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### **Report Highlights:**

Over the past two decades, India's political landscape continues to hinder the developments in agriculture biotechnology. Bt cotton (*Bacillus thuringiensis*) approved in 2002 remains the sole biotech-derived crop approved for commercial cultivation. Despite regulatory clearances for environmental release of GE eggplant and mustard events, the approval remains stuck under judicial review and political considerations. Soybean and canola oils from select GE soybean and canola events, and some food ingredients from microbial biotechnology are approved for import. On July 29, 2024, India's apex regulatory authority recommended the imports of GE alfalfa hay from the United States subject to other statutory clearances. Formal notification is pending. On July 23, 2024, the Supreme Court of India directed the Indian government to evolve a national policy on genetically modified crops by holding national consultation with all stakeholders within the next four months.

**DISCLAIMER:** Some information contained in this report is retrieved from various Indian government websites. [Note: Use Google Chrome to access the links that do not open in Microsoft Edge. Indian host sites will geo-block site access on a rolling basis]

## ***EXECUTIVE SUMMARY***

The Environment Protection Act (EPA) of 1986 is the basis of India's biotechnology (biotech) regulatory framework for genetically engineered (GE) plants, animals, and their products and by-products. The Food Safety and Standards Act (FSSA) of 2006 regulates GE food products, including processed foods. However, GE food product approval was deferred to the Genetic Engineering Approval Committee (GEAC) in the absence of regulations and operational infrastructure of the Food Safety and Standards Authority of India (FSSAI). In August 2017, the Supreme Court of India (SCI) directed the FSSAI to regulate approval of GE food products, and the FSSAI released its second draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulation (2021) for public comment which is still under review.

Bt cotton (*Bacillus thuringiensis*) is India's sole GE crop approved for commercial cultivation. Vegetable oils derived from GE soybeans and canola are the only products approved for import. Prior to the August 2017 Supreme Court ruling, the GEAC received applications for the import of DDGS, soybean meal, and processed food products with GE or GE-derived components. Approval of these products have been languishing as FSSAI is still working on regulation and infrastructure, coupled with confusion on regulatory domains of the two-apex regulatory authorities, i.e. GEAC and FSSAI. In December 2023, the government clarified that GEAC shall undertake the environmental safety assessment, and FSSAI will conduct the health safety assessment for GE food, feed fodder and product derived thereof.

In March 2021, the FSSAI implemented the order requiring a "non-GM (genetically modified) origin/GM-free" certificate, issued by the competent authority in the country of export, to accompany food product consignments from a 24-select food crops list, which affects export certification of some US products. In August 2021, the Ministry of Commerce and Industry (MoCI) allowed imports of 1.2 million metric tons (MMT) soybean meal derived from GE soybeans for a specified period (September 30, 2022). This provided the poultry and animal feed sectors temporary relief from the spike in soymeal prices.

Despite the regulatory clearance for Bt eggplant in 2010, and a locally developed GE mustard event in October 2022, a decision is pending clearance from the SCI in connection with an ongoing case challenging India's Biotech Regulatory System that dates to 2004. On July 23, 2024, the Supreme Court bench directed the Indian government to evolve a national policy on genetically modified crops regarding research, cultivation, trade and commerce in the country by conducting national consultation with stakeholders, preferably within the next four months. On July 29, 2024, the GEAC recommended the imports of alfalfa hay (including GE) from the United States to be allowed subject to other statutory clearances. However, a formal notification is still pending.

The U.S.-India bilateral trade in food, agriculture and related products in 2023 totaled \$7.9 billion, with the balance of trade skewed nearly 3-to-1 in India's favor. U.S. exports of products derived from GE crops are mostly cotton (\$ 231 million) and some soybean oil. Bt cotton represents 95 percent of India's cotton production of 25.8 million bales (480-lbs. bales) in marketing year (MY) 2023/2024 (August-July), of which 2.3 million bales are for export. India is not commercializing animals or animal products derived from biotechnology, though it clones Murrah water buffaloes for breeding purposes. Indian food processors use food ingredients derived from microbial biotechnology as processing aids (e.g., enzymes, food additives/vitamin supplements).

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

#### a. Research and Product Development

**GE Crops:** Indian seed companies and public sector research institutions are at various stages of genetically engineered (GE) crop research and development. Over 85 plant species are being developed for traits like 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 continues to constrain the advancement of research on GE crops to the product development stage. Post's sources report that companies developing GE crops have suspended 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 a 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<sup>1</sup>. 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. Since then, the GEAC has yet to initiate the approval process for the above Bt eggplant event. However, the GEAC has authorized confined field trials of a separate Bt eggplant event developed by a local public sector research institution.

Meanwhile, a GE mustard variety (containing events bn 3.6 and modbs 2.99) developed using barnase, barstar, and bar genes developed by the Delhi University (a public sector entity), has progressed through India's regulatory approval system. On October 18, 2022, India's MOEFCC/GEAC recommended the environmental release of the locally developed GE mustard parental lines bn 3.6 carrying barnase and bar genes, and modbs 2.99 containing barstar and bar genes. These are intended for the development of new parental lines and hybrids, as well as with the GE mustard hybrid DMH-11 for seed production (see, [GAIN-INDIA | IN2022-0100 | India Approves the Environmental Release of Genetically Engineered Mustard](#)). However, anti-biotechnology activists challenged the decision before the Supreme Court of India. The challenge is in the form of an add-on to an ongoing case challenging India's Biotech Regulatory System dating to 2004. In the court's hearing of November 9, 2022, the government agreed to suspend

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<sup>1</sup> In 2010, the MOEFC changed GEAC name to Genetic Engineering Appraisal Committee.

further planting until the final court ruling. To date, the planting of GE mustard seeds remains suspended.

