FOUNDATION FOR BIOTECHNOLOGY
AWARENESS AND EDUCATION, BANGALORE

GENETICALLY ENGINEERED CROPS IN INDIA

A Gordian Knot Needing An Alexandrian Solution

C Kameswara Rao and Seetharam Annadana

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FOREWORD

Science produces not only our greatest public goods, but some of our most contentious politics. The history of denying progress in science and technology is long and embarrassing to our self-perception as a species endowed with reason. The genomics revolution in biological science produced tools for many fields of human endeavor unimagined a century ago. Most of the advances induced by genetic engineering have met with public appreciation or quiet acceptance. In pharmaceuticals, medicine and industrial applications, recombinant DNA technology has been widely accepted as providing useful tools and thus progress toward betterment of the human condition; in agriculture, products using these same tools have been marked off and stigmatized as 'GMOs,' evoking almost universally an aura of unique risk.

National governments and international bodies have responded to public concerns about risks from genetic engineering in agriculture with protocols and institutions to assure biosecurity along multiple dimensions: allergenicity from novel proteins, weediness, gene flow, etc. Assuring mass publics that risks are being investigated and addressed is by necessity reliant on systematic investigation of consequences: in a word, science. As with pharmaceuticals, tests of new agricultural crops are designed to provide data for rigorous assessment of safety and risk. The reasons are obvious: we rely on science, full stop, in the major life-and-death decisions of our lives. That human insulin is produced by a GMO prevents almost no one from use, certainly not diabetics.

Yet science itself has become an object of contentious politics in this sphere of collective knowledge. Results of commonly accepted procedures for testing plausible *hazards* of transgenic plants - without which there can be no 'risk' in a true sense - are attacked by political forces opposed to the technology itself. That is, objections are not to the safety of any particular product for any specifiable reason, but to the way it is made, the way traits - such as resistance to insect pests -- are introduced in plants. Assurances of safety based on normal scientific procedures and global literature go only so far in some countries at some times; there is much resistance to genetic engineering of crops for farmers, especially in cities. State officials are accused of being duped by 'science' produced for corporate interests backed by corporate money. No matter how many tests are run, all are discounted and yet more are demanded.

These demands often constitute an absolute obstacle to moving technology forward: there must be more testing, but testing under actual field conditions is held to be too risky. Ironically, risk cannot be assessed because assessment is said to be unacceptably risky. Logically, 'proving' absence of risk is essentially impossible, just as no one can 'prove' there is no life on other planets. Neither the common peanut nor the airplane could have met the demands for proof of absolute absence of risk demanded of many opponents of genetically engineered crops. Indeed, it is literally unimaginable what tests from normal science could conceivably eliminate all uncertainty among all stakeholders. Sociology of knowledge alone suggests the reason: organized groups around the world remain unconvinced by the science supporting evolution, the safety of vaccines, viral origins of AIDS, or global warming. The political opportunity structure for opposition to scientific consensus is vast in scope and depth and there is virtually no sphere of science without a dissident fringe to confirm conspiracy fears. Science and scientists -- and policy makers reliant on both -- then face a very difficult situation. Risk-averse public demand certainty; science can respond only with "given the current state of knowledge." All science is thus inevitably incomplete, and vulnerable to politics by its very epistemological commitments: tentative results subject to continuous revision driven by better evidence or better tests or both. And yet without science the state of the species would be bleak, to say the least.

In contrast to this inherent vulnerability of science, the political potential of opponents of biotechnology in agriculture is boosted by multiple levers. The first is fundamentalism, which in every sphere has adherents whose absolute certainty is itself a political resource. Field trials in India present a telling example. If we are to know the risks - i.e., a probability distribution of hazards - of biotech crops, we would need to do multiple trials in different agro-ecologcal zones and conditions. There is no other way to know either the risks *or the benefits* of new technologies. The crops have to grow up outside the laboratory, exposed to conditions of real agriculture. Only then can we know the answer to questions of plausible risk and potential benefit. Opponents of genetically engineered crops in India, as in some other countries, know the answer before they do the tests: field trials themselves are inherently too risky to sanction. This proposition follows from a fundamentalist construction of agricultural biotechnology as unacceptable regardless of absence of evidence of hazard or demonstration of benefits. Risks thus remain hypothetical - that is, no hazards have been demonstrated -- and demonstrable benefits do not become a matter of public discussion or policy concern for want of systematic evidence. There can be no balancing of risks and benefits since obtaining the facts needed for such assessment is blocked by partisan politics.

This dynamic prevented the commercialization and cultivation of *Bt* brinjal in India after nine years of testing and scrutiny. Interestingly, this blockage did not eventuate in Bangladesh, where the public-sector institution, the Bangladesh Agriculture Research Institute, developed cultivars from the transgene constructed and donated by the Indian firm Mahyco. The benefits demonstrated in field trials in India are appearing in actual fields in Bangladesh. In India, ironically, standard protocols likewise produced no evidence of hazard from the transgene in new hybrids or varieties, but proved insufficient to convince sections of the public and one minister with clout of the usefulness of the crops. *Bt* brinjal was proved guilty in India for lack of sufficient evidence of innocence. Lost in this political discourse were two key factors all of us use in our daily lives to assess choices: acceptable risk (e.g. air travel or surgery or pharmaceuticals with side effects) and comparative benefits (attending a wedding, removing a tumor, treating chronic disease). The balance is the deciding factor: taking an acceptable risk is a common outcome. Otherwise none of us would ever leave the bed -- or cradle.

This dialectic of risk and benefit encounters the Goldilocks Paradox of all regulation. Regulation by governments must strike a balance of risk and benefit given an assessment based on sound science. There really is no other way. The paradox introduced by Goldilocks is that the level of cautionary restriction on technology should be not too much, not too little, but just right - but it is hard to know where that balance

lies. Excessive regulation is suffocating; nothing moves, no new solutions can be found, no one will invest a life in searching for solutions. There would be no mobile phones, nor human insulin produced by a GMO. Too little precaution might produce hazards that entail unacceptable risk - one thinks of specific nuclear power plants in Japan. But in both cases, assessment depends on the best evidence available, and thus entails scientific assessment, monitored by public officials with full transparency. Getting the balance right is obviously hard. Getting it wrong is costly to the society as a whole. In India, political rejection of scientific conclusions of the Genetic Engineering Approval Committee was discouraging to public sector scientists who might contribute to new crops for India: if criteria for risk are essentially arbitrary, and state science can be overruled by a single politician, then investing a career in plant breeding at international frontiers of technology looks increasingly irrational. If there is no definable hazard, and no rational way to set levels of acceptable risk, scarce public resources are diverted to endless whirlpools of political and official turbulence rather than agricultural innovation. Uncertainty about regulatory outcomes as a consequence depresses investment in both public and private sector research and development. If effective and safe technologies are blocked, agriculture is needlessly crippled, farmers needlessly deprived. There are issues of democracy and ethics as well. Much of the 'GMO' debate evokes ethical principles of democratic decision-making and equality: everyman should pass on the science too, as expertise is an elitist project. Yet when populist mobilization discounts scientific expertise, the result seems ethically difficult to justify in a democracy. How could it be ethical to deprive farmers of the same technical progress urban people take for granted? To move up from field trials and protest petitions, to the global picture, climate change continually produces daunting challenges to agriculture and to global provisioning from the land. Under these conditions, ruling out any tools in the toolkit for ideological reasons constitutes risk very difficult to justify under any logic.

The success of *Bt* cotton in India illustrates the risks of suppressing technological innovation in agriculture. Without *Bt* cotton, both farmers and the environment - as well as the import-export balance and rural economies - would have fared far more poorly. Gains would have been foregone for no good reason. Claims that *Bt* cotton was 'suicidal,' or even 'genocidal,' in oppositional social networks and the media frightened a great many people and made acceptance of new applications of the technology - in fact the same transgene for the same trait in *Bt* brinjal - needlessly difficult. That this uneasiness about biotechnology has halted even field trials of new crops indicates the very real risks of fundamentalist approaches to agriculture. Without data there can be no assessment of hazard, and thus no idea of risk other than that conjured by imaginations. Discourses of threat do, however, resonate powerfully with a pervasive culture of risk in modern societies, fed by unsubstantiated claims of catastrophe - the idea that *Bt* cotton caused an epidemic of suicides in India, for example, or the death of livestock and bizarre human ailments. Such risk discourses are not harmless, nor without risk. To eliminate so powerful a tool as biotechnology from the toolkit of agricultural innovation on purely ideological and partisan political grounds would be an inexcusable assault on Indian agriculture, as the following essay so amply explains.

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Cornell University
August 23, 2014

PREFACE

Genetically engineered (GE) crops in India, opposed by virulent activism, faced an uphill task all the time. The regulatory regime was in place when Monsanto applied in 1990 to the Government of India (GoI) for permission to import the American Coker *Bt* cotton hybrid seed for backcrossing it with the Indian hybrids. This was rejected in 1993 on grounds of high technology costs, and some other considerations. However, a very similar application from Mahyco, without the element of technology costs and without the responsibility to introgress the American material into the Indian on the Indian public sector scientists, was approved in 1996 and field trials began, before they were actually officially approved for five States in 1998. Soon the activists, who have no holds barred and nothing to lose, became desperate and burnt field trial *Bt* cotton in November (Karnataka) and December (Andhra Pradesh) of 1998, projecting *Bt* cotton as an issue of grave public concern. By 2000-01 there was widespread illegal cultivation of *Bt* cotton in Andhra Pradesh, Maharashtra and more particularly in Gujarat, placing the regulatory oversight in bad light, but this has actually hastened the official release of *Bt* cotton for commercial cultivation in April 2002. And without this, India would not have had even a single commercialized GE crop today.

