

**Fourth Meeting
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**Meeting of Experts
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Items 5 of the provisional agenda

**Consideration of ways and means to enhance
national implementation, including enforcement
of national legislation, strengthening of
national institutions and coordination among
national law enforcement institutions**

**NATIONAL LEGISLATIVE MEASURES ADOPTED
BY THE REPUBLIC OF KOREA TO IMPLEMENT
THE BIOLOGICAL WEAPONS CONVENTION**

Submitted by the Republic of Korea

Introduction: “Biological Weapons” Prohibition and “Peaceful Use of Biotechnology”

1. Advances in biotechnology and its widespread availability provide greater opportunities for economic development and prosperity, but they also give rise to such complex issues as biosafety and biosecurity. Concerns about these have been shared by many nations. Such challenges imbue still greater significance into the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological and Toxin Weapons and on their Destruction (the “BWC”) and its national implementation.

2. The Republic of Korea ratified the BWC in 1987 and has attached ever greater importance to its domestic implementation. This is in recognition of the fact that full compliance by States Parties can be effective in addressing the abovementioned problems as well as enable nations to fully harvest the benefits of the peaceful uses of biotechnology. Here, the key is to devise and build a comprehensive system that firmly prohibits biological weapons while providing a safe and sound industrial environment in which biotechnology can contribute to economic growth and prosperity.

3. The Republic of Korea has exerted manifold efforts for the implementation of the BWC. Of these one important step has been the enactment in 2006 of the “Act on the Prohibition of Chemical and Biological Weapons and the Control of the Production, Export, and Import of Specific Chemicals and Biological Agents” (CBWPA), the revised version of the Chemical

Weapons Prohibition Act. This comprehensive legislation acts as an axis for various prohibition and control regulations, such as the “Act on the Prevention of Infectious Diseases of 2006”.

4. What this signifies is that the Republic of Korea’s past legislative mechanisms, which provided controls in the interests of securing public health and biological safety, have developed into an implementation system that reinforces legal and administrative national security measures, encompassing the concept of “biological security.”

5. This Law may be termed an “umbrella,” a pivot which serves as a central instrument for various separate regulations for prohibitions and controls. This Law will help the Republic of Korea to faithfully follow the principles of the BWC while fully harvesting the benefits of biotechnology for peaceful uses. It is the hope of the Republic of Korea that this legislation will also encourage domestic legislative efforts of other Member States.

Domestic Implementation of the BWC: “Act on the Prohibition of Chemical and Biological Weapons and the Control of the Production, Export, and Import of Specific Chemicals and Biological Agents” and other Legal Mechanisms

6. The strengths of the CBWPA are as follows. First, with the legislation of the CBWPA, jurisdiction of the management and regulation of biological weapons, agents and toxins has been unified under the authority of the Ministry of Commerce, Industry and Energy. This will enhance and consolidate the mechanisms for the management of separate laws such as the Act on the Prevention of Infectious Diseases, the Plant Quarantine Act, and the Act of the Prevention of Contagious Animal Disease.

7. Secondly, while serving to supplement existing laws in a systematic way, the CBWPA will provide additional measures for biological security. This will have a synergy effect, further promoting the reinforcement of other laws.

8. Finally, the CBWPA contains provisions for scheduled and occasional inspections and provisions for strong punishment for any violations, therefore ensuring a stable and steady implementation mechanism despite the absence of an international inspection system in the BWC.

9. The abovementioned aspects of the CBWPA can be categorized into three mechanisms: Prohibition, Management and Implementation.

Prohibition of Biological and Toxin Weapons

10. The CBWPA is a comprehensive and rigorous law which is in compliance with the BWC and UNSC Resolution 1540. Any and all activities regarding the development, production, acquisition, possession, stockpiling, transfer, transport, or use of biological weapons and agents (for the purpose of developing or producing biological weapons), including all actions of support or solicitation, are strictly prohibited (Paragraph 1, Article 4 bis). Over 60 types of biological agents and toxins are included in a list under the law, and their use is strictly prohibited except for peaceful purposes such as the prevention and treatment of illness.

11. The CBWPA also stipulates punitive provisions for violations of the law. A prison sentence of at least five years or a penalty of 100 million KRW (approx. 110,000 USD) is stipulated for anyone involved in activities related to the development, production, acquisition, possession, stockpiling, transfer, transport, or usage of biological weapons and agents.

Management for Legitimate Purposes

12. The law for the implementation of the BWC allows for the peaceful use of biological agents and toxins. Peaceful use of those agents and toxins is defined as “for prophylactic, protective or other peaceful purposes” as in Article I of the BWC. Biological agents and toxins authorized for peaceful applications such as the prevention and treatment of illness are also required to be declared, authorized and inspected through a tight regulatory system. Declaration regulations are required for Production (Article 5 bis) and Possession (Article 13 bis). Failure to comply with these measures will result in the suspension of production or closure of facilities (Article 8 bis).

