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Evolution of Biosafety Policies in India: The Limits of its Governance in GM Crops

Dr. V. Gunasekaran,
Department of Political Science, Ramanujan College (University of Delhi)
Kalkaji, New Delhi-110019
Mobile: 9717025490
E Mail.: v.sekaran@ramanujan.du.ac.in

Abstract
The article analyses the evolution of biosafety policies in India and its experience in governing Genetically Modified (GM) crops. The protocols of GM crops evolved in India where tandem with the global efforts to address the biosafety concerns with GM crops and promote it as a viable technological choice in agriculture. The policies on biosafety and GM crops in India are even though of international standard were mired with controversies over procedures and approvals. The nuanced opinion on GM crops among the public and stakeholders has exposed the limitations of the governance structure as well hampered the progress of a technological choice in agriculture.
Keywords: Biosafety, Biotechnology, Genetically Modified Crops (GM Crops), Regulations

Introduction

The developments in the agriculture biotechnology sector are considered by India to offer good prospects for the ailing agriculture sector (Ministry of Science and Technology, 2035). The Government of India (GOI) constituted a Cabinet Committee on Science and Technology (CCST) in 1981 under the chairmanship of the Prime Minister, which formed a Science Advisory Committee (SAC) headed by M. S. Swaminathan. The SAC studied the developments of biotechnology across the world and prepared a roadmap for the sectoral growth in India. It announced a Technology Policy Statement in 1983 which recommended a National Biotechnology Board (NBTB) to carry forward the vision enumerated in it. The policy statement also identified the broad areas of biotechnology development and set a mandate for the NBTB to work on it. Prof M. G. K. Menon was appointed as the first chairperson of the board and top -most bureaucrats of different departments were appointed as its members (Chaturvedi , 2004). The ambitious agenda of the NBTB and its inability to fulfil multitask led to the formation of a full scale Department of Biotechnology (DBT) under the Union Ministry of Science and Technology. It was observed by Sachin Chaturvedi that the recommendation of a separate department is a setback to the earnest work of NBTB. He identified that the establishment of a separate department would create problems of coordination in different areas of research and might lead to discontinuities in the development of new technologies associated with earlier research agenda. The separation of biotechnology from other areas of research like agriculture and health might result in abrupt disbandment of their conventional research. The new technological development would not to be a corollary of the already existing technology; 'The technological frontier for a developing country like India has to be an outcome of accumulation of both new and conventional techniques, rather than an outright replacement of conventional techniques with new ones. For

instance, most of the Green Revolution varieties of various crops have reached their peaks in terms of productivity' (Chaturvedi , 2004, p. 3693).

In 1986, the then Prime Minister, Rajiv Gandhi, approved to set up a separate department in the Ministry of Science and Technology. It was named the Department of Biotechnology (DBT) which started its function to achieve the vision set by the NBTB. Dr S. Ramachandran said that Prime Minister Shri Rajiv Gandhi recognised the pace of biological sciences globally and told that 'unless we leap forward, there is no way of catching up with the rest of the world' (Department of Biotechnology, 2017). The government consistently supported an increased budgetary allocation to the DBT, and it has gradually 'gone up from Rs. 404 million in 1987-88 to Rs. 1,138 million in 1997-98 and by 2001-2002 it became Rs 1,863 million'(Chaturvedi , 2002, p. 4).

The Evolution of Biosafety Norms in India

The Environment Protection Act of 1986 proved to be a wide -ranging act which guided the DBT to frame many important biosafety guidelines. It's reference of hazardous substance as 'any substance or preparation which, by reason of its chemical or physico-chemical properties or handling is liable to cause harm to human beings other living creatures like plants, micro-organism or the environment' paved way for the guidelines on the biosafety GMOs. The first such biosafety guidelines on GMOs, '*The Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms Genetically Engineered Organisms or Cells Rules, 1989'* (Ministry of Environment & Forests, 1989) , was notified in the *Gazette of India* on 13th September 1993. The Rules of 1989 were so comprehensive that it covered most of the areas relating to the safe use of organisms at the research level as well as when the biotechnological products are released into environment. The Rule 2(2) covers 'all genetically engineered organisms, micro-organisms, cells and the substances, products or foodstuff in which such cells, tissues or organisms find a place'. The Rule 2(4) applies to '(i) sale, offers for sale, storage for the purpose of sale, offers of any kind of handling over with or without consideration; (ii) exportation and importation of genetically engineered cells or organisms; (iii) production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the genetically engineered products; and (iv) production, manufacture, etc., which make use of micro-organisms/genetically engineered micro-organisms in one way or the other'. (Ministry of Environment & Forests, 1989) .