On July 23, 2024, the Supreme Court 2-Judge bench gave a split verdict on the validity of the government's November 2022 decision granting conditional approval for environmental release of genetically modified (GM) mustard crops. The case is now referred to a three-judge Bench to be constituted by the Chief Justice of India. India's approval of the first GE food crop developed by a public sector research organization now hinges on India's apex court clearance, and subsequent approval from other statutory authorities, including the Food Safety and Standard Authority of India (FSSAI).

The ruling National Democratic Alliance (NDA) government remains indecisive on GE crops approvals. The existing policy environment has created uncertainty amongst stakeholders and is discouraging investment in agricultural biotechnology research and development (R&D) in India. If the Indian government would decisively move to approve additional GE crops, through a science-based regulatory assessment, then besides GE mustard there are three other crop events ready for commercialization: 1) a stacked herbicide tolerant (HT) Bt cotton event, 2) HT corn, and 3) three Bt eggplant events. Sources inform that event developers have withdrawn or placed on hold the pursuit of approvals of various other GE crop events due to the policy stalemate.

**Use of Innovative Biotechnologies:** Facing political opposition, and the slow pace of India's biotechnology regulatory approval system, public sector researchers have shifted towards genomics and marker-assisted breeding in their biotech programs. Several biotech research organizations are also exploring research on the application of new biotech techniques such as genome editing in agriculture.

Fortuitously, the Indian government in October 2022 decided to exempt genome edited plants falling under the categories of SDN-1 and SDN-2 from the onerous regulations for transgenic plants often referred to simply as "Rules of 1989" (see, Chapter [B], POLICY).

To incentivize innovation and promote development of genome-wide analysis and engineering technologies, India's Ministry of Science and Technology (MOST)/Department of Biotechnology (DBT) is supporting various programs and initiatives. The Indian Council of Agricultural Research and affiliated state agricultural universities (SAUs) and other public sector institutions are also researching the use of gene editing and other new tools. Work focuses on developing traits such as abiotic and biotic stress, nutritional improvement, crop architecture, herbicide tolerance, and yield enhancement.<sup>2</sup> These developments will encourage research and development of genome edited products over the next few years.

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<sup>2</sup> Genome Editing for Crop Improvement - A Perspective from India. Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8152710/>

Genome Editing: a boon for plant biologists, breeders, & farmers. Link: <https://www.currentscience.ac.in/Volumes/123/01/0015.pdf>.

**Use of Biotechnology in Other Sectors:** [Biopharmaceuticals for human and animal use](#) and GE microorganisms and derived products utilize biotechnology extensively.<sup>3</sup> Most of these manufacturers are in the category of biosimilars 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 biosimilars, fall under the regulatory oversight of:

- (i) The Drug Controller General of India, under the [Drugs and Cosmetics Act 1940](#).
- (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 \(1989\)](#) (commonly referred as “Rules 1989.”) and notified under the [Environment \(Protection\) Act \(1986\)](#).

The Review Committee of Genetic Manipulation assesses the applications up to the preclinical studies stage, with the GEAC reviewing 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, which remains the only GE crop approved for production at present. Over the past two decades, Bt cotton area has expanded to cover over 95 percent of total cotton acreage, allowing India to become the world’s largest producer and a leading exporter. Cotton production in MY 2013/2014 (August-July) peaked at a record 31 million bales (480-lbs. bales) from 11.9 million hectares, with exports estimated at 9.3 million bales. This volume is three times greater than that of MY 2002/2003, which was when Bt cotton was first approved and registered (10.6 million bales from 7.7 million hectares). Production in MY 2023/2024 is estimated at 25.8 million bales from 12.7 million hectares.

Over the period 2002 to 2008, the Indian government [approved five cotton events](#) and more than 1,400 hybrids for cultivation in various agro-climatic zones. Most Bt cotton hybrids come from the two Monsanto (i.e., now Bayer) events (Mon 531 and Mon 15985). An Indian joint venture company, MaHyCo Monsanto Biotech (India) Private Limited (MMBL), has licensing rights for the two Monsanto events. MMBL has sub-licensed the two events to 45 Indian seed companies for use in their cotton hybrids. The commercial cultivation of Bt cotton is approved for use as fiber (clothing), food (oil for human consumption), and feed (meal for animals).

**Illegal Cultivation of Unapproved GE Events Continues:** Industry sources inform that herbicide tolerant Bt (HTBT) GE cottonseed may account for 25-30

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<sup>3</sup> Ministry of Environment, Forest, and Climate Change/Genetic Engineering Appraisal Committee, <http://geacindia.gov.in/approved-products.aspx>.

percent of total cotton acreage, being grown in the Indian states of Gujarat, Maharashtra, Telangana, Andhra Pradesh, Odisha, Karnataka, and Madhya Pradesh. Reports allege GE soybeans (HT) being cultivated in Gujarat and Madhya Pradesh. Post sources inform that illegally sourced Bt eggplant seeds from Bangladesh making their way into West Bengal and Orissa and are gradually spreading to other states.

Since 2019, a Maharashtra state farmer group spearheaded the “[GM Satyagraha](#)” movement, openly planting unapproved HTBT GE cottonseed in the presence of media. The farmer group agitation targets the Indian government’s indecisiveness on approval of new GE events. While the Indian and state governments have measures in place to stop the sale of illegal GE seeds, sources confirm that the sale and use continues unabated. The continued deliberate cultivation of unapproved GE seeds reflects both receptivity for the technology and frustration with the government’s GE approval process on the part of farmers.

