Genetically Modified Organisms in India

Regulatory Policies, Comparison with Global Policies and Suggested Revisions

THEBIGPIE

Beta cells In Gut Producing Insulin using E.coli

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Abbreviations

A	
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
B	
Bt.	Bacillus Thuringiensis
C	
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
D	
DBT	Department of Biotechnology
DACFW	Department of Agriculture, Cooperation & Farmers Welfare
DARE	Department of Agricultural Research and Education
DLC	District Level Committee
DSIR	Department of Scientific and Industrial Research
F	
FSSAI	Food Safety and Standards Authority of India
G	
GEAC	Genetic Engineering Appraisal Committee
GM	Genetically Modified
GMO	Genetically Modified Organism
I	
IBSC	Institutional Biosafety Committee
M	
MoEF&CC	Ministry of Environment, Forests & Climate Change
MEC	Monitoring cum Evaluation Committee
R	
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
S	
SBCC	State Biotechnology Coordination Committee

1. Introduction

1.1 Genetically Modified Organisms (Functional Definitions)

Conventionally organisms whose genetic materials are modified artificially (that is by methods other than natural breeding, selection, mating etc.) are defined to be Genetically Modified Organisms. Thus, it implies genetic modification using modern molecular biology techniques as opposed to conventional methodologies of inducing genetic modifications such as crossbreeding. GMOs seek to bypass these lengthy methods to modify and select the best gene profile by directly introducing necessary changes.

1.2 Applications of GMOs

GMOs have wide ranging applications for producers and consumers as well as for other entities in the supply chain. GMOs can help reduce the cost of production or dependence on certain resources, increase the durability for transport and storage purposes and improve the quality of the product for use by the consumers.

The primary fields with large scale implications of GMOs are:

1.2.1 Agriculture & Animal Husbandry

Agriculture & Animal Husbandry has traditionally been a field where genetic modification or rather artificial selection was applied extensively using passed on wisdom of crossing of different breeds, selection of breeds with certain traits etc. Applied to both crops and livestock it sought to incorporate and consolidate favourable traits with respect to the producer and consumer. The breadth of practical knowledge extended to practices such as outcrossing with the aim of introducing diversity to counter the unfortunate accumulation of favorable traits while selecting for favourable ones. These Genetic Modification practices were the key driving factors behind the successful Green Revolution which is responsible for saving millions of people from starvation.

With increasing population and swindling resources, it is of paramount importance to apply GMOs in a wider context to improve global food security while also taking care to maintain sustainable development goals. The capabilities of GMOs include:

- Increasing Crop / Animal Resource's Productivity.
- Reducing Production Cost.
- Reducing dependency on certain resources.
- Improving Nutritional Values of products.

- Improving Food Security.
- Alleviation of Economic Stress & Poverty.
- Conservation of Biodiversity & Sustainable Development.

1.2.2 Food

While most GMO Agriculture & Animal Resources yield food products, the range of GMOs also includes GMOs as food products. Although this is an upcoming field, the first GMO Animal was approved for consumption in the United States in 2015. GMOs are perceived to be at the centre of the development of novel food products such as Single Celled Proteins, High density foods and are also expected to play a part in Lab Grown Meats.

GMOs have implications on the production of non-drug medicinal products such as probiotic drinks, supplements, additives etc. as well as in development of Animal feed.

1.2.3 Drug Development

The production of several complex drugs with vast potential and applications is not possible using chemical synthesis. These are conventionally extracted from living organisms and involve complex procedures thus making them unfeasible on a larger scale. Genetically Modified organisms can be employed as 'Bioreactors' to mass produce the necessary drugs (often proteins) and yield a high product to resources ratio. Since the product rarely contains any trace of the GMO and public knowledge of drug development being limited, this was among the first fields to widely incorporate GMOs. GMOs have not only been responsible for greatly improving the production of certain drugs but also for producing novel drugs.

