

India

India is a State Party to the 1972 Biological and Toxin Weapons Convention (BTWC). India ratified the Convention in 1974. India maintains that the norms against biological weapons enshrined in the BTWC must be upheld, particularly at a time of heightened threat of BW proliferation and bio-terrorism, and meaningful multilateral efforts should be pursued to strengthen these norms. India is in favour of inclusion of provisions of an adequate and effective mechanism in the BTWC, while at the same time providing for increased international cooperation in transfers and exchanges of biological materials and technologies for peaceful purposes. India has been playing a constructive role in international efforts aimed at enhancing the effectiveness of the BTWC and is committed to the ongoing process of annual meetings of experts and States Parties to the BTWC. Domestically, relevant agencies of the Government regularly interact with the industry to increase awareness about our obligations under the Convention.

Preventing Biological Weapons proliferation: Legislative basis

India has in place a regulatory mechanism for the maintenance of security and oversight of pathogens, micro-organisms, genetically modified organisms and toxins in production, import, export, use and research. The Environment (Protection) Act, 1986 provides the mandate to the Government to lay down procedures and safeguards as it deems necessary for the handling of hazardous substances. 'Hazardous substance' has been defined as any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plants, micro-organisms, property or the environment while 'handling' denotes the "manufacture, processing, treatment, package, storage, transportation, use, collection, destruction, conversion, offering for sale, transfer or the like" of such substances (Sections 2 and 3). The Act prohibits handling of such substances except in accordance and compliance with the prescribed procedural safeguards (Section 8). The Act has provisions for entry, inspection and sample analyses by enforcement officials (Sections 10 and 11) and offenses by companies and Government Departments (Sections 16 and 17). Contravention of the provisions of the Act, or the rules, orders, directions issued there under are punishable with imprisonment for a term which may extend to five years or with fine or with both (Section 15(1)).

Deriving the necessary mandate from the Environment (Protection) Act, 1986 (Sections 6, 8 and 25), the Government of India in 1989 notified the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms and Genetically Engineered Organisms or Cells. These Rules also apply to new gene technologies.

These Rules *inter alia* are applicable for the sale, offer for sale, storage for the purpose of sale, any kind of handling of hazardous micro-organisms and the export and import of genetically engineered cells organisms. The Rules also provide the Government with the authority to regulate micro-organisms which "have not been presently known to exist in the country or have not been discovered so far" (Section 3 (v)). The Rules prohibit unauthorized deliberate release of genetically engineered organisms/ hazardous micro-organisms or cells into the environment or nature (Section 9).

Preventing Biological Weapons proliferation: Country-wide biosafety network

The use of recombinant technologies are well regulated under the Environment Protection Act, 1986, the 1989 Rules and the Recombinant DNA Safety

Guidelines issued by the Government in 1990. Any institution, including research institutions, handling micro-organisms/genetically engineered organisms is required by law to have an Institute Bio-Safety Committee to examine and monitor projects from the point of view of safety and biohazard potential. More than 300 Institutional Bio-safety Committees have been set up all over the country. These Committees, which include a Government representative as a member, also assist in training of personnel on biosafety, safe disposal of hazardous wastes, and the adoption of an emergency plan.

Institutionalized advisory and regulatory bodies such as the Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC), and Recombinant DNA Advisory Committee (RDAC) have been set up, with the scope of their mandate and functions being statutorily defined. Bodies such as the Review Committee on Genetic Manipulation (RCGM) provide for consultations between the relevant agencies of the Government and other relevant autonomous/semi-autonomous bodies for monitoring the safety-related aspects of on-going research projects and activities involving hazardous micro-organisms, including drawing up of regulatory guidelines and procedures restricting or prohibiting production, sale, importation and use of genetically engineered organisms or cells. All ongoing projects involving high risk category and controlled field experiments are reviewed by the RCGM, which is coordinated by the Department of Bio-technology, to ensure that adequate precautions and containment conditions are followed. Use of pathogenic micro-organism or any genetically engineered organisms or cells for the purpose of research is permitted only in laboratories authorized for the purpose.

IV.C. Bio-safety: A list-based approach

15. The 1989 Rules under the Environment Protection Act, 1986 and the 1990 Guidelines list micro-organisms on the basis of differential risk assessment. These lists, which are applicable from the biosafety point of view, are more elaborate than the list of micro-organisms and toxins included in Category 2 of the SCOMET List (reference paras below) notified by the Government for the purpose of dual-use export controls.

Domestic Dual-Use Export Control Regime

India's commitment to non-proliferation is anchored in a conscious decision to prohibit or control export of materials, equipment and technologies of direct and indirect application to weapons of mass destruction and the means of their delivery.

Conscious of its responsibilities arising from the possession of advanced technologies, civilian or strategic, India is committed to an effective and comprehensive system of export controls to deny unlawful access – whether to States or non-State actors. To this end, a rigorous domestic regime has been instituted through the creation of laws, interagency administrative mechanisms, and effective enforcement. These controls are subject to continuous review in consonance with changes in the technology environment and other requirements.

The SCOMET List is currently notified in the Export Policy in Schedule 2 Appendix 3 of the Indian Tariff Classification (Harmonized System) {ITC(HS)} Classifications of Export and Import Items, 2004-2009. The list contains all dual-use items and technologies within 8 categories, in keeping with the Government of India requirements. These are as follows:

....(other nuclear and chemical sections).....and Category 2: Micro-organisms and Toxins