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Swiss Expert Committee for Biosafety SECB

SECB opinion on

dealing with scientific findings having a potential of misuse

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It is in the nature of scientific findings that they bring both benefits and, to a lesser extent, dangers. This also applies to research concerned with development and reproduction of organisms. Research activities in biotechnology, biochemistry, biological pest control, and conventional breeding techniques and their results are associated with very different risks. As with all other activities, these risks must be countered with appropriate and proportionate safety measures.

The Swiss Expert Committee for Biosafety (SECB) works to ensure the safety of humans and the environment. In terms of the handling of hazardous biological agents the SECB is committed both to compliance with biosafety measures and to protection from the abuse of hazardous biological agents (biosecurity). Accordingly, the SECB considers a scientific and socio-political discourse on protection from possible abuses to be important.

In recent years there has been increasing discussion of dual use research and the publication of research findings. For reasons of safety, the SECB calls in general for scientific data to be published without censorship.

What do biosafety, biosecurity and dual use mean?

Biosafety serves to protect employees, the population and the environment from hazardous biological agents (viruses, bacteria, biological toxins).

Biosecurity concerns the protection of the population and the environment from the intentional, criminal misuse of biological agents.

The term **Dual Use** refers to objects, technologies and knowledge that have a dual function in both civilian and military/terrorist fields. In the case of biosciences, the possibilities for misuse are criminal (bioterrorism) and military (bioweapons).

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General considerations

Research on highly pathogenic organisms is important for human health and civil protection

Thanks to the publication of findings of research on highly pathogenic organisms, countermeasures can be taken or vaccines developed in good time. This serves to protect humans and the environment. Even in the case of natural epidemics, we can respond more quickly if the appropriate research projects have been carried out and their results published. From the public health perspective, therefore, various international organisations, including the WHO, consider that public access to scientific findings and publications is vital.

Censorship is disproportionate and is also a security risk

The censorship of scientific literature may result in findings not appearing in reputable, peer-reviewed journals and therefore not being available to and discussed by the scientific community.

From the SECB's point of view, the risk that scientific publications on organisms that are highly pathogenic to humans will be misused for terrorist purposes is small. The artificial development of a highly pathogenic virus requires great specialist knowledge and is costly in terms of both money and time. The prospect of success is also small. Unpublished findings can still be passed on, for example to the military or to security services, where they could be used for further research outside the public domain. Moreover, various attacks in the USA, Japan and Norway show that there are far simpler methods of causing great damage.

Restrictions on research because of biosecurity concerns must be proportionate. The SECB believes that research projects on highly pathogenic organisms should continue to be approved and funded despite their dual-use potential. Not generating knowledge poses equivalent risks, particularly when similar projects cannot be prevented from being carried out elsewhere. Raising staff awareness is however a sensible and expedient measure that can be achieved using simple means.

Freedom of expression and information

The freedom to hold opinions and to receive and impart information is a fundamental freedom, as set down in Article 10 of the Convention for the Protection of Human Rights and Fundamental Freedoms[1]. In addition, Article 16 of the Swiss Federal Constitution[2] stipulates that freedom of expression and of information in Switzerland shall be ensured. In consequence, every person has the right to form his or her own opinion and to express and publish this opinion without restriction.

Today's high standard of living would be unimaginable without scientific advances. Freedom of research and access to information have been and still are important conditions for gaining new knowledge and applying it to the benefit of humans and the environment. While censorship may delay the dissemination of new knowledge, it cannot prevent it.

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[1] European Convention for the Protection of Human Rights and Fundamental Freedoms: https://www.echr.coe.int/Pages/home.aspx?p=basictexts&c

[2] Federal Constitution of the Swiss Confederation (in German, French and Italian): http://www.admin.ch/ch/d/sr/101/index.html

Case studies

The following examples illustrate that censorship of research results may have unforeseeable safety consequences.

Case study 1: Anthrax diagnosis

Diagnosis of anthrax is a good example of the importance of open access to genetic information, even of highly pathogenic agents. After the autumn 2001 attacks with weapons-grade anthrax spores in the USA (following the terrorist attacks in the USA known as 9/11), large numbers of envelopes containing white powers were also sent as a threat to various public offices and private persons in Europe. These substances had to be investigated in most countries by university or hospital laboratories that were not prepared for the identification of anthrax, as they either did not yet exist for public protection or were completely overwhelmed with this new task. It was only because the toxin gene sequences of *Bacillus anthracis* were openly accessible in public databases that the necessary gene technological methods for rapid and safe identification of *Bacillus anthracis* could be developed and implemented by the different laboratories within a short time (1–2 days), so that the samples could be investigated effectively. Fortunately, all these further cases of presumed threats using anthrax proved to be negative. The availability of specialised laboratory analysis contributed significantly to preventing unfounded fear in the population and to calming the situation.

