



## GENETICALLY MODIFIED ORGANISM THE CONCERN AND FUTURE PROSPECT OF GMOS IN INDIA: CRITICAL ANALYSIS \*

### *Introduction*

Today's high-tech world is reaching a high height with modern science and technology. Human life has changed with the advancement of this modern technology and innovation which has added benefit to the life of human being and life has become more hassle free. Science and technology has changed the outlook of the society and the advancement in modern biotechnology in prominent field which have enormous prospective for the developing country like India. The use of biotechnology for genetically modified crops for agriculture and food items is being used across the globe and India is on the same footing and taking the benefit of this innovation. Human beings have exploited biotechnology to improve, modify, and change the genetic components of the foods and crops which has changed the quality of life of human being in all stratum. Biotechnology has brought about a revolution in agriculture crops and products through various methodologies in agricultural technology as compared to conventional agricultural methods. Genetically modified seeds have increased the production of crops which are disease and stress resistant along with that it gives a high agricultural productivity.

Genetically modified food and crops have wide range of socio, economic, technological and political impacts. Scientific technological innovation has contributed to significant improvements in GMOs crops and products which are available in the market but the concern with it pertaining to certain risks associated with it, which continue to create major problems in many parts of the world. GMOs are the challenge for policy makers to find an optimal balance between technological innovations to improve quality and standard of food grains, make policies to minimize the risk involved in such modification with clear rules and regulation and on other hand aware the general public about the benefits of such modified food and organism which can serve the need of the huge population. Majority of the countries have made rules and regulation to regulate and made precise policies for GMOs. When taken into consideration these complexities, it is being observed that there is no theoretical framework which is able to handle properly these issues and address them with proper solution in India. How to find the cooperation, co-existence in respect of agro biotech GMOs with organic food without hampering the environment and maintaining the sustainable development? Further raising the issues related with GMO's acceptance by the general public taking into account the risk, need and regulation of such agro biotech industry.

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\* Ms. Nanda Pardhey, Ph.D. Scholar of Department of Law, Savitribai Phule Pune University Pune, Pune & Assistant Professor at School of Law, Sandip University, Nashik.

Various surveys reveal that people are sceptical about agrifood on various ethical, moral, social, health, safety and environmental issues, due to which major problem in the agro biotech GMOs crops and product leading to debate across the nations. Many people believe they know something about genetically modified organisms and therefore are confident in their answers to questions, but are wrong<sup>1</sup>. This state of affairs is clearly worse than people recognizing and admitting they do not know much about GMOs and simply guessing answers to questions<sup>2</sup> by misinterpreting and misunderstanding the whole terminology of agro biotech like ‘*biotechnology*’ and ‘*genetically modified biotechnology*’. For a lay man just biotechnology means something is done with original food and that modified food or crops are going to harm them and ecosystem that is the scenario in India. Majority of the public is not aware about GMOs in detail whatever they hear, understand with their best knowledge they take it in that way without finding the real fact and going through the actual details given by an expert or a person who has thorough knowledge of the these biotechnology. Awareness need to be created amongst the people relating to GMOs which can be a boon if used in a proper manner with regulatory framework by law. People need to understand the true nature of biotechnology which includes many techniques which is being used to add, delete, or modify genetic information or formation in plant, animals or microbe, such agro biotech which is being used in crops like Bt corn, Bt Cotton, disease-resistant papaya etc.

