

# Coping with the Challenges of the Dual-Use Aspects of Life Science Research in Japan

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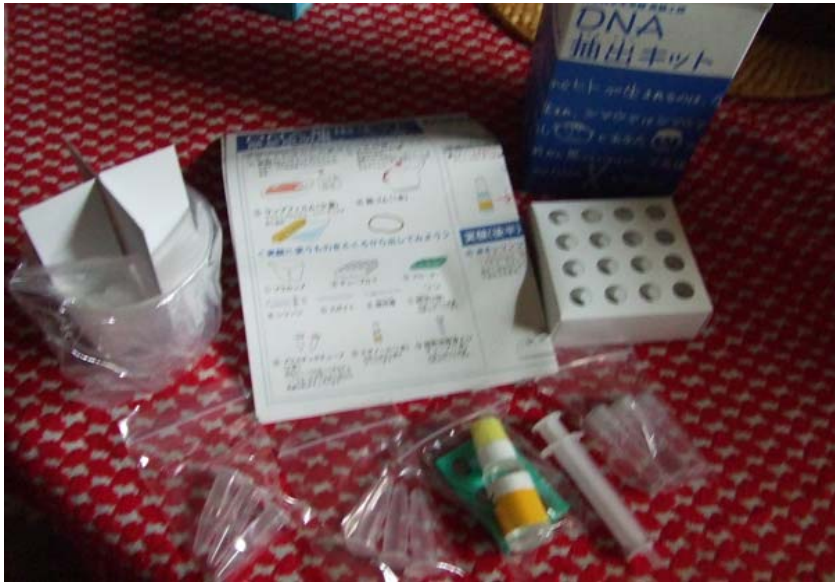
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Expanding Knowledge of Biology  
and the Misuse of Scientific Knowledge  
in Japan

# Expanding Knowledge of Biology for Kids...

- A DNA extraction kit, sold by the National Museum of Emerging Science and Innovation
- Target age: Over 10 years old