### **c. Exports**

India is the fourth largest exporter of cotton in the world; trailing behind the United States, Brazil, and Australia. It also exports small quantities of cottonseed and cottonseed meal also derived from Bt cotton. India exported a record 11.1 million bales (480-lbs. bale) in MY 2011/2012, which dropped to 1.1 million bales in MY 2022/2023 and is estimated at 2.3 million bales in 2023/2024 on growing domestic demand and stagnant production over the last few years. Sources indicate that export documentation for Indian cotton, as a fiber product (i.e., cellulose), does not require a GE declaration to any destination. India does not export significant quantities of cotton, cottonseed, or cottonseed meal to the United States.

### **d. Imports**

There are only two non-Living Modified Organisms (LMO) GE-derived food products authorized for import into India: 1) soybean oil, derived from GE soybeans (glyphosate tolerant and five other events) and 2) canola oil, derived from GE canola (a select herbicide tolerant event). India imports significant quantities of soybean oil. Imports in calendar year 2023 were 3.5 million metric tons (MMT), mainly from Argentina (1.33 MMT) and Brazil (1.26 MMT). To augment the quality requirement of the local textile industry, India also imports significant quantities of cotton, including Bt cotton, estimated at 0.9 million bales in MY 2023/2024. Cotton, a cellulosic fiber devoid of protein, does not require a GE declaration.

On August 24, 2021, the Ministry of Commerce and Industry (MOCI)/Directorate General of Foreign Trade (DGFT) authorized the import of 1.2 MMT of crushed and de-oiled soy cakes, commonly known as soybean meal derived from GE soybeans in response to high soybean meal prices that were impacting India’s poultry and livestock sectors as these sectors are critically dependent on this feed



input.<sup>4</sup> The imports were initially allowed through October 31, 2021, and then extended until September 20, 2022.<sup>5</sup> The imports were allowed as a one-time relief measure to the domestic livestock/poultry growers based on the MOEFCC note that, “since soy de-oiled and crushed cake does not contain living modified organisms, the ministry has no concerns and no objection for the import of soy cakes from the environmental angle.”<sup>6</sup>

On January 11, 2021, the MoCI announced that India and the United States had agreed to a framework implementing market access for agricultural products from both countries, including U.S.-origin alfalfa hay (that encompasses GE alfalfa hay). After penning the agreement, India’s Ministry of Agriculture and Farmers Welfare (MoAFW) informed the U.S. Department of Agriculture (USDA) that imports of GE alfalfa hay would require prior approval from the GEAC and forwarded the request to GEAC for approval.

In late 2023, the Food Safety and Standard Authority of India (FSSAI) Scientific Panel on GMO and Foods (SPGF) recommended GE alfalfa as a livestock safe feed. The GEAC’s Review Committee on Genetic Manipulation assessed environmental risk due to GE alfalfa hay as negligible. Based on the FSSAI/SPGF and RCGM assessments, on July 29, 2024, the GEAC recommended the imports of alfalfa hay (including GE) from the United States subject to other statutory clearances.<sup>7</sup> Government sources reported that the Ministry of Agriculture and Farmers Welfare is reviewing the FSSAI and GEAC recommendations, and subsequently will issue a notification authorizing the import of all alfalfa hay, including GE varieties from the United States.

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 normally a food aid provider. Only under extreme, sporadic circumstances does India provide food aid shipments to neighboring countries. In case of natural disasters, it mostly ships wheat and rice, both non-GE foods. India is not a U.S. food aid recipient, nor likely to be one in near future.

#### **f. Trade Barriers**

India bans the import of all GE products, except for soybean and canola oil derived from GE soybean and canola (select events), and the temporary approval in 2021 for imports of soybean meal derived from GE soybeans. In April 2006, the Ministry of Commerce and Industry issued Notification No. 2(RE2006)/2004-2009 specifying that the GEAC

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<sup>4</sup> See, [GAIN-INDIA | IN2021-0102 | India Officially Permits Limited Soybean Meal Imports](#))

<sup>5</sup> See, [GAIN-INDIA | IN2022-0048 | Indian Government Resumes GM Soyabean Meal Imports](#)

<sup>6</sup> The ministry houses India’s apex biotech regulatory authority Genetic Engineering Appraisal Committee.

<sup>7</sup> See [GEAC published meeting notes of July 29, 2024](#) section 7.2.



must approve all GE product imports. The directive requires a GE declaration by the importer at the time of import.<sup>8</sup>

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. Only the import of previously GEAC-approved, GE-derived soybean and GE-derived canola oils are permissible.

Effective March 1, 2021, the FSSAI implemented an order stipulating that every food product consignment from a list of 24-select crops requires an accompanying “non-GM origin cum GM-free” certificate issued by the competent authority in country of export. This FSSAI order creates an additional certification requirement affecting the trade of U.S.-origin agricultural products (e.g., apples, rice and select pulses) and those of other Indian trading partners. The United States and other likeminded trading partners continue to express their collective opposition to the FSSAI’s non-science-based certification requirement, which creates an undue burden on exporting countries.

Since 2015, the GEAC has received applications for the approval of imports of distiller’s dried grains with solubles (DDGS) derived from GE corn, soybean meal derived from GE soybeans, and GE soybeans (for animal feed). In July 2018, the GEAC formed a sub-committee to establish a procedure for dealing with applications for imports of animal feeds, including DDGS and soybean meal. In November 2019, the sub-committee submitted to the GEAC its draft recommendation for comments and approval. On August 25, 2022, the GEAC as per the Supreme Court of India order of August 2017 stated that proposals to import GE products for use as animal feed should be forwarded to the FSSAI for necessary action. However, FSSAI is still in the process of drafting rules and regulations for regulatory assessment of GE food, feed, fodder and products thereof.

The [Plant Quarantine Order \(PQO\) Regulation of Import into India \(2003\)](#) 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 overly cumbersome.

