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Genetically Modified Food: A Critique of The Existing Regulatory Framework in India

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ABSTRACT

In the field of agriculture, biotechnology has played a key role in increasing the crop productivity, reducing the cost of production and decreasing the adverse effect on the environment. Genetically modified crops are chosen for a number of reasons. The crops are altered to make them pest-resistant, thereby reducing the adverse effect on environment and human health. Further, it has reduced vulnerability of the crops to various environmental stresses; increased its nutritional quality, taste, texture and appearance; reduced the use of fertilizers, pesticides and other agrochemicals and increased resistance of crops to insects. However, there are several risks associated with the use of genetic engineering and the release of genetically modified plants in to the environment. It may have adverse effect on biodiversity as the nature of interaction with other organisms cannot be anticipated. It poses certain risks and apprehensions, both known and unknown.

The introduction of genetically modified organisms in the ecosystem can impact the diversity of species. It may pose a risk to human health. Potential negative effects of genetically modified organisms on the ecosystem are contested but cause considerable concern. They have the ability to reproduce, transfer its characteristics, mutate in response to environmental influences, contaminate the biodiversity, alter the composition of species and even threaten the extinction of various species. There is a need for judicious harnessing of genetic modification technologies. Its impact on the environment is inadequately understood. In the absence of effective legislation and enforcement of biosafety regulations, the release of genetically modified crops is a poorly defined risk, and this is likely to continue.

The paper therefore aims to provide a brief overview of the existing regulatory framework in India pertaining to genetically modified food and to critically analyse the same with a view to identify the lacunae under it.

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I. INTRODUCTION

Naturally, man strives to improve the quality of life but this can only be done if environmental quality and development go together. The quest for human development should be accompanied by the safety of the environment. Food, clothes, and shelter have always been considered fundamental human needs. But simultaneously environmental protection and health are greatly concerned with human existence. Food requirements can be fulfilled but not on the cost of environmental and health.

Since independence, India has made rapid progress in agriculture and associated sectors. From a net importer of food grains the country has not only achieved food security through domestic production, even export of several commodities is being regularly undertaken. Notwithstanding these impressive successes, there are many obstacles to the path of achieving and sustaining food security in the years to come. The deceleration in the supply of food grains is a challenging issue that needs to be tackled with equal severity.

According to the US Census Bureau Report, India's population is projected to rise to 1.396 billion by the year 2025[2], making food security a significant social problem. There is therefore an immediate need to increase the food production to meet the growing population needs. In addition to this, there are various other challenges such as, decreasing land and water resources, diminishing soil fertility, worsen climatic conditions, crop failure due to pests, diseases, etc. The challenges require the use of powerful molecular biology and biotechnology tools in the field of agriculture. Scientific and technological advances in these fields have progressed, at remarkable pace, during last decade and most compelling case of intervention of biotechnology is its capability to contribute to:

i) accelerating crop productivity and thereby significantly contributing to food, feed security globally,

ii) decreasing cost of production,

iii) conserving biodiversity,

iv) increasing production stability, etc.

In order to meet the requirements of the growing population, there is a need to increase food productivity. Furthermore, eco-friendly and sustainable measures needs to be adopted to curb crop loss due to factors like diseases, pests, insects, etc. The problems relating to crop

[2] *India to outnumber China in population by 2025: US Census Bureau*, TIMES OF INDIA (Feb.14, 2019, 3:24PM), https://timesofindia.indiatimes.com/india/India-to-outnumber-China-in-population-by-2025-US-Census-Bureau/articleshow/7189858.cms

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diversification, malnutrition, and increased production can only be addressed through effective management of resources and ensuring that the crops are not only nutritious but also less resource demanding.

To address these challenges, genetically modified technologies have been introduced. These technologies have significantly contributed towards increase in food productivity, sustainable development and reduction in environmental degradation.

Genetic engineering is a technique that involves the transfer of heritable material from one organism to another. These material do not naturally occur in the organism or cell concerned. It also means the formation of new combinations of genetic material either through modification of an organism or by removal and deletion of parts of heritable material in a cell or by incorporation into a host cell of a cell, where they occur naturally.[3] Thus, in other words, genetic engineering means the manipulation of genes within a species or the transfer of genes from one species to another. The introduction of genetic engineering has several benefits, such as it may allow crops to be grown, harvested or shipped at lower cost, using less pesticide or with less damage, thereby reducing the overall cost of production.

