Regulatory options for genetically modified crops in India

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Summary

The introduction of semi-dwarfing, high-yielding and nutrients-responsive crop varieties in the 1960s and 1970s alleviated the suffering of low crop yield, food shortages and epidemics of famine in India and other parts of the Asian continent. Two semi-dwarfing genes, Rht in wheat and Sd-1 in rice heralded the green revolution for which Dr. Norman Borlaug was awarded the Nobel Peace Prize in 1970. In contrast, the revolutionary new genetics of crop improvement shamble over formidable obstacles of regulatory delays, political interferences and public misconceptions. India benefited immensely from the green revolution and is now grappling to deal with the nuances of GM crops. The development of GM mustard discontinued prematurely in 2001 and insect-resistant Bt cotton varieties were successfully approved for commercial cultivation in 2002 in an evolving nature of regulatory system. However, the moratorium on Bt brinjal by MOEF in 2010 meant a considerable detour from an objective, science-based, rigorous institutional process of regulatory approval to a more subjective, non-science-driven, political decision-making process. This study examines what ails the regulatory system of GM crops in India and the steps that led to the regulatory logjam. Responding to the growing challenges and impediments of existing biosafety regulation, it suggests options that are critical for GM crops to take roots for a multiplier harvest.

A multiplier of harvest – empirical evidences

The introduction of the green revolution in India in the mid-1960s saved the country from devastating famine epidemics. The results of growing semi-dwarf and high-yielding varieties of wheat and rice were very significant (Evenson and Gollin, 2003; IFPRI, 2002; Pingali, 2012; Pinstrup-Andersen and Hazell, 1985; Randhawa, 1986; Ruttan, 1977). The Indian Council of Agricultural Research (ICAR) led by Prof. M.S. Swaminathan heralded the green revolution by successfully deploying the genetics comprising of genes and cultivars including Norin-10 & Gaines pedigree cultivars, carriers of Rht genes from Mexico into locally adapted bread wheat, Triticum aestivum germplasm. This resulted in dwarfing of wheat plants that were less-prone to lodging, early maturing and high yielding with improved uptake of nutrients and more responsive to nitrogen fertilizers (Rajaram, 2001; Walcott and Laing, 1976). Kalyansona and Sonalika – two of the five semi-dwarf and high yielding wheat varieties released in late sixties became highly popular in the principal wheat growing areas especially in the Indo-Gangetic Plains (IGP) of the country. The semi-dwarf wheat varieties were readily adopted by millions of farmers on 12.5 million hectares in the first 10 years period representing 62% of total wheat cultivated area of 20 million hectares in 1976–1977, with a modest beginning of 0.54 million hectares during the first year of release of Kalyansona and Sonalika in 1966–1967 (DAC, 2002). A sizeable increase in yield at farm level shored up the area under wheat production by 60% from 12.84 million hectares in 1966–1967 to 20.45 million hectares in 1975–1976. The average national wheat productivity grew to an all time high of 1410 kg per hectare in 1975–1976 from 827 kg per hectare in 1965–1966 (Randhawa, 1986). Figure 1 reflects significant changes in wheat and rice production expressed as % increase over a 10 years moving average from 1950–1951 to 2010–2011. Smallholder wheat farmers experienced a multiplier of harvest increasing income by outperforming the conventional popular tall wheat varieties NP824, S227 and C306 at farm levels.

During the same period, the deployment of the semi-dwarfing trait in rice, Oryza sativa, another vital staple crop of Asia was even more pronounced and turned out to be life and livelihood-saving for about 150 million rice growing farmers in Asia. Notably, the semi-dwarfing single Sd-1 gene derived from a deeo-geo-woo-gen rice variety sourced from Taiwan led to the development and release of the first most popular semi-dwarf IR-8 rice variety in 1966 in India, the Philippines and other parts of rice-growing areas of Asia (Gale and Youssefian, 1985; Hargrove and Coffman, 2006; Khush, 2001; Sasaki et al., 2002). Across Asia, smallholder rice farmers obtained a yield advantage of 1–2 tons per hectare growing the IR-8 variety compared with popular traditional varieties on irrigated land (Chandler, 1972). This instantaneously sparked a mass adoption of semi-dwarf rice varieties in India by the mid-seventies. Subsequently, IR-8 and other IR series have been used as parents in breeding programmes under the National Agricultural Research System (NARS) resulting in numerous improved high-yielding rice varieties conferring desirable traits including insect and disease resistance,
improved grain quality, early maturity etc. These varieties were suitable for different rice-growing seasons of *khair*, winter and summer across India (Khush and Virk, 2005; Randhawa, 1986). As a result of yield transformation at farm level in irrigated areas, the country realized a noticeable shift in national average rice yield from less than 1 ton per ha in 1966–1967 to 2.5 tons per ha in 2010–2011. Rice production at national level increased to a landmark 100 million tons in 2011–2012, more than tripling the production of base year 1966–1967. The momentum of green revolution continues to propel scientific breakthroughs by blending conventional technologies with marker aided selection (MAS) for the improvement of not only ordinary rice but also aromatic basmati rice. This resulted in the release of the first high-yielding dwarf aromatic basmati rice variety Pusa Basmati-1 in 1989 and later the release of the first aromatic basmati rice hybrid RH-10 and Pusa-1121 in 2002 (IARI, 2007).