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<sup>8</sup> Notification No. 2(RE2006)/2004-2009 “Amendments in Schedule – 1 (Imports) of the ITC(HS) Classifications of Exports and Import Items, 2004-09,” pertaining to the import of GE products is accessible of the Directorate General of Foreign Trade website located at <https://www.dgft.gov.in/CP/?opt=notification>. To access the archived notification, in the notification search engine type in year “2006.” In the following “Search Notifications/Public Notice/Circular/Trade Notice” page, type in the search engine box for “number” 2(RE2006)/2004-2009.

## PART B: POLICY

### a. Regulatory Framework

The [Environment Protection Act \(EPA\) of 1986](#) provides the basis for India’s biotechnology (biotech) regulatory framework for GE plants, animals, and their products and by-products, along with 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, Appendix I).

**TABLE 1: India, Legal Terms and Definition**

Legal Term	Laws and Regulations	Legal Definition
Genetically Engineered Organism or Cell	<ul style="list-style-type: none"> <li>- Environment Protection Act 1986 (EPA 1986)</li> <li>- Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organism or Cells (Rules 1989)</li> </ul>	Any organism or cell produced through use of genetic engineering, which is defined as ‘the technique by which heritable material, which does not usually occur or will occur naturally in an organism or cell concerned, generated outside the or the cell is inserted into said cell or organism. It shall also mean the formation of new combination of genetic material by incorporation of a cell or 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.
Gene Technology	-----	The application of the gene technique called genetic engineering, to include self-cloning and deletion as well as cell hybridization.
Genetic engineering	-----	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
Genetically modified (GM) food, feed and fodder	<ul style="list-style-type: none"> <li>- FSSAI’s Draft Food Safety and Standards (Genetically Modified Foods) Regulations, 2022 (<b><u>Proposed/ Not yet implemented</u></b>)</li> </ul>	Food and food ingredients composed of, or containing, genetically modified or genetically engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified organisms obtained through modern biotechnology. Government sources report FSSA 2006 will be amended to include animal feed and fodder under FSSAI

Modern Biotechnology	- FSSAI's Draft Food Safety and Standards (Genetically Modified Foods) Regulations, 2022 ( <b><i>Proposed/ Not yet implemented</i></b> )	Application of (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.
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On August 24, 2006, the Indian government enacted an integrated food law, the [Food Safety and Standards Act \(FSSA\) of 2006](#), which includes specific provisions for regulating GE food products, including processed foods. Under the Act, the FSSAI is the national authority responsible for regulating food, including GE foods. On November 15, 2021, the FSSAI issued a draft notification – [Draft Food Safety and Standard \(Genetically Modified or Engineered Food\) Regulation \(2021\)](#) for public comments.<sup>9</sup> On November 21, 2022, the FSSAI notified the revised [DRAFT Food Safety and Standards \(Genetically Modified Foods\) Regulations, 2022](#).<sup>10</sup> The notification pertains to Genetically Modified Organisms (GMO) intended for food use; food ingredients produced from GMOs that contain modified DNA; and food ingredients produced from GMOs that do not contain modified DNA, including ingredients/additives/processing aids derived from GMOs. The FSSAI, however, to date has yet issued further notifications or revisions regarding implementation of the proposed draft regulation. The FSSAI also has yet to develop the institutional capacity to fulfill this regulatory function.

The Biosafety approval of GE crops and products (including LMO and seeds) for research, development, and cultivation, and processed non-food products is handled by the GEAC. The Food Safety and Standard Authority of India has the authority to handle the food safety approval of GE food including processed food and products. Since 2017 Supreme Court direction to FSSAI regarding regulating GE food and products, there was a prolonged ambiguity regarding the responsibility for the approval of animal feed and fodder derived from GE crops and animals between the GEAC and FSSAI authorities. After series of inter-ministerial consultations, in December 2023 the regulatory roles of FSSAI and GEAC for GE food, feed fodder and product derived thereof was clarified by specifying: (i) GEAC shall undertake the environmental safety assessment, and (ii) FSSAI/SPGF will undertake the health safety assessment of GE feed and fodder. However, concerned ministries such as the Ministry of Fisheries, Dairying and Animal Husbandry and the Ministry of Agriculture and Farmers' Welfare will have a role in regulatory approval and notification for animal feed and fodder.

<sup>9</sup> See, [GAIN-INDIA | IN2021-0138 | India's FSSAI Proposes New Regulations for Genetically Modified or Engineered Foods](#)).

<sup>10</sup> See, [GAIN-INDIA | IN2022-0113 | India Proposes Draft Regulation for Genetically Modified Food for Second Time](#).

**TABLE 2: India, Role of Various Ministries\State Governments**

<b>Authority</b>	<b>Roles and Responsibility</b>
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) <sup>11</sup>	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, and animal feed and fodder. 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’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 regulatory approval system under GEAC lacks a defined timeline for stages of regulatory authorization for GE crops and LMOs. The MoEFCC published the document “[Procedure for Import and Export of GM Plant and Planting Material](#)” to assist traders and researchers. The [Plant Quarantine Order Regulation of Import into India \(2003\)](#), 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.

The **Rules 1989** do not provide regulatory distinction between GE plant products containing DNA in final form of the product and those of plant products that do not. Nor is a distinction made between products containing LMOs and products not containing LMOs. There is no provision for the approval for food, feed, fiber, processing, and environmental release. While granting one-time approvals for

<sup>11</sup> In 2019, a separate Ministry of Fisheries, Animal Husbandry and Dairying (MoFAHD) was carved out of Ministry of Agriculture and Cooperation. MFDH will be responsible for evaluation and commercial release of transgenic animals and feed. However, the ministry has not an established regulatory approval system in place as there are no transgenic animal at the regulatory approval stage.

vegetable oils derived from specified GE soybean and canola events, the GEAC specifies that approval is subject to consumption after refining to ensure there is no GE modified protein, nor DNA presence in the oil. The MoEFCC's decision of 2021 granting no objection on the imports of GE soybean meal was premised on the product not containing LMOs.

