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Report Highlights:

India is undecided on genetically engineered (GE) crops despite regulatory authorities having cleared on the environmental release of GE eggplant and mustard events. BT cotton is the only biotech crop approved for commercial cultivation. Soy and canola oils derived from select GE soy and canola events, and some food ingredients from microbial biotechnology are products approved for import. On August 21, 2020, the Food Safety and Standard Authority of India (FSSAI) issued an order, effective January 1, 2021, stipulating that every food products consignment from a list of 24 food crops will require an accompanying "Non-GM origin cum GM-free" certificate issued by the competent authority in country of export. The order may disrupt the trade of U.S. agricultural products which may not be of GE origin (e.g., apples and select pulses). Indian animal biotech research and development is at a nascent stage, except for some animal cloning work. A new section on microbial biotechnology is included in this report.

EXECUTIVE SUMMARY

The Environment Protection Act (EPA) of 1986 provides the foundation for India's biotechnology (biotech) regulatory framework (see Annex I) for genetically engineered (GE) plants, animals, and their products and by-products. The Food Safety and Standards Act (FSSA) of 2006 includes specific provisions for regulating GE food products, including processed foods. The Food Safety and Standard Authority of India (FSSAI) previously deferred the approval of GE food products to the Genetic Engineering Approval Committee (GEAC) in the absence of regulations and operational infrastructure. In August 2017, the Supreme Court of India issued directives for the FSSAI to regulate approval of GE food products. Notwithstanding the court's ruling, the FSSAI is still in the process of framing regulations and guidelines for the approval of GE food products.

On August 21, 2020, the FSSAI issued an order, effective January 1, 2021, stipulating that every food products consignment from a list of 24 food crops require an accompanying "Non-GM origin cum GM-free" certificate issued by the competent authority in country of export. The August 2020, FSSAI order stands to severely disrupt the trade of several U.S.-origin agricultural products which may not be of GE origin (e.g., apples and select pulses). On December 3, 2020, the FSSAI extended the compliance date now to March 1, 2021.

BT cotton is the only GE crop approved for commercial cultivation in India. Vegetable oils derived from GE soybeans and canola are the only products approved for import. In prior years, the GEAC received applications for the import of distiller's dried grains with solubles (DDGS) derived from GE corn and for soybeans, as well as for soybean meal derived from GE soybeans and other processed food products with GE content. Following the Supreme Court of India's August 2017 order, the GEAC began forwarding applications for the approval of GE food and agricultural products to the FSSAI; since then GE food products approvals have languished.

The U.S.-India bilateral trade in food, agricultural and related products reached $7.5 billion in calendar year (CY) 2019, with the balance of trade skewed 2.4 to 1 in India's favor. U.S. exports of products derived from GE crops are mostly cotton ($587 million), and a small quantity of soybean oil ($0.2 million). BT cotton, accounts for over 95 percent of India's cotton production, estimated at 29.5 million bales (480-lb bales) in marketing year (MY) 2019/20 (August-July), of which 3.3 million bales were exported. India does not commercially produce animals or animal products derived from agriculture biotechnology, including cloned animals. Indian food processors use food ingredients derived from microbial biotechnology, mostly processing aids like enzymes and food additives such as vitamin supplements.

The National Democratic Alliance (NDA) government remains indecisive on GE product approvals; the regulatory system has effectively halted. In May 2017, the GEAC cleared the environmental release of locally developed GE mustard, but the government opted to defer the approval of GE mustard due to opposition from anti-biotech groups, including right-wing organizations. In 2017, the Ministry of Agriculture and Farmers' Welfare (MAFW) launched its own market restrictive actions against biotech seed companies, including price controls on BT cottonseeds and a proposal for licensing regulations for biotech seeds. The existing policy environment creates significant uncertainty and discourages investment in agricultural biotechnology research and development (R&D).

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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 (more than 85 plant species), for pest resistance, herbicide tolerance, abiotic stress tolerance, 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. Private seed companies are focusing on crops like cabbage, cauliflower, chickpeas, corn, cotton, mustard/rapeseed, okra, pigeon peas, rice, and tomatoes. Policy uncertainty and delays in the regulatory approval system severely constrained the advancement of research on GE crops to the product development stage, both in the private and public sectors. Sources inform that companies involved in developing GE crops are suspending research and development efforts and/or are exploring commercialization in other countries (e.g., BT eggplant in Bangladesh and Philippines).

On October 14, 2009, the Genetic Engineering Approval Committee (GEAC) recommended the approval of commercial cultivation of BT eggplant event (Monsanto event) developed by a local seed company, which was forwarded to the Ministry of Environment, Forests and Climate Change (MOEFCC) for a final decision (note, the GEAC changed its name to Genetic Engineering Appraisal Committee in 2010). On February 9, 2010, the MOEFCC (under the previous United Progressive Alliance government) announced a moratorium on the approval until the regulatory system could ensure human and environmental safety through long-term studies. More than 10 years later, the GEAC has yet to initiate the approval process for the BT eggplant event. Notwithstanding this delay, the GEAC has authorized confined field trials of a BT eggplant event developed by a local public sector research institution.