●このキットには3回分の試薬が入っています。

自分で用意するもの／実験1回分

- ニワトリレバー／1cm角程度（新鮮なもの）
- お湯／約150ml
- ラップフィルム／少量
- 輪ゴム／1本

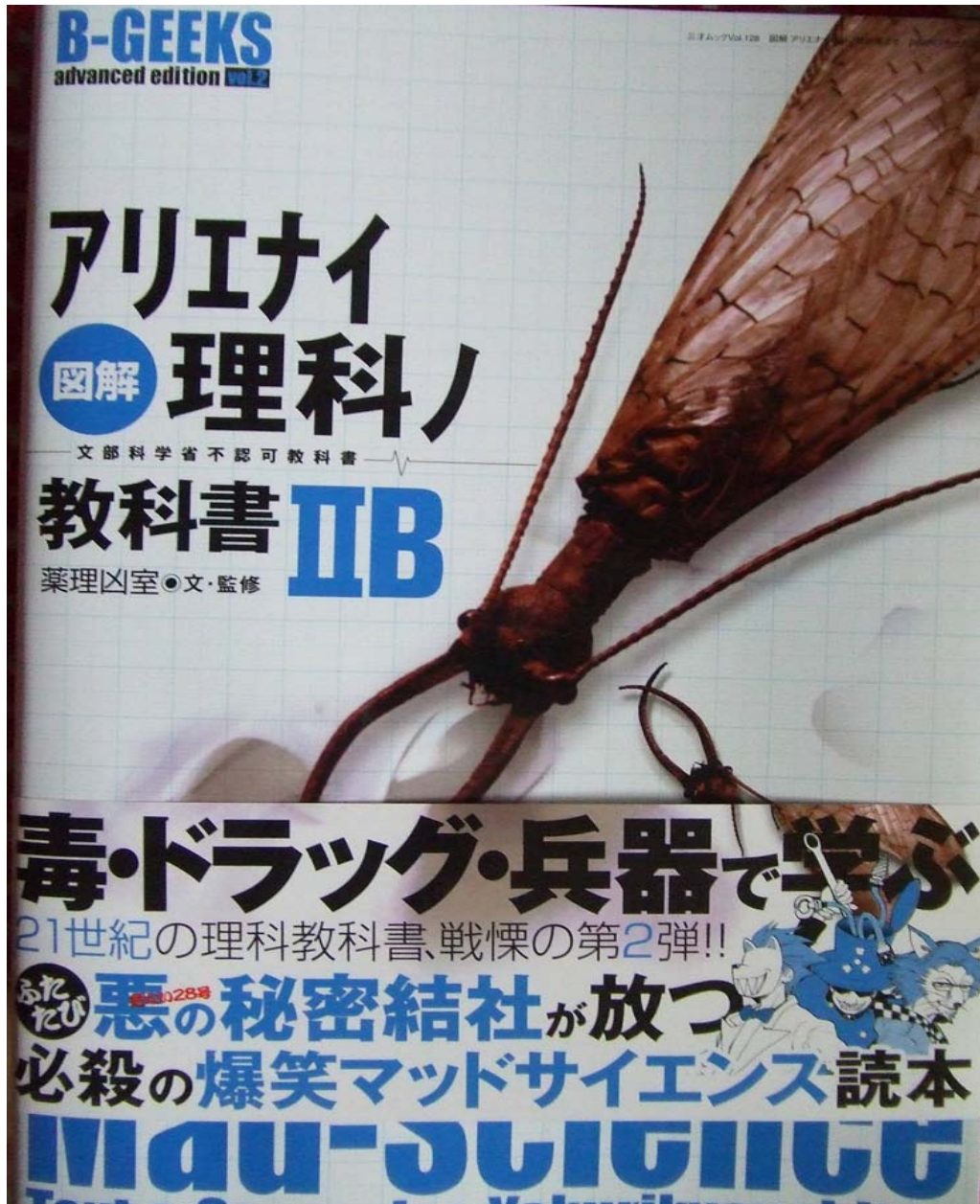
対象年齢 | 10歳以上

⚠ 注意！ | 保護者の方へ 必ずお読みください。

- 熱湯を使いますので、やけどには十分ご注意ください。
- 付属のエタノールは引火性の薬品です。火中に投げ入れたり、火に近づけたりしないようにしてください。
- 付属のエタノールや細胞溶解液、抽出したDNAや実験に使用した液は目や口に入れないでください。万が一目に入った場合は、大量の水で洗い流してください。また、舌が一飲み込んでしまった場合は、口の中をよく洗い様子を見てください。

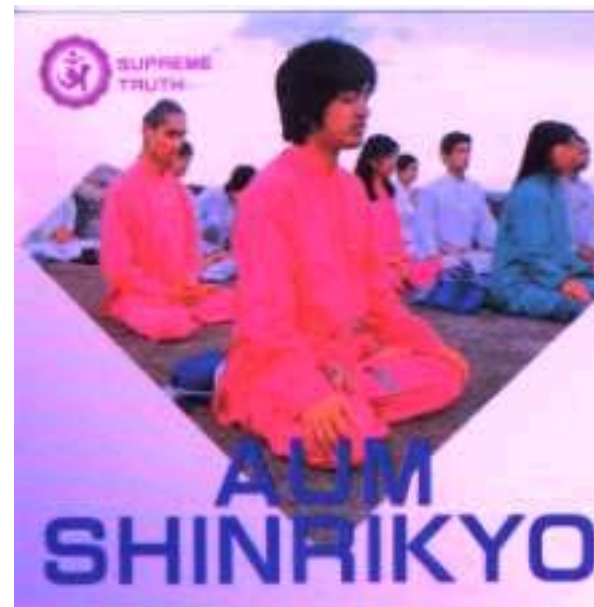


# Challenges of the Freedom of Expression...



- A “mad science textbook” about toxin, drug, and weapons, sold in July 2007 in Japan.
- It explains about:
  - How to breed dangerous bugs, such as vespa mandarinia;
  - How to extract toxic components from plants, such as cyanotoxin, anatoxin, saxitoxin, microcystin;
  - How to cultivate germs and virus, including influenza virus;
  - Basic concept of how to weaponize anthrax;
  - How to extract tetrodotoxin from a blow-fish, etc.