1.3 Global Scenario of GMOs

As of 2018, GMO crops have been adopted by 70 Countries (21 via Cultivation & 49 via Import) with 191.7 million hectares of land cultivating GMO Crops. 5 Industrialized countries and 16 developing countries are responsible for all the GMO Crops production. The incorporation of GMOs in the global supply chain has been continuous and consistently increasing for the last 23 years which is indicative of positive response form the farming bodies. Adoption of GMOs has resulted in a 37% reduction in chemical pesticide use along with increasing yield by 22% and profits by 68%. (Primarily owing to pest-resistant varieties).

Although perceived to be having no adverse impact on human health by the scientific community, public perception about GMOs is varied. Subsequently

GMOs are extensively regulated in almost all producing countries with vastly different applying to all aspects of GMOs such as production, distribution, import etc. Consequently, the field of GMO Crops is dominated by a few Agriculture Corporations with the field being tough for entry of small-scale private players. Nevertheless, application of GMOs to novel fields such as GMO Pets (incorporating Bioluminescence) etc. is undertaken by small labs and enthusiasts.

1.4 History of GMO Policy

1.4.1 Global

Regulation of GMO Policies began with self-regulatory guidelines set by the scientific community following the Asilomar Conference on Recombinant DNA in 1975. Held at a very early stage in development of Biotechnology, the consensus was in favour of a precautionary viewpoint owing to a lack of extensive understanding. As research expanded various small and large meets and conventions defined the GMO policy in use.

The need for a global policy was highlighted by a 1982 report on GMOs by the Organization of Economic Co-operation and Development (OECD) an intergovernmental organization of 37 countries including all the top economies. Subsequently GMO Policy has been driven by the World Health Organization (Public Health Aspects) and the Food & Agriculture Organization (Environmental Aspects). The two bodies were responsible for another milestone report in the form of the 'Strategies for Assessing the Safety of Foods Produced by Biotechnology' in 1991. Following that these three organizations have been responsible for organizing various committees, conventions etc. to define a framework for the regulation and safety of GMOs.

These efforts culminated in a supplement to the Convention of Biological Diversity namely the Cartagena Protocol on Biosafety (to the convention on Biological Diversity) in 2003. This is a comprehensive set of protocols for framing regulatory policies as well as providing a framework of essential requisites. The salient features include a balance of Public Health & Environment concerns with Economic consequences along with enforcing the Precautionary Principle while dealing with emerging technologies. The signatories to the Protocol include 170 member states of the United Nations as well as the European Union.

1.4.2 India

Regulation of GMOs in India began with the framing of the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous microorganisms / Genetically engineered organisms or cells* in 1989 under the Environment Protection Act of 1986. Following that relevant section of several other Acts were updated or modified accordingly. India is also among the founding signatories of the Cartagena Protocol / Convention.

2. GMO Policy in India

2.1 Acts covering GMO

India does not have a separate Act dealing with GMOs instead opting to include sections in relevant acts. While the primary framework is set under the Environment Protection Act, 1986 other Acts & Guidelines cover different aspects of the policy.

2.1.1 Environment Protection Act (1986)

The EPA was enacted by the Parliament of India and came into effect in November 1986. It was based on the consensus set by the United Nations Conference on Human Environment. In 1989, specific policy was created in what is popularly referred to as Rules, 1989.

2.1.1.1 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous microorganisms/Genetically engineered organisms or cells, 1989

The Rules, 1989 is the most comprehensive set of rules, regulations and guidelines which define the core of the GMO Policy of India. It establishes the scope of the regulations as well as bodies tasked with enforcement of the same.

2.1.2 The Biological Diversity Act (2002)

This Act broadly considers Biodiversity as a resource and thus deals with its conservation, optimal utilization and equitable sharing of research, knowledge generated etc. including but not limited to Genetically Modified Organisms, Genetic Material etc.

2.1.3 Food Safety & Standards Act (2006)

The FSSA categorically prohibits the manufacturing, distribution and sale of Genetically Modified articles of food. It further makes provisions for the Government of India to constitute Scientific Panels for undertaking review of GMO / GMO derived food products in order to allow their incorporation.

