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Global Agricultural Information Network

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Report Highlights:

Although Bt cotton remains the only biotech crop approved for commercial cultivation, the Government of India (GOI) made some progress in 2016 toward approving a locally-developed genetically engineered (GE) mustard event. Despite momentum on GE mustard, India's political landscape continues to hinder the agricultural biotech regulatory system. Soy and canola oils derived from select GE soy and canola varieties are the only biotechnology food-derived products approved for import. Indian animal biotech research and development remains nascent, although Indian scientists have achieved some success in animal cloning.

SECTION I. EXECUTIVE SUMMARY:

Agricultural trade between the United States and India was estimated at about \$5.4 billion in calendar year (CY) 2015, although the balance of agricultural trade was skewed roughly 3 to 1 in India's favor. Vegetable oil derived from select GE soy and canola (since Sept. 2015) is approved to be imported. Bt cotton is the only GE crop currently approved for commercial cultivation in India. Since 2002, the GOI has approved six Bt cotton events and nearly 1,400 Bt cotton hybrids and varieties for commercial cultivation. India does not commercially produce GE animals, including cloned animals, and/or any products derived from GE animals.

The 1986 Environment Protection Act (EPA) provides the foundation for India's biotechnology regulatory framework (see Annex 1) for GE plants, animals, their products, and by-products. Current Indian regulations stipulate that the Genetic Engineering Appraisal Committee (GEAC), India's apex regulatory body, must conduct an appraisal of all biotech food and agricultural products, and products derived from biotech plants and/or other biotech organisms prior to commercial approval or importation. Annex 2 of the EPA outlines the procedures for biotech product imports, including products used for research. The Food Safety and Standards Act of 2006 include specific provisions for regulating GE food products, including processed foods. However, the principal food safety regulatory body identified by the Act, the Food Safety and Standard Authority of India (FSSAI), is still in the process of formulating specific regulations for overseeing GE food products. Consequently, the GEAC continues to regulate processed food products containing GE ingredients, as per the 1989 Rules.

India's biotech regulatory policy environment from 2010 through early-2014 during the previous administration severely hampered forward momentum for product applications in the regulatory pipeline. Although some new events achieved advanced stages within India's regulatory approval process, these were ultimately stymied. In 2011, the GEAC introduced new regulatory procedures for biotech crop field trials, requiring applicants (technology developers) to obtain a 'no objection certificate' (NOC) from the relevant state government prior to conducting the trials. That decision has since hindered GE crop field trials, as most states remain unwilling to issue the requisite NOCs. The current *Bharatiya Janata Party* (BJP)-led National Democratic Alliance (NDA) administration has facilitated a more active, functional regulatory process under existing regulations, although internal politics continue to hold back substantive progress. For example, under the current administration, few new field trials have been allowed and no additional imported biotech-derived products have been cleared. Also, aggressive actions led by the Ministry of Agriculture and Farmers' Welfare (MAFW) over the past year, first against Bt cotton seeds, and later against biotech seeds more generally, has created significant uncertainty throughout the agricultural biotechnology sector.

Nonetheless, Prime Minister Narendra Modi and many other senior GOI officials continue to express support for adopting new agriculture technologies, including biotechnology. In 2016 substantial progress was made toward approving a public sector, domestically-developed GE mustard event. In spite of slow progress and setbacks, most local biotech stakeholders remain cautiously optimistic that the GOI will continue to allow biotechnology research and field trials.

Section II. PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. Product Development

GE Crops: Several Indian seed companies and public sector research institutions are developing GE crops, mainly for pest resistance, herbicide tolerance, nutritional enhancement, and abiotic stress tolerance (*e.g.* drought, salinity and soil nutrient). GOI sources report that over 20 crops with 70 biotech traits are at different stages of development. The crops being developed by public sector institutions include bananas, cabbage, cassava, cauliflower, chickpeas, cotton, eggplant, rapeseed/mustard, papayas, pigeon peas, potatoes, rice, sugarcane, tomatoes, watermelon and wheat. Private seed companies are more focused on cabbage, cauliflower, chickpeas, corn, rapeseed/mustard, okra, pigeon peas, rice, tomatoes, and stacked events for cotton.

On October 14, 2009, the GEAC recommended the approval of commercial cultivation of Bt eggplant, which was forwarded to the MOEF for a final decision. On February 9, 2010, the MOEF under the previous United Progressive Alliance government announced a moratorium on the approval until the GOI's regulatory system could ensure human and environmental safety through long-term studies. More than six years later, the GEAC has not provided a clear any decisive path forward for the approval of Bt eggplant. However, throughout 2016, the GEAC made progress toward approving a Delhi University (public sector and domestically-developed) GE mustard variety (containing events *bn 3.6* and *modbs 2.99*) developed using *barnase*, *barstar*. and *bar* genes. The GEAC established a technical sub-committee to review safety of GE mustard for environmental release. On September 5, 2016, the MOEF released the [Assessment of Food and Environmental Safety \(AFES\) report](#) published in the [MOEF website](#) for public comment. Industry sources report that the GEAC is currently reviewing the public comments and will subsequently forward their recommendations for a final decision. Besides the GE mustard, there are at least two or three other GE crop events that could also be ready for approval over the next 2-3 years.