In summary, the dwarfing genes introduced in wheat and rice helped to reduce plant height, minimize plant lodging, maximize uptake of nitrogen fertilizer and increase spikelet/tiller fertility. These new features allowed plants to have robust seed settings and uniform grain filling that contributed to a significantly higher harvest index. It was reported that the semi-dwarfing genes *Rht* and *Sd-1* in wheat and rice, respectively, have a similar mode of activity. The genes interfere with the action or production of gibberellin (GA) plant hormones resulting in a semi-dwarfing trait in the plants (Ashikari et al., 2002; Hedden, 2003). This action of dwarfing genes translates growth through a so-called gain-of-function mutation attributing plants with shorter stem and higher grains in spikelet and tillers in wheat and rice, respectively, (Khush, 2001). The dwarfing genes also optimize the plants capability to effectively utilize the increased availability of nitrogen fertilizer, which was made available in sufficient quantities to smallholder farmers. The invention of the Haber–Bosch process for synthetically fixing nitrogen, for which Fritz Haber was awarded a Nobel Prize in 1919, was a key component of the success of green revolution. The year 2013 marks the 100th anniversary of the landmark invention enabling farmers to maximize yield of staple crops during and post-green revolution period (Mingle, 2013; Posgate, 1974; Tilman et al., 2002). The yield increases translated into higher production of staple crops that was required to meet burgeoning food demand in Asia that saved an estimated 18–27 million hectares additional area from being brought into agricultural production (Stevenson et al., 2013). As a consequence of the green revolution, the food grains production achieved a record milestone of 100 million tons in early seventies. It helped the country to reduce import of food grains from 10 million tons per year prior to green revolution to less than half a million ton in 1972, making the country self-sufficient and substantially reducing reliance on imported food (Randhawa, 1986). It is also noted that the semi-dwarfing genes *Rht* and *Sd-1* have been extensively used to develop most modern wheat and rice varieties across Asia (Saville et al., 2012; Spielmeyer et al., 2002). However, the yield potential of modern rice and wheat varieties has remained constant under best farm conditions since the release of the semi-dwarfing trait in 1966 (Cassman, 1993), which is a major concern for further increasing average farm yield in Asian countries. Stagnation in the yield is reflected at national level exhibiting a plateauing trend in per capita availability of wheat, rice and total staple food grains in India since the 1990s (Figure 2). In addition to the demonstrated positive impacts of the green revolution, it is important to bear in mind the adverse effects of the green revolution technology, which range from excessive use of nitrogen fertilizers, exploitation of surface and aquifer water and other resources.

Towards a biotech-led agricultural production system

By 2050, the world will have to produce 70% more food, feed and biomass on about the same area of land (FAO, 2009). Rising population, income, dietary preferences and urbanization in developing countries, and certainly in India, requires extraordinary steps to intensify agriculture production to meet the growing demand by substantially increasing crop yield and optimizing the use of input resources. It has been recognized repeatedly since the Earth Summit in 1992 that neither the current agriculture production system nor the modern biotechnology alone can solve the complex challenges of feeding the world of tomorrow. A successful strategy must combine multiple approaches that integrate conventional crop improvement with modern...
biotechnology that has shown promising results by optimizing productivity and contributing to food, feed and fibre security over the last couple of years.

The biotech revolution started with a landmark discovery of a tumour-inducing plasmid in 1974 (Schell and Van Montagu, 1977), commonly referred as Ti-plasmid carrying a T-DNA in the soil bacterium Agrobacterium tumefaciens. That system was used for the first time as a tool to transfer the gene(s) of interest from another organism into plant cells around the early eighties (Bevan et al., 1983; Fraley et al., 1983; and Herrera-Estrella et al., 1983). The discovery and development of the Ti-plasmid and the process of gene transfer using Agrobacterium-mediated transformation resulted in novel plant types. The genetically enhanced plants contain a set of desirable traits that could not be incorporated through conventional breeding techniques during the green revolution period. The new crop improvement technique became a universal tool of gene transfer between unrelated species, both in public and in private sector in industrial and developing countries. It is often used to assist the development of crop varieties with higher yield potential and yield stability and to combat the prevailing yield ceiling of food staples, commercial and vegetable crops in tropical and subtropical regions (Cassman, 1993; Khush, 2001). Notably, this new crop improvement strategy integrates the best of biotech traits and the best of conventional breeding techniques during the green revolution period.

A consequence, two similar but independent projects were commenced in the mid-1990s. The first was led by the public sector institute ICAR under the World Bank funded National Agricultural Technology Project (NATP) to develop indigenous insect-resistant Bt cotton. Second, a private sector initiative was worked out between the Indian seed company Mahyco and Monsanto to develop and deliver insect-resistant Bt cotton hybrid varieties. Smallholder cotton farmers were suffering huge losses in cotton production due to high susceptibility to Lepidopteran insect-pests commonly known as bollworm complex consisting of American bollworm Helicoverpa armigera, Pink bollworm Pectinophora gossypiella and Spotted bollworm Earias vitellia (Karihloo and Kumar, 2009; Kranthi, 2012; Mayee et al., 2002). Helicoverpa armigera was by far the most damaging insect-pest, occurred in a periodic cycle causing devastating losses of cotton up to 80% resulting in frequent crop failures. Dhawan et al. reported the occurrence of the outbreak of American bollworm to the extent of epidemic nature in cotton-growing areas across India in 1978, 1983, 1987, 1990, 1995, 1997, 1998 and 2001 (Dhawan et al., 2004; Mayee et al., 2002). On an annual average, the losses due to bollworms ranged between 30 and 35% of cotton crop. Controlling this required minimum 6–8 spraying of chemical insecticides of which some became ineffective due to resistance of bollworms (CICR, 2007; Kranthi, 2012; Kranthi et al., 2009; Mayee et al., 2002; Ramasundaram and Gajbhiye, 2001). It was estimated that insecticides in Indian agriculture valued at US$504 million in 2001 of which about 46% were used on cotton alone (Balasubramani et al., 2000; CICR, 2007; James, 2002; Kranthi, 2012). Smallholder cotton farmers suffered considerable losses season after season with annual average cotton yield remaining as low as 300 kg lint per hectare, and often <154 kg lint per hectare in rain-fed cotton regions. The indiscriminate usages of chemical insecticides guided by subjective assessment of the visual presence of bollworms rather than guided by the more objective science-based methodology of economic threshold levels led to deleterious consequences on health, biodiversity and environment (Abhilash and Singh, 2009; Balasubramani et al., 2000; Mancini et al., 2005).

