Biosecurity Policy Landscape in Japan

BWC Meeting of Experts, 2014

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Bio-preparedness/-defense/- security in Japan

Bio-preparedness/-defense

Capacity Building for Biodefense

Strengthening Biopreparedness

R&D for Biodefense
  “Safe and Secure Society”

Pandemic Preparedness

late 1990’s

Early 2000’s

Mid 2000’s

late 2000’s

Biosecurity

Establishing Pathogen Control System

Dual-use in Pathogen Research

2020 Tokyo Olympic &Paralympic
Today’s Topics

- Laws and Regulations for biorisk management in Japan
- Approach to DURC in life science by scientists in Japan
LAWS & REGULATIONS
FOR BIORISK MANAGEMENT IN JAPAN
## Laws & Regulations
for Biorisk Management in Japan

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<th>Lab -biosecurity</th>
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<th>Import &amp; Export Control</th>
<th>Surveillance &amp; Response</th>
<th>Regulation for Production Release, etc.</th>
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*For genetically modified organisms*

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*Biosecurity Policy Landscape in Japan*

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Pathogen Control under Infectious Disease Control Act in Japan

- Amendment of Infectious Diseases Control Act (enacted on June, 2007)
  - The pathogen control scheme was added to the Infectious Disease Control Act

- Background
    - Called for *early establishment of a pathogen control system* through revision of the Infectious Diseases Control Act
### Pathogen Control under Infectious Disease Control Act in Japan

#### Possession etc. is prohibited
(Class 1 pathogens)
- Ebolaviruses
- Crimean-Congo hemorrhagic fever virus
- Smallpox virus
- South American hemorrhagic fever viruses
- Marburgvirus
- Lassa virus

#### Possession etc. requires permission
(Class 2 pathogens)
- SARS coronavirus
- Anthrax bacteria
- Francisella tularensis
- Plague bacillus
- Botulinus bacillus
- Botulinum toxin

#### Possession etc. requires registration
(Class 3 pathogens)
- Coxiella burnetii
- Rabies virus
- Multi drug-resistant TB
- Hemorrhagic fever with renal syndrome viruses
- Western equine encephalitis
- Tick-borne encephalitis virus
- Omsk hemorrhagic fever virus
- Kyasanur forest disease virus
- Eastern equine encephalitis virus
- Nipah virus
- Japanese spotted fever rickettsia
- Epidemic typhus rickettsia
- Hantavirus pulmonary syndrome viruses
- Q fever
- Burkholderia mallei
- Brucella viruses
- Veneraelae equine encephalitis virus
- Hendra virus
- Rift Valley fever virus
- Burkholderia pseudomallei
- Rocky Mountain spotted fever rickettsia
- Severe Fever with Thrombocytopenia (SFTS)
- Middle East Respiratory Syndrome (MERS)

#### Relevant standards must be complied with
(Class 4 pathogens)
- Influenza viruses (subtypes H2N2, H5N1, H7N7 and H7N9, excluding pathogens of pandemic flu and other infections)
- Pathogens of pandemic flu and other infections
- Yellow fever virus
- Cryptosporidium
- Tubercule bacillus (excluding multi drug-resistant TB)
- Cholera bacteria
- Shiga toxin
- Shigella
- Salmonella typhi
- Enterohemorrhagic Escherichia coli
- Salmonella paratyphi A
- Poliovirus

- To be specified by ordinance

- Types of pathogens etc. shall be registered within 7 days of possession to the Minister of Health, Labour and Welfare.
- Transportation must be registered with the Public Safety Commission.

- Compliance with facility standards, as well as standards for storage, use, transportation, sterilization etc. (Ordinances of Ministry of Health, Labour and Welfare), specified for respective pathogens
- Reporting and interviewing and on-site inspection by the Minister of Health, Labour and Welfare etc.
- Improvement orders by the Minister of Health, Labour and Welfare
- Punishments for violation of improvement orders etc.
Pathogen Control under Infectious Disease Control Act in Japan

- Relationships with **security sectors**
  - Transportation of Class I~III pathogen should be notified to the Public Safety Commission.
  - National Policy Agency/Japan Coast Guard may deliver an observation to MHLW on biosafety/biosecurity measures.
  - MHLW should report the designation/permission/registration of Class I~III pathogen to National Police Agency/Japan Coast Guard/Fire and Disaster Management Agency.
# Laws and Regulations for H5N1 GOF Research