The Rules 1989 specify that approvals are for a specified period, not to exceed four years from the first instance but renewable for two years at a time. In 2009, the GEAC, following years of monitoring GE cotton events, granted approval for five Bt cotton events. The GEAC gave one-time approvals for imports of vegetable oils derived from various GE soybean and canola events.

Despite enactment of the Food Safety and Standard Act in 2006, the FSSAI lacks the technical capacity and regulations in place for approving GE food products. Hence, the Ministry of Health and Family Welfare (MHFW) designated the GEAC to regulate processed GE-derived food products under the Rules 1989. In August 2017, the Supreme Court of India directed the FSSAI to issue guidelines and regulations for the approval of GE food and products. The GEAC transferred to the FSSAI the GE foods and products applications for approval. Despite issuing the draft regulations on genetically modified twice in the past two years, the FSSAI has not implemented any regulation and or establish guidelines for food and processed food products derived from GE crops and animals; all applications (except GE alfalfa hay) received since 2017 are still pending.

**Supreme Court Directs Government to Evolve a National Policy on GE Crops:** On July 23, 2024, the 2-judge bench issued a directive to the Government of India (GOI) to evolve a national policy with regards to genetically modified crops regarding research, cultivation, trade and commerce in the country. They further directed that the MoEFCC shall conduct a national consultation with all stakeholders, preferably within the next four months, and the states should be involved in evolving the national policy. Since the case was first filed in 2004, the GOI has argued that the existing biotech regulatory system is science based and adequate to address biosafety concerns for GE crops.

## **b. Approvals**

There are five events approved for cultivation in India, all Bt cotton. The GEAC has also granted import approval for vegetable oils derived from six GE soybean events and one GE canola event. 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 approved 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).

**TABLE 3: 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

[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.

Source: [GEAC, MOEFCC, Government of India](#), FAS New Delhi office research.

#### c. Stacked or Pyramided Event Approvals

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

#### d. Field Testing

The 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 for Bt cotton an “event based” approval system. In April 2017, the GEAC authorized the ICAR responsibility for evaluation, approval, management, and monitoring of Bt cotton hybrids. 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 Bt cotton hybrids.

On July 6, 2011, the GEAC amended field trial authorization procedures, requiring the applicant (i.e., the technology developer) to obtain a no objection certificate, or “NOC” (a permit), from the state government. Sources inform that only select states issued NOCs for GE field trials of select events affecting the developer’s ability to conduct GEAC approved trials and consequent slowed progress of meeting requirements for regulatory approval. 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, applications not denied are considered as approved. The GEAC was also authorized to waive the NOC requirement for small-scale, institutionally confined event trials.

**e. Innovative Biotechnologies**

In February 2020, the DBT posted the draft document on [Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment \(2019\)](#) for public comments. In April 2022, MOEFCC issued a decision note to concerned ministries and the state governments involved in the biotech regulatory process about exempting genome edited plants falling under the categories of SDN-1 and SDN-2 within the provisions of “Rules of 1989”. The decision was made based on the assessment that SDN1 and SDN2 categories of genome editing technologies do not involve or carry exogenous DNA and are comparable naturally occurring variance. On May 17, 2022, the DBT issued [Guidelines for Safety Assessment of Genome Editing Plants \(2022\)](#). On October 4, 2022, the Department of Biotechnology issued the [Standard Operating Procedures for Regulatory Review of Genome Edited Plants Under SDN-1 and SDN-2 Categories \(2022\)](#). Informed sources report several gene edited products at advanced stage of development and advancement through the regulatory approval system, which include rice (drought and salt tolerant), mustard (*Brassica juncea*) seeds with reduced glucosinolate content, and vitamin A-fortified bananas.

**f. Coexistence**

There are no 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. 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](#)).

Industry sources report that the FSSAI is likely to have provisions for labeling of GE food and/or food derived from GE products when they come out with the GE food regulations. 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 FSSAI and the state governments' local food safety authorities 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 cases where the imported products contain unapproved GE events, the importer is subject to legal action.

The MOAFW monitors approved GE crop events (cotton) for three years for agronomic performance and environmental implications. There is no regular monitoring of field crops to detect unapproved GE events, except in case of specific reports of planting of unapproved GE events. Since reports of the cultivation of illegal GE crop events in MY 2017/2018, various state governments have been testing and destroying illegal GE crops, followed by legal action against the responsible farmers and seed suppliers.

## **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. On February 8, 2021, the FSSAI clarified that the implementation of the requirement for a Genetically Modified-Free Certificate for imported food products will apply within the permissible tolerance limit for the adventitious presence of genetically modified organisms (i.e., genetically engineered) at below one percent.<sup>12</sup>

## **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. With the commercial release of a new GE crop, the MOAFW, along with the state departments of agriculture, monitors field performance for three-to-five years.

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<sup>12</sup> See, [GAIN-INDIA-IN2021-0026- India - Clarifications on the FSSAI Genetically Modified-Free Certificate Order for Imported Food Products](#).

## **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 \(PPVFRA\)](#) 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, Appendix III). A [Biosafety Clearing House \(BCH\)](#) has been set up within MOEFCC to facilitate the exchange of scientific, technical, environmental, and legal information on LMOs. The Genetic Engineering Appraisal Committee approves trade of GE products, except food products, which is under the purview of the FSSAI. In October 2014, India became the 28<sup>th</sup> country to ratify the Nagoya Kuala Lumpur supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

## **m. International Treaties/Fora**

In Codex *Alimentarius* discussions, India supports mandatory labeling of “GM” foods, requiring a compulsory declaration should food and food ingredients contain genetically modified organisms.