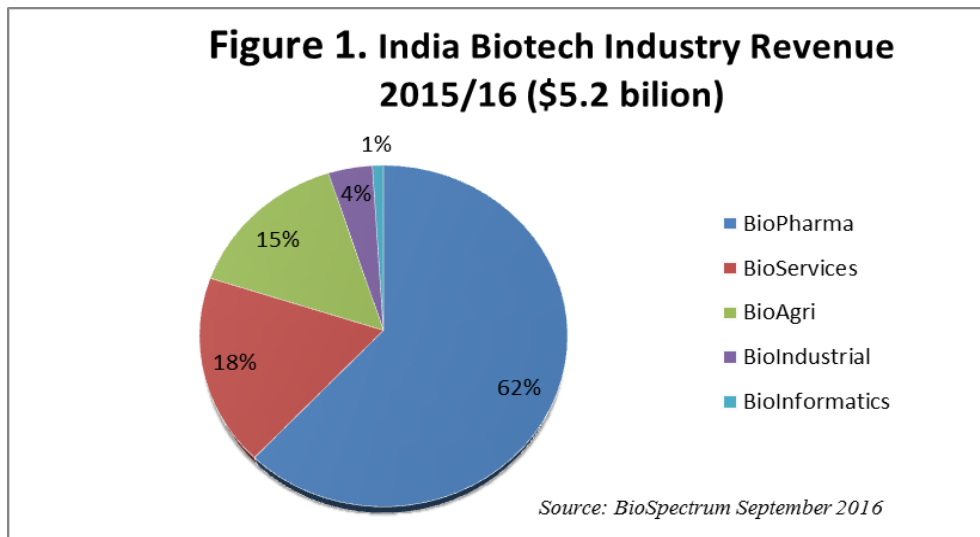
Use of Innovative Biotechnologies: Research and development of biotechnology and more advanced technology like genome editing has been initiated by some organizations. The Ministry of Science and Technology's (MOST) Department of Biotechnology (DBT) has established a task force on genome editing research and its applications, as a means to incentivize innovation and to promote development of genome-wide analysis and engineering technologies.

Use of GE in Other Sectors: GE techniques are extensively used in the production of biopharmaceuticals for human and animal use in India. Most of these products (more than 30) are in the category of biosimilars and include products such as insulin, hepatitis B vaccine, human growth hormone, monoclonal antibodies, among others, and are produced using host systems such as bacteria, yeast, and cell lines. To date, GE plants have not been used as host system. Biopharmaceuticals including biosimilars are regulated jointly by Drug Controller General of India (DCGI) under Drugs and Cosmetics Act, the Review Committee of Genetic Manipulation (RCGM), and GEAC under Rules, 1989. The RCGM reviews the applications up to the conduct of preclinical studies, GEAC reviews the application from environmental angle and the DCGI regulates the conduct of clinical trials and final registration, and undertakes the post marketing surveillance/monitoring.

b. Commercial Production

In 2002, Bt cotton was approved for commercial cultivation and remains the only GE crop approved for production. In a period of 14 years, Bt cotton area has grown to account for about 95 percent of total cotton acreage, and has led to a surge in Indian cotton production. India's cotton production in 2015 was estimated at 26.4 million bales (480 lbs.) from 11.9 million hectares, compared to 10.6 million bales from 7.6 million hectares in 2002. As a result, India has emerged as the world's second largest producer and exporter of cotton. To date, the GOI has approved six cotton events and more than 1200 hybrids for cultivation in different agro-climatic zones. Most of the approved Bt cotton hybrids are produced from two Monsanto events (Mon 531 and Mon 15985). The commercial cultivation of Bt cotton events is approved for seed, fiber, and cotton seed for feed production/consumption.

India's biotechnology sector was estimated at \$5.2 billion in Indian fiscal year 2015/16, dominated by the biopharmaceutical sector, which accounted for a market share of 62 percent, followed by bio-services with a market share of 18 percent, and agricultural biotechnology which accounted for 15 percent of India's biotech sector. Biopharmaceuticals including vaccines, diagnostics, and therapeutics, are likely to continue dominating the biotech sector, largely due to the global high demand for low-cost drugs. The growth of agricultural biotechnology has slowed down in the last few years (acres under Bt cotton production are essentially at full potential) and will likely weaken unless the GOI approves additional biotech crops for cultivation.



c. Exports

India is the one of the world's leading cotton exporters, and occasionally exports small quantities of cotton seed and cotton seed meal derived from Bt cotton. India exported about 3.9 million bales (480 lbs.) in 2015 and had exported a record 11.1 million bales in 2011. Market sources report that export documentation for cotton as a fiber product (cellulose) does not require any GE declaration, as it has no protein content. India does not export significant quantities of cotton or cottonseed meal to the United States.