<table>
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<tr>
<th>Subjects</th>
<th>Laws and Regulations</th>
<th>Details</th>
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<tbody>
<tr>
<td>Possession of H5N1 virus</td>
<td>Infectious Disease Control Act (Class 4)</td>
<td>Must comply with standards on facilities, storage, use, transport and sterilization</td>
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<td>Must immediately report incidents to police e.g. missing or stolen</td>
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<tr>
<td>Act on Domestic Animal Infectious Disease Control (H5N1 of high pathogenicity to birds and/or animal-derived)</td>
<td>Should be permitted by the Minster of Agriculture, Forestry and Fisheries before possession</td>
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<tr>
<td>Gene modification making H5N1 virus transmissible among mammals</td>
<td>Cartagena Act (Type II use of LMO)</td>
<td>Should have containment measures confirmed by MEXT before experiments</td>
</tr>
</tbody>
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>> Biosafety of H5N1 GOF research may be assured through these Acts.
Laws and Regulations for H5N1 GOF Research ~Do we need more?~

- Modified organisms with high transmissibility in human may be categorized in the upper tier (if such organisms clearly be defined).
  - Can we make the criteria prior to the experiment?
- “If research were required to obtain higher tier permission before being started, this would slow and limit effective research that should be contributing to public health and security (Makino, 2013)”.

Biosecurity Policy Landscape in Japan
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APPROACH TO DURC IN LIFE SCIENCE BY SCIENTISTS
Approach to DURC in life science by scientists

- Predawn stage – establishing a basis for interdisciplinary discussion
- Activities in life science communities
- Activities by the Science Council of Japan
- Education
Predawn Stage
establishing basis for interdisciplinary discussion

- Key players
  - National Defense Medical College
    - Started dual use education in MD course in 2005
  - Research Institute of Science and Technology for Society, Japan Science and Technology Agency (JST)
  - Keio University Global Security Research Institute (Keio G-SEC)
    - Funded by MEXT “PJ for S&T for a Safe and Secure Society”
    - Hosted workshops/seminars on dual use issues in life science from 2007
Project for Science and Technology for a Safe and Secure Society by MEXT (FY2007~FY2011)

- Background
  - “Safest and Most Secure Society in the world” as a goal in 3rd National Science and Technology Basic Plan (FY2006~2010)

- Project
  - Purpose: to promote R&D for countermeasures against terrorist attack.
  - Biosecurity became a key agenda
    - Development of Biological Detection System
    - Building a platform for commoditizing knowledge and networking of experts
      >> Keio G-SEC (FY2007~FY2010)
        succeeded by Nagasaki Univ. for FY2011
Biosecurity Workshops and Seminars at Keio G-SEC, FY2007~FY2010

- 11 workshops and 15 seminars, 30~80 participants/event
- Concepts
  - Linking public health and security
  - Networking experts in public and private sectors
- Topics covered
  - Risk and threat assessment
  - Legislation for biopreparedness and response
  - Biosecurity and migration of human, resources & technology
  - Medical countermeasure development
  - Detection and diagnosis
  - Decontamination
Activities in Keio G-SEC (1)

- Hosted a seminar in 2008 for the first time
  - “Biosecurity: Current and Future Concerns and Response” (February 5th, 2008)
  - Speakers:
    - Prof. Malcom Dando (Univ. of Bradford)
    - Dr. Brain Rappert (Univ. of Exeter)
    - Professor Nancy Connell (Department of Medicine at the University of Medicine and Dentistry of New Jersey)
  - Co-hosted with JST/RISTEX
Activities in Keio G-SEC (2)

