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Illegal Seeds and Regulatory Delinquency: Regulatory Vacuum in the Governance of Biotechnology in India

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Abstract

The recent controversy over the illegal and unapproved use of Bt brinjal in the fields of Maharashtra once again raises questions on the paradoxical nature of governance of Biotechnology in India. Most of the academic and policy literature on the regulation of biotechnology focuses on state institutions and procedure. After the introduction of Bt cotton in the late 1990s and the 'Bt brinjal controversy' on the commercial introduction of Bt Brinjal in mid 2000s, and recent controversy on the illegal cultivation of GM seeds and Kisan Satyagraha, biotechnology and life sciences have become contentious subjects in India. These three decades (1990-20120) represents a unique point in history in which India has tried to address different kinds of ethical, socio-political, legislative and administrative dilemmas related to agricultural biotechnology. In this context, this paper will explore the regulatory issues related with transgenic technologies in India.

Keywords: Biotechnology, GM Crops, Governance, Public Engagement, Civil Society, Agriculture, Bt Brinjal.

Introduction

The recent controversy on the illegal cultivation of Bt brinjal in Maharashtra and subsequent legal action against farmers and Kisan Satyagraha under the farmers organizations triggered the debate about the exiting regulatory architectures of the country and its working culture. Since the 1980s, applications of Genetic Engineering technologies in agriculture became a site of contestations and it produced mixed responses in the society. On the one hand, the policy makers, mainstream scientist and technocrats consider biotechnology as a solution for the local and global food crisis due to the

unprecedented increases in the population. On the other hand, environmentalists, anti-globalisation activists, and various groups of farmers who consider this technocratic intervention in agriculture as a threat to the environment, biodiversity and local agricultural systems. Largely, there were multitudes of stands and frames on the application of biotechnology and GM crops in agriculture.

After the introduction of Bt* cotton in the late 1990s and the 'Bt brinjal controversy' on the commercial introduction of Bt Brinjal in mid 2000s, and recent controversy on the illegal cultivation of GM seeds and Kisan Satyagraha, biotechnology and life sciences have become contentious subjects in India. These three decades (1990-20120) represents a unique point in history in which India has tried to address different kinds of ethical, socio-political, legislative and administrative dilemmas related to agricultural biotechnology. There are different studies on the risks and benefits of biotechnology, its effects on biodiversity and sustainable agricultural practices, as well as on the corporate takeover of agriculture and its impact on small scale farmers (Chaturvedi, S; 2002, 2010, Bhargava, PM; 2009, Visvanathan, S. and Parmar, C. (2002)). These studies looked different aspects of transgenic technology regulation in India. since second half of 2000, the debate about transgenic technologies in India focused on the Bt brinjal and its commercial release.

Back Ground of the Controversy

In India, Brinjal is the second most popular vegetable after potatoes (Rajam. M V. et al. 2008). Its importance in the dietetic practices, medicinal value, biodiversity etc. made this vegetable popular among common people and genetically engineered brinjal triggered debate in the last decades. Another important reason for this public appraisal against or for Bt brinjal is that India is the place of origin of this vegetable and there are around 2400 verities of brinjal in the country with different shapes and various colors. The development of new Bt brinjal by inserting a bacterial gene (cry1Ac) derived from Bacillus thuringiensis (Bt) which resists infection from various pathogens opened up a new debate and discussion in the context of India.

The official reason for the introduction of this new technology in the traditional brinjal was to prevent high level of loss due to the fruit and shoots borer (FSB, Leucinode orbonalis) most common insecticide which weakens the plant and reducing yield. It caused 70 percent of the loss of the Brinjal output and led to the heavy use of chemical pesticides in the field to resist insects. On the other hand, those who oppose these arguments state that there are a number of domestic and wild varieties of Brinjal in our country. The introduction of transgenic Brinjal leads to the loose of varieties due to cross pollination and gene flow. And Genetically Engineered Brinjal will have adverse impact up on human health and environment. The controversy on Bt brinjal gives us a black and white picture of the story. This 'science war' between pro and anti-bt brinjal advocates didn't touch up on the gray areas in the debates and dynamics of the issues involved in the genetic engineering technology.