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 Delhi University (a public sector entity), has torturously progressed through the regulatory approval system. On May 11, 2017, the GEAC recommended to the MOEFCC approval to allow the environmental release of GE mustard. Various anti-biotechnology (biotech) stakeholders, including right wing anti-biotech groups, have challenged the GEAC's decision.

The Ministry of Environment, Forests and Climate Change, confronting strong opposition, backtracked and issued a note indicating that the environmental release of transgenic mustard is on hold pending further review. The ministry subsequently returned to the GEAC the proposal for reconsideration. In March 2018, the GEAC reiterated having fully addressed stakeholders' concerns when approving the event for environmental release. Nonetheless, the GEAC did advise the developer the following July to conduct additional field demonstration studies on the impact of GE mustard on honeybees and other pollinators; these studies have concluded. However, there has been no additional progress towards approval to date.

Should the Indian government opt to move in the near-term to commence anew approving GE crops, by means of a science-based regulatory assessment, then besides BT eggplant and GE mustard there are three other crop events ready. One of the latter is a stacked GE cotton event at the advance approval stage (i.e., 2-3 years). Sources report, however, that most of the event developers have now withdrawn or are keeping on hold further efforts to pursue approvals due to the ongoing policy stalemate.

Shifting Focus to Use of Innovative Biotechnologies: Due to political opposition and the slow pace of the biotechnology regulatory approval system, public sector researchers are shifting towards genomics and marker-assisted breeding in their agriculture biotech programs. Organizations are starting preliminary research on application of new biotech techniques such as genome editing in agriculture. To incentivize innovation and promote development of genome-wide analysis and engineering technologies, the Ministry of Science and Technology's (MOST) Department of Biotechnology (DBT) has been supporting various programs and initiatives. The Indian Council of Agricultural Research and affiliates, state agricultural universities (SAUs), and other public sector institutions are researching the use of gene editing in agriculture.

Use of Biotechnology in Other Sectors: Biopharmaceuticals for human and animal use and GE microorganisms and derived products utilize biotechnology extensively. Most of these manufactures are in the category of biosimilar and include products such as insulin, hepatitis B vaccine, human growth hormone, and monoclonal antibodies, enzymes and additives used in the food industry. Bacterium, yeasts, and cell lines serve as host systems in the production of the foregoing. GE plants do not serve as host systems in the production of biopharmaceuticals.

Biopharmaceuticals including biosimilar fall under the regulatory oversite of:

(i) The Drug Controller General of India under the Drugs and Cosmetics Act and;
(ii) The Review Committee of Genetic Manipulation (RCGM), and the 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 Review Committee of Genetic Manipulation reviews the applications up the preclinical studies stage. While the GEAC reviews applications from the environmental angle. The Drug Controller General of India (DCGI) regulates the conduct of clinical trials, final registration and conducts post marketing surveillance and monitoring.

b. Commercial Production

In 2002, India approved BT cotton for commercial cultivation; it remains the only GE crop approved for production. Over the past 18 years, the BT cotton area has expanded to cover 95 percent of India's total cotton acreage; allowing India to become the world's largest producer and a leading exporter. Cotton production in MY 2013/14 (August-July) reached a record 31 million bales (480-lb bales) produced from 11.9 million hectares, compared to 10.6 million bales from 7.7 million hectares in MY 2002/03. Cotton production in MY 2019/20 is estimated at 29.5 million bales produced from 13.3 million hectares.

To date, the Indian government approved five cotton events and more than 1,400 hybrids for cultivation in various agro-climatic zones. Most of the approved BT cotton hybrids come from the 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 Monsanto events in India. Monsanto MaHyCo Biotech Limited has sub-licensed the two events to more than 40 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 Continues Unabated: In 2017, following reports of unapproved GE cotton, soybean, and eggplant events plantings, the Department of Biotechnology (DBT) instituted the Field Inspection and Scientific Evaluation Committee (FISEC); confirming the spread of unapproved GE crop events. Industry sources inform that herbicide tolerant BT (HTBT) GE cottonseed may account for 15 percent of total cotton acreage in the MY 2019/20 season in the states of Gujarat, Maharashtra, Telangana, Andhra Pradesh, Odisha, Karnataka, and Madhya Pradesh. Reports also allege that HT GE soybean is now cultivated in Gujarat. Sources also indicate that BT eggplant seeds from Bangladesh have found their way into the fields of West Bengal and Orissa and are slowly spreading to other states.

