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**Meeting of Experts**  
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Item 5 of the provisional agenda  
**Consideration of national, regional and  
international measures to improve biosafety  
and biosecurity, including laboratory safety  
and security of pathogens and toxins**

**NATIONAL, REGIONAL AND INTERNATIONAL MEASURES  
FOR IMPROVING BIOSAFETY AND BIOSECURITY WITH  
A FOCUS ON THE SAFETY OF PATHOGENS AND TOXINS  
AT THE LABORATORY LEVEL**

Submitted by Japan

**I. Introduction**

1. The highest level of safety needs to be ensured in the handling of pathogens and toxins for accident prevention, and to date measures have been taken for this purpose. However, with the recent growing threat of bioterrorism, it has become crucial to strengthen security measures for the prevention of the development, acquisition and use of biological weapons, which is an objective of the Biological Weapons Convention (BWC).

2. In Japan there is no uniform definition of biosafety or biosecurity, since their meanings vary according to the context in which they are used. Nonetheless, Japan views that the following concepts of biosafety and biosecurity are commonly used within the context of the BWC:

- (i) **Biosafety** - is understood as measures taken for the safety of personnel handling pathogens and toxins and of others in the laboratory, including accident prevention, as well as for preventing the contamination of people and the environment outside the laboratory through the leakage of pathogens and toxins. In ensuring biosafety, the approach of safety management is employed.

- (ii) **Biosecurity** - is understood as measures taken for preventing the illicit development, acquisition and use of pathogens and toxins and relevant information and technology for purposes that run counter to the aims of the BWC. In ensuring biosecurity, the approaches of non-proliferation and counter-terrorism are employed.

3. Although, as the above makes clear, biosafety and biosecurity differ in their approach, there are quite a few common measures in their implementation. Particularly, in order to ensure biosecurity, first and foremost, it is required to take solid measures for biosafety.

4. As the working paper submitted by Japan in consultation with JACKSNNZ addresses the prevention of the misuse of biotechnology, which is one aspect of the above biosecurity concept, this working paper will concentrate on and examine the measures for laboratory biosecurity<sup>1</sup> defined by the World Health Organization (WHO) with regard to biosecurity.

5. Japan believes that taking the following national measures, as well as regional and international actions, for biosafety and biosecurity is important.

## **II. Regulations for risk management**

### Control of pathogens and toxins

6. Since there is a risk of dangerous pathogens and toxins being directly employed for illicit purposes, their possession should be controlled strictly. For conducting controls, a list of such agents needs to be compiled in order to clarify which pathogens and toxins should be regulated. Further, in addition to the control of dangerous pathogens and toxins in the laboratory, appropriate control of their transport is necessary. Accordingly, to ensure appropriate control of pathogens and toxins, legal regulations including proper penal legislation should be taken. In this connection, the Government of Japan has been taking the following measures:

- (i) In 1982, Japan enacted the “Law Concerning the Implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (the BWC Implementing Law)”. Under this Law, the possession of biological agents and toxins is restricted to peaceful purposes (Article 3 Para 1).
- (ii) Moreover, the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, the Ministry of Education, Culture, Sports, Science and Technology as well as the Ministry of Agriculture, Forestry and Fisheries have been surveying and identifying facilities that possess dangerous pathogens and toxins, and instructing these facilities to notify their storage conditions. These activities are being undertaken in accordance with the “Action Plan for the Prevention of Terrorism” (2004) and the “Civil Protection Plan (Basic Guidelines for protection of the people)”, which each Ministry prepared based on the “Law Concerning the

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<sup>1</sup> **Laboratory biosecurity (WHO)**

Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

Measures for Protection of the Civilian Population in the Situation of Armed Attack (Civil Protection Law)” (2004).

- (iii) Notably, in 2006 the Ministry of Health, Labour and Welfare revised the “Law Concerning the Prevention of Infectious Diseases and Medical Care for Patients of Infections (the Infectious Diseases Control Law)”. This revised law ensures thorough safe control of pathogens and toxins in a number of ways. It classifies pathogens and toxins that could be used in acts of bioterrorism into four categories depending on their virulence and effects on the lives and health of citizens, defines standards for facilities, usage, storage and transportation and establishes penal legislation for illegal acts.

#### Monitoring system

7. To make the appropriate control of pathogens and toxins effective, monitoring whether facilities that possess such agents are taking adequate measures is important. In Japan, the following measures have been taken for monitoring.