* Bacillus thuringiensis is a soil bacterium that carries in its DNA a gene which produces a toxin for certain insect pests (cotton bollworm, Asian and European corn borers). By transfer of this gene into the plant DNA an automatic resistance is developed in the plant against such insect pests.

In India Bt brinjal is developed by Maharashtra Hybrid Seeds Co (Mahyco) by inserting a crystal protein gene (Cry1Ac) from the soil bacterium Bacillus thuringiensis into the genome of brinjal. Mahyco obtained license to use Cry1Ac from Monsanto. The first agreement to develop Bt Brinjal was signed in 2005 between Mahyco, and two agricultural universities - University of Agricultural Sciences, Dharwad (UAS) and Tamil Nadu Agricultural University (TNAU) in Coimbatore. When Mahyco approached regulatory agencies for approval of Bt Brinjal commercial release, two expert committees were formed in 2006 and 2009 to examine the biosafety data submitted by the company. Both EX-1 and EX-11 nod for the approval of the event by stating that "the benefits of Bt brinjal event EE-I developed by M/s Mahyco far outweigh the perceived and projected risks", and they recommended to GEAC for the commercialization of the Bt brinjal.

In 2009, its commercial release was approved by the Genetic Engineering Appraisal Committee under the environment ministry, but the outcry of the civil society and farmer's organization forced then Union Environment Minister Jairam Ramesh to stop its release in February 2010. After Nationwide public consultation government put an indefinite moratorium to the environmental release of transgenic bt brinjal in India. But, after three years, four varieties of Bt brinjal, developed by Mahyco and the Bangladesh Agriculture Research Institute, was approved by the Bangladesh government for commercial release.

Illegal Seeds in the Indian Agriculture

Recently transgenic technology became a site of public controversy in India following the news report of illegal Bt brinjal found in field of Hariyana in April. It is reported that Genetically Engineered Bt brinjal is being illegally cultivated in Fatehabad district of Haryana. This report and following controversy raised different questions on the process of regulation of biotechnology as well as the regulatory institutions. In a press conference on April 23, Prof. Rajinder Chaudhary of Kudarti Kheti Abhiyan, along with other civil society organizations and scientists, reported his discovery of a farmer in Fatehabad, Haryana, growing Bt.Brinjal. Even in the absence of the application of insecticides for the pest, the immunity of this particular brinjal to attack of 'Fruit and shoot Borer' insect arose suspicion among the farmers and civil society groups. The Bt brinjal is developed particularly to resist 'Fruit and shoot Borer' insects.

Civil society groups and Haryana government picked up samples of the suspected Bt. Brinjal crop and sent it different private and government testing laboratories to confirm presence of Bt brinjal. And different test proved positive for Bt crylAc. They also submitted samples of this brinjal plant to the Director General of Horticulture and of Agriculture in Haryana government and central government's regulatory body Genetic Engineering Appraisal Committee (GEAC) for further investigation. As a response to this report, civil society activist and legal experts wrote a letter to Minister to take proper actions against the culprits. The GEAC approached Haryana state government to investigate this issue and under Sections 15-17 of the Environment Protection Act, 1986, which has provisions to deal with illegal cultivation of GM.

Back Door Entry and Regulatory Delinquency

This Bt brinjal is the latest in the list of illegal seeds cultivated in Indian fields in last two decades. This kind of regulatory ‘overtake’ is very frequent in the history of Indian regulatory architecture.

In 2001 seed companies and regulatory agencies are found that illegal Bt cotton was cropped up in the fields of Gujarat. In 2009 illegal herbicide-tolerant (H) cotton and Bollgard cotton, or BG 3 was found in Andra Pradesh and Maharashtra. From the regulatory point of view in India the only legally sanction Bt cotton is insecticide-containing Bt cotton or Round Up Ready technology, which protect cotton plants from to external threats. In 2017 herbicide-tolerant (HT) soybean spread across the fields Gujara, Maharashtra and Telangana. In February illegal sowing of HT (herbicide-tolerant) cotton has found in Andhra Pradesh and government cancelled the licenses of one Seed Company and suspended licenses of 13 other companies for one year. And now organic farmers identified illegal and unproved Bt Brinjal in the field. All this moves epitomize the back-door entry of GMOs into India agriculture and market.