The Indian *Bt* cotton Events Bollgard I and II have performed exceedingly well dramatically changing the Indian cotton scenario to the immense advantage of the farmers and the country. Nevertheless, vehement and persistent activism trashed the demonstrated benefits of the Indian *Bt* cotton and targeted it for various assumed and presumed ills to farmers and the country. Problems were made to recur, new problems added, but none solved.

A number of developments caused immense damage to R & D and deployment of GE crops in the country, the more important being: a) a Writ Petition in the Supreme Court of India (SCI) pending since 2005, which helped the activists and the GoI to, i) impose a moratorium on *Bt* brinjal, ii) impose impracticable distances of separation between GE and non-GE crops and high levels of detection of transgenic proteins in non-transgenic crop samples, and iii) to withhold GE crop field trial approvals; b) the report of the Technical Expert Committee appointed by the SCI, which recommended a 10 year ban on open field trials among other unwarranted negative recommendations, c) the report of the Parliamentary Standing Committee on Agriculture which recommended that GE crop R & D may continue only in laboratories and the green houses, but all field trials should be stopped, and d) GEAC's

insistence on 'No Objection Certificates' from the State Governments before giving approval for field trials. Field trials in themselves do not constitute agriculture as the low volume products do not go the farmers, markets or consumers, but are essential to assess both risks and benefits and to balance them, under agricultural conditions. The activists and the GoI have ignored the overwhelming published evidence on the demonstrated benefits and safety of GE crops, based on 30 years of experience in regulatory research and 18 years of experience in commercial cultivation and consumption, in over 30 countries. All this has been a damper on the R & D activity of GE crops, going well in both public and private sectors.

The hope placed on the new government for a pro-science policy is yet to materialize. The product developers in both the public and private sectors are still reluctant to come out into the open and stand for technology and products, for the fear of antagonizing the GoI. The bureaucracy in the concerned Ministries, scientific community and the product developers are all wary of the aggressive stance of the activists. Unfortunately, the public is not aware of the causes, forces and international funding behind anti-tech activism and so are carried away by the din caused by the activists. Today the future of GE crops in India is very bleak.

GE crops offer a political platform for many, to make their otherwise anonymous presence, felt. It requires a bold and decisive action on the part of the GoI to change present situation for the better and to promote R & D and deployment of GE crops in India. Otherwise, soon the fringe groups dominate, and that would not leave any chance for the GE crops to get out of the present suffocation.

The major cause for the success of anti-tech activism is that there has been no adequate and appropriate communication among different stakeholders to enhance levels of awareness. The politicians, bureaucrats, the media and even some scientists have an incomplete understanding of issues of science, technology and regulation (which is science in itself), related to the GE crops. The activists have exploited this situation to hijack the agenda and with the help of pliable media, spread a lot of misinformation and disinformation, to create and sustain an emotionally charged atmosphere against GE crops. Communication among the pro-tech groups and reaching the public with factual information are crucial, more so now than ever. There is an equally serious and urgent need to educate the a) judiciary now hearing petitions on GE crops, and b) the media, who till now have publicized only the activist version of issues, severely affecting public acceptance of GE crops. The FBAE has been doing the job of communicating and enhancing awareness of issues of agricultural biotechnology through diverse means, since January 2001. This article is one more effort in this direction.

The present article should be read in conjunction with the Chapter *'Specific issues confronting development, biosecurity regulation and deployment of genetically engineered crops'* (Kameswara Rao, 2014), which discussed in greater detail several issues presented herein and many others such as a) the science of regulatory evaluation to establish biosecurity, b) misinterpreted regulatory science, and c) management issues projected as technology deficiencies.

We are grateful to Professor Ron Herring, Department of Government, Cornell University, who has worked in India and is well versed in economics, agrarian policy and GE crops in developing countries, for a decade long interaction on these issues and for writing the Foreword. Dr. B. Gajendra Babu, Hyderabad, provided inputs on the current process to conduct field trials (Sections 7.5 & 7.6) and reviewed Tables 1 and 2.

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C Kameswara Rao and Seetharam Annadana

EXECUTIVE SUMMARY

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Genetically Engineered (GE) crops, commonly known as 'genetically modified' (GM) crops, are developed using mainly the recombinant DNA (rDNA) technology. A large number of GE crops and their products are being commercialized globally for over 18 years.

GE crops and products are stringently regulated for their efficacy, biosafety, environmental safety and socio-economic benefits, through mandatory rules and procedures. No conventionally bred crop or product undergoes any such evaluation.

About 30 years of biosecurity research on GE crops and consumption of their products for over 18 years in several countries, have assured their safety. Nevertheless, in some countries a number of hurdles have been created by politically motivated activism, frustrating the development, evaluation, regulation, and deployment of GE crops.

In India, persistent and vehement activism supported by appeasing governments and pliable media, has hampered the development of GE crops. Activists have been working to prevent field trials to halt the regulatory process at the first stage itself.

The objective of this article is a) to highlight the global performance of GE crops, b) to review the biosecurity regulatory regime in India, c) to draw attention to the impact of anti-tech activism on development of GE crops in India, and d) to suggest course correction in the implementation of policy to make the regulatory regime more purposeful and effective without being restrictive. These issues are discussed under the following structure.

1. Global performance of GE crops in 18 years

GE crops were first commercially planted in 1996 on 1.75 million hectares. In 2013, they were grown on 175.2 million hectares, by 18 million farmers, across 27 countries, of which 19 were developing countries. The development and commercialization of GE crops has continued at a rapid rate, resulting in very significant net economic benefits at the farm level.

2. Biosecurity regulation of GE crops

GE crops and products are evaluated for biosafety and environmental safety basing on the mandatory procedures developed through international collaborative efforts. Currently there are no serious differences between the biosecurity regulatory regimes of different countries.

Biosafety evaluation of GE products involves assessment for a) toxicity, b) carcinogenicity, c) allergenicity, d) nutritional effects, and e) any unintended effects. Environmental safety assessment involves a) the impact on non-target organisms, b) pollen mediated gene flow, c) and impact on biodiversity and environment. The safety of GE crops along these parameters has now been amply demonstrated by 30 years of research and 18 years of commercialization.

The excessive time and financial costs of GE crop development, with the costs of regulation often being more than the costs of product development, discourage the public sector institutions.

The Indian regulatory regime is in line with global practices of biosecurity evaluation and is similar to regimes of other countries such as the US, Canada, Australia, Argentina, etc. The Indian regulatory process based on the Environment Protection Act 1986 (EPA, Rules of 1989), should satisfy different provisions in several Acts of Government and the process involves the Central Ministries of Environment and Forests (MinistryEF), Science and Technology, Agriculture (MoA), Health and Family Welfare, and Commerce, at one or the other stage.

The following competent authorities oversee the Indian regulatory regime: a) Recombinant DNA Advisory Committee (RDAC), b) Institutional Biosafety Committees (IBSCs), c) Review Committee on Genetic Manipulation (RCGM), d) Genetic Engineering Approval Committee (GEAC), e) State Biosafety Coordination Committees (SBCCs), and f) District Level Committees (DLCs).

The GEAC is the apex body empowered to approve large scale open field trials and release of GE crops for commercialization. The norm of non-interference by the Minister of Environment and Forests (MoEF) with the functioning of the GEAC, which is a statutory body, was violated when an indefinite moratorium was imposed on *Bt* brinjal by the then MoEF on February 2010. Two other subsequent MoEFs also interfered by putting GEAC's decisions on hold.

In order to improve the Indian regulatory regime, the Government of India has drafted the Biotechnology Regulatory Authority of India Bill, 2013, yet to be passed by the Parliament.

3. Open field trials on GE crops in India

Open field trials are essential to establish efficacy of a new GE crop and its biosafety and environmental safety. Under the Indian regulatory system open field trials are to be conducted in two phases, in different States so as to gather data from various agro-climatic zones: a) Biosafety Research Level I (BRL I), usually conducted on sites of the State Agricultural Universities, for two to three years, on small plots at two to three location; and b) Biosafety Research Level II (BRL II), conducted for three to four years at eight or nine approved locations, after a satisfactory completion of BRL I stage trials. An approved completion of these two phases of trials is essential for the commercial release of a new crop.

4. GE crops in India

India has commercialized only one GE crop, the *Bt* cotton with the *Cry 1 Ac* gene (Bollgard I). In 2013, the area under *Bt* cotton was 11 million hectares involving 7.3 million farmers. *Bt* cotton is now grown

on over 95 per cent of cotton area and about 80 per cent of this is under Bollgard II, which contains two different stacked insect tolerance genes. India is now at the 4th global position in hectarage under GE crops. *Bt* cotton greatly contributed to a significant increase in farm income and India's transformation from a cotton importer into an exporter.

Bt brinjal was approved by the GEAC for commercial release, but this was blocked by a politically motivated moratorium imposed by the then MoEF in February 2010, which has affected development of other GE crops too. At the same time, Bangladesh has recently released *Bt* brinjal for commercial cultivation. The Indian *Bt* brinjal does not need any new tests or field trials, only should be released for commercial cultivation by the GEAC.

The Golden Rice, designed to ameliorate vitamin A deficiency, comes free of technology costs. However, even after a decade, there has been no progress in commercialization of Golden Rice, due to activist pressure and governmental apathy, affecting millions, particularly poor women and children in India, who suffer from vitamin A deficiency disorders.

There are over 70 applications for initiating biotech research or field trials of various GE crops pending with the GEAC. There are about eight GE traits in 17 crops at different stages of development by about 15 private and 17 public sector institutions in India. The development of these GE crops is stuck up on account of several hurdles in conducting field trials.