Case study 2: Gain-of-function[3] research on highly pathogenic avian H5N1 viruses

The research groups of Ron Fouchier (Rotterdam, NL) and Yoshihiro Kawaoka (Wisconsin, USA) independently succeeded in modifying highly pathogenic avian H5N1 viruses so that they could be transmitted aerogenically between ferrets. The original H5N1 virus had not previously been aerogenically transmissible between vertebrates. Before publication in 2012, both studies were examined by the NSABB[4] and finally released for uncensored publication after controversial debate and a voluntary moratorium on research activities concerning the transmission of H5N1. For the publication of his study in the American journal *Science*, however, Ron Fouchier had to apply for an additional export permit from the Dutch government.

From the SECB's viewpoint the decision to publish the research results was important and correct. Keeping knowledge under lock and key does not promote security. The SECB does admittedly have concerns because of the export permit demanded. This could have created a precedent that may have an impact on the publication of dual use research in the future. In addition, an export permit contributes nothing to security, as research findings are presented at conferences long before publication and are thus made known to interested parties.

Case study 3: Export permit for Ebola diagnostic kits

During the 2014 Ebola epidemic, a charity in Germany wanted to send PCR kits for the identification of the Ebola virus. However, to do this it required authorisation to export dual use goods, and this authorisation was granted only after a considerable delay. The question arises of why an Ebola detection kit should be included in an export control list when it presents no risk. The kits contain only primer and an RNA strand as a positive control for investigating the serum or plasma from potentially infected persons: i.e. no Ebola viruses at all.

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[3] Gain-of function research in this context means scientific research activities using hazardous biological agents in which the capacity of causing disease is increased, by heightening either the organism's pathogenicity or its transmissibility to mammals including humans, for example through aerogens.

[4] The US government's National Science Advisory Board for Biosecurity.

In acute cases, an unnecessary delay like this can have a devastating effect, quite apart from the extra workload it causes.

From the SECB's viewpoint this example shows that too strict legislation can have severe consequences. A procedure like this is irresponsible in the situation of an epidemic and is an argument against regulating dual use goods too restrictively.

Conclusions

Careful, professional and responsible handling of pathogenic organisms is key. An unnecessary restriction of scientific research and medical advances should however be avoided.

The SECB is convinced that safe and responsible research can be achieved through discussion between all participants that is reasonable and balanced, and that raises awareness of potential risks.

Literature

- Biologischer Terrorismus in Bezug auf die Schweiz. Guery Michael (2005). In: Zürcher Beiträge No. 74, Wenger A. ed. ETH Zurich Centre for Security Studies (CSS). ISBN 3-905696-01-0
- *Bacillus anthracis*: Anthrax. Antwerpen M., Pilo P., Wattiau P., Butaye P., Frey J. and Frangoulidis D (2012). In: BSL3 and BSL4 Agents, Epidemiology, Microbiology and Practical Guidelines. M.C. Elschner, S.J. Cutler, M. Weidmann and P. Butaye (eds). Wiley Blackwell, Weinheim, Germany, ISBN 978-3-527-31715-8; pp 5-18.
- Detection of Highly Dangerous Pathogens. Kostic T., Butaye P. and Schrenzel J. (2005). In: Microarray Methods for BSL3 and BLS4 Agents. Wiley-Blackwell. ISBN 978-3-527-32275-6
- Science Should Be in the Public Domain. V. R. Racaniello, mBio 31 January 2012: e00004-12. http://mbio.asm.org/content/3/1/e00004-12.full.pdf+html
- Controversial Studies Give a Deadly Flu Virus Wings. M. Enserink, Science 2 December 2011: 1192-1193. http://www.sciencemag.org/content/334/6060/1192.full.pdf
- Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets. Herfst S. et al., Science 22 June 2012: 1534-1541. http://www.sciencemag.org/content/336/6088/1534.full.pdf
- The Potential for Respiratory Droplet-Transmissible A/H5N1 Influenza Virus to Evolve in a Mammalian Host. C.A. Russell et al., Science 22 June 2012: 1541-1547. http://www.sciencemag.org/cgi/reprint/336/6088/1541
- Responsible life science research for global health security, WHO 2010. http://www.who.int/csr/bioriskreduction/lifesciences_research/en/index.html
- Science and Security in a Post 9/11 World, Chapter IV: Biosecurity and Dual-Use Research in the Life Sciences; Washington (DC): National Academies Press (US); 2007; ISBN-13: 978-0-309-11191-1. http://www.ncbi.nlm.nih.gov/books/NBK11496/
- European Convention for the Protection of Human Rights and Fundamental Freedoms https://www.echr.coe.int/Pages/home.aspx?p=basictexts&c