2.1.4 Destructive Insects and Pests Act (1914)

This Act allows the Government of India to regulate the import and transport (interstate) of any substances deemed to have potentially harmful effects / capability to infect plants (crops). Thus, this covers various GMOs which often have the said capacity of harm.

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

The Order sets a framework for regulating the entry of controlled germplasm (Plants, plant parts, seeds, tissues, cell lines, DNA etc.) into India. It restricts places of import to 5 Cities (Amritsar, Chennai, Kolkata, Mumbai & New Delhi) with GMO / Transgenic Plants being barred at New Delhi Airport and also provides guidelines for the inspection and processing of such material.

2.2 Rules, 1989

2.2.1 Scope & Applications

The rules and regulations provided cover each and every possible GMO in absolute. The scope of the Rules, 1989 extends to manufacture, import, storage, sale, handling packaging (& repackaging) of microorganisms (including GMOs) and Agricultural products, Food products, Drugs and other material derived from GMOs. The rules are not limited to current Gene Editing technologies and are automatically applied to any new technology.

2.2.2 Competent Authorities

The rules make provision for and introduce 6 competent authorities tasked with the interpretation and enforcement of the Rules as we all for providing necessary resources, expert advice etc. These are:

2.2.2.1 Genetic Engineering Approval Committee

The committee functions under the Department of Environment, Forest & Climate Change. It is tasked with approving research and industrial projects involving large scale use of hazardous microorganisms and GMOs. Its primary responsibility is to scrutinize the same from an Environment point of view. By extensions it also regulates the release of GMOs or products from GMOs into the environment in any form.

The committee is designed to be chaired by a representative of the DoEFW and co-chaired by a representative of the Department of Biotechnology. Its members include representatives of concerned departments / agencies and expert members in the form of the Director Generals of various Councils and Services concerned with Public Health, Research, Industry, Agriculture etc. There is also a provision to co-opt members or experts as deemed necessary.

2.2.2.2 Institutional Biosafety Committee

Research Institutes engaging in GMO work are expected to constitute the IBSC whose members comprise the Head of the Institutes, Scientists involved in GMO work, a medical expert and a member nominated by the Department of Biotechnology. The IBSC is tasked with providing assistance to researchers to produce a 'Site Emergency Plan' as per the guidelines defined by the Review Committee on Genetic Manipulation and provide the same to the GEAC and the concerned District / State level committee.

2.2.2.3 Review Committee on Genetic Manipulation

The RCGM functions under the Department of Biotechnology and monitors all ongoing research projects and activities involving GMOs. It is also tasked with publishing Guidelines (Manuals) for the regulatory processes for all activities involving GMOs (Research & Industrial). It also draws procedures for the restriction of certain GMOs that are deemed to be hazardous.

The RCGM includes representatives from the DBT, Indian Council of Medical Research, Indian Council of Agricultural Research, Council of Scientific and Industrial Research and other relevant independent experts.

2.2.2.4 Recombinant DNA Advisory Committee

Functioning under the Department of Biotechnology it reviews all upcoming developments in the field of Biotechnology thus staying abreast of new knowledge generated in India as well as Globally and suitably recommends regulatory policies for India. (included updates).

2.2.2.5 State Biotechnology Coordination Committee

Wherever necessary a SBCC is constituted to inspect, investigate and take appropriate actions against defaulters to the statutory rules and regulations. It is also tasked with regular reviews of Institutions (Research & Industrial) engaged in activities involving GMOs. The SBCC executes its powers via Nodal Committees, the State Pollution Control Board and the Directorate of Health / Medical Services as necessary.

The committee comprises representatives of concerned Departments (Environment, Health, Agriculture, Industries, Forests, Public Works, Public Health) along with State Microbiologists, State Pathologists and the Chairman of the Pollution Control Board.

2.2.2.6 District Level Committee

Constituted under the District Collector wherever necessary, it serves a similar purpose as the SBCC on a District Level. It monitors the safety infrastructure and regulations of institutions engaged in activities involving GMOs. It undertakes on-site inspections and coordinates relevant activities. It provides reports to the SBCC on a regular basis.

