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Report Highlights:

India's political environment continues to hinder the development of agricultural biotechnology regulatory system: the Government of India (GOI) remains undecided on the approval of genetically engineered (GE) crop events (namely mustard and eggplant), which have already been cleared by the regulatory authorities. Bt cotton remains the only biotech crop approved for commercial cultivation. Soy and canola oils derived from select GE soy and canola events are the only products derived from GE crops, animals or their by-products approved for import. Other than limited success in research on the cloning of buffaloes, Indian animal biotech research and development is at a nascent stage.

Section I. Executive Summary:

The 1986 Environment Protection Act (EPA) provides the foundation for India's biotechnology regulatory framework (see Annex 1) for genetically engineered (GE) plants, animals, and their products and by-products. Prior to commercial approval or importation, 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 also of products derived from biotech plants and animals or other biotech organisms. The Food Safety and Standards Act of 2006 includes specific provisions for regulating GE food products, including processed foods, but the Food Safety and Standard Authority of India (FSSAI) has deferred the approval of food products to GEAC in the absence of regulations and operational infrastructure. However, in August 2017, the Supreme Court of India issued directives to FSSAI for framing regulations, which would enable approval of GE food products.

Bt cotton is the only GE crop currently approved for commercial cultivation, and vegetable oils derived from select GE soy and canola are the only products approved for imports in India. In the last few years, GEAC has received several applications for import approval of distiller's dried grains with solubles (DDGS), which are derived from GE corn; they have also received applications for GE soybeans, as well as for oil and meal derived from GE soybeans and other processed food products from GE crops. Subsequent to the August 2017 court order, GEAC has forwarded the applications for approval of GE food products to FSSAI. However, FSSAI is still in the process of making regulations for approval of GE food products.

The U.S.-India bilateral trade in food, agricultural and related products was estimated at about \$ 7.0billion in calendar year (CY) 2017, with the balance of trade skewed at 2.5 to 1 in India's favor. U.S. exports of products derived from GE crops are mostly cotton (\$435 million), and a small quantity of soybean oil. Bt cotton, the only GE crop approved for commercial cultivation, accounts for over 95 percent of India's cotton production, estimated at about 29.7 million bales (480-lb bales) in MY 2017/18 (August-July), of which about 5.2 million bales were exported. India does not commercially produce animals or animal products derived from agriculture biotechnology, including cloned animals.

The current ruling National Democratic Alliance (NDA) government has allowed the biotech regulatory system to function but has been indecisive on product approvals. GEAC has continued to clear field trials, streamline the approval process, and, in May 2017, cleared the environmental release of locally developed GE mustard. However, the government deferred approval of GE mustard due to opposition from right wing organizations and anti-biotechnology groups. While senior government functionaries express support for adopting biotechnology, local biotech stakeholders believe that the current government may not allow approval of GE crops until the upcoming parliamentary elections (likely to be held around March-April 2019). In 2017 the Ministry of Agriculture and Farmers' Welfare (MAFW) implemented market restrictive actions against biotech seed companies, including price controls on Bt cotton seeds and a proposal for licensing regulations on biotech seeds. Such restrictions create significant uncertainty in the agricultural biotechnology sector, and discourage investment in biotech research and development (R&D).

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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 (about 85 plant species), mainly for pest resistance, herbicide tolerance, abiotic stress tolerance (*e.g.* drought, salinity and soil nutrient depletion), nutritional enhancement, and nutritional, medicinal or metabolic phenotypes. The crops being developed by public sector institutions include bananas, cabbage, cassava, cauliflower, chickpeas, cotton, eggplant, rapeseed/mustard, papayas, peanuts, pigeon peas, potatoes, rice, sorghum, sugarcane, tomatoes, watermelon and wheat. However, the private seed companies are focused on cabbage, cauliflower, chickpeas, corn, rapeseed/mustard, okra, pigeon peas, rice, tomatoes, and stacked events for cotton. The policy uncertainty and prolonged delays in the regulatory approval system have severely constrained the advancement of research on GE crops to the product development stage, both in the private and public sector. Sources report that developers of the GE products developed in India are exploring commercialization in other countries because they are unable to get it through the regulatory system in India (*eg.* Bt eggplant in Bangladesh and Philippines).