Here we can see a parallel between the entry of Bt cotton and Bt brinjal. Bt cotton entered in to the market and to the field through the illegal roots. In 2001 Mumbai-based Mahyco, the applicant for permission to sell GM cotton seeds in India, conformed that illegal GM cotton seeds are sold out in Gujarat and farmers are using it in their fields. And found out that about 10,000-13,000 acres have been sown with this illegal Bt cotton in Gujarat, other than Maharashtra and Andhra Pradesh. As a response, Raju Barwale, MD of Mahyco, wrote a letter to the Department of Biotechnology and other authorities to take action against the illegal seed distributers. The GEAC asked the Gujarat government to take immediate action and burn down the crop.

This blatant violation of biosafety rules and regulatory procedure happened while Modi was the Gujarat Chief Minister. When GEAC conformed the violation of biosafety rules and regulations it ordered to burn down the crops and uproot issue a public warning in regional newspapers. It also ordered to retrieval and destruction of seeds from farmers' houses and ginning mills and procurement of all yet-to-be harvested crops from farmers. Because of the farmers organized resistance then Gujarat government could not do anything at all. Here political interest and farmers protest overruled the regulatory procedure and actions.

Vacuum in Regulatory Architecture

Since 2010, there have been five official reports which questioned the legitimacy of the existing institutional frameworks and official mechanism to regulate GMOs in India. The 'Jairam Ramesh Report' after a series of consultation with different stakeholders issued an order in February 2010 imposing an indefinite moratorium on Bt brinjal and it overturned the approval of GEAC to commercialize Bt Brinjal in India.

The committee constituted by Indian Council of Agricultural Research (ICAR) under Sopory submitted its report on August 2012, which raised serious question about transgenic regulation in the country. The Sopory Committee stated that the existing institutional set ups for the regulation of transgenic technology is 'lacking scientific expertise in GM technology, scientific deception and fraud, regulatory inefficiency and lack of monitoring and oversight' (Sahai, Suman 2015). Furthermore, the Parliamentary Standing Committee (PSC) on Agriculture chaired by Sri Basudeb Acharia submitted its final report on GM crops in August 2012, which also pointed towards the flaws in the implementation of GM technology in India agriculture. The committee "recommended that Indian government must not allow field trail of GM crops till there is a strong, revamped, multi-disciplinary regulatory system in place" to look after the R&D of transgenic plants and its

implementation in agriculture. It also highlighted the shortcomings in the existing regulatory institutions such as GEAC and RCGM in their functions, compositions, power and mandates. It recommended a new transparent mechanism to address these flaws in the regulatory mechanisms.

The supreme court of India constituted TEC as a response to write petition failed by Aruna Rogriguse from Gene Campaign in 2004. In 2013 Technical Expert Committee (TEC) submitted its Final Report on June-July. In its interim report in 2012 TEC stated that "based on the safety dossiers, the TEC has found in unambiguous terms that at present the regulatory system has major gaps and these will require rethinking, investment and relearning to fix. A deeper understanding of the process of risk assessment is needed within the regulatory system for it to meet the needs of a proper biosafety evaluation. This is not available in the country at present. It is therefore recommended that the requisite understanding be developed through consultation, collaboration and capacity building" (TEC:2012). To address this issues TEC recommended different corrective measures such as 'Stakeholder participation, need, socioeconomic considerations, societal impact, and sustainability should be some of the dimensions to be incorporated in the risk assessment and this should be done at an early stage in the risk assessment process' (Parsai, Gargi:(2013).

And latest report by high-level committee chaired by T S R Subramanian to review six laws concerning with environment not only cautioned the country about the application of GM technology but also highlighted the need of keeping vigil in the context of environmental release of such product. All these official reports suggested a precautionary regime in the governance of transgenic product in the country. Jairam Ramesh's report implemented indefinite moratorium to Bt brinjal and called for strengthening regulatory mechanism before grading permission for field trail. TEC suggested ten years of moratorium for all GMOs in the food sector. Some commentators recommended for a serious of measures to handle the governance issues.

In the case of Bt Brinjal, the prevailing secrecy and lack of accountability and transparency, especially in the release of biosafety data and toxicity information, led to the loose of public trust in the executive system. The academes' report[†] and question on trust in expert bodies in producing objective knowledge for policy relevant issues come under the shadow of plagiarism and conflict of interest (Menon, G.I & Siddharthan. R: 2015). At another level there are anxieties about promoters becoming regulators, especially in the case of the Department of Biotechnology becoming both promoters and regulators at the same time.

