Session III
Analysis of the Current Policy Landscape and Potential Policy Options for Gain-of-Function Studies

Moderators:
Joseph McDade, Ph.D.
Marie-Louise Hammarskjold, M.D., Ph.D.
Members, NSABB Working Group

Overview of the Current Policy Landscape

Purpose

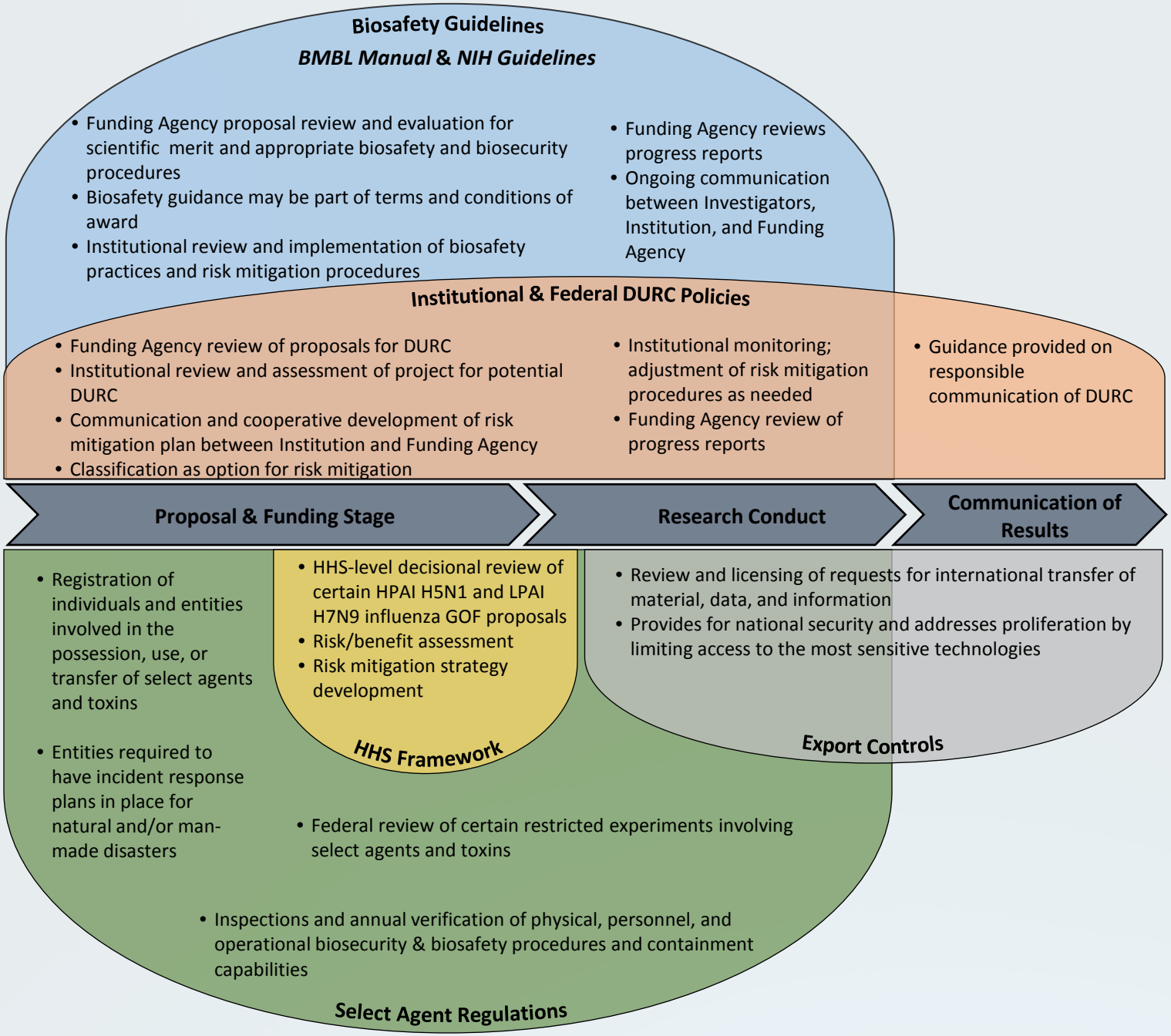
NSABB WG analyzed current USG policies and guidelines for oversight of pathogen research to:

- Identify existing oversight policies relevant to the funding, conduct, and communication of research involving pathogens and GOF studies
- Analyze whether and how existing policies apply to and manage risks associated with GOF studies of concern

Overview of the Current Policy Landscape

- Biosafety guidelines
- Federal Select Agent Program
- Oversight of Dual Use Research of Concern (DURC)
- Pre-funding Review of Certain GOF Studies (HHS Framework)
- Export control regulations

USG Oversight of Life Sciences Research Involving Pathogens



BMBL – Federal guidance on biosafety and containment practices for life science research involving biological infectious agents or hazardous material

NIH Guidelines – Federal guidance for oversight of biosafety and containment for research involving recombinant or synthetic nucleic acid molecules

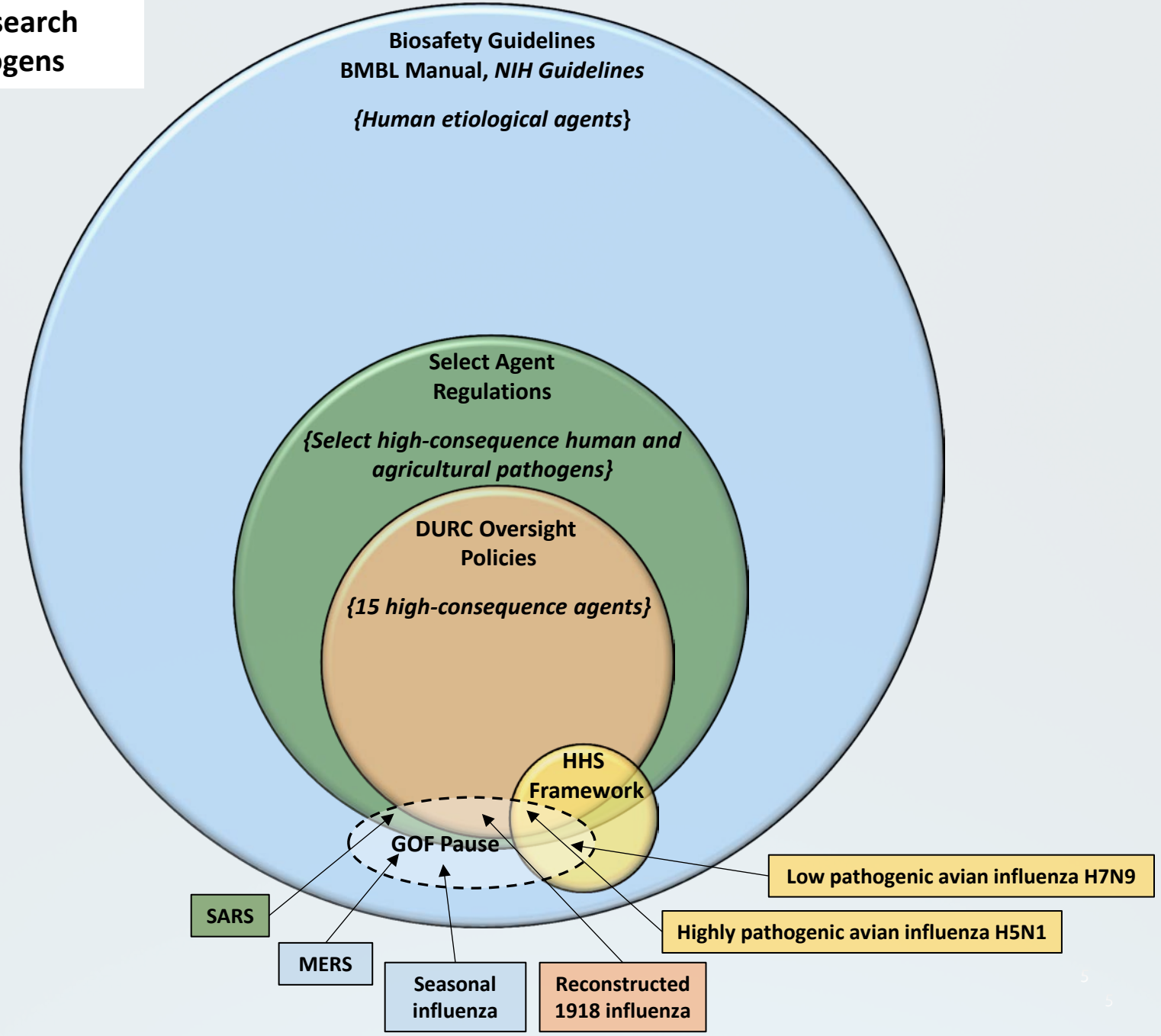
DURC Policies – Federal & Institutional oversight of biosecurity risks, particularly involving the misuse of research information, products, and technologies