On October 14, 2009, GEAC recommended the approval of commercial cultivation of Bt eggplant, which was forwarded to the Ministry of Environment, Forests and Climate Change (MOEFCC) for a final decision. On February 9, 2010, the MOEFCC 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. Nearly 10 years later, including over four years of the current NDA government, GEAC has not initiated any definitive process for the approval of Bt eggplant.

Meanwhile, a domestically developed GE mustard variety (containing events *bn 3.6* and *modbs 2.99*) developed using *barnase*, *barstar*, and *bar* genes developed by a public sector entity (Delhi University), progressed through the regulatory approval system. On September 5, 2016, the MOEFCC released the [Assessment of Food and Environmental Safety report](#) for public comment. GEAC also established a technical sub-committee to review the safety of GE mustard for environmental release in view of public comments. After reviewing the public comments and a series of consultations with stakeholders, the technical subcommittee submitted its report to GEAC in April 2017. [On May 11, 2017, GEAC](#) reviewed the report submitted by the technical subcommittee and submitted for final approval from the GOI the proposal to allow environmental release of GE mustard. However, GEAC's decision was strongly opposed by various stakeholders, including right wing anti-biotech groups. Subsequently, [MOEFCC issued a notification](#) that "subsequent to receipt of various representations from different stakeholders, matters related to environmental release of transgenic mustards are kept pending for further review." Further, the government sent back the proposal for approval of GE mustard to GEAC for reconsideration. In March 2018, GEAC reiterated that the concerns raised by various stakeholders had been adequately considered when the decision for environmental release of GE mustard was made in May 2017. Nevertheless, GEAC advised the developer to conduct field demonstration studies on honeybees and other pollinators at two locations up to five acres, each, in Punjab and Delhi.

If the government decides to approve GE crops using a science-based regulatory assessment in the near future, then besides GE mustard and Bt eggplant, there are at least three other GE crop events, including a stacked GE cotton event that could be ready for approval over the next 2-3 years.

Use of Innovative Biotechnologies

In response to political interests and the slow drag on the biotech regulatory approval system, most public sector researchers are shifting focus to use of genomics and marker-assisted breeding in their agriculture biotech programs.

Some organizations have started research and development of biotechnology and new breeding techniques such as genome editing. To incentivize innovation and to promote development of genome-wide analysis and engineering technologies, the Ministry of Science and Technology's (MOST) Department of Biotechnology (DBT) has established a task force on genome editing research and its applications.

Use of Biotechnology in Other Sectors

Biotechnology is used extensively in the production of [biopharmaceuticals for human and animal use in India](#). Most of these products are in the category of biosimilars and include products such as insulin, hepatitis B vaccine, human growth hormone, and monoclonal antibodies, among others. These are produced using host systems such as bacteria, yeast, and cell lines. To date, GE plants have not been used as host systems. Biopharmaceuticals including biosimilars are regulated jointly by

- (i) the Drug Controller General of India (DCGI) under Drugs and Cosmetics Act, and
- (ii) the Review Committee of Genetic Manipulation (RCGM), and GEAC under the "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 to as "Rules, 1989."

The RCGM reviews the applications up to the conduct of preclinical studies; GEAC reviews the application from the environmental angle; and the DCGI regulates the conduct of clinical trials and final registration, and it also undertakes post marketing surveillance and 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 India's total cotton acreage, and has led to a surge in Indian cotton production. India's cotton production in 2016 was estimated at 27 million bales (480-lb bales) from 10.9 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 largest producer, and second largest exporter, of cotton. To date, the GOI has approved five cotton events and more than 1400 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). An Indian joint venture company Monsanto MaHyCo Biotech Limited (MMBL), has the licensing rights for the two events in India. MMBL has sub-licensed the two events to about 42 Indian seed companies allowing the right to

use the events in their cotton hybrids through a licensing agreement.

The commercial cultivation of Bt cotton events is approved for use as fiber (clothing), food (oil for human consumption), and feed (meal for animals).