d. Imports

The only GE food products currently authorized for import into India are soybean oil derived from GE soybeans (glyphosate tolerant and five other events) and canola oil derived from a GE canola (a select herbicide tolerant event). India imports significant quantities of soybean oil (3.5 million metric tons in 2015), mainly from Argentina (2.6 MMT), Brazil (0.7 MMT), and Paraguay (0.13 MMT) and small quantities of canola oil, mainly from Canada. All other GE crops, processed products or seeds are technically banned.

e. Food Aid

India is not a food aid recipient from the United States and is not likely to be in the near future.

f. Trade Barriers

India's trade policy effectively bans imports of all GE products, except for soybean and canola oil derived from GE soybean and GE canola (select events). On July 8, 2006, the Ministry of Commerce and Industries issued a [notification](#) specifying that all imports containing GE products must have prior approval from the GEAC. This directive requires a GE declaration at the time of import. In 2006, the MOEF published the [Procedure for GEAC Clearance for Imports of GM Products](#). The specific procedure for filing an import application for a GE product is found in Annex 2 of this report.

Industry sources report that the procedures to obtain GEAC clearance for importing GE products are cumbersome and not science based, which effectively prohibit imports. On June 22, 2007, the GEAC granted permanent approval for importation of soybean oil derived from glyphosate-tolerant soybeans for consumption after refining. On July 17, 2014, the GEAC also approved importation of soybean oil derived from four other GE events. On September 3, 2015, the GEAC allowed imports of soybean oil derived from another HT tolerant event (Event FG72 from Bayer Bioscience) and Canola oil derived from HT canola (Event Ms8xRF3 by Bayer Bioscience Private Ltd).

No other GE food products, including bulk grains, semi-processed, or processed foods are currently authorized for import. However, the GEAC is reviewing applications for the approval of imports of dried distillers grains with solubles (DDGS) derived from GE corn, as well as GE soybean meal.

The import of GE seeds and planting material is also regulated by the 2003 "Plant Quarantine Order (PQO Regulation of Import into India)," which came into force in January 2004. The PQO regulates the import of germ plasm/bioengineered organisms/transgenic plant material for research purposes. NBPGR is the authorizing authority for issuing import permits. The complete text of this order is available at <http://agricoop.nic.in/gazette/gazette2003.htm>.

PART B: POLICY

a. Regulatory Framework

The regulatory framework for GE crops, animals, and products in India is governed by the EPA of 1986 and the ‘Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989.’ These rules govern research, development, large-scale use, and import of GE organisms and their products. The rules identify six competent authorities (see Annex 1).

On August 24, 2006, the GOI enacted an integrated food law, namely the Food Safety and Standards Act of 2006, which has specific provisions for regulating GE food products, including processed foods. Under the Act, FSSAI is cited as the single authority responsible for establishing and implementing science-based standards for food, including GE foods. However, the FSSAI has not yet developed the institutional capacity to fulfill this function and the GEAC continues to regulate GE food.

Table 1. India: Role of Various Ministries/State Governments:

Authority	Role/Responsibility
MOEF	Houses the GEAC, the nodal agency responsible for the implementation of Biotech Rules of 1989 under the EPA Act.
DBT	Provides guidelines and technical support to the GEAC. Evaluates and approves biosafety assessment of GE product research and development in the country.
MAFW	Evaluates and approves the commercial release of transgenic crop varieties after conducting field trials for assessing agronomic performance. Also responsible for post approval monitoring.
FSSAI	Evaluates and approves the safety assessment of GE crops and products for human consumption. FSSAI has not yet established regulations and the GEAC continues to oversee this responsibility.
Various state governments.	Monitors the safety measures at biotech research facilities, and assess damage, if any, due to the release of GE products. Approve field trials and commercial cultivation of GE crops finally approved by the GEAC in their respective states.
DBT, MAFW, and various state governments.	Supports, research and development of agriculture biotechnology through various research institutions and state agriculture universities.

In 1990, the DBT developed the ‘Recombinant DNA Guidelines’, which were subsequently amended in 1994. In 1998, the DBT issued separate guidelines for biotech plant research, including the import and shipment of GE plants for research use. In 2008, the GEAC adopted ‘Guidelines and Standard Operating Procedures for the Conduct of Confined Field Trials’. The GEAC also adopted new ‘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, are available online at <http://dbtbiosafety.nic.in/>.

GEAC Functioning Since Late 2015

After the current government was formed in May 2014, the first GEAC meeting was held on July 17, 2014, wherein approvals were granted for field trials of several GE crop events. This was strongly opposed by several ideological organizations affiliated with the ruling BJP-led government.

Consequently, the GEAC did not consider any new applications for GE crop field trials during subsequent meetings held in September 2014 and February 2015. Since September 2015, the GEAC has been convening on a regular basis but the approvals granted for field trials have been mostly related to the renewals of the earlier permission (prior to 2015).