In the landmark case of *Diamond v. Chakrabarty*<sup>3</sup>, the United States Supreme Court held that a genetically engineered bacterium qualifies as patentable subject matter under general federal patent law. Certain varieties of bioengineered organisms may also qualify for protection under the Plant Patent Act or the Plant Variety Protection Act. After the decision in Diamond case it lead a revolution in genetic engineering, in California biotech firm Calgene promoted as longer shelf-life tomato defunct Flavr Savr tomato which was first genetically engineered wholefood crop in 1994 and since then series of other genetically modified foods and crops were released for commercial production which were herbicide-tolerant like varieties of corn, soya, canola, cotton, disease-resistant papaya and squash etc. Biotechnology which deals with genetic engineering of plants and food is known as ‘*Green Biotechnology*’ which is applied to agricultural processes, producing herbicide-tolerant soybeans, Bt corn, Bt cotton and disease resistant fruits and food grains, like betacarotene enhanced rice, or India’s “Protato,” hepatitis B vaccine in banana, or reduced mycotoxin in Bt corn. Genetically modified crops were rapidly accepted and commercialized from 1996 across the globe. By 2010, genetically engineered crops were annually planted across 140 million hectares in 29 countries<sup>4</sup>. The technology was adopted on 42 percent of land planted to the four principal genetically engineered crops: corn, soybean, cotton, and rapeseed<sup>5</sup>. Twenty percent of all cropland was planted to genetically engineered seed<sup>6</sup>. Genetically engineered seed was planted to 70 percent of total soybean area, 25 percent of total corn area, 60 percent of total cotton area, and 20 percent of total rapeseed area<sup>7</sup>. The majority of genetically engineered crop arena was concentrated among a few countries that aggressively adopted the technologies: the United States and Brazil planted 85 percent of genetically engineered corn, and, with Argentina, 92 percent of genetically engineered soybean. Ninety percent of genetically engineered cotton was

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<sup>1</sup> Alan McHughen, What can Nanotechnology learn from Biotechnology? Social and Ethical lessons for Nanoscience from the debate over agrifood biotechnology and GMOs. “*Learning from Mistakes: Missteps in Public Acceptance Issues with GMOs*” Academic press is an imprint of Elsevier, Pg. 54

<sup>2</sup> Ibid

<sup>3</sup> 447 U.S. 303 (1980)

<sup>4</sup> Geoffrey Barrows, Steven Sexton and David Zilberman, “*Agricultural Biotechnology: The Promise and Prospects of Genetically Modified Crops*”, The Journal of Economic Perspectives, Vol. 28, No. 1 (Winter 2014), American Economic Association, pp. 99-119

<sup>5</sup> Ibid

<sup>6</sup> Ibid

<sup>7</sup> Ibid

planted in India, China, and the United States, while Canada alone planted 85 percent of genetically engineered rapeseed<sup>8</sup>. Numerous surveys proved that genetically modified crops in various countries increased the yield of the crops. Qaim (2009) summarizes impact studies, finding yield gains of 37, 33, and 24 percent for the insect-resistant genetically engineered Bt cotton in India, Argentina, and China, respectively<sup>9</sup>. Consumers in the various part of the globe capture 6-30 percent of total benefit. A case study by Kathage and Qaim (2012) in India showed that adoption of insect-resistant Bt cotton resulted in a 50 percent increase in profit per hectare and an 18 percent increase in expenditures<sup>10</sup>. Genetically modified plants have been useful in many ways<sup>11</sup> like made crops more tolerant to biotic stresses (cold, drought, salt, heat, etc.)<sup>12</sup>, reduced reliance on chemical pesticides (pest resistant Crops)<sup>13</sup>, helped to reduce post harvest losses and increased efficiency of mineral usage by plants<sup>14</sup>, enhanced nutritional value of food (e.g. vitamin 'A' enriched Rice)<sup>15</sup>. Indian Agricultural Research Institute (IARI) has come up with an inexpensive algal biofertiliser technology for rice which gave higher grain yields have been demonstrated in field trials in various regions<sup>16</sup>.

It is argued by various people that genetically engineering is hampering the ecosystem and the environment but in contrast it is being observed that environmental risks posed by agricultural biotechnology, theory and empirical evidence suggest genetically engineered crops deliver environmental benefits by saving land and agrochemicals and by maintaining rather than diminishing agricultural biodiversity<sup>17</sup>. If we go by the traditional method of harvesting, in that more chemicals, pesticides and insecticides are being used which poses higher risk of infertility of the land, air pollution and emission of greenhouse gases which is a greater risk to the environment. On this condition science and modern biotechnology can be helpful and useful in form of genetically modified food which does not inherently transfer risk to human health as stated by various agencies.