Illegal Cultivation of Unapproved GE Events

In 2017, media sources reported that cotton, soybean and eggplant seeds with unapproved GE events were being clandestinely sold by ‘nefarious’ producers and cultivated by farmers across the country. The Department of Biotechnology (DBT) instituted the Field Inspection and Scientific Evaluation Committee (FISEC) to ascertain the spread of unapproved GE crop events. Although the official report is not available, industry sources suggest that unapproved GE cottonseeds, which includes Monsanto’s insect and herbicide tolerant (HT) technology Bollgard II® Roundup Ready Flex ® (BGII-RRF), may account for up to 15 percent of total cotton acreage during MY 2017/18 across the states of Gujarat, Maharashtra, Telangana, Andhra Pradesh, Odisha, Karnataka, and Madhya Pradesh. Media reports also allege HT GE soybean being cultivated in pockets of Gujarat. Field sources report that Bt eggplant seeds from Bangladesh have found their way into the fields of neighboring states (West Bengal, Orissa, etc.).

While the GOI and several state governments have initiated measures to stop the sale of ‘illegal’ GE seeds, sources report that its sale and use continues unabated in the ongoing season. Cultivation of the unapproved GE seeds reflects farmers’ need for new technologies while the government continues to delay approvals of GE crops in various stages of the regulatory pipeline.

c. Exports

India is world’s second largest exporter of cotton, and it occasionally exports small quantities of cottonseed and cottonseed meal derived from Bt cotton. India exported about 5.2 million bales (480-lb bales) in 2017 (the Indian record for exports is 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 and it is not being used for food or feed purpose. 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 (3.3 million metric tons in CY 2017), mainly from Argentina (2.7 MMT), Brazil (0.5 MMT), and Paraguay (0.2 MMT) and small quantities of canola oil, mainly from Canada. All other imports of GE crops, processed products, and seeds are banned.

e. Food Aid

Historically, India is not a major food aid provider, except for occasional food aid to neighboring countries in case of natural disaster. India is also not a food aid recipient from the United States, nor it

is 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 Industry issued a [notification](#) specifying that all imports containing GE products must have prior approval from GEAC. This directive requires a GE declaration at the time of import. In 2006, MOEFCC 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 prohibits imports. On June 22, 2007, GEAC granted permanent approval for importation of soybean oil derived from glyphosate-tolerant soybeans for consumption after refining. On July 17, 2014, GEAC also approved importation of soybean oil derived from four other GE events. On September 3, 2015, GEAC allowed imports of soybean oil derived from another HT event (Event FG72 from Bayer Bioscience Private Ltd) 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. GEAC has received applications for the approval of imports of DDGS, which is derived from GE corn; soybean meal derived from GE soybean; and GE soybean, which is under the process of review. In January 2017, GEAC set up a sub-committee for drafting guidelines for imports of DDGS. In March 2018, the sub-committee submitted the Draft Guidelines on DDGS imports to GEAC, and GEAC forwarded the 11 applications for import approval of DDGS to the MAFW's Department of Animal Husbandry, Dairy and Fisheries for comments. Subsequently, in July 2018, GEAC formed another sub-committee to establish a procedure for dealing with applications related to imports of animal feed including DDGS and soybean meal. GEAC deferred any decision on imports of animal feed until the new sub-committee submits the proposed procedure and guidelines dealing with applications related to animal feed imports.

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 germplasm or bioengineered organisms and transgenic plant material for research purposes. The National Bureau of Plant Genetics Resources (NBPGR) is the authority for issuing import permits for GE seeds and plant materials. Sources report that the process of getting approval of bioengineered organism and transgenic plant material under the PQO is very cumbersome.

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,' known as the Rules, 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, FSSAI has not yet developed the institutional capacity to fulfill this function.

Currently, the approval of GE processed food and products will be handled by FSSAI, while the approval of GE crops and products (living modified organisms including seeds) for research, development and cultivation, processed non-food products and others will be handled by GEAC. India's current regulatory approval system does not have any defined timeline for various stages of regulatory approval.

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

Authority	Role/Responsibility
MOEFCC	Houses GEAC, the nodal agency responsible for the implementation of Biotech Rules of 1989 under the EPA Act.
DBT	Provides guidelines and technical support to 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 GEAC continues to oversee this responsibility.
Various state governments	Monitor the safety measures at biotech research facilities, and assess potential 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	Support 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, GEAC adopted 'Guidelines and Standard Operating Procedures for the Conduct of Confined Field Trials'. GEAC also adopted new 'Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants'. In 2016, GEAC accepted a new set of guidance on environmental risk assessment (ERA) of GE plants, which include Guidelines for ERA of GE plants, User's Manual and Risk Analysis Framework. The ERA guidelines are a positive step towards a systematic process for environmental risk assessment, wherein the Risk Analysis Framework provides a structured approach for public consultation for the first time in the approval process. The official GEAC website provides all [guidelines and protocols](#), the [EPA Act of 1986, and the 1989 Rules](#).