Chaired by the District Collector its members include District level representatives of the same Departments as the SBCC along with District Factory Inspector and the Commissioner of Municipal Corporation.

2.2.3 Classification

Microorganisms / GMOs have been classified in a detailed manner to facilitate appropriate regulations and guidelines while working with them.

2.2.3.1 Microorganisms

Microorganisms are divided into 5 categories:

- Bacterial Agents
- Fungal Agents
- Parasitic Agents
- Viral, Rickettsial & Chlamydial Agents
- Special Category

2.2.3.2 GMOs

Both Microorganisms and GMOs are broadly classified as Animal Pathogens and Plant Pests.

2.2.4 Prohibitions & Approvals

2.2.4.1 Prohibitions

- The import, export, transport, manufacturing, sale and use of any GMOs or GMO derived substances (and hazardous microorganisms) is strictly prohibited without the approval of the GEAC.
- Research involving GMOs is allowed only in laboratory areas notified by the MoEF&CC under the EPA, 1986.
- Industrial use of GMOs requires appropriate license which is issued by the GEAC further the protocol for the release of GMOs, Field Trials etc. is directed by the GEAC at each step.

- The IBSC is authorized to carry out restricted experiments outside designated laboratory areas for educational purposes.

2.2.4.2 Approval Procedure

- Any person seeking approval is required to submit requisite information and carry out relevant experiments to present the case and prove various safety aspects.
- The seeker is also required to provide an on-site emergency plan to the GEAC.
- The expenses for any examinations carried out by the GEAC are to be borne by the applicant.
- A person who has obtained approval is required to provide any updates or notify any change in status to the GEAC.
- Upon grant of approval the GEAC also stipulates terms and conditions with respect to regulations to be followed by the applicant, the layout of the enterprise and submission of information to the SBCC / DLC.
- The GEAC approvals are limited to a duration of 4 years with provision for renewal of up to 2 years (at a time).
- The GEAC also reserves power to revoke any approvals in case of availability of new information, evidence of harmful effects of the GMO or in case of failure to follow the stipulated regulations by the applicant.

2.2.5 Guidelines

The GEAC, RCGM, RDAC and several concerned ministries such as MoAFW, MoCAFPD etc. have published relevant general guidelines for various aspects of handling GMOs. These are as follows:

- Recombinant DNA Safety Guidelines, 1990
- Recombinant DNA Safety Guidelines and Regulations, 1994
- Revised Guidelines for research in transgenic plants & Guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant part, 1998
- Guidelines for generating Pre-clinical and clinical data for rDNA Vaccines, Diagnostics and other Biologicals, 1999
- New Industrial Policy & Procedures, 1991
- Seeds Rules, 1968
- Seeds (Control) Order, 1983
- Seeds Policy 1988 & 2002
- Protection of Plant Varieties and Farmers' Rights Regulations, 2006

- Guidelines & Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, GE Plants, 2008
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (by ICMR), 2008
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008

2.2.6 Enforcement & System Preparedness

Although the Rules, 1989 are constituted under the EPA 1986 and managed by the MoEFW, the enforcement of various aspects may be done by Ministries / Departments constituted under different Acts.

2.2.6.1 Department of Agriculture, Cooperation & Farmers Welfare, Ministry of Agriculture & Farmers Welfare

The responsibility of incorporating Science & Technology (including Biotechnology) in such a manner that the resources such as land, water, biodiversity and genetic resources are protected and improved lies with the Department of Agriculture. To pursue that very goal, the DACFW has introduced the following legislations:

- Biological Diversity Act, 2002
- Protection of Plant Varieties and Farmers‟ Rights (PPV&FRA) Act, 2001
- National Seeds Policy, 2002
- Seeds Act, 1966 (and relevant rules)

The DACFW also shoulders the responsibility of coordinating with various State Governments and committees about conducting Field Trials among other concerns.