In agriculture sector, genetic engineering is used with an objective to improve the productivity and introduce new traits in crops, such as better nutrients, resistance to unsuitable climatic conditions and ability to grow in saltier soils. However, despite this, there are various shortcomings and the risks associated with genetically modified crops which outweigh their benefits. It poses certain risks and apprehensions, both known and unknown.

The issues relating to the Genetically Modified Crops have generated intense public debate in many parts of the world relating to the costs and benefits of the genetically modified crops and the inherent safety concerns. There are various issues such as environmental safety, food security, food safety and standards, etc.

The present paper therefore aims to study the environmental aspects of genetically modified food in the light of the existing regulatory framework in India.

II. REGULATORY FRAMEWORK WITH RESPECT TO GM FOODS IN INDIA

(A) The Environment (Protection) Act, 1986.[4]

[3]MINISTRY OF ENVIRONMENT AND FORESTS, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf, (last visited Dec.29, 2019).

[4]MINISTRY OF ENVIRONMENT AND FORESTS, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/The-Environment-Protection-Act-1986.pdf (last visited Jan.1, 2019)

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It is the central legislative authority with respect to biosafety regulations. The Act under its various provisions as contained under Sections 6, 8 and 25 forms the basis through with all other biosafety regulations in India emanates. Under the Act, GMOs and foods are categorized ad hazardous substances for which rules and regulations should be laid down.

The Act empowers the Central Government to make rules with respect to matters relating to hazardous substances. It specifically empowers the government to issue safeguards and procedures for handling of such substances and place the necessary restrictions for their handling in different areas[5]. Chapter 3 provides for prevention, control and abatement of environmental pollution. It imposes a restriction on the handling on any substances considered hazardous under the Act except when the procedure and safeguards as provided has been duly complied with by the person involved in such handling.[6]

It also confers upon the Central government the power to make rules for fulfilling the purposes of the Act.[7] Consequent to responsibility of stipulating rules in relation to the procedure and safeguards for handling of hazardous substances, the Biosafety Rules, 1989 was promulgated by the Ministry of Environment and Forest.

(B) Biosafety Rules, 1989

Provisions of the EPA led to the adoption of Biosafety Rules, 1989[8] . These rules have been given a statutory recognition.

The rules extend to the whole of the territory of India. It is applicable to the manufacturing, import and storage of micro organisms, gene technology products, genetically engineered micro-organisms, cells and other substances forming a part of such organisms and cells. It has a specific application to the cases relating to sale, exportation, importation, production, manufacturing, storage, packaging , research etc of GMOs and drugs, pharmaceuticals, distilleries , tanneries, etc which uses microorganisms or GMOs. [9]

It mandates the prior approval of the regulatory body called the GEAC for the production and discharge of GMOs or cells into the environment.[10]

It prohibits the intentional or unintentional release and transfer of the GMOs, hazardous

[5] Environment (Protection) Act, 1986, sec. 6
[6] *Id*. sec. 8
[7] *Id.* sec.25
[8] MINISTRY OF ENVIRONMENT AND FORESTS, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf (last visited Dec.30, 2019)
[9] *supra* note 8
[10] Biosafety Rules, 1989, Rule 8

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organisms and cells for experimentation, unless approved by the GEAC in special cases.[11] Further, Rule 10 and 11 makes it obligatory to obtain prior permission and approval from the regulatory body concerned or all substances, products, foodstuffs and additives that consists of GMOs or cells. One of the most interesting feature of the Rules is that categorises animal and human pathogens on the basis of their risk profile in its Schedule. For the effective implementation of the Rules, a multi-layered decision making body along with the respective functions has been provided for under Rule 4 which is as follows:

- RDAC – It forms a part of DBT. The committee has been entrusted with the duty to review and recommend expedient safety regulations with respect to development, use and application of genetic engineering at both the national and international levels from time to time.
- RCGM – It is also constituted by and based in the DBT. It consists of members of DBT, ICMR, Indian Council of Agricultural Research, Council of Scientific and Industrial Research and other independent experts. The committee is empowered to appoint sub-groups.