In 2019, a Maharashtra state farmer group launched the "GM Satyagraha" movement, openly planting unapproved GE (HTBT) cottonseed. The farmer group justifies its action as a protest against governmental indecisiveness in approving a new, beneficial technology needed by farmers. While the Indian government and several state governments initiated measures to stop the sale of illegal GE seeds, sources confirm that the sale and use continues unabated. The Maharashtra state farmer group again planted unapproved HTBT cottonseed (in the presence of the media) during the MY 2020/21 season. Cultivation of the unapproved GE seeds reflects farmers' frustration with the government's GE approval process, and shows demand for the technology.

c. Exports

India is the third largest exporter of cotton in the world; trailing just behind the United States and Brazil. It also exports small quantities of cottonseed and cottonseed meal derived from BT cotton. India exported a record 11.1 million bales (480-lb bale) in MY 2011/12, which has since dropped to 3.3 million bales in MY 2019/20. Sources inform that export documentation for cotton, as a fiber product (i.e., cellulose) does not require a GE declaration. India does not export significant quantities of cotton, cottonseed or cottonseed meal to the United States.

d. Imports

The only GE food products 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. It imported 3.2 million metric tons (MMT) in CY 2019, down slightly from the CY 2016 record volume of 3.9 MMT, mainly from Argentina (2.4 MMT) and Brazil (0.32 MMT) along with a small quantity of canola oil (30 metric tons).

India imports large quantities of cotton, including Bt cotton, to augment the quality requirement of the local textile industry (2.3 million bales in 2019/20). Cotton does not face a GE declaration requirement as a cellulosic fiber product devoid of protein.

Imports of other GE crops for seed, human food use, and animal feed as well as processed products derived from GE plant crops are not permissible.

e. Food Aid

India is not a major food aid provider, except for occasional food aid shipments to neighboring countries in case of natural disaster, mostly wheat and rice (non-GE). India is not a food aid recipient of the United States, nor is it likely to be one 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 canola (select events). In April 2006, the Ministry of Commerce and Industry issued a notification specifying that the GEAC must approve all imports containing GE products. This directive requires a GE declaration by the importer at the time of import.

In August 2017, the Supreme Court of India directed the FSSAI to issue guidelines and regulations for the approval of GE food and products. Although the GEAC transferred to the FSSAI the applications for approval of GE foods and products, the latter has yet to establish guidelines for food and processed food products derived from GE crops and animals. Currently only the import of GE soybean and canola oils are permissible.

On August 21, 2020, the FSSAI issued an order, effective January 1, 2021, stipulating that every food products consignment from a list of 24 food crops require an accompanying "Non-GM origin cum GM-free" certificate issued by the competent authority in country of export. The August 2020, FSSAI order will significantly disrupt the trade of several U.S.-origin agricultural products which may not be of GE origin (e.g., apples and select pulses). On December 3, 2020, the FSSAI extended the compliance date now to March 1, 2021 (see GAIN-INDIA (IN2020-0180) India Extends Compliance Timeline for Genetically Modified-Free Certificate for Imported Food Products).[1]

It appears that the Indian government seeks to shift to the competent authority of the exporting country the onus of ensuring exports of only approved GE products. This measure has no food or biosafety basis. The United States and other likeminded trading partners are concerned that the FSSAI's non-science based certification requirement will create a trade restrictive, undue burden on exporting countries. The order will disrupt the trade in agricultural products such as apples and select pulses, as well as of other products, which may not be of GE origin.

[1] See, https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=India Extends Compliance Timeline for Genetically Modified-Free Certificate for Imported Food Products_New Delhi_India_12-01-2020

Since 2015, the GEAC has received several applications for the approval of imports of distiller's dried grains with solubles (DDGS) derived from GE corn; soybean meal derived from GE soybean; and GE soybean (for animal feed). In July 2018, the GEAC formed a sub-committee to establish a procedure for dealing with applications for imports of animal feed, including DDGS and soybean meal. In November 2019, the sub-committee submitted to the GEAC its draft recommendation for comments and approval; there has been no further action to date.

The 2003 "Plant Quarantine Order (PQO) Regulation of Import into India" regulates the import of GE seeds and planting material for research purposes. Sources report that the process of getting approval for the import of bioengineered organisms and transgenic plant material under the PQO is cumbersome.

PART B: POLICY

a. Regulatory Framework

India's regulatory framework for GE crops, animals, and products is regulated by the Environment Protection Act 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." The rules govern research, development, use, and import of GE organisms and products. The rules identify six competent authorities (see Annex I).

On August 24, 2006, the Indian government enacted an integrated food law, namely the Food Safety and Standards Act (FSSA) of 2006, which has specific provisions for regulating GE food products, including processed foods. Under the Act, the FSSAI is the authority responsible for regulating food, including GE foods. However, the FSSAI has not yet developed the institutional capacity and regulatory framework to fulfill this function.

The approval of GE crops and products (living modified organisms including seeds) for research, development and cultivation from the biosafety aspect, and processed non-food products is handled by the Genetic Engineering Appraisal Committee. The Food Safety and Standard Authority of India handles the approval of GE food including processed food and products from food safety aspect.