2.2.6.2 Department of Food and Public Distribution, Ministry of Consumer Affairs. Food and Public Distribution

The DoFPD is engaged in the storage, transport and distribution of food grains and food products and hence is prepared to adopt strategies as per GEAC / FSSAI guidelines while dealing with GMOs. It is also tasked with attending International Conventions related to Food, Food Security etc. and thus is tasked with adopting and implementing policies concerning GMOs. Nevertheless, till a point where GMO derived food products are in a wider circulation the role of DoFPD is minimal. As and when applicable it will need to adopt policies for food labelling, segregation, storage and testing.

2.2.6.3 Department of Consumer Affairs, Ministry of Consumer Affairs. Food and Public Distribution

The DCA has the responsibility to ensure that appropriate information about the product when pertaining to GMOs is conveyed to the consumer by the producer / distributor. Subsequently it is also tasked with ensuring that free trade policies, advertisement policies etc. are appropriately applied for GMO derived products.

2.2.6.4 Department of AYUSH

Traditional medicine is often based on plant and plant derived products which are grown on a limited scale and often at a slow pace. Biotechnology has the potential to completely disrupt the system thus making it necessary to set into place provisions to deal with the intellectual property concerns and the protection of practitioners.

2.2.6.5 Department of Commerce, Ministry of Commerce and Industry

The DoC deals with commercial aspects of GMOs and is equipped with data and policies for fair trade and equitable distribution of Biotechnology derived knowledge. It also plays a role in the import and export of GMOs and is appropriately prepared for the same.

2.2.6.6 Department of Health Research, Ministry of Health and Family Welfare

The DoHR needs to have broad programs in place for post release surveillance in order to gauge and effects of GMOs on Public health. Unfortunately, no such program is in place and such data is unavailable.

2.2.6.7 National Biodiversity Authority

The NBA deals with Intellectual Property Rights of Biological resources generated in India (including GMOs). It is also tasked with regulating activities involving Biological Resources and enforcing the Biological Diversity Act.

2.2.6.8 Food Safety and Standards Authority of India

FSSAI was constituted under the Food Safety and Standards Act to eliminate confusion caused by multiple acts dealing with specific aspects of Food Safety. FSSAI lays down guidelines based on the recommendations of GEAC, RDAC, RGCM pertaining to GMO and GMO derived Food products.

2.2.7 Scope for Incorporating Newer Technology

The Recombinant DNA Advisory committee incorporates policies for newer technologies by publishing guidelines or updating existing guidelines. Owing to the comprehensive yet vague nature of the Rules, 1989 updating the same is rarely necessary. There is no dedicated Policy Research Body and instead the RDAC often depends on policies adopted by other countries in order to frame its own.

3. GMO Policy in Other Countries

3.1 BRICS

3.1.1 Brazil

GMO Policy of Brazil is defined by Brazil's Biosafety Law No. 11,105 which creates a general set of regulations for establishing biosafety of GMOs and creating a regulatory mechanism for inspecting and reviewing GMO related activities. It also created the enforcement body that is the National Technical Commission which regulates all aspects of GMOs (and Biotechnology). Besides that, concerned ministries such as Agriculture, Drug etc. are also involved in the approval process.

3.1.2 Russia

GMOs in Russia are regulated by a set of Federal Laws and Decrees, with the core framework set by the 'On the State Regulations of Genetically Modified Organisms'. This is aided by relevant laws set under different agencies such as Customs, Health etc.

3.1.3 China

The State Science and Technology Commission publishes the GMO Policy which is administered and enforced by concerned departments within the Government. The singular commission deals with all the aspects of GMO Policy and regulations.

3.1.4 South Africa

South Africa has a dedicated Genetically Modified Organisms Act which frames the GMO Policy and executes them via an Executive Council which deals with the legislature and Scientific Advisory Committee and an enforcement agency in the form of an Inspectorate. Further import and export are regulated by the Agricultural Pests Act whereas biosafety aspects of food and food products are dealt with by the Foodstuff, Cosmetic and Disinfectants Act.

3.2 EU

The EU has amongst the most detailed and stringent rules and regulations concerning GMOs. The GMO Policy is set by European Commission Directives which are updated /replaced when needed. The enforcement of policies is done by the EC along with the concerned authorities of member states. The latest Directive particularly stresses on phasing out of antibiotic resistance genes.