# Case Study: The Aum Shinrikyo's BW Programs



# Chronology of the Aum's BW Programs

- Around in April 1990, Aum planned to disperse bacteria botulinum by balloon, which was not carried out because of the delay of the cultivation of the bacteria.
- In May 1990, Aum dispersed what they believed to be “bacteria botulinum” from a car window with electric fan, targeting at the US military base in Yokosuka, areas surrounding the Imperial Palace, a headquarter of Soka Gakkai (a rival religious organization), and Kasumigaseki area.
- In July 1990, Aum dispersed what they believed to be “bacteria botulinum” water reservoir in the mountain.
- In May 1993, Aum planned to disperse anthrax targeting at the wedding ceremonial parade of the imperial family.

Source: a summary of court testimonies in Masaaki Sugishima, “Nihon no Baio Hanzai (Biocrimes in Japan)”, in Sugishima ed., *Baiotero no Houkatsuteki Kenkyu (A Comprehensive Study of Bioterrorism)* (2003: Asahi University Publication); and excerpts of court testimonies in Kenichi Kohata, ed., *Aum Houtei (Court Trials of Aum shinrikyo)* (Asahi Bunko, Tokyo).

# Chronology of the Aum's BW Programs

- From June through July 1993, Aum dispersed anthrax from its headquarter in Tokyo.
- In July 1993, Aum dispersed anthrax by car nearby the headquarter of Kanagawa prefectural government and Imperial Palace, which failed.
- In November 1993, Aum dispersed sarin and “bacteria botulinum” from car, targeting at the headquarter of Soka Gakkai.
- In June 1994, Aum imported a helicopter from Russia with the purpose to arm it with bacterial weapon, which was not carried out because the Japanese Ministry of Transportation did not grant approval for flying the helicopter.

Source: a summary of court testimonies in Masaaki Sugishima, “Nihon no Baio Hanzai (Biocrimes in Japan)”, in Sugishima ed., *Baiotero no Houkatsuteki Kenkyu (A Comprehensive Study of Bioterrorism)* (2003: Asahi University Publication); and excerpts of court testimonies in Kenichi Kohata, ed., *Aum Houtei (Court Trials of Aum shinrikyo)* (Asahi Bunko, Tokyo).

# Chronology of the Aum's BW Programs

- In November 1994, the Aum planned to kill Taro Takimoto, a lawyer who was warning about the Aum's CW program, by injecting botulinum toxin, which was not carried out.
- In March 1995, an attaché case with a spraying device was found in the Kasumigaseki metro station.
- ✓ Originally, Aum even dreamed of dispersing germs in countries around the world and came up with the idea to produce a “balloon bomb” containing germs and to remodel their ship so that they could disperse the germs from the sea. However, none of these plans materialized.

Source: a summary of court testimonies in Masaaki Sugishima, “Nihon no Baio Hanzai (Biocrimes in Japan)”, in Sugishima ed., *Baiotero no Houkatsuteki Kenkyu (A Comprehensive Study of Bioterrorism)* (2003: Asahi University Publication); and excerpts of court testimonies in Kenichi Kohata, ed., *Aum Houtei (Court Trials of Aum shinrikyo)* (Asahi Bunko, Tokyo).

# Botulinum Program

- In March or April 1990, after the defeat in the national election, Asahara expressed his intention to carry out mass indiscriminate mass killing by dispersing bacteria botulinum. The original idea was to disperse the bacteria by balloons.
- The first attempt was planned in April 1990. Asahara evacuated the Aum members under the guise of a seminar in Ishigakijima Island. But the program was not ready, and the plan could not be implemented.
- Yoshihiro Inoue, who engaged in the Aum's BW program, stated in 1995 that about 300,000 people might die when botulinum toxin would be used as weapon (\* This is most likely a mistaken belief).
- The Aum dispersed what they believed to be "bacteria botulinum" to kill the targets, but none of them succeeded.
- ✓ There is no indication to suggest that the Aum successfully produce bacterial botulinum nor botulinum toxin.