13. Except for cases of import authorization under the Foreign Trade Act, the export of biological agents and toxins requires a license issued by the Minister of Commerce, Industry and Energy, as stipulated under Export Authorization (Article 11) and Import Authorization (Article 12). All imports are regulated under the CBWPA except for cases authorized by the Act on the Prevention of Contagious Animal Diseases and the Plant Quarantine Act.

14. In addition, the “Notification on the Designation of Goods Subject to Customs Verification of Clearance Requirements and Verification Methods Pursuant of the Provisions of Article 226 of the Customs Act” have applied to all biological agents as of June 2007, thus further contributing to the building of credibility and strengthening of domestic biological safety standards.

15. Producers and possessors of biological agents are subject to scheduled inspections (Article 2 bis), thus providing for supplementary measures in the absence of an international inspection regime for biological weapons. Due to these periodic inspections provided for in the Law, handlers of hazardous agents and toxins have become more cautious, exerting greater efforts for safety and security measures. In addition, producers and possessors are advised to submit their security management plan reports with a view to promoting biological security awareness (Article 6 bis).

Implementation of the Act: “Supplementation” and “Reinforcement”

16. The CBWPA is designed to be a central pivot for all legislative mechanisms for the implementation of the BWC. That is, the CBWPA prevents overlapping among relevant regulations and at the same time closes loopholes in the system through the adoption of comprehensive prohibition measures. For example, the declaration requirement rules for production (Article 5 bis) and possession (Article 13 bis) and rules for permission for export/import (Articles 11 and 12) of the CBWPA allow for the application of relevant regulations of other laws, such as the Act on the Prevention of Infectious Diseases, the Plant Quarantine Act, and the Act on the Prevention of Contagious Animal Diseases.

17. As the implementation law provides stricter enforcement rules, the other laws have been revised to meet just as high a level of enforcement. Entering into force in January 2006, the Act

on the Prevention of Infectious Diseases has expanded the number of controlled pathogens from 10 to 33, and stipulated punitive provisions.

18. In April 2007, the Foreign Trade Act and the “Combined Notification of the Import and Export of Strategic Materials and Technology” were revised to regulate 104 types of biological agents and toxins, adding declaration and notification requirements for their production and import and requirements for permission for their export.

Mechanisms for Biological Safety and Security

19. The recent outbreak of SARS and Avian Influenza has heightened public awareness of the dangers of the spread of infectious diseases. The concerns have spread to the danger of contamination of laboratory workers who work in the field of pathogenic bacteria research that might result in the unintentional or intentional outbreak of an infectious disease. Given these concerns the issue of the importance of biological safety and security has been the focus of fresh attention.

20. The Republic of Korea amended the Act on the Prevention of Infectious Diseases in July 2007 to include the definition of pathogens and related requirements. In January 2006, a system for safety management for the safekeeping, separation, transportation and exposal of pathogens was established through the Amendment to the Enforcement Ordinance and Enforcement Regulation.

21. To facilitate the safe management of pathogens a Tracking System was developed and is currently in operation. The Tracking System issues tracking numbers based on the type, date of separation, region and separation resource information and monitors the separation and transportation of pathogens. Other laws including the Plant Quarantine Act operate similar electronic tracking systems and are maintaining strict standards in the safe management of pathogens.

22. In addition, the “Laboratory Biosafety Guidelines” have been created to provide information on the management of laboratories, handling of pathogens, risk assessments, biological safety equipment and requirements, and the biological safety management system.

23. The Korea Center for Disease Control and Prevention (KCDC) conducts training programs. The KCDC provides the “Biological Safety Management Course” for researchers in non-governmental institutes and the “Laboratory Biological Safety Course” for researchers in government agencies. The KCDC also publishes the Biological Safety Newsletter and provides consultation services on the installation and management of air-tight research facilities.

24. In addition, it provides for control for bio-safety through its reporting and monitoring system. Organizations handling hazardous pathogens are required to submit a biannual status report on storage to the KCDC. The KCDC also conducts annual on-site biological security and safety monitoring.

25. There have also been concerns expressed regarding the increasing danger of the release of genetically modified biological organisms due to the development of genetic engineering. In order to establish biological safety in genetic recombination experiments, the “Genetic

Recombination Guidelines” were created in 2007 to provide information on necessary procedures and requirements.

26. It is with the aim of preventing harm that could derive from the development, production, export, import and distribution of genetically modified organisms that the “Act on the Transnational Transportation of Genetically Modified Organisms” was established. Efforts are now being made to require agencies involved in genetic experiments to establish guidelines for the establishment and management of research facilities for each pathogen, and to acquire or declare authorization for each research facility safety management level.

27. This Law was enacted in March 2001, its Enforcement Ordinance enacted in September 2005, and its Enforcement Regulations enacted in March 2006. A Combined Notification for all related organizations and agencies is being drawn up, with a planned enactment date set for January 2008.

Conclusion

28. The Republic of Korea has successfully devised and operated a two-track system. Biological weapons and all related activities are comprehensively prohibited while activities for peaceful purposes, such as the development of medications, are permitted under effective controls. This approach has served national security interests in the field of the non-proliferation of WMD as well as other purposes. The Korean Government will also continue to cooperate with the private sector in order to faithfully adhere to the principles of the BWC.