Supreme Court Case Deadlock

In 2005, a petition was filed in the Supreme Court of India which alleged that field trials of GM crops were being allowed without proper scientific evaluation of biosafety concerns. On May 10, 2012, the Court 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 allowing for open field trials. (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 agricultural 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 developments have occurred on this case.

When Will FSSAI Regulate GE Food?

Subsequent to the enactment of the 'Food Safety and Standard Act of 2006, [MOEFCC issued a notification](#) on August 23, 2007, stating that processed food products derived from GE products (in which 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 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 GEAC continue to regulate processed, GE-derived food products under the Rules 1989. Thus, MOEFCC's notification on processed food products has been deferred through a series of notifications allowing GEAC to regulate imports of processed GE products.

On August 11, 2017, the Supreme Court of India directed FSSAI to frame relevant guidelines and regulations related to approval of GE food and products. Sources report that FSSAI is in the process of framing guidelines related to processed food products derived from GE crops and animals. Consequently, all new applications for import approvals of processed food products will be on hold until new guidelines are published.

Biotechnology Regulatory Authority Bill on Hold

On November 13, 2007, MOST issued a paper titled 'National Biotechnology Strategy'. The paper outlines how to strengthen the regulatory framework and proposed 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. The BRAI bill lapsed due to inaction in May

2014 with the dissolution of the 15th Lok Sabha (lower house of the Parliament). The ruling NDA government has not initiated any steps on the proposed BRAI Bill since then, and is unlikely to do so before the upcoming Parliamentary elections in 2019. The new government will have to decide whether to proceed with the current draft BRAI bill or make revisions. Pending the parliamentary approval of the BRAI bill, whatever form of bill the government in power decides to push forward, India's regulatory mechanisms will continue to be governed by EPA 1986 and the Rules of 1989.

NDA Government's National Biotechnology Development Strategy 2015-20

While the BRAI bill continues to be on hold, the NDA government announced its [National Biotechnology Development Strategy 2015-2020](#) in December 2015. The Strategy aims to establish India as a world-class bio-manufacturing hub. The government intends to launch a major mission with significant investments with the goal of creating new biotech products, creating a strong infrastructure for research and development (R&D) and commercialization, and empowering India's human resources through science and technology. Although the Strategy emphasizes R&D and human resource development and has food and nutrition as one of the four mini-missions, lack of progress on a regulatory approval system will continue to severely constrain growth in agricultural biotechnology.

b. Approvals

Five events have been approved for cultivation in India, all for Bt cotton. Seven events have import approval for use in edible oils (six soybean and one canola).

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
Cry1C (Event MLS 9124)	Metahelix Life Sciences Pvt Limited	Fiber/Seed/Feed

Source: MOEFCC, GOI <http://www.geacindia.gov.in/biosafety-data-approved-GM-crops.aspx>

^[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 pyramided event approvals

A stacked or pyramid event, even if consisting of already approved events, is essentially treated as a new event for approval for environmental release.

d. Field Testing

GEAC is responsible for approving all open field trials on the recommendation of the Review Committee on Genetic Manipulation (RCGM). The applicant has to submit an application in a [prescribed format for the permission to conduct field trial](#) to the RCGM and GEAC at least 60 days in

advance of the proposed trial. Before any GE event can be approved for commercial use, it has to 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 may also conduct agronomic trials in conjunction with biosafety trials, or they may do so separately after GEAC recommends environmental clearance and the GOI gives final authorization.

In April 2009, GEAC adopted an “event based” approval system for Bt cotton. This involved reviewing the efficacy of the event/trait and focusing on biosafety, particularly on environmental and health safety. In April 2017, GEAC authorized ICAR to take full responsibility for evaluation, approval, management and monitoring of Bt cotton hybrids. Henceforth, ICAR shall be responsible for confirming the presence or absence of approved genes/events and the level of protein expression along with the agronomic trials for new Bt cotton hybrids.