The biosafety regulations of 1989 were revised in 1994 and 1998 periodically to regulate new developments in the biotechnology research and to fulfil the obligations of the international framework regulating the research and release of GMOs in the environment. The revisions of the biosafety guidelines did not include specific rules and guidelines to oversee the entry of GM foods through the ports, nor did the agencies possess gadget to detect the GM foods which enter through the ports (Lianchawii, 2005, p. 4285). The GOI enacted Plant Quarantine (Regulation of Import into India) Order, 2003, to fulfil the gap of biosafety regulations which regulated the transgenics entering through ports and any import of transgenics used for agricultural research(Chaturvedi *et al*., 2015, p.24).

The Rules of 1989 have assigned DBT a prime role at par with MoEF in the regulation of biosafety. DBT, by default, is present in most of the committees which implements biosafety regulation and assess the risk of GMOs. The Recombinant DNA Advisory Committee (RDAC) is an apex regulatory body at the research level

functions under the umbrella of DBT, which is empowered to review the scientific developments in biotechnology at the national and international levels and suggests biosafety mechanisms to be adopted in India. The committee enacted 'The Recombinant DNA Safety Guidelines (1990)' to prescribe safety guidelines during research and field cultivation (Chaturvedi *et al*., p.300). Table 1 describes the role of different ministries in the promotion and regulation of GM crops enumerated by the Rajya Sabha report (December 2017) on 'Genetically Modified Crops and its Impact on Environment'.

Table 1

Ministry of Environment, Forest & Climate Change	• Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of Living Modified Organisms (LMOs)
Department of Biotechnology(Ministry of Science & Technology)	• Promotion of biotechnology • Provide services in areas of research, infrastructure and generation of human resources
Ministry of Agriculture	• Policies aimed at agriculture growth • ICAR responsible for monitoring agronomic benefits of GM technology • Post release performance of GM crops
Ministry of Health and Family Welfare	• Policies aimed at protecting and monitoring human health
Ministry of Commerce and Industries Department of Customs	• Enhance trade with other countries through export/import policies • Enforcement at point of entry

Source: Rajya Sabha Report on 'Genetically Modified Crops and its Impact on Environment', December 2017, p. 9.

The EPA 1989 rules demarcated the role of different ministries/authorities/committees that would monitor the promotion of GM crops at the research level and its post -approval level. The rules aimed to create a decentralised biosafety monitoring system involving authorities from the Central government to the District level. The biotech research labs have to constitute an Institutional Biosafety Committee (IBSC), approved by the DBT, which would monitor the research at the lab and greenhouse levels. The Review Committee on Gene Manipulation (RCGM) under the Ministry of Science and Technology would approve and prescribe guidelines for conducting small scale field trials. The small -scale field trials under the guidance of RCGM have to undertake basic agronomic monitoring, pest -incidence, pollen flow and toxicity and allergencity test in the process of trials.

The large -scale field trial is approved by the Genetic Engineering Appraisal Committee (GEAC) which functions under the MoEF. During the large -scale trials the agronomic and biosafety data are compiled by the Monitoring -Cum -Evaluation Committee (MEC) which visits the site and evaluates the trials. The MEC submits the report to GEAC for final approval of the product to be commercially released in the environment. The final approval of the GEAC has to be endorsed by the MoEF, without which the product cannot be released into the environment. The commercial release of Bt Brinjal and Bt Mustard is in the cold storage of MoEF even after the

