

India's Agri-Biotech Policies, Regulations, and Decision-making

Hugh Dang

Transnational Corporations Review, Canada

Brad Gilmour

Mouralea Trade, Agriculture, and Resource Consulting, Canada

Nawal Kishor

Indira Gandhi National Open University (IGNOU), India

India is one of the most significant emerging economies in the world. With a population of over 1.2 billion, India's agri-biotech development from cotton and brinjal (eggplant) to other crops as well as relevant trade concerns is growing in importance within a global context. While agri-biotech is still highly controversial in India, its major agri-biotech product, Bt cotton, reached 11 million hectares in 2013, an increase of 3% compared to the previous year. This represents more than 6% of the global agri-biotech crop area, which ranks it at number five, right after the United States, Brazil, Argentina, and Canada, and before China. India has been identified as one of the key markets to Canada. The market access for Canadian canola seed and canola oil in India is complicated by several issues, including the GM regulatory issue. This article discusses aspects of India's agri-biotech crops, including the current status, policy development, and institutions. It also looks into its potential impact of agriculture and trade on Canada and the rest of the world.

Key words: India, agri-biotech, policies and regulations, institutions, BRAI.

Introduction

Many scientists and policy officials are seeing agri-biotech as a key driver for agricultural productivity from a global perspective. A number of developed and developing countries, such as the United States, Brazil, Argentina, Canada, India, and China, have become significant producers and/or exporters of agri-biotech products such as GM soybeans, cotton, corn, and canola (James, 2012). During this process, many concerns and controversial issues, such as low level presence (LLP) of agri-biotech related products for trade, are arising. When looking into agri-biotech development, including the LLP issues, people are often confronted with the issue of where to find policies and institutions to address market access concerns for development objectives. Meanwhile, we rarely find studies related to agri-biotech policies, regulations, and institutions on a country-by-country basis. This study is an attempt to analyze agri-biotech-related policy, regulations, and institutions.

As one of the significant emerging economies globally, India has the second-largest population in the world after China. Its population reached 1.2 billion as of 2012. India's gross domestic product (GDP) has grown at an average of 4.2% yearly (Figure 1) and the GDP per capita was US\$1,510¹ in 2012. This is well ahead of Vietnam at about \$1,223 and behind the Philippines at

about \$2,258 (Agriculture and Agri-Food Canada, 2013). India is an agriculture-based country: its agricultural sector comprises 18% of India's total GDP. As a comparison, Vietnam's is 20% and Indonesia's is 15%. Employment in the agricultural sector in India makes up about 52% of the total workforce. To compare, China's agricultural employment is about 37% of the total workforce and Indonesia's is about 38%. India's major crops include rice (paddy), wheat, cotton, potato, vegetables, and sugarcane.²

While reviewing India's agricultural sector, it is important to look into its agri-biotech development. India is the world's largest country to cultivate genetically modified (GM) cotton. The country grew a record 11 million hectares of Bt cotton with an adoption rate of 95% in 2013. India enhanced farm income from Bt cotton by \$14.6 billion from 2002 to 2012 and \$3.2 billion in 2011 alone (James, 2013). By 2012, led by the United States, 28 countries planted biotech crops on a total of 160 million hectares. Among those, developed countries accounted for about 48% of the area, while developing countries cultivated 52%. India ranks in the top five countries in the world in terms of planting agri-biotech crops. In order to understand India's agri-biotech development, it is important to review its agri-biotech policies, regulations, and institutions. To understand India's

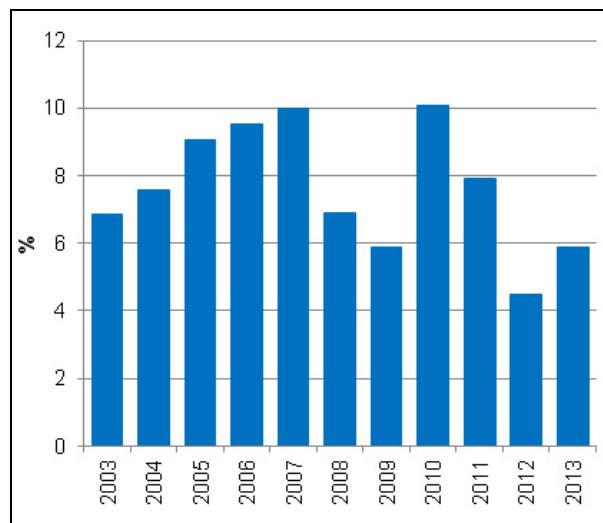
1. Unless otherwise noted, all figures are in US dollars.

2. For more statistic information, see the latest figures at http://eands.dacnet.nic.in/latest_2006.htm.

Table 1. Farm-level income impact of using Bt cotton in India (2002-2010).

Year	Cost savings (net after cost of technology: US \$/ha)	Net increase in gross margins (US\$/ha)	Increase in farm income at a national level (US\$ millions)	Increase in national farm income as % of farm-level value of production
2002	-12.42	82.66	3.6	0.26
2003	-16.2	209.85	20.98	0.47
2004	-13.56	193.36	96.68	1.86
2005	-22.25	255.96	332.74	5.26
2006	3.52	221.02	839.89	14.04
2007	26.41	356.85	2,093.97	22.84
2008	24.28	256.73	1,790.16	24.27
2009	22.19	211.17	1,863.29	24.91
2010	23.10	265.80	2498.53	24.91

Source: Brookes and Barfoot (2012)

**Figure 1. India: Real GDP growth rate.**

Source: International Monetary Fund (2013)

policies related to agri-biotech and trade issues, this study will look into the agri-biotech development status in India. It will then examine India's agri-biotech policies, regulations, and governance system. The study is concluded by discussing the implications of Indian agri-biotech for Canada and the rest of the world.