Paarlberg (2010) surveys evidence from the British Medical Association, French Academies of Science, Organization for Economic Co-operation and Development, and the UN Food and Agriculture Organization in asserting that "GM foods and crops currently on the market have brought no documented new risks either to human health or to the environment<sup>18</sup>". If we go through the surveys and reports then it is evident that at present there is so far no risk in GMOs food and crops and they need the protection and the total success of future genetically engineered plant technologies, however, depends on legal regimes and safety regulations governing them. While going through this specific characteristic it requires a thorough determination of law as to look into its regulation like –

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<sup>8</sup> Ibid

<sup>9</sup> Ibid

<sup>10</sup> Ibid

<sup>11</sup> <http://www.sciencetuts.com/> "biotechnology and its application" accessed on December 15<sup>th</sup> 2016.

<sup>12</sup> Ibid

<sup>13</sup> Ibid

<sup>14</sup> Ibid

<sup>15</sup> Ibid

<sup>16</sup> Ibid

<sup>17</sup> Geoffrey Barrows, Steven Sexton and David Zilberman, "Agricultural Biotechnology: The Promise and Prospects of Genetically Modified Crops", The Journal of Economic Perspectives, Vol. 28, No. 1 (Winter 2014), American Economic Association, pp. 99-119

<sup>18</sup> Ibid

a) The scope for legal protection and promotion of GMOs for future generations and applying “Precautionary Approach<sup>19</sup>” which reaffirms the precaution language of Principle 15<sup>20</sup> of the Rio Declaration on Environment Development.

b) Exhaustion regimes for GMOs at regional and national level,

c) Formation of special rules and regulation in this regard for curbing misuse by multinational companies who exploits the farmers and creating monopoly in the market which indirectly related with farmers suicide somewhere.

In India GMOs are considered as a risk to the farmers because major cause for farmers suicide is GMOs which are manufactured and sold by multi-national companies in their own benefit and not in the interest of the society and in public at large. If we take the case of Monsanto which is a leading seed providing company in India which sells genetically modified seeds to the farmers and the poor farmers are totally dependent on the company for their seeds which are again sold at a very high price and not available elsewhere except the company. In 2002 they introduced their first Bt Cotton seeds which were high yield, pest and insect resistant wherein they assured to the farmer that after using the GM seeds they will have a high yield of crops and they will be benefited by the same and relying on the promises they started using them but the company failed to keep their promises in India. Monsanto again introduced its second Bt cotton seed which was again sold at high price and also needed use of pesticides which were again sold by the same company which created a monopoly leading to high debts incurred by the farmers. Monsanto misuses the patent even though if we go through the patent regime of India which does not allow patenting of seeds, which is exploitation of farmer's at the hands of company. It is being observed that they misrepresented the farmers by luring them to buy the genetically modified seeds stating that these seeds are going to have high yield, pest resistant, less water consumption etc. but the company failed to take into consideration that harvesting is totally dependent on monsoon and the seeds sold by them consume more water and were not pest resistant. The farmers earlier used to preserve the seeds for the next harvest in the coming year but that could not be done in case of seeds which were sold by Monsanto. Taking advantage of this the company sold the seeds at very high price for which the farmers took debts and due to failure of the harvest leading to suicide of farmer for which company is responsible. If we go through the data so far 3 lakh plus farmers committed suicide in India. The regulatory body in India has to take necessary steps to regulate and frame rules for curbing such menace and exploitation of farmers by the hands of company like Monsanto.

Majorly across the countries patent on GMOs are not protected and hardly protection is given to them and companies invest huge amount in research on advanced breed of various food crops. It is being observed that many new GMOs were stranded in the research and development pipeline, which may boost nutrient content of staple crops and such genetic engineering, can protect the crops from drought, flood and saline soils. Agro biotech needs a regulatory scrutiny which should be done carefully in the interest of public as well as the investor and innovator. Regulatory mechanism should be adopted in the arena of GMOs to balance and make coexistence of genetic food with organic food by evenly balancing pre-market testing and post market review of crops and food to look into the novelty of the crops and the type of safety risk assessment and risk management involved in it. Policy maker must take initiative to regulate agro biotech, by systematic risk assessment, laying down liability on the defaulter, educate and create awareness amongst the general public for their misconception

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<sup>19</sup> Cartagena Protocol on Biosafety, 2000

<sup>20</sup> Wrie principle 15

and misinterpretation for GMOs as Agro biotech has raised various ethical principles and debates are going in rounds to find the legal method to answer such ethical and social principles which are the outcome of GMOs.