# Anthrax Program

- In the summer of 1992, Seiichi Endo, who was in charge of the Aum's BW program, obtained the Stern culture of anthrax, probably from an Aum member in the university in northern part of Japan.
- Endo began cultivating the anthrax in the fall of 1992. Approximately 30-40 members were engaged in this program. (Source: excerpts from court testimonies in Kenichi Kohata, ed., *Aum Houtei (Court Trials of Aum Shinrikyo)* (Asahi Bunko, Tokyo), Vol. 9, p. 75.)
- In April or May 1993, Fumihiro Joyu, an executive member of the Aum, ordered Endo to culture anthrax vaccine. (*Ibid.*, Vol. 1-a, pp.175-176)
- Members of the anthrax program were ordered to drink about 1 liter of antibiotics everyday and injected with the purpose to strengthen immune system against anthrax.
- The anthrax program was continued even after the Aum moved its headquarter to the Satian complex in Kamikuishikimura village. However, according to the testimony by Yoshihiro Inoue, the production process was significantly messed up, and he did not feel that there was any sense of reality. (*Ibid.*, Vol. 9, p.77.)

# Spraying of Anthrax



Figure 1. Spraying scenes from the Aum Shinrikyo headquarters building (photographs taken July 1, 1993, by the Department of Environment, Koto-ward).

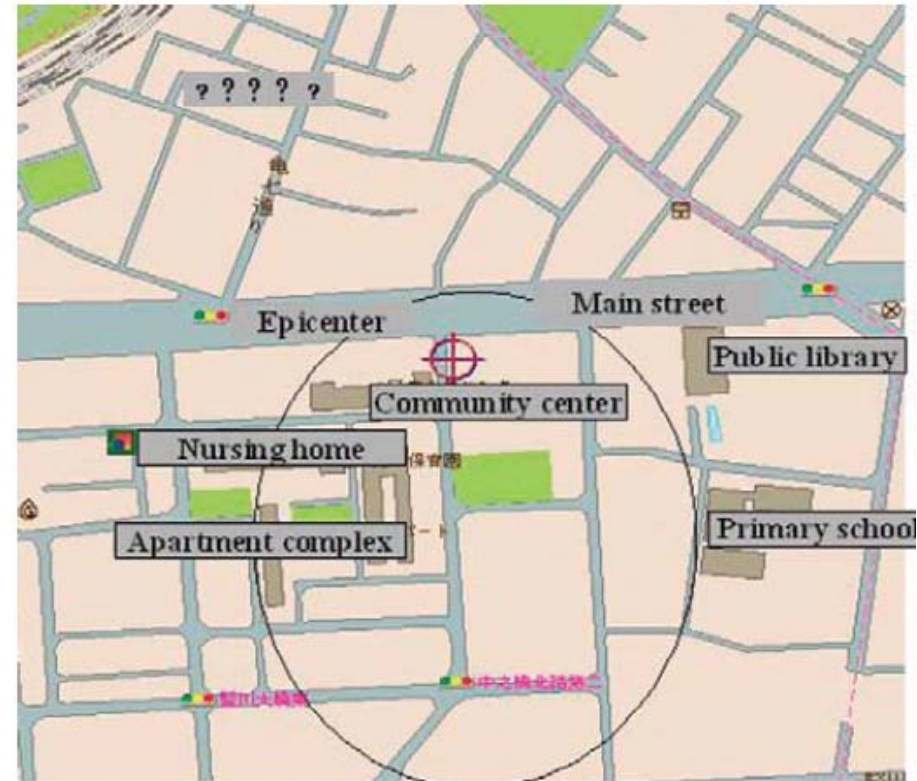


Figure 4. High-risk area for infection, based on foul odor complaints.