Development Status

India's successful adoption of Bt cotton has facilitated its development into one of the fastest growing segments in agri-biotech. Since its introduction in India in 2002, Bt cotton has grown to cover 95% of the total cotton area. As a result, India has emerged as the second-largest producer and exporter of cotton in the world. As shown in Table 1, since 2006, the average cost of biotech has been less than the insecticide costs. Following

this reduction, farmers in India began to record a net cost saving. Coupled with the yield gains, net gains to levels of profitability of \$82/ha and \$356/ha during 2002 and 2007 were achieved. At a national level, the farm income gain in 2010 was about \$2.5 billion, and cumulatively, the farm income gains have totaled \$9.4 billion since 2002. Biotech cotton contributed about 25% of the total increase in farm income.

According to the analysis from International Service for the Acquisition of Agri-biotech Applications (ISAAA), a new generation of biotech cotton offers India a range of beneficial traits including stacked Bt/HT, salinity and drought tolerance, disease resistance, and other traits. Biotech crops being developed by the public sector in India other than cotton include brinjal (eggplant), groundnut, mustard, papaya, potato, rice, sorghum, sugarcane, tomato, and watermelon. The private sector is also developing eight biotech crops—brinjal, cabbage, cauliflower, cotton, maize, okra, rice, and tomato. There were 16 biotech crops under field trials in India, including Bt maize, HT maize, and Bt/HT maize which, subject to regulatory approval, could be deployed commercially within two to three years (ISAAA, 2012).

Agri-biotech development in India varies in terms of different states. While some states are proactive in adopting this technology, others are cautious about applying for development and commercialization. Generally speaking, the states in the west and south, as well as some of the northern states in India, are relatively active in agri-biotech applications. Among these, the states in the west include Gujarat, Madhya Pradesh, and Maharashtra. The states in the south active in agri-biotech include Andhra, Karnataka, and Tamil Nadu. In the

northern region, Punjab, Haryana, and Rajasthan are active in agri-biotech development and applications.³

The state of Karnataka is a good example. Karnataka, as India's biotech hub, is the leader for global and domestic biotech investment in the country. The state has advantages with research capabilities, resource base, skilled manpower, and government support, which create a conducive environment for biotech growth. As the biotech capital of India, Karnataka is host to 60% of the biotech companies with a base in Bangalore, the state capitol, which drives 50% of the total revenues in the national biotech sector. As a fast-growing technology and the world's fourth-largest tech cluster, this state is also a destination for biotech firms looking for specialized research faculties and engineering graduates (Ma, 2013). The state has biotech projects worth Rs. 150 million on offer with a potential of providing 8,000 jobs in the sector. In its Millennium Biotech Policy in 2009, agri-biotech was seen as one of the most significant priorities in the state.⁴

In terms of the more cautious states with regards to the agri-biotech applications, they are mainly within the eastern region, and a few from the north and south. In general, the states, such as Bihar, Madhya Pradesh, and Karnataka in the east, are relatively cautious with regards to agri-biotech. Himachal Pradesh in the north and Kerala in the south are also relatively cautious in their policies for applications.⁵ The State of Bihar is a representative example. Bihar was the first state to ban GM seeds in the larger interest of farmers. The state also vowed to block entry of biotech companies and field trials of GM maize. In order to resist Bt brinjal, this state enacted the 'GM-Free Bihar Movement,' which sought to awaken the farming community and emphasize indigenous seeds in lieu of the imperialistic expansion of multinationals.⁶

In India, Bt cotton is currently the only biotech crop which has been broadly planted and received benefits from its applications. As we discussed, agri-biotech commercialization is different from state to state

depending on each state's policy and regulations. For Bt cotton planting and commercialization, Maharashtra and Gujarat in the west and Andhra Pradesh in the south are the three major states to take advantage of this biotech product. Among these states, Maharashtra shares about one-third of the total areas of the Bt cotton, which reached over 3 million hectares in 2010. Gujarat and Andhra Pradesh share about one-fourth and one-seventh, respectively, with smaller areas in other states.⁷

In addition to Bt cotton, another important biotech crop is brinjal (eggplant), which would be the first biotech food crop in India if it can be commercialized. It is currently unlawful to plant biotech varieties. India plants about 550,000 hectares of brinjal per year, equal to about 20% of total global area; it is the second-largest producer after China. Brinjal production is mostly concentrated in the east. The number one producer of brinjal is the state of West Bengal, which is home to about 30% of the total area. Orissa shares about 20% of the total plant area. Bihar and Madhya Pradesh share about 10% of the total.⁸

Policy and Regulation

Since the late 1980s, India has started to establish its policy and regulatory system for agri-biotech development, and the country is currently undergoing a serious push for changes. *The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989* (which we will refer to as 'Rules 1989') is the first and fundamental set of regulations related to agri-biotech enacted under the Environment Protection Act (EPA) of 1986. Pending parliamentary approval of the Biotech Regulatory Authority of India (BRAI), India's policy and regulatory mechanism is still governed by the EPA 1986 and the Rules 1989. In this section, we briefly look at Indian biotech policy developments, which is considered as three stages: a) policy and regulatory establishment from 1989 to 2002 when Bt cotton was approved for commercialization; b) policy developments from 2003 to 2010 when the Ministry of Environment and Forests (MOEF) imposed a moratorium on Bt brinjal; and c) policy debates since 2010, during which Bt brinjal and BRAI are under suspension.

3. The information about the nine states listed here as relatively active in agri-biotech was collected by the author from various sources, mainly from ISAAA at <http://www.isaaa.org>.

4. For more information, see *Non-Resident Indians (NRI) Forum Karnataka (2010)* and *The Hindu (2010a, 2010b)*.

5. The information about these states listed as being relatively active in agri-biotech was collected by the author from various sources, mainly from an article in *The Hindu (2011)*.

6. For more information, see *The Times of India (2012)* and *Agri Activism (2013)*.

7. In 2011, there were more than 10 million hectares for Bt cotton in India. For more information, see *James (2009)* and *Choudhary and Gaur (2010)*.