5 Activism against GE crops in India

Anti-tech activism which opposes GE crops is the most serious threat to India's future food security. Criticizing the Indian regulatory regime severely on vague, inconsistent and unscientific assumptions, the activists have raised the bar on the number and kinds of tests to be done, without relevance to the need for such tests to establish biosafety and environmental safety. The Indian activists who failed in stopping *Bt* cotton, have scored impressively in engineering a moratorium on *Bt* brinjal, in preventing international collaborative research projects and in creating hurdles in conducting field trials.

Most of the global anti-GE crop activism is sustained through liberal international funding a fact also recognized by the Government of India.

The anti-tech groups are not independent in the arena of policy as their survival depends upon how effectively they coerce governments into adopting the policies of their sponsors. Continued donor grants depend on sustaining one's influence in the policy arena. Well funded activism is a source of livelihood and not a calling for most of the activist groups operating in India. The government should strictly apply the Foreign Contributions (Regulation) Act, 2010 and bring the NGOs under the Right to Information Act (RtI), to regulate their funding and functioning.

6. Hurdles impeding the development of GE crops in India

The activists could not force the Central government to ban all GE crop R & D but succeeded in preventing open field trials to block the process at the very first step. Activists have used all the tricks of the trade to frustrate the product developers, among which the following had a more serious impact:

a) For about one and half decades, there were many Writ Petitions (WPs) in the Supreme Court of India (SCI), against GE crops. Some of the petitions were either dismissed or withdrawn, but there is one going on since 2005. The pendency of this WP came in handy for three MoEFs either to impose the

moratorium on *Bt* brinjal or delay regulatory clearances or put on hold approved clearances. Another fall out of the SCI WP is the imposition of an unreasonable Distance of Separation between GE and non-GE crops and an impracticable Level of Detection of transgenic protein in a crop sample;

b) A more serious impact of the SCI WP is the report of the Technical Expert Committee appointed by the SCI. This report is wholly against GE technology and totally disregarded the national and international scientific opinion and recommended a ten-year ban on field trials, among many other negative recommendations;

c) Unconnected with the SCI WP is an equally damaging report of the Parliamentary Standing Committee on Agriculture (PSCA) which recommended stoppage of field trials and suggested several other impediments to the developments of GE crops, based almost entirely on the submissions of anti-tech activists; and

d) Initiated by the then Chief Minister of Bihar and ruled by the then MoEF in July 2011, the GEAC ordered that permission for field trials would be accorded only when the State governments give 'No Objection Certificates' to conduct them in their States. This prevents gathering data from all the agro-climatic zones in the country, as only five or six States have permitted field trials in their States. Perplexingly, the MinistryEF itself submitted before PSCA that the GEAC is empowered to approve field trials on its own and that the permission of the State governments is not necessary.

7. The need for a rethink on a regulatory policy

The world over, scientists have been dissatisfied with a) excessive regulation, b) frequent unwarranted raising of the bar of regulatory standards and c) unjustified delays in granting regulatory approvals. Arising out of activist pressure and political expediency, these constraints deny farmers access to novel technologies, discourage investment in research and slow down innovation and development of products. The international scientific community feels that the lack of appropriate, science-based and cost/time-effective regulatory systems is the major constraint to a wider adoption of GE crops. In such a situation, public institutions have not been able to deliver GE crops and products, conceding the field to a few industries. The need for a responsible and rigorous but not onerous, regulatory regime is strongly felt, more particularly for small and poor developing countries. Hopefully the BRAI would fulfill this need.

8. Conclusions and recommendations

A number of conclusions were drawn in this document and several recommendations made, of which the following are more important:

a) The BRAI should be fast tracked through the Parliament to put in place an improvised regulatory regime. Till the BRAI is in place, the present regulatory regime should be allowed to function without interference from the MoEF;

b) The requirement of No Objection Certificates from the State governments should be lifted, as the MinistryEF itself feels that the GEAC is empowered to permit field trials and State government approval is not necessary and some States (Karnataka) do not believe that they have a *locus standi* in the matter;

c) The government should respect the combined global and national scientific wisdom in evaluating GE products through their regulatory regimes, and the decisions on the process of biosecurity evaluation and acceptance or rejection of products should not be allowed to be hijacked by the vested interest using junk science pursuing inept politics;

d) The MinistryEF and the GEAC should encourage more research to establish biosafety and environmental safety. The policy on regulatory approvals should be predictable and reassure on the fairness of the structure and implementation of the regulatory regime, providing for a level playing field for all the stakeholders;

e) The Central government should resist interference by all activist groups in formulating and implementing national policy and rein in all activist groups by bringing them under the provisions of the Foreign Contributions (Regulation) Act, 2010 and the RtI so that the public can seek information on their funding, expenditure and activities;

f) The MinistryEF and the GEAC should release *Bt* brinjal for commercial cultivation without further delay. Golden Rice should be fast tracked with a time frame for commercialization;

g) There is a strong need for awareness workshops conducted by the MinistryEF in coordination with GEAC, DBT and the MoA to promote informed decisions at the State level;

h) The scientists and product developers all should join together to take legal action, i) against false charges against scientists, technology, and industry and ii) vandalization of approved field trials and attacking personnel and facilities by the activists. They should also stand up against unjust and illegal moves of the governments; and

i) All those involved in GE crop development should provide the public with appropriate timely information countering activist propaganda as soon as it emerges. They should also conduct public awareness programmes to untangle the misinformation and disinformation from factual information on the efficacy, safety and benefits from GE crops to build up public confidence in them.

1. INTRODUCTION

Genetically Engineered (GE) crops are developed through elegant, predictable, precise and trackable tools of modern biotechnology. Elegant as it seamlessly combines several bioscience techniques, predictable as we can clearly determine the kind of change being introduced, precise as the gene of interest can be inserted at a specific position on a specific chromosome and trackable as we can map back and forth the genes and the changes that they cause.

GE crops are commonly known as 'genetically modified' (GM) crops, which is an imprecise term as the products of agriculture and animal husbandry of 10,000 years, are all genetically modified. The term 'genetically engineered' is better, although some other terms such as 'genetically optimized' (Dr Laura Privelle, personal communication) and 'genetically fortified', were suggested.

The recombinant DNA (rDNA) technology, which facilitates the insertion of a chosen gene from any organism into the genome of any other organism irrespective of the degree of genetic relationship, which was not possible earlier, is the most predominant tool of GE, though some products such as decaffeinated coffee and tearless onion were developed using such protocols as gene silencing. A large number of GE products in medicine, environment and agriculture are now commercialized globally.

Today, in every country that develops them, GE crops and products are stringently regulated by mandatory rules and procedures for their efficacy, biosafety, environmental safety and socio-economic benefits, while no conventionally bred crop or its product undergoes any such evaluation, even when they were developed through induced mutations and/or artificial hybridization, which are imprecise and unpredictable, and may cause undesirable effects on the consumers and the environment.

About 30 years of biosecurity evaluation of GE crops (detailed in section 3 of this article), and consumption of their products for over 18 years by more than 350 million people in North & Latin America, ASEAN, China and elsewhere, have not thrown up any health or environmental hazards, reiterating the effectiveness of the regulatory regimes in establishing the safety of GE crops and the safety of the GE crops *per se.* Nevertheless, in the EU block and some other countries, more particularly

the developing countries, a number of hurdles have been created by politically motivated activism, making the development, evaluation, regulation, and deployment of GE crops very frustrating.

In India, persistent and vehement activism supported by appeasing governments and pliable media, has created many hurdles in the smooth functioning of the regulatory regime and hampered the development of GE crops from the very beginning. More serious issues arose in the context of the conduct of field trials which are very essential in biosecurity evaluation and which the activist have been trying to block. Stopping field trials halts the regulatory process at the first stage itself, leaving no scope for commercial deployment of GE crops. Delaying field trials also escalates development costs that would fall on the farmers and consumers. There is an urgent need to remove such hurdles to provide for a smooth regulatory process. The hurdles created are basically from political compulsions and are against the very principle of the Environment Protection Act, 1989 (see section 3.4 of this article), within which biosafety and environmental safety of the GE crops are evaluated.

The objective of this article is a) to highlight the global performance of GE crops, b) to review the biosecurity regulatory regime, c) to draw attention to the impact of anti-tech activism on development of GE crops in India, and d) to suggest course correction in the application of policy to make the existing regulatory regime (or a new regime like Biotechnology Regulatory Authority of India), more purposeful and effective without being restrictive.

2. GLOBAL PERFORMANCE OF GE CROPS IN 18 YEARS

The performance of GE crops, in 18 years of their global cultivation, was reviewed by James (2013). GE crops were first commercially planted in 1996 on 1.75 million hectares. In 2013, they were grown on 175.2 million hectares, by 18 million farmers, across 27 countries, of which 19 were developing countries. Cotton, soybean, maize, potato, papaya, Canola and others carrying insect/disease/herbicide/drought tolerance genes are the predominant GE crops and traits. As of November 30, 2013, a total of 2,833 regulatory approvals involving 27 GE crops and 336 GE Events were issued by competent authorities in 36 countries, since 1994 (James, 2013). Of these, 1,321 are for food use (direct use or processing), 918 for feed use (direct use or processing) and 599 for environmental release or planting.

The economic impact of a GE crops at the farm level is the key part of an assessment of the global value of crop biotechnology in agriculture. Brookes and Barfoot (2014) followed earlier annual studies which examined economic impacts on yields, key costs of production, direct farm income, and effects and impacts on the production base of the four main crops of soybean, corn, cotton and canola.

The commercialization of GE crops has continued at a rapid rate, with important changes in both the overall level of adoption and impact. The annual updated analysis of Brookes and Barfoot (2014) shows that very significant net economic benefits were derived at the farm level amounting to $18.8 billion in 2012 and $116.6 billion for the 17 year period (in nominal terms), with the economic gains to farmers roughly equally divided between the developed and developing countries. GE technology has also made important contributions to increasing global production levels of the four main crops, having added 122 million tonnes and 230 million tonnes respectively, to the global production of soybean and maize on commercialization of the technology since 1996.