If we go by utilitarian principle of *Bentham* which says “maximum Social Welfare” and “respect for rights” so in case of GMOs the consumer right to know about the product which is outcome of genetic modification is a basic right given by the legislature by recognising the rights of consumer under Consumer protection Act, 1986 which clearly lays down who is a “Consumer”<sup>21</sup>. Further the act has talked about various rights of the consumers like right to be protected from hazardous goods which are harmful to life or property, herein the farmers and consumers are not made aware of the risk involve in GMOs in India and they are subjected to be directly used in the market without being informed for the same. The multinational companies like Monsanto are taking advantage of poor regulation in India, the farmers are not aware about the side effects of this seeds on the health and on the soil in coming years, there is no data available which can show that they are being assessed well in consonance with all regulatory measures and in the benefit for the public. Utilitarianism simply defines ethical acceptability in terms of consequences and positive net outcomes of actions. Utilitarianism states that, “the greatest good for the greatest number”. The principle of maximum social good asserts that if a product does no harm, and produces some desirable social outcome, it is ethically acceptable<sup>22</sup>.

Agro biotech helps to feed the population which is not possible by the traditional method, as agro biotech enhance yield of food, nutrients and benefit the farmer as well as the consumer but the concern left over here is about the rules and regulation of such GMOs and the companies selling them. If we go by *Dworkin*'s rights principle it says, “Rights are trumps against other socially desirable goods or goals<sup>23</sup>”. People have right to get food clothing and shelter without which their rights have no existence, survival of a person is when he get food<sup>24</sup> and all have equal right<sup>25</sup>, which can be better given by using modern biotechnology to enhance quality, quantity and nutrients of food and can help in sustainable development in India. If we go by Social Engineering theory by Roscoe Pound it say, “Maximum satisfaction of wants with minimum friction”, agro biotech is helping in satisfying the increasing need of people for food which is possible through modern biotechnology but then we need to have strong laws for dealing with defaulter or wrong doer who take undue advantage of lack of regulation in India. John Locke theory of Interest says the person who has invented something and which is outcome of his intelligence or labour that person should be given incentive for his labour and from this point of view patent law can give protection to the innovator of agro biotech wherein they can exploit their goods at reasonable price and in the interest of Public at large.

Today green biotechnology had grounded well in the agricultural farming to improve, add nutrients or remove the unwanted defects from the food grains. Agro biotech is also helping to tackle the scarcity of food as the enhanced breed of grains are disease-resistant which were unforeseen and undesirable properties, presently in India we have 14 GMO crops

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<sup>21</sup> sec. 2 (1) (d), Consumer Protection Act, 1986.

<sup>22</sup> Jeffrey Burkhardt, What can Nanotechnology learn from Biotechnology? Social and Ethical lessons for Nanoscience from the debate over agrifood biotechnology and GMOs. “*The ethics of Agri-food biotechnology: How can an agricultural Technology be so important?*” Academic press is an imprint of Elsevier, Pg. 87