8. For more information, see *Kutty (2012)* and *James (2012)*.

Regulatory Establishment (1989-2002)

Biosafety concerns are leading to the development of policy and regulatory regimes in various countries for research, testing, safe use, and handling of genetically modified organisms (GMOs) and relevant products. India is one of the earliest countries to establish a biosafety system for regulation of GMOs. With respect to the policy and regulatory issues related to agri-biotech, India develops them based on its EPA from MOEF in 1986. MOEF enacted EPA, which is intended to protect and improve environmental matters.

Under the EPA, the *Rules for Manufacture, Use/Import/Export & Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells* were ratified by MOEF on December 5, 1989, which are commonly known as the Rules 1989. The Rules 1989 provide the general policies and regulations for import, manufacturing, and other use of the GMOs, as well as products made by the use of such organisms. The rules also cover research as well as large-scale applications of GMOs and products made in India.⁹

Since the Rules 1989, the policy and regulations in India have been altered from time to time. During this period, the Department of Biotechnology (DBT) in the Ministry of Science and Technology (MOST) developed the rDNA Guidelines in 1990 and amended them in 1994. The rDNA Guidelines include measures for research and development (R&D) on GMOs, transgenic crops, large-scale production, and deliberate release of GMOs, plants, animals, and products into the environment, shipment and importation of GMOs for laboratory

research. The Guidelines for research in transgenic plants cover the areas of rDNA research on plants, including the development of transgenic plants and their growth in soil for molecular and field evaluation (US Department of Agriculture, Foreign Agricultural Service, 2012). Another important development was the DBT guidelines in 1998 for biotech plant research. These involve regulations around the import and shipment of biotech plants for research use.¹⁰

Coordinated by DBT under the Rules 1989, India achieved a number of milestones in agri-biotech R&D during the 1990s. For example, since 1998, India's economic data has included biosafety evaluation criteria. In 2000, along with Indian companies, Monsanto received regulatory approval for large-scale trials for Bt cotton. In 2002, while unapproved Bt cotton was discovered in West India (Gujarat), a Monsanto-based company in India was granted Bt cotton commercialization (Pradhan, 2011).

Policy Development (2003-2010)

The growth of the Indian biotech sector has significant implications for policy and regulation development. Since 2002, when it approved Bt cotton for commercialization, India has undertaken a number of notable actions, including ratification of the Biosafety Protocol in 2003 and approval of a national biotech development strategy in 2007, which was an important guiding document for 10 years.

In addition to India's ratification of the Biosafety Protocol in 2003, there was an important report in 2004 commissioned by the Ministry of Agriculture (MOA) and MOEF to evaluate the regulatory framework for agri-biotech products. This *Report on the Application of Agri-Biotech* was chaired by M.S. Swaminathan, a geneticist renowned for his leadership and success in introducing and developing high-yielding varieties of wheat in India. The report recommended establishment of an autonomous, statutory, and professionally-led National Biotechnology Regulatory Authority (NBRA). This is the first time a national biotech authority had been proposed. According to the proposed NBRA, there would be two separate wings—one dealing with food

9. For more information, see <http://www.moef.nic.in/division/genetic-engineering-approval-committee-geac>. Main paragraphs in the Rules 1989 relate to agri-biotech guidelines include: Approval to individuals on import, export, transport, manufacture, process, use or sale of GMOs, including the use for research (Para 7); Authorization for production of GE microorganisms, plants and animals (Para 8); Approval for deliberate or unintentional release of GMOs (Para 9); Approval for production, sales, and import of substances or products that may contain GMOs or cells (Para 10); Approval for production, sale and import of foodstuff, ingredients in foodstuff including processing aid that may contain GMOs or cells (Para 11); Procedure for obtaining approvals in different conditions (Para 12); Conditions of approval of GMOs (Para 13); Mechanism for supervising implementation of term and conditions given with authorization for commercial use (Para 14); Penalties levied for noncompliance of measures on safe use of GMOs (Para 15); Redress mechanism through National Environment Appellate Authority (Para 19).

10. In 2008, the Genetic Engineering Appraisal Committee (GEAC) adopted the Guidelines for Safety Assessment of Foods Derived from Genetically Engineered Plants. All guidelines and protocols, including the EPA Act of 1986 and the 1989 Rules can be found online at <http://dbt-bio-safety.nic.in/>.

and agri-biotech, and the other with medical and pharmaceutical biotech. The report asserted that NBRA is essential for generating the necessary public, professional, and commercial confidence in the science-based regulatory mechanism in place in the country (Government of India, DBT, 2008).

In 2005, DBT published a draft of a National Biotech Development Strategy which elaborated a 10-year vision for the future of biotech in India. This would be achieved through a process of multi-stakeholder consultations that focused on cross-cutting issues of relevance to all sub-sectors of the biotech community. Under the topic of regulatory mechanisms, this document recommended the national biotech regulatory authority to be established with separate divisions for agricultural products/transgenic crops, pharmaceuticals/drugs and industrial products, and transgenic food/feed and transgenic animal/aqua culture. This authority is to be governed by an independent administrative structure with a common chairman (Government of India, Department of Science & Technology, 2005). In 2007, this National Biotech Development Strategy was approved by the Government of India.

Policy and Regulatory Debate (2010-Now)

While India maintained its growth in agri-biotech, this has, since 2010, been seriously debated within the government, academia, and civil society. Because of this debate, two significant initiatives—Bt brinjal and BRAI—were suspended by MOEF and the Parliament of India, which has seriously challenged Indian agri-biotech policy and regulatory developments. Brinjal, known as eggplant in North America, is the second-most popular vegetable in India next to potatoes.¹¹ It accounts for about 9% of Indian total vegetable production and is cultivated on about 8% of vegetable-growing land (Kutty, 2012). Brinjal is grown in almost all parts of the country but mainly in eight states: West Bengal, Orissa, Bihar, Gujarat, Maharashtra, Karnataka, Uttar Pradesh, and Andhra Pradesh. Among these states, West Bengal accounts for 30% of production; Orissa 20%; and Gujarat and Bihar share about 10%, respectively (ISAAA, 2013a). Bt brinjal is the first food crop under evaluation for commercial release in India. Since its development in 2000, this has undergone a series of scientific evaluations to assess its food safety, environmental safety, human and animal health, and biodiversity. In

11. India is also the second largest producer after China, with a share of 26% in the world production (see ISAAA, 2013a).

