety level (BSL)'. 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 respondents 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 GMM) 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 on 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 makes the exchange of scientists between member states sometimes problematic.

Recommendations

- To merge or at least harmonize the Directives 2000/54/EC and 98/81/EC as the same control measures based on risk assessment, to be applied to both biological agents and GMMs.
- To regularly update the classification list of microorganisms and the technical measures according to current scientific knowledge (Directive 2000/54/EC).
- To require national authorities to collect and report data on laboratory acquired infections. These data should then be compiled and reported on a European level.
- To require organizations handling biological agents and toxins to ensure competent advice commensurate to the risks through e.g. an organizational biosafety committee or a biosafety professional.

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- To develop a consistent terminology for biosafety levels (BSL).
- To develop an EU-wide, evidence-based guidance on biosafety practices and procedures.

Laboratory Biosecurity

Laboratory biosecurity is a relatively new concept that is still developing and there is currently little consensus across Europe as to what laboratory biosecurity means, even within the laboratory environment. Biosafety-Europe has used this term in the following meaning: Laboratory biosecurity describes protection against, control of, and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.

So far, no EU level legislation exists that has been specifically developed to address the protection of biological agents in the laboratory from loss or intentional misuse. However due to the many synergies between biosafety and laboratory 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(1).

Many facilities do implement some laboratory biosecurity controls but these are often not based on risk assessment and are often focused on physical security. Less emphasis is put 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

- To develop and promote consensus based definitions of laboratory biosafety and laboratory biosecurity.
- To introduce risk-related laboratory biosecurity assessments alongside biosafety into already existing biosafety legislation.
- To develop methodology and guidance for laboratory 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 laboratory biosecurity measures.
- 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.
- To ensure that new laboratory biosecurity measures do not hinder the exchange of scientific personnel, data and knowledge.

Cost effectiveness

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 laboratory biosecurity. Technical measures in the existing legislation are 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 laboratory 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 high containment facilities.

The collective expertise of the biosafety community is a valuable resource that can make a big contribution in this area and for briefing lay administrators and politicians on biosafety matters.

The project consortium recommends

- To fund applied research on biosafety and laboratory biosecurity in order to gain more in depth knowledge on evidence-based control which could lead to the development of improved containment measures and procedures that are both efficient and cost-effective.
- To encourage the inclusion of applied biosafety aspects into future research project applications.
- To initiate and support a Europe-wide platform for exchange of knowledge and experience on biosafety and laboratory procedures and practices including biosafety professionals from high containment facilities (human and veterinary) as well as biosafety and laboratory biosecurity legislators.
- To encourage a discussion on how best to achieve biosafety minimum standards in a cost-efficient way.

Training

Biosafety-Europe has identified training needs for biosafety and laboratory biosecurity within European countries by means of questionnaires and workshops. As there is no general agreement about the best practices in biosafety and laboratory biosecurity throughout the EU and the international community and the legislative environment is 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 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.

Regular training at different levels and on different topics is crucial to establish good biosafety and laboratory 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.

(1) E.g. Denmark has introduced biosecurity legislation in 2009 and France in 2010.

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Recommendations

- To bring experts in biosafety and laboratory biosecurity together, taking account of training experiences (e.g. European Biosafety Association EBSA and other professional networks).
- 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.
- To fund biosafety/laboratory biosecurity scholarships to educate and train biosafety professionals throughout the EC (e.g. Marie Curie mobility instruments).
- To define requirements for competency of biosafety/laboratory biosecurity professionals in the legislation.
- To provide a high standard of off-site training on state-of-the-art devices and techniques by European Competence Centers on biosafety/laboratory biosecurity training.
- To extend the principles set out here to other territories with which they have scientific interchange such as International collaboration partner countries (ICPC).

To get more information on the project and additional documents, visit the website of Biosafety Europe at: http://www.biosafety-europe.eu/