There is some ambiguity as to the responsibility for the approval of animal feed derived from GE crops and animals between the GEAC and FSSAI authorities, as well as other concerned ministries such as the Ministry of Fisheries, Dairying and Animal Husbandry and the Ministry of Agriculture and Farmers' Welfare. India's current regulatory approval system lacks a defined timeline for stages of regulatory approval.

The Genetic Engineering Appraisal Committee's website provides the EPA Act of 1986 and the 1989 Rules and all guidelines and protocols (including recombinant DNA guidelines, guidelines for biotech plant research, import and shipment guidelines for GE plants for research use, guidelines for environmental risk assessment of GE plants).

The Ministry of Environment, Forests and Climate Change published the document "Procedure for Import and Export of GM Plant and Planting Material" to assist traders and researchers. The 2003 "Plant Quarantine Order (PQO) Regulation of Import into India," that entered into force in January 2004, regulates the import of GE seeds and planting material. The Plant Quarantine Order regulates the import of germplasm, bioengineered organisms, and transgenic plant material for research purposes. The National Bureau of Plant Genetics Resources (NBPGR) is responsible for issuing import permits for GE seeds and plant materials.

TABLE 1: India, Role of Various Ministries\State Governments

Authority	Roles and Responsibility
Ministry of Environment, Forests and Climate Change (MOEFCC)	Houses the GEAC, the nodal agency responsible for the implementation of biotech Rules of 1989 under the EPA Act.
Department of Biotechnology (DBT)	Provides guidelines and technical support to the Genetic Engineering Appraisal Committee. Evaluates and approves biosafety assessment of GE product research and development in the country.
Ministry of Agriculture and Farmer Welfare (MAFW)	Evaluates and approves the commercial release of transgenic crop varieties after conducting field trials for assessing agronomic performance. Is responsible for post approval monitoring.
Food Safety and Standard Authority of India (FSSAI)	Evaluates and approves the safety assessment of GE crops and products for human consumption. It has not yet established regulations and the GEAC continues to oversee this responsibility. It has yet to establish regulations and begin the process.
Indian States Governments	Monitor the safety measures at biotech research facilities, and assess potential damage, if any, due to the release of GE products. Approves field trials and commercial cultivation of the GEAC approved GE crops in their respective states.
DBT, MAFW, and Indian States Governments	Support research and development of agriculture biotechnology through research institutions and state agricultural universities.

Source: FAS New Delhi office research.

The Genetic Engineering Appraisal Committee Slows: Following the National Democratic Alliance (NDA) taking power in 2014, the Indian biotech regulatory system under the GEAC has lagged, and slowed considerably following the 2017 deferral decision on GE mustard.

Continued Dithering on Regulating GE Food: Following the enactment of the "Food Safety and Standard Act of 2006," the MOEFCC issued a notification on August 23, 2007. The notification states that processed food manufactures derived from GE products (in which the product is not a living modified organism) do not require approval from the GEAC for their production, marketing, import and use in India. Since the FSSAI at that juncture lacked the technical capacity and regulations in place for approving GE food products, the Ministry of Health and Family Welfare (MHFW) designated the GEAC in the interim to regulate processed GE-derived food products under the Rules 1989.

On August 11, 2017, the Supreme Court of India issued directives that the FSSAI regulate approval of GE food products. Notwithstanding the court's ruling, the FSSAI is still in the process of framing regulations and guidelines for the approval of GE food products. All

applications for import approvals of processed food products are on hold until the FSSAI formulates the new guidelines and implements the regulations.

On August 21, 2020, the FSSAI issued an order, effective January 1, 2021, stipulating that every food products consignment from a list of 24 food crops require an accompanying "Non-GM origin cum GM-free" certificate issued by the competent authority in country of export. Subsequently on December 3, 2020, the FSSAI extended the compliance date to March 1, 2021.

b. Approvals

There are five events approved for cultivation in India, all of which are Bt cotton. The Genetic Engineering Appraisal Committee has granted import approval for vegetable oils derived from six GE soybean events and one GE canola event.

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: GEAC, MOEFCC, Government of India, FAS New Delhi office research.
[1] Gene sourced from Monsanto.
[2] Stacked gene event sourced from Monsanto.
[3] Gene sourced from Indian Institute of Technology., Kharagpur.
[4] Gene sourced from China featuring fused genes.

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 approved the import of soybean oil derived from four other GE events. On September 3, 2015, the GEAC allowed imports of soybean oil derived from another HT event (Event FG72 from Bayer Bioscience Pvt. Limited) and canola oil derived from HT canola (Event Ms8xRF3 by Bayer Bioscience Pvt. Limited).

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

The Genetic Engineering Appraisal Committee (GEAC) is responsible for approving all open field trials on the recommendation of the Review Committee on Genetic Manipulation (RCGM). A GE event prior to commercial use approval undergoes extensive agronomic evaluation in field trials supervised by the Indian Council of Agricultural Research (ICAR) or a

state agricultural university for at least two crop seasons. Product developers can conduct agronomic trials in conjunction with biosafety trials.