## **n. Related Issues**

**Government Regulate Cotton Trait License Fee:** On December 7, 2015, the MoAFW 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 2016/2017 (July-June) 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). The government continued to revise cotton seed prices and trait fee on Bollgard II lower, scrapping the trait fee from the Indian crop year 2021/2022 onwards.

Industry sources indicate that the delayed biotech regulatory approval system coupled with the CSPCO-2015 have imposed significant barriers for agriculture biotech seed business - discouraging innovation, research and development, and investments. The provisions of the CSPCO-2015 hurt existing technology providers who are having several products at advanced stage of regulatory approval. This

regulation is a strong disincentive to potential new innovators seeking to introduce new technologies to Indian farmers, which are critical for improving their livelihoods and making them globally competitive.

## **PART C: MARKETING**

### **a. Public/Private Opinions**

Public opinion about biotechnology and GE crops is generally ambivalent as anti-biotech groups driven 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 on various ground including biosafety concerns and fears of seed monopolies by multinational seed companies.

Most Indian farmers, except cotton growers and a few (but growing number) of farmers planting illegal GE crops, lack awareness of the technology due to the absence of other GE field crops. Major industry associations are 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. Due to the tight domestic supplies of animal feeds and fodders, most livestock and poultry industry groups are increasingly vocal in support imports of GE-derived animal feeds and fodders.

Many agricultural 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 and/or genome editing. Public sector researchers are exploring the use of genome editing tools, but the private sector is adopting a cautious wait-and watch position on concerns with commercial approval following a similar political opposition as experienced in GE crop 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 MOST/DBT, the MOAFW's Indian Council of Agricultural Research, and bodies like the National Academy of Agriculture Science (NAAS) have supported outreach activities to the public on the benefits of biotechnology and GE crops, but success is limited due to absence of a viable public sector event.

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 MOAFW and the MOST are supportive of agricultural biotechnology and GE crop research and development.

#### **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 and a growing number of farmers growing 'unapproved' GE crops. Reports of illegal cultivation of GE crops with unapproved events suggest that farmers are willing to cultivate other GE crop events, including the several crop 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 GE animal feed like DDGS from GE corn and soybean meal from GE soybean.

Over ten feed manufacturers had applied to the GEAC for permission to import DDGS; a handful of importers as well have applied to import GE soybean meal. Facing high soymeal prices, local poultry and animal feed industry joined forces to push the government to allow imports of GE soymeal to augment their supplies. Expected tight feed ingredient supplies in coming years will push the industry to seek continued market access for GE soymeal and feed ingredients such as DDGS and GE alfalfa hay.

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 focus on the opportunity cost of non-approval of other GE crops and products to farmers, consumers, and the Indian economy.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

#### a. Product Development

India's animal biotechnology research and development is in its infancy. There have been some notable successes the cloning of the Asian domestic buffalo. 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. On March 9, 2012, scientists from the Sher-e-Kashmir University of Agricultural Sciences and Technology at Srinagar attest to have delivered a cloned pashmina goat by the same cloning technique. In December 2015, a scientist of NDRI claimed to have successfully produced a female clone of the endangered wild buffalo of Chhattisgarh. In December 2015, the ICAR-Central Institute for Research on Buffaloes (CIRB) also cloned a buffalo calf to become the second Indian organization to clone buffalo.



Source: FAS New Delhi office research.

Scientists from the NDRI and the CIRB continue to research on refining the cloning technique to address the concerns like low birth rate and premature calf deaths. Meanwhile, the Indian government has tasked the two institutes with an ambitious cloning program to multiply high-value bulls of traditional breeds of buffaloes and cattle to expand the national breeding program. Recent reports suggest that NDRI and CIRB have produced more cloned buffaloes, and some of the adult animals are being used by the two institutes and other government breeding farms for semen collection to be used in breeding programs at research institutes and other experimental breeding centers.

Besides cloning, 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 the 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 report that a local research institute has successfully conducted lab trials on GE silkworm resistant to BmNPV (*Bombyx mori nucleopolyhedrovirus*) which is now advancing to controlled field trials. A local company has licensed research from a United Kingdom company pertaining to mosquito-borne illnesses by producing GE 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. Reports suggest that some research facilities are also working on using gene editing techniques for research on insects for beneficial traits.

#### **b. Commercial Production**

India does not produce GE animals or products derived from GE animals, except for limited use of cloned buffaloes for production of semen for breeding in experimental facilities buffalo herds. Some of the public sector institutions have started preliminary research on use of genome editing targeting select traits like milk yield, fat percentage, and meat growth rate.

#### **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 and early commercialization stage, there are currently no regulations on commercial production or marketing of cloned animals.

On April 17, 2023, the Department of Biotechnology released the [Guidelines and Standard Operating Procedures \(SOP\) for Research on Genetically Engineered Insects \(2023\)](#), which includes data requirements for conducting research on GE insects under contained facilities.

**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 ongoing animal biotech research in genome edited animals or insects is at an early stage.

**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 (WOAH) discussions, FAS New Delhi is not aware of India taking 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 largely limited to buffaloes and still at an early stage of development.

## 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. However, there is no reliable official or industry information on food ingredients produced from microbial biotechnology in use by the Indian food processing industry.

#### b. Exports

There are neither official statistics, nor reliable industry estimates on exports of microbial biotechnology products. However, India exports alcoholic beverages, dairy products, and food ingredients such as enzymes, some of which may come from microbial biotechnology.

#### c. Imports

There are neither official statistics, nor reliable industry estimates on imports of microbial biotechnology products. However, India imports alcoholic beverages, dairy products, and food ingredients such as enzymes, some of which may come from microbial biotechnology.

