

BIOSAFETY-EUROPE: Coordination, Harmonization and Exchange of Biosafety and Biosecurity Practices Within a Pan-European Network

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BIOSAFETY-EUROPE is a Coordination Action funded by the European Commission (EC) through the 6th Framework. Its aim was to explore harmonization and exchange of biosafety and biosecurity practices within Europe. It ended on November 30, 2008 following a meeting in Brussels at which the project members presented their findings and recommendations to stakeholders, including representatives of European and North American agencies and the World Health Organisation.

The group studied the facilities, equipment, practices, and procedures used to achieve Laboratory Biosafety, which is the reduction and prevention of the risk of exposure of workers and the environment to dangerous pathogens. They also surveyed the related topic "Laboratory Biosecurity" whereby physical and administrative measures designed to secure biological material and related information could prevent harm to health or economic loss resulting from malicious release, intentional loss, theft, or misappropriation.

The group has identified several areas where biosafety and biosecurity practices could be harmonized further within Europe and has formulated recommendations for the relevant EC authorities. These include the merger, or at least the harmonization, of Directives 2000/54/EC and 98/81/EC as the same control measure, based on risk assessment, that can be applied to both biological agents and genetically modified microorganisms (GMMs). The group also proposes regular updating of the classification list of microorganisms and associated technical safety measures. It further recommends that national authorities be required to collect and report data on laboratory-acquired infections and that organizations handling biological agents and toxins should identify a source of competent advice commensurate with the risks (such as an organizational biosafety committee and/or a biosafety professional).

Regarding terminology and risk assessment, the group recommends developing a consistent terminology for biosafety levels, the development of EU-wide, evidence-based guidance on biosafety practices and procedures, and the introduction of risk-related laboratory biosecurity assessments into existing biosafety legislation.

The project group encourages the use of the English

terms "biosafety" and "biosecurity" in those languages where discrimination between them does not exist and would be difficult or even impossible to provide.

Regarding specific biosecurity aspects, the group recommends a requirement for organizations handling biological agents, toxins, and GMMs to have an up-to-date inventory of these materials. Furthermore, new biosecurity measures should be based on evidence-based risk assessment and should not hinder the exchange of scientific personnel, data, and knowledge.

Recommendations regarding training include the promotion of biosafety and biosecurity training courses throughout the EC by experts and professional networks including the European Biosafety Association. To this end, a Europe-wide expert group linked to European agencies (e.g., ECDC, EFSA, OSHA Europe) should be funded to develop "Train-the-Trainer" courses. Further training recommendations include setting out the requirements for competency of biosafety/biosecurity professionals via legislation and providing a high standard of off-site biosafety/biosecurity training using state-of-the-art devices and techniques associated with European Competence Centres.

Additional recommendations include the funding of applied research on biosafety and biosecurity in order to develop improved minimum standards of containment that are both efficient and cost-effective, funding for biosafety/biosecurity scholarships to educate and train biosafety professionals throughout the EC, and encouraging applicants for research funding to routinely adopt good biosafety practices wherever appropriate.

Finally, a Europe-wide platform should be initiated for the exchange of knowledge between biosafety professionals from high-containment facilities and biosafety and biosecurity legislators with experience in biosafety and laboratory procedures and practices.

The project group encourages extending the principles set out here to other territories with which European biological scientists have scientific interchange such as International collaboration partner countries (ICPC).

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