

4.8 India



4.8.1 Environment Protection Act (1986) and Environment (Protection) Rules (1986)

The Act relates to the protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property. The Act mainly covers the rules to regulate environmental pollution and the prevention, control, and abatement of environmental pollution.

The Environment (Protection) Rules cover management and handling of hazardous wastes, manufacture, storage and import of hazardous chemicals and rules for the manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells.

4.8.2 Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells. (notified under the EP Act, 1986) (1989)

These Rules include the rules for pharmaceuticals, transit and contained use of genetically engineered organisms micro-organisms and cells and substances/products and food stuffs of which such cells, organisms or tissues form a part, LMOs for intentional introduction into the environment, handling, transport, packaging and identification.

These rules are applicable to the manufacture, import and storage of micro-organisms and gene technology products.

The rules are specifically applicable to:

- (a) Sale, storage and handling
- (b) Exportation and importation of genetically engineered cells or organisms
- (c) Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of genetically engineered products that make use of genetically engineered microorganisms in any way.

4.8.3 Recombinant DNA Safety Guidelines (1990)

The Guidelines prescribe safety measures for the research, field cultivation and also the environmental impact during field applications of genetically altered material products.

They are applicable to research involving genetically engineered organisms originating from genetic transformation of green plants, rDNA technology in vaccine development, and also large scale production and deliberate/accidental release of organisms, plants, animals and products derived by rDNA technology into the environment.

The Guidelines also prescribe the criteria for assessment of the ecological aspects on a case by case basis for planned introduction of rDNA organism into the environment.

4.8.4 Foreign Trade (Development & Regulation) Act, 1992 (2006) (draft amendment)

The Act provides for the development and regulation of foreign trade by facilitating imports into, and augmenting exports from India and for matters connected with it. In 2006, the government made changes in the foreign trade policy, making labeling of imported GM products mandatory.

4.8.5 Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts (1998)

The Guidelines cover recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. It also includes LMOs for contained use and intentional introduction into the environment, and LMOs for use as food or feed or for processing, pharmaceuticals and transboundary movement. The Guidelines also specify requirements for import and shipment of GM plants for research use only.

4.8.6 Guidelines for generating preclinical and clinical data for rDNA Vaccines, Diagnostics and other Biologicals (1999)

The Guidelines covers preclinical and clinical evaluations of rDNA vaccines, diagnostics and other biologicals/pharmaceuticals. The objectives of the preclinical studies are to define physiological, toxicological and efficacious potential of r-DNA product prior to initiation of human studies. Both *in vitro* and *in vivo* studies can contribute to evaluate the effects of r-DNA products.

The Guidelines also covers safety, purity, potency and effectiveness of the rDNA products, *in vitro* diagnostic recombinant reagents and monoclonal antibodies, and describe in detail procedures for generating monoclonal antibodies. Sensitivity and specificity required for diagnostics of infections of widespread diseases like HIV-I/II are also prescribed.

4.8.7 Plant Quarantine (Regulation of Import into India) Order (2003)

The Order allows import of transgenics/GMOs into India for the purpose of agricultural research or experimentation purpose only. No commercial imports are allowed under this order. However, commercial imports are governed by separate Guidelines issued by the Genetic Engineering Approval Committee.

4.8.8 The Seed Bill (2004) (draft)

The Bill provides for regulating the quality of seeds for sale, import and export and to facilitate production and supply of seeds of quality and other related matters. Apart from other provisions related to seed, the Bill has special provisions for registration of transgenic varieties. Clause 15 of the draft bill covers specific provisions requiring clearance under the provisions of the Environment (Protection) Act, 1986.

4.8.9 The Food Safety and Standards Act (2006)

The objective of the Act is to bring out a single statute relating to food and to provide for a systematic and scientific development of food processing industry. The Act incorporates the salient provisions of the Prevention of Food Adulteration Act, 1954 (37 of 1954) and is based on international legislations, instrumentalities and Codex Alimentarius Commission Guidelines. The Act is in tune with the international trend towards modernization and convergence of regulations of food standards with the elimination of multi-level and multi-departmental control. The emphasis is on (a) responsibility with manufacturers, (b) recall, (c) GM and functional foods, (d) emergency control, (e) risk analysis and communication and (f) food safety and good manufacturing practices and process control viz., hazard analysis and critical control point.

Source:

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4. <http://exim.indiamart.com/act-regulations/ftrd.html>; accessed on 27 October 2007
5. <http://www.envfor.nic.in/divisions/csurv/geac/groundrules.htm>; accessed on 27 October 2007
6. <http://envfor.nic.in/divisions/csurv/biosafety/Files/Biologicals.PDF>; accessed on 27 September 2007
7. <http://www.plantquarantineindia.org/pdf/Consolidated%20Version%20PQ%20Order%20ason-7May2007.pdf>; accessed on 27 September 2007
8. http://agricoop.nic.in/seeds/seeds_bill.htm; accessed on 16 October 2007
9. <http://envfor.nic.in/legis/hsm/hsm3.html>; accessed on 27 September 2007
10. http://www.pfndai.com/Food_Safety_and_Standards_Act.doc; accessed on 27 September 2007