- (i) The BWC Implementing Law grants the competent ministers with the authority to request necessary reports from personnel handling biological agents and toxins on their activities (Article 5, Para1).
- (ii) The Infectious Disease Control Law contains provisions for the collection of necessary reports, on-site inspections and other regulations to make sure that facilities are maintaining reasonable control of pathogens and toxins in accordance with this Law. The Law also stipulates that an improvement order can be issued for the repair, renovation and modification of storage methods at facilities where necessary. In addition, the Infectious Disease Control Law prescribes that periodic inspections are to be conducted at facilities in order to maintain their functions to meet the standards set in this Law.

#### Import-Export Controls

8. Controls on the import and export of pathogens and toxins should be considered as key measures from the viewpoints of both biosafety and biosecurity.

9. In Japan, with regard to the export of pathogens and toxins, regulations for license applications were established under the Foreign Exchange and Foreign Trade Control Law as well as the Export Trade Control Order to put in place reasonable controls on the waterfront. As for the import of pathogens and toxins, the Infectious Diseases Control Law provides regulations for the prohibition, authorization and notification of import, depending on the classification of the specific pathogen in question. Regarding the pathogens of infectious diseases of domestic animals, the import of such pathogens is prohibited in principle by the Domestic Animal Infectious Disease Control Law, except for special reasons permitted under this Law, such as research purposes.

### **III. Strengthening of capacity for the handling of pathogens and toxins**

#### Physical protection of research facilities

10. Many countries and organizations have adopted manuals that regulate accident prevention within research facilities from the perspective of biosafety. However, biosecurity manuals have yet to be adopted in many places and there is still significant room for improvement. In this regard, the guidance related to laboratory biosecurity established by the WHO or the Centre for Disease Control and Prevention (CDC) of the United States could be used as a reference.

11. Until controls on pathogens and toxins were introduced under the revised Infectious Diseases Control Law, in Japan each research facility had undertaken independent control measures with WHO Laboratory Biosecurity Guidance as their reference. Subsequent to revising the Law, storage and facility standards were established for possessors of categories one to four pathogens and toxins, and thorough safety management was made a legal obligation from the perspectives of both biosafety and biosecurity. The drafting of regulations for the prevention of infectious disease outbreaks was also made an obligation from the same perspectives with regard to possessors of categories one and two pathogens and toxins. At present, the relevant research institutions and universities are also in the process of sequentially reforming the control procedures for pathogens.

#### Education and training for Personnel handling of pathogens and toxins at research facilities

12. Personnel handling pathogens and toxins are required to acquire accurate knowledge and skills and to properly control such biological agents for biosafety and biosecurity purposes. Accordingly, the provision of education and training for appropriate workers is also an important measure.

13. In Japan, the Infectious Diseases Control Law requires that personnel handling pathogens and toxins be familiarized with the regulations for the prevention of the outbreak of infectious disease. The Law also requires personnel to be given the necessary education and training to prevent epidemics and protect against outbreaks caused by pathogens and toxins.

14. In addition, the Government of Japan has been holding meetings and seminars related to pathogen controls around Japan and it intends to carry out the required efforts.

### **IV. Regional and international actions**

15. As the potential effects of inadequate biosafety and biosecurity measures could spread beyond national boundaries, regional and international cooperation is indispensable. Taking the following actions is recommended.

### Coordination with international organizations and organizations for regional cooperation

16. In order to improve implementation measures, it is encouraged to strengthen coordination with relevant international organizations, such as the WHO, as well as to engage in mutual feedback on the discussions concerning biosafety and biosecurity.

17. In this regard, the revised International Health Regulations (2005), which prescribes, amongst other things, the notification of events to WHO within a country's own territory that may constitute a public health emergency of international concern, is one of the notable activities of the WHO which the BWC should pay due attention to.

### Convening workshops and seminars

18. It is also recommended to hold biosafety and biosecurity workshops and seminars, since they contribute to the enhancement of awareness and capacity building of stakeholders in countries that have not taken adequate safety measures. In particular, since the consequences of accidents and terrorism involving biological agents have a high risk of spreading regionally, the convening of workshops to consider regional responses would be beneficial.

19. To this end, Japan has been organizing seminars on biosecurity in Japan with the involvement of international experts. Japan also convened seminars overseas on the prevention and crisis management of biological terrorism mainly for Southeast Asian countries. These seminars have provided the opportunity for the participants to share the importance of biosecurity.

### Establishing networks among researchers

20. Not only coordination amongst governments, but also the establishment of researcher networks would facilitate and expedite information sharing, and thus should be promoted actively. Moreover, the meetings of international organizations and organizations for regional cooperation and relevant workshops and seminars could also serve as opportunities for developing researcher networks.

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