

JAPAN

(ONLY MEASURES PERTAINING TO BIOLOGY)

Penal Measures

Japan has laws specifically addressing biological attacks and bio-terrorist threats. Acts of bio-terrorism are punishable by a prison term of two years to life.

Since 1982, Japan has had legislation prohibiting the production, possession, and transfer of biological weapons. Japan is a party to the International Convention for the Suppression of Terrorists Bombings. This convention requires state parties to prosecute those who commit, attempt to commit terrorist acts. The Convention also requires state parties to prosecute or extradite suspected terrorists.

Regulations of Pathogens and Equipment

The Ministry of Agriculture, Forestry, and Fisheries is the government authority primarily responsible for the regulation of biological material. Japan has defined a group of pathogens subject to regulation. Japan has promulgated regulations concerning the transport, storage and disposal of biological material. As part of the Australia Group, Japan has developed and implemented export controls on biological material and critical equipment.

The National Institute of Health Sciences (NIHS) is one of seven research institutes operated under the Ministry of Health, Labour and Welfare. NIHS is responsible for conducting basic research to ensure the quality, efficacy and safety of various pharmaceutical products and for regulating advances in science and technology. The Biological Safety Research Center (BSRC) within the NIHS, conducts biological studies for safety and risk assessments of chemicals, such as pharmaceuticals, cosmetics, food, food additives, pesticides, industrial chemicals, etc.

Oversight of Research

Under the Pharmaceutical Affairs Law of April 1, 1997, the Pharmaceutical and Medical Safety Bureau (PMSB) handles clinical studies, approval reviews and post-marketing safety measures, such as approvals and licensing. The Health Policy Bureau handles promotion of research and development, and production and distribution policies, such as functions related to pharmaceutical companies. The Pharmaceuticals and Medical Devices Evaluation Center, established in the NIHS, has been strengthening approval reviews since July 1, 1997. This organization consists of three parts: the PMSB, the Evaluation Center, and the Organization for Pharmaceutical Safety and Research (OPSR).

The Ministry of Education, Culture, Sports, Science, and Technology (MEXT) is responsible for planning, formulating, and promoting basic policies related to science and technology. In addition, MEXT is responsible for comprehensive policy spanning the formulation of research plans, promotion of research evaluations, training of researchers and technicians, advancement of science and technology in local communities, promotion of greater understanding of science and technology, and international research exchanges. Furthermore, MEXT monitors implementation of such plans and encourages relevant ministries to take the necessary measures to ensure the success of those plans.

Guidelines for Recombinant DNA Experimentation define basic conditions required to promote and ensure safety for recombinant DNA and related experiments. The experiments must be conducted under proper safety measures generally employed in microorganism laboratories, incorporating combinations of physical and biological containment measures as required by the

safety evaluation of the experiment. Large-scale containment experiments must be conducted in a facility equipped with appropriately large scale apparatuses. Laboratory workers must be aware of the necessity of safety measures in the experiments, actually taking those measures, and must have been thoroughly trained with expertises in standard methods and practices in microbiological experiments.

The National Institute of Infectious Diseases under the Ministry of Health, Labour and Welfare established the Infectious Disease Surveillance Center (IDSC) as the national center for infectious disease surveillance and for exchanging information on infectious diseases with other nations' surveillance centers. As of January 1999, all patients who visit designated clinics or hospitals are reported to health centers (about six hundred in the nation), which are then electronically reported to the prefectural/municipal health departments and the IDSC.

Measures Pertaining To Public Health

There are seventy-three prefectural/municipal public health institutes (PHI's with microbiology laboratories) throughout Japan. They isolate/detect and identify pathogens from clinical specimens sent by some sentinel clinics and hospitals, food and fecal specimens collected from foodborne infection outbreaks, and sewage water and animals/insects in the environment. Individual reports for isolation/detection of viral and enterohemorrhagic *E. coli* pathogens from patients and bacterial and viral pathogens from foodborne outbreaks are electronically transferred from PHI's to IDSC.

Enactment in April 1999, the Law Concerning the Prevention of Infectious Diseases and Medical Care for Patients of Infections (Infectious Diseases Control Law) combined the Communicable Disease Prevention Law of 1897, the Venereal Disease Prevention Law of 1948, and the AIDS Prevention Law of 1989. This new law defines the National Epidemiological Surveillance of Infectious Disease (NESID) program as its main objective. The NESID consists of sentinel surveillance for occurrence of patients of 27 kinds of infectious diseases other than legally notifiable diseases and infectious agents surveillance. The new law plans to intensify the surveillance system to promote effective and accurate infectious disease control measures by reinforcing and expanding the conventional surveillance system, restructuring the computer network system to obtain, analyze and quickly publish the information on a nation-wide scale and conducting active surveillance.

BIBLIOGRAPHY OF JAPANESE LEGISLATION

1. Law for Control of Poisonous and Powerful Agents
2. Foreign Exchange Control Order, 1980
3. The Export Trade Control Order, 1949
4. Control of Pathogens Regulations of the National Institute of Infectious Diseases
5. Notice from the Minister of Health, Labour, and Welfare Strengthening Safeguards of Pathogenic Micro-organisms (October 2001)