2009, India's biotech regulator, Genetic Engineering Appraisal Committee (GEAC) under MOEF, recommended the commercial release of Bt brinjal.

After receiving GEAC's recommendation, MOEF conducted a number of public consultations across India at the beginning of 2010. After listening to the participants and reviewing the responses received, Jairam Ramesh, the then-MOEF Minister, announced a decision on February 9, 2010 to declare a moratorium on Bt brinjal, which was "responsible to science and responsive to society" (Kutty, 2012, p. 10).¹² In regards to the biotech regulatory mechanism, DBT proposed that BRAI be established as independent, autonomous, and professionally led to provide a single body for biosafety clearance. DBT has been given the responsibility to set up this authority. However, BRAI has been highly controversial up to now. People against this establishment argue that BRAI is unconstitutional, unethical, unscientific, self-contradictory, and not civil-society oriented (*The Hindu*, 2011).

In order to empower BRAI, DBT is considering putting it into legislation. Elements of biotech regulation are currently spread over multiple acts. Some of these have been amended in order to establish BRAI. Drafting this legislation is intended to provide an opportunity to enhance the efficiency and effectiveness of biotech regulation, increase collaboration with state governments, promote public confidence in the regulatory system, and facilitate international trade.¹³ On April 22, 2013, India's S&T Minister S. Jaipal Reddy introduced the BRAI bill in the Lok Sabha (the Lower House of the Parliament). However, a number of the Parliament members opposed the BRAI bill that was introduced. They asked the government to withdraw the bill and introduce a bio safety protection law in its place.¹⁴

12. In addition to the feedback from civil society, Jairam Ramesh's main reasons for this moratorium concern the 11 state governments' opinion, including major brinjal-growing states, and the number of scientists who disagreed on the safety of Bt brinjal. Among these scientists, three of them are most influential to this decision. They are S. Swaminathan, a biologist in India; Jack Heinemann from the University of Canterbury in England; and David Schubert from the Salk Institute of Biological Studies in California, USA.

13. For more updated information, see *The Hindu Business Line* (2013b).

14. For more information, see ISAAA (2013b) and *The Hindu Business Line* (2013a).

States Policy and Regulation

India's central government is called a "union," which allows state governments to own a number of relatively independent powers. At the central-government level, because of its "union" feature, one department may veto another department's decision. For example, while MOST agreed with the Bt brinjal commercialization, MOEF rejected it. In the same case, some states in India are interested in accepting biotech; others are cautious to this technology. Therefore, the agri-biotech policies and regulations differ from state to state. Generally speaking, the southern states, which cultivate a large amount of cotton, are inclined to accept agri-biotech. For example, the states, such as Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra, as well as Karnataka, have developed biotech policies since 2000 that promoted the agri-biotech development in their areas.

Biotech Policy in Tamil Nadu. Tamil Nadu is endowed with plentiful bio-resources. The advancement in biotech provided larger opportunities for generating employment in this state. Therefore, Tamil Nadu, in its budget for the year 2000, announced that biotech policy for the state would be formulated and implemented. After then, a committee of experts under the chairmanship of M.S. Swaminathan was set up to consider the relevant issues. The government, after careful examination of the Swaminathan report, formulated its biotech policy for the state as one of piloting states to promote this technology in India (Government of Tamil Nadu, 2000). The Tamil Nadu government is currently revising its biotech policy in consultation with industry and academia to enhance the state's performance in this sector. As biotech was seen as the next wave of knowledge economy, the government was determined to make Tamil Nadu a leading global center in biotechnology (*Business Standard*, 2011).

Biotech Policy in Andhra Pradesh. In 2001, Andhra Pradesh formulated its biotech policy. In this policy, the state pointed out that biotech was an emerging technology. It had potential to provide substantial benefits to society in a wide range of sectors such as agriculture, medicine and health, forestry, animal husbandry, and environmental protection. Biotech could also be used to improve the quality of products and services (Government of Andhra Pradesh, Department of Industries and Commerce, 2001). In 2006, Andhra Pradesh introduced a number of changes that created an investor-friendly environment for biotech. The updated policy is in line

with the national biotech policy, including a single window clearance system, sales tax, and provision of rebate based on the jobs being created (*Rediff India Abroad*, 2006).

Biotech Policy in Karnataka. In 2000, Karnataka released its Millennium Biotech Policy. This document indicated that Karnataka had a knowledge base necessary to drive a biotech revolution. The state has a mass of biotech companies and research institutions. The current challenge is to foster innovation, promote entrepreneurship, and facilitate effective technology transfer to the end users (Government of Karnataka, 2000). Karnataka believes that emerging biotech holds the potential to boost the state's economy, which can lead to a qualitative improvement in the lives of people at large. Hence, the state pioneered the launch of Karnataka Biotech Policy II in 2009 to boost sustainable growth for the biotech industry in the state (Government of Karnataka, 2010).

Biotech Policy in Maharashtra. In 2001, Maharashtra formulated its biotech policy in which a State Biotech Board was proposed. At the same time, the state set up a special biotech development fund. In the policy guidelines, the state endeavored to create a biotech resource center with a number of biotech parks. It was also worth mention that fiscal incentives were granted, including exemptions from paying stamp and electricity duties. The state's policy pointed out that biotech has potential to transform the lives of the population by having an impact on agriculture, animal husbandry, health, environmental protection, and material transformation. Maharashtra has exhibited the potential to be a lead in biotech, not only in the country, but also in the world. In order to do so, the state announced its biotech policy at the beginning of the 21st century (Government of Maharashtra State, 2001).