Supreme Court Case Stalemate Continues

On May 10, 2012, the Supreme Court of India appointed a six-member Technical Expert Committee (TEC) to review and recommend risk assessment studies (for health and environmental safety) for all GE crops before they can be approved for open field trials. The Court's action was in response to a petition filed in 2005 which alleged that field trials of GM crops were being allowed without proper scientific evaluation of biosafety concerns. (NOTE: For more information on the 2005 Supreme Court's case, refer to GAIN report [IN8077](#)). On July 18, 2013, the five members of the TEC submitted their final report recommending a ban on field trials until the gaps in the existing regulatory system are properly addressed. However, the sixth member (an agriculture scientist) submitted a separate report dissenting against the TEC recommendation. On April 1, 2014, the GOI submitted an affidavit to the Court against the five-member TEC report. The five-member TEC report was also strongly opposed by industry stakeholders in court hearings on April 22, 2014 and May 7, 2014. To date, no further hearings have occurred on this case.

FSSAI Unable to Regulate GE Food

Subsequent to the enactment of the 'Food Safety and Standard Act of 2006, the [MOEF issued a notification](#) on August 23, 2007, stating that processed food products derived from GE products (where the end-product is not a living modified organism) do not require approval from GEAC for production, marketing, import and use in India. As processed food products are not replicated in the environment, they are not considered to be an environmental safety concern under the 1989 EPA.

Although technically the FSSAI has regulatory authority over GE food products in India, there are no specific regulations in place for FSSAI to approve GE food products. Consequently, the Ministry of Health and Family Welfare (MHFW) requested that the GEAC continue to regulate processed, GE-derived food products under the 1989 Rules. Thus, the MOEF notification on processed food products has been deferred and the GEAC continues to regulate imports of processed GE food products. Until new regulations are in place, the 1986 EPA remains the cornerstone of India's GE food regulatory system.

Biotechnology Regulatory Authority Bill Uncertain

On November 13, 2007, the MOST issued a 'National Biotechnology Strategy' to strengthen the regulatory framework, suggesting the establishment of a National Biotechnology Regulatory Authority of India (NBRAI) that would provide a single window mechanism for biosafety clearance. On April 22, 2013, the DBT submitted the 'National Biotechnology Regulatory Bill', together with a draft 'Establishment Plan for Setting up the National Biotechnology Regulatory Authority' to the Parliament for approval. Subsequently, the bill was referred to the Parliamentary Standing Committee on Science, Technology, Environment and Forests. Meanwhile, the BRAI bill lapsed due to inaction in May 2014 with the dissolution of the 15th Lok Sabha (lower house of the Parliament). To date, the ruling NDA

government has not decided on whether to present the proposed bill in its current form, or conduct further consultations and make additional changes before presenting it to the Parliament for approval. Pending parliamentary approval of the BRAI, India’s regulatory mechanisms continue to be governed by the EPA 1986 and the Rules of 1989.

b. Approvals

Bt cotton is the only GE crop approved for cultivation in India.

Table 2. India: Bt cotton events approved

Gene/Event	Developer	Usage
Cry1Ac (Mon 531) ^[1]	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed
Cry1Ac & Cry2Ab (Mon 15985) ^[2]	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed
Cry1Ac (Event 1) ^[3]	JK Agrigenetics	Fiber/Seed/Feed
Cry1Ab and Cry1Ac (GFM Event) ^[4]	Nath Seeds	Fiber/Seed/Feed
Cry1ac (BNLA1)	Central Institute of Cotton Research	Fiber/Seed/Feed
Cry1C (Event MLS 9124)	Metahelix Life Sciences Private Limited	Fiber/Seed/Feed

Source: [IGMORIS, GOI](#).

^[1] Gene sourced from Monsanto.

^[2] Stacked gene event sourced from Monsanto.

^[3] Gene sourced from Indian Institute of Tech., Kharagpur.

^[4] Gene sourced from China featuring fused genes.

c. Stacked or Pyramid Events Approvals

For approval purposes, a stacked or pyramid event, even if consisting of already approved events, is essentially treated as a new event.

d. Field Testing

The GEAC is responsible for approving all open field trials on the recommendation of RCGM. In June 2008, the GEAC approved ‘[Guidelines and Standard Operating Procedures for Regulated Genetically Engineered Plants](#)’. The GEAC also adopted an “event based” approval system for Bt cotton, reviewing the efficacy of the event/trait, and focusing on biosafety, particularly on environmental and health safety.

Before any GE event can be approved for commercial use, it must undergo extensive agronomic evaluation through field trials under the supervision of an Indian Council of Agricultural Research (ICAR) institution or a state agriculture university (SAU) for at least two crop seasons. Product developers can also conduct agronomic trials in conjunction with the biosafety trials, or do so separately after the GEAC recommends environmental clearance and the GOI gives final authorization.