Some state governments have refused to allow GE crop field trials without state permission. On July 6, 2011, GEAC amended the procedures for field trial authorization; they now require the applicant (the technology developer) to obtain a no objection certificate, or NOC, which is a type of permit, from the relevant state government. 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; however, in some of these states trials have been restricted to non-food crops (cotton), only. Despite 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.

On July 7, 2017, GEAC issued a notification requiring state governments to announce decisions to approve or deny the validity of field trials within 90 days from the date of submission of the application; beyond 90 days applications not denied are considered approved. The GEAC also removed the NOC requirement for event selection trials as they are small and within the confines of the institution. These steps have helped developers expedite the process of regulatory approval for field trials from the state governments.

e. Innovative biotechnologies

India has not defined the regulatory status of innovative technologies such as genome editing in plants and other organism; the issue is still under discussion. However, all GE organisms are regulated per the Rules 1989. These Rules define gene technology and genetic engineering as follows:

- (i) “Gene Technology” means the application of the gene technique called genetic engineering, to 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 a regulatory system for innovative biotechnologies will be based on the

above definitions in Rules 1989. Preliminary discussion on regulation of new gene technologies have been held in various scientific conferences in the last few years, but Post is not aware of any government move on regulation of new innovative technologies, including genome editing.

f. Coexistence

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

g. Labeling

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](#)).

In May 2018, FSSAI published [draft labeling and display regulations](#), which stipulate mandatory labelling provisions for food products containing GE ingredients. The draft regulation mandates that all food products having a total of 5 percent or more GE ingredients shall be labelled as “Contains GMO/Ingredients derived from GMO”. The regulation, when implemented, may have implications for imported processed food products containing ingredients from GE crops.

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. No instances are known of interception of import consignments containing unapproved GE events. FSSAI and food safety authorities in the state governments can draw samples for testing at various government and private food testing labs; those labs have facilities for identifying events and they have authority to initiate penal action against the importer if unapproved GE events are detected.

No regular monitoring of field crops is done to detect unapproved GE events. However, MAFW does monitor the approved GE crop events (cotton) for three years for agronomic performance and environmental implications. After the reports of cultivation of illegal GE crop events, in August 2018, FISEC submitted a report to GEAC recommending state governments and appropriate ministries to destroy illegal GE crops and take suitable legal action against responsible seed companies and persons.

i. Low level presence (LLP) policy

India has a zero tolerance policy for unapproved GE food and crop events in import shipments. The trade policy states that if an import shipment is found to contain any level of an unapproved GE event at

the time of import, the importer shall be penalized.

j. Additional regulatory requirements

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, MAFW, together with the various state departments of agriculture, monitors field performance for 3-5 years.

k. Intellectual property rights (IPR)

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 150 crop species for registration](#), including Bt cotton hybrids.

l. 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 MOEFCC to facilitate the exchange of scientific, technical, environmental, and legal information on living modified organisms (LMOs). GEAC approves trade of GE products, except food products, which is under the purview of FSSAI. In October 2014, India became the 28th country to ratify the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

m. International treaties/forums:

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

MAFW Regulates Cotton Trait License Fee...

On December 7, 2015, India's MAFW passed an order called the [Cotton Seed Price Control Order \(CSPCO\), 2015](#)s. The order seeks to regulate the maximum sale price of cottonseed, including royalty/trait value. On March 8, 2016, MAFW 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. [On March 12, 2018, MAFW](#) further reduced the Bollgard II cottonseed prices to INR 740 per packet, with trait value at INR 39/packet.

Intentions to Impose Licensing Guidelines for GE Crops Suspended...

On May 18, 2016, the MAFW notified [Licensing and Formats for GM Technology Agreement Guidelines, 2016](#), which created 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. Various stakeholders, including the U.S. Government and other foreign and international organizations, submitted their comments to the MAFW. To date, MAFW has not announced its decision on the implementation of the licensing guidelines. Industry sources contend that while MAFW may have dropped the draft licensing guidelines for the time being, an alternative way of regulating licensing could be created through the current provisions of the Protection of Plant Variety and Farmers Right Act (PPVFRA) 2001.