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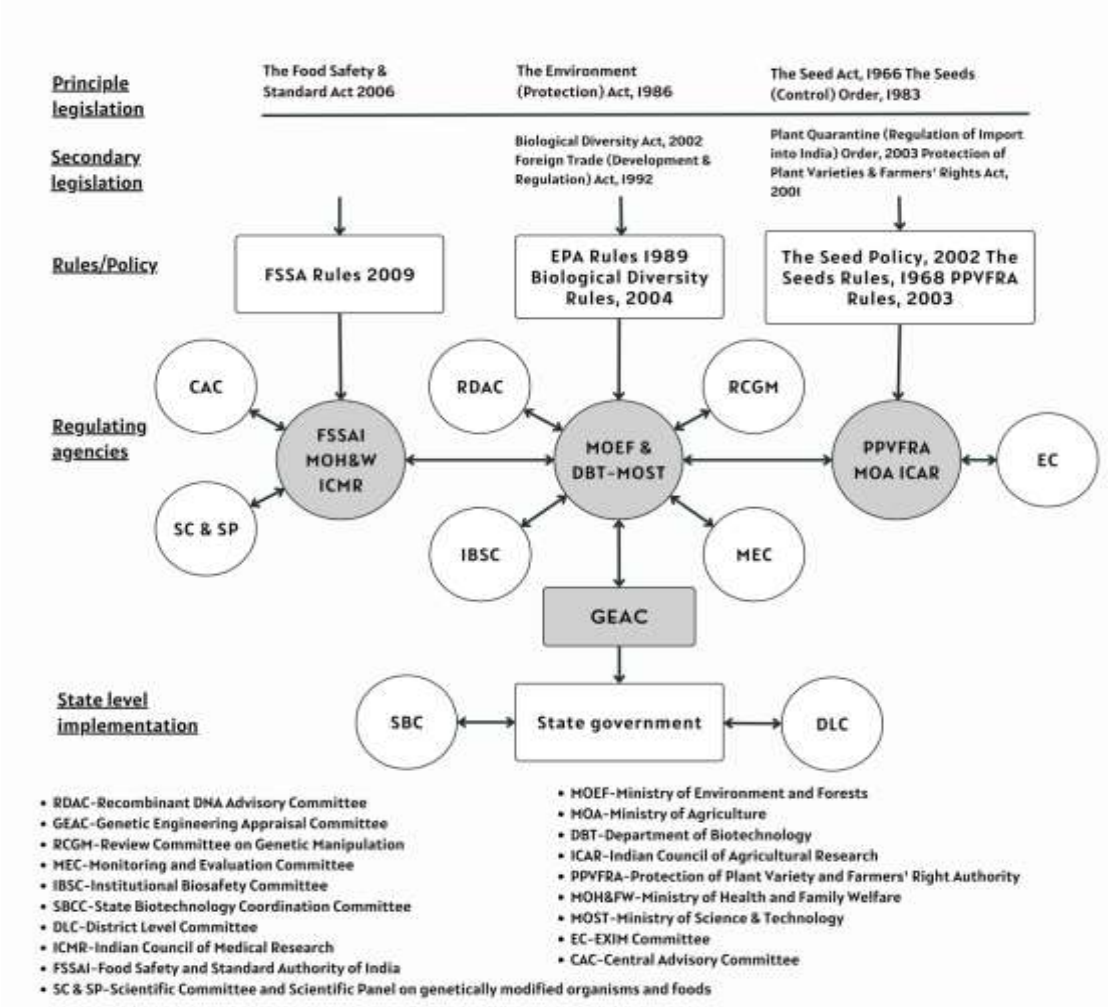
approval of GEAC because of cases pending in the Supreme Court and for various other political reasons which signify that the ministry is the final approver of GM crops. The State Biotechnology Co-ordination Committee (SBCC) and District -Level Committee (DLC) assist in monitoring, evaluation and reporting of any risks associated with the trials at the field level and also after the commercial release of GM crop.

The biosafety of GM crops are covered under three principal legislations, viz., The Seed Act 1966, The Environment (Protection) Act 1986, and The Food Safety and Standards Act 2006. The above three Acts propose the theoretical framework for the institutions which were formed and later through the enactment of rules to oversee the biosafety of GMOs. The sale of GM seeds is covered under the Seed Rules, 1968, Seed (Control) Order (1983) and the Protection of Plant Variety and Farmers' Right Authority Rules, 2003, which are administered by the Ministry of Agriculture. The Food Safety and Standard Rules, 2009 provides for a Commissioner of Food Safety in each state to monitor and address issues of food safety. The following Chart 1 describes the role of different agencies and acts in the regulation of GM crops.

Chart1



Source: Choudhary, Bhagirath et al., (2014) 'Regulatory Options for Genetically Modified Crops in India.' *Plant Biotechnology Journal*, 12, 141.

The guidelines framed in India have taken a middle path between precautionary and proactive approach which strived to promote biotechnology not at the cost of environment and human health (Lakshmanan, 2018, p. 299). The perceived middle path of the biosafety rules does not stand valid since the functioning of the EPA rules favour a stricter precautionary principle. The approval of GM crops is considered case by case for the potential risks it could pose to environment, health, economic benefits and safety of biodiversity. Moreover, the socio-economic provision of CPB which does not bind the nation either to adopt or ban GM crops which has influenced a lot to the ban of Bt brinjal in India. Thus, the EPA rules have operated more in a precautionary perspective than the middle path which is envisaged in the rules.

The Convention on Biological Diversity, 1992, paved the way for the Biological Diversity Act, 2002, in India sought to protect and better use of biodiversity. It is perceived to be more favourable for the developed countries rather than the developing countries. The biopiracy of turmeric, neem and ayahuasca is cited to argue that the developing countries are not in a position to save their biodiversity and the benefits that accrue out of the protection of biodiversity (Sahai *et al*, 2007). The other side of the debate sees that 'foreign companies have found it difficult to access India's wealth of biodiversity, while both Indians and foreign individuals have found it difficult to commercialise their research findings' (Padmanabhan *et al*., 2017, p. 16) after the formulation t of the biodiversity rules.

The Biological Diversity Rules, 2004, provisioned an institution called the National Biodiversity Authority (NBA) in Chennai, Tamilnadu. The primary function of the authority is to advise the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilisation of biological resources; and advising the State Governments in the selection of areas of biodiversity importance to be notified under Sub-Section (1) of Section 37 as heritage sites and measures for the management of such heritage sites' (National Biodiversity Authority, 2019).

