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Research Group for
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Neither Safety nor Security Without Cooperation - Control Measures for Biological High Risk Research in EU States

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The concept of biosecurity has gained enormous attention in recent years and many new regulations for life science research have been proposed and implemented. Analysing the regulations around BSL4 facilities within the EU, we address the following questions:

1) How do the existing accreditation and control measures for BSL4 facilities for human pathogens look like?

2) How must they be improved to enhance biosecurity and prevent the proliferation of biological weapons while at the same time protecting freedom of research?

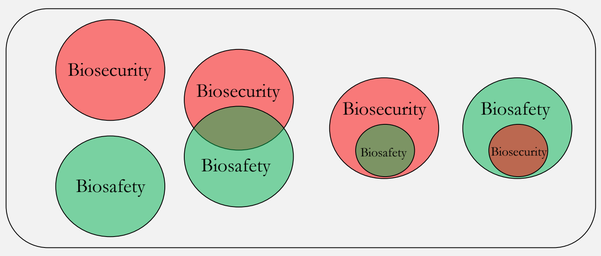
The Theory : Different Concepts and Meanings – Biosecurity, Biosafety and the Dual Use Dilemma

The concept of biosecurity is highly related to the one of biosafety. Additionally, there is a problem in defining what areas in the life sciences are dual use of concern and need special biosecurity oversight.

How do Biosecurity and Biosafety interact?

Biosafety is a concept focusing on preventing the **unintentional** release of pathogens in order to protect laboratory workers, the population and the environment. It describes laboratory best practice as well as containment measures.

Biosecurity is a term that has many very different meanings. It ranges from transmissible diseases risk reduction, protection of the food supply, and preventing the invasion of new species into existing ecosystems, to the protection of the environment against Genetically Modified Organisms (GMOs). In biological arms control it is mainly understood as *"the principles, technologies and practices that are implemented to secure pathogens, toxins and sensitive technologies from unauthorized access, loss, theft, diversion or* ***intentional*** *release".*[1]



What do you think ? Which one is correct?

Dual use is …

… *"a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications."* [2]

The misuse potential of life science research can be defined by using two different approaches:

Agent based

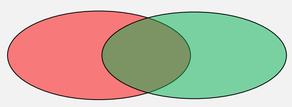
Defines dual use research of concern by the agent used. Relevant agent lists differ from country to country. The most widely known is the Category A US CDC Select Agents List containing anthrax, botulism, plague, smallpox, tularemia and viral hemorrhagic fevers.[5]

Activity based

Defines dual use research of concern by the activity conducted. Relevant activity list differ from assessment to assessment. A review of existing assessments rendered the following list:

- Conferring resistance to therapeutically useful antibiotics or antiviral agents
- Demonstrating how to render a vaccine ineffective
- Enabling the evasion of diagnostic or detection modalities
- Altering the host range of a pathogen
- Enhancing the virulence of a pathogen
- Increasing the transmissibility of a pathogen
- Enhancing dissemination of a pathogen by powder or aerosol
- Synthetic creation of pathogens
- Increasing environmental stability
- Enabling the weaponization of a biological agent or toxin
- Rendering a non-pathogen virulent[4]

Or a mix of both!



The Practice: Regulations on BSL4 research in the EU

- Operational BSL4 facilities for human pathogens exist in France, Germany, Sweden and the UK.
- In all four countries a detailed regulatory framework exists for work with BSL 4 agents, based on common EU Directives relating to work with GMOs, environmental and worker protection as well as on export control regimes. These regulations were put in place long before biosecurity became an important topic in biological arms control.
- All research involving genetic modification has to be registered and is overseen by national authorities. Genetic modification of BSL 3 and 4 agents requires, in addition, a risk assessment and a permission before work can start.
- The importance of dual use and biosecurity considerations in the risk assessment process differs from country to country, mostly depending on the awareness of the stakeholders involved.

"If there would be more paperwork coming up I would spend my whole day only doing paperwork." [3]

"There is a great deal of science fiction made up in the name of biosecurity."[3]

Work in BSL 4 facilities is controlled by:

- Institutional boards on safety and security.
- National authorities on genetic engineering.
- Extensive approval processes for facilities in which pathogens and toxins are handled.
- Regular obligatory staff training courses.
- Announced and unannounced inspections through national authorities.

Conclusions

- There is a limited understanding of and no agreement on what research constitutes dual use research of concern. Consequently, there is an ongoing discussion about the shape and content of biosecurity measures. Instead there is only a vague feeling that some kind of oversight measure is needed. And approaches to define dangerous research often remain simplistic; they use different select agent lists thereby leaving parts of relevant research uncovered by oversight.
- Existing EU regulations on GMOs establish a special oversight process for all work with pathogenic agents. Together with regulations on environmental protection and occupational health and safety, they are comprehensive enough that they could provide for biosecurity in an arms control context also.
- Problematically, scientists are only marginally involved in the biosecurity debate. Scientists often are reluctant to become involved; they have other work to do than developing policy. However, their expertise is indispensable in shaping workable and effective life science regulations. It is up to the security community to further enhance the dialog with the scientists. Researchers, on the other hand, need to be willing to become involved.

Food for Thought

Given the divergent understanding of biosecurity, there would be much use in rethinking biosecurity as a broad concept of governing the use of the live sciences to prevent negative impacts – intended or unintended – on humans, animals, plants and the environment. This would include laboratory accidents, the introduction of GMOs into the environment, and biowepons development. Using such a holistic approach would make the differentiation between biosecurity and biosafety superfluous, thereby reducing the tendency to establish parallel oversight structures.

"It is not important how many rules and regulations you have set up – it is important that the people that have to work with these regulations are aware and have understood the risks and dangers of their work"[3]

"The most important thing is awareness of scientists- this includes stopping or refusing dual use research."[3]

Literature:

1. Clevestig, P., *Handbook of Applied Biosecurity for Life Science Laboratories* (SIPRI, 2009).
2. McLeish C, Nightingale P. The Impact of Dual use Controls on UK Science: Results From a Pilot Study, SPRU Electronic Working paper Series, Paper 132, April 2005.
3. Personal communication with scientists.
4. Zmorzynska et al. Unfinished business- Efforts to Define Dual Use Research of Bioterrorism Concern Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science Volume 9, Number 4, 2011 (in print).
5. See http://www.bt.cdc.gov/agent/agentlist-category.asp.

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