... Discourage R&D and Investment in Agriculture Biotechnology

Industry experts report that the CSPCO 2015 and the move to regulate licensing agreements impose significant barriers on the ease of doing business, discourage innovation, and discourage long-term commitments to research and development (R&D) and investments in the agriculture biotechnology sector. The provisions of the CSPCO not only hurt existing technology providers but are also a disincentive to potential new innovators. R&D 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 or introduce new technologies to Indian farmers. Such technologies might, in fact, improve farmers’ livelihoods and make them more globally competitive.

PART C: MARKETING

a. Public/Private Opinions

While Indian public opinion about agricultural biotechnology and GE crops is generally ambivalent, political pressure continues to hamper the regulatory environment. Most Indian farmers lack awareness of the technology due to the absence of various approved GE field crops, except for cotton. Major industry associations are generally supportive of agricultural biotechnology and GE crops. The Federation of Seed Industries of India (FSII), comprised of leading seed technology developers, works with other pro-biotech organizations, biotech regulators, the scientific community, farmer groups, and the general public to highlight the benefits related to agricultural biotechnology. In April 2018, major seed and agricultural technology companies (mostly MNCs) operating in India formed a new association, ‘Alliance for Agri-Innovation (AAI)’, to promote new and emerging agricultural technologies, including agricultural biotechnologies and other plant breeding innovations, for the benefit of Indian farmers.

Several anti-biotech environmental and consumer groups, often supported by Greenpeace and other international affiliates, run aggressive and sustained campaigns against GE crops and products in India. Most agricultural researchers and Indian scientists believe that biotechnology is an important tool for addressing India’s future food security, sustainability, and climate change concerns. MOST/DBT,

MAFW's Indian Council of Agricultural Research (ICAR), and bodies like the National Academy of Agriculture Science (NAAS) have supported several outreach activities to educate the public about the benefits of biotechnology and GE crops, but with limited success.

Indian regulators and policy makers generally adopt the precautionary approach towards bio-safety of GE crops and products. Due to the adverse media campaigns, several state governments have adopted policies such as imposing bans on GE crop field trials in their states, which of course discourages agricultural biotech R&D. MAFW and MOST have generally been supportive of agricultural biotechnology and GE crop R&D. Under the Supreme Court of India's directive, FSSAI has been forced to work on the regulations for approval of GE food and food products, but would need significant capacity building assistance from various stakeholders.

b. Market Acceptance/Studies

Bt cotton (cultivation) and imported vegetable oil (consumption) derived from select GE soybean and canola events are the only commercially approved products in India. There are no market restrictions for domestically produced Bt cotton (fiber use), cottonseed oil (food), cottonseed meal (animal feed), or imported soybean and canola oils (food).

Most Indian farmers are largely unaware of the potential benefits from other GE crops, except for about 8 million cotton farmers who produce Bt cotton. Reports of illegal cultivation of GE crops with unapproved events clearly suggest that farmers are willing to cultivate other GE crop events, including most of the events that are currently stagnating in the Indian regulatory approval system.

There are virtually no concerns about food and clothing products derived from GE cotton, cottonseed/soybean/canola oils, and cottonseed meal among the manufacturers, processors, importers, retailers and consumers of these products. Recently, local animal feed manufacturers have expressed interest for sourcing DDGS from GE corn, and soybean meal from GE soybean. More than 10 feed manufacturers have applied to GEAC for permission to import DDGS; a handful of importers have applied to import GE soybean meal.

There have been several studies on the benefits of Bt cotton to the cotton economy of India, which are strongly contested by the anti-biotechnology groups. Post is not aware of any significant studies by reputable organizations focused on the production and marketing of other GE crops and products in India.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. Product Development

Indian research and development 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 successfully

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 and a bull calf were born. 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. In December 2015, a scientist of NDRI claimed to have successfully produced a female clone of the endangered wild buffalo of Chhattisgarh. 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 cloning research is still at an experimental stage as they address constraints of low birth rate and premature death of newborns. Sources report that the government has launched an ambitious cloning program to multiply high value bulls of traditional breeds of buffaloes and cattle to expand the national breeding program. Experts report that it may take another 7-10 years before the ongoing cloning techniques are 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. The bovine genomics program focuses on characterizing and identifying genes for heat and cold tolerance, disease resistance, and economic factors like period between calvings, length of lactation, and milk yield. The research is typically done on the traditional Indian breeds. 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. The government has also encouraged researchers to undertake a genomics program for traditional Indian animal breeds, including cattle and buffaloes.