Against this backdrop, the Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment and Forests (MOEF) in the 32nd meeting held on 26 March 2002 accorded the approval for release into the environment of three Bt cotton hybrid varieties namely MECH 12, MECH 162 and MECH 184 developed by Mahyco (GEAC, 2002a; Jayaraman, 2002). The cry gene(s) are derived from a ubiquitous soil-borne bacterium, Bacillus thuringiensis (Bt) that is commonly used as a biological
pesticide to control borer insect-pests. The insect-resistant Bt cotton varieties, expressing novel cry gene(s) primarily in Gossypium hirsutum species were approved for commercial cultivation in 2002 – 8 years after the first commercial release of Bt cotton varieties in the USA, Australia and Mexico (James and Krattiger, 1996). This decision was based on regulatory studies conducted during 1996–2001 demonstrating efficacy, environmental protection and agronomic performance of Bt cotton in the country (Barwale et al., 2004; GEAC, 2002b; Manjunath, 2004; Mayee et al., 2002). After obtaining an import permit in 1995 from the Review Committee on Genetic Manipulation (RCGM), Mahyco imported 100 gm seeds of cotton variety Coker312 containing Cry1Ac from Monsanto, USA by early 1996. Subsequently, the Bt trait was introgressed into locally adapted cotton parent materials using the standard recurrent backcross breeding techniques, which served as a pool to develop MECH/MRC denominated Bt cotton hybrids. A series of risk assessment studies was undertaken on Bt cotton in conformity with increasingly strict requirements set by the regulatory committees between 1996 and 2002. To assess the agronomic performance and other parameters of insect resistant cotton and its interaction with the environment, a set of controlled multilocation field trials were conducted in major cotton growing States between 1998 and 2000 followed by 2 years large-scale field trials of Bt cotton hybrids with respect to non-Bt cotton counterparts and control checks. These trials allowed regulators to carefully examine the Bt trait with regard to food and feed safety, gene flow, cross-pollination, effect on non-target beneficial organisms and impact on soil microorganisms, etc. (Barwale et al., 2004; GEAC, 2004; Manjunath, 2004). Concurrently, GEAC called on the public sector ICAR to validate the safety, efficacy and performance of Bt cotton hybrids under the independent All India Coordinated Cotton Improvement Project (AICCIP) in 2001. Both confined, multi-location and large-scale field trials were closely monitored by the Monitoring and Evaluation Committee (MEC) under the aegis of regulatory system. The decision of GEAC to approve the release of India’s first insect resistant Bt cotton in 2002 was based on a large number of scientific studies, multipoint datasets, and compelling field-level evidences indicating a significant reduction in insecticide sprays and noticeable increase in cotton yield across irrigated and rain-fed cotton-growing areas. Guided by an evolving nature of technology and regulatory system, GEAC attached an extraordinary importance to post-release conditions necessitating the developers to exercise diligence in implementing insect resistance management strategy and monitoring, reporting and outreach activities across cotton-growing areas (GEAC, 2002b; Jayaramanan, 2002). The regulatory oversight and product stewardship – a new concept to Indian agriculture have been implemented to the extent that Bt trait continues to provide effective protection against bollworms over a long period overriding public concerns.

The outcomes of introducing insect-resistant Bt cotton in Indian agriculture have been exceptional and unparalleled. The adoption and impact of Bt cotton not only contributed to doubling national cotton production but also delivered broad-based, inclusive and scale-neutral benefits to smallholder cotton farmers. (Bennett et al., 2006; Dev and Rao, 2007; Gandhi and Nambudiri, 2006; James, 2012; Kathage and Qaim, 2012; Lok Sabha, 2012; Qaim et al., 2006; Subramanian and Qaim, 2009). Cotton farmers irrespective of their farm size quickly replaced the commonly used chemical-based crop protection method, which carries great health risks of workers, with the insect resistant Bt cotton – a more efficient and cost-effective method of crop protection. In a short period of 10 years, around 7 million small cotton farmers representing ~90% of total cotton farmers in the country adopted Bt cotton on 9.5 million hectares, occupying 88% of the cotton crop in 2011–2012 (James, 2012; PIB, 2011; Rajya Sabha, 2012a). A series of studies confirmed a significant reduction in the number of insecticide sprays by half, and more specifically, a steep reduction of insecticide sprays from 7 to 8 sprays to almost nil to control bollworm complex – a target pest for the Bt trait (Bambawale et al., 2003; Bennett et al., 2006; ICAR, 2002; James, 2002, 2012; Kranthi, 2012; Naik, 2001; Qaim and Zilberman, 2003). As a result, the sale of insecticides and spraying equipments has plummeted in rural India. The use of chemical insecticides on cotton measured in active ingredient, halved from 46% of total insecticides used in agriculture in 2001–2002 to 20% in 2011–2012 despite a significant increase in cotton cultivation area in the same period (Figure 3) (Kranthi, 2012). Likewise, studies reported that 9 of 10 farmers who planted Bt cotton repeated planting in subsequent years – a very high level of repeat adoption, which was consistent with the remarkably high % adoption rate of Bt cotton listed in a chronological order, 1% adoption in 2002; 1 in 2003; 6% in 2004, 15% in 2005, 42% in 2006, 66% in 2007, 81% in 2008, 81% in 2009, 85% in 2010 and 88% in 2011 (James, 2012; Kranthi, 2012).