In April 2009, the GEAC adopted an "event based" approval system for Bt cotton. In April 2017, the GEAC authorized the ICAR to take full responsibility for evaluation, approval, management, and monitoring of Bt cotton hybrids. Going forward the ICAR is 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.

On July 6, 2011, the GEAC had amended the procedures for field trial authorization; requiring the applicant (i.e., the technology developer) to obtain a no objection certificate, or NOC (a type of permit) from the state government. Sources inform 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. 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.

On July 7, 2017, the 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. After 90-days, those applications not denied are considered as approved. The Genetic Engineering Appraisal Committee may waive the NOC requirement for small-scale, institutionally confined event trials.

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. The Rules 1989 regulates all GE organisms. 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;

Over the past few years, various scientific organizations and the Ministry of Science and Technology's Department of Biotechnology have been organizing discussions on regulation of new gene technologies. In February 2020, the DBT posted the draft document on "Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment, 2019" for public comments[2].

[2] See, Government of India, Ministry of Science and Technology – Department of Biotechnology, http://dbtindia.gov.in/latest-announcement/dbt-invites-comments-%E2%80%9Cdraft-document-genome-edited-organisms-regulatory.

On March 12, 2020, the DBT organized a stakeholder consultation and formed a committee to review the draft guidelines based on the comments received from 90 individuals/organizations. On July 28, 2020, the DBT committee presented the "Draft Guidelines for Safety Assessment of Genome Edited Plants" to the GEAC suggesting that that SDN1 and SDN2 categories of genome editing technologies do not involve or carry exogenous DNA and are comparable naturally occurring variance. These technologies for genome editing should be exempted from EPA 1986 under the under Rule 20 of the Rules 1989 to grant such exemption. The Genetic Engineering Appraisal Committee will deliberate on the draft guidelines further; other factors will likely influence the final guidelines and timeline for approval.

f. Coexistence

The Indian government has no specific regulations on the coexistence of GE and non-GE crops. On January 10, 2007, the 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 and Traceability

On June 5, 2012, the Ministry of Consumer Affairs, Food and Public Distribution's Department of Consumer Affairs (DCA) 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 Department of Consumer Affairs states that the "GM" labeling requirement is for consumers' right to know, but sources report that there has been no enforcement of the labeling requirement by the department. As the FSSAI is still in the process of establishing labeling regulations for GE foods, the future status of the DCA's GE labeling regulation remains uncertain (see GAIN-INDIA (IN2078) – 6/14/2012 – 2012's First Amendment to Legal Metrology Rules).

On April 13, 2018, the FSSAI published draft labeling and display regulations, which stipulate mandatory labeling provisions for food products containing GE ingredients (see GAIN-INDIA (IN8043) – 4/17/2018 – Draft Labeling and Display Regulations Invite WTO Member Comments). The draft regulation mandates that all food products having a total of five percent or more GE ingredients require labeling stating "Contains GMO/Ingredients derived from GMO." Subsequently, on June 27, 2019, the FSSAI published the revised draft labeling and display regulations, wherein they dropped the labeling provisions (see GAIN-INDIA (IN9060) - 7/3/2019 - GOI Publishes New Draft Labeling and Display Regulations). Industry sources report that the FSSAI is working on a separate set of draft regulations that would include provisions for labeling of GE food and/or food derived from GE products.

FAS New Delhi is not aware of any regulation on traceability of GE plant and plant products, including processed products derived from GE products.

h. Monitoring and Testing

The Food Safety and Standard Authority of India and the food safety authorities in the state governments have the authority to draw samples at any stage of production, imports, marketing, and use for testing at various government and private food referral labs that have facilities for identifying events. 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. Sources report that since 2019, FSSAI officials have been collecting samples of food products, mostly grains for consumption, at select ports-of-entry and testing samples at specific referral labs. FAS New Delhi is not aware of any reports of interception of import consignments containing unapproved GE events. In case the imported products contain unapproved GE events, the importer is subject to legal action.

There is no regular monitoring of field crops to detect unapproved GE events, except in case of reports of planting of unapproved GE events. However, the Ministry of Agriculture and Farmers' Welfare monitors approved GE crop events (cotton) for three years for agronomic performance and environmental implications. Since reports of the cultivation of illegal GE crop events in MY 2017/18, various state governments have been testing and destroying illegal GE crops, followed by legal action against the responsible seed companies and individuals.

i. Low Level Presence (LLP) Policy

India has a zero-tolerance policy for unapproved GE food and crop events in import shipments. The policy states that if an import shipment contains any level of an unapproved GE event at the time of import, the importer is subject to legal action.

j. Additional Regulatory Requirements

Following an event's approval 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 new GE crop, the MAFW, together with the various state departments of agriculture, monitors field performance for 3-5 years.

k. Intellectual Property Rights (IPR)