There is also conflict of interest among different ministries such as the Ministry of Science and Technology, Ministry of Environment, Forest and Climate Change and Ministry of Agriculture. For instance, while the Ministry of Agriculture supports the introduction of GMOs, the Ministry of Environment proposes a precautionary policy before commercializing it. Ironically, in the regulatory level, the members of the regulatory body such as GEAC are members of the multinational funded research institute and companies they produce and promote transgenic crops.

[†] 'Environment Minister Jairam Ramesh had asked the six science academies - the Indian Academy of Sciences, the Indian National Academy of Engineering, the Indian National Science Academy, the National Academy of Agricultural Sciences, the National Academy of Medical Sciences and the National Academy of Sciences (India) - to give scientific assessment on the feasibility of transgenic crops and the proposed regulatory mechanism for GM food. They submitted the report to Jairam Ramesh and recommended the commercial release of Bt brinjal' .

All this factors collided in a regulatory delinquency in the country and marked the failure of the existing regulatory architectures.

The failure of GEAC to develop and implement a comprehensive regulatory practice also led to the intervention of judicial system to look in to the matter of governance. The GEAC has failed to implement different rules and regulation put forwarded by Environment Protection Act and the Rule of 1989. Without a proper regulatory mechanism proposed by the environment protection act such as establishing state and district biotechnology coordination committee, GEAC allowed field trails in different states. This led to the increases in illegal cultivation and marketing of Bt cotton in different part of the country.

Critics against Normative Institutions

Different people also raised different concerns against existing regulatory architecture, as Sunita Narain, director; CSE stated "[C]clearance of such a crop requires the authorities to practice extreme caution. Currently in India, there is no labeling regime for genetically modified foods which will give consumers a choice to make a decision whether they want to consume genetically modified food or not. Till the time this is done regulators should not clear edible GM crops"[‡]. Along this line there has been different call from diver's corners to strengthen the regulatory framework in various levels (Sheelendra: 2015) to address the delay in commercialization of GM products, in grading permission for the field trials, etc. As Ian Scoones (2012) stated 'biotech regulation in India needs an overhaul. There are too many overlapping responsibilities, unclear mandates, and lots of red tape. Regulatory delays result in losses of revenues for businesses, and the lack of transparency and unclear procedures are frustrating for applicants and opponents alike' (Scoones, Ian : 2012).

For Suman Sahai, (2015) scientist and founder chairperson of Gene Campaign, "The government must make a new beginning with a review of the existing reports and hold consultations to improve the regulatory system. Much thought and many inputs have gone into defining the contours of a rigorous and a credible regulatory system that can evaluate both the scientific and socio-economic impacts of GM crops. The output of such a review will enable policymakers to take correct decisions about this new and dichotomous technology" (Sahai, Suman: 2015). These focused critics on existing regulatory regimes looked at three important issues in the regulatory epistemology. The first point is the lack of epistemological and institutional base for conceptualizing and implementing rules and regulation. 'Uncertainty' in different level, such as in scientific and technical knowledge and in the socio-political and ethical domain created uncertainty in governance as well. Other than this, the lack of financial and human resources limits the operation of the regulatory rules and frameworks.

As some studies highlighted, the limits in infrastructure create constrain the scope of biosafety assessment. The second, the problem at our hand is 'complex' and 'socio-technical' in nature. This complex socio-technical 'assemblage' can't fix with some technical tools; it demands a socio-technical solution. Science based approach has to acknowledge that it has limits and the assessing

[‡]Times of India (2009) Bt brinjal debate goes to people, October 16. Accessed on 26, October 2016. http://timesofindia.indiatimes.com/india/Bt-brinjal-debate-goes-to-people/articleshow/5128675.cms

biosafety issues have technical limits. Third, the existing rules for regulation of transgenic products and programs focuses on biosafety issues and it ignores the socio-economic-ethical and political question. Fourth is the lack of accountability and transparency in the operation of these institutions and procedures.