Despite this documented trend, the allegation of failure and ill-effects of Bt cotton continues to rage. Without presenting...
empirical evidences, Bt cotton has been alleged to cause sheep and cattle deaths, adversely affect human health and to some extent attributed to have caused farmers’ suicides in Vidharbha region of Maharashtra. The Government of India when briefing on the farmers’ suicides to both houses, Rajya Sabha and Lok Sabha of the Parliament of India has termed the allegations as very speculative without any reasonable assessment of the technology strength of Bt cotton (Lok Sabha, 2013). ‘There seems to be no evidence of direct relationship between Bt cotton and farmers’ suicides’, stated in the Rajya Sabha of the Parliament of India (Rajya Sabha, 2012b). Similarly, several empirical assessments of Bt cotton have found no evidence of a resurgence of farmers’ suicides in the country (Guillaume and Sengupta, 2011; IFPRI, 2008). Notably, Bt cotton has been referred as neither suicide seeds nor silver bullets, but a remarkably valuable technology (Herring, 2013).

On the contrary, at national level, the average cotton yield, which used to have one of the lowest lint yields in the world, increased significantly from 308 kg lint per hectare in 2001–2002 to 493 kg lint per hectare in 2011–2012. Figure 4 shows a steep growth in changes in yield expressed as kg lint per hectare concomitant with the introduction of Bt cotton measured over a 10 years moving average from 1950–1951 to 2010–2011. The yield increases were also correlated with the large-scale adoption of Bt cotton in the major cotton growing areas, which later exhibited a sign of tapering of national average yield. This is primarily caused by a substantial overall increase in cotton areas over non-traditional cotton areas with 3 million hectares, from 9.1 million hectares in 2006–2007 to 12.1 million hectares in 2011–2012 (CAB, 2012). Farmers preferred to grow Bt cotton because it became comparatively more profitable than other crops such as millets and legumes in non-traditional cotton areas of semi-arid tropics. Consequently, the national cotton production increased from 13.6 million bales in 2002–2003 to 35.3 million bales in 2011–2012, a steep increase in 160%. Figure 5 shows a consistent rise in cotton production measured as million bales per year over 10 years moving average from 1950–1951 to 2010–2011 indicating a positive trend regardless of a yearly fluctuation in cotton yield in recent years. As a result, the country’s cotton accounted for more than one-fifth or 21% of the total world cotton production in 2011–2012, which is substantially higher than the 14% in 2002–2003. India is projected to become the number one cotton producing country in the world in the near future (Choudhary and Gaur, 2009a; OECD/FAO, 2012; PTI, 2013).

In summary, 35 years after the green revolution, in which the introduction of semi-dwarfing genes in wheat and rice had significant positive impacts on lives and livelihoods of the farmers and people of India, a new set of gene(s) popularly known as Cry genes, were successfully deployed in cotton to impart an effective control of Helicoverpa armigera – the most dominant and destructive insect-pest of cotton in the country.

Despite the mounting empirical evidence, decades of farm-level experience and large-scale acceptability by farmers, the societal and political discussions on the usefulness of gene(s) is far from waning. On the contrary, the high-pitch debate about biotech revolution tips to a broad spectrum of topics targeted at the general public and policy makers and has disrupted the regulatory decision-making process on GM crops in the country.

Regulatory beginning

The National Biotechnology Board, which was constituted in 1982 issued a set of biotechnology safety guidelines in 1983 to undertake biotech research in laboratory and contained use settings. In 1986, the National Biotechnology Board was promoted to a full fledge Department of Biotechnology (DBT) under the Ministry of Science and Technology (MOST) (Sharma et al., 2003). In the early years, DBT monitored developments in the biotech field globally, developed safety guidelines and made efforts to promote large-scale use of indigenously relevant biotechnologies in the country. Realizing the importance of adequately assessing biosafety, biodiversity and environmental risks (Ghosh, 1997), the research, product development and commercial release involving GMOs, hazardous microorganisms and trans-boundary movement of the living modified organisms (LMOs) by default were reallocated to MOEF. The Government of India (Allocation of Business) Rules 1961 assigned the responsibilities of ‘biodiversity conservation’ and ‘environment protection’ to MOEF in 1961 (Government of India, 1961).