India is a signatory to the Trade Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) and changed its patents legislation in 2005 moving from a process patent regime to a product patent one. 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, established in 2005, to date has notified 161 crop species for registration, including BT cotton hybrids.

l. Cartagena Protocol Ratification

On January 17, 2003, India ratified the Cartagena Protocol on Biosafety, and since then has established rules for implementing the provisions of the articles (see Annex III). 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). The Genetic Engineering Appraisal Committee approves trade of GE products, except food products, which is under the purview of the Food Safety and Standard Authority of India. 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 supports mandatory labeling of GM foods, requiring a compulsory declaration whenever food and food ingredients contain genetically modified organisms.

n. Related Issues

Ministry of Agriculture and Farmers' Welfare Regulates Cotton Trait License Fee: On December 7, 2015, the MAFW passed the Cottonseed Price Control Order (CSPCO)-2015 regulating the maximum sale price of cottonseed, including royalty/trait value. On March 8, 2016, the MAFW issued a Notification capping Bollgard I cottonseed prices in crop year 2016/17 (July-June). Prices were set at Indian rupee (INR) 635 ($9.43) per packet (450 grams BT seeds plus 120 grams *refugia* non-BT seeds) with trait value zero and Bollgard II cottonseed prices at INR 800 ($11.88) per packet with trait value at INR 49 ($0.73) per packet (FOREX INR 67.33 to $1.00). On March 12, 2018, the MAFW reduced Bollgard II cottonseed prices to INR 740 ($11.39) per packet, with trait value at INR 39 ($0.60) per packet (FOREX INR 64.99 to $1.00).

Industry sources indicate that the delayed biotech regulatory approval system coupled with the CSPCO-2015 have imposed significant barriers for business - discouraging innovation, research and development, and investments - in the agriculture biotechnology sector. The provisions of the CSPCO-2015 not only hurt existing technology providers, they are also a strong disincentive to potential new innovators to introduce new technologies to Indian farmers critical for improving their livelihoods and making them globally competitive.

PART C: MARKETING

a. Public/Private Opinions

While public opinion about biotechnology and GE crops is generally ambivalent, political pressure continues to hamper the regulatory environment. Several anti-biotech environmental, farmer and consumer groups, often supported by Greenpeace and other international affiliates, run aggressive and sustained campaigns against GE crops and products in India.

Most Indian farmers, except cotton growers and a few farmers planting illegal GE crops, lack awareness of the technology due to the absence of other GE field crops (some mired in the regulatory pipeline). 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 (both local and multinational corporations), works with other

pro-biotech organizations, biotech regulators, the scientific community, farmer groups, and the public to highlight the benefits from agricultural biotechnology. Major seed and agricultural technology companies (mostly multinational corporations) operating in India have formed the Alliance for Agri-Innovation (AAI), to promote new and emerging agricultural technologies, including agricultural biotechnologies and other plant breeding innovations for Indian farmers. Many agriculture biotechnology companies, local and multinational, are curtailing their biotech crop development programs due to the ongoing policy uncertainty in regulatory approvals and the CSPCO-2015 regulation. Sources report that public sector research institutions are shifting from GE crop research to genomics and its application in marker assisted crop breeding programs for identified traits. Researchers are exploring the use of genome editing tools, but have concerns with regulations following a similar regulatory path as those for GE events.

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. The Ministry of Science and Technology/Department of Biotechnology, the MAFW's Indian Council of Agricultural Research, 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 success is limited.

Indian regulators and policy makers adopt the precautionary approach towards biosafety of GE crops and products. Due to the adverse media campaigns, several state governments have adopted restrictive policies (bans on GE crop field trials), discouraging biotech research and development. The Ministry of Agriculture and Farmers' Welfare and the MOST have generally been supportive of agricultural biotechnology and GE crop research and development.

Industry sources report that the FSSAI has is formulating regulations for approval of GE food and food products, but needs significant capacity building assistance from various stakeholders to implement a science based efficient regulatory system for processed food products in place and may take few years for effective implementation. Until then, there is a major policy vacuum in approval of GE food and food products for consumption and use by food processing industry.

b. Market Acceptance/Studies

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 benefits of GE crops, except for the eight million farmers benefitting from 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 the events that are currently stagnating in the Indian regulatory approval system.

There are virtually no concerns about food and clothing products derived from BT 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 the 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 for the Indian economy. Anti-biotech groups in the media, lacking valid studies of their own, contest the results. FAS New Delhi is unaware of any studies by reputable organizations that focuses on opportunity cost of non-approval of other GE crops and products to farmers, consumers, and the economy of India.

PART D: PRODUCTION AND TRADE

a. Product Development

India's animal biotechnology research and development is in its infancy, except for some successes in animal cloning. On February 6, 2009, scientists of the National Dairy Research Institute (NDRI) successfully delivered the first cloned buffalo (heifer) calf through the advanced 'hand guided cloning technique,' but the calf died shortly after birth. The institute has now produced several cloned heifer and bull calves, including a cloned calf delivered from a cloned buffalo heifer. 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 the NDRI report that the ongoing buffalo cloning research is still at experimental stage as they address severe constraints of low birth rate and premature death of newborns. Sources report that the Indian government tasked the NDRI with 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 cloning techniques are ready for commercial use.