#### d. Trade barriers

The FSSAI approved imports of GE microbes (LMOs) used in the manufacture of food ingredients derived from microbial biotechnology, which are already being imported based on the GEAC's clearances. The FSSAI 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 (LMOs) 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 FSSAI is still in the process of framing regulations and guidelines related to “GM” processed food products, including food ingredient derived from microbial biotechnology and has scientific panels for these topics. These panels are engaged in the development of guidelines and review of applications and 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.

## b. Approvals

Most of the GEAC approvals for GE microbes and food ingredients derived from microbial biotechnology have been for use in the dairy, baking industry and industrial use.

**TABLE 4: India, 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 <i>Kluyveromyces lactis</i> )	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 denied approval 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 ( <i>Saccharomyces cerevisiae</i> ).	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 ( <i>Saccharomyces cerevisiae</i> ) with volume up to 4000L.
5	Production of Xylanase enzyme by using recombinant <i>Pichia pastoris</i> .	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.
6	Production of recombinant silk protein using GE <i>Pichia pastoris</i> for non-therapeutic purpose	On July 29, 2024, the GEAC granted permission subject to specified conditions and other statutory clearances.
7	Production of lactic acid and lactide using GE <i>Pichia kudriavzevii</i> strain PMCC/Y/107	On July 29, 2024, the GEAC granted permission subject to specified conditions and other statutory clearances.

8	Production of 2,3 Butanediol from sugar-based feedstocks using GE <i>Saccharomyces cerevisiae</i>	On July 29, 2024, the GEAC granted permission subject to specified conditions and other statutory clearances.
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Source: The Genetic Engineering Appraisal Committee; [www.geacindia.gov.in](http://www.geacindia.gov.in).

There are several applications for commercial production of ethanol using GE yeast, which will be considered after development of standard risk assessment and management plan (RARMP) for environmental safety. The applications are deferred till the time standard RARMP is finalized.

[On July 12, 2021, the FSSAI issued a directive](#) to all states and Union Territories Commissioner of Food Safety and Regional Directors of FSSAI allowing use of processing aids (enzymes) derived from genetically modified microorganisms/sources already in use by food business operators until appropriate amendments for these products were officially notified. The notice listed out 109 processing aids derived from GE microorganism. Subsequently, the FSSAI issued a [draft notification](#) approving select products. Industry sources report that the FSSAI is ready to issue final notification for these products but are awaiting the FSSAI's final regulation on approval of GE foods and products. Until then, the products listed under the July 12, 2021, order will continue to be allowed for use by the domestic industry.

#### **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)**

There are no specific regulations on IPR for GE microbes or food ingredient derived from microbial biotechnology.

#### **g. Related Issues**

Nothing significant 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.

## APPENDIX I: Existing Biotech Regulatory Authorities – Function/Composition

Committee	Members	Functions
The Genetic Engineering Appraisal Committee (GEAC); functions under the Ministry of Environment, Forests and Climate Change (MOEFCC).	<ul style="list-style-type: none"> <li>- Chairman: Additional Secretary, MOEFCC.</li> <li>- Co-Chairman: Nominee of Department of Biotechnology (DBT).</li> <li>- Ministry of Industrial Development, DBT and the Department of Atomic Energy.</li> <li>- 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 a few outside experts in an individual capacity.</li> <li>- Member Secretary: An official from the MOEFCC.</li> </ul>	<ul style="list-style-type: none"> <li>- Review and recommend the use of bio-engineered products for commercial applications.</li> <li>- Approve activities involving large-scale use of bio-engineered organisms and recombinants in research and industrial production from an environmental safety angle.</li> <li>- Consult RCGM on technical matters relating to environmental safety angle.</li> <li>- Consult RCGM on technical matters relating to clearance of bio-engineered crops/products.</li> <li>- Approve imports of bio-engineered food/feed or processed product derived thereof.</li> <li>- Take punitive actions on those found violating GE rules under EPA (1986).</li> </ul>
Review Committee on Genetic Manipulation (RCGM); function under DBT, Ministry of Science and Technology (MOST).	Representatives from: <ul style="list-style-type: none"> <li>- The DBT.</li> <li>- The Indian Council of Medical Research (ICMR).</li> <li>- Indian Council of Agricultural Research (ICAR).</li> <li>- Council of Scientific and Industrial Research (CSIR).</li> <li>- Other experts in their individual capacity.</li> </ul>	<ul style="list-style-type: none"> <li>- Develop guidelines for the regulatory process for research and use of bioengineered products from a biosafety angle.</li> <li>- Monitor and review all ongoing GE research projects up to the multi-location restricted field trial stage.</li> <li>- Undertake visits to trial sites to ensure adequate security measures.</li> <li>- Issue clearance for the import of raw materials needed in GE research projects.</li> <li>- Scrutinize applications made to the GEAC for the import of bioengineered products.</li> </ul>

