

Elements of a preventive approach to bio-preparedness

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Informal Seminar on Bio-preparedness of the
European Union

Brussels

24-25 July 2006

Toward an EU strategy on bio-preparedness

- Pilot Project 2004 – External orientation
 - Stockholm a center of expertise (ECDC, Karolinska Institutet, SMI, biotechnology industry, defence research, etc.)
 - Meeting at SIPRI 29 May 2006 on bio-prevention
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Three strands of activities

- Minimizing risk of unauthorized access to the most dangerous microorganisms in laboratories
 - Minimizing risk of diversion to unauthorized end-users of controlled items in the course of legitimate commercial activities.
 - Export controls and other legislation
 - The role and responsibility of biotechnology industry and research
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How many containment laboratories are needed in Europe?

- A perceived risk of multiplication of the number of containment laboratories.
 - How should the work be organized (e.g. national efforts or cooperation)?
 - How can the amount of such work be minimized?
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Laboratories

- Standard system for biosafety certification that includes the security element
 - Biosafety as a precondition for biosecurity
 - Elaborated measures relating to work on dangerous pathogens (background checks, phys. sec, etc)
 - The risk for confusion due to multiple guidelines
 - Relationship between WHO guidelines and measures at the European level
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Export controls, legislation and regulation

- Effective export control increasingly requires cooperation with industry
 - Effective implementation/enforcement
 - Authorities need to know who exports controlled items
 - Authorities need information on end-users
 - Customs need to recognize controlled items
 - Regulation on transfers of dual-use material many times only when passing out of the EU
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The role of industry

- Internal compliance system must meet proliferation concerns regardless of location of end-user
 - ‘Red flag’ alerts - assessment process
 - Industry commercial incentives
 - ‘Earned autonomy’ - simplified procedures in exchange for demonstrated, verified effective compliance
 - Globally relevant, voluntary standards
 - ISO Technical Committee 223 (Societal Security) as a model?
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Academic research

- Do biosafety committees examine issues of 'pure biosecurity'?
 - Are proposed experiments vetted against security or proliferation criteria?
 - Are procedures in place to address security or proliferation concerns if raised by scientists?
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The role of academic research

- ❑ Biosafety committees need to be equipped to examine issues of biosecurity.
 - ❑ Questions need to be formulated as part of the process of vetting research proposals.
 - ❑ Procedures are needed to address concerns raised by scientists.
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Areas for further discussion

- ❑ Develop biosafety guidelines to ensure that biosecurity becomes an integrated element.
 - ❑ Develop a certification system for high containment laboratories. Discuss the implication of increased numbers of high containment laboratories and examine the alternatives.
 - ❑ Stimulate effective implementation of these measures.
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Areas for further discussion

- ❑ Adjust activities by industry and trade controls to an approach more in tune with modern business practices and based on a working partnership between the industry and the authorities.
 - ❑ Further develop company compliance systems and extend these systems to more companies as a priority.
 - ❑ Audit and monitor the implementation of compliance systems.
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Areas for further discussion

- ❑ There is an urgent need for an effective mechanism to address research carried out in the academic sector.
 - ❑ Biosafety committees need to develop capacities to address security issues.
 - ❑ Relevant training should be introduced as part of further education and as part of subsequent career development.
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