It is entrusted with the duty of monitoring safety-related measures with respect to research projects, issue guidelines specifying regulatory procedure and processes for activities involving GMOs. The committee also reviews all projects falling under the category of high risk and controlled field experiments in order to ensure adherence to the conditions laid down under the guidelines. It also sets out the procedure to limit or prohibit the production, selling and import and use of GMOs or cells as are mentioned in the Schedule.

- IBSC - The committee consists of the research institution head, a medical expert, scientists involved in DNA work, a DBT nominee. It is constituted by any person, occupier or research institutions involved in the handling of micro-organisms or GMOs, who are then required to prepare an updated on-site emergency plan in accordance with the RCGM regulatory guidelines with the assistance of the ISBC. The copies of the plan are to be made available to the DLC/SBCC and the GEAC.
- GEAC - It is a body functioning under the Department of Environment, Forest and Wildlife. It is entrusted with the duty to give approval from the environmental perspective with respect to activities concerned with the large scale use of hazardous microorganisms, recombinants in research and industrial production.
- SBCC - It acts as the nodal agency to assess damages, if any, from the release of GMOs. It functions at the state-level. It is empowered to inspect, investigate and take punitive action

[11] *Id.* Rule 9

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in case of violations of statutory provisions with the aid of the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee is also required to review from time to time the safety and control measures in various industries and institutions handling GMOs or hazardous micro-organisms and take on-site control measures.

- DLC - It is established in the district wherever necessary and is headed by the District Collectors. The Committee is cast with the duty to monitor safety regulations in installations involved in the use of GMOs and hazardous substances. The Committee is authorised to investigate these installations and send periodical reports to the SBCC or the GEAC. The Committee also coordinates activities, at the district level with a view to meet any emergency situations.

To ensure due compliance with the orders given by the regulatory bodies, the DLC and SBCC is empowered to impose penalties on person responsible for such violations. In cases, which require immediate intervention, these bodies are also authorised to take all necessary steps without issuance of any prior order or notice.

The Biosafety Rules, 1989 are implemented by the competent authorities through various biosafety guidelines. These guidelines aim at reducing the ill effects and adverse impact that the GMOs and related substances would have on the environment, human health as well as animals.

Some of such guidelines along with their key features are detailed as follows:

1. Recombinant DNA Safety Guidelines, 1990[12] and Revised Guidelines for Safety in Biotechnology, 1994[13]

With rapid advancement in the field of biotechnological research, the DBT formulated guidelines supplementary to the Biosafety Rules, 1989 called the Recombinant DNA Safety Guidelines in the year 1990. The guidelines encompass research activities in relation to genetically engineered organisms. Genetic transformation of green plants, rDNA technology in vaccine development and on large scale production and deliberate or accidental release of organisms, plants, animals and products derived by rDNA technology into the environment also comes within its ambit.[14]

[12]DEPARTMENT OF BIOTECHNOLOGY, MINISTRY OF SCIENCE AND TECHNOLOGY, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/guidelines-and-protocols.aspx,(last visited, Jan. 12, 2020)

[13]DEPARTMENT OF BIOTECHNOLOGY, MINISTRY OF SCIENCE AND TECHNOLOGY, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/guidelines-and-protocols.aspx, (last visited, Jan. 12, 2020)

[14] *supra* note 8

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The 1990 guidelines were revised by the DBT to accommodate the safe handling of GMOs in research, application and technology transfer in 1994, under the title "Revised Guidelines for Safety in Biotechnology". The guidelines are made applicable to transgenic crop, R&D activities, shipment and importation of GMOs for research in laboratories. It also covers large scale production and intentional release of GMOs, animals, plants and substances in the environment. The guidelines have set out the environmental aspects assessment requirements on a case-by-case basis for proposed introduction of rDNA organism into the environment. It also recommends regulatory measures to ensure that GE products, plants, and animals are imported under safety. The recommendations also cover the different methods of quality control necessary to establish safety, efficacy and purity of rDNA products.