Thereafter, MOEF began regulating genetically modified organisms and products thereof under the existing Environmental Protection Act 1986, commonly referred as EPA 1986, which was enacted by the Parliament of India in 1986. Whereas the EPA 1986 does not describe GMOs and GM crops in the law per se, it lays down the legislative provisions to regulate ‘hazardous

![Figure 4](image-url) Changes in cotton yield expressed as kg/ha over a 10 years moving average from 1950–1951 to 2010–2011 (CAB, 2012).
substances’ *(Hazardous substance of the EPA 1986 section 3, 2 (iv) means any substance or preparation which, by reason of its chemical or physicochemical properties or handling, is liable to cause harm to human beings or other living creatures, plants, microorganism, property or the environment) and to make administrative rules to regulate environmental pollution caused by hazardous substances. Henceforth, MOEF drafted and notified ‘the rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells in 1989’ referred as the EPA Rules 1989 under ‘hazardous substances’ section of the EPA 1986. As a result, GM crops, GMOs and the products of genetic engineering were de facto categorized as ‘inherently harmful’ in the same manner as hazardous substances that cause harm to human beings or other living creatures, property or the environment. Notably, the EPA Rules 1989 to regulate GMOs and GM crops were issued by an ‘administrative order’ through publication in the Gazette of India vide notification GSR 1037(E) dated 5 December 1989 and came into force vide notification S.O.677(E) dated 13 September 1993 (Gazette of India, 1989, 1993).

The EPA Rules 1989 cover a range of activities involving manufacture, use, import, export, storage and research of all genetically engineered organisms including microorganisms, plants and animals and products thereof. The Rules also apply to hazardous microorganisms that are pathogenic to human beings, animals or plants, regardless whether they are genetically modified. The Rules 1989 not only regulate research, development and large-scale commercialization of GM crops but also order compliance of the safeguard through regulatory approach, post-approval monitoring of violation and non-compliance (Ahuja, 2005). The Rules define competent authorities and composition of such authorities for handling of various aspects of GMOs. There are six competent authorities that function into a three-tier system; the first tier includes the ‘Policy Advisory Committee’ such as the Recombinant DNA Advisory Committee (RDAC); the second tier consists of ‘Regulating and Approval Committees’ such as the Institutional Biosafety Committee (IBSC), the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC), and finally, the third tier includes the ‘Post Monitoring Committee’ comprising of the State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC). The functions of each of the committees have been articulated in the Rules 1989. In the spirit of interministerial coordination, the implementation of the Rules 1989 was fast tracked with the subject matter expertise and experience of DBT. As a matter of fact, the EPA Rules 1989 assigned the biosafety, risk assessment and risk management related aspects of GM crops to DBT. Notably, DBT was made an integral part of the EPA Rules 1989, which was a unique feature allowing both ministries – MOEF and DBT of MOST – to regulate and safeguard from any foreseeable harm and weigh risks and benefits of GM crops and hazardous microorganisms under the Rules 1989. However, in case of post-monitoring of GM crops, the EPA Rules assigned the responsibility to the respective State(s). It established a regulatory framework involving multiple government departments and delineated the administrative structure, authority, procedure and requirements for the regulation of GM crops at Union and States level. However, the Rules 1989 were unclear on the role and responsibility of the Ministry of Health and the Ministry of Agriculture – the important ministries that are empowered to regulate seed and human health and matters related to regulation of GM crops. Over the years, the biosafety regulatory system has evolved into a dynamic and comprehensive regulatory framework that involves different ministries; first, the ministries authorized under the EPA Rules 1989 and second, the ministries that indirectly deal with GM crops. Figure 6 describes the interministerial coordinated regulatory framework on GM crops in India.

The regulation of GM crops from development, environmental release to commercial approval has been covered by three legislative Acts enacted by the Parliament of India and administered by different ministries. These included the Environment Protection Act 1986 implemented by MOEF, the Seed Act 1966 & the Seeds (Control) Order by Ministry of Agriculture (MOA) and the Food Safety and Standard Act 2006 (subsumed the Prevention of Food Adulteration Act 1954) by the Ministry of Health and Family Welfare (MOH&FW).

The EPA Rules 1989 were made central to the biosafety regulation of GM crops whereas others applied to food safety and quality of seeds for sale and matters connected thereto (Asia Law House, 2005). The next layer of legislations (secondary legislation) dealt with import of material for R&D, access to biological resources and intellectual protection of plant varieties. Each Act has been implemented through a detailed guideline termed as
Rules that described function, process, power and composition of different regulating agencies to implement the Act (Figure 6).

As per the EPA Rules 1989, the Recombinant DNA Advisory Committee (RDAC) set up by DBT brought out a first set of ‘Recombinant DNA Safety Guidelines’ in 1990 to regulate rDNA technology in medicine and agriculture. These guidelines were revised in 1994 as ‘Revised Guidelines for Safety of Biotechnology’. Realizing the need for comprehensive guidelines for transgenic plants in the mid-nineties, DBT framed and released a comprehensive guide for GM crops in 1998 referred to as ‘Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts’ to regulate GM crops and products. With regard to the application of GM crops, the guidelines 1990, 1994 and 1998 outline safety procedures, testing and use of genetically modified organisms and products. Considering the ecological consequences and the potential risks associated with the environmental release of GM crops, the guidelines prescribe the biosafety evaluation and risk assessment of the environmental aspects and agronomic performance on a case-by-case basis taking into consideration specific crop, trait and agro-ecological system (DBT, 1990; Ghosh, 1997; Rao, 2007; Tripathi and Behera, 2008). These guidelines also call for regulatory measures to ensure safety of imported GM materials in the country (Randhawa and Chhabra, 2009).

