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GENETICALLY MODIFIED ORGANISM AND LAW: NAVIGATING THE REGULATORY LANDSCAPE IN INDIA

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GMOS IN THE INDIAN PERSPECTIVE:

Genetically Modified Organism (GMO) are the ones whose genome has been engineered in the laboratory in order to favor the expression of desired physiological traits or biological products. Biotechnology has equipped the scientists with the capabilities to redesign crops, altering bacterial plasmid & DNA to produce medicines and use the recombinant DNA technology to develop the Genetically Modified Organisms (GMO). However, this power raised a complex legal and ethical concern over biosafety, public health and ecological impact.

REGULATING FRAMEWORK GOVERNING GMOS IN INDIA:

The legal landscape for GMOs in India is based on the Environment (Protection) Act, 1986, which regulates hazardous substances, including GMOs of any kind. Under this Act, the apex body of Genetic Engineering Appraisal Committee (GEAC) approves the GM crops, while the Review Committee on Genetic Manipulation (RCGM) oversees research involving GMOs-recombinant products like GM derived insulin and vaccines. Rules related to manufacture, import, use and release of GMOs and their products, have been notified by Ministry of Environment and Forests (MoEF) in 1989, ensuring that their use is safe to the environment and beneficial to people. Department of Biotechnology (DBT) issued separate guidelines for research in transgenic plants (1998) and clinical products (1999). Other competent authorities like State Bio Safety Co-ordination Committee, etc ensure institutional, district and state level safety compliance.

The FSSAI, under the Food Safety and Standards Act, 2006, regulates the genetically modified foods, including mandatory labelling of packages having 1% or more GM composition.

DEBATE ON PATENTABILITY OF GMO:

The process of genetic modification, being expensive and time consuming, the scientists need ample financial support to continue their research and innovation in agriculture and biotechnology and develop crops with improved yields, nutritive value and resistance to pests or climate stress. Patent protection of GMOs will disclose the technological expertise, safeguarding the farmers' traditional practices and reasonable licensing promotes food security and public access.

However, treating life-forms as patentable commodities highlights issues on ownership, informed consent, credits and compensation for biological materials used for modifying human cell lines.

Patents for GMOs are a disadvantage for developing countries, whose genetic resources and traditional knowledge are commercially exploited. The farmers are forced to use genetically modified seeds with more licensing costs, narrowing the crop diversity and long term dependence on the corporate sector. Even life-saving drugs remain too costly for the people whose biodiversity and clinical data helped to create them.

LANDMARK CASES AND CONTROVERSIES:

Several cases involving GMOs in India sparked a debate on clinical trial approvals, biosafety compliance and patentability, though fast growing recombinant pharmaceutical products like vaccines or insulin are free from controversies.

The Bt Brinjal moratorium of 2010, despite GEAC clearance was an instance of political intervention, citing concerns over long term safety data and public opposition. Bt cotton case has raised disputes about seed pricing, royalties by companies and unauthorized production of herbicide tolerant variants, seeking attention from the Competition Commission of India and other state bodies.

The *Dimminaco A.G. v. Controller of patents and Designs* was a landmark Calcutta High Court case involving a poultry vaccine manufactured from a live virus. The Patent Office, though rejected the application, the Supreme Court held that, if the process is novel, useful producing a commercially marketable product, it qualifies as a patentable 'manufacture' under the Patents Act, 1970. Years later, in the *Monsanto-Nuziveedu* dispute, the Supreme Court reinforced the patent eligibility for genetically modified cotton technology and this paved the way for many biotech companies operating in the country. Recently the Madras High Court in *Sakata Seed Corporation v. Deputy Controller of Patents and Designs* case clarified that even a breeding

process involving human intervention is also patentable and each case must be judged on the degree of that intervention.

RECENT GMO SCENARIO:

Recent gene editing technologies produced genome- edited rice that are free of foreign DNA, high yielding and stress tolerant- a significant innovative and regulatory milestone. India has also approved of two more gene edited rice and a mustard type is in its trial stage. Regulatory bodies require only Bio-Safety Committee approval and exempted these modified groups from the stringent bio-safety rules.

THE WAY FORWARD:

The law behind GMO should be guided by science, accountability and philosophy- a balance between complimenting innovative technology and commercializing nature? There is a need to understand the global landscape to create an unified legal authority, transparent labelling policies, clear risk assessment method and strict enforcement rules to reduce illegal cultivation. Finally it is how biotechnology advances responsibly to produce beneficial products with an eye on protecting human health, environment, traditions and public awareness.