Challenges of Biosecurity from Japan's Perspectives

Regional Biosecurity Workshop

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Main Questions to be Addressed

- Why Should We Care about the Misuse of Life Sciences Research?
- A Case Study of WMD Terrorism: Aum Shinrikyo's Development and Use of BW and CW
- Definitions of the Term "Biosecurity"
- What is dual-use research?
- What are the challenges associated with defining the most consequential areas of dual-use research?
- What are the implications for individual scientists and their work?

Why Should We Care about Misuse of Life Sciences Research?

Necessity to Meet with the Full Spectrum Biological Risks

- Environmental protection
- Animal health
- Food safety
- Chronicle diseases
- Naturally-occurring diseases and toxins
- Accidental release of diseases and toxins
- Intentional release of diseases and toxins
- Misuse of life science technologies
- Sustaining and strengthening public health infrastructure

New Scientists: ““Disaster in the Making: An engineered mouse virus leaves us one step away from the ultimate bioweapon”

- **<u>Early</u>** 2001 Australian university and government agency researchers employ mousepox to immunize mice against egg protein, insertion of the IL-4 gene to increase antibody response.

- Recombinant virus killed mice genetically resistant to mousepox and those immunized against it.

- Potential for enhanced lethality of smallpox

(Source: Malcolm Dando, *Bioterrorism and Biowarfare*, One World, Oxford, 2006)

- The Guardian, “Did anyone order smallpox?”, June 23, 2006.
  - “…ordering part of (smallpox virus’s) DNA proved easier than anyone dared imagine. All it took was a invented company name, a mobile phone number, a free email address and a house in north London to receive the order by post.
  - “The investigation makes clear that anyone, without attempting to prove a link to a legitimate research organisation, can order DNA sequences from any potential pathogen without fear of extensive questioning. In our case VH Bio Ltd did not realise it was supplying part of the smallpox genome…”

Other Examples of Potentially Serious Dual Use Risks

- In 2002, researchers from the State University of New York had artificially synthesized a virulent poliovirus from scratch, using mail-order segments of DNA and a viral genome map freely available on the internet.

- Construction of “fusion toxins”, derived from two distinct toxins, for the purpose of killing cancer cell.

- Development of a genetically engineered strain of Bacillus anthracis containing an inserted gene for a foreign toxin, potentially rendering the agent resistant to the existing anthrax vaccine.

- Development of the stealth virus that can evade the human immune system

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 47.)

Other Examples of Potentially Serious Dual Use Risks

- Publication of the molecular details of the highly virulent strains of the 1997 Hong Kong flu and 1918 Spanish flu.

- Publication of the complete DNA sequences of human pathogens which is available on the internet.

- Development of new technologies for delivering drugs by aerosol spray.

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 47.)

Dual-Use Risks on the Rise

- Scientists are expected to be able to synthesize complete microbial genomes by 2010.
- Complete genomes of some viruses can be synthesized presently, but not all DNA synthesis companies have this capability. (NSABB)
- Global diffusion of life science
- Life science technologies is expected to proliferate even among students in the very near future, like computer technologies.

Examples of Imagined Future Biological Weapons

- Designer genes, viruses, and other life forms (such as the one designed to be drug resistant)
- Designer diseases
- Binary biological weapons (i.e., one involving infectious agent that has little initial pathogenic consequence until a subsequent co-infection from a second organism activates the pathogenic aspect of the original infection)
- Gene therapy as a weapon
- Stealth viruses (i.e., cryptic viral infection)
- Host-swapping (zoonotic) diseases

- Bioregulators and all research concerning immune system could also pose serious dual-use risk.

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 47.)

Potential Misuse of Research Results

- DNA Shuffling will allow biologists to generate novel proteins, viruses, bacteria, and other organisms with desired properties within a much shorter period of time than before. Virologists can use this technology to optimize viruses for gene therapy and vaccine application.

- Similarly, dual use risks can be considered in other technologies including DNA synthesis, bioprospecting, combinatorial chemistry, high-throughput screening, rational drug design, synthetic biology, genetic engineering of viruses, RNA interference, high-affinity binding reagents, computational biology and bioinformatics, sytems biology, genomic medicine, modulators of homeostatic systems, aerosol technologies, microencapsulation technology, gene therapy, and targeting biologically-active materials to specific locations in the body.

- **Pathogens are not the only problem! Advancing technology landscape has an uncertain future and unpredictable dual-use risk implications.**

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 47.)

