MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Consideration of the content, promulgation, and adoption of codes of conduct for scientists

INDIAN INITIATIVES ON CODES OF CONDUCT FOR SCIENTISTS

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1. It is recognized that science & technology can have dual use; it can be applied not only for peaceful purposes but also for hostile ones. Modern biology and bio-technology offer novel ways of manipulating basic life processes. Purposefully or unintentionally, genetic modification of microorganisms can be used to create organisms that are more virulent, are antibiotic-resistant, or have greater stability in the environment. Advances in gene therapy can facilitate changes in the immune response system of the host population to modify susceptibility to a pathogen or disrupt the normal host response.

2. Genetic research involving humans has provided immense benefits to humankind in the form of drugs, vaccines, diagnostics and other knowledge for better management of health and disease. New vistas for molecular medicine have opened for human welfare especially in the areas of improved diagnosis of diseases, early detection of genetic predisposition to diseases, rational drug design, new drug targets and pharmacogenomics etc. At the same time it has also raised questions of social and ethical consequences such as privacy, confidentiality and individual rights to access personal records.

3. In order to prevent the use of bio-medical sciences for bio-terrorism or bio-warfare, persons and institutions engaged in all aspects of bio-medical sciences need to abide by a voluntary code of conduct, governed by the principles of non-malfeasance, beneficence, institutional arrangements, risk minimization, ethical review, transmission of ethical values and compliance.

4. The goal of Indian Government is to ensure that research and applications in bio-sciences and biotechnology are guided by a system of monitoring and review that safeguards human health, environment and ensures observance of the highest ethical standards. A scientific, rigorous, transparent, efficient, predictable and consistent regulatory mechanism and protocol for bio-safety and bio-security evaluation and related system need to be followed to meet these objectives.

5. Scientists should be made aware of the potential risks and concerns relating to science and its wider applications and the ethical responsibilities they shoulder. They should also be aware of and comply with the requirements of international conventions and treaties relevant to their research work.

6. The Indian Government and agencies and professional bodies, working under it, have drafted codes of conduct or principles of ethics for scientists engaged in life sciences in order to ensure that activities involving microbial or other biological agents, or toxins, whatever their origin or method of production, are of types and in quantities that have justification for prophylactic, protective or other peaceful purposes.

7. The Indian Government, keeping in view potential risks to human beings and to the environment, have enacted regulatory mechanisms for import, export, use and research on microorganisms including genetically modified organisms. These include guidelines for scientists conducting research, which deal with microorganisms and toxins and genetic modifications, if any, and are of direct relevance to the provisions of BTWC.

8. **The Indian Environment (Protection) Act of 1986** deals with protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property. Under this Act, the government has the power to take all such measures, as it deems necessary or expedient, for the purpose of protecting and improving the quality of the environment and preventing, controlling and abating damage to the environment, including laying down procedures and safeguards for handling of hazardous substances and carrying out and sponsoring investigations and research relating to problems of environmental pollution.

9. The Government enacted in 1989 **Rules for the Manufacture, Use/ Import/ Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells.** These rules are applicable to the manufacture, import, export and storage of:

(i) micro-organisms and gene-technological products;

(ii) genetically engineered organisms/ micro-organisms and cells and, correspondingly, to any substance and products and food stuff etc. of which such cells, organisms or tissues hereof form part; and

(iii) new gene technologies and organisms/ micro-organisms and cells generated by the utilization of such or other gene-technologies and substances and products of which such organism and cell form part.

10. Under these Rules, competent authorities have been identified to ensure implementation of the provisions of the Act and to provide guidelines on ethical and social responsibilities of scientists, institutions, industries, who conduct research, and of those who conduct, fund, administer and regulate work on biological sciences.

11. **Recombinant DNA Advisory Committee (RDAC)** recommends, from time to time, suitable and appropriate safety regulations for recombinant research, use and applications.

12. It is mandatory for all research institutions / universities / industries handling microorganism / genetically engineered organisms to constitute **Institute Bio-safety Committee (IBSC)** that prepares an up-to-date site emergency plan according to the manuals/guidelines of the Review Committee on Genetic Manipulation (RCGM). **About 300** such committees are already functioning in various research institutions / universities / industries handling microorganism / genetically engineered organisms. This committee also looks into the bio-safety aspects including experimentation and containment issues.

13. **Review Committee on Genetic Manipulation,** based in the Department of Biotechnology, monitors the safety related aspects in respect of on-going research projects involving genetically engineered organisms/hazardous microorganisms. The Committee also brings out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving high-risk category and controlled field experiments and conducts reviews to ensure that adequate precautions and containment conditions are followed as per the guidelines.