Biotech Policy in Kerala. The 2003 policy in Kerala pointed out that Kerala's agricultural economy is driven by its dominant commercial crops. The tools of biotech, such as molecular genetics and breeding (including the use of molecular markers and descriptors as well as rDNA technologies and bio-informatics), need to be harnessed in conjunction with tissue culture techniques and conventional breeding. It is not only to combat biotic (insects, fungal, bacterial, and viral pathogens) and abiotic (drought, salinity) stresses, but also to enhance the value of the commercialized biotech crops in domestic and international markets while improving

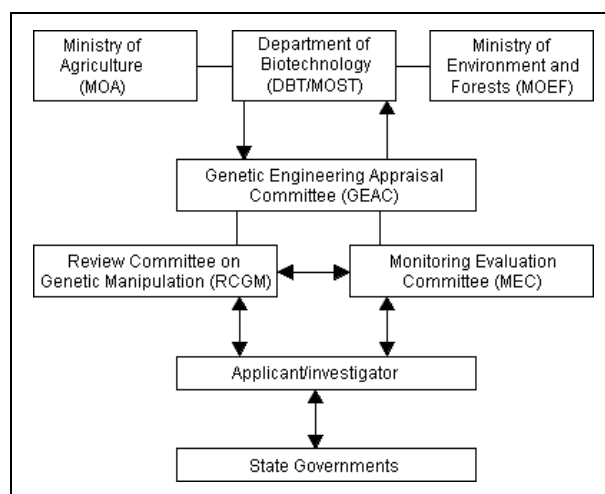


Figure 2. Biotech regulatory mechanism in India.

Source: Authors' collection.

the genetic pool (Kerala State Council for Science, Technology, & Environment, 2003).

Governance System

Like its economic system, India's agri-biotech regulatory governance is relatively independent. Three central governmental ministries—MOST (DBT), MOEF, and MOA—are involved in this governance, along with a number of risk-management institutions within or outside of these ministries (Figure 2). Since three ministries are involved in this governance, some different regulatory management is likely to be taking place among them. In the Indian federal-state system, there are several different bodies to manage agri-biotech in individual states. In addition to these differences, both central and state governments' regulatory measures might receive broad debates among different interest groups. In this section, we briefly look at India's major institutions that involve the agri-biotech sector, its governance framework, its approval process, as well as a proposed national biotech authority.

Institution Players

In addition to the ministries involved in Indian agri-biotech research and commercialization, a number of other significant institutions at either the central or national level are involved in Indian agri-biotech review, assessment, and the approval process. These institutions are authorized to gather experts for overseeing agri-biotech research and commercialization in India. They are granted moderate independence to consider their own review process from different perspectives or fields.

Let's briefly look at these institutions and their roles in terms of agri-biotech research and commercialization.

As discussed, GMOs and relevant products in India are regulated as per the Rules 1989 implemented by MOEF. These rules are enforced by both MOEF and DBT through the authorized institutions identified under the Rules, which mainly include rDNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotech Coordination Committee (SBCC), and District Level Coordination Committee (DLCC; MOST DBT, 2011).

While the RDAC is advisory only, IBSC, RCGM, and GEAC are involved in regulatory enforcement. Both SBCC and DLCC are responsible for monitoring the activities related to GMOs at a state level. RDAC, RCGM and GEAC are constituted at a national level governed by DBT and MOEF. The IBSCs work on the areas of GMOs, while SBCC works for states and DLCCs works for districts wherever necessary.

Governance Framework

India is taking a so-called "democratic" approach for its biotech management, which is somewhat different from China and other countries. In the Indian biotech governance system, we see three-level interest groups who are interactive and interrelated.

- At the central government level, DBT at MOST, MOEF, and MOA are significant institutions who work on agri-biotech under different approaches;
- Authorized review and appraisal groups, mainly including the important institutions, such as IBSCs, RCGM, and GEAC (the first two institution members are appointed by DBT, while GEAC members are appointed by MOEF).
- State- and district-level interactions, mainly including SBCC and DLCC.

While DBT at MOST is generally the coordinator of agri-biotech operations in India, other important ministries, MOEF and MOA, play a significant role in managing agri-biotech. In addition, the Ministry of Health and Family Welfare (MHFW) is also actively involved in many cases. While these four institutions involved with agri-biotech development bring different perspectives, they also interact with one another. For example, when DBT reviews agri-biotech development in terms of an application from the S&T perspective, MOEF

looks into it in terms of an environmental concern. This interaction can be coordinated in many situations. However, in certain cases, their group interest is inconsistent and even in conflict.

As mentioned, IBSCs, RCCM, and GEAC relatively independently review and appraise agri-biotech related research, applications, and commercialization. While both IBSC and RCCM are affiliated with or appointed by DBT, GEAC reports to MOEF. These institutions have different roles in looking into the agri-biotech practices in India. IBSCs review the experiments from Category I and II.¹⁵ RCGM reviews Category III GM products and field experiments and recommends the reviewed GM products to relevant institutions, such as GEAC. GEAC is a relatively important institution for GM products. Its major function involves assessing large-scale agri-biotech applications and making recommendations to the ministerial-level authorities.¹⁶

Indian agri-biotech is not only managed at the central government level through designated ministerial agencies and other authorized institutions, it is also bound to the state-level institutions for review and monitoring. At the state and district level, SBCC and DLCC are mainly involved. The former works with the state-level governments on biotech and the latter relates to other shareholders for GM products at a district level. They also investigate the GM products and report to other relevant institutions, such as GEAC. To be specific, SBCC periodically reviews the safety and control measures in various institutions handling GMOs to act as an agency at a state level to assess the damage, if any, due to release of the GMOs and to take on site control measures. DLCC monitors the safety regulations in installations and acts as an agency at a district level to