Animal biotechnology research in India focuses 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 calving, length of lactation, and milk yield. Ongoing research focuses on traditional Indian cattle and buffalo breeds to be used in future breeding programs for incorporating the target genes. Public sector research organizations such as the ICAR institutions, Council of Scientific and Industrial Research (CSIR) institutions, state agricultural universities, and research organizations backed by the Department of Biotechnology conduct most animal biotechnology research.

Other Animals: Sources also 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, the Zika virus, and the chikungunya virus. After successfully conducting lab and contained facility trials, sources report that the company has suspended the research for now due to the ongoing policy uncertainty.

b. Commercial Production

India does not produce GE animals or products derived from GE animals or cloned 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 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 to GE plants and products are also applicable for GE animal and products.

PART E: POLICY

a. Regulatory Framework

The Environment Protection Act of 1986 governs the research, development, commercial use and imports of GE animals, and non-food animal products, and the FSAA 2006 will govern food and ingredients from GE animals. Currently, most of the animal biotech research is at a preliminary stage and there are no transgenic animals, except GE mosquitoes, available even for research. Research on cloning and genomic research on animals does not come under the purview of Environment Protection Act of 1986. With animal cloning still at research stage, there are no current regulations on commercial production or marketing of cloned animals.

b. Approvals

None.

c. Innovative Biotechnologies

There is no defined regulatory status for innovative technologies such as genome editing in animals, nor has the DBT drafted guidelines as there is no ongoing animal biotech research in genome edited animals.

d. Labeling and Traceability

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

e. Intellectual Property Rights (IPR)

India is a signatory to the TRIPS Agreement of the WTO and changed its patents legislation in 2005 moving from a process patent regime to a product patent one. There are no specific regulations on IPR for animal biotechnology or GE animals.

f. International Treaties/Fora

While India actively participates in the World Organization for Animal Health (OIE) discussions, FAS New Delhi is not aware if India has taken any position on animal biotechnologies, which includes GE animals, genome editing and cloning, in international fora.

g. Related Issues

Nothing significant to report.

PART F: MARKETING

a. Public/Private Opinions

The general population is largely unaware about GE animals and products, or 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 and may take another 7-10 years before they have commercial production.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a. Commercial Production

Market sources report that the local food industry uses ingredients derived from microbial biotechnology as processing aids (mostly enzymes) and some additives (nutrient) in the dairy and bakery industry. There is no reliable information on food ingredients produced from microbial biotechnology in use by the Indian food processing industry.

b. Exports

India exports food ingredients such as enzymes, and food preparations, some of which may come from microbial biotechnology, but there is no breakout of these exports figures. There is no reliable source of information on India's exports of food ingredients derived from microbial biotechnology.

c. Imports

India exports food ingredients like enzymes, and food preparations, some of which may come from microbial biotechnology, but there is no breakout of these import figures. There is no reliable source of information on India's import of food ingredients derived from microbial biotechnology.

d. Trade barriers

The approval process for imports of GE microbes used in manufacture of food ingredients derived from microbial biotechnology is a very long and tedious process. The Food Safety and Standard Authority of India is still in the process of drafting guidelines for imports and use of food ingredients derived from microbial biotechnology.

PART H: POLICY

a. Regulatory Framework

The Environment Protection Act of 1986 and Rules 1989 and FSSA 2006 provide the regulatory framework for research, development, commercial use and imports of GE microbes and food ingredients derived from microbial biotechnology. Until 2017, the GEAC regulated the approval of GE microbes and food ingredients derived from microbial biotechnology. Currently, the GEAC is responsible for approval of GE microbes for research, development, use and imports for manufacture of food ingredients derived from microbial biotechnology. While the FSSAI regulates food derived from genetic engineering, including ingredients derived from microbial biotechnology. (See Chapter 1, Part B: Policy, Section a) Regulatory Framework).
The Food Safety and Standard Authority of India is still in the process of framing regulations and guidelines related to GM processed food products, including food ingredient derived from

microbial biotechnology. The Food Safety and Standard Authority of India has scientific panels for these topics; these are engaged in the development of guidelines and review of applications. The scientific panels will handle regulations and approvals related to food ingredients derived from microbial biotechnology:

(i) Panel on Genetically Modified Organisms and Foods.
(ii) Panel for Food Additives, Flavorings, Processing Aids and Materials in contact with Food.
(iii) Panel on Genetically Modified Organisms and Foods.

b. Approvals

Most of the GEAC approvals for GE microbes and food ingredient derived from microbial biotechnology has been for use in dairy and baking industry.