In early 2011, some state governments objected to authorization of GE crop field trials without state permission. On July 6, 2011, the GEAC amended the procedures for field trial authorization, which now require the applicant (the technology developer) to obtain an NOC from the relevant state

government. Applications that had previously received approval from the GEAC now also require an NOC from the state government before commencing the field trials. Market sources report that only a few states (Punjab, Haryana, Delhi, Rajasthan, Gujarat, Maharashtra, Karnataka and Andhra Pradesh) have issued NOCs for GE field trials of select events in the Indian crop year 2014/15 and 2015/16 (July-June), and some of the states have restricted the trials to non-food crops (cotton) only.

Despite the GEAC approvals for field trials of several crop events, problems in obtaining permission (in the form of NOCs) from state governments have limited field trials to only few events (chickpea, and cotton) in the crop year 2015/16 (July-June). Since September 2015, the GEAC has approved field trials of several GE crop events for planting in Indian crop year 2015-16 (July/June) and 2016/17, mostly renewals of the approvals prior to 2015.

e. Innovative Technologies

India has not clearly defined the regulatory status of innovative technologies such as genome editing in plants and other organism, and the issue is still under discussion. However, all genetically modified organisms are regulated as per “Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989” notified under the Environment (Protection) Act, 1986, commonly referred as Rules, 1989. These Rules provided for definition for gene technology and genetic engineering as follows:

- (i) “Gene Technology” means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridization;
- (ii) “Genetic engineering” means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

Consequently, the decision on regulatory system for innovative biotechnologies will be based on the above definitions in Rules, 1989. Preliminary discussion on regulation of new gene technologies was initiated in the South Asia Biosafety Conference, 2013. An International Conference On New Plant Breeding Molecular Technologies –Technology Development And Regulation” held in October 9-10, 2014 at Jaipur also deliberated on the issue. However, Post is not aware of any government initiatives on regulation of new innovative technologies, including genome editing, etc.

f. Coexistence

The GOI has no specific regulations on coexistence of GE and non-GE crops. On January 10, 2007, the GEAC decided against allowing multi-location GE crop field trials in basmati rice growing areas, particularly in the geographical indication (GI) states of Punjab, Haryana and Uttaranchal.

g. Labeling

In March 2006, the Ministry of Health and Family Welfare issued a draft amendment to the 1955

Prevention of Food Adulteration (PFA) Rules, extending a labeling requirement to “Genetically Modified foods” (For more information on the proposed regulation, refer to GAIN reports [IN6024](#) and [IN6060](#)). The FSSAI has been consulting with various stakeholders on the draft amendment to consider labeling options under the new Food Safety and Standard Act 2006, but no decision has been taken on labeling of GE food products to date.

On June 5, 2012, the Department of Consumer Affairs (DCA), Ministry of Consumer Affairs, Food and Public Distribution, issued notification G.S.R. 427 (E) amending the [Legal Metrology \(Packaged Commodities\) Rules, 2011](#), effective January 1, 2013, which stipulates “every package containing genetically modified food shall bear at the top of its principal display panel the word “GM.” The DCA stated that the “GM” labeling requirement is for consumers’ right to know. Industry sources report that there has been no enforcement of the labeling requirement by DCA. As the FSSAI is still in the process of establishing labeling regulations for GM foods, the future status of the DCA GM labeling regulation remains uncertain (see GAIN report [IN2078](#)).

h. Monitoring and Testing

India does not actively test for GE traits at the time of import/export due to lack of testing facilities at the Ports of entry/exit. There has not been any known instance of interception of import consignments containing unapproved GE events. In case of suspicion of an unapproved GE food product in the market, the FSSAI and food safety authorities in the state governments can draw samples for testing at various government and private food testing labs with facilities for identifying events and taking penal action against the importer in case found containing unapproved GE events.

There is no regular monitoring of field crops for testing against unapproved GE events. However, the Ministry of Agriculture does monitor the approved GE crop events (cotton) for three years for agronomic performance and environmental implications.

i. Low Level Presence

India has a zero tolerance policy for unapproved GE food and crop events in import shipments. The trade policy states that if import shipment is found containing any level of products containing unapproved GE event at the time of import, the importer shall be penalized.

j. Additional Regulatory Requirement

Once an event is approved for commercial use, the applicant can register and market seeds in various states according to the provisions of the 2002 National Seed Policy and other relevant seed regulations specific to each state. Following the commercial release of a GE crop, the Ministry of Agriculture, together with the various state departments of agriculture, monitors field performance for 3-5 years.

k. Intellectual Property Rights

In 2001, India enacted the Protection of Plant Varieties and Farmers’ Rights Act to protect new plant varieties, including transgenic plants. The Protection of Plant Varieties and Farmers’ Right Authority was established in 2005, and to date has [notified 114 crops species](#) for registration, including Bt cotton

hybrids.