The regulatory architectures of the country is based on or heavily drawn from the environment act of 1986 and the rule of 1989 developed around three and half decades. As critics pointed out the existing rules, especially rule of 1989 are not capable to address new regulatory challenges posed by the new development in the area of transgenic technology. And the institutions and regulatory agencies established under these rules lack technical competency to tests, monitor and track new biosafety issues. In another level these rules and institutional set up lack transparency and accountability in their decision making and policy formulation (PM Barghava, Interview).

Choudhary, B, et. al (2014) pointed out three important loopholes in the existing regulatory mechanism. First, in the EP Act 1986 the GM crops are listed under 'hazardous substance' and considered as 'inherently harmful' to health and environment. By assuming GM crops as inherently harmful leads to different kind of misperceptions about the safety and potential risk of GM crops to health and environment. Second, the Rules 1989 to regulate transgenic crops were issued by an 'administrative order'. The Ministry of Environment and Forest can make any change whenever they feel, which affects the credibility and predictability of the regulations. Other ministries, such as health, agriculture and industrial development are kept away from the policy table. Finally, the conflict between centre and state is very much obvious under the Rule 1989. Union environment ministry is the in charge of regulating GM crops in India whereas agriculture at large is under the State(s) governments. It leads to difference in the perspective from which they look at the regulatory issues and contradictions in the decisions they take.

As Reid & Ramani (2012) pointed out "There are also wide gaps between theory and practice of regulation as enforcing compliance is a major problem. Sometimes, it is downright impossible as was the case in the commercialization of Bt cotton. The main private stakeholders, the firm (Monsanto -Mahyco-Biotech Ltd) and the intermediate buyers of the genetically modified seed — namely farmers, openly fluted regulation" (Reid & Ramani, 2012).

From early 1990s to recent time there are lot of international protocols and guidelines such as Agenda 21 (1992), the UN Convention on Biological Diversity (1992), the Biosafety Protocol (2001), the UNEP Technical Guidelines on Biosafety (1995) and UNIDO Code of Conduct for the Release of Organisms into the Environment (1991) and the International Treaty on Plant Genetic Resources (2001) etc. And India is a signatory of different protocols and Conventions. As Ujjwal Kumar, policy analyst at the Gene Campaign said "These international instruments have certain provisions that are not reflected in current regulations. For instance, the Biosafety Protocol provides for public participation in the decision making process concerning genetically modified organisms. India has signed and ratified this protocol but our regulatory system does not have any window whereby public can participate. Neither is there a systematic opportunity for the public to obtain relevant information (like field trial data) so that they are well informed to participate[§]"

[§] Quoted in India Together (2004)

It has been observed that the seed industry has been lobbying with the committees, especially the GEAC. In 1995, MAHYCO, the Indian seed company imported cotton seed with Bt gene after obtaining permission from the RCGM, and not the GEAC, which is empowered to monitor the "manufacture, use, import and storage of hazardous genetically engineered organisms or cells". In 1998, Monsanto-MAHYCO carried out open field trials in 40 locations in nine states without obtaining permission from the GEAC. These developments have raised serious doubts about the regulatory bodies' commitment to transparency and democratic decision making (Haribabu. E 2004). So, the important challenge before policy makers in India is 'how to combine institutional mechanisms to generate legitimate policy-relevant science with those that can ensure that societal concerns have a systematic rather than ad hoc place in risk governance' (Gupta Arti: 2012). In the case of Bt Brinjal "GEAC had not done as comprehensive a job as it should have. It had not listened to voices within GEAC" (Ramesh: 2015).

Along with these, the new forms of 'technocracy' controlled over the regulatory processes and the instrumental rationalities and technical or functional world views got prominence in the decision making process. The excessive bureaucratic norms and regulation is another issue related with regulatory institutions. As in different domain problem of 'red tap' create regulatory delay and miss management in the country. On the other side, the social values, collective demands, socio-political interests are kept aside while considering for regulation. It leads the process of over scientization of socio-political issues related to agriculture and application of transgenic technology. This scientisation of regulation emphasizes a standardized and formalized account of governance against more contextual and situates practice of governance. The biotechnology regulation, especially biosafety regulation in India looks at international standards and frameworks to translate those in to Indian context. It ignores socio-cultural and bio-political peculiarities of the country and its implication on agricultural development. It also ignores the public participation and inclusion of different 'framing' such as socio-political and ethical in issues in the rules and institutions of transgenic regulation.

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