## ***Bacillus anthracis* Incident, Kameido, Tokyo, 1993**

Hiroshi Takahashi,\* Paul Keim,† Arnold F. Kaufmann,‡ Christine Keys,† Kimothy L. Smith,† Kiyosu Taniguchi,\* Sakae Inouye,\* and Takeshi Kurata\*

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 10, No. 1, January 2004



Figure 2. Fluid collected from the Kameido site cultured on Petri dishes to identify potential *Bacillus anthracis* isolates.

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## Problems with Spraying Device

- The spraying device did not function well, which was clearly regarded by the Aum leaders as a major problem in BW programs. The Aum decided to turn to CW programs.

## Other Biological Weapons

- *Coxiella burnetii*:
  - There are media reports about the Aum's attempt to cultivate *Coxiella burnetii* or obtain relevant information from Gifu University in Japan.
  - But during the court trials, the Aum member made no specific reference to the attempt to weaponize *Coxiella burnetii*.
- Ebola virus
  - No indication to prove that the Aum was able to obtain the Ebola virus.

# Characteristics of Seiichi Endo

- In Aum, only one person (Ph.D.) had the experience handling viruses. This person was Dr. Seiichi Endo. Endo studied genetic engineering at the graduate school in Japan, to obtain master's degree. A former senior member of the Aum evaluated Endo as a person with high pride.
- In the spring of 1986, Endo moved to the research institute of virology of another university, but his research did not go well. In the fourth year of his doctoral degree program, Endo moved into the Aum Shinrikyo. (Source: excerpts from court testimonies in Kenichi Kohata, ed., Aum Houtei (Court Trials of Aum shinrikyo) (Asahi Bunko, Tokyo), Vol. 1-a, p. 213.)
- During the interrogation, Endo confessed to the inspector about his inferiority complex. Endo felt that his position within the Aum was challenged by Masami Tsuchiya who was in charge of the Aum's CW programs.

## Characteristics of the Aum's BW Programs

- The BW programs miserably failed, which is believed by many experts to be the results of the inability of Endo.
- The Asahara referred to these biological weapons in his speeches publicly.
- The Aum targeted at the Japanese government institutions, the Imperial Families, the US military base, a rival religious organization, and the public in general.
- The Aum came back to the same targets even after failed once.

# Characteristics of Aum Shinrikyo's Perpetrators

- ✓ Involved were many young elite with highly excellent academic records who studied at the top universities in Japan. They were brilliant young scientists with relatively low future expectation.
- The Cult was seen as more attractive than the famous universities. An authoritative structure of Japan's academic institutions deprived these young elites with the dream to become renounced scientists in the future, according to some perpetrators of the Aum.
- Should we beware of scientists with relatively low future prospects?

## Lessons Learned

- Aum Shinrikyo incident highlighted the importance of addressing the “dual-use” challenges through a variety of measures, including:
  - Educating the young scientists with social norm
  - Improving the management of research program at universities

# Coping with the Biosafety and Biosecurity Challenges

# Japan's Policy Relevant to Biosafety and Biosecurity

- “Catch-All” Export Control Law
- Civil Protection Law
- Civil Protection Plan
- BWC Implementation Law
- Action Plan for the Prevention of Terrorism
- Domestic Animal Disease Control Law

# Initiatives by the Japanese Government on Issues Relevant to Biosecurity

- In 2007, the Ministry of Economy, Trade and Industry (METI) and the Ministry of Education, Science and Technology (MEXT) jointly issued an administrative guidance to Japanese universities which asked professors to be careful for granting foreign students access to R&D programs with sensitive dual-use potential.
- In July 2008, the METI issued a report on the management of information about sensitive technologies.
  - The METI referred to the necessity to create a guideline to assist the scientists to identify those technological research with significant dual-use concern.
- Science Council of Japan (SCJ)
  - Revised the Code of Conduct of Scientists, but dual-use element is almost non-existence in the Code.

