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Gain of function research: advice from EASAC

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What is EASAC?

- European Academies Science Advisory Council formed in 2001 to enable European national academies of science to collaborate in giving advice to EU policy-makers (e.g. European Commission and Parliament)
- Comprises all EU national academies of science (plus Norway, Switzerland)
- Core secretariat in Halle, Germany and networking office in Brussels, Belgium
- Objective to deliver consensus outputs to provide a means for the collective voice of European science to be heard
- Programmes cover Biosciences, Environment and Energy: sustained interest in policy issues relating to control of infectious diseases

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EASAC GoF research project: why this collective academy work at the EU level?

- Drawing on analysis, commitment and prior work by EASAC member academies, including KNAW, and international discussion (2012-)
- Research and regulation issues, and societal implications, are relevant for all EU Member States and for collaborative EU research (Horizon 2020) and for provision of shared infrastructure, e.g. biocontainment facilities
- Scientific community expressed differing views to President of European Commission in 2013 on benefit-risk in GoF influenza virus (H5N1) research
- Request from European Commission and Chief Scientific Adviser to EASAC to clarify and advise on issues

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EASAC goals for the project

- Bringing together scientists, nominated by academies, with a broad range of expertise and views
  - To explore where there is consensus
  - To clarify which issues are still unresolved
  - To advise on what additional analysis is needed to assess future options for the research area
- Emphasising which current EU regulations govern research and what good practice already exists at national level
- Identifying what is national or EU-level responsibility

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Scope of the EASAC project: addressing critical issues for GoF research

- Self-governance and scientific responsibility
- Benefit-risk assessment
- Research review and management systems
- Research moratoria and alternatives
- Bioethics – issues and place in research review
- Biosecurity advisory issues – mechanisms and advisory bodies
- Publication of sensitive information and options for management
- Public engagement – and the responsibilities of academies
- Global context – and how to inform discussion and action worldwide

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Introduction to EASAC recommendations

- Emphasising a layered approach with integration of responsibilities and action at researcher, research institution, research funder, national and international levels
- Focus on virology research but recommendations are also relevant more broadly in microbiology
- Focus on biosafety but biosecurity also recognised as very important
- Some issues remain controversial but the outputs represent EASAC Working Group consensus

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EASAC key messages: Self-regulation and harmonisation

- Good practice requires – conforming with regulations/safety conditions/codes of conduct, justifying proposed research
- Self-regulation means – checks and balances on research within the scientific community, requires raising awareness of researchers and their institutions, with need for education
- Attention to biosafety issues – at all stages e.g. in proposal
- Academies of science have a continuing role – in promoting biosafety and biosecurity norms and supporting audit of research practices

EASAC key messages: Benefit-risk assessment

- Not a “once and for all” calculation but continuing, collective commitment to understand and communicate the issues
- Incommensurable parameters measured in risk and benefit do not allow a value-free determination to be made
- Can benefit be quantified as prospective public health impact or described in terms of generation of scientific knowledge?
- Academies and learned societies need to continue to promote discussion across scientific community and with other stakeholders: EASAC publications

EASAC key messages: EU/national activities and organisations in biosafety/biosecurity

- Collating available information – a possible role for European Commission (DG Sante) Health Security Committee
- Importance of guidance for research funded by Horizon 2020 as well as at national level
- Importance for all researchers and their institutions conforming with EU regulations as implemented nationally
- No new EU-level body is recommended
- Member States should have clear national advisory approach and governance mechanism with statutory powers

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How does EU currently manage research?

- Overarching EU legislation
  - Directive on contained use of GMOs
  - Directive on protection from risks relating to exposure to biological agents at work (containment level 3 and 4 laboratories)
  - Regulation on control of export of dual-use technology
  - Legislation is implemented by Member States with enforcement by their regulatory authorities
- Practical procedures for biorisk management
  - e.g. WHO and OECD guidance, development of ISO Standard
- Codes of conduct
  - e.g. IAP/IAC 2012, Leopoldina with DFG 2014

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Case study of layered national framework for managing research: UK

Infrastructure	• National legislation implements EU Directives • Institution/individual requires appropriate training, equipment and facilities (inspected), health protection, national guidance
Institutional assessment	• Biological Safety Committee, peer and senior research management consideration, ethical review, biosecurity aspects • Justification of research approach (alternatives), minimising risk
Health and Safety Executive	• National HSE Contained Use proposal review, consulting scientific advisers • Notified experiment cannot begin unless permission granted

EASAC key messages: Publication of sensitive information

- Researchers and their institutions all have responsibility to make decisions about publishing sensitive information
- Journals should be encouraged to seek appropriate advice, including from security experts
- European Commission's Export Control Regulation is an inappropriate and ineffective vehicle to block publication
- European Commission (DG Research) attempts to raise awareness about revision of this Regulation were welcome - researchers should continue to inform policy-makers about the issues

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Response from the European Commission to EASAC report

EASAC main messages	European Commission response, October 2015 (further detail in outputs from launch of report http://www.easac.eu/home/easac-news/detail-view/article/summary-of-t.html)
Self-regulation and harmonisation	Welcomed and agreed
Benefit-risk assessment	Welcomed and agreed
Public engagement	Welcomed and agreed
Global dimensions	Welcomed and agreed
Need for appropriate guidance but no new EU-level bodies	Welcomed and agreed
Publication of sensitive information	Subject to ongoing discussion in revising Export Control Regulation

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US Biosafety and Biosecurity relevant to GoF

- Key US policy instruments for biosecurity:
  - Select Agent Program, Export Controls
  - Also applicable - BMBL and NIH Biosafety Guidelines, Federal/Institutional DURC policies, HHS Framework
- Gryphon risk-benefit analysis:
  - Semi-quantitative for biosafety
  - Qualitative for biosecurity – Malicious (insider) acts and use of information
- Other recent activities:
  - National Academies second symposium on GoF research (March 2016)
  - NSABB final recommendations (May 2016)

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NSABB Final Recommendations - 1

- Additional multidisciplinary review prior to funding plus ongoing oversight (based on identifying GoF research of concern)
- Advisory body designed for transparency and public engagement as part of US government ongoing evaluation of oversight policies
- Adaptive policy approach to ensure oversight remains commensurate with risks

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NSABB Final Recommendations - 2

- In general, oversight mechanism should be incorporated into existing policy framework where possible
- Consider ways to ensure all GoF research of concern in US is subject to oversight, regardless of funding source
- Broad efforts to strengthen laboratory biosafety and biosecurity
- US government should engage the international community in dialogue about oversight and responsible conduct

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Ongoing international academy activities

- BWC:
  - EASAC GoF input in Geneva, December 2015 and August 2016, preparatory to 8th review of BWC
  - IAP Biosecurity Working Group
  - Continuing importance of academy-supported outreach/science advisory process for BWC
- EASAC-NAS:
  - Potential for interaction on principles and strategy in support of wider international coherence on managing GoF research on layered, integrated approaches
  - Potential for global discussion supported by IAP