1. Cartagena Protocol Ratification

On January 17, 2003, India ratified the Cartagena Protocol on Biosafety, and has since established rules for implementing the provisions of the articles (see Annex 3). A Biosafety Clearing-House (BCH) has been set up within the MOEF to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs). The GEAC has the responsibility of approving trade of GE products, including seed and food products. India has traditionally advocated strict liability and redress to the trans-boundary movement of LMOs, a position that could complicate the movement of Bt cotton seed to neighboring countries.

m. International Treaties/Fora

In Codex Alimentarius discussions, India has supported mandatory labeling of GM foods, requiring a compulsory declaration whenever food and food ingredients contain genetically modified organisms.

n. Related Issues

MOAFW Intends to Regulate Cotton Trait License Fee/Licensing Guidelines for GE Crops

On December 7, 2015, India's MOAFW passed an order called the [Cotton Seed Price Control Order \(CSPCO\), 2015](#), seeking to regulate the maximum sale price (MSP) of cotton seed, including royalty/trait value and prescribe licensing guidelines and format for all the GM Technology Licensing Agreements. On March 8, 2016, MOAFW issued a [Notification](#) capping Bollgard I cotton seed price for the crop year 2016/17 (July-June) at INR 635 per packet (450 gram Bt seeds plus 120 gram *refugia* non-Bt seeds) with trait value zero and Bollgard II cotton seed prices at INR 800 per packet with trait value at INR 49/packet.

Subsequently, on May 18, 2016, the MOAFW notified [Licensing and Formats for GM Technology Agreement Guidelines, 2016](#) creating a system of compulsory licensing of technology, developing terms and conditions of the contract as well as fixing upper limits on the royalty that can be paid in such license. On May 24, 2016, the [government rescinded the notification](#) due to the concerns expressed by various stakeholders on the wide ranging implications of the notification, and issued the same as "Draft Licensing Guidelines and Formats for GM Technology Agreements" for comments from all stakeholders for a period of 90 days.

The CSPCO 2015 and the March 2016 price notification have been challenged in Indian Courts by various industry stakeholders arguing that the order is unconstitutional and exceeds the authority granted to the MOA under the Essential Commodities Act. Various stakeholders, including US Government and other foreign and international organizations, have submitted their comments to the MOAFW for review. Currently, the MOAFW is reviewing the comments and have held some consultations with stakeholders. Industry sources report that the MOAFW is likely to drop the draft licensing guidelines, and are exploring the possibility of introducing the licensing regulations through the provisions of the Protection of Plant Variety and Farmers Right Act (PPVFRA) 2001.

Industry experts report that the CSPCO 2015 if implemented in current form will impose significant barriers to the ease of doing business, discourage innovation and long term research and developments (R&D) and investments in agriculture biotechnology sector. The provisions of the CSPCO not only hurt existing technology providers but are a disincentive to potential new innovators. Research and development of GE crops, which typically takes several years to yield results, require reasonable IPR protection in order to provide some opportunity to recoup such investments. Interfering with the trait fee and licensing agreements will distort incentives to undertake innovation and/or introduce new technologies to Indian farmers to improve their livelihood and make them globally competitive.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. Product Development

Indian research and developments on animal biotechnology is in its infancy, except for some successes in animal cloning. On February 6, 2009, scientists of the [National Dairy Research Institute delivered the first cloned buffalo heifer calf](#) through the advanced hand guided cloning technique, but the calf died shortly after birth. Subsequently, two cloned heifer calves were born on [June 6, 2009](#), and [August 22, 2010](#), and a bull calf was born on [August 26, 2010](#). While the second cloned heifer died two years later, the third heifer and the cloned bull calf are alive (see below). On January 25, 2013, the cloned heifer calved after being bred by a progeny tested bull. On December 27, 2014, the first cloned buffalo delivered its second calf using the 'hand-guided cloning technique', which is the eighth cloned calf by the institute. On March 9, 2012, scientists from the Sher-e-Kashmir University of Agricultural Sciences and Technology at Srinagar claimed to have delivered [a cloned pashmina goat](#) by the same cloning technique. Scientists from NDRI reported that the cloning research is still experimental and it may take another 3-5 years before the technique can be standardized for commercial production.

Cloned Buffalo Cow

Cloned Buffalo Bull



Most animal biotechnology research in India is currently focused on the genomics of important livestock, poultry and marine species for identifying genes for heat/cold tolerance, disease resistance and economically important production factors. The bovine genomics program focuses on characterizing and identifying genes for heat tolerance, disease resistance, and economic factors like duration between calving, length of lactation, and milk yield. The ongoing genomics studies can be used in future breeding programs for incorporating important traits through traditional breeding or future genetic engineering or genome editing.

Most animal biotechnology research is conducted by public sector research organizations like ICAR institutions, Council of Scientific and Industrial Research (CSIR) institutions, state agricultural universities and other research organizations supported by the DBT.