# Devising a Legally-Binding Measure to Oblige the Scientists to be Responsible for Security

- Concerned with the relative lack of security at many laboratories, the Japanese government revised the Law Concerning the Prevention of Infections and Medical Care for Patients of Infections, for the third time in 2006. This revised law has gone into effect on June 1, 2007. (However, this legislation invoked confusion among the public health and scientific communities, and a 3-year moratorium was set.)
- Under this revised law, a legally-binding standard of laboratory facilities has been established, together with legally-binding standards of possession, storage, use, and transportation of specific pathogens.
- 49 Genus, 79 Strains and 2 Toxin are specified as the subject of regulation.
- A new legal standard has been set, and contravention to the law, including facility, devices, registration of pathogens, and documentation, will be punished, either in the form of fine or imprisonment.

# National (Regional) Classification of Micro-organisms by Risk Group

1. Pathogenicity of the Organisms
2. Mode of transmission and host range of the organism. These may be influenced by existing levels of immunity in the local population, density, presence of appropriate vectors and standards of environmental hygiene.
3. Local availability of effective preventive measures. Prophylaxis by immunization or administration of antisera, sanitary erasure, food, water hygiene, control of animal reservoirs.
4. Local availability of effective treatment. passive immunization, postexposure vaccines and use of antimicrobials, antivirals and chemotherapy agents, possibility of the emergence of drug-resistant strain.

(Source: Presentation material by Takeshi Kurata, at the Regional Biosecurity Workshop, Singapore, May 28-30, 2007)

# 4 Groups of Pathogenic Microbial

- Group I: possession, import, assignment and transfer are prohibited except for those entities designated by the government.
  - Ebola virus, Crimean Congo virus, Variola virus, South American hemorrhagic fever virus, Marburg virus, Lassa virus
- Group II: possession, import, assignment and transfer are allowed at the approval of the Minister of Welfare and Labor for the purposes of testing and research, etc.
  - Plague, SARS Corona virus, Anthrax, Tularemia, Botulinum, Botulinum toxin
- Group III: possession is allowed at the notification to the government.
  - Q fever Coxiella, Rabies virus, MDR MTb, Coccidioides immitis, Monkey pox, HFRS, Nipha virus, Brucellosis, B virus
- Group IV: compliance with the standard is required.
  - West Nile virus, Influenza virus (H2N2), Yellow fever virus, Chlamydia psittaci, Cryptosporidium, Cholera, Mycobacterium tuberculosis excluding MDR-MTb, Polio virus, Shigella, Typhus-Palatyphus, Enterohemorrhagic E.coli, Dengue virus, Avian Flu influenza virus, Japanese encephalitis virus, Shiga toxin.

(CITATION: a presentation material of Takeshi Kurata, at the Regional Biosecurity Workshop in Singapore, May 28-30, 2007.)

# Remaining Challenges

- How to categorize newly genetically-engineered biological agents?
  - For example, harmless culture of Ebola virus...
  - To what extent an agent-based approach pragmatic as compared with technology-based approach?
- How to manage the knowledge and expertise associated with dual-use concern?
- What responsible management structure should be instituted at universities and academic institutions?
- Universities and academic institutions have been already experiencing resource constraints, and rarely have the sufficient capability to invest to address issues related to dual-use.

# Coping with the “Dual-Use” Challenges: The RISTEX Efforts

# The RISTEX Initiatives

- Creating a network among the stakeholders of biosecurity, including officials of all relevant ministries and agencies, and experts of universities and research institutions as well as journalists.
- Raising awareness among the relevant stakeholders in the government, academic community, media, and private sector about the necessity to deal with the dual-use aspects of the life science research.
  - Seminars, and briefing to officials, experts and political authorities as well as members of the Science Council of Japan
- Assisted the Japanese official and academic institutions to address the broad biosecurity challenges
  - Especially, we plan to assist those efforts to establish a guideline for management of the sensitive dual-use technologies.
- Approaching key members of the Science Council of Japan to inform them about the necessity to address the dual-use concern in the discussion of the Code of Conducts for the Scientists which will be reviewed in 2009.
  - The RISTEX plans to arrange meetings with SCJ members to raise awareness among the scientific community about the necessity to address the dual-use challenges.