The NBA has a Chairperson, usually a senior bureaucrat which consists of 15 members (10 Official Members from different ministries and 5 Non-Official Members who could be experts/specialists in the field of environment). The NBA claims to have processed 183 access sharing agreements for commercial purposes (National Biodiversity Authority, 2019), which involves sharing the genetic resources of India with commercial or scientific establishments for the purpose of devising new plants or any biotechnology products. The authority plays a pivotal role in securing bioresource being misused by any entities; but it could not find even a single case of misuse of bioresource by any foreign country after the enactment of the Act (Bhutani & Kohli, 2012, p. 17).

The biosafety mechanisms in India are very elaborate and the responsibilities are distributed in many ministries. The Task Force on Application of Agricultural Biotechnology appointed by the GOI in 2003 under the chairmanship of M. S. Swaminathan recommended a separate agency, National Biotechnology Regulatory Authority, to deal with biotechnology products similar to the functioning pattern of the Atomic Energy Regulatory Board. The recommendation seeks to see through industry boundaries which fail to understand the lack of 'unanimity across the globe about the breadth of a regulatory authority. It is being observed that more and more countries are going for a regulatory authority with the broadest possible mandate, but in India we are doing just the opposite' (Sachin Chaturvedi, 2004, p. 3696). The GOI

proposed a Biotechnology Regulatory Authority Bill in 2013 which was modelled according to the recommendation of a task force. It sought to establish a single agency to approve GM crops from application stage to the commercial release. The bill was introduced by Shri. J. Jaipal Reddy, Minister of Science and Technology and Earth Science, on 22 April 2013 which lapsed due to the end of UPA-II government. The BJP government that came to power in May 2014 has not taken keen interest in reintroducing the bill and establishing an authority proposed in the Biotechnology Regulatory Authority Bill, 2013.

The Experience of Biosafety Protocols in India

The approval procedure of GM crops is considered to be lengthy and exhaustive, but leaves a lot of scope for negotiations and bargaining within the process. The biosafety data for a long time were kept as a trade secret and were never revealed to the public by the companies. The biosafety data were revealed to the public after the intervention of the Supreme Court which also turned out to be partial and the true sense of the data could be never examined by the public (Aggarwal, 2016). The lengthy procedure is considered by the private companies to hinder the progress of biotechnology research and give chance only to large private groups to spare a lot of time and money to bring a product into social reality. The 2018 merger of Bayer and Monsanto signified that Monsanto was not ready to invest more money in getting products in the market. Monsanto India have many times publicly expressed that the approval of GM crops take long time and is often mired by the socio-economic and political issues. Farmers union like the Shetkari Sanghtana (A pro-technology farmers union based in Kolhapur, Maharashtra, led by Sharad Joshi) supports introduction of new technologies in agriculture and demands for a prompt introduction of GM crops.

The biosafety guidelines, apart from the procedural delays, lacks indigenous preparation and overlooks the Indian conditions of cultivation. The Genetic Engineering Appraisal Committee (GEAC) submitted to the Parliamentary Report on GM Crops (2012) that various new guidelines are often being produced in keeping with the dynamic nature of crops science and the biosafety associated with it. It also submitted that the new guidelines and protocols are based on the forms prescribed by the Organisation for Economic Co-operation and Development (OECD), Code Alimentarius Commission (CAC) and International Plant Protection Convention (IPCC). The submission of GEAC signifies that the guidelines were influenced, enacted and followed by the countries which do not address the concerns of biosafety rather their aim is to accommodate the trade framework of WTO (Lok Sabha, 2012, p.123).

The biosafety guidelines of India have seen temporary shifts in enacted policies due to the pressure of developed countries. The GEAC in September 2007 issued a notification declaring that there is no need of permission required to import GE food products but the same was restored in February 2008. There was no explanation given by the Ministry on the shifts of position in importing GE food products. It is argued by Kavitha Kuruganthi that the shift of positions was made to accommodate the request of the USA according to the agreement of *Knowledge Initiatives in Agriculture (KIA, 2008)* entered between these countries. The relaxation of the biosafety guidelines by India which is a signatory to all the international protocols on biosafety guidelines relaxing its guideline to a nation which is not a signatory to any of the biosafety protocol mechanisms signifies that the commercial

aspirations of both the nations acquiring more priority than the biosafety protocols. (Kuruganti, 2008, pp. 19-22)