Select Agent Regulations – Federal & Institutional oversight of biosecurity and biosafety risks associated with the use and transfer of high-consequence agents & toxins

HHS Framework – HHS department-level review and approval of proposed gain-of-function experiments involving HPAI H5N1 & LPAI H7N9

Export Controls – Federal oversight to limit access to, and international proliferation of, sensitive material and technologies

Scope of USG Oversight of Life Sciences Research Involving Pathogens



Potential Approaches and Options

The WG is considering a number of approaches that could be applicable to decisions and oversight of the types of GOF studies that have raised concerns.

- **Permissive approach:** in general, allows an activity unless the environment, health, or security are clearly compromised
- **Precautionary approach:** in general, limits an activity unless the environment, health, or security are clearly protected
- **Planned adaptation or risk-based approach:** provides a systematic, iterative approach to deal with managing risks in the face of uncertainty
- **Threshold approach:** would entail creating a risk threshold beyond which certain studies are given special attention or subject to additional scrutiny or oversight
- **Point-source approach:** involves controlling where and under what conditions certain studies are conducted

Session III – Analysis of the Current Policy Landscape and Potential Policy Options for Gain-of-Function Studies

Discussion Panelists:

- **Gigi Kwik Gronvall, Ph.D., UPMC Center for Health Security**
- **Michael Imperiale, Ph.D., University of Michigan Medical School**
- **Barbara Jasny, Ph.D., Science Magazine**
- **Regine Aalders, M.Sc., Embassy of the Kingdom of the Netherlands**

Submit questions: nsabb@od.nih.gov

Analysis of the Current Policy Landscape – Discussion

Questions for Discussion

- What are the major drivers of risks associated with GOF studies of concern? Are there any deficiencies with current policies in managing those risks?
- If risks are not currently adequately managed, what policy options or oversight might be available to help manage the risks? What should that oversight entail? Should that oversight occur at the federal or institutional level, or both?
- What challenges are associated with managing risks at the stage where research results are being communicated or published? What would journal editors find most helpful upstream to manage risks prior to publication?
- How can oversight measures be developed and employed in ways that would allow the benefits associated with GOF studies of concern to be realized?

Policy Landscape for GOF Research – Issues for Further Deliberation

Issues for further deliberation

- Adequacy of existing policies, guidelines, frameworks and programs for managing the potential risks associated with GOF research
- Rigor and thoroughness of review processes within each
- Are there provisions for updating policies/guidelines?
- Is there a robust mechanism for gathering and considering public input about proposed updates changes?
- Is there one current guideline or framework that is amenable to revision that would be sufficient to address current concerns surrounding GOF studies?

GOF: analysis of current policy landscape

Gigi Kwik Gronvall, PhD
ggronvall@upmc.edu

January 7, 2016

1. Biosafety, not biosecurity, is the major driver of risks.

- Biosecurity risks are plentiful and growing, however there are many more actionable paths for deliberate misuse than GOF.
- Little agreement about the threat, but in our recent study, experts rated risks of misuse of synthetic pathogens lower than unmodified bacteria, viruses, toxins.
- Policy options should not stem from security concerns. (i.e. should not be made a select agent or subject to export control regulations.)