The regulatory system evolved along with the import of transgenic crops, GM mustard by Proagro and Bt cotton by Mahyco for R&D purpose in the mid-nineties. The development of GM mustard *Brassica juncea* was discontinued in 2001 by Bayer CropScience that acquired Proagro at the penultimate stage of commercial approval. The insect-resistant Bt cotton varieties primarily *Gossypium hirsutum* developed by Mahyco in collaboration with Monsanto received approval for commercial cultivation in 2002. The approval process witnessed an intense debate and protest as a result of the evolving nature of regulatory system responding to scientific, technological, policy and social chal-

Figure 6 Interministerial coordinated regulatory framework on GM crops in India (Compiled by author, 2013).
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Challenges. After gaining a considerable field-level experience with BG-HIC Bt cotton event, GEAC approved three new cotton events in 2006 namely BG-IIC Bt cotton expressing Cry1Ac and Cry2Ab developed by Mahyco. Event-1 Bt cotton expressing Cry1Ac developed by JK Seeds and GFM event expressing Cry1Ab and Cry1A developed by Nath Seeds. Subsequently, two more events namely BNLA-601 expressing Cry1Ac developed by UAS, Dharwad and MLS-9124 expressing Cry1C developed by Metahelix Life Sciences in 2008 and 2009, respectively. In the meantime, the regulatory agencies processed the hybrid-based regulatory approval of Bt cotton, a more cumbersome and time-consuming process to the event-based approval mechanism (EBAM) in 2009 (MOEF, 2009a). This system allowed regulators to closely evaluate, monitor and assess risk and benefits of other GM crops including Bt brinjal, Bt/HVT maize, Bt/HVT cotton, Bt cauliflower, Bt rice and GM mustard that were extensively field tested in the country. The GEAC in the 97th meeting held on 14th October 2009 concluded that Bt brinjal event EE-1 is safe for environmental release. However, GEAC referred the decision to approve or reject the environmental release of Bt brinjal to MOEF (GEAC, 2009a). Bt brinjal event EE-1 was developed indigenously by Mahyco in collaboration with the University of Agricultural Sciences Dharwad, the Tamil Nadu Agricultural University Coimbatore and the Indian Institute of Vegetable Research Varanasi. The project was subjected to a rigorous and stringent regulatory approval process strictly complying with two-dozen regulatory permits issued by RCGM and GEAC between 2000 and 2009. On farm-level conditions, Bt brinjal demonstrated an effective resistance to the deadly fruit and shoot borer Leucinodes orbonalis that required sprays twice a week resulting in 15–40 insecticide sprays or more in one season and caused significant losses of up to 60–70% in commercial plantings (Choudhary and Gaur, 2009b; GEAC, 2009b). In spite of that, MOEF decided to impose a moratorium on the commercial release of Bt brinjal on 9th February 2010 pre-empting long-term health risk and liability relating to loss of biodiversity (MOEF, 2010).

Political impasse

The moratorium decision on Bt brinjal by MOEF marked a considerable detour from an objective science-based rigorous institutional process of regulatory approval to a more subjective non-science-driven decision-making process. This appeared primarily based on the high-pitched public consultations and selective invited interventions while ignoring the well-established regulatory and institutional norms of the country. Later, the notification issued on behalf of MOEF curtailed the role of GEAC from an ‘approval’ to an ‘appraisal’ committee and thereby systematically diminished the statutory authority of the former Genetic Engineering Approval Committee (Gazette of India, 2010). Apparently, the reasons were to effect the ministry’s intention to subjugate approval power of GEAC and to some extent justify with retrospective effect, the ministry’s controversial action to overrule the GEAC decision on Bt brinjal (Business Standard, 2010; MOEF, 2010). On the contrary, MOEF maintained that changing the name of GEAC does not undermine the authority and institutional framework of the regulatory system implemented by GEAC as per the EPA Rules 1989 (GEAC, 2010). This was the beginning of administrative and political interventions in the process of regulatory approvals of GM crops in the country.

These decisions have a far reaching consequence on the overall functioning of the biotech regulatory system. It is important to note that GEAC is authorized to accord the approval of GM crops for import, field trials and release into the environment. The committee does not have a legitimate authority to grant commercial approval of GM crops. It is in this context that the environment ministry issued approval for environmental release of Bt cotton, whereas the seed licenses for commercial sale of each Bt hybrid were granted by the respective State(s) as per the provisions of the Seed Act 1966 and the Seeds (Control) Order 1983 (Figure 6). The approval for commercial sale of Bt cotton seeds by respective State(s) was possible because the Indian constitution makes the environment the responsibility of the Union government whereas agriculture that of the respective State(s) (Choudhary, 2002).

In the case of Bt brinjal, GEAC did not accord the approval for environmental release but concluded that ‘Bt brinjal is safe for environmental release’. The committee forwarded the recommendation and report of the Expert Committee (EC-II) on the safety and efficacy of Bt brinjal event EE-I to MOEF. Subsequently, MOEF organized public consultations with a view to arrive at a decision to commercially release Bt brinjal (MOEF, 2009b), which in fact overrode the legitimacy of the State governments to approve the commercial sale of seeds with or without biotech traits.

According to the EPA Rules 1989, GEAC is the statutory committee with a sole mandate to regulate GM crops and accords approval for contained, confined and environmental release of GM crops in the country. GEAC is also entrusted with various provisions of the EPA Rules 1989 that require approval including:

1. Approval for the import of genetically modified microorganism for research purpose (section 7(1)).
2. Approval for the use of hazardous microorganisms and recombinants in research and industrial production (section 4(3)(i)).
3. Approval for all kind of experimental field trials of GM crops (section 4(3)(ii)).
4. Approval for measure concerning discharge of hazardous microorganisms (section 7(3)).
5. Approval for licenses for scaling up pilot project involving genetically engineered microorganism (section 7(4)).
6. Approval for the deliberate release of genetically engineered organism (section 9(2)).
7. Approval for certain substances containing genetically engineered organisms (section 10).
8. Approval for food stuffs containing GMOs (section 11) and finally.
9. Hold power to revoke any approval (section 13(2)).