3. BIOSECURITY REGULATION OF GE CROPS

The term *'Biosafety'* is now being generally used while referring to the safety of GE products to the consumers and the environment, in preference over the more inclusive term *'Biosecurity'* adopted by the Food and Agriculture Organization (FAO) of the United Nations (UN). As per the FAO (2003), *'Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyze and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk'*. FAO's concept of biosecurity covers' *the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and enotypes. Biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity'*.

Unfortunately, the concept of biosecurity of the World Health Organization (WHO) is at variance from that of the FAO. For WHO biosafety is the safety of the personnel and life and (laboratory) biosecurity is the protection of all physical and biological material from theft, pilferage accidental escape and misuse, which may impact biosafety outside the lab and greenhouse (WHO, 2006).

3.1 The evolution of regulatory systems

Long before the products of modern agricultural biotechnology were developed, the scientists (not the activists) were conscious of the possibility of risks to the consumers and the environment from rDNA products involving microorganisms (Kameswara Rao, 2014). In 1976 a 'Recombinant DNA Advisory Committee' was established by the US National Institutes of Health (NIH). In course of time, the NIH (1976), the WHO (1982), the Organization for Economic Cooperation and Development (OECD, 1986) and the US National Academy of Sciences (NAS,1987) published critical studies of modern biotechnology and set guidelines to establish their safety. Soon as the guidelines of NIH, WHO, OECD and NAS for biosecurity evaluation of GE products were released, the major US developers of GE crops approached the United States Department of Agriculture (USDA) to issue guidelines for the evaluation of biosafety and environmental safety of GE crops. To the USDA's guidelines were added the recommendations of the *Codex Alimentarius* Commission (CAC), the international food standards

institution established by the FAO and the WHO. These guidelines, developed through international collaborative efforts, have been adopted by both the developed and developing countries. Currently, there are no serious differences between the biosecurity regulatory regimes of different countries, which have been incrementally revised and strengthened.

3.2 Objectives of biosecurity evaluation

In general terms and in the context of GE crops, the concept of biosecurity has two components: a) biosafety, the safety of the crops and their products to the consumers as food, feed and medicine, and b) environmental safety, the safety of the non-target organisms and biodiversity. This concept is used in this article.

Biosafety assessment of GE products involves, a) direct health effects caused by the food (toxicity), b) tendencies to cause cancer (carcinogenicity), c) tendencies to provoke allergic reactions (allergenicity), d) nutritional effects that may be associated with genetic modification, and e) any unintended effects which may result from the gene insertion. Environmental safety involves assessing a) the impact of GE crops on non-target organisms, b) pollen mediated gene flow that may affect other varieties of the crop, c) impact on biodiversity and environment and d) that GE crops do not become super weeds invading the environment. Although activists have been vocal that all of these do happen, none were scientifically shown to have materialized in 30 years of regulatory experience and 18 years of consumption. The safety of GE crops to the consumers and the environment, and the benefits to the farmers have now been amply demonstrated by their phenomenal growth in terms of hectarage, commercial volume and socio-economic benefits (James, 2013; Chandrasekhara Rao, 2014).

3.3 Time and financial costs of biosecurity regulation

GE crop development, from the idea to commercialization costs about US$ 140 million and takes about 12 to 15 years (McDougall, 2011). Often the costs of regulation are more than the costs of product development. In most countries GE crops are subjected to an excessive regulation and slow processing which add to time and financial costs, an additional burden on the farmers and consumers. The public sector institutions may get funds to develop the prototype but find it difficult to get funds for biosecurity evaluation and so most public sector efforts stop at the prototype stage.

3.4 Biosecurity regulation of GE crops in India

The Indian biosafety regulatory regime for GE crops is similar to regimes of other countries such as the US, Canada, Australia, etc., and is actually more stringent than that of most other countries (Kameswara Rao, 2014). The Indian regulatory regime is in line with global practices of biosecurity evaluation performed by federal regulatory agencies in the ministries of agriculture, environment, and science and technology (Rowe et *al*., 2012). Powered by several Acts of Government, managed by the Department of Biotechnology (DBT) and the Ministry of Environment and Forests (MinstryEF), and supported a large number of public sector research institutions and scientists, the Indian regulatory regime has been effective, though thoroughly but unfairly criticized by the anti-tech activists.

The Indian regulatory process based on the Environment Protection Act 1986 (EPA, Rules of 1989), should satisfy different provisions in several Acts of Government and the process involves the Central Ministries of Environment and Forests (MinistryEF), Science and Technology (MST), Agriculture (MoA), Health and Family Welfare, and Commerce, at one or the other stage and takes much more than a decade.

The Indian regulatory regime is overseen by the following competent authorities: a) Recombinant DNA Advisory Committee (RDAC), b) Institutional Biosafety Committees (IBSCs, one for each institution in

GE development), c) Review Committee on Genetic Manipulation (RCGM, located in the DBT), d) Genetic Engineering Approval Committee (GEAC, located in the MinistryEF), e) State Biosafety Coordination Committees (SBCCs, one for each State that develops or cultivates GE crops), and f) District Level Committees (DLCs, one for each district that develops or cultivates GE crops).

The GEAC is the apex body empowered to approve large scale open field trials and release of GE crops into the environment for commercialization, on receiving satisfactory inputs from the ICAR and RCGM. Being a statutory body, the GEAC has functioned without interference from the Minister of Environment and Forests (MoEF) for a long time. In the current context of GE crops, there have been four MoEFs: MoEF1, till July 12, 2011, MoEF2 till December 21, 2013, MoEF3 till the new government formed on May 26, 2014 and MoEF4, in the new government. The norm of non-interference with the functioning of the GEAC was violated on February 9, 2010 by MoEF1 who imposed an indefinite moratorium on *Bt* brinjal (MoEF, 2010), that was cleared for commercialization by the GEAC, and MoEF2 and 4 adopted a similar policy of rendering GEAC's decisions infructuous. To add credibility to his unwarranted interference with the functioning of the GEAC, MoEF1 has changed the name of the GEAC from 'Approval' to 'Appraisal'. As no change was made in the mandate of the GEAC, this has no legally binding consequence to the status and functioning of the GEAC and only misguides the public.

As per the EPA Rules of 1989, the SBCCs and DLCs are monitoring bodies at the State and District level to, a) oversee the research facilities in establishments in the State, b) to check for any safety violations, c) to assess any damage arising from GE crops after commercial release, and d) to take corrective action (Ghosh, 1997; Gupta, 2000). It is illegal to cultivate GE crops in any State without these committees in place. Nevertheless, there is not a single State that has put together all the committees, as required by law, in spite of reminders from the Government of India.

The Government of India issued the following documents to guide product developers and evaluators through the regulatory oversight: a) Recombinant DNA Safety Guidelines and Regulations (1990, revised in 1994; DBT, 1994). b) Handbook for IBSC Members (2005), c) Regulatory Frame Work for GMOs in India (2007), d) Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated and Genetically Engineered Plants (DBT and MoEF, 2008), and e) Guidelines for the safety assessment of foods derived from GE plants (IGMORIS, 2013). Important developments are posted on the website of the GEAC and lists of Events approved for field trials are available at IGMORIS (2014).

A number of public sector organizations such as the a) the Indian Council of Agricultural Research (ICAR), b) the Indian Council of Medical Research (ICMR), c) the State Agricultural Universities (SAUs), and d) the Drugs Controller General of India (DCGI), are contextually involved in the biosafety regime. About a dozen private and public sector institutions are involved in biosafety evaluation of GE Crops. The ICAR and its designated institutions evaluate agronomic performance and environmental safety and recommend the crop for commercial release to the RCGM. The SAUs and the State Departments of Agriculture (SDoA) are involved in the pre- and post-release monitoring of the GE crops.

In pursuance of the recommendations of different task forces and responding to activist criticism on the content and management of the current regulatory regime, the Government of India introduced into the 15th Lok Sabha the Biotechnology Regulatory Authority of India Bill, 2013 (BRAI, 2013), on April 22, 2013. The BRAI Bill was referred to a Parliamentary Committee, (different from the Parliamentary Standing Committee on Agriculture discussed in section 7.4 of this article). The Committee did not complete its work before the 15th Lok Sabha dissolved and with the term of the 15th Lok Sabha ending, the BRAI Bill also lapsed. The BRAI issue will have to go to a Committee constituted by the new Parliament. It would a long time before the BRAI Bill is reintroduced and approved by the just formed 16th Lok Sabha.

4. OPEN FIELD TRIALS ON GE CROPS

The development of the prototype of a transgenic crop happens in the lab and the green house. Some important data on the stability of the transferred gene and its expression in the new genetic environment, the selection of the appropriate Event, some aspects of efficacy and biosafety are also gathered in the lab (about three years) and the greenhouse (about three years). For the complete range of tests on these and many other aspects of biosafety and environmental safety, open field trials, which provide an agricultural environment, are essential.

Under the Indian regulatory system open field trials are to be conducted in different States so as to gather data on their efficacy and safety from different agro-climatic zones. Besides, if open field trials are not conducted in all States that are likely to cultivate the GE crop, the States may say that as no field trials were conducted in their state, a particular GE crop cannot be commercialized there. The open field trials are conducted in two phases:

a) Biosafety Research Level I (BRL I): These trials are conducted for two to three years, on small plots at two to three locations, no more than 1 acre (0.4 ha) per trial site location and a cumulative total of 20 acres (8.1 ha), for all locations for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per applicant, per crop season. Usually conducted on SAU sites, permission for BRL I trials is granted by the RCGM, after clearance from the GEAC.

b) Biosafety Research Level II (BRL II): These trials are conducted for three to four years, after satisfactory completion of BRL I stage trials, on plots limited in size to no more than 2.5 acres (1 ha) per trial site location and to no more than eight locations within India for each plant species/construct/ combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per applicant, per crop season. Permission for BRL II trials, conducted at approved locations, is granted by the GEAC.