2. Policy options need to be inclusive and adaptive.

- Dual-use and biosafety concerns are longstanding, and well-captured by Fink report/NSABB's experiments of concern.
- Recommendations for future GOF funding reasonable, and bolstered by USG actions (Monaco, Holdren 2015 "A National Biosafety and Biosecurity System in the United States). Additional measures to broaden biosafety knowledge and understanding needed.
- Precautionary approach is shortsighted, and will not advance international governance.

3. Raising nations' biosafety levels should be a USG priority.

- What constitutes effective national governance and adequate funding for biosafety is not well defined; biosafety guidance has been concentrated on user level/institutions and through GHSA to focus donor country efforts.

- There are many drivers for governments to fund research, some will be controversial, internationally. Yet even in future controversies, common ground can be found in ability to contain and manage risks, and minimize consequences.

For further information

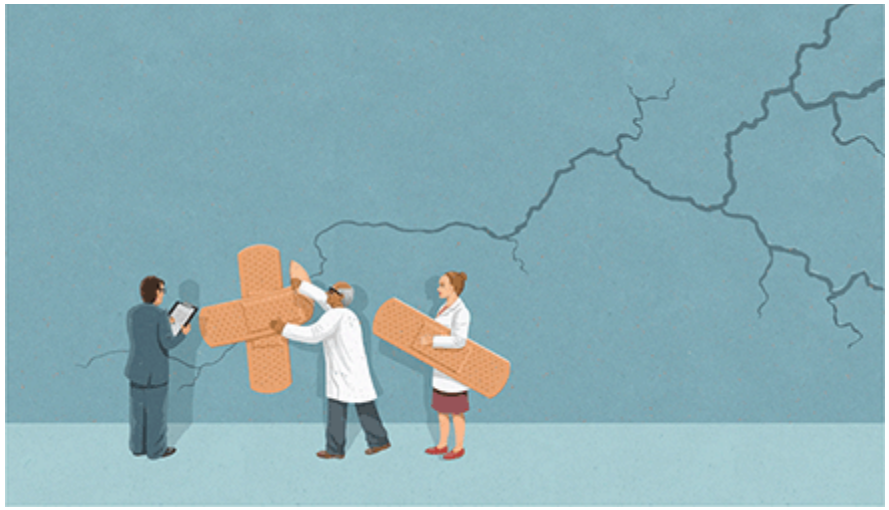
- Gronvall GK, Rozo M (2015) "Addressing the Gap in International Norms for Biosafety." Trends in Microbiology, Vol 23, Issue 12, pp 743-744, December 2015.

- Boddie C, Watson M, Ackerman G, Gronvall GK (2015) "Assessing the bioweapons threat." Science, Vol 349, no. 6250, pp. 792-793. Doi: 10.1126/science.aab0713. August 21, 2015.

- Gronvall GK (2015). "US Competitiveness and Synthetic Biology." Health Security. 13(6): 378-389. doi:10.1089/hs.2015.0046.

CHALLENGES FOR RISK MANAGEMENT - COMMUNICATION AND PUBLICATION

Barbara R. Jasny, Ph.D.
Deputy Editor, Science
January 7, 2016



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CHALLENGES

- Normal challenges of review are exacerbated
- Decision-making in the face of uncertainty
- Unanticipated results
- Future challenges
- Lack of options other than publication or rejection
- Research that has not received federal funds-international, industry sources
- Responsible communication with the public

WHAT WOULD HELP?

- **Consistent federal oversight**
- **Documentation that oversight of federally funded research had continued until the time of submission**
- **Mandatory training in communication with the public for researchers and institution or gov't representatives**
- **An independent agency to set standards and provide advice to journals**
- **Continued efforts to harmonize international standards**

‘Bioveiligheids’ policy Netherlands

Biosafety

Biosecurity

Dual use research and non-proliferatie

Biorisico

Pillars of policy:
- ❑ Overview
- ❑ (Bio)risk assessment
- ❑ (Bio)risk management
- ❑ Supervision

1

2

Responsibilities:

Security & Justice
- In general: coordination crisis and contra-terrorism
- Law on safety regions – Preparation on disaster, crises and response