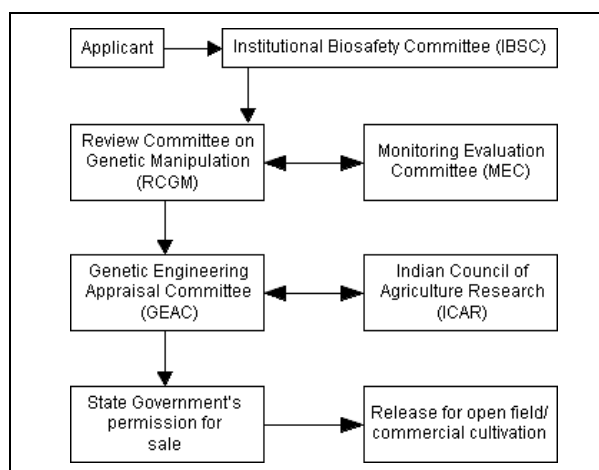


Figure 3. Agri-biotech approval process in India.

Source: Kumar (2007) and US Department of Agriculture (USDA), Foreign Agricultural Service (FAS; 2011, 2012).

assess the damage, if any, due to release of the GMOs and to take on-site control measures.¹⁷

Approval Process

The duration of India's agri-biotech approval processes vary from three to five years. Some might even be over 10 years, depending on the different products imported or domestic biotech applied. Throughout the process, an applicant is involved with a number of authorized institutions for review and assessment (Figure 3). After these steps, the applicants go for final approvals at the ministerial level before releasing for commercialization. The Bt brinjal application is a typical example of how the Indian agri-biotech review, appraisal, and approval process works.

It takes time for an agri-biotech review, appraisal, and approval process due to India's complicated governance system. The applications are at first reviewed by an IBSC. In this stage, applicants need to conduct a number of initial evaluations and field trials. In terms of the Bt brinjal application, Mahyco, an Indian seed company at Maharashtra state, conducted transformation and breeding for integration of Cry1Ac gene into brinjal hybrids in 2000.¹⁸ Following this, a preliminary greenhouse assessment of the development and efficacy of Bt brinjal was done during the period between 2001 and 2002. Then confined field trials were conducted from 2002 to 2004 to study Bt brinjal's pollen flow and growth, germination, and biochemical toxicity.¹⁹

15. India categorizes agri-biotech into three groups. Category I refers to GM food and feed production for human use, Category II relates to the GM food and feed production for R&D, and Category III is the GM food and feed production for manufacturing processes.

16. In addition to these three major institutions, there are two other important institutions involved in agri-biotech development. These are a) Indian Council of Agricultural Research (ICAR), generating and providing comprehensive data for GM studies and recommending suitable GM crops for commercialization; and b) Monitoring and Evaluation Committee (MEC), which, along with the RCGM, provides experts from the ICAR, the State Agricultural Universities, and other shareholders; monitoring and evaluating trial sites, analyzing data, and inspect facilities; and recommending for further assessment in the RCGM/GEAC.

17. See the Rules 1989 for details.

18. See the ISAAA information for details.

For those biotech crops with a high level of risk, their applications are further reviewed by RCGM, along with the Monitoring Evaluation Committee (MEC) review of the field trials. In 2004, the data on the effect of Bt brinjal on soil microflora, efficacy against the fruit and shoot borer (FSB), pollen flow, and chemical composition was submitted to RCGM. In the same year, RCGM approved multi-location research trials (MLRTs). By 2007, Mahyco and the Indian Council of Agricultural Research (ICAR) conducted MLRTs separately for this crop.²⁰ The applicant submitted the bio-safety, environmental safety, gene efficacy, and agronomic performance data to GEAC in 2007.

In the third step, GEAC reviews and appraises the applications. This is the last but significant step before an application is submitted to the ministerial-level authority for approval and release. From 2007 to 2009, GEAC approved seven Bt brinjal hybrids for large-scale field trials under the Indian Institute of Vegetable Research in ICAR. In the meantime, GEAC also approved the experimental seed production of seven Bt brinjal hybrids.²¹ After this process, GEAC, as one of India's authorized biotech regulators, recommended to MOEF in October 2009 for a commercial release of Bt brinjal.

MOEF conducted a number of consultations across India after GEAC's recommendation for Bt brinjal's commercial release. During the consultation, several states and cities, including Kolkata, Bhubaneswar, Ahmedabad, Nagpur, Chandigarh, Hyderabad, and Bangalore, expressed opposition to Bt brinjal (Kutty, 2012). As a result, Jairam Ramesh, the minister in charge of MOEF, declared a moratorium on Bt brinjal in February 2010. Since then, commercial release of Bt brinjal has been suspended.²² As we know, India is a country with ongoing controversies among the policy makers, aca-

demia, and public. The final step for the applicant to request the government's permission for commercial production and sale of Bt brinjal failed. If this step was successful, the applicant would also need to go to SBCC and/or DLCC for review and assessment.

Proposed BRAI

India's existing agri-biotech governance includes a number of ministries within a complicated system. Meanwhile, the current system lacks a solid legal foundation for support. It relies simply on the Rules 1989, which focused on environmental concerns. According to the document,²³ the purpose for developing BRAI is to promote the safe use of modern biotech by enhancing the effectiveness and efficiency of regulatory procedures. It also intends to regulate the research, transport, import, manufacture, and use of organisms and products of modern biotechnology. Since the draft of this bill was released in 2008, there has been a continuous debate on its necessities and functions. Those opposed view BRAI as unconstitutional due to agriculture being a state subject. BRAI assumes the state government's authority to make decisions, such as those surrounding GM products. It is also argued that BRAI is non-scientific and lacking in public participation due to most of the officials proposed being bureaucrats without involving a civil society representation.