OK, Understood. However,…

- Isn't this a *Cry-Wolf*? We have already many other existing problems to take care of immediately, in realm of public health…

- Why should we invest into preparing for an event with low probability and high consequence, while we need to tackle with many existing problems of public health with high probability and low consequences? (cancer and heart disease treatment, etc.)

Key Points to Consider

- Threat vs. Risk:
  - Are we talking only about "threat"? Or should we also talk about "risk"? If so, how do you assess "risk"?

- Risk Assessment
  - Adversary's capability and intent
  - Vulnerability on our side
  - Probability and potential consequences

- Biological hazard events could have potentially catastrophic consequences?
  - How do you weight the event with low probability but potentially high consequence should it occur?

✓ One thing is sure: it would be too late if you would start thinking about this question only after such an event should actually take place...

Threats Certainly Exist. Psychological Profiling of Those Who May Employ CBRN

- “End of the world”-type cults
- Those who hold strong hatred against specific ethnicity or race
- Those who are not constrained by public opinion
- New world order-oriented
- Individual with strong ego, or those who are obsessed with power
- Those who are not satisfied with slow changes
- Lone wolf
- Those who already know CBRN to some extent
- Those who want to die, or those who are already dying

(Source: summary of the key points of a FBI briefing, February 2006)

Importance of Implicit Knowledge in the Process of WMD Production

- The key point for the successful construction of biological weapon is whether the individual/groups interested in the BW may have the implicit knowledge (nuance gained from experience and expertise) in addition to the explicit knowledge (information written on the manual, etc.).

- See Aum Sinrikyo’s case study in the following section.

A Case Study of WMD Terrorism:

Aum Shinrikyo's Development and Use of BW and CW

Aum Shinrikyo: A Precursor to Future Terrorism?

- A multinational religious organization with extensive international networks
- Conducted WMD Terrorism
- Procured various conventional weapons
- Received almost-virtual state-sponsorship from Russia
- Recruited members from police and military
- Presumed to have close connections to organized crime networks
- Sophisticated mind control techniques
- Strong belief in a conspiracy theory of US and a “shadowy organization”

✓ Some of the above features somewhat resembles to the ones held by Al Qaeda.

What Is Aum Shinrikyo?

- A religious cult started as a yoga class in 1984
- Leader: Shoko Asahara
- Attracted many people, cutting across various generations.
- Purpose: Establish Aum's state in order to save the souls of human being
- Accumulated hundreds of millions of dollars in asset and 10,000 members in Japan, 30,000 in Russia, and offices in Germany, Taiwan, Sri Lanka, Australia, and the United States.

Beginning of Aum's Military Plans

- Asahara dreamed of taking over Japan through the national election. But, they were miserably defeated in the 1990 National Election
  - A major blow to Aum's recruitment activities

- Asahara abandoned efforts to rule the government through election. Instead, he began to dream of defeating the government and annihilating the public by force.
  - Stronger emphasis on the coming of the apocalypse and Aum's ascendance thereafter
  - April 1990: "Since they will commit more sins as they continue to live, we will *poa* all the world by dispersing botulinum toxin."

- Began Aum's BW programs

BW Programs

- In around April or May in 1990, Aum started to disperse biological materials what they claimed to be bacteria botulinum in areas nearby the Japanese Diet, the Imperial Palace, U.S. Embassy in Tokyo, U.S. military base in Yokosuka, Kasumigaseki, and a river that led to a filtration plant, as well as anthrax in Yokohama city and Kasumigaseki, according to court testimonies of several Aum perpetrators.

- Aum even dreamed of dispersing the 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. Luckily, none of these plans materialized. The dispersal of “bacteria botulinum” failed partly because the Aum gave up attempt to create a functional spraying machine.

✓ BW programs failed.

Forging International Networks

- Aum opened an office in the United States in 1987 and a European headquarters in Bonn, Germany in 1991. Also in 1991, Aum members met with Oleg Lobov, the head of the Russian Security Council, and the president of Sri Lanka.

- Aum established a trading company in Taiwan, purchased a tea plantation in Sri Lanka and a ranch in Australia on which a geologist indicated there were deposits of uranium oxide.

- Aum launched a “Russian Salvation Tour” in 1992 and opened its first branch office in Moscow. Aum membership in Russia grew from 10,000 to more than 30,000. Aum’s members in the Russian branch included former Special Forces troops, KGB officials, and scientists at defense facilities.