The approval of an event by GEAC and MoEF signifies that the crop is environmentally safe and fit for human consumption. As per the biosafety guidelines the product has to be continuously monitored to identify any threats to the environment and human consumption. It is learned in these years that the government agencies do not have a robust post -release monitoring system to understand the behaviour of the product in environment. It is delegated to the companies to submit biosafety data about its product and behaviour in the environment. None of the companies has reported about the unsafe nature of any product nor has the government found any evidence that the product is unfit to be released in the environment. There has been no substantial evidence to prove the damage caused to living organisms by Bt cotton. Apart from the company's own submission on the safety of crops, there are various government laboratories where the safety of GM crops is tested. The following are the various centres which test the safety of GM crops or any biotechnology products: National Dairy Research Institute (Karnal), Central Asian Research Institute (Bareilly), Industrial Toxicological Research Centre (Lucknow), National Institute of Nutrition (Hyderabad), Central Institute of Fisheries Education (Mumbai), GB Pant University and Technology (Pantnagar).

The various biosafety guidelines in India assess the products of the GM crops for its allergenicity and toxic presence in food. There are various tests conducted to observe the equivalence with non-GM food 'using test protocols such as – protein thermal stability, pepsin digestibility, molecular characterisation, compositional assessment, acute oral toxicity (mice or rat), 90 -day sub-chronic rat feeding and livestock feeding (case by case)' (Lok Sabha, 2012, p.34). The government labs have not found any potential risks of GM crops so far in the cases referred to it.

Biosafety Issues in Bt cotton

The GOI as enumerated in the above made necessary policy enactments and put in place an administrative structure to introduce GM crops in India. In the year 1990 Monsanto submitted an application to the Department of Biotechnology to evolve Bt cotton seed in Indian soil. The application was rejected by the Committee headed by V.L. Chopra due to the high demand on the technology -transfer fee as well as the committee being of the opinion that backcrossing an American variety with the Indian might result in unintended environmental impacts. But in the year 1996, when the same application was resubmitted, it was accepted by the DBT Committee where V.L. Chopra was not a member. The revised decision was justified by the scientific circles, except that in the year 1990 the application was submitted by a foreign company but in the year 1996 it was an Indian company. It was claimed by scientists that 'if developed by Indian scientists, transgenics may have seen the light of day much earlier' (Scoones, 2005, p. 253). The biosafety guidelines practiSed by the committee was according to its convenience and comfort which left biosafety to the background.

The CryIAc protein obtained from the bacteria Bacillus Thruringiensis (Bt) forms the main technological invention to contain H.armigera(American Bollworm), which is a major pest in cotton. The researches around the world showed that CryIAc can be very effective against tobacco budworm but not on the H.armigera species of pest. The researches also revealed that H.armigera under lab study is more susceptible to become resistant but in the field condition the susceptibility to resistance varies. The behaviour of CryIAc under lab condition and at the field level varied

substantially which needed a lengthy study to test its efficacy and its susceptibility to gain resistance against the pests (Daniell, 1999, p. 362). The incorporation of CryIAc protein in cotton was a trial to control bollworm in cotton and executed without a biosafety plan of controlling the pests in cotton.

The experience of Bt cotton cultivation has proven that the Bollgard(BG) I(Injection of single Cry1Ac protein in cotton) was not effective for controlling the bollworm and thus the Monsanto came up with Bollgard(BG) II(Injection of two protein genes of soil bacteria, viz. Cry1Ac and Cry2Ab) to do away with the resistance development in pests. The Bollgard II attained resistance to the pests in the recent years proving that the Bt technology in cotton has to be upgraded every now and then. There are now reports available that illegal cultivation of herbicide resistant Bt cotton is practised in many parts of India which is yet to be approved by the government. The failure of bollgard series is not accepted as a technological failure; rather it is argued that it is a cyclical phenomenon in pests to attain resistance to interventions and it is the challenge for the technology to come up with new inventions to break the resistance in pests. The technology has modified its pest management strategy and has come up additional stacks of Bt to do away with the resistance of pests. The additional stacks of Bt gene 'involving different pest-control mechanisms make rapid resistance build-up less likely' (Qaim, 2016, p. 54). The resistance of bollworm to the Bt stacks might be delayed but the phenomenon of pests attaining resistance to new interventions could not be stopped even in GM and non GM crops (Qaim, 2016, p. 54).

The seed companies also have a plan of stacking different bacteria or virus in cotton to control other pests like pink bollworm, spotted bollworm and mealybug. The technological options are wide open in biotechnology to stack external agents into the genetic structure of cotton to offer new products. The farmers are logically replaced from one product to other product with the hope of better management of pest -resistance. It is suggested by the seed companies that the farmer can prolong the resistance of pests by adopting refuge area. The farmers are insisted to keep 20% of their cotton plantation as refuge area. It is constructed across the Bt cotton farm by planting rows of non Bt cotton seeds or other seeds. The refuge area attracts the bollworms from the cotton crop which might reduce the pest attack in the cotton crop. This technique helps to prolong the resistance of bollworms to Bt. 'The theory is that when that first Bt-resistant insect does show up, it can be induced to mate with a susceptible bug living on the refuge side of the tracks thereby diluting the new gene for resistance'(Pollan, 2001, p. 214).