Reports suggest that a local company has licensed from a United Kingdom based company GE male mosquitos containing a self-limiting gene that causes the progeny to die to control mosquito population in areas affected by mosquito borne diseases like dengue fever and the chikungunya virus. The Indian company is in the process to obtaining permission to conduct lab and contained trials.

b. Commercial Production

To date, India does not produce GE animals, including cloned animals or products derived from GE animals for commercial production.

c. Exports

India does not export any GE animals, animal clones or products from these animals.

d. Imports

Currently India does not allow imports of any GE animals or products derived from GE animals.

e. Trade Barriers

The trade barriers applicable to plant products are also applicable for animal GE products.

PART E: POLICY

a. Regulation

The EPA 1986 also governs the research, development, commercial use and imports of GE animals and animal products. Currently, most of the animal biotech research is at preliminary stage and there are no transgenic animals even for research. However, research on cloning and genomic research on animals does not come under the purview of EPA. With animal cloning still being researched, there are no current regulations on commercial production or marketing of cloned animals.

b. Innovative Biotechnologies

India has not clearly defined the regulatory status of innovative technologies such as genome editing in animals as there is no ongoing animal biotech research in these areas.

c. Labeling and Traceability

India does not have any regulations on labeling or traceability of GE animals and products, including cloned animals, nor there any major policy discussion on the issue.

d. Intellectual Property Rights

There are no specific regulations on IPR for animal biotechnology or GE animals.

e. International Treaties/Fora

Post is not aware if India has taken any position on animal biotechnologies, which includes GE animals, genome editing and cloning, in international fora.

f. Related Issues

Not applicable

ANNEXURES

Annex 1: Existing Biotech Regulatory Authorities – Function/Composition

<i>Committee</i>	<i>Members</i>	<i>Functions</i>
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<p>Genetic Engineering Appraisal Committee (GEAC); functions under Ministry of Environment and Forests (MOEF).</p>	<p>Chairman-Additional Secretary, MOEF Co-Chairman - Nominee of Department of Biotechnology (DBT) Members: Representatives of concerned agencies and departments namely Ministry of Industrial Development, DBT, and the Department of Atomic Energy Expert members: Director General-ICAR, Director General-ICMR; Director General-CSIR; Director General of Health Services; Plant Protection Adviser; Directorate of Plant Protection; Quarantine and storage; Chairman, Central Pollution Control Board; and few outside experts in individual capacity. Member Secretary: An official from the MOEF</p>	<p>Review and recommend the use of bio-engineered products for commercial applications. Approve activities involving large-scale use of bio-engineered organisms and recombinants in research and industrial production from an environmental safety angle. Consult RCGM on technical matters relating to clearance of bio-engineered crops/products. Approve imports of bio-engineered food/feed or processed product derived thereof. Take punitive actions on those found violating GE rules under EPA, 1986.</p>
<p>Review Committee on Genetic Manipulation (RCGM); function under DBT.</p>	<p>Representatives from: DBT, Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR) Other experts in their individual capacity.</p>	<p>Develop guidelines for the regulatory process for research and use of bio-engineered products from a bio-safety angle. Monitor and review all ongoing GE research projects up to the multi-location restricted field trial stage. Undertake visits to trial sites to ensure adequate security measures. Issue clearance for the import of raw materials needed in GE research projects. Scrutinize applications made to the GEAC for the import of bioengineered products. Form Monitoring and Evaluation Committee for biotech crop research projects. Appoint sub-groups when required in topics of interest to the committee.</p>
<p>Recombinant DNA Advisory Committee (RDAC); function under DBT</p>	<p>Scientists from DBT and other public sector research institutions</p>	<p>Take note of developments in biotechnology at the national and international level. Prepare suitable guidelines for safety in research and applications of GMOs. Prepare other guidelines as</p>

		may be required by the GEAC.
Monitoring Cum Evaluation Committee (MEC)	Experts from ICAR institutes, State Agricultural Universities (SAUs) and other agricultural/crop research institutions and representatives from DBT.	Monitor and evaluates trial sites, analyze data, inspect facilities and recommend safe and agronomically viable transgenic crops/plants for approval to RCGM/GEAC
Institutional Biosafety Committee (IBC); functions at research institution/ Organization level.	Head of the Institution, Scientists engaged in biotech work, Medical Expert, and Nominee of the Department of Biotechnology	Develop a manual of guidelines for the regulatory process on bio-engineered organisms in research, use and application to ensure environmental safety. Authorize and monitor all ongoing biotech projects to the controlled multi location field stage. Authorize imports of bio-engineered organisms/transgenic for research purposes. Coordinate with district and state level biotechnology committees.
State Biotechnology Coordination Committee (SBCC); functions under the state government where biotech research occurs.	Chief Secretary, State Government; Secretaries, Departments of Environment, Health, Agriculture, Commerce, Forests, Public Works, Public Health; Chairman, State Pollution Control Board; State microbiologists and pathologists; Other experts.	Periodically reviews the safety and control measures of institutions handling bio-engineered products. Inspect and take punitive action through the State Pollution Control Boards or the Directorate of Health in case of violations. Nodal agency at the state level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.
District-Level Committee (DLC); functions under the district administration where biotech research occurs.	District Collector; Factory Inspector; Pollution Control Board Representative; Chief Medical Officer; District Agricultural Officer, Public Health Department Representative; District Microbiologists/Pathologists; Municipal Corporation Commissioner; other experts.	Monitor safety regulations in research and production installations. Investigate compliance with rDNA guidelines and report violations to SBCC or GEAC. Nodal agency at district level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.