Weapons Procurement in Russia

- In 1993, Aum members visited various facilities of military and universities where they got briefing on guns and rockets.
- Met with Lobov, Vice President Aleksandr Rutskoi and parliamentary leader Ruslan Khasbulatov.
- Visited the Kurchatov Institute, a nuclear weapons design facility and several Spetznaz training camps where Aum members received military training.
- Aum was able to buy access to senior political leaders, scientists, military training, and weapons capabilities.
- Imported Mi-17 Helicopter, smuggled AK47 assault rifle.

Initiating Robust BCW Programs

- From the summer of 1993, Aum launched several significant operations using poison or disease.

  – From June through around August 1993, Aum dispersed Stern culture of anthrax vaccine from the top of its Tokyo headquarters in the Kameido neighborhood for three times. No harm was caused.

  – VX gas and sarin: Produced based on Russian CW manuals.
    - Original idea was to to disperse sarin over major cities in Japan and the United States from the air.

  – On June 27, 1994, Matsumoto sarin incident: 7 people killed.

- Aum eventually perfected the manufacture of TNT and the central component of plastic explosives, RDX.

Problems of Japanese Law Enforcement

- Lack of expertise in BCW
- Arrest people only after police assembles a preponderance of evidence against a suspect: avoid preemptive law enforcement
- Initially wrongly suspected North Korea’s involvement behind Matsumoto sarin incident (coincided with the 1994 North Korea’s Nuclear Crisis)
- A limited number of police investigators suspected Aum’s involvement, but waited for more evidence.

Was Japan Lucky…?

- The Aum's failed attempts of bio-terrorism were led by Seiichi Endo, Aum's Minister of the First Welfare. It is believed that he did not have the expertise nor knowledge about technology to convert the vaccine strain of anthrax to harmful strain as he was a graduate of Institute for Virus Research of the University of Kyoto. He was an expert on virus, but not necessarily on bacillus.

- However, if he were a graduate of a medical department of other particular universities in Japan which are famous for their advanced research capability in the areas of bio-technology, it is quite possible that he might have been able to convert this harmless strain into the harmful one, according to a senior expert of the NIID. The NIID expert said, "We were lucky."

Japan Was Lucky…? (cont.)

- No official investigation on how Aum obtained this Sterne strain of anthrax. There are views that Aum obtained the anthrax from a particular laboratory in a university located in northern part of Japan. But there is no official confirmation on this matter.

Characteristics of Aum Shinrikyo's Perpetrators

- Intuitive decision-making without any thorough serious comparison of relative merits and demerits of each weapon.
- Driven by a strong sense of mission to save the human being, (whatever it means).
- Many young elite with highly excellent academic records who studied at the top universities in Japan.
- Many Aum leaders clearly presented a childish aspect in their characters. Especially, they were easily influenced by animation cartoons and mistakenly replaced the real world with this animation world.
- Crimes and violent acts of terrorism were not well planned nor well prepared.

Characteristics of Aum Shinrikyo's Perpetrators

- Almost all of the Aum's perpetrators had felt some form of frustration in their life.
- Perpetrators entered into Aum trying to find out their identity.
- The members in their 20s and 30s expressed strong fear toward his/her own death.
- Motivation of violence and crimes: complete control Asahara and his closest collaborators had over their followers, either by means of a religious order or a threat of deadly violence.

Characteristics of Aum Shinrikyo's Perpetrators

- ✓ At the top leadership tiers of Aum Shinrikyo, there were many members with prominent academic records in natural science fields.

- ✓ Many of them were not even recruited by the Aum. They entered into the Aum at their own will. They may have aspired for recognition for their talent.

- ✓ According to the law enforcement official who prosecuted Aum, the perpetrators were frustrated with their living environment in one way or another.

  - ➢ Some scientists and engineers could be relatively easily detached from the reality on the ground?

  - ➢ Also, low-future prospects of the scientists seemed to matter in shaping their motivation to enter into the Aum.

Beware of Dissatisfied Scientists…?

- By 2050, Japanese population is estimated to decrease by approximately 26 million. （Source：The National Institute of Population and Social Security Research）
- With the decrease in the population size, the number of universities has been also decreasing due to the smaller number of children.

➢ This means that there will be fewer positions available at universities for Ph.D holders. Senior Ph.D holders have to endure with relatively low-rank positions at these institutions.

➢ Beware of scientists with relatively low future prospects…?

