

Gain-of-Function Debate A Disputed Testcase for Biosecurity Policy

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Overview of presentation

1. The gain-of-function concept
2. Highlights of the debate
3. The H5N1 debate in The Netherlands as an example

What is gain-of function research? (1)

- Gain-of-function experiments are experiments in which new properties are added to biological agents such as viruses. The reverse – loss of function - is also possible: properties are taken away from biological agents.
- Gain-of-function is not a new concept. Gain-of-function experiments in a general sense have become daily practice in the modern life sciences. As Lipsitch and Galvani state: “Gain-of-function is a common and important approach in biological experimentation, and is not by itself cause for concern”.

What is gain-of function research? (2)

- In practice the debate on gain-of-function has concentrated to those experiments that increase the transmissibility, increase the pathogenicity, or alter the host range of HPAI H5N1 viruses.
- Although gain-of-function by itself is not a cause of concern, it is remarkable that the so called experiments of concern that were described already in the so called Fink Report of 2004, are in fact examples of gain or loss of function .

H5N1 debate: what happened (1)

- September 2011: Fouchier announces research results on aerosol transmissibility of H5N1 virus.
- Manuscript submitted to Science; comparable manuscript (Kawaoka) submitted to Nature.
- December 2011: NSABB advises not to publish all details because of biosecurity risk
- International debate: US, WHO, media, moratorium.
- March 2012: NSABB agrees to publication of reviewed versions.
- April 2012: Publication Kawaoka-article in Nature; June 2012: Publication Fouchier-article in Science.
- January 2013: end of moratorium, but not end of debate.

H5N1 debate: what happened (2)

- Continuing debate between virologists: letters to EU, debates in London, Amsterdam, Hannover. Shift of debate from biosecurity to biosafety
- Summer 2014: Incidents with highly pathogenic microbes in federal laboratories: accidental shipment of live anthrax, discovery of forgotten live smallpox samples, shipment of a dangerous influenza strain.
- October 2014: The White House Office of Science and Technology Policy announces a “pause” that suspends new grants for gain-of-function research involving flu, Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS). New debates still going on.

H5N1 Debate in The Netherlands (1)

- It started on Malta: Fouchier (Erasmus Medical Center) announces research results on aerosol transmissibility of H5N1 virus.
- Debate in US about this project surprises government.
- Export licence for publication is seen as the only instrument available.
- Much criticism from scientific community: censorship, threat for academic freedom.
- Fouchier asks for export licence under protest.

H5N1 Debate in The Netherlands (2)

- April 2012: Dutch government gives export licence; Erasmus MC appeals against procedure.
- September 2013: Court states government was right in asking for export licence; higher appeal by Erasmus MC.
- 22 June 2015: Court of Appeal Amsterdam annulated decision of lower Haarlem Court. Court was not authorized to give a judgment, because Erasmus medical center had no case, since they had got the licence.

Meanwhile in The Hague

- Departments decided to develop common biosecurity policy.
- Ministry of Science asks KNAW to give advice on dual use policy.

Request for advice to KNAW (Royal Academy of Arts and Sciences)

Main questions:

- How should dual use research be assessed?
- Who should assess dual use research?

Recommendations (1)

- An integrated approach for weighing/debating dual use risks and benefits from a security, health care and scientific perspective.
- No more bureaucracy, but clear rules within or in addition to the existing regulatory framework.
- Reinforcing awareness by Code of Conduct and other measures.

Recommendations (2)

- It is important to consider biological factors and properties as well as the social and political context in determining dual use risks; an integrated approach from security and scientific perspective.
- Take politically attainable as well as scientifically feasible institutional and policy measures: no more bureaucracy, but more clarity. **This could be realized by a small permanent biosecurity advisory board.**
- More international cooperation and coordination is necessary.

Present situation

- There is a Biosecurity Office: the national information centre for the Dutch Government and for organisations that work with high-risk biological material.
- Departments have not (yet) succeeded in developing a common biosecurity policy.
- Report KNAW submitted November 2013; until now no official reaction.
- Continuing lack of clarity about the legal basis for an export licence policy regarding dual use publications.



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