The approval of Bt cotton in 2002 for three years came alongside with a number of conditions. The conditions were 'growing of a refuge area of five rows surrounding each *Bt* cotton plot, early removal of the cotton crop following harvest, and continuous scouting through the season' (Scoones, 2003, p. 9). The refuge technique was least followed by the farmers due to their size of farm. The farmers tend to resist creating refuge area since it affects the overall yield of the crop and would not be economical in a small farm (Gupta, 2002, p. 2766). The lack of creating refuge area resulted in bollworms acquiring fast resistance to Bt. The Bombay Agricultural Commission has recently asked the companies to pay compensation of more than Rs 1,600 crores to 3.5 lakh farmers who have filed petitions against the seed companies claiming that the Bt has failed to protect bollworms.

The small -scale trials approved by RCGM and the large -scale trials approved by GEAC do not scientifically match the scale of trials that take place in the USA

where even 100 acres of trial is considered to be small. The RCGM has the mandate of approving small -scale fieldtrials upto 20 acres and fieldtrials above 20 are approved by GEAC(Lianchawii, 2005, p. 4287) which is considered to be a large scale field trial. The release of Bt cotton in 2002 signified that the project was hurried and any substantial study on the environmental effects could not be studied in detail. The data of the fieldtrials examined by the RCGM as well as the GEAC were argued to be ceremonial without any physical verification of fields (Bharathan, 2000, pp. 1067-75). The fieldtrials were destroyed in many parts of India even before the assessment of environment and health issues related with GM crops. The NGOs have organised movements such as 'Operation Cremate Monsanto' or 'March against Monsanto' which destroyed many fieldtrials in Raichur and Bellary Districts of Karnataka (Herring, 2007, p. 137).

The approval of Bt cotton for Andhra Pradesh was done by the GEAC without the reports from the State Biotechnology Coordination Committee (BCC) and the District -Level Committee (DLC) (Lianchawii, 2005, p. 4285). It was also revealed by studies that many states had not formed any such committees envisaged in the biosafety guidelines to give their reports about the GM crops trials (Dhar 2002).. Though agriculture is a state subject, the Central government has bypassed the states in many policy issues of GM crops. The States also showed differing administrative willingness in prohibiting farmers from using illegal Bt cotton seeds before its formal introduction in 2002 or in destroying the illegal Bt cotton plantations. The illegal seeds of Bt cotton were supplied in the market from the transboundary movement of goods as well as some seed companies stealthily manufacturing illegal varieties of Bt cotton. This also reflected poor monitoring of markets by the State or bringing to book those violating the laws.

It was observed that the GEAC comprises mainly of the public scientists and there were no social scientists in the approval process of GM crops to give their opinions about risk assessment or conduct social audit of GM crops (Lianchawii, 2005, p. 4285).There was a lot of 'adhocism' in the appointment of GEAC members and the constitution of the body itself was not for a fixed tenure; instead, the Ministry by its order constituted, reconstituted or extended the term at its will (Rajya Sabha, 2017). The members of the committee in the top level were from the bureaucracy and scientists did not get any of the top positions. It was also a fact that scientists who were at the level of approving the GM crops also reviewed the crop at the stage of field trial. The conflict of interests was not there in the functioning of the committees since most of the scientists in the committee were in favour to the introduction of the technology. It was also found that some members were there in multiple committees and hence devoted less time to attend meetings. The Rajya Sabha (2017) Report suggested that the members of the GEAC should be able to devote time for the reports presented and make decision only with a thorough understanding on what is happening rather than be busy with other things that inhibits them to form a good opinion (Kesavan & Swaminathan, 2018, pp. 92-98).

The Politics of Biosafety and GM crops in India

The biosafety concerns and debates after the advent of GM crops is day by day progressing to reveal differed shades of the technology. The emergence of many issues on Bt cotton approval in the public domain led to negative perceptions on GM crops. It signified that the biosafety guidelines in India did not reflect the letter and spirit in actual execution (Lok Sabha, 2012). The government lacked the co-ordination between different agencies to implement the biosafety guidelines. In an

experience spanning over 19 years from the Bt cotton release in 2002 to the present, there have been major administrative flaws which have shown that the government mechanisms were not able to live up to its promises on biosafety regulation of GM crops .

The campaign against GM crops witnessed a number of judicial cases targeting the implementation of biosafety protocols and the procedures followed in the trials. Vandhana Shiva filed a case in the Supreme Court in 1999 against the illegality of the GM field trials citing that the 'it is the GEAC, under the Ministry of Environment and Forests, and not the RCGM, under the DBT, that can approve field trials and that no biosafety regulations were followed in the exercise' (Krishnakumar, 2003).

