

## **Compendium of National Activities**

### **Republic of Korea**

#### **Measures to Improve Biosafety and Biosecurity**

Since the Republic of Korea ratified *the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (the “BWC”), it has attached ever greater importance to the enhancement of biosafety and biosecurity by enacting effective legislation and establishing a comprehensive national regulatory regime to ensure the measures for prohibition and prevention required by the BWC.

#### **Legislative Measures**

- The Republic of Korea enacted in 2006 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*, and it came into effect on January 2007. As a central pivot for all legislative mechanisms for the implementation of the BWC, the CBWPA has played a role in preventing overlap between relevant regulations and strengthening comprehensive measures for prohibition. Furthermore, the CBWPA contains provisions for scheduled and occasional inspections and provisions for strong punishment for any violations, thereby ensuring a stable and steady implementation mechanism despite the absence of an international inspection system in the BWC.
- Under this law, the use of 67 types of biological agents and toxins is strictly prohibited except for peaceful purposes such as the prevention and treatment of disease. Even in the case of use for peaceful purposes, the biological agents and toxins are to be declared, authorized and inspected through a tight regulatory system pursuant to the CBWPA.
- The Ministry of Defense established a system for the internal regulation of military biological laboratories and facilities, which entered into force in May

2008, in order to screen whether they faithfully follow the provisions and principles of the CBWPA as well as the BWC and enhance the implementation of the CBWPA. The Ministry of Defense is confident that this internal regulation contributes to guaranteeing the compliance with the international regime as well as enhancing the strict implementation of the BWC for a biological weapons free world.

- In April 2007, *the Foreign Trade Act* and *the Combined Notification of the Import and Export of Strategic Materials and Technology* (the Combined Notification) were revised to regulate 104 types of biological agents, plant pathogens and animal pathogens which had been on the Common Control List of the Australia Group. This revised act requires the declaration and notification of the production and import of those agents and toxins, and also requires permission for their export.
- *The Prevention of Contagious Diseases Act* was amended in December 2005 to include the definition and the lists of highly dangerous pathogens and related requirements for enforcing biorisk management. Pursuant to this amendment, a system for safety management for the safekeeping, separation, transportation and exposal of pathogens was established in January 2006 through the Amendment to the Enforcement Ordinance and Enforcement Regulation of this act.
- *The Guideline on Recombinant DNA Experiments* was notified in 1997 under *the Biotechnology Promotion Law* and revised in 2007 to prevent any mishap or fallout in advance as the rapid development of biotechnology in Korea had lead to increased concerns over adverse effects and the possibility of misuse.
- *The Notification on the Designation of Goods Subject to Customs Verification of Clearance Requirements and Verification Methods Pursuant of to the Provisions of Article 226 of the Customs* has applied to all biological agents as of June 2007, thus further contributing to the building of credibility and strengthening of domestic biological safety standards.
- *The Act on the Transnational Transportation of Living Modified Organisms* (LMO) was legislated in 2001, and has finally come into effect from January

2008 to implement *the Cartagena Protocol on Biosafety* and to prevent any potential risks which can be generated in the process of development, production, import, export and *distribution* of LMO. This act stipulates provisions related to the national authorization of specific experiments and the specific facilities such as Biosafety Level 3 (BSL-3) in compliance with the containment level.

- On the basis of *the National Regulations on Livestock Infectious* of November 2007, the National Veterinary Research and Quarantine Service (the NVRQS) has carried out inspections to assess the management of *livestock infectious disease* of laboratories, thus examining the conditions of storage and facilities for infectious agents, the safety standards in research facilities, and education on the National Regulations.
- The Korea Center for Disease Control and Prevention (KCDC) offers *the Laboratory Biosafety Guidelines* to provide information on the safe handling of pathogens, risk assessment procedures, and the operation of the Institutional Biosafety Committee.

## **Administrative Measures**

- The export of biological agents and toxins requires a license issued by the *Ministry of Knowledge Economy (MKE)* as stipulated under the Foreign Trade Act and the Combined Notification. In addition, all imports are regulated under the CBWPA except for cases authorized either by *the Act on the Prevention of Contagious Animal Diseases or the Plant Quarantine Act*.
- As part of efforts to enhance biosafety, the MKE has implemented the national declaration and authorization system for biological agents and toxins, and has conducted inspections of facilities producing and possessing biological agents and toxins regulated by the CBWPA together with relevant government agencies. According to the CBWPA, producers and possessors of those agents and toxins should submit declaration reports on their production and possession.

- Concerning the LMO, research facilities are required to set standards relating to installation and management of such facilities and also to be certified or declare themselves in accordance with the risk level of pathogens they handle. When the facilities conduct experiments involving the genetic modification of DNA of pathogens or experiments using living modified organisms, they are also required to observe the safety rules at each level in appropriate research facilities.
- Along with the revision of the Foreign Trade Act and the Combined Notification, in December 2007 the MKE modified the system for the categorization of export control items compatible with Export Control Numbers in trade with the EU, Australia and the USA.
- To facilitate the safe management of specific pathogens, the KCDC has developed a tracking system to monitor highly dangerous pathogens. Under this tracking system unique tracking numbers are issued according to the specific traits, the date of isolation or importation, the related institution, and other relevant information. The use, transportation, and conservation of the pathogens are then monitored.

## **Others**

- The KCDC provides training programs on biosafety. There are two major programs; one is the “Biological Safety Management Course” for researchers in non-governmental institutes, and the other is the “Laboratory Biological Safety Course” targeted for researchers in government agencies. The KCDC also publishes the “Biosafety Newsletter” and provides consultation services on the installation and management of the research facilities for biosafety.
- The KCDC held “*The International Symposium on Biosafety and Biosecurity*” with the Bioindustry Association of Korea and Korea University on the 10<sup>th</sup> July 2008. Inviting biosafety and biosecurity experts from the USA, Canada, and Japan, the KCDC organized this symposium with the aim of strengthening awareness-raising and reviewing the domestic biosafety and biosecurity system.