# The RISTEX Initiatives: Assisting the Japanese Universities to Address the Dual-Use Challenges

- Assist the effort by the Consolidated Research Institute of Advanced Science and Medical Care of the Waseda University to establish a class on the ethics of life science research which will include issues of biosecurity.
- National Defence Medical College has initiated efforts to produce education module together with Bradford University.
- Co-hosted a seminar on biosecurity with the School of Medicine of Keio University.
- The RISTEX plans to arrange dual-use conferences/meetings to raise awareness and discuss measures to manage biosecurity challenges among the stakeholders and to share best practice among the universities.
- Assisting the Hitotsubashi University's class to educate the social science students about the importance of managing the dual-use challenges and the necessity to bridging between national security community and scientific community.

# The RISTEX Initiatives: Raising Awareness among the Relevant Stakeholders and the Public

- Invited foreign experts and officials to exchange views and information about biosecurity.
  - Professor Nancy Cornnell
  - Professor Malcolm Dando
  - Dr. Gerald Epstein
  - Professor Seumas Roderick Macdonald Miller, Australian National University
  - Professor Brian Rappert
  - Dr. Terrence Taylor
  - US Department of Homeland Security, FBI, etc.
- Met with Japanese journalists, officials of all relevant ministries and agencies, and experts.
- Exchanging information and expertise with foreign institutions, experts and officials is essential in order for us to advance our efforts to enhance biosecurity. The RISTEX intends to continue arranging such interactions between Japanese and foreign experts/officials to build on past achievements.

# Our Findings and Areas of Further Examination

# Engaging Scientists and Officials

- Scientists generally feel unhappy when somebody points out the possibility of harmful application of the research results.
  - A significant majority of the scientists do not like to talk about anything related to regulating research activities.
  - However, the scientists do like to engage in discussion about advanced research experiments. It was effective to engage scientists through the discussion of dual-use challenges within a broad discussion over experiments of advanced technologies with significant dual-use concerns.

# Engaging Scientists and Officials

- Scientists and officials highly appreciated their interactions with foreign academic experts and officials. The visits/ invitations of foreign experts and officials were essential for advancing our activities to engage the relevant stakeholders in Japan.
  - Interaction between scientific communities, inviting renowned scholars, are very useful in engaging scientists.
  - Officials have been encouraged by other countries' endeavors.

# Engaging Scientists and Officials

- There are some scientists and officials who were inspired to address the biosecurity challenges. They began asking such questions as:
  - “How can we know which technologies could have the dual-use implications? We have no idea...”
  - “Are there any experts who could help us identifying the dual-use aspect of scientific research? We have no professional staff member who could do so...”
  - “Why should we prioritize life science areas, while dual-use challenges can be observed in almost all areas of science?”
- Engaging scientists on social norm is also important. There are at least some scientists who could be detached from the reality on the ground relatively easily.

# What Needs to Be Done

- Need more detailed information about the expertise and experience of internal reviews in universities abroad.
  - Who does the review? How can we find such staff member who understand both science and its national security implications?
  - How to establish a review mechanism at the universities?
    - Should we expand the existing board, such as review board for the rDNA experiments? If so, in what modality?
    - What type of experts should be included in such a review mechanism?

# What Needs to Be Done

- Need to exchange experience and information about effective guideline to identify dual-use experiment with significant concern.
  - “The Fink Commission’s criteria is too broad.”
  - Need some more detailed guidelines. What criteria has been employed at foreign institutions to identify research with significant dual-use concerns?
- Need an educational module to educate the scientific students and researchers about the dual-use challenges by gathering specific case studies of the misuse of scientific research.
- Need more coordinated approach to assisting other countries efforts on biosecurity, such as those in Asian region.
  - Existing relevant example: Japan-US-Australian Trilateral Meeting to assist the capacity building efforts by the Southeast Asian countries against biological terrorism.