Suman Sahai of Gene Campaign has filed the following cases which challenge the biosafety protocols of India, 'Writ Petition (WP) in Supreme Court asking for a Biotech Policy and a better GM Regulatory Regime – Jan-2004;

Writ Petition-2004 - Interim Application for release of Allergenicity and Toxicity data of Bt brinjal – October2004;

Writ Petition 2007 – To stop the deregulation of import of GM Foods – October 2007;and

Public Interest Litigation- Interim Application on Bt rice contamination in Jharkhand- Sept. 2008' (Gene Campaign, 2021).

The above list of cases largely questions the biosafety regulations of GM crops and seeks to improve it. She has listed in her website about the various changes brought out in the biosafety regulations of the government through the campaign and verdict of the above cases (Gene Campaign, 2021).

The Supreme Court appointed a Technical Expert Committee (TEC) in 2012 to assess the safety of GM crop and its biosafety protocols in a case filed by Aruna Rodrigues. The Technical Committee barred fieldtrials of GM crops 'singularly or collectively' and agreed that 'GMOs produce unintended effects' that are not immediately apparent and may take years to detect (Roudriges, 2013). She also claimed that the TEC Report is the fourth Report to recommend the ban of GM field trials, the other three are the 'Jairam Ramesh Report, 2010', the 'Sopory Committee Report, 2012' and the 'Parliamentary Standing Committee Report on GM crops, 2012'.

In the year 2005 and 2006 there were a number of reports of cattle -deathS especially goats dying after grazing on the cotton field in Warangal District of Andhra Pradesh (Venkateshwarlu, 2007). The issue got highlighted in the national dailies and the GEAC too responded to the claims of the public and the NGO's. The GEAC in its finding argued that the deaths of goats were not due to Cry1Ac gene of Bt cotton. It highlighted the animal feed study conducted by the Industrial Toxicological Research Centre in Lucknow, the study of G.B. Pant University of Agriculture, Pantnagar on cows and the study of Avian Research Institute on fish. The ex-Director of the Central Institute for Cotton Research (CICR) K. R. Kranthi observed that 'scientific evidence indicates that the possibility of Cry toxins killing goats and sheep is remote. The Cry toxins do not get activated under the acidic conditions of non-target animals such as goat, sheep and cattle. Feeding studies did not show any toxicity symptoms that could lead towards extreme toxicity symptoms or mortality'.

The NGOs criticised the Report of GEAC on the basis of the procedure of the study but could not substantially prove that the deaths had occurred due to the toxins of the Bt cotton plant (Herring, 2008, pp. 145–159).

A recent study of the Centre for Science and Environment has revealed are many food products in the market having GM contents (Bhushan *et al*., 2018). It has shown how the government lacked the vigilance and prevention of GM contaminated food products entering the market without its approval. The protest of farmers' union by cultivating herbicide tolerant Bt cotton, which is an unapproved variety of cotton, signifies that biosafety protocols have already been bypassed and suggests that the approval of new technology is a political decision *(The Indian Express, 2019 & The Hindu Business Line, 2019)*. The unmatched government response during crisis situation establish scepticism in the minds of the people and does not allay any fear on GM crops.

The legitimisation of GM crops in India is taking place within an already high -risk context, which 'is characterised by an agrarian crisis resulting from erratic monsoons, the commercialisation and individualisation of agriculture and the reduced investment by the State in the agrarian sector, particularly with regard to irrigation' (Desmond, 2017, p. 5). The high -risk context does not prohibit India to adopt rapid advancement of 'knowledge in life sciences (molecular biology and biotechnology, especially genetic engineering), nuclear science, nanotechnology (risks for human health and environment) and information technology (risk for large-scale data bases) in the twentieth century, risk perceptions about technologies have been increasing across the world today' (Haribabu, 2019, p.62). The biosafety of GM crops is not even settled but we are witnessing advanced gene editing or gene replacing technology called Cluster Regulated Interspaced Short Palindronic Repeats (CRISPR). The new technology is capable to produce different type of GM crops by 'repairing or replacing a stretch of DNA' which needs to be brought under the biosafety guideline. The modern society is progressing as a risk society where regulatory structures are evolved through power relations to manage risks' (Haribabu , 2019, p.64). The risks of science and technology have been regulated through the efforts of the nations to enhance the well-being of society. The regulation of risks is a strategy to legitimise science and technology which creates a 'biopolitical' condition in the society. It is a condition in the society where individuals become helpless if the biosafety protocols fail or if the perceived risks of GM crops become a reality. The success of biosafety protocols and the effective management of risks dictate the society since 'science today claims to provide forms of well-being, such as life, health, and livelihoods, that once were the defining responsibility of the modern state exercising biopower '(Hurlbut *et al*., 2020, p.8).