Changing the name of GEAC from approval to appraisal committee contradicts the aforesaid provisions of the EPA Rules 1989. It also precludes the committee to exercise the authority to grant permission for approval of import, field trials and environmental release of GM crops in the country.

Moreover, in July 2011, MOEF required GEAC to adopt measures to issue permits to conduct field trials for research purpose only after the applicants submitted the ‘no objection certificate (NOC)’ from the respective State governments (GEAC, 2011a; MOEF, 2011). Unfortunately, there is no provision either in the Seed Act or the Seeds (Control) Order under which the respective State(s) can issue the no objection certificate for conducting field trials for research purpose (GEAC, 2011a). Secondly, there are inadequate
resources in the State(s) to assess and evaluate impending risk-benefits of GM crops based on simple request from the applicant intending to conduct field trials of GM crops. Ironically, GEAC has been granting hundred of field trial approvals of a dozen of crops from 1997 to 2011 without requiring a NOC from the States. The provisions of the EPA Rules 1989 have established a coherent mechanism to coordinate and monitor field trials by involving the respective State(s) through SBCC and DLC – state and district level committees. As a consequence of mandatory NOC, it triggers conflict between ‘Union Vs States’ resulting into an emergence of two sets of States, the ones that categorically refused to allow field trials and others setting up committee-after-committee to arrive at the decision of granting NOC (Indian Express, 2012; The Hindu, 2011). In the meantime, GEAC recognized that the frequent refusal of NOC by States was mainly due to lack of clarity and awareness on technical issues associated with biosafety measures (GEAC, 2011b; PIB, 2012). For the last 2 years, the requirement for a NOC issued by the State(s) greatly complicated and delayed the approval process of field trials of GM crops (see Table S1 for details).

In summary, this review identifies three fundamental flaws in the current biosafety regulatory framework in the form of the EPA Rules 1989 that need to be rectified for the Indian regulatory system to function in a cost-effective and time-bound manner:

Firstly, GM crops are categorized as ‘inherently harmful’ under the ‘hazardous substance’ provision of the Environmental Protection Act 1986, which is scientifically incorrect and gives rise to misconceptions about the safety and potential risk of GM crops to health and environment.

Secondly, the EPA Rules 1989 to regulate GM crops were issued not by a ‘legislative act’ but by an ‘administrative order’ that remains untenable and liable to change with the desire of MOEF, which affects the predictability of the regulations and ignores the need to take into account the views and policies of other concerned ministries and the Parliament of India.

Finally, the Union environment ministry administers the regulation of GM crops in India whereas agriculture falls under the respective State(s). This often confronts approvals posing a ‘Union Vs State’ conflict in decision-making on GM crops.

**Legislative corrections**

The semi-dwarfing technology and public policy – both legislative and political support were the key driving forces behind the green revolution in India and other Asian countries (Paroda and Kumar, 2000; Swaminthan, 2006). Availability of credit and fertilizer, human resources, natural resources such as water and farmers' enthusiasm played a considerable role in changing the landscape of growing wheat and rice in the countryside. Had the institutional and policy environments not been conducive, the green revolution would not have occurred in the developing countries of which India is a major beneficiary (Pinstrup-Andersen and Hazell, 1985).

It is evident that the ‘modern biotech revolution’ will cease in the absence of an enabling public policy – a vital component for the delivery of technology to smallholder farmers. The potential for modern biotechnology to contribute to sustainable farming and food security largely builds on the green revolution technologies by protecting well-adapted germplasms against biotic and abiotic stresses, enhancing genetic potential and fortifying them with micronutrients. It is partnerships, public-private, private-private and public-public (North–South and South–South) that would allow to harness the best of biotech traits and the best of adapted germplasms and therefore, public misconceptions about safety and ownership have to be dissipated for the ground-breaking technologies to reach to smallholder farmers in India and other developing countries.

The public consultation conducted by MOEF on Bt brinjal is a classic example of generating policy based evidences to impose a predetermined outcome – the moratorium on Bt brinjal in this case (Koshy, 2010; Malhotra, 2011; The Hindu, 2009). In addition, the ministry took steps to emasculate GEAC and imposed strictures on health, safety and biodiversity against the collective wisdom of the regulatory system (Jayaraman, 2009). The developments of the last couple of years have eroded the credibility of the regulatory system and exacerbated public mistrust to the extent that it derailed the process of approving field trials of GM crops for the last 2 years in the country – stalling a scientific process of R&D, safety assessment and field evaluation of crops prior to the environmental release. Secondly, it compounded the on-going litigation of GM crops in the Supreme Court of India. Finally, the regulatory system has increasingly been succumbed to political interventions and subjected to inappropriate interpretations of the precautionary approach as laid down in Principle 15 of the Rio Declaration.