Foreign Affairs / Trade
- International conventions- BTWC, VNR1540
- EU dual use regulation - Export control: license and ‘sondage’

Health, Welfare & Sport
- Law on Public Health – Management outbreaks
- Directing Biosecurity Office (National Institute for Public Health and the Environment

Education, Culture & Science
- Stimulating education (KNAW: Code of Conduct biosecurity)

Infrastructure & Environment
- Law on environmental management: license for institutions, inclusive labs
  - License GGO
  - Institute biosafety officer GGO
  - Reporting new animal pathogens

ILT

Economic Affairs
- EU regulation animals – import license animal pathogens
- Law on plant diseases – license plant pathogens and quarantine record

NVWA

Social Affairs & Employment
- Law on working conditions:
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Inspection SZW

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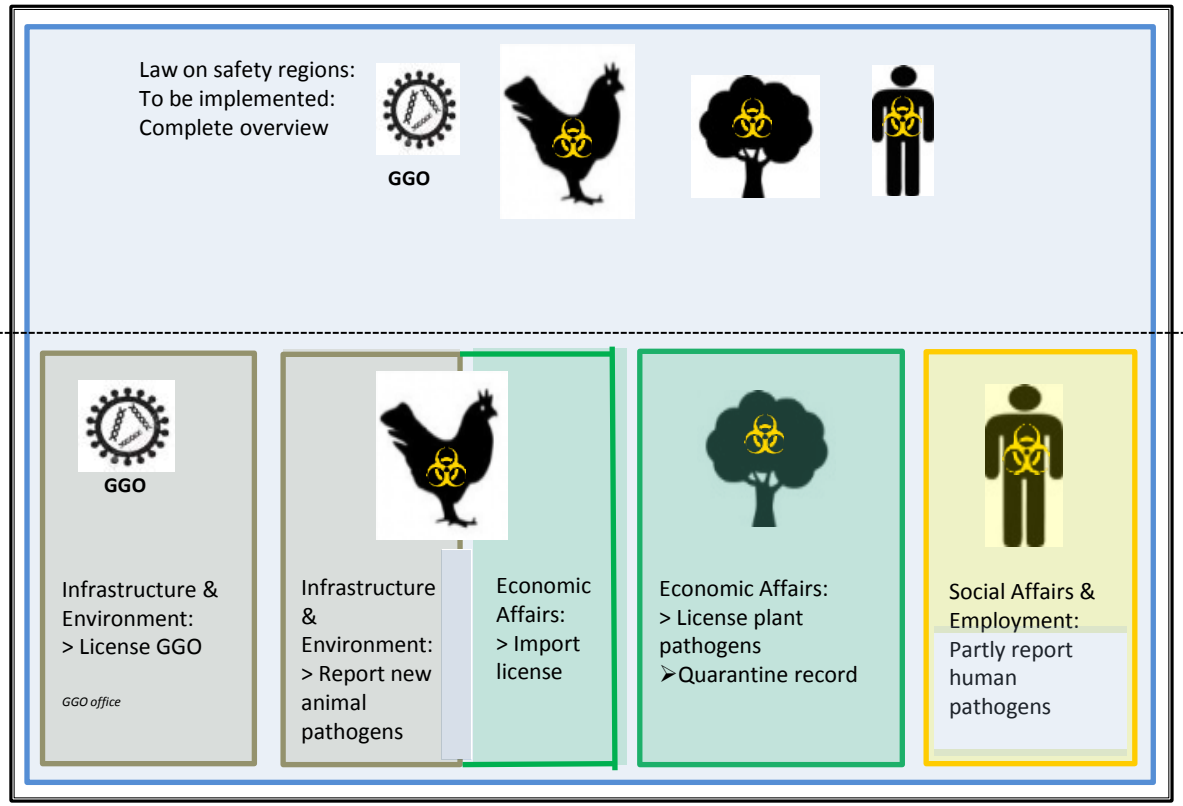
Biosecurity Office (National Institute of Public Health and the Environment):
Supporting institutions and policy, biosecurity tools, education (no legal advisory status)



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