There is some overlap of data gathered during BRL I and II, but both are essentially needed to be completed satisfactorily, to establish product efficacy, biosafety and environmental safety, for approval of commercial release of the new crop.

5. GE CROPS IN INDIA

5.1 *Bt* cotton

India has commercialized only one GE crop, the *Bt* cotton with the *Cry 1 Ac* gene (Bollgard I), tolerant of the most serious cotton pest, the American bollworm. The performance of *Bt* cotton in India has been phenomenal and the progress it made since 2002, when it was first approved, is both fast and far.

In 2002, *Bt* cotton was planted on 0.5 million hectares by a few hundred farmers. In 2013, the area under *Bt* cotton was 11 million hectares involving 7.3 million farmers, across nine Indian States (James, 2013). *Bt* cotton is now grown on over 95 per cent of cotton area and about 80 per cent of this is under Bollgard II, the two gene *(Cry 1Ac and Cry 2 Ab)* stacked *Bt* cotton with a far higher level of pest tolerance. India is now at the 4th global position in hectarage under GE crops (James, 2013).

A comparison of statistics on various aspects of *Bt* cotton development and performance between 2002 and 2013 illustrates the impressive contribution of *Bt* cotton to the Indian cotton scenario (James, 2013; Brookes and Barfoot, 2014):

a) Only one Event in 2002 and six Events in 2013;

b) One developing company in 2002 and more than 40 companies in 2013;

c) Three hybrids in 2002 and over 1,095 in 2013;

d) There was a sharp decline in insecticide use, coinciding with the large scale adoption of *Bt* cotton, from 5,748 metric tons of active ingredients in 2001 to 222 metric tons resulting in a saving of about US$135 million. In 2001, 46 per cent of pesticide used in India was sprayed on cotton while it was 17.2 per cent in 2012 (Mayee and Choudhury, 2013);

e) *Per* hectare average cotton yields steeply rose from about 308 kg per hectare in 2001-02 to 550 kg in 2013-14;

f) Cotton production increased from 13.6 million bales (bale=170 Kg) in 2002-03 and 37 million bales in 2013-14;

g) *Bt* cotton has greatly contributed to the transformation of India from a cotton importer to an exporter. India imported 4.25 million metric tons of cotton in 2001 and exported 1.25 million metric tons in 2011-12; and

h) India was estimated to have enhanced farm income from *Bt* cotton by US$14.6 billion in the 11-year period 2002 to 2012, and US$ 2.1 billion in 2012 alone (Brookes and Barfoot, 2014).

That *Bt* cotton in India is no more an open question and that it has immensely benefitted the farmers and country was emphasized by a number of surveys (Bury, 2013; James, 2013; Mayee, and Choudhary, 2013; Chandrasekhara Rao, 2014). Every question raised against *Bt* cotton has been answered (Manjunath, 2011). The false attribution of farmer suicides to *Bt* cotton crop failures was also repudiated (Gruere, *et al.,* 2008; Sheridan, 2009; Gruere and Sengupta, 2011; Bury, 2013). Nevertheless, every new Event of *Bt* cotton has to go through the process of biosecurity regulation involving field trials. And every other day activists scream that *Bt* cotton has failed causing immense misery to the farmers.

5.2 *Bt* brinjal

Bt brinjal has passed through the mandatory biosecurity regulatory process and was approved by the GEAC for commercial release. Nevertheless, on February 9, 2010, MoEF1 sided with the activists and imposed a moratorium of an unspecified period on its commercial release, ignoring extensive scientific opinion in support of commercialization of *Bt* brinjal (MoEF, 2010). That this moratorium was in fact a political decision and not a compulsion for any biosafety or environmental concerns is evident from a review of the Moratorium Order and its appendices (Kameswara Rao, 2010). After imposing the moratorium, the MoEF1 directed the constitution of a Committee to look into safety of *Bt* brinjal, and this Committee opined in April 2011, that *Bt* brinjal is safe to the consumers and the environment, beneficial to the farmers and that no more new tests are needed for commercializing it. Yet, in four years, there has been no effort from the government to release *Bt* brinjal for commercialization. The technology to develop *Bt* brinjal varieties by the public sector institutions comes free of costs through international agreements. Even these are blocked by the moratorium, whose thrust was actually against *Bt* brinjal hybrids developed by the private sector. *Bt* brinjal does not need any new tests or field trials, only should be approved for commercial cultivation by the GEAC.

Having processed *Bt* brinjal largely based on the Indian biosecurity dossier, Bangladesh has released *Bt* brinjal for commercial cultivation for the 2014 crop season (Choudhary *et al.,* 2014b).

5.3 Golden Rice

The Golden Rice is designed to ameliorate vitamin A deficiency and comes free of technology costs through the Golden Rice Humanitarian Board. Even after a decade, there has been no progress in commercial release of Golden Rice. Both activist pressure and governmental apathy contributed to this delay affecting millions, particularly poor women and children in India, who suffer from vitamin A deficiency disorders (Potrykus, 2010b; Dubock, 2013).

The Indian varieties of rice with the Golden Rice Event, being developed in three public sector institutions (the Tamil Nadu Agricultural University, Coimbatore, The directorate of Rice Research, Hyderabad and the Indian Agricultural Research Institute, New Delhi), need to undergo field trials for biosecurity clearance.

5.4 Other crops

MoEF1 categorically stated that the moratorium is only on *Bt* brinjal and that it would not affect other GE crops in development (MoEF, 2010). However, subsequent to the moratorium on *Bt* brinjal, GE crop R & D activities in both public and private sectors went into slow motion and some are on hold since 2010, for the fear of an uncertain future, resulting in an enormous delay in making these technologies available to farmers. There are over 70 applications for initiating biotech research and/or field trials of various GE crops pending with the GEAC. At stake is over Rs 8,000 crore, invested in research by the public sector institutions over the past five years.

There are about eight GE traits in 17 crops at different stages of development by about 15 private and 17 public sector institutions in India (IGMORIS, 2014). However, the development of these GE crops is stuck up on account of several hurdles in conducting field trials which are basic to establishing biosecurity, without which no GE crop can be commercialized (see sections 3.2, 3.4 and 4 of this article).

6. ACTIVISM AGAINST GE CROPS IN INDIA

Anti-tech activism which opposes GE crops is the most serious threat to India's future food security. The bureaucracy, scientific community and the product developers are all wary of the aggressive stance of the activists who have no holds barred and nothing to lose. The dimensions and the influence of Indian anti-GE activists were reviewed by Kameswara Rao (2010, 2014).

The criticism of the regulatory regime by the activists has been vague, inconsistent in content and unscientific in approach. All the time they have raised the bar on the number and kinds of tests to be done, without understanding their relevance to establish biosafety and environmental safety, issues discussed in detail by Kameswara Rao (2014). The contention is not about the mandated protocols or on whether what should be done has been done. Regulation is about what we need to know to ensure safety of GE crops and products but not what is nice for the activists to know.

6.1 Success of Indian anti-GE activism

The Indian activists who failed in stopping *Bt* cotton, have scored impressively in engineering a moratorium on *Bt* brinjal (Kameswara Rao, 2010), succeeded in preventing international collaborative research projects (Kameswara Rao, 2014) and in creating hurdles in conducting field trials (see section 5.4 in this article). Indian activism affects only GE crops, not other products of modern biotechnology in the areas of medicine and environment.

6.2 International support for anti-GE activism in India

Supporting anti-tech activism costs enormous amounts of money. Some quantum of financial and logistic support certainly comes from the Indian sources, but it was recognized for long that the whole of global anti-GE crop activism is sustained through direct or indirect liberal international funding. There is a lot of evidence in the public domain on foreign funding of activism in different countries, particularly in India (Kameswara Rao, 2010, 2014; Reddy 2013). This was also recognized by the former Prime Minister of India (PM) and the Deputy Chairman, Indian Planning Commission. A recent

report of the Indian Intelligence Bureau (June 18, 2014) to the Office of the new PM has named Green Peace and recommended suitable action for its anti-developmental activities in India, including anti-GE crop activism.

No Indian non-governmental organization (NGO) would get funds if it were to support GE crops and foods. These anti-tech groups cannot be called independent in the arena of policy and absolute objectivity does not exist as the survival of the activist groups depends upon how effectively they agitate and coerce governments into adopting the policies of their sponsors. While a few activist groups may be dedicated to genuine causes, most others have vested interests in ensuring certain outcomes. The future donor grants depend on sustaining one's influence in the policy space. Well funded activism is a source of livelihood and not a calling for most of the activist groups operating in India. Once the funding stops, so would the activism. Unfortunately the public is not aware of the forces behind anti-tech activism and so carried away by the din caused by the activists. It is necessary that both the Indian and overseas players of anti-tech activism in India are made to publicize the details of the sources of their funding and expenditure and be accountable for their activities. The government should strictly apply the Foreign Contributions (Regulation) Act, 2010 and bring the NGOs under the Right to Information Act (RtI), so that public can access information on their funding and activities.

7. HURDLES IMPEDING DEVELOPMENT OF GE CROPS IN INDIA

The prime objective of anti-GE activism in India is to force the government to ban all GE crops. Since this has not happened the thrust has been to prevent open field trials which are fundamental to the development and safety assessment of the new crops, and block the process at the very first step. Activists have used a variety of tactics to frustrate the product developers, among which the following had a serious impact.