3.3 US

The regulatory framework is defined by three agencies. The relevant legislature is an extension to the preexisting legislature.

- The US Department of Agriculture (and the Plant Health Inspection Services) regulates the incorporation of GM Crops including the necessary examinations and trials.
- The Environment Protection agency deals with the Environmental implications of GMOs and takes effort to safeguard biodiversity resources.
- The Food & Drug Administration is responsible for establishing the safety of GMO / GMO derived food and drugs and establishing regulatory policies for the same.

3.4 Argentina

The Secretary of Agriculture, Livestock, Fisheries and Food reserves the supreme authority to regulate the environmental release and application of GMOs to Agriculture, Food etc. The powers are derived from preexisting and novel legislatures. The Secretary is advised by the National Advisory Committee on Agricultural Biosafety. Some regulations by the advisory committee are derived from resolutions without any legislative backing thus making them legally non-binding.

3.5 Australia & New Zealand

Australia & New Zealand have a dedicated Act for dealing with Biotechnology / GMOs namely the Gene Technology Act 2000 which confers powers to the Gene Technology Regulator (along with a Technical Advisory committee, Ethics committee and a Community Consultative Committee). Furthermore, there are several agencies dealing with specific aspects such as registration, impact assessment, food, quarantine etc.

3.5 Canada

The regulatory framework is set by these agencies with powers derived from an extension to the preexisting legislature.

- Canadian Food Inspection Agency regulates the import, export, registration and environmental release of GMOs.
- Health Canada is tasked with reviewing Human Health impact.
- Environment Canada deals with enforcing regulations and reviewing the impact of GMOs on the Environment.

3.6 Japan

The following agencies are tasked with addressing biosafety concerns associated with GMOs:

- Ministry of Science and Technology concerned with technical aspects.
- Ministry of International Trade and Industry which deals with the import, export and industrial application of GMOs.
- The Ministry of Agriculture, Forestry and Fisheries regulates GMO Crops, Animal Feed and environmental release of GMOs.
- The Department of Health and Welfare ensures that public health standards are met while dealing with GMO and GMO derived Food products.

4. International Conventions / Guidelines

4.1 Cartagena Protocol on Biosafety

The CPB was affirmed under the aegis of the Convention on Biological Diversity. Its main goal is to establish procedures to ensure safe transfer, handling and use of GMOs (Live Modified Organisms) with respect to conservation and sustainable development of Biological Diversity and Human Health. It also establishes protocol for transboundary movement of GMOs. The Protocol has 40 Articles which define the rules and regulations to be adopted It established a Biosafety Clearing House for Parties to facilitate exchange of information (under the Advance Information Agreement) along with establishing financial mechanisms and compliance procedures. This seeks to allow members to take informed decisions on import of GMOs from other countries. The protocol also promotes programs for increasing public awareness.

Setting up a National Biosafety Regulatory Framework is a requirement for all parties involved and thus the CPB was influential in establishing the GMO policies of several countries. Members are also obligated to submit a periodic Report on Implementation.

4.2 Convention on Biological Diversity

The CBD is a legally binding agreement between its 193 member states (the US is not a party to the agreement). The convention set three binding goals for the member states:

- Conservation of Biological Diversity
- Sustainable use of Biodiversity components
- Fair & equitable sharing of benefits arising from the use of genetic resources

The Conference of the Parties (CoP) to the CBD is a regular conference hosted by various member states. This has resulted in adoption of further protocols such as the Nagoya Protocol. All members are obligated to prepare a Biodiversity Strategy and Action Plan and report measures undertaken to the CoP. The Biological Diversity Act, 2002 (and the subsequent Biological Diversity Rules, 2004) of the Indian Government was enacted to ratify the CBD.

Protocols arising from the CoP:

4.2.1 Nagoya Protocol on Access and Benefit Sharing

The protocol primarily deals with fair and equitable sharing of benefits arising from the utilization of genetic resources. It establishes regulations and framework for obtaining genetic resources and associated knowledge. A key feature of the Protocol

is the obligation for all Parties to ensure that users of genetic resources respect the domestic regulatory framework of the Party from which the resource has been obtained. Thus, it expands the scope of the national regulatory framework beyond the country.