Definitions of the Term “Biosecurity”

National Academy of Sciences in the US

- The term “biosecurity” is used to refer to security against the **inadvertent, inappropriate, or intentional malicious or malevolent use** of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling, or use of biological weapons as well as natural outbreaks of newly emergent and epidemic diseases.

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 32.)

National Science Advisory Board for Biosecurity

- Any biosecurity concerns pertain to the misapplication of information or technologies resulting from the research, not the conduct of the research itself.

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 32.)

EU's Position on Biosecurity

- "The difference between the two concepts is primarily based on two issues. Firstly, as already mentioned, both are based on the inherent risks of certain micro-organisms and toxins. While a biosafety risk classification system is based on the inherent capability of micro-organisms to cause disease, of lesser or greater severity, in humans, animals and plants, a biosecurity risk classification system is founded on the potential of a micro-organism or toxin **to be used as a weapon**. In practice, with respect to safety/security of sensitive biological materials, there is little difference between the risk classes; however the biosafety concept covers a far wider number of biological materials than the biosecurity concept.

- Secondly, while the majority of measures under both concepts are more or less the same, the biosecurity concept focuses primarily on the prevention of access to sensitive materials by theft, diversion or intentional release. For this reason biosecurity concepts usually include additional measures to harden and safeguard facilities containing sensitive biological materials with a BW potential."

(Source: EU Paper on Biosafety and Biosecurity, Submitted at the BTWC 6th Review Conference 2006, Germany, 19th September 2006)

Australian Government's Position on Biosecurity vs Biosafety

- Many countries, including Australia, have used the term "biosecurity" almost synonymously with the term "biosafety". Many of the measures currently in place or being developed have been built upon pre-existing 'biosafety' considerations, where 'biosafety' refers to measures taken to protect people and the environment from biological pathogens and toxins. It includes workplace health and safety issues and the prevention of the accidental release of biological agents.

- A uniform definition of the term biosecurity was discussed during the BWC discussions of 2003. Along with many like minded countries, DFAT understands the term 'biosecurity' to mean the prevention of **deliberate misuse** of biological pathogens and toxins, a term which cannot be simply replaced with 'biosafety'.

- 'Biosecurity', however, has other meanings in different contexts: the FAO use it in terms of securing food supplies and within Australian agriculture circles it means protecting the country from exotic pests and diseases through quarantine, surveillance and early detection measures.

(http://www.dfat.gov.au/security/elements_of_biosecurity_best_practice.html)

Australian Government's Position on Biosecurity vs Biosafety (contd.)

- DFAT considers that biosecurity is a discipline in its own right: it should not be overshadowed by the common understanding of biosafety. Standard biosafety precautions do provide some security measures, such as restricting access to facilities to authorised people; but further measures are required to ensure effective, comprehensive biosecurity.

- Additional features of biosecurity over biosafety include: <u>Controlling access through knowledge of workers i.e. identity and security assessment of those authorised to access relevant biological materials; restricting access to material to those people needing it for legitimate use, rather than to those competent in handling the risks; and educating legitimate users of the dangers of misuse: instilling an organisational culture of securing materials</u>.

- These features need to be applied across all those labs in the lifetime of a research project.

WHO's Definition on Laboratory Biosecurity

- **Biosafety:** Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release (*2*).

- **Laboratory biosecurity:** Laboratory biosecurity describes the protection, control and accountability for valuable biological materials (VBM, see definition below) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

(WHO, "Biorisk management: Laboratory biosecurity guidance", September 2006, WHO/CDS/EPR/2006.6.)

Definition Determines the Scope of the Subject

- In Japan, the term “biosecurity” often refers to “laboratory biosecurity”. (Or often, it is also used to mean security measures employing biometric technologies.)

- Definition of the term “biosecurity” determine the scope of the target issues.
  - Are we talking about *laboratory biosecurity* or broader concept of *biosecurity*?
  - Should we also include unintentional/accidental spread of diseases?
  - How about weaponization of biological agents by state actor for defensive purpose?

What is “Dual-Use” Research in Life Sciences?

Dual-Use Research in Life Sciences

- The term “Dual-Use” has different meanings for different stakeholders.
  - Traditionally, <u>in military realm</u>, “dual-use” has meant <u>potential military application for a civilian technology</u>. (In Japanese scientific community, however, “dual-use” has meant at least two applications in civilian realm for a civilian technology.)
  - <u>In life science research</u>, “dual-use” means “<u>the capacity or potential for biological agents, information, materials, and supplies, or technologies to be used for either harmful or peaceful purposes</u>.” (Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, p. 29.)
  - <u>WHO</u>: “Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer <u>not only to military and civilian purposes, but also to harmful misuse and peaceful activities</u>.”