<sup>23</sup> Ibid

<sup>24</sup> Art. 21, The Constitution of India

<sup>25</sup> Art. 14, The Constitution of India

and food available in market and widely available in the market without being labelled. GMOs foods and crops are misused against farmers and consumers which are the victim of exploitation at hands of companies like Monsanto. Agro biotech advancement has left behind conventional plant breeding which remained inherently random and slow but this technology has give a boost to the increase in yield and add nutrients to the ordinary crops which are definitely benefited when used in regulation with the norms, rules and law. In contrast, agro biotech employs the modern tools of genetic engineering to reduce uncertainty and breeding time and to transfer traits from more distantly related to plants<sup>26</sup>. Critics express concerns that technology imposes negative environmental effects and jeopardizes the health of those who consume the “*frankenfoods*” and supporters emphasize potential gains from boosting output and lowering food prices for consumers<sup>27</sup>, with that agro biotech farming practices had lower or minimize use of agrochemicals and reduce soil erosion due to GMOs technology. Since 1996 it is evident that farmers adopted enhanced agro biotech and thereafter it started commercializing in the market and with it inventors started protecting their invention under Intellectual Property Rights. Opponents of such agrifood put forth various arguments posing various environmental issues with genetically engineered seeds which need to be scrutinized even though they are benefiting the consumers by framing down stringent penalty for not following the rules and regulation on the defaulter. The policy makers also have to see that innovation should take into consideration due risk with such modification of each new trait of genetic modified crops and policy must be incorporated to not only benefit innovators but protect the small farmers and the consumers. In 21<sup>st</sup> Century to feed world population is a challenge where GMOs can help to feed the fast growing population and cater their needs. The traditional mode of agriculture which is failing to cop up with food crises and over growing demand of such a huge population in which use of huge amount of chemicals leading to soil erosion and infertility of the soil will surely have an impact on human health and also on the ecology. With such problems with traditional agriculture technique, agro biotech with the help of GMOs is the need of the time.

Today people across the world think that GMOs are harming the ecosystem and endangering the environment. They also raises issues on ethical bases that we are going against the mother nature by exploiting it by agro biotech which will have also health issues to human being who consumes such GMOs. It is assumed that GMOs are harming the organic crops and habitats through weeds, rains, wind etc. Harmonization of the GMOs and organic plants must be segregated by labelling them and making the general public the part of policy making in India. Further the problem with GMOs is that, there are no uniform protections, Convention or treaty in the world. In India GMOs plants and crops are regulated by Environment Protection Act, 1986 (EPA) when it comes to ecology and environment protection with that we have Protection of Plant Varieties and Farmers’ Rights Act, 2001 and now by the Protection of Plant Varieties and Farmers’ Rights (Amendment) Rules, 2016, but there is no legislation to govern the GMOs. There are various regulatory bodies in India when it comes to use, handling and transfer of GMOs The EPA Act 1986 and Rules 1989 of **Ministry of Environment and Forests**, Genetic Engineering Approval Committee (GEAC), Biotechnology Coordination Committee under the GEAC functions as the legal and statutory body with judicial powers to inspect, investigate and take punitive action in case of violation of statutory provision under EPA. Review Committee on Genetic Manipulation (RCGM) under the **Department of Biotechnology (DBT)**, Recombinant DNA Safety Guidelines, 1990, Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic

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27 Ibid

seeds, plants and plant parts, 1998 are again under DBT. IBSC is the nodal point for interaction within an Institute, University, Commercial Organization included in rDNA research or implementation of rDNA guidelines and also at State level we have State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC).

If we go through the Preamble of WIPO<sup>28</sup> says-The Contracting Parties,

**Desiring** to make a contribution to the progress of science and technology,

**Desiring**, to perfect the legal protection of inventions,

**Desiring** to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase efficiency of their legal systems, whether national or regional, instituted for the protection of inventions by providing easily accessible information on the availability of technological solutions applicable to their special needs and by facilitating access to the ever expanding volume of modern technology<sup>29</sup>.

