

**MEETING OF THE STATES PARTIES TO THE
CONVENTION ON THE PROHIBITION OF
THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS AND
ON THEIR DESTRUCTION**

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Geneva, 13-24 June 2005**

Item 5 of the agenda

**Consideration of the content, promulgation, and
adoption of codes of conduct for scientists**

**CODES OF CONDUCT FOR SCIENTISTS:
A VIEW FROM ANALYSIS OF THE BIOINDUSTRIAL SECTORS IN JAPAN¹**

Prepared by Japan

1. Japan Bioindustry Association (JBA) is a non-profit organization established to promote bioscience, biotechnology and bioindustry in Japan and around the world, through the support and cooperation of industry, academia, and government. JBA functions as a think tank and platform for communication between scientists, technologists, policymakers and managers. At the end of May 2005, JBA membership comprised 126 Promoting and 97 Supporting Company Members from a variety of industrial sectors, as well as 90 public organizations, 4 bio-ventures and 1,237 individuals.

2. With the active participation of its members, JBA carries out the following activities relating to the promotion of bioscience, biotechnology and bioindustry:

- (i) *Promotion of Science and Technology*: scientific seminars, exploration of new R&D projects, contract research projects, intellectual property issues
- (ii) *Socio-Industrial Harmonization*: communication with the public, promotion of regional development, Green Biotechnology Strategy Forum
- (iii) *International Exchanges and Cooperation*: exchange of views through International Bioindustry Federation (IBF), organization of international symposia and trade fairs, group training course for developing countries, cooperation with the OECD

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- (iv) *Collection and Dissemination of Information*: lectures and seminars, publication of monthly journal and quarterly newsletter

3. We have analyzed the current situation in our Member companies regarding biosecurity measures in place in the context of codes of conduct for scientists.

4. There exist in Japan several laws and ministerial ordinances, which regulate handling of biological materials, including pathogens and toxins, for research and development purposes. For example, the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" applies to research and development by the use of recombinant DNA technology on the laboratory scale and commercial application. It should be noted, however, that most industrially useful microbes are non-pathogens. In addition, transgenic microorganisms developed so far fall in the category of "GILSP" (Good Industrial Large Scale Practices), which are safe enough to satisfy all the regulatory requirements by the governments.

5. In accordance with export controls under the "Foreign Exchange and Foreign Trade Control Law", exporters must obtain licenses from the government for biological agents and toxins, which may be used as biological weapons, or equipments likely to be used to produce biological weapons. Another example is the recently issued "Law Concerning Measures to Protect the People in a Situation of Armed Attack (2004)." The law describes in the case of emergency or predicted emergency, the government could order facilities, which possess biological agents and toxins, to move, restrict the use of, or destroy such dangerous materials. In order for the government authority to keep an updated record of which facility possesses which biological agents and toxins, JBA is assisting the updating of the list of such facilities.

6. "Biosafety in Microbiological and Biomedical Laboratories", biosafety guidelines of National Institute of Infectious Diseases (Ministry of Health, Labour and Welfare, 1999), which is based on the WHO laboratory safety manual and the U.S. CDC guidelines, is utilized by bioindustrial sectors for implementing their rules in handling pathogens. The NIID guidelines provide a list of pathogens, their biosafety classes and required physical containment levels.

7. Each enterprise is advised to provide its own internal rules in conformity with the guidelines as to laboratory organizations, responsibilities, biosafety measures, facility maintenance, inspections, handling (containment, storage, transfer, disposal, etc.), documentation, emergency measure, accident measure, education, training, medical examination, and so on. Important biosecurity measures include restricted entrance to the restricted working space, precise documentation on the usage of materials, and systematic and regular education and training.

8. The Japanese industry is fully aware of the importance of corporate compliance matters. Compliance is a social responsibility of the industrial sector. Compliance rules in the industrial sector usually include compliance with various laws, environmental preservation, safety and disaster prevention, product safety, disclosure of business information, respect for human rights, privacy protection, health and safety at the workplace, and prohibition of conflicts of interest. Employees are thoroughly informed about these rules. In addition, adequate handling of such

biological agents and toxins would also help research employees to prevent unexpected hazardous risks from them.

9. As far as the education and training of researchers in the industrial sector is concerned, all the companies we surveyed conduct education and training as well as health checks of all the researchers at the beginning of the work and at a regular interval, at least once a year. The education and training programs include not only technical knowledge and skills to handle biological materials but also codes of conduct required for professional researchers in the industrial sector.

10. Sound development of science and technology is an essential driver for innovations, which in turn are a basis for economic growth. Industry operates on this principle. Once governments decide to issue biosecurity regulations and standards, including ethical and social codes of conduct for research scientists, the industrial sector is willing to comply with them. However, such regulations and standards should be balanced between the cost of anti-terrorist attack measures and freedom required for research and development activities in the industrial sector. In addition, such regulations and standards should be arranged through coordination among administrative authorities. We are willing to support the governments' efforts by submitting our own opinions based on our experience.