✓ <u>Intent-based definition</u> is employed.

NSABB on “Dual-Use Research”

- The argument could be made that most if not all life sciences research could be considered “dual use”. (NSABB)

- NSABB focuses upon “specific life sciences research that could be of greatest concern for misuse”.

Intent-Based Definition of “Dual-Use” Research

- Harmful purposes
  - Inappropriate use:
    - the use of technology without the intent to cause harm but with unanticipated dual-use consequences
  - Malicious or malevolent use
    - Deliberate use of technology for the creation, development, production, or deployment of biological weapons

- Excluded cases:
  - Deliberate use of technology to create potentially harmful materials or other disease-causing agents for defensive research purposes in the absence of any intent to cause harm.

(Source: Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Globalization, Biosecurity, and the Future of the Life Sciences, pp. 31-32.)

How Do You Precisely Read “Intent”?

- However, others’ “intents” is very difficult to read. (Iraqi WMD programs, etc.) Monitoring/observing the researchers’ activities is very important in assessing his/her/their intent/intents.

- Reading other’s intents requires sophisticated management of research programs in a layered and coordinated manner, while minimizing negative impact on research activities as much as possible:
  – personal responsibilities
  – institutional oversight
  – federal/local regulations

✓ However, it is easy to say so but difficult to implement…

To Begin with, Is There Such Thing as "Intent-Neutral" Science?

- "Science has no national border. However, scientists have. They have home countries (to contribute to)."

(Remarks by a senior staff member of the Association of Scientists and Engineers of North Korean Japanese. The Japanese law enforcement authorities believe that this Association has been illicitly exporting dual-use technologies from Japaenese universities and research institutions to North Korea.)

Challenges Associated with Defining the Most Consequential Areas of Dual-Use Research

Challenges of Bridging between Many Constituencies

- **<u>Too many stakeholders</u>** in a variety of industries, universities, research institutions.
  - Defining “who the stakeholders are” is problematic.
  - Most of the stakeholders have been barely associated with the concept of “security”.

- **<u>Stove-piping phenomena</u>** is still prevailing among various stakeholders.
  - Almost no tradition of communication between security community and scientific community in Japan.
  - Security community is not so much interested in public health.
  - Life sciences community is not so much interested in security. They barely understand biological weapons.

- Scientists generally feel unhappy when somebody points out the possibility of harmful application of the research results.

Balancing among Various Policy Considerations

- Security vs. Vigor of Scientific Activities
  - Security community generally weighs stringent control of sensitive research results over the necessity to sustain vigor in the scientific community.

- Security vs. Economic Considerations
  - Cost of security measures
  - Government's possible interference with private sector's intellectual property rights

- Security vs. Privacy/Human Rights
  - Access control, background screening of personnel, whistle-blowing

- Stringent regulation vs. Relative Lack of Experienced Personnel
  - Where are the investigators? Does the police know about life sciences?

Technical Challenges

- Difficulties in assessment regarding the future projection of the development of life science researches.
  - Reliance upon the taxonomic definitions of Select Agents becomes increasingly irrelevant in an age of synthetic or engineered genomes that can produce biological agents with novel features and properties that might render them as harmful as Select Agents. (NSABB)
  - Future oversight of work with agents should be based on presumed/predicted functionality rather than sequence homology or taxonomy. (NSABB)

- A lack of consensus among scientists regarding an appropriate approach and methods for identifying/defining Select Agents and for screening sequences. (NSABB)
  - Virulence is a complex multigenic trait that is not easily defined on the bases of sequence, nor well-understood. (NSABB)

What Should We Do?

Implications for Individual Scientists and Their Work

Implications for Individual Scientists and Their Work

- Different Views
  - "I don't know dual-use, and as far as I am concerned, it's not my problem."
  - Fatalism: "Technology will proliferate anyway, eventually. So, what can we do about it?"
  - Emphasis on some type of regulatory mechanism: scientists should do something about dual-use. But what?
    - Stringent regulation/oversight by the government
    - Voluntary restrictive measures and better self-governance by the scientific/academic communities
    - Other measures somewhere in-between the two extreme options

Scientists Also Need to Consider Public Reaction

- "Because of the potential for misuse of dual use research results, one can and should anticipate sensitivities on the part of the public (including members of the scientific community) about the sharing of such information. In addition, <u>the public is increasingly sensitized to issues pertaining to research involving dangerous pathogens and the risk of accidental or intentional release of such agents. A lack of public understanding and appreciation for the reason for conducting and communicating dual use research, sensationalism of dual use research findings, and concerns about public safety and national security all serve to undermine public trust in the life sciences research enterprise.</u> It is therefore the responsibility of the scientific community to ensure that dual use research results and technologies are communicated responsibly."