- Started to include topics on preventive aspects of biological weapons in workshops and seminars
  - “Future Perspectives of Synthetic Biology”
    Dr. D Kiga (Tokyo Institute of Technology)
    4th Keio G-SEC Biosecurity Workshop (July, 2008)
  - “Controlling Dangerous Pathogens: A Prototype Protective Oversight System Seminar Series on Bioterrorism and Infectious Diseases”
    Dr. Nancy W. Gallagher (University of Maryland)
    Seminar Series on Bioterrorism and Infectious Diseases (Aug., 2008)
  - “Biodefense and Biosecurity Education Program in US/UK/Japan”
    Dr. Masa Minehata (University of Bradford)
    Dr. Gregory Koblentz (George Mason University)
    Keio G-SEC Biosecurity Expert Meeting (March, 2010)
Activities in Keio G-SEC (3)

- Keio G-SEC Biosecurity Workshop
  “Ethics for Science & Technology and Risk Management for Sensitive Technologies” (Dec., 2010)
  - Interactive panel discussion regarding governance, ethics, sensitive technologies, etc. with life and social scientists
Activities in Keio G-SEC (4)

- Japan-UK Joint Seminar
  “Biosecurity, Dual Use Dilemma and Education for Life Scientists” (Jan., 2011)
  - 1 day discussion with experts from US/UK/Japan
Approach to DURC in life science by scientists

- Predawn stage – efforts by motivated institutions
- Activities in life science communities
- Activities by the Science Council of Japan
- Education
Activities in Life Science Communities

Special symposiums/workshops on dual-use were organized in the annual meetings of the following academic societies in 2012:

- Japanese Society for Virology
- Japanese Society for Cell Synthesis Research
- Japan Association for Bioethics
- Molecular Biology Society of Japan
Activities in Life Science Communities

- **Strategic Proposal: Preparedness Framework and Its Governance of Dual Use Research of Concern for Promising Progress of Life Sciences (March 2013)**
  - by Center for R&D strategy, Japan Science and Technology Agency
  - Reviewed related domestic/international activities on dual use issue in life science research
  - Proposed actions and governance system for
    - Offices and ministries of governmental agency
    - Research personnel and laboratories
    - Research institutions
    - Academic societies
    - Funding Agencies

Approach to DURC in life science by scientists

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Dual use issue and Science Council of Japan

- Proclaimed support of IAP statement on Biosecurity (2005)
- Hosted symposium on “Emerging risk posed by the development of life science and role of the scientists” (2011)
- Established an *ad hoc* committee on dual-use issues in science and technology (2011)
  - Report on Dual Use of Life Science and Technology (2012)
    - Code of Conduct regarding Dual Use
- Revised the Code of Conduct for Scientists to include dual use issues (2013)
- Proposal: Dual Use Issues in Pathogen Research (2014)
Generic Code of Conduct to guideline for individual research field

Code of Conduct for Scientists
Science Council of Japan (2011)

Code of Conduct for Scientists: revised
Science Council of Japan (2013)

Proposal: Dual Use Issues in Pathogen Research
Science Council of Japan (23 January, 2014)

Code of Conduct Regarding Dual Use
ad hoc committee on dual-use issues in science and technology (2012)

For all science disciplines

Dual use concept to be included

For individual science fields

Approach to DURC in life science by scientists

- Predawn stage – efforts by motivated institutions
- Activities in life science communities
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- Education
Education on dual use in life science research

- National Defense Medical College
  - For MD/PhD
  - Biosecurity education program including dual use issues at undergraduate and graduate level (2005~)

- Tokyo Institute of Technology
  - For non-medical Master/PhD students
  - “Ethics for Scientists/Engineers” (Interdisciplinary Graduate School of Science and Engineering, 2010~)
  - “Bioethics” (Education Academy of Computational Life Sciences, 2012~)
Need for learning materials in native language

- Educational Materials for Japanese Scientists

Translation of Code of Conduct for Biosecurity
Published in January 2010
By T. Saito
*including translation of IAP statement of biosecurity

Translation of Executive Summary of Fink Report
Published in September 2010
By T. Saito

Need for learning materials in native language

- Educational Materials for Japanese Scientists

“Life Science and Biosecurity”
- Dual use dilemma and countermeasures
Edited by N. Shinomiya & N. Kawahara

Published in December 2013
Summary

- “Hard measures” such as laws and regulations are the basis to ensure biosecurity; however, a risk of over regulation jeopardizing public health and R&D for biopreparedness & response should carefully be considered.

- Multi-sectoral and inter-disciplinary platform is crucial to promote discussion on biosecurity.