14. **Genetic Engineering Approval Committee (GEAC),** under the Ministry of Environment, Forest and Wildlife, approves, from the environmental angle, activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production and proposals related to release of genetically engineered organisms and products into the environment, including in experimental field trials.

15. **Recombinant DNA Guidelines, formulated by the Department of Biotechnology in 1990**, were revised in 1994 for large-scale production and deliberate release of GMOs, plants, animals and products into the environment and shipment and importation of GMOs for laboratory research. It also deals with genetic transformation of green plants, rDNA technology in vaccine development and on large-scale production and deliberate/ accidental release of organisms, plants, animals and products derived by rDNA technology into the environment. Research work has been classified into categories based on the level of the associated risk and requirement for the approval of competent authority. The guidelines give principles of occupational safety and hygiene for large-scale practice and containment, safety criteria and physical containment conditions. They specify appropriate containment facilities depending on the type of organisms handled, potential risks involved and various quality control methods needed to establish the safety, purity and efficacy of rDNA products.

16. The **Guidelines developed in 1999 for generating pre-clinical and clinical data for rDNA vaccines, diagnostics and other biologicals**, address issues of safety, purity, potency and effectiveness of the project.

17. **The Drug Policy of 2002** deals with the rDNA products where bulk drugs, produced by the use of rDNA technology, requiring *in vivo* use of nucleic acid as the active principles and specific cell/tissue targeted formulations, require an industrial license for production

18. **The guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts** provide a complete design of a contained green house suitable for conducting research with transgenic plants, besides, providing the basis for generating food safety information on transgenic plants and plant parts.

19. **National Seeds Policy, 2002** ensures that all genetically engineered crops/varieties are tested for environment and bio-safety before their commercial release.

20. The Indian Parliament passed in May 2005 **the Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Bill, 2005.** It is an over-arching and integrated legislation to prohibit unlawful activities in relation to weapons of mass destruction and their means of delivery and to build upon the regulatory framework related to controls over the export of WMD-usable materials, equipment and technologies.

21. Industry is a user of special materials, equipment and dual-use technologies and products. Fully aware of the possibilities of the misuse of the uncontrolled proliferation of these technologies and products of direct and indirect application to weapons of mass destruction (WMD) and their means of delivery, India has been exercising **control over the export of Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET)**, which also include microorganisms/toxins, including bacteria, fungi, parasites, viruses, rickettsials, plant pathogens, and genetically modified organisms. Conditions are specified for export of SCOMET items, including requirement of a license. Export of these items is also controlled by other applicable guidelines, issued from time to time.

22. Department of Biotechnology developed in 2002 **the Ethical Policies on the Human Genome, Genetic Research and Services.** The objective is to provide guidance to the researchers, ethical committees, institutions, organizations and the public on the conduct of research, based on the recognized ethical principles and values. It addresses issues related to integrity, respect and beneficence; justice; consent; dissemination of research results; gene therapy and human cloning; genetic testing and counseling, genetic privacy and discrimination; intellectual property rights and benefit sharing; DNA and cell-line banking; and international collaboration. Even though these guidelines relate to the ethical policies for genetic engineering research and services, any such research work needs to be approved by the competent authorities, including ethical clearances of the institutions, animal and human concerns, and bio-safety issues. These guidelines provide guidance and also exercise control over the conduct of the life- science scientists.

23. The Indian Council of Medical Research, under the Ministry of Health and Family Welfare, has developed code of conduct for scientists engaged in biomedical research. The Ethical Guidelines developed in 2000 for the biomedical researchers are consistence with the Declaration of Helsinki, adopted by the World Medical Assembly in 1964, and amended in October 2000 based on principles of autonomy, privacy, justice and equity.

24. Development of policies, governing the publication of sensitive research works, with the aim to address the bio-security aspects of research in bio-sciences and bio-technology is another requirement. Effective steps to ensure bio-security without hampering research and free exchange of information in the field of bio-sciences and bio-technology are needed. A system of checks and balances could provide the assurance that the advances in life sciences are only used to protect life and not to destroy it. Issues requiring consideration may include:

(i) The need to increase awareness of the risk of bio-terrorism among scientists and scientific leaders.

(ii) Development of training programmes and materials for educating scientists on bio-safety and bio-security issues.

(iii) Establishment, in universities and other scientific institutions, of procedures to monitor scientific activities and mechanisms to prevent dissemination of information that may be utilized for bio-terrorism

(iv) A bottom-up approach in formulation and implementation of bio-safety and bio-security policies through direct involvement of scientists.

(v) Adoption of a policy of outreach to industry to inform and involve it in the process of evolution of bio-safety and bio-security policies.

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