Most animal biotechnology research is conducted by public sector research organizations such as ICAR institutions, Council of Scientific and Industrial Research (CSIR) institutions, state agricultural universities, and other research organizations supported by the DBT. Sources report that a local research institute has successfully conducted lab trials on GE silkworm resistant to BmNPV (*Bombyx mori nucleopolyhedrovirus*). Of note: a local company reportedly has licensed research from a United Kingdom company pertaining to mosquito-borne illnesses. The research has succeeded in producing genetically engineered male mosquitos which contain a gene that causes their own progeny to die. Such

techniques could help control mosquito populations in areas affected by mosquito borne diseases like dengue fever, zika, and the chikungunya virus. The Indian company is currently conducting lab and contained facility 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

India does not allow imports of any GE animals, livestock clones, or offspring of clones or products derived from such animals, except products derived from GE animals for pharmaceutical use.

e. Trade barriers

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

PART E: POLICY

a. Regulatory Framework

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 a preliminary stage and there are no transgenic animals available 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 are there any major policy discussions on the issue.

d. Intellectual property rights (IPR)

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

e. International treaties/forums

While India actively participates in OIE discussions, 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

Nothing significant to report.

PART F: MARKETING

a. Public/Private Opinions

The general population is largely unaware about GE animals and products, and about the ongoing programs on animal cloning. Some of the anti-biotech activists have started including GE animals in their protest activities, but have excluded cloned animals for various reasons.

b. Market Acceptance/Studies

Market acceptance is not an issue in India as there are no GE animal or products in the market, nor are there any marketing studies on GE animal/products. The animal cloning program is still at the experimental stage.

ANNEXURES

Annex 1: Existing Biotech Regulatory Authorities – Function/Composition

<i>Committee</i>	<i>Members</i>	<i>Functions</i>
Genetic Engineering Appraisal Committee (GEAC); functions under Ministry of Environment, Forests and Climate Change (MOEFCC).	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.	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

	Member Secretary: An official from the MOEFCC	processed product derived thereof. Take punitive actions on those found violating GE rules under EPA, 1986.
Review Committee on Genetic Manipulation (RCGM); function under DBT, Ministry of Science and Technology (MOST).	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.	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.
Recombinant DNA Advisory Committee (RDAC); function under DBT	Scientists from DBT and other public sector research institutions	Take note of developments in biotechnology at the national and international level. Prepare suitable guidelines for safety in research and applications of biotechnology. Prepare other guidelines as 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 MOEFCC, 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	IBSC/ RCGM/ GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	GEAC Form II B

(including field trials)				
GM LMOs per se for food/feed/processing	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 ¹	FSSAI (Previously GEAC)	FSSAI working on the rules. Previous GEAC Rule: 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 ¹	FSSAI (Previously GEAC)	FSSAI working on the rules. Previous GEAC Rule: 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

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

Note ¹- Since the Supreme Court of India directive of August 11, 2017, regulations of these products under the purview of FSSAI. The FSSAI is still in the process of formulating the guidelines and regulations.

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	Rules 1989 and competent authorities in place.

	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	
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	Rules 1989 ^[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	Rules 1989
Article 18	Handling, transport, packaging and identification	Rules 1989, 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://geacindia.gov.in/india-bch.aspx) 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, DBT and ICAR have specific websites on biotech developments and regulatory system including website of GEAC ^[3] , DBT Biosafety ^[4] , ICAR Biosafety ^[5] , etc.
Article 24	Non-Parties (trans-boundary movements of LMOs between Parties and non-Parties)	1989 rules in place for all import and export
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	Ratified the Nagoya Kuala Lumpur Protocol on Liability and Redress in December 2014

Source: MOEFCC and Industry Sources.

^[1] See Annex 2

^[2] https://dgft.gov.in/sites/default/files/not2_0.pdf

^[3] <http://geacindia.gov.in/index.aspx>

^[4] <http://www.dbtindia.nic.in/biosafety/>

^[5] <https://biosafety.icar.gov.in/>