Biotechnology Regulatory Authority of India Bill (BRAI) 2013<sup>30</sup> was considered as dream legislation for biotechnology when it comes to GMOs, but unfortunately the bill lapsed and henceforth there is no legislation to govern genetically modified crops. Parliamentary Standing Committee Report on Agriculture 59<sup>th</sup> Report<sup>31</sup> was introduced to assess the benefits and drawbacks of the introduction of genetic modification in food crops in India. The major finding of the report was that, there are various shortcomings when it comes to GMOs regulatory framework in India. This committee report also highlighted about the trials of GMOs and there was no provision for mandatory consultation with the State Government for such activities. The report recommended that all ongoing trials of the GMOs should be stop in India as at present there is no proper regulatory framework to see all the trials done in India of GMO crops. The Committee expressed their extreme displeasure at the response of GEAC, which showed a complete lack of concern towards its role and responsibility and rather conveyed its strong inclination towards the benefit of industry<sup>32</sup>. The Committee, therefore, recommended the Government to not leave such a crucial decision in the hands of GEAC but to come up with a clear-cut policy in this regard immediately<sup>33</sup>. The Committee feels that there should be no compromise even remotely on human health and environment by the use of antibiotic-resistance marker in GM crops<sup>34</sup>. It has been stated that since technology for generating marker gene technology is available, it is a matter of policy whether to allow GM crops with antibiotic resistance markers<sup>35</sup>. The Committee urges that the Government should formulate a policy in this regard without delay keeping the human health and environment in view<sup>36</sup>. The committee stated that there are concerns with Biosafety assessment of GM crops which is a multidisciplinary and scientific endeavour and so requires multiple kind of expertise in area of GMOs food and feed which is need of the time and urgent steps need to be taken in this behalf by the government by laying down policy in this behalf. The Standing Committee also recommended and also referred international convention and treaties Nagoya – Kuala Lumpur Supplementary Protocol (N-KLSP) which contributes for conservation and sustainable

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28 <http://www.wipo.int/pct/en/texts/articles/a0.htm> accessed on 1<sup>st</sup> August, 2016.

29Ibid

<sup>30</sup>[The Biotechnology Regulatory Authority of India Bill, 2013, Lapsed Bill](#)

<sup>31</sup> Parliamentary Standing Committee Report on Agriculture “*Cultivation of Genetically Modified Food Crops – Prospects and Effects*” 59<sup>th</sup> Report, Presented to Lok Sabha in 2014

<sup>32</sup> Ibid

<sup>33</sup> Ibid

<sup>34</sup> Ibid

<sup>35</sup> Ibid

<sup>36</sup> Ibid.

use of biodiversity by providing rules and procedures on liability and redress damage done to the ecosystem. Other international conventions and agreements governing the GMOS are WTO are mainly involved in establishing rules for international trade in GM foods; a) Two agreements in the WTO apply to risk assessment and labeling of GM foods & b) Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). Organization for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO), World Health Organization (WHO) and Codex Alimentarius Commission (CAC). The general consensus of these organizations has been that the safety assessment of GM foods requires an integrated and stepwise case-by-case approach and with that we need to have precautionary approach.

India is being part with the high tech technology, but it is behind all other countries which have laid down various laws for governing GMO crops and product, name them the few are European Union, China, USA, and Australia etc. we have majorly sign all the international convention in India but we are failing to make policy to govern GMOs in India relating to the food safety, risk assessment, standardize authorities to strictly apply the rules and regulation in India. India need a strong policy relating to GMOs food, feed, crops and products so that the general public is not misguided and does not raise question on the GMOs. India needs to have a mechanism which will implement rules and regulation in letter and spirit of the laws. The public must be made a part of policy making and details pertaining to GMOs must be *communicated to the public* so that the average consumer is rightly informed and misinformation is minimized leading to debates and controversies. There needs to be transparent mechanism for policy making for GMOs. The government should assist and foster a expertise mechanism which will help in risk assessments and risk management of GMOs and also creating public awareness. Compliance of all procedure should be made strict and right to information and education should be available to the public to have a clear transparency in the system for regulation of GMOs. There must be a effective risk management at District, State and National level including monitoring systems, research programmes, technical training and improved domestic coordination amongst government system. Public awareness and participation can be one of the major key if they are informed and involved by the government for decision making and framing policy.

### **Conclusion**

Agro biotechnology has brought drastic and innovative changes in the lifestyle and the products of daily use in day today life with that brought various pros and cons with it. Now a day due to globalization the world has become a global village and we have to be at par with other countries and have to legislated law on GMOs in India. The GMO industry is successful which has witnessed consistent growth over the past few decades. It is the need of the time to balance the need, risk and make new policies with rules and regulation for GMOs. Such kind of agro biotech can be a boon if used in a regulated manner in the welfare of the society.

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