7.1 Writ Petitions in the Supreme Court of India

For about one and half decades, there were many Writ Petitions (WPs) in the Supreme Court of India (SCI), challenging one or the other aspect of development of GE crops. Some of the petitions were dismissed and some were withdrawn (Kameswara Rao, 2010), but there is one with several petitioners, respondents and impleaders, going on since 2005. The pendency of this petition served as one of the excuses for MoEF1 in imposing moratorium on *Bt* brinjal (MoEF, 2010, p. 15). MoEF2 also used the same excuse to put on hold the clearance of GEAC for field trials of several GE crops in development, given in March 2013. Notwithstanding the objections of his predecessors, MoEF3 has allowed the GEAC in March 2014, to revalidate the earlier clearance of March 2013. On July 18, 2014, the GEAC has approved open field trials of some Events of rice, wheat, maize and cotton, which are a part of a backlog of about 70 applications pending since 2011-12. Perplexingly, on July 29, 2014, MoEF4 (the present MoEF) placed GEAC's approval on hold in response to pressure from fringe groups, repeating the performance of MoEF2. However, the GEAC has approved some field trials again on August 28, 2014. Approval of field trials has now only a partial benefit on account of the requirement of 'No Objection Certificates' (NOC) from the State governments to conduct open field trials in different States (see section 7.5 in this article).

The activists chose petitioning the SCI as a means to delay things, since they know that court cases usually drag on and serve as a speed breaker to GE crop field trials and not so much in the hope that the SCI will ban GE crops altogether.

The moratorium on *Bt* brinjal has certainly been a damper on the R & D of GE crops, further burdened by the slow pace of GEAC's approvals for field trials, and the MoEF2 and 4's hold up of GEAC's March 2013 and July 2014 approvals for field trials. The SCI WP wanted the SCI to halt all field trials. The Bench of the SCI was reported to have said that the SCI was *'not an expert body to determine the issue… the GM crops field trials had become an emotional issue in India….but it is true that courts are being used by pressure groups through PILs'* (Times of India, February 13, 2008). However, the SCI constituted a Technical Expert Committee to go into the question of field trials among other issues concerning GE crops (see Section 7.3 of this article).

7.2 Distance of Separation and Level of Detection of Transgenic Proteins

The respondents failed to impress upon the SCI on the just and scientific position on several issues. Two decisions of the SCI, the Distance of Separation (or isolation, DoS) and the Level of Detection of transgenic protein in a crop sample (LoD), have caused more serious problems and the GE crop developers are now stuck up with unreasonable and impracticable restrictions.

i) Distance of Separation: The issue of physical 'Distance of Separation' (DoS) between GE and non-GE crops arises out of common misconception (or deliberate and mischievous insistence) that there is rampant pollen mediated gene flow among all crops and so GE, conventional and organic crops cannot co-exist without 'contamination' (the scare word of the activists), from a GE to a non-GE crop. There has never been any evidence of significant gene flow between the varieties of any of the crops under cultivation for centuries (Kameswara Rao, 2010, 2014). If at all a DoS is necessary to assuage the fears of the organic and other farmers, it should be reasonable, practicable, crop based, and not a blanket regulation (Kameswara Rao, 2014). In India the limit of DoS has gone too far with the SCI stipulating a 200 meter DoS during field trials for all crops and this is highly unreasonable. A 20 to 30 meter separation distance is more than adequate for most crops.

ii) Level of Detection of Transgenic Proteins: There are two situations when it is necessary to know the quantity of transgenic protein in a sample of crop produce (Level of Detection, LoD): a) to determine the degree of gene flow, if any, by estimating the quantity of transgenic protein in a non-GE crop sample, or b) an importer of a crop produce may like to know the quantum of transgenic protein in an imported non-GE lot. The EU permits 0.9 per cent GE component while the other countries permit 1 to 5 per cent level of GE component in a non-GE or organic crop produce and in China there is no such restriction (Kameswara Rao, 2014). The SCI stipulated a 0.01 per cent as the maximum permissible LoD of transgenic protein for all crops. Besides being entirely unnecessary, this stipulation has practical difficulties since the protocols to detect at 0.01 per cent level exist in only sophisticated laboratories and there are no field detection kits. Such a high level of detection is unwarranted in many cases, as for example animal feed and non-food crops.

7.3 Report of the Technical Expert Committee

The SCI constituted a 'Technical Expert Committee' (TEC), with five members to review the Indian regulatory system and the TEC submitted an interim report on October 7, 2012. The TEC ignored overweighing scientific opinion in support of the efficacy, safety and benefits of GE crops and the interim report was so totally anti-GE crops that it caused a furore among the product developers and scientists, on several grounds. The most destabilizing recommendation of the TEC was to ban all field trials for 10 years. The interim report of the TEC was analyzed providing the scientific response to issues raised by the Committee (Kameswara Rao, 2012). The SCI did not accept the recommendation of 10 year ban on field trials, but added one agricultural scientist to the TEC in response to serious objections on the constitution of the TEC. The TEC submitted its final report on June 30, 2013, but the new member

did not agree with the majority report and submitted his own report on July 16, 2013. The SCI has now to look into these two 'final' reports and rule on the future course of action. The relevant Ministries of the Central government are reportedly submitting a joint response to the TEC reports for SCI's consideration at the next hearing.

Had the Government handled the present SCI cases deftly and promptly, these petitions would have been disposed of by the SCI long ago, as there is no scientific basis for the allegations made. Several problems emerged from the inept handling of the WP by the respondents.

7.4 Report of the Parliamentary Standing Committee on Agriculture

A good deal of Parliament's work is transacted by several categories of Parliamentary Committees, the Standing Committees being one category. Routinely constituted, different Parliamentary Standing Committees have jurisdiction over different departments of the Central government. Some Committees are serviced by the Secretariat of the Lok Sabha and some by that of the Rajya Sabha. The Parliamentary Standing Committee on Agriculture (PSCA) of the 15th Lok Sabha was chaired by a Lok Sabha Member from the Communist Party of India, Marxist (CPM), with 20 Members from the Lok Sabha and 10 from the Rajya Sabha, belonging to different political parties. The PSCA is different from the Parliamentary Committee to which the BRAI Bill was referred (see section 3.3 in this article).

The PSCA had 42 sittings from March 4, 2010 to August 3, 2012 and submitted its report on the *'Cultivation of Genetically Modified Food Crops—Prospects and Effects',* to the Parliament on August 9, 2012 (PSCA, 2012). This report is voluminous, containing 532 pages (text of 378 pages and eight Annexures).

Of the 50 oral submissions made to the PSCA, about 16, mostly from known anti-tech NGOs were over critical of GE crop technology and the Indian regulatory regime, demanded a ban on all R & D of GE crops. The rest, scientists, representatives of scientific institutions, relevant ministries, etc., supported GE crops. Nevertheless, like the TEC, the PSCA too has ignored overwhelming scientific opinion and supporting the activists recommended that *'for the time being all research and development activities on transgenic crops should be carried out only in containment, and that the ongoing field trials in all States should be discontinued forthwith',* (PSCA, 2012, p. 244). The depositions of the anti-tech activists were repeatedly quoted in the PSCA in support of its rejection of GE crop technology.

The opposition of the Chairman of the PSCA to GE crop technology is anticipated as he belongs to the CPM with ingrained repulsion to the west and its technology. What surprises most is that not even a single one of the 30 other Members of the PSCA, belonging to different parties with conflicting political philosophies and affiliations, came in support of the technology, let alone recording a dissent. The report is unanimous. Either these members did not understand the importance, safety and benefits of GE crop technology detailed in the scientific depositions made before the PSCA or just that they did not care.

Both the TEC's interim report and the PSCA report have come in very handy to the activists and the governments of many States are now wary of doing anything in support of GE technology, fearing the wrath of the activists. While TEC's report may be rejected by the SCI, the PSCA's report will haunt us for quite some time.

7.5 No Objection Certificates from the State Governments for Conducting Field Trials

Until July 2011, field trials of GE crops were conducted at suitable locations in any State, on approval from the RCGM and the GEAC (see section 4 in this article). The applicants would inform the RCGM,

GEAC, the offices of DoAs in the respective State and District and/or the SAUs, a week before or a week after, planting for field trials. Following this procedure, thousands of field trials of GE crops were conducted in Andhra Pradesh, Karnataka, Tamil Nadu, Madhya Pradesh, Maharashtra, Gujarat, Rajasthan Punjab and Haryana (IGMORIS, 2013), without any recorded opposition from the States.

On March 5, 2011, the then Chief Minister of the State of Bihar informed the MoEF1, that he is opposed to the transgenic maize field trials in Bihar and permission given by the GEAC in this regard should be withdrawn. The MoEF1 immediately used this opportunity to drive one more nail into GE crop efforts and ruled quickly that that the developers of GE crops should obtain the permission of the State governments to conduct open field trials of GE crops, even before the GEAC permits these trials. This restriction applies to both public and private sector institutions. The activists enthusiastically welcomed the move arguing that since agriculture is a 'State subject', a 'No Objection Certificate' (NOC) from the State governments is essential and praised the MoEF1 once more for his bold move. The request from Bihar is to withdraw the specific permission given, applicable to that State alone and not about bringing in the requirement of NOCs from all the States. The request from one State should have stopped with that State or the issue would have died naturally if the MoEF1 did not act upon it.