4.2.2 Nagoya –Kuala Lumpur Supplementary Protocol on Liability and Redress in the Context of Cartagena Protocol on Biosafety

The protocol fulfills a pre-set commitment to create international rules and procedures for ensuring liability and redress for any damage to Biological diversity caused by transboundary movement of GMOs. (Live Modified Organisms).

5. Comparison of GMO Policies - Salient Features

Top 5 Producers of GM Crops & the European Union

	USA	Brazil	Argentina	India	Canada	China	EU
Use of Existing Legislation	Yes	No	Yes	Yes	Yes	No	No
New Legislation	Addendums and regulations	Yes	Addendums, resolutions and regulations	Addendums and regulations		Yes	Yes
Agencies Involved	USDA, EPA, FDA	National Technical Commission	Secretariat of Agriculture, Fisheries and Foods	Ministry of Environment & Forests, Department of Biotechnology	Canadian Food Inspection Agency, Health Canada, Environment Canada	Unknown	Authorities of Member States, European Commission
Products Covered	GMO Plants as Food. Potential Plant Pests. Plants engineered to produce insecticides/pesticides	All genetically modified organisms	All genetically modified organisms	All genetically modified organisms and products thereof	Plants with novel traits	Unknown	All genetically modified organisms; all novel foods and novel food ingredients
Transparency	Yes	Yes	Yes	Yes	Yes	Unknown	Yes
Public Participation	Limited	No	No	Minimal	No	Unknown	Limited
Consultation with Independent Experts	Yes	Yes	Yes	Yes	Yes	Unknown	Yes
Post Approval Review	Limited	Limited	Minimal	Yes	Yes	Unknown	Yes
Enforcement Authority	Limited	_____	Present & Functional	Present & Functional	Present & Functional	Concerned Admin Depts.	Present & Extensive

6. Discussion on GMO Policy in India

6.1 Robust Features

The backbone of India's GMO Policy that is the Rules, 1989 are comprehensive, all-encompassing yet to an extent general in nature. This has resulted in a potential for quickly incorporating policy provisions for new and upcoming technologies without necessitating large scale legislative changes. While the core policy framework remains unchanged and in force, supplementary Guidelines / Regulations can be modified, changed or introduced to adapt to new technology or an update in available knowledge. This also prevents policy loopholes thus preventing a dilution of their purpose. With Biotechnology & GMOs being a field where advancement is occurring at a rapid pace, India's GMO Policy is perfectly equipped to swiftly adapt accordingly. The decentralized nature of the regulatory framework and enforcement bodies perfectly fits a complex scientific field with the federal nature of governance in India ensuring due diligence in the inspection, review and implementation of the policies. Active engagement of ground machinery at District level aids the hierarchical review system. All of the committees at various levels have representation of several Departments / Ministries thus placing the proposal in the proper context along with ensuring that all spheres that can be affected / influenced by GMOs are efficiently tended for. The provision to co-opt experts in the advisory or approval committees offer the involvement of the Scientific Community.

The enforcement of the GMO Policy is not done by a singular entity and is instead delegated to several Departments which are each familiar and experienced with their respective branch are in charge of incorporating GMOs in the same. This improves efficiency of the policies at the same time opening up avenues for experienced insights. The separation of Food & Drug agencies is often perceived to be beneficial in the Indian scenario and the same is extended while dealing with GMOs.

6.2 Drawbacks

The regulatory framework for GMOs is unfortunately mired with complicated overlaps and conflicts primarily among various agencies involved. While certain aspects of the same GMO / related product come under the purview of one agency, others being under the jurisdiction of others cause conflicts or policy stagnation. A good example is the adoption of policy to make Labeling of GMO / GMO derived food products compulsory. While all regulatory aspects are to be dealt with by the GEAC, labeling is not its concern. At the same time while policy about Labeling is the responsibility of the FSSAI, it doesn't have approval authority thus cannot interfere with the process.