Source: DBT and MOEF, GOI.

Annex 2: Procedure and Application Formats for Import of Biotech Products

Item	Approval According Agency	Governing Rules	Form No.	Links for Downloading
GMOs / LMOs for R&D	IBSC/RCGM/NBPGR	Rules 1989; Biosafety guidelines of 1990 and 1998; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; and Guidelines for the import of germplasm, 2004 by NBPGR	I	GEAC Form I
GMOs / LMOs for intentional release (including field trials)	IBSC/RCGM/GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	GEAC Form II B
GM food /feed as LMOs per se	GEAC	Provide biosafety & food safety studies, Compliance with the Rules 1989 and Biosafety guidelines of 1990 & 1998	III	GEAC Form III
GM processed food derived from LMOs	GEAC	One time “event based” approval given based on importer providing the following information: i. List of genes/events approved in the crop species for commercial production in the country of export/country of origin; ii. Approval of the product for consumption in countries other than producing countries; iii. Food safety study conducted in the country of origin; iv. Analytical/compositional report from the country of export/origin; v. Details on further processing envisaged after import; vi. Details on commercial production, marketing and use for feed/food in the country of export/origin; vii. Details on the approval of genes / events from which the product is derived	IV	GEAC Form IV
Processed food containing ingredients derived from GMO	GEAC	If the processed food contains any ingredient derived from category 2 and 3 mentioned above, and if the LMO / product thereof has been approved by the GEAC, no further approval is required except for declaration at the port of entry. In case it does not have the approval of GEAC, the procedure mentioned in category 3 above to be complied.	IV , if required	GEAC Form IV B

Source: MOEF Website http://www.envfor.nic.in/divisions/csurv/geac/gmo_lmo.htm

Annex 3: India's Compliance with Various Articles of the Cartagena Protocol

Article	Provisions	Present Status
Article 7	Application of the Advanced Informed Agreement procedure prior to the first trans boundary movement of LMOs intended for direct use as food or feed, or for processing.	Competent authority (GEAC) notified. Border control through NBPGR only for contained use. Projects initiated to strengthen DBT and MOEF's capabilities to identify LMOs.
Article 8	Notification – The Party of export shall notify, or require the exporters to ensure notification to, in writing, the competent authority of the Party of import prior to the intentional trans boundary movement of LMOs that falls within the scope of Article 7	Rules 1989 and competent authorities in place.
Article 9	Acknowledgement of receipt of notification-The Party of import shall acknowledge receipt of the notification, in writing to the notifier	Point of contact notified, the regulatory body (GEAC) in place
Article 10	Decision Procedure-Decision taken by the Party of import shall be in accordance with Article 15	Regulatory body (GEAC) in place
Article 11	Procedure for LMOs intended for direct use as food or feed, or for processing	1989 Rules ^[1] , DGFT Notification No. 2(RE-2006) / 2004-2009 ^[2]
Article 13	Simplified Procedure to ensure the safe intentional trans-boundary movement of LMOs	1989 rules
Article 14	Bilateral, regional and multilateral agreements and arrangements	--
Article 15	Risk assessment	DBT Biosafety Guidelines for research in plants, guidelines for confined field trials guidelines for safety assessment of foods derived from GE plants.
Article 16	Risk Management	DBT Guidelines for research
Article 17	Unintentional trans-boundary movements and emergency measures	1989 rules
Article 18	Handling, transport, packaging and identification	1989 Rules, guidelines to be developed
Article 19	Competent National Authorities and National Focal Point	Ministry of Environment and Forests designated as competent authority and national focal point
Article 20	Information sharing and the Biosafety Clearing House	Biosafety Clearing House (http://www.indbch.nic.in) has been set up.
Article 21	Confidential information	--
Article 22	Capacity building	Ongoing capacity building activities by DBT, MOEF, USTDA and USAID-sponsored SABP
Article 23	Public awareness and participation	Ongoing, MOEF and DBT have specific websites on biotech developments and regulatory system including website of IGMORIS ^[3] , GEAC ^[4] , DBT Biosafety ^[5] , etc.
Article	Non-Parties (trans-boundary movements of	1989 rules in place for all import and export

24	LMOs between Parties and non-Parties)	
Article 25	Illegal trans-boundary movements	--
Article 26	Socio-economic considerations	Socioeconomic analysis is an integral part of decision making
Article 27	Liability and redress	National Consultation ongoing

Source: MOEF and Industry Sources.

^[1] See Annex 2

^[2] <http://164.100.9.245/exim/2000/not/not06/not0206.htm>

^[3] <http://igmoris.nic.in/>

^[4] http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html

^[5] <http://dbtbiosafety.nic.in/>