The GEAC at its 110th meeting on July 6, 2011, adopted a resolution which states that, *'In order to take the views of the state government on board and to promote their involvement in activities pertaining to GM crop field trials specially in its effective monitoring, it was decided that in respect of all GM crop field trials, the GEAC and the Review Committee on Genetic Manipulation (RCGM) would issue an approval letter only on the receipt of an No Objection Certificate from the respective state government'* (MoEF, 2011a). Surprisingly, some months later, when asked to clarify the position in the matter, the MinstryEF informed the PSCA (see section 7.4 of this article) that *'as per Clause 4 (4) under Rules 1989, the GEAC is the apex authority responsible for approval of proposals relating to GM crops into the environment including experimental field trials. As per Clause 4 (5 & 6) under Rules 1989, the role of the State Government through the State Biotechnology Coordination Committee (SBCs) and District Level Committees is to monitor the compliance of the safety guidelines and conditions stipulated by the GEAC during the field trials. It also has powers to inspect, investigate and take punitive action in case of violations of statutory provisions.* ***Therefore, prior approval of the State Government is not necessary',*** (PSCA, 2012, Section 7.2, p. 236; emphasis introduced).

If this is so, why NOCs are insisted upon by the GEAC (and RCGM)? Can the MinistryEF and the GEAC maintain conflicting positions? In continuation of what is said in the previous para here, the MinistryEF stated that *'However, as the State Governments are involved in the monitoring of the field trials, GEAC taking into consideration the objections raised by some of the State Governments, has directed the applicant to obtain no objection from the respective States where the trials are proposed to be conducted'*. The validity and legality of the objections of the State governments were never deeply analyzed by the MinistryEF or challenged by the product developers.

Significantly, some States do not believe that they have the final say in the matter of open field trials conducted in their States. Shri Sandeep Dave, the Principal Secretary of Agriculture, Government of Karnataka, said in the context of States permitting (or not permitting) open field trials approved by the GEAC, that *'the Centre has every right to give permission (for field trials) and the State has no locus standi in the matter'* (Deccan Herald, December 22, 2011).

This decision of the MinistryEF and the GEAC may be politically correct but is potentially disastrous for GE crop R & D. It is odd that the Central government is imposing something which itself has conceded as 'not necessary'. This is not governance.

7.6 Implication of NOC Requirement for R & D of GE Crops

The insistence of NOCs even before RCGM/GEAC permit open field trials has several negative implications for the R & D of GE crops. The following are the more serious issues:

a) The governments of Andhra Pradesh, Maharashtra, Gujarat, Rajasthan, Punjab and Haryana issued NOCs for certain crops and Events (Table 1). While the governments of Madhya Pradesh, Bihar, Odisha, and Kerala have declined NOCs, the governments of Karnataka, Tamil Nadu, and Uttar Pradesh have yet to decide. The NOC given for a public sector GE mustard was arbitrarily revoked by the Rajasthan government close to harvest time, not for any reasons of biosafety or environmental safety (Table 1; MoEF, 2012), forcing termination of the trials. This cautions that the NOCs given by State governments do not carry an assurance that the NOCs are valid till BRL I or II trials are completed;

b) When some States do not issue NOCs, it is impossible to evaluate a GE crop in all seasons and all prospective commercializing regions. For example, of the five zones of corn in India, NOCs are available only for two zones and the large market zones in the south have not provided a NOC. Now even cotton cannot be field trialed in all the growing zones;

c) The NOC requirement caused delays in conduct of field trials and in many cases even halted them altogether. The number of field trial approvals have decreased and the number of pending application have increased during 2012 and 2013 (Jayaraman and Jia, 2012; GAIN, 2013). Denial of field trial opportunities is a serious impediment to the development of GE crops, as the whole process is blocked at the first step itself. The crops and Events negatively impacted by the NOC requirement are given in Table 2;

d) The number of technical and non-technical personnel needed in the context of obtaining NOCs and conducting field trials has gone up enormously pushing the costs up alarmingly. Experience of a number of product developers indicates that the cost of field trials in the SAUs has increased by 3 to 4 times between 2010 and 2013;

e) The States are expected to review the applications for NOCs in consultation with the respective SAUs. There is no uniformity in forms of application or the documents that are expected from the applicants. In some States it is a simple form of application but others require filling in large sets of questionnaires and making presentations. Information is sought on a variety of aspects such as sequences of novel gene and protein, their expression, stability, bioefficacy, experimental protocols, intellectual property protections, food and feed safety, environmental safety, socio-economic benefits etc., along with details of proposed field trials. An applicant for a NOC for BRL I trials does not have such information. Most of this information becomes available only at an advanced stage of field trials, such as the 3rd year of BRL I, and which is anyway submitted to the RCGM/GEAC for review and approval. For BRL II, such data should not be required to be submitted again, as data from BRL I were gathered in the respective States under the supervision of the SAUs. Resubmitting voluminous data to the States involves duplication of efforts resulting in avoidable time and financial burden;

f) A more serious issue is that much of the data constitute 'Confidential Business Information', and there is no guarantee of protection of confidentiality of the information provided to the State governments;

g) The number and frequency of meetings of the NOC Committees are not time-tabled and so results in lots of time delays;

h) The activists and the anti-tech governments of some States support the NOC requirement for political reasons taking shelter behind the much repeated cliche that *'Agriculture is a State Subject'* and so the Centre has no jurisdiction over it. Even though agriculture is included in the State List of the Seventh Schedule of Article 256 of the Indian Constitution, besides the provisions of the EPA, 1986 (Rules of 1989), there are number of saving clauses that empower the Central government to act for the whole country on any issue. A provision is made in the Regulatory Regime defining a role for the States in the form of SBCCs and DLCs, which no State has made use of;

i) Field trials are not agriculture. In fact, no aspect of the R & D of GE crops is agriculture, as the products have no commercial value and do not go to the farmers, market or consumers, until approved for commercialization. Consequently, GE crop R & D does not attract the protection under the Seventh Schedule;

j) Item 14 in the State List of the Seventh Schedule reads *'Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases'* and the States neglected this mandated serious responsibility but cling to something which is outside their legitimate rights;

k) The NOC requirement is the most serious setback to GE crop R & D. The revalidation of March 2013 field trial clearances authorized by MoEF3 in March 2014 or the approvals given by the GEAC on August 28, 2014, (see section 7.1 in this article) mean something only in those States that give NOCs, and the GEAC would not approve field trials in those States that did not give NOCs; and

l) Rescinding of the NOC order by the MinistryEF and the GEAC, or even a decision from a Court of Law declaring the NOC restriction as null and void, will not change the situation drastically. The sanction or refusal of NOCs by the State governments cuts across the lines of the party in the Central and State governments. With appeasement of activists as the sole objective, the politicians will side with the activists and together they would engineer disruption of field trials through one or the other means, as they have done so many times earlier as in no State either the government or the pro-tech farmers are strong enough to take upon the anti-tech groups.

8. THE NEED FOR A RETHINK ON THE IMPLEMENTATION OF THE REGULATORY POLICY

For a long time, scientists have been expressing dissatisfaction regarding a) excessive regulation, b) frequent raising of the bar of regulatory standards and c) unjustified delays in granting regulatory approvals, most of which stem from activist pressure and political expediency. Overregulation, delays and disruptions in conducting field trial have negative short and long term implications, denying farmers the access to novel technologies. Continued uncertainty of regulatory oversight discourages investment in research and slows down innovation, development of next-generation products, talent retention and many more (Graff *et al.,* 2009; Padmanaban, 2013; Choudhary *et al.,* 2014a).

Several scientists feel that the lack of appropriate, science-based and cost/time-effective regulatory systems continues to be the major constraint to a wider adoption of GE crops (Potrykus, 2010 a, b; Miller, 2012; Dubock, 2013; James, 2013). In such a situation, no public institution can deliver public good GE products, which gives a *de facto* monopoly in favour of a few potent industries (Potrykus, 2010b). The need for a rethink and shift in attitudes in the implementation of the regulatory regime was discussed by Cantley and Kershen (2013) and Heap (2013). A responsible, rigorous but not onerous, regulation is needed, particularly for small and poor developing countries, which are completely 'locked out' because of the high cost of developing and gaining approval of biotech crops (James, 2013). A fast-track approval system in Brazil facilitated rapid adoption of biotech crops and such an option would immensely benefit the developing countries.

9. CONCLUSIONS AND RECOMMENDATIONS

A number of conclusions were drawn contextually in different sections of this article. The crucial issues are, a) the Central government should free the GEAC from political and ministerial interference as was exercised by MoEF1, 2 and 4 and allow the GEAC to carry out its mandated functions, which is not happening now, b) the government should ensure that till the BRAI gets in place the current regulatory regime functions without external pressures, and c) the order requiring NOCs from the States for conducting field trials should be withdrawn immediately, as the MinistryEF itself has stated before the PSCA that it is not necessary and also because even some States (Karnataka) do not believe that they have a *locus standi* in permitting or not permitting of open field trials of GE crops conducted in the States.

Some of the following conclusions and recommendations were taken from Kameswara Rao (2014) and some of them are relevant only so long as the NOC requirement is in place:

a) The efficacy, safety and benefits from GE crops have been well established in different countries, as well as their crucial role in enhancing agricultural production contributing to food security in the developing countries. In India *Bt* cotton, now grown over 95 per cent of cotton area, has demonstrated the potential of the technology and its benefits to the country;

b) The current regulatory regimes in different countries are similar and scientifically sound, notwithstanding the noises made by the activists. The technical expertise of the product developers and biosecurity evaluators is no longer in question. Nevertheless, the scientifically established and rigorously implemented Indian regulatory system has taken a sound beating from, i) the activists, ii) the MoEF1, 2 and 4 who sided with the activists, iii) moratorium on *Bt* brinjal, iv) the long pending WP in the SCI, v) the TEC, vi) the PSCA and vii) the requirement of NOCs from the State governments;

c) The government should respect the combined global and national scientific wisdom in evaluating GE products through their regulatory regimes, and the decisions on the process of biosecurity evaluation.