The subsequent conflict led to inaction for several years over enforcing a draft notification for the same.

A Centre - State conflict also arises while dealing with GMOs particularly when Agriculture is concerned. Constitutionally all Agriculture related aspects are under the authority of the State Government. But the Rules, 1989 declare the GEAC to be the Apex Body while dealing with all aspects of GMOs. This particularly comes to fore while permitting Field Trials, Limited Release etc. where even after approval of the GEAC, States might not permit. This has also led to a convention of obtaining a NOC from the State Government which is often delayed beyond the period offered by the GEAC to the applicant.

On a legislature level since the bulk of the GMO Policy is derived from Rules drafted under an Act and not an Act itself it doesn't enjoy the full powers of an Act. This particular set up and the presence of various competent authorities makes various aspects of the policy open to interpretation of various individuals at various levels. Subsequently scientific temperament is often ignored or given less value during the approval process. It's necessary for a good policy framework to be set in such a way that the final say rests with the scientific community.

The Policy opens up unfortunate loopholes where certain applications of a GMO Crop might be approved but no such process has been done on other products from the same GMO. For example, Cottonseed oil derived from Bt. Cotton isn't actually approved for the said presence but is thought to be available. Testing to determine if it is derived from a GMO is near impossible for most such products.

There is also a lack of clarity on the regulations pertaining to processed foods derived from GMOs which contain no traces of either the DNA or any novel proteins. The policy for this is dependent on Gazette notifications issued by concerned agencies which are modified or reputed by others.

The GMO Policy lacks regulations for the concerned agencies to conduct large scale surveillance and studies to assess the effects of GMOs on biodiversity, public health etc. There is no framework to conduct meta-studies to detect traces of novel proteins that might be entering the environment unintentionally.

7. Recommended Revisions to GMO Policy

After careful consideration of the GMO Policies adopted by various countries and conventions and the drawbacks of the GMO Policy of India, following upgrades would ensure that the policy stays robust in light of upcoming technology, improved ease of access and increased scientific research and industrial interest in GMOs:

1. Consolidation of legislation into a separate singular Act dealing with Genetically Modified Organisms thus ensuring that the legal framework has the full powers of an Act.
2. Establishment of / incorporation of regulatory frameworks by the State Governments to work in tandem with the Central GMO Policy thus formalizing the role of the State Government and resolving the State - GEAC Jurisdictional conflict.
3. Incorporation of non-regulatory duties such as labeling, public awareness etc. into the charter of duties of the primary enforcement body.
4. Establishment of clear distinction between GMO derived products free from any Genetic Material and Live Modified Organisms in order to resolve legislative complexities and ease their incorporation.
5. Opting for a 'Process Based' approval procedure instead of a 'Product Based' one wherein all products obtained from an approved GMO Process would be automatically approved. Ex. Any products from a GMO Plant.
6. Establishment of a singular body to approach for the production, distribution, sale, utilization etc. of any product derived from GMOs, made in Lab or produced by modern biotechnology / molecular biology. The body has the responsibility to determine the category of risk it falls under and swiftly direct it to the GEAC or concerned Department if the involvement of the GEAC is not needed.
7. Increasing transparency by ensuring that the examination and trial data is made publicly available in case of either approval or disapproval.
8. Constitution of an Inspection & Review committee with all-India jurisdiction composed of Scientific Representative and Law Enforcement authorities to conduct inspections of facilities engaged in GMO related activities. This will help streamline the complicated process of review.
9. Establishing responsibility and a system to conduct large scale post-release surveillance to analyze for effects of GMOs on the public health if any as well as meta-analysis to establish effects on the Environment.
10. Establishment of annual reports pertaining to the broader topic of Incorporation of Science & Technology in Agriculture, Food, Drugs etc. to be published by the

DST & concerned Department which will involve reporting on GMOs which can be summarized into annual reports on the GMO Scenario in India.

11. Establishment of an online Portal for registration of any party involved in GMO related work to submit the scope of their work, required examination data etc. which will support Pt. 5 & 6 by also making certain sections of each applicant publicly available.

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