It also prescribes the guidelines for rDNA research activities, which are classified into the following three categories:

- Category I - covers those experiments which are exempted from the requirement of intimation and approval of the competent authority, such as self cloning, use of strains, etc.
- Category II- experiments falling under containment levels II, III and IV and activities requiring the prior intimation to the competent authority comes under this category.
- Category III- those activities which require review and approval by the competent authority before commencement comes under this category. It includes experiments such as, those involving cloning of genes for production of vaccines, toxin gene cloning, cloning of mosquito and tick DNA experiment, gene therapy for hereditary diseases of genetic disorders and such other experiments as laid down in the guidelines.

The associated levels of risk of the organisms within these categories and its classification have been defined in the guidelines. The guidelines also make recommendation for the safe handling of the organisms, plants and animals in the various risk groups. It mentions the principle of good laboratory practices and the concept of physical and biological containment. Recommendations on genetic engineering techniques involving microorganisms of different risk groups in the WHO laboratory safety manual have been incorporated under the guidelines for containment facilities and biosafety practices.

Experiments involving production of bio-molecules from GE microorganisms, beyond 20 litres capacity for research as well as industrial purposes are categorised as large scale experimentation/operations under the guidelines. The principles for occupation safety and hygiene have also been laid down.

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The guidelines make provisions for environmental safety. It specifies the use of appropriate containment facilities so as to ensure worker's safety and to prevent any unwanted release in the environment. It mandates the appropriate treatment of biowastes, incineration of all refuse and carcasses of experimental animals, so that they are rendered harmless before their disposal in the environment. It also requires an evaluation of the potential risk associated with the rDNA modified organisms, such as the possible interaction with other disease causing agents and the infected wild plant species prior to their application in agriculture and environment. An independent review of potential risks should be conducted on a case by case basis prior to application.

2. Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation Transgenic Seeds, Plants and Plant Parts, 1998[15]

With extensive development in the field of research and increased applications for field trials of genetically modified crops, the DBT and MoEF formulated detailed guidelines for confining the field trials of the GE crops. The Guidelines make provisions to monitor and evaluate the mechanisms for green house experiments and limited field trials in the open environment.[16]The guidelines deal with a number of aspects, such as considerations that are to be followed for conducting limited field experiments of GE crops, guidelines for toxicity and allergenicity of transgenic plants, seeds and plant parts, rDNA research on plants, etc. The guidelines also deal with transfer of genetically modified plants for research purposes.

The guidelines classify the genetic engineering experiments on plants into the following categories:

- Category I- the experiments under this category need only intimation to the IBSC in the prescribed proforma. These experiments are conducted in the lab in contained environment and includes routine cloning of defined genes of microbial, animal and plant origin which are generally considered as safe to human, animal and plants , use of defined reporter genes to study transient expression in plants cells and genetic transformation condition, etc.
- Category II- for conducting experiments under this category, prior permission of the ISBC is to be taken, who is then required to intimate its decision to the RCGM before such experiments and executed. The category includes lab and green house experiments

[15]DEPARTMENT OF BIOTECHNOLOGY, MINISTRY OF SCIENCE AND TECHNOLOGY, GOVERNMENT OF INDIA, https://biosafety.icar.gov.in/wp-content/uploads/2015/11/Rev_Guidelines_Research1998.pdf, (last visited Jan.12, 2020)
[16] *supra* note 15

which are carried out in a contained environment. The experiments make use of DNA fragments which are not harmful to humans and animals for genetic transformation of plants, crop species, etc.

- Category III and above- All experiments not falling under the Category II, falls under this head. It pertains to those experiments which are highly risky and can cause significant changes in the ecosystem, biosphere, the animals and plants with its escape into the open environment. In lieu of the potential risk involved in conducting these experiments, they can only be carried out after obtaining clearance from RCGM and notified by the DBT.

The RCGM has set up a special Monitoring and Assessment Committee to track the environmental impact of transgenic plants over a period of time. The committee has been given the duty to conduct field visits at the experimental sites and, based on the prevalent situation, recommends remedial measures where appropriate. It also gathers and reviews information relating to the agricultural advantages, associated risk and benefits of the transgenic plants.

The guidelines provide for a detailed model plan for construction of green house/ net house for conducting experiments using transgenic plants.

3. Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants, 2008.[17]

The SOPs have been formulated with the objective to act as a guiding tool for conducting CFTs of regulated, GE plants. It addresses the issues relating to transport, storage of GE plant materials and management of CFTs. All Permitted Party and their agents must duly comply with the SOPs, failing which, the GEAC/ RCGM is empowered to take remedial action.

It provides for recording formats for transport and transport inventory list, storage, planting, harvest/ termination, post-harvest monitoring, etc. All the relevant records are required to be maintained in the format prescribed. A comprehensive glossary of terms used in the SOPs in the context of CFTs has been enumerated. It also provides guidance for monitoring of CFTs.

With an objective to ensure that the CFTs are conducted in a safe and efficient working manner under controlled conditions, SOPs have been provided for transport, storage, planting and harvest of all regulated, GE plants.

It is applicable to the import, export, inter-state movement and intra-state movement of

[17] MINISTRY OF ENVIRONMENT AND FORESTS, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/resource-documents/biosafety-regulations/guidelines-and-protocols/Standard-Operating-Procedures-for-confined-field-trials.pdf, (last visited Jan. 12, 2020)

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regulated GE seeds or propagable plant material. All these substances must be labelled, securely stored and kept separately for transportation.

With respect to storage of these substances, the SOPs mandates suitable storage facilities to be provided for before such consignment of regulated plant materials are accepted by the Permitted Party. Specific requirements, such as, fully enclosed space for storing which is secured by a lockable door, separate storage of each sample in a sealed and labelled container, limited access to only the authorized personnel in the storage areas, maintenance of cleanliness of the area or unit to be used for storage have been provided for under the SOPs. Access to such storage area is to remain open during the regular working hours for inspection by the regulatory officials.

It also lays down specific requirements for planting and harvest or termination of the CFTs of regulated, GE plants. It provides for the use of clean equipment and tools, maintenance of the trial site, use of acceptable methods of cleaning, such as hand cleaning, high-pressure water, vacuuming of remaining seed and compressed air.

A map of each trial area along with the Record of Planting is to be prepared and submitted to the RCGM/GEAC within 7 days of planting. A Record of Harvest/Termination is to be duly prepared and made available to the regulatory officials upon request.

The SOPs mandated the non-use of trial site as pastures for animals during the post- harvest period.

In the event of accidental release of these substances, the SOPs provide for recovery of the material as far as possible and to make them non-viable by heating, burning or crushing. A record of such an event must be duly documented in a Record of Corrective Action.

(C) Biological Diversity Act, 2002.[18]

It was adopted by the Ministry of Law and Justice on 5th February, 2003 in pursuance of India being a signatory of the United Nations Convention on Biological Diversity, 1992. The Act is applicable to whole of India and consists of 65 sections spread over 12 chapters.

It provides for the establishment of a three-tiered structure, namely the NBA, SBB and the BMC to achieve the objectives enshrined under the Act.

The Act addresses the issues of conservation, sustainable use of biological resources in the country, issue related to use of genetic resources and associated knowledge and fair and

[18]MINISTRY OF LAW AND JUSTICE, GOVERNMENT OF INDIA, http://www.geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/bio_div_act_2002.pdf, (last visited, Jan. 14, 2020)

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equitable sharing of benefits arising from utilization of biological resources to the country and its people. It also regulates the use of biological resources including genes used for improving crops and livestock through genetic intervention.

The Act prohibits the taking of any biological resource occurring in India or its associated knowledge for research or for commercial utilization or for bio-survey and bio-utilization, by any person, without the prior approval of NBA, provided that such person falls in any of the category specified under Section 3(2). The Act also prohibits the transfer of results of any biological resource related research in India, for monetary consideration or otherwise to any persons specified under Section 3(2), without the prior approval of the NBA, unless it is a collaborative research project. Such persons include the following: A person who is not a citizen of India or citizen of India who is non-resident as defined in Section 2, clause 30 of the Income Tax Act, 1962 or a body corporate or organization which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management.[19] In other words, the Act stipulates that access to foreign companies, citizens and NRIs to biological resources and traditional knowledge shall be based on 'prior approval of NBA'.[20] With respect to Indian citizens, companies, associations and other organizations registered in India access shall be permitted on the basis of prior intimation to the SBB.[21] It exempts the local people and communities from the requirement of prior approval and intimation.[22]

At the State and local level, the Act mandates the setting up of the SBB and BMCs, respectively. The Act also provides for the creation of National, State and Local Biodiversity Fund which shall be used for the conservation of biodiversity and benefit-sharing.