BRAI is a comprehensive proposal to rebuild an Indian biotech governance system. According to this proposal, there would be a three-level governance system. At the top governance body, there would be one chairperson, two full-time members, two part-time members, and two advisory bodies—Inter-Ministerial Governing Board (about 10 delegates) and Biotech Advisory Council (no more than 15 members). The operational level would include one product ruling committee, risk assessment and enforcement units, and three divisions covering agriculture, forestry, and fisheries; human health and veterinary; and industrial and environmental application (Figure 4).

This proposal would make BRAI an independent, autonomous, statutory agency established by the Government of India to safeguard the health and safety of the people of India and to protect the environment by identifying risks posed by, or as a result of, modern biotech, and managing those risks through regulating the safe development and deployment of biotech products

19. For more information, see ISAAA (2013) and Kutty (2012).

20. *Ibid.*

21. *Ibid.*

22. *India's agri-biotech policy is the focus of serious debate. When the GEAC held its meeting on Bt brinjal with selected experts in April 2011, the National Biosafety Authority decided to take legal action against Mahyco, Monsanto, and collaborators for violation of the Biological Diversity Act 2002 for releasing Bt brinjal varieties without approval. In August 2012, Indian Parliamentary Standing Committee on Agriculture released "Cultivation of Genetically Modified Crops—Prospects and Effects," which recommended a thorough investigation into the approval process of Bt brinjal and a halt to all field trials of GM crops in the country.*

23. The draft of BRAI can be found at http://indiagminfo.org/wp-content/uploads/2011/09/BRAI_Bill_2011.pdf.

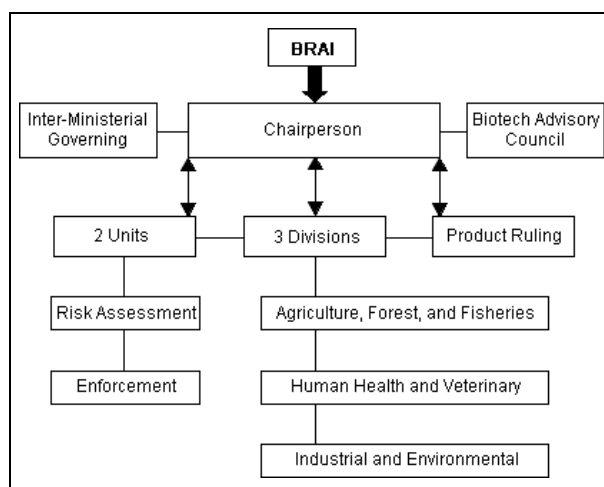


Figure 4. Proposed biotech regulatory authority of India.

Note: This chart is based on the BRAI bill (2011).

and processes. In the interim, in addition to the Rules 1989 governing biotech products, GM foods are also regulated by the Food Safety and Standards Authority under the Food Safety and Standards Act (FSSA) of 2006. Product safety, efficacy, clinical trials, and market authorization of recombinant drugs are regulated by the Drug Controller General of India (DCGI) under the authority of the Drugs and Cosmetics Rules 1945 (well-known as the “Rules 1945”) of the Drugs and Cosmetic Act 1940. BRAI would work to consolidate all the regulations into one authorized body for enforcement.

BRAI would also be responsible for GM-food safety assessment. The rules and regulations that pertain to food (e.g., conventional safety provisions related to adulterants, extraneous matter, and unhygienic/unsanitary processing or manufacturing of food) would still apply to GM food as regulated by FSSA and other authorities in India under BRAI. Finally, BRAI would be responsible for regulating GMOs with applications in human and veterinary health and derived products. This would include the regulation of recombinant biologics such as DNA vaccines, recombinant gene therapy products and recombinant- and transgenic-plasma-derived products like clotting factors and veterinary biologics. This excludes therapeutic proteins derived from recombinant organisms, which continue to be regulated by DCGI in India.²⁴

24. For more information, see Konde (2010).

Concluding Remarks

India is traditionally an agricultural-based country, with the largest area under cotton production in the world. Bt cotton adoption in India reached 11 million hectares, almost three times the Bt cotton area of China at about 4 million hectares. The number of farmers using Bt cotton increased from 50,000 in 2002-2003 to 7 million in 2011-2012. Despite the unprecedentedly high adoption rate of Bt cotton (95% of area and by more than 7 million farmers), anti-biotech groups still continue to vigorously campaign against biotech in India. These groups use all available means to discredit biotech, such as filing public-interest writ petitions and pursuing litigation in the Supreme Court to contest the biosafety of biotech products (James, 2011, 2012).

In order to establish and empower the biotech regulatory incentives, the Indian policy and regulatory agency (DBT) has been promulgating the legislation to implement the BRAI. Elements of biotech regulation are currently spread over multiple acts and agencies, many of which will need to be amended in order to establish and operate BRAI. The new legislation, when it becomes effective, would provide an opportunity to consolidate and enhance the efficiency and effectiveness of biotech development, increase collaboration with state governments in this area, promote public confidence in the regulatory system, and facilitate international trade.

References

- Agri Activism. (2013, April 24). GM-free Bihar movement cries foul over BRAI bill. Author. Available on the World Wide Web: <http://indiafarm.wordpress.com/2013/04/24/gm-free-bihar-movement-cries-foul-over-brai-bill>.
- Agriculture and Agri-Food Canada. (2013). *Agri-food trade service* [website]. Available on the World Wide Web: <http://www.agr.gc.ca/eng/programs-and-services/list-of-programs-and-services/agri-food-trade-service/?id=1410965065217>.
- Biotechnology Regulatory Authority of India (BRAI). (2011). *Biotechnology regulatory authority of India* (Bill No. 54, to be introduced in Lok Sabha). Available on the World Wide Web: http://indiagminfo.org/wp-content/uploads/2011/09/BRAI_Bill_2011.pdf.
- Brookes, G., & Barfoot, P. (2012, May). *GM crops: Global socio-economic and environmental impacts 1996-2010*. Dorchester, UK: PG Economics Ltd.
- Business Standard*. (2011, February 1). *TN plans new biotech policy*.
- Choudhary, B., & Gaur, K. (2010). *Bt cotton in India: A country profile* (ISAAA Series of Biotech Crop Profiles). Ithaca, NY:

- International Service for the Acquisition of Agri-biotech Applications (ISAAA).
- Government of Andhra Pradesh, Department of Industries and Commerce. (2001, April). *Biotechnology policy 2001*: Andhra Pradesh. Hyderabad, India: Author.
- Government of India, Department of Biotechnology (DBT). (2008). *Establishment plan for the national biotechnology regulatory authority*. New Delhi: Author.
- Government of India, DBT. (2011, May). *Guidelines and handbook for institutional biosafety committees* (2nd edition). New Delhi: Author and Biotech Consortium India Ltd. Available on the World Wide Web: http://dbtbiosafety.nic.in/Files/CD_IBSC/Files/Guidelines%20_Handbook_2011.pdf.
- Government of India, Department of Science & Technology. (2005, April). *Draft national biotech development strategy released for public debate* (Press release). New Delhi: Author. Available on the World Wide Web: http://dst.gov.in/whats_new/press_releases05/draft-national.htm.
- Government of Karnataka. (2000). *The millennium biotech policy I*. Karnataka, India: Author. Available on the World Wide Web: <http://karnatakaindustry.gov.in/documents/The%20Millenium%20Biotech%20Policy.pdf>.
- Government of Karnataka. (2010). *Karnataka biotechnology policy 2010*. Karnataka, India: Author.
- Government of Maharashtra State. (2001). *Maharashtra biotechnology policy 2001*. Mumbai, India: Author.
- Government of Tamil Nadu. (2000, December 9). *Biotechnology policy of Tamil Nadu 2000* (G.O. Ms. No.318). Tamil Nadu, India: Author.
- The Hindu*. (2010, January 20). Agri-biotech to be focus of Bangalore India Bio this year.
- The Hindu*. (2010b, June 4). Karnataka keen on agri-biotech companies.
- The Hindu*. (2011). Unconstitutional, unethical, unscientific. Available on the World Wide Web: <http://www.thehindu.com/opinion/lead/unconstitutional-unethical-unscientific/article2752711.ece>.
- The Hindu Business Line*. (2013a, April 29). 16 MPs want government to withdraw the bill on biotech regulator. Available on the World Wide Web: <http://www.thehindubusinessline.com/industry-and-economy/agri-biz/16-mps-want-govt-to-withdraw-bill-on-biotech-regulator/article4667162.ece>.
- The Hindu BusinessLine*. (2013b). Bill on independent regulator for biotech sector introduced in Lok Sabha. Available on the World Wide Web: http://www.thehindubusinessline.com/industry-and-economy/agri-biz/bill-on-independent-regulator-for-biotech-sector-introduced-in-lok-sabha/article4644273.ece?homepage=true&ref=wl_home.
- International Monetary Fund (IMF). (2013). *World economic outlook database—India* [database]. Washington, DC: Author. Available on the World Wide Web: <http://www.imf.org/external/pubs/ft/weo/2014/01/weodata/index.aspx>.
- International Service for the Acquisition of Agri-biotech Applications (ISAAA). (2012). *Biotech facts & trends: India*. Los Baños, Philippines: ISAAA SEAsiaCenter.
- ISAAA. (2013a). *Bt brinjal In India* (Pocket K No. 35). Manila, Philippines: Author. Available on the World Wide Web: <https://isaaa.org/resources/publications/pocketk/35/default.asp>.
- ISAAA. (2013b). *Biotechnology regulatory authority of India bill introduced in Parliament* (Crop Biotech Update April 24, 2013). Available on the World Wide Web: <http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=10885>.
- James, C. (2009). *Global status of commercialized biotech/GM crops: 2009* (ISAAA Brief No. 41). Ithaca, NY: ISAAA.
- James, C. (2011). *Global status of commercialized biotech/GM crops: 2011* (ISAAA Brief No. 43). Ithaca, NY: ISAAA.
- James, C. (2012). *Global status of commercialized biotech/GM crops: 2012* (ISAAA Brief No. 44). Ithaca, NY: ISAAA.
- James, C. (2013). *Global status of commercialized biotech/GM crops: 2013* (ISAAA Brief No. 46). Ithaca, NY: ISAAA.
- Kerala State Council for Science, Technology, & Environment. (2003). *Biotechnology, the flavour of the twenty-first century*. Kerala, India: Author. Available on the World Wide Web: <http://www.old.kerala.gov.in/annualprofile/biotech.htm#fla>.
- Konde, V. (2010, September 30). *Biotechnology regulations in India: Progress-so-far*. Available on the World Wide Web: <http://network.nature.com/groups/biotechmanage/forum/topics/8277>.
- Kumar, A. (2007, June). *Indian agri-biotech sector* (Working Paper). Mumbai: Rabobank International.
- Kutty, S.L. (2012). *India's Bt brinjal battle*. Penang, Malaysia: Pesticide Actions Network Asia and the Pacific.
- Ma, A.C., & Van Assche, A. (2013). Is East Asia's economic fate chained to the West? *Transnational Corporations Review*, 5(3), 1-17.
- Non-Resident Indians (NRI) Forum Karnataka. (2010). [website]. Available on the World Wide Web: <http://www.nriforumkarnataka.org/>.
- Pradhan, J.P. (2011). Non-equity operation of multinational enterprises in India: Focus on outsourcing. *Transnational Corporations Review*, 3(2), 1-11.
- Rediff India Abroad. (2006, May 10). *Andhra to redraft biotech policy*. Hyderabad: Author. Available on the World Wide Web: <http://www.rediff.com/money/2006/may/10bio.htm>.
- The Times of India*. (2012, July 9). Bihar to continue ban on genetically modified seeds.
- US Department of Agriculture, Foreign Agricultural Service. (2012, July 17). *India: Agricultural biotechnology annual* (GAIN Report Number IN2098). Washington, DC: Author.