TABLE 3: India, The GEAC Approvals of GE Microbes, and Food Ingredients derived from Microbial Biotechnology

S.No.	Product	Approval Status
1	Import of Maxiren (GE Chymosin Rennet from GE organism *Kluyvercomyces lactis)*	On September 24, 1991, the GEAC approved the import of Maxiren to the extent of 100 kg for one year. No further updates in subsequent GEAC meetings.
2	Manufacture and commercialization of recombinant Chymosin	On October 8, 2008, the GEAC gave no clearance to manufacture and commercialization of r-Chymosin.
3	Import of recombinant Chy-Max (Chymosin B)	On October 8, 2008, the GEAC gave no objection for imports of r-Chy-Max.
4	Non-commercial trials to scale up yeast biotransformation process using GMO yeast Category I yeast (*Saccharomyces cerevisiae*).	On August 28, 2014, the GEAC approved the request to carryout non-commercial trials to scale up yeast biotransformation process using GMO yeast Category I yeast (*Saccharomyces cerevisiae)* with volume up to 4000L.
5	Production of Xylanase enzyme by using recombinant *Pichia pastoris.*	On November 11, 2019, the GEAC granted permission, but subject to the compliance report on Environmental Risk Management and Safety Plan being submitted every six months to the regional office of the Ministry of Environment, Forest and Climate Change and for other statutory clearances.

Source: The Genetic Engineering Appraisal Committee; www.geacindia.gov.in.

Market sources report that some food ingredients derived from microbial biotechnology, mostly processing aids (enzymes) and novel food ingredients, in use by the domestic industry prior to 2017, have been granted interim approval by the FSSAI for import and use. However, others are awaiting approval as the new rules and guidelines are being finalized.

c. Labeling and Traceability

There are no specific regulations on labeling or traceability of food ingredients derived from microbial biotechnology. (For general regulations on food ingredients, see Chapter 1, Part B: Policy, subsection g) Labeling and Traceability).

d. Monitoring and Testing

India does not actively test for evidence of genetically engineered microbes or food ingredients derived from microbial technology used in food industry**.** (For general regulations on food ingredients, see Chapter 1, Part B: Policy, subsection h) Monitoring and Testing).

e. Additional Regulatory Requirements

Not applicable.

f. Intellectual Property Rights (IPR)

India is a signatory to the TRIPS Agreement of the WTO and changed its patents legislation in 2005 moving from a process patent regime to a product patent one. There are no specific regulations on IPR for GE microbes or food ingredient derived from microbial biotechnology.

g. Related Issues

No issue to report.

PART I: MARKETING

a. Public/Private Opinions

FAS New Delhi is not aware of studies that researched public or private opinions of food that uses ingredients derived from microbial biotechnology.

b. Market Acceptance/Studies

FAS New Delhi is not aware of marketing studies that have evaluated food processor or public attitude towards use of food ingredients derived from microbial biotechnology.

ANNEXURES

ANNEX I: Existing Biotech Regulatory Authorities – Function/Composition

Committee	***Members***	***Functions***
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. Member Secretary: An official from the MOEFCC	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.
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. Convoke monitoring and evaluation committees 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 agronomical viable transgenic crops/plants for approval to RCGM/GEAC
Institutional Biosafety Committee (IBC); functions at research institution 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 at controlled multi- location field sites. 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.
Food Safety Standard Authority of India.	Still in the process of drafting regulations and guidelines.	FSSAI has the mandate for regulating approval of GE food and products.

Source: The DBT, MOEFCC, FSSAI, Government of India sources, and FAS New Delhi office research.

ANNEX II: Procedure and Application Formats for Import of Biotech Products

Item	Approval According Agency	Governing Rules	Form No.	Links
"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 and 1998.	II B	GEAC Form II B
GM LMOs per se for food[/1]/feed/ processing	GEAC and FSSAI	Provide biosafety and food safety studies, Compliance with the Rules 1989 and Biosafety guidelines of 1990 and 1998. The FSSAI is working on the rules for approval of GE food after GEAC clearance on biosafety aspect.	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 is 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: The GEAC, MOEF Website http://www.geacindia.gov.in/applications.aspx, and FAS New Delhi office research.
Note [/1]- Since the Supreme Court of India directive of August 11, 2017, regulations of these products under the purview of FSSAI; it is still formulating the guidelines and regulations.

ANNEX III: India's Compliance with Various Articles of the Cartagena Protocol

Article No.	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 notifying entity.	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] The 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)
Article 21	Confidential information	---
Article 22	Capacity building.	Ongoing capacity building activities by the DBT and MOEF; with the support of the Global Environment Forum (GEF) through the United Nations Environment Program (UNEP) (since 2012).
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, India industry sources, FAS New Delhi office research.
[1] See Annex II
[2] http://dgftcom.nic.in/exim/2000/not/not06/not0206.htm
[3] http://geacindia.gov.in/index.aspx\
[4] http://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme
[5] https://biosafety.icar.gov.in/

Attachments:

No Attachments