However, on a critical appraisal of the Act, it can be concluded that there are several lacunas under the Act which can be summarised as follows:

The NBA was established for the effective implementation of the Act. It is entrusted with the function of laying down guidelines and procedures relating to access and benefit sharing and IPR. It is responsible for coordinating the activities of the SBB and BMC, by providing them the necessary guidance and technical assistance. However, the NBA lacks autonomy and independence. The Central Government is empowered to remove the chairperson and members of the Board.[23] The NBA is bound to comply with the directions given by the Central

[19] Biological Diversity Act, sec. 3(2)
[20] *Id.* sec. 3, 4, 6
[21] *Id.* sec. 7
[22] *Id.*
[23] Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation

Government.[24] Moreover the ILCs are not adequately represented in the Board.

The SBB is set up as a body corporate by the State Government, with the function to render advise on matters relating to biodiversity to the State Government, and to regulate commercial utilization of bio-survey and bio-utilization of any biological resource by Indians. However, it is criticized that the SBB functions merely as an advisory body. It lacks autonomy as the exercise of its powers is subjected to the guidelines issued by the Central Government. Further, the Act does not mandate the representation of ILCs in the SBB.

For promoting the conservation, sustainable use and documentation of biological diversity, the Act provides for constitution of BMC, by every local body within its jurisdiction. The NBA is under an obligation to consult the Committee before taking any decision with regards to the utilization of biological resources. However, it is under no obligation to follow the suggestions or the decisions of the BMC. Thus, despite having the responsibility to conserve biological resources and knowledge, the BMC only plays an advisory role in the grant of approvals. The NBA is conferred with exclusive power to deal with it.

The Act fails to provide a comprehensive regime for the conservation and sustainable use of biological resources. It gives more importance to the matters relating to access to resources and related issues. It mandates all inventors to obtain consent of NBA before applying for IPR, where the invention is based on biological resources obtained from India. The NBA is further empowered to "impose benefit sharing fee or royalty or both or impose conditions including the sharing of economical benefits arising out of the commercial utilization of such rights." Notably, the efficacy of such a provision is extremely doubtful as the NBA lacks extra-territorial jurisdiction and therefore cannot monitor applications overseas.

Further, the local communities do not have an active role in the decision making process with respect to regulation of access. They are only consulted to work out the benefit sharing mechanism after the decision to allow access is made by the National and State Boards. This centralized approach is not of great benefit.

An aggrieved person cannot directly approach the court. A prior notice of the intention to make a complaint must be given; else the complaint has to be filed with the NBA. The absence of locus standi to all citizens is of great concern. Such institutional framework would only delay the ability to get any remedy.

Transgenic Seeds, Plants and Plant Parts, 1998, sec. 9

[24] *Id.* sec. 38

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III. CONCLUSION AND SUGGESTIONS

GM approach is a dynamic process; it should be continuously enriched scientifically and evolved in a transparent and socially inclusive manner. There is a need to addresses all issues of concern and science-based recommendations and concrete actions for safe, inclusive and judicious harnessing of the GM technologies for accelerated and sustained crop production are also required.

Biotechnology in general, and modern biotechnology in particular, creates both costs and benefits, depending on how it is incorporated into societies and ecosystems and whether there is the will to fairly share benefits as well as costs. For example, the use of modern plant varieties has raised grain yields but sometimes at the expense of reducing biodiversity or access to traditional foods. Neither costs nor benefits are currently perceived to be equally shared, with the poor tending to receive more of the costs than the benefits.

To address the issues related to GM food several legislative framework have been adopted from time to time. Indian legal regime regulating GM crops consists of guidelines of Biosafety Rules, 1989 issued under the EP Act 1986. It exhaustively covers the handling, use, import and export of GMO. There are other guidelines adopted under the Rules to address various issues related to GM food. In addition to it, the Biological Diversity Act also contains provisions for the regulation of GM foods.

