

Legal Assistance that can be rendered to
BIRAC (Biotechnology Industry
Research Assistance Council):

LAW CAPSULE
(OFFICIAL NEWSLETTER OF
TRANS-INDIA LAW ASSOCIATES ,
ADVOCATES & LEGAL
CONSULTANTS)
VOLUME XV, PART-XXII

5TH OCTOBER 2015

The current Indian norms and web of agencies that deal with biotechnology do not follow an exhaustively defined plan. By contrast, the present normative and institutional framework is the outcome of a relatively unsystematic evolution which has in its origin from the *Environment (Protection) Act of 1986*.

The norms of the *Environment (Protection) Act* provide the legal background to the Rules for Manufacturing, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells. This is a key piece of the Indian legislation on biotechnology, which is also known as *Bio Safety Rules of 1989*. The Biosafety Rules deal with the research, manufacturing, importation, usage and storage of microorganisms, gene technology products and products made out of genetically modified microorganisms.

- Rule 9 of the Bio Safety Rules establishes that unless special permission by the *Genetic Engineering Approval Committee* is granted, it is prohibited the unintentional and deliberate release of genetically modified organisms and cells covered under the schedule for experimental purposes;
- According to Rule 7, the *Genetic Engineering Approval Committee* must also approve the import, export, transport, manufacture,

process, use or sell of any hazardous microorganisms of GMO/substances or cells;

- Any person shall apply to the *National Biodiversity Authority* for access to biological resources and associated knowledge for research or for commercial utilization shall make an application in Form I as per Rule 14 of the *Biological Diversity Act, 2002*;

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