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Table 1

Ministry of Environment, Forest & Climate Change	• Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of LMOs
Department of Biotechnology(Ministry of Science & Technology)	• Promotion of biotechnology • Provide services in areas of research, infrastructure and generation of human resources
Ministry of Agriculture	• Policies aimed at agriculture growth • ICAR responsible for monitoring agronomic benefits of GM technology • Post release performance of GM crops
Ministry of Health and Family Welfare	• Policies aimed at protecting and monitoring human health
Ministry of Commerce and Industries Department of Customs	• Enhance trade with other countries through export/import policies • Enforcement at point of entry

Source: Rajya Sabha Report on "Genetically Modified Crops and its Impact on Environment", December 2017, p. 9.

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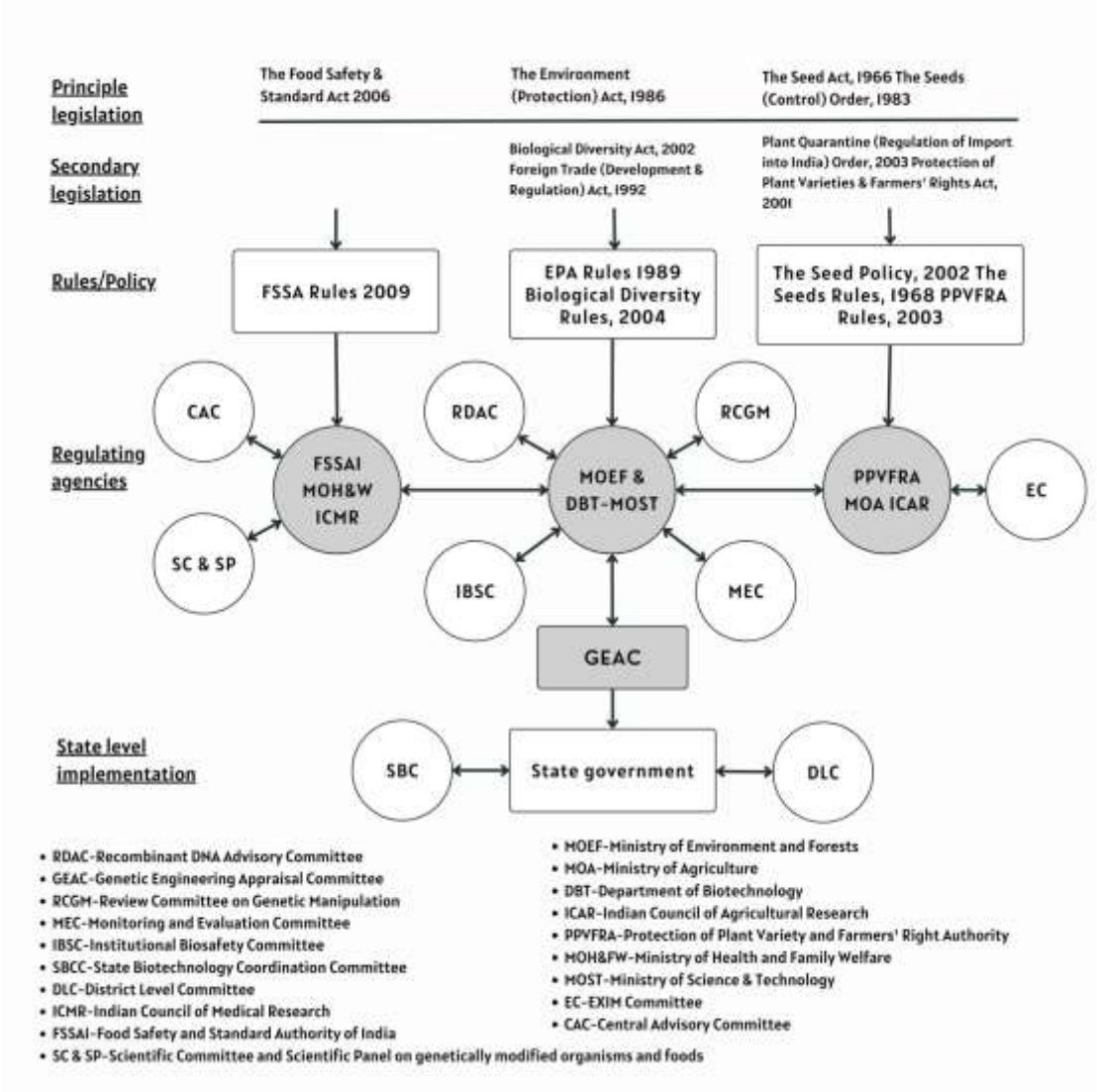
Chart 1



Source: Choudhary, Bhagirath et al., (2014) Regulatory Options for Genetically Modified Crops in India. *Plant Biotechnology Journal*, 12, 141.