(NSABB Draft Guidelines)

What to Do?

- Coming up with creative pragmatic measures
  - Establishing uniform and standardized screening practices among providers of synthetic DNA. (NSABB)

- Communication guidelines: shooting in-between the two extreme cases of “do-nothing” and “strong governmental regulations”.
  - Content, timing, and modality of the publication as well as the extent of distribution should be at least thought through.

- Establish educational/training programs is important!

Ethics and Conduct of Scientists In Japan

Status of the Misconduct by the Scientists 1999-2004

- Fabrication of data: unknown number of cases
- Falsification of data: 2 cases
- Plagiarism: 26 cases
- Invasion of privacy: 14 cases
- Misuse of research fund: 2 cases
- Multiple submissions of the same papers: more than 80 cases
- Others: 43 cases

(Source: Survey published by the Science Council of Japan in July 2005)

Status of the Code of Conduct by Scientists

- A survey was conducted by the Committee on the Code of Conduct for Scientists, of the Science Council of Japan (August 2006).
  - 13.3% of respondents have already established a code of ethics in some form, while the 41.3% do not have any future plan.
  - The survey reports that 12.4% of respondents experienced problems related to academic misconduct, and 12.5% have procedures for dealing with an allegation of misconduct, while 75.9% stated that they do not.

Code of Conduct

- The SCJ requests all organizations to design and implement an ethics program for research.
- The elaboration of the code of conduct by the SCJ addresses the problems of fabrication, forgery, or falsification in the articles submitted by scientists in general.
- However, it barely focus on the national security implications of scientific research, including the management of the dual-use aspects of the scientific researches.
- Also, the Code of Conduct has been revised, but so what?

Caser Study: the Consequence of the Scientific Community's Negligence of Responsible Governance in Japan

A Loose Control of Dangerous Pathogens…

- According to the research by the Japanese Ministry of Health and Labor Affairs published in October 2005, there were 144 facilities that stores pathogenic microbial, including 35 facilities with anthrax agent and 87 facilities with multi-drug resistant tubercle bacillus.

- Among them, only 56 facilities have management manuals, and only 64 facilities have a central management system.

- Until recently, there was no systematic mechanism within the Japanese government to review the status of implementation of a biosecurity guideline established by the National Institute of Infectious Diseases.

Status of Management of the Storage of Pathogenic Microbial

	Centrally managed	Managed by each division	Unknown	Others
Medical Institutions	39	25	0	6
Hygiene Inspection Offices	6	2	0	3
Prefectural and Municipal Public Health Institutes	16	12	0	1
Local Public Health Centers	0	0	0	0
Others	3	5	0	0
TOTAL	64	44	0	2

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 will go into effect on June 1, 2007.

- 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.

- 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.

Specified Pathogens

- 49 Genus, 79 Strains and 2 Toxin are specified as the subject of regulation.
  - Group I: 6 Genus
  - Group II: 5 Genus + 1 Toxin
  - Group III: 23 Genus
  - Group IV: 15 Genus + 1 Toxin
- Note, however, that there is no exact correlations on BSL-1~4 levels between this law and international classification.

(CITATION: a presentation material of Takeshi Kurata, at the Regional Biosecurity Workshop in 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

4 Groups of Pathogenic Microbial

- 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, Japanise encephalitis virus, Shiga toxin.

Emerging Problems: Security vs. Research

- Researchers must report to the prefectural public safety commission for transportation and assignment of the designated pathogenic microbial. It is presumed that the approval process may take a few weeks.
  - Concerns are raised about the possibility of incapability to respond to public health emergencies.

- Hampering the research activities.
  - On MRSA and MDRP, research institutions collaborate with each other and construct regional networks. Could this be continued?
  - Some researchers began throwing away pathogenic microbial.

Lessons Learned

- ✓ **Unless the scientists take initiative to address security concerns responsibly, this is what’s going to happen! Other stakeholders will step in and try to regulate the scientific activities. Once they do so, do not expect them to be considerate about your scientific research.**