		<ul style="list-style-type: none"> <li>- Convoke monitoring and evaluation committees for biotech crop research projects.</li> <li>- Appoint sub-groups when required in topics of interest to the committee.</li> </ul>
Recombinant DNA Advisory Committee (RDAC); function under DBT.	<ul style="list-style-type: none"> <li>- Scientists from the DBT and other public sector research institutions.</li> </ul>	<ul style="list-style-type: none"> <li>- Take note of developments in biotechnology at the national and international level.</li> <li>- Prepare suitable guidelines for safety in research and applications of biotechnology.</li> <li>- Prepare other guidelines as may be required by the GEAC.</li> </ul>
Monitoring Cum Evaluation Committee (MEC).	<ul style="list-style-type: none"> <li>- Experts from ICAR institutes, State Agricultural Universities (SAUs) and other agricultural/crop research institutions and representatives from DBT.</li> </ul>	<ul style="list-style-type: none"> <li>- Monitor and evaluates trial sites, analyze data, inspect facilities, and recommend safe and agronomical viable transgenic crops/plants for approval to RCGM/GEAC.</li> </ul>
Institutional Biosafety Committee (IBC); functions at research institution level.	<ul style="list-style-type: none"> <li>- Head of the institution.</li> <li>- Scientists engaged in biotech work.</li> <li>- Medical experts.</li> <li>- Nominee of the Department of Biotechnology.</li> </ul>	<ul style="list-style-type: none"> <li>- Develop a manual of guidelines for the regulatory process on bio-engineered organisms in research, use and application to ensure environmental safety.</li> <li>- Authorize and monitor all ongoing biotech projects at controlled multi-location field sites. Authorize imports of bio-engineered organisms/transgenic for research purposes.</li> <li>- Coordinate with district and state level biotechnology committees.</li> </ul>
State Biotechnology Coordination Committee (SBCC); functions under the state government where biotech research occurs.	<ul style="list-style-type: none"> <li>- Chief Secretary, State Government.</li> <li>- Secretaries, Departments of Environment, Health, Agriculture, Commerce, Forests, Public Works, Public Health.</li> <li>- Chairman, State Pollution Control Board.</li> <li>- State microbiologists and pathologists.</li> <li>- Other experts.</li> </ul>	<ul style="list-style-type: none"> <li>- 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.</li> <li>- Nodal agency at the state level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.</li> </ul>

<p>District-Level Committee (DLC); functions under the district administration where biotech research occurs.</p>	<ul style="list-style-type: none"> <li>- District Collector.</li> <li>- Factory Inspector.</li> <li>- Pollution Control Board Representative.</li> <li>- Chief Medical Officer.</li> <li>- District Agricultural Officer, Public Health Department Representative.</li> <li>- District Microbiologists/ Pathologists.</li> <li>- Municipal Corporation Commissioner.</li> <li>- Other experts.</li> </ul>	<ul style="list-style-type: none"> <li>- Monitor safety regulations in research and production installations.</li> <li>- Investigate compliance with rDNA guidelines and report violations to SBCC or GEAC.</li> <li>- Nodal agency at district level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.</li> </ul>
<p>Food Safety and Standards Authority of India.</p>	<ul style="list-style-type: none"> <li>- Still in the process of drafting regulations and guidelines.</li> </ul>	<ul style="list-style-type: none"> <li>- FSSAI has the mandate for regulating approval of GE food and products.</li> </ul>

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



## APPENDIX II: Procedure and Application Formats for the Import of Biotechnology 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	<a href="#">GEAC Form I</a>
GMOs/ LMOs for intentional release (including field trials)	IBSC/R CGM/G EAC/ ICAR	Rules 1989; biosafety guidelines of 1990 and 1998.	II B	<a href="#">GEAC Form II B</a>
“GM LMOs” per se for food <sup>1</sup> /feed /processing	GEAC and FSSAI	Provide biosafety and food safety studies, Compliance with the Rules 1989, and the 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	<a href="#">GEAC Form III</a>
“GM” processed Food Derived From	FSSAI (Previously GEAC)	<p><i>FSSAI working on the rules.</i></p> <p>Previous GEAC Rule: One time “event based” approval given based on importer providing the following information:</p> <ul style="list-style-type: none"> <li>i. List of genes/events approved in the crop species for commercial production in the country of export/country of origin;</li> <li>ii. Approval of the product for consumption in countries other than producing countries.</li> <li>iii. Food safety study conducted in the country of origin;</li> <li>iv. Analytical/compositional report from the country of export/origin;</li> <li>v. Details on further processing envisaged after import;</li> <li>vi. Details on commercial production, marketing and use for feed/food in the country of export/origin;</li> <li>vii. Details on the approval of genes/events from which the product is derived.</li> </ul>	IV	<a href="#">GEAC Form IV</a>

Processed Food containing ingredients Derived From GMO <sup>1</sup>	FSSAI (Previously GEAC)	<u>FSSAI working on the rules.</u> 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 in category 3 above needs to be completed.	IV, if required	<a href="#">GEAC Form IV</a>
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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.

Source: MoEFCC/GEAC <http://www.geacindia.gov.in/applications.aspx>, FAS New Delhi office research.

### APPENDIX 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 <sup>[1]</sup> The DGFT Notification No. 2 (RE-2006)/2004-2009. <sup>[2]</sup>
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 <a href="http://geacindia.gov.in/india-bch.aspx">http://geacindia.gov.in/india-bch.aspx</a> )
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 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.

[1] See Annex II.

[2] Notification No. 2(RE2006)/2004-2009 “Amendments in Schedule – 1 (Imports) of the ITC(HS) Classifications of Exports and Import Items, 2004-09,” pertaining to the import of GE products is accessible of the Directorate General of Foreign Trade website located at <https://www.dgft.gov.in/CP/?opt=notification>. To access the archived notification, in the notification search engine type in year “2006.” In the following “Search Notifications/Public Notice/Circular/Trade Notice” page, type in the search engine box for “number” 2(RE2006)/2004-2009.

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

[4] <http://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme>

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

Source: MOEFCC, India industry sources, FAS New Delhi office research.

#### **APPENDIX IV: FAS New Delhi Issued GAIN-INDIA Biotech Reports**

1	GAIN-INDIA   <a href="#">IN2023-0082</a>   FAIRS Export Certificate Report Annual-2023
2	GAIN-INDIA   <a href="#">IN2023-0086</a>   FAIRS Annual Country Report Annual- 2023

#### **Attachments:**

No Attachments