To maximize the benefits of the revolutionary new genetics (Swaminathan, 2012) and at the same time minimize risks, a number of policy and regulatory steps have to be taken either to re-establish the functioning of the current regulatory system or implement a new regulatory framework that can provide smallholder farmers access to genetically enhanced crops. Both regulatory options seem to be a daunting challenge for the government of India. The first option requires the government to reverse many political decisions including the moratorium on Bt brinjal, renaming GEAC and imposing NOC conditions prior to issuing permits – discussed at length in the previous section. The second option requires establishing a new regulatory framework by enacting a new law by the Parliament of India that has the following characteristics:

1. Purposeful, that is, a system that allows the government to make informed decisions, weighing potential benefits and risks.
2. Clear, transparent and predictable, that is, decisions based on sound science, clear rules for public information, decision criteria and time limits for decision-making.
3. Non political, that is, approvals are given by an intergovernmental body, of which the members are experts in relevant fields, nominated by the ministries involved and other relevant government bodies.
4. Efficient, that is, reduce the number of different bodies involved in the decision-making process to a minimum.
5. Consistent with international obligations and practices, such as definitions (e.g., GMO/LMO), regulatory categories (e.g., contained use, environmental release, placing on the market) and decision criteria based on sound science.
6. Clear transition provisions with regard to ongoing activities, and repealing existing laws and regulations, to avoid duplication.

The new system has to be responsible to the objective and science-based evaluation of GM crops and at the same time underscore the principles of openness and transparency in the regulatory approval system. Notably, the current regulatory system has to be effective and functional in a time-bound manner until the new system is enacted and implemented, which is a cumbersome and long drawn process. The common denominator is the proper functioning of the regulatory system.
that is not only rigorous but also cost- and time-effective in assessing risk and benefits of GM crops. There should be no reason for the so-called conflict between Union and State(s) for the projects that aim at improving yield and enhancing agricultural production ultimately benefiting the smallholder farmers in the respective State(s). The green revolution is an exemplary evidence of an effective coordination between the Union and respective State(s). Similarly, it is becoming increasingly important to ensure the public understanding of GM crops by institutionalizing the outreach activities that are proactive, responsible to science and responsive to public scrutiny.

In conclusion, it is an imperative for the country to rely and guide the agricultural growth and food production with the help of scientific expertise and institutional capacity that have been built with painstaking efforts and enormous investment over a period of time. At no point in time should it endanger the institutional capacity of R&D, innovation and product deployment that are required to reverse the declining availability of food production. The new generation biotech traits, input traits in the short run and output traits in the long run have the potential to contribute to sustainable food, feed and fibre production. The development and deployment of novel traits would require the pooling of expertise and resources of both public and private sector institutions. Similarly, the regulatory processes have also to solicit the expertise of professionals and accredited laboratories from within and outside India to perform the regulatory oversight, stewardship and monitoring. Therefore, the current and future regulatory systems have to continue to harness the collective strength of interdisciplinary institutions to ensure the safety and efficacy of biotech crops. The current regulatory system of RCGM and GEAC has effectively utilized the existing expertise and capacity to build a system that regulates GM crops. However, it remains untenable due to the fundamental flaws in the EPA Rules 1989. The impact of the draft law on the Biotechnology Regulatory Authority of India (BRAI), which was recently introduced in the Parliament of India to create a new biotech regulator will largely depend on the extent to which it clarifies the Union’s and States’ jurisdiction and consolidates the decision-making responsibility in a non-politicized fashion, by adhering to the legislative parameters of purposefulness, clarity, transparency, predictability and efficiency. Adhering to the principles of federalism, the Government of India and the respective State(s) have to make major decisions to ensure the independence and proper functioning of the current and future regulatory system but not to be circumvented by rhetoric of precautions that may in the long-term jeopardize the national food security – a crucial part of the overall national security of 1.2 billion people.

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Author contributions
B.C. & J.B. analysed data. B.C., G.G. & PvdM discussed the regulatory system. B.C. wrote the paper. All authors discussed the paper and commented on the manuscript.

Conflict of interest
While undertaking academic studies at Gent University, B.C. serves to the International Service for the Acquisition of Agri-biotech Applications, a not for profit international organization that shares knowledge on crop biotech with global society, particularly with resource-poor farmers in India.

References
Background Note on Bt Cotton Cultivation in India

Gazette of India (1989)

GEAC (2002b) Approval of GEAC for commercial release of Bt cotton hybrids

GEAC (2002a) Ministry of environment and forest

GEAC (2009b) Expert Committee (EC-II) Report on Bt Brinjal Event EE-1

GEAC (2009a) Ministry of the proposal for environmental release of Bt Brinjal event EE-I developed by M/s Maharashtra Hybrid Seeds Company Ltd. (Mahyco), Agricultural University.


GEAC (2009b) Approval of GEAC for commercial release of Bt cotton hybrids. Minutes of 2nd meeting of GEAC held on 26 March 2002, Genetically Engineering Approval Committee, Ministry of Environment and Forests, Govt of India.


GEAC (2009b) Report on Bt Brinjal Event EE-1 Developed by M/s Maharashtra Hybrid Seeds Company Ltd. (Mahyco), Mumbai, University of Agricultural Sciences (UAS), Dharwad and Tamil Nadu Agricultural University (TNAU), Coimbatore submitted to Genetic Engineering Approval Committee, Ministry of Environment and Forests.


GEAC (2011a) Approval from State Governments to conduct GM crop field trials, Minutes of 111th meeting of the Genetic Engineering Appraisal Committee, Ministry of Environment and Forests.

GEAC (2011b) Constraints in getting NOC from the State governments for conduct of GM crop field trials, Minutes of 114th meeting of the Genetic Engineering Appraisal Committee, Ministry of Environment and Forests.