The acceptance or rejection of products should not be allowed to be hijacked by the vested interest using junk science pursuing inept politics;

d) Specific data sets required to be gathered for different crops from BRL I and II trials vary from crop to crop, from one agro-climatic zone to another and are often dependent upon the end use. A uniform policy on the procedures and content of applications for NOCs and for monitoring the open field trials by the SAUs should be in place. Consensus documents on these issues should be prepared in order to avoid arbitrary and whimsical demands for additional information by the State governments, RCGM and the GEAC, halfway through the process;

e) The present impasse surrounding different aspects of GE crop evaluation can be reversed only if there is a strong desire and the courage of conviction on the part of the MinistryEF and the GEAC to do so. The MinistryEF and the GEAC should advise the States on the illegality and undesirability of the NOC requirement and provide guidelines to be followed in the conduct of open field trials in the States;

f) A speculative environment will discourage biotechnological research triggering loss of further investments, talent and opportunities. It also curtails the farmer and the consumer the choice of crops and foods. It denies the country urgently needed remedial measures to enhance food security and to ameliorate nutritional deficiencies. Delay or denial of crops favoured by the farmers would result in illegal cultivation as has happened in Gujarat and Andhra Pradesh;

g) The MinistryEF and the GEAC should encourage more research to establish biosafety and environmental safety rather than thwarting research through unnecessary restrictions such as the NOCs. Both the short and long term policy on regulatory approvals should be predictable and reassuring to build up the confidence of the product developers about the fairness of the structure and implementation of the regulatory regime, providing for a level playing field for all the stakeholders;

h) The Central government should resist interference by all activist groups in formulating and implementing national policy and rein in all activist groups by bringing them under the provisions of the RtI so that the public can seek information on their funding, expenditure and activities;

i) There is an alarming amount of inflow of foreign funds and evidence of their use to thwart developmental activity by several Indian activist groups. Those activist groups that are supported by international funding to enforce the agenda of western governments on Indian policy should be investigated as per the provisions of the Foreign Contributions (Regulation) Act, 2010;

j) The MinistryEF and the GEAC should release *Bt* brinjal for commercial cultivation without any further delay, as it does not need any more field trials or tests but only an official order for commercialization. This will help the Indian brinjal farmers, boost up the confidence of the scientific and industrial circles, and energize them to continue research on GE crops. The Indian brinjal farmers would then derive the same reported benefits as the *Bt* brinjal farmers in Bangladesh (Choudhary *et al.,* 2014b). Golden Rice should be fast tracked with a time frame of three to four years for commercialization so that no more time is lost in saving millions of poor women and children from vitamin A deficiency disorders;

k) NOCs are issued smoothly when the Vice Chancellor of the SAU chairs the NOC Committee (for example, Gujarat, Haryana and Punjab), than when the Principal Secretary to the State government or the State Ministry of Agriculture chairs the Committee. The GEAC had conceded that the *'States'*

objections to field trials of GE crops were due to lack of their understanding on issues of biosafety and environmental safety, the science of regulatory evaluation and the States' own role in the governance of regulatory process' (MoEF, 2011a). There is a strong need for awareness workshops conducted by the Ministry of EF in coordination with GEAC, DBT and the MoA to promote informed decisions at the State level;

l) The MinistryEF should ensure that the governments of all States constitute the SBCCs and DLCs to monitor research and field trials in their States for any violation of mandatory responsibilities by the product developers, instead of preventing field trials altogether;

m) By refusing NOCs, State governments are ruining the prospects of agricultural development in their own States. All State governments should permit open field trials in their States in order to facilitate a country wide picture of biosecurity evaluation. If they so desire, the State governments may later prevent commercial cultivation of particular GE crops in their State, but then may have to face such consequences as illegal cultivation by farmers;

n) State government NOCs for field trials are not a serious impediment provided, i) there is a level playing field devoid of vested political interest in stopping them, ii) a uniform set of information requirement and procedure for processing the applications and iii) a time frame to decide on the applications;

o) The product developers should make collective efforts to impress upon the governments of all States on the need and importance of conducting field trials in their States for their own benefit and press for a shift in the policy that permits smooth conduct of open field trials and commercialization of approved products;

p) The activists use every means to block GE crop technology at every phase, while the product developers and scientific organizations have been mute spectators suffering the consequent losses of credibility, time and financial investment. They all should join together to take legal action against false charges against scientists, technology, and industry. They should also stand up against scientifically unjust and illegal moves of the governments such as the NOC requirement;

q) There is a distinct shift in public response in favour of GE crops. All those involved in GE crop development should provide the public with appropriate, adequate and timely information on the efficacy, safety and benefits of GE crops, countering activist propaganda as soon as it emerges. The activists mix up management, political, economic, societal and ethical issues and project them as technology burden, sidelining sound science to mould public opinion against technology. An important step the product developers, scientists and the governments should take is to conduct public awareness programmes to untangle the misinformation and disinformation from factual information on the efficacy, safety and benefits from GE crops to build up public confidence in them;

r) The scientists and the product developers have placed a lot of hope on the new NDA government at the centre and expected it to be supportive of GE crop technology, as the PM encouraged it in Gujarat, but that hope seems to have been misplaced. On some important issues including GE crop field trials, the NDA government yielded to pressure from fringe groups with political expediency at heart and without concern for consequences. On July 18, 2014, the GEAC has approved open field trials of some Events of rice, wheat, maize and cotton, which are a part of a backlog of about 70 applications pending since 2011-12. But on July 29, 2014, the present MoEF (MoEF4) placed GEAC's approval on hold in response to

activist pressure, repeating the performance of MoEF2 (see section 7.1). This smacks of a knee jerk reaction to even mild pressure and shatters the confidence of the GEAC in its own functioning. Evidently, the present situation reflects a lack of a sense of direction and policy on GE crops technology, and is indicative of a conflict of opinion between the PM's pro-technology statements and MoEF4's political expediency. The mantra of the government should be containing anti-development activism and placing trust in the national and international scientific community;

s) The events since February 2010 amply demonstrate the political power the anti-GE crop activists have over the past and the present governments at the centre and the apathy bordering contempt of the latter towards the national and international scientists, scientific institutions and GE crop technology. This position has to change drastically before it further damages the country's agricultural prospects. This cannot happen unless the national and international scientific community and the product developers come together to oppose mindless anti-tech activism; and

t) The government has to adopt the 'Alexandrian solution' of cutting the ‘Gordian knot’ to resolve the present impasse and place GE crop development on track. Only the PM's intervention and decisive positive action to remove all the hurdles, can save the situation.

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Table 1: NOCs issued by State Governments since July 2011

States	Field trials	GE crops/ traits approved
Andhra Pradesh	Approved	Castor (IT), cotton (IT, HT, IT+HT), Rice (SPT, Salinity tolerance), sorghum (salinity and drought tolerance)
Gujarat	Approved	Cotton, maize (IT, HT, IT+HT)
Haryana	Approved	Maize (IT, HT, IT+HT), cotton (IT, HT, IT+HT)
Maharashtra	Approved@	Details not available
Punjab	Approved	Maize (IT+HT), cotton (IT, HT, IT+HT)
Rajasthan	Approved#	Mustard (male sterility)

IT: insect tolerant, HT: herbicide tolerant, SPT: Seed Production Technology
@Approved with conditions (based on industry sources)
#NOC revoked later; trial discontinued
Table compiled from MoEF (2012) and information in http://igmoris.nic.in

Table 2: GE crops and traits negatively impacted by the NOC requirement

Crop	Trait	Events (gene) or products
Cotton	Insect tolerance	ILK- *Bt (cry1Ac)*; Anjali-Ac *Bt (cry1Ac);* Anjali- F*Bt (cry1F);* RG822 *Bt (cry1Ac);* PA255 *Bt (cry1Ac);* T304-40xGHB119 *(cry1Ab, cry2Ae & bar);* MLS9124xGFM Cry1A *(cry1c,cry1A);* Event 281-24-236x; Event 3006-210-23 *(cry1F, cry1Ac)*
	Herbicide tolerance	GHB614 *(2mepsps)*; MON88913 *(CP4 epsps)*
	Insect + herbicide tolerance	T304-40xGHB119xGHB614; MON15985xMON88913
	Others:	Nitrogen use efficiency *(AlaAt);* Water use efficiency *(ipt)*
Maize	Insect tolerance	MON89034 *(cry1A.105, cry2Ab); Bt11 (cry1Ab);* TC1507 *(cry1F)*
	Herbicide tolerance	NK603 (CP4 *epsps*); GA21 *(mepsps)*
	Insect +herbicide tolerance	*Bt11*xGA21; MON89034xNK603; TC1507xNK603; TC1507xMON810xNK603;
Rice	Insect tolerance	*Bt* rice *(cry1Ac); Bt* rice *(cry2Ax1);* Dual *Bt (cry1Ab, cry1Ca); Bt* rice *(cry1Ab, cry1C, cry2Ad), Bt* rice *(cry1C, cry2Ad), Bt* rice *(cry1Ab, cry2Ad)*
	Insect +herbicide tolerance	Dual *Bt* + *bar;* Dual *Bt* x LLRice62 + *bar*
	Others:	Nitrogen use efficiency *(AlaAt);* Salinity tolerance *(OSnhx1);* Seed production technology *(Zm-AA1, Os-Msca1, and DsRed2);* Yield increase (seven plant genes)
Wheat	Herbicide tolerance	MON71800 (CP4 epsps)
Others	Multiple	Insect tolerant *Bt* castor *(cry1EC, cry1Aa), Bt* chickpea *(cry2Aa);* Late blight tolerant potato (rb gene) Fusarium wilt tolerant banana *(amp gene),* Leaf curl virus tolerant tomato; Salinity and drought tolerant sorghum; Bud necrosis virus tolerant watermelon; Ring spot virus tolerant papaya, Male sterile mustard

Table compiled from MoEF (2011a,b,c,d,e; 2012, 2013a,b,c)

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