Notably, there are several gray areas in the existing framework in India. While an attempt has been made in the previous chapter to highlight the lacunas, there are several other issues, such as:

The regulation of biotechnology involves many scientific complexities and has to address a wide range of legal, ethical, social, economic, political, human health and environmental issues. In India there is a need to establish an efficient and trustworthy regulatory mechanism that should be based on transparency and public participation. The existing regulatory mechanism in India is scattered, ambiguous and involves avoidable time taking process.

The composition of each authority under the DBT and MoEF has been described in the earlier chapter. One of the criticisms of the regulatory processes is regarding its composition, the process of appointment of members to the various committees and the lack of checks and balances to ensure independent functioning. Members of the various committees are primarily from the various Government departments.

The RCGM also comprises of scientists from several public sector institutions and Government

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departments engaged in transgenic research. Both the RCGM and the GEAC also provide for non-Government "experts". Such experts are to be nominated by the Government. There are no guidelines as to the qualifications of such experts. They are recommended by official members of the various committees and appointed by the Government.

The rules and guidelines do not prescribe any terms for any of the members of the committees for aspects such as appointment, tenure, disqualification or removal. There is also no independent source of funding for the committees. The budget for the committees is part of the budget of the Government departments under which they function, namely the DBT and MoEF. Neither the Rules nor Guidelines prescribe the frequency and time lines for the committee meetings. As a matter of practice, the number of meetings depends on the number of applications to be considered.

Regulators in India frequently rely on assessments conducted on a case-by-case basis using information submitted by the developer of a GM crop which draws on private tests and field trials also conducted by the developer. The process is therefore almost akin to a private one between the applicant and the regulator, with the latter dependent on the integrity of the former. An independent impartial decision-maker, transparency in decision-making and public accessibility to information, are highlighted as critical features that are found lacking in the Indian legal framework. Moreover, information submitted is not in the public domain, and private companies justify this as being necessary to protect confidentiality.

An aspect that industry representatives have been emphasizing on is the need for a 'single window clearance' which, it is believed, would ensure greater efficiency and speed. This would essentially entail integration of the process of submission of applications and test results to the RCGM and the GEAC. There have been several demands for speeding up the approval process, as well as for parallel field trials and acceptance of data across agencies. As of now, there are no statutory time limits prescribed.

It can therefore be maintained that the existing legislative framework in India is not sufficient to address the problems associated GM foods. There is a need to streamline the existing regulatory framework.

The researcher in this regard makes the following suggestions:

- The GM technology is a powerful tool for developing future crop varieties with in-built genetic resistance to various biotic and abiotic stresses for reducing crop losses and enhanced input use efficiency, yield potential and quality traits. Their use will be crucial for the food and nutritional security of the country and therefore research on them must

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be continued with the aim of developing safer, more productive and nutritious food crops. However, this should be done in a more transparent and socially inclusive manner for wider public acceptance.

- Currently our preparedness for risk assessment research is inadequate to provide scientific support to the regulatory process. Therefore, a "National Institute of Bio-safety and Bio-Security" should be created with necessary infrastructure, human resource and research programs for conducting frontier research, capacity building in this field and providing policy support and technical advice to the government on this issue.
- There is a need to strictly enforce the regulation on the ground because a good "Regulatory Act", if poorly implemented will bring disrepute to this wonderful technology. For example, experimental GM crop events should not land at farmer's hand for widespread cultivation before they are approved by the regulatory authority.
- Program should be initiated to inform and educate the policy makers, farmers and public about merits of GM crops for food security and potential benefits and risks of GM crops on biodiversity. Steps should be taken to harmonize the policies at the level of State and Central Governments so as to minimize the hindrance in conveying the benefits of proven pro-poor technologies to the farmers.

Given that there is inherent risk involved in modern biotechnology and its products, the main mandate of the regulatory system should be to safeguard human health, the environment and consider various other issues. The decision making in such a system should follow the basic principles like precautionary principle, absolute liability, polluters pay principle and effective public participation in environmental decision making and access to information.

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