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Assessment

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# The need for new risk assessment approaches: the case of biological risks

- Is there a need?
- If so what is it and how can that need be met?

# Involvement with biological risk assessment of life sciences:

- A scientist undertaking genetic modification of poxviruses
- Chair, Royal Society Committee on Scientific Aspects of International Security (SAIS) ([www.royalsoc.ac.uk](http://www.royalsoc.ac.uk))
- Royal Society Science Policy Advisory Group
- Chair, WHO Advisory Committee on Variola Virus (smallpox) Research
- President-Elect, International Union of Microbiological Societies (IUMS) ([www.iums.org](http://www.iums.org))
- Editor-in-Chief, Journal of General Virology 2002-7

# New Approaches to Biological Risk Assessment

- Royal Society Policy Document 08/09
  - [www.royalsociety.org/policy](http://www.royalsociety.org/policy)
- A Royal Society Science Policy Centre International Workshop July 2009

# The spectrum of biological risks

- Naturally occurring:
  - e.g. pandemic influenza, re-emerging infectious diseases
- Unintended (outcomes of research)
  - Laboratory accidents, pathogen escape
  - Dual use research
- Deliberate (bioterrorism)
  - Release of micro-organisms
  - poisoning with toxins

# Perspective on relative risks

- Infectious diseases
  - Kills 14 million people each year
- Chronic diseases
  - 17 m die from cardiovascular disease
  - 7 m die from cancer
  - 4 m die from chronic lung disease
- Who has died from dual risk research?

# Can life sciences research be misused?

- Yes, for example:
- Any gene can be cloned and the protein produced
- The protein may be a poison or toxin: directly harmful
- The protein may increase the virulence of a micro-organism
- The genome sequence of a virus can be used to re-create infectious virus from cloned DNA
  - Polio 1981, 2002
  - Now possible for most viruses
  - Potential mis-use in economic or biological terrorism

# New developments in life sciences research with potential for mis-use

- Restriction enzymes and cloning in bacterial plasmids
- Reverse transcriptase
- Polymerase chain reaction (PCR)
- Genetic engineering of live viruses or bacteria
- Recreation of infectious agents from cloned DNA
- Synthetic biology



## Has this potential mis-use been exploited?

- Few examples of dual use research have been found:
  - Regeneration of poliovirus (2002)
  - Re-creating 1918 influenza virus
  - Ectromelia / IL-4, (2001)

# Mouse plagues in Australia



# Engineering ectromelia virus as an immunocontraceptive (for mice)

- Express zona pellucida antigens from ectromelia virus (the cause of mousepox)
- Immunise mice to induce sterility by breaking immunological tolerance
- Enhance the antibody response by co-expressing Th2 cytokines from the same virus

# Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

Ronald J. Jackson, Alistair J. Ramsay, Carina D. Christensen, Sandra Beaton, Diana F. Hall, and Ian A. Ramshaw

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**Journal of Virology, February 2001, p. 1205-1210, Vol. 75, No. 3**

You are in: [Health](#)

Wednesday, 10 January, 2001, 19:18 GMT

## Deadly virus fuels bio-terror fears



The threat of bioterrorism worries many experts. Scientists who accidentally created a deadly version of mouse smallpox in the laboratory say lethal human viruses are only a step away.

The prospect of such dangerous organisms being produced relatively easily have left bioterrorism experts fearful of killer global epidemics.

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### See also:

- ▶ [23 Apr 99 | Health](#)  
US retains smallpox supplies
- ▶ [07 May 99 | Health](#)  
Smallpox vaccine warning
- ▶ [05 May 00 | Health](#)  
Twenty years free of smallpox
- ▶ [17 Jul 00 | Americas](#)  
Scientists assess bio-terrorism threat
- ▶ [27 Jul 00 | Health](#)  
Anthrax vaccine 'ineffective'

**Internet links:**

# The benefits of life science research

- Enormous benefits have come from life science research that might have dual use, e.g.:
  - Vaccine for HBV
  - Screening blood products for HIV, HCV
  - Recombinant insulin, clotting factors etc:
- Consider balance of real benefits versus potential misuse
- Use existing legislation, build on this if necessary, but don't over-legislate: enactment of new legislation will neither ensure compliance nor disable terrorists

# What concerns do countries have about the potential misuse of life sciences research?

- What is prohibited in one country might be permitted elsewhere
- Scientists might do work that may be:
  - Dangerous, e.g. creation of dangerous microbes
  - Unregulated,
  - Publish methods that educate others how to make or deliver dangerous microbes or toxins
- The public may be concerned about scientific research: is it dangerous, secret, out of control?

# Is there a need to introduce new safeguards / controls?

- What safeguards / controls exist in UK at present ?
- Health and Safety Executive (HSE)
- Genetic Manipulation Advisory Group (GMAG)
- Advisory Committee on Dangerous Pathogens (ACDP)
- Gene Therapy Advisory Committee



# What must be done in UK to undertake & publish research?

- Employee signs contract with employer stating compliance with all local and national safety legislation
- A risk assessment for all projects must be submitted to local safety committee: what's the purpose of research?
- If GM is involved, the project must be scrutinised by local GM committee. All GM work with pathogens cat 2 or higher must be considered by and registered with HSE
- Grant proposals are considered for dual use issues by referees and funding agency board members
- Papers submitted to journals are considered for dual use by referees, editors and publishers

# Managing risks of misuse associated with grant funding activities: A joint MRC, BBSRC and Wellcome Trust policy statement

[www.bbrsc.ac.uk/society/accountability/position\\_statements/joint\\_misuse.html](http://www.bbrsc.ac.uk/society/accountability/position_statements/joint_misuse.html)

- Introduction of question on application forms asking applicants to consider risks of misuse associated with their proposal
- Explicit mention of risks of misuse in guidance to referees as an issue to consider
- Development of clear guidance for funding committees on this issue and the process for assessing cases where concern has been raised
- Modification of organisational guidelines on good practice in research to include specific reference to risks of misuse

# Society for General Microbiology (SGM): Policy on Scientific Publication, Security and Censorship:

[www.sgm.ac.uk/pubs/policy.cfm](http://www.sgm.ac.uk/pubs/policy.cfm)

- Scientific publication is important for the communication of ideas and findings for improvement of human, animal and plant health
- The integrity of the process of publishing articles in peer-reviewed journals must be protected
- Pathogen genome sequences have been published and could conceivably be exploited by a determined terrorist. The same information has been exploited for public benefit, including biodefence and health protection. The benefits greatly outweigh the potential dangers
- It is responsible to recognize that in rare cases, papers submitted for publication might raise particular concerns that the methods or results could have possible use in bioterrorism
- Editors, referees and publishers should consider safety and security issues... The final decision should be the responsibility of the Editor-in-Chief of the journal concerned

Is there a need for countries to work together to increase awareness about potential misuse of life science research?

**Yes !**

- Remind principal investigators, postdocs and graduate students of:
  - existing legislation and the need for compliance
  - the need to consider the potential dual use aspects of their research
- Tighten measures to ensure compliance
- Normalise legislation across international boundaries
- Encourage international forums for discussion of these issues, OECD, WHO, ISC, IUMS
- Publicise policy statements such as IUMS ([www.iums.org](http://www.iums.org))
- Encourage nation states to sign up to Biological and Toxin Weapons Convention

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**This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumers DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**