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## **India**

### **Agricultural Biotechnology Annual**

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**Report Highlights:**

Bt cotton is currently the only commercially approved biotech crop in India. Over the last ten years, six events and more than 1100 Bt hybrids have been approved for commercial cultivation. As a result, India has emerged as the second largest producer and exporter of cotton in the world. In 2010, the Government of India (GOI) announced a moratorium on the approval process for Bt *brinjal* (eggplant). Since then there has been no movement in resuming the approval process. Research has also been hampered by a new Genetic Engineering Appraisal Committee directive which requires applicants to obtain a "No Objection Certificate (NOC)" from the relevant state authority before commencing biotech field crop trials. On May 10, 2012, the Supreme Court of India instituted a six-member Technical Expert Committee to review and recommend biosafety risk assessment studies for genetically modified (GM) crops.

## Section I. Executive Summary:

Agricultural trade between the United States and India reached \$3.4 billion in calendar year (CY) 2011. U.S. exports to India amounted to \$723 million, while U.S. imports from India reached \$2.68 billion, skewing the agricultural trade balance nearly 4 to 1 in India's favor. India's agricultural exports to the U.S. include guar gum, shrimp, cashew nuts, spices, tea, essential oils, rice, vegetable oil and processed fruits & vegetables. U.S. agricultural exports to India include tree nuts, soybean oil, fresh fruits, cotton, pulses and forest products.

The 1986 Environmental Protection Act (EPA) lays the foundation for India's biotechnology regulatory framework (see Annex 1). The Indian biotech regulatory system adopts a precautionary approach for the biosafety assessment of food and agricultural products. Annex 2 of the EPA outlines the procedures for importing biotech products, including products used for research.

Under current Indian regulations, all biotech food/agricultural products or products derived from biotech plants/organisms must receive formal approval from the Genetic Engineering Appraisal Committee prior to commercialization or imports (the GEAC is India's apex biotech regulatory body). Soybean oil derived from Round-up Ready soybeans is the only biotech food/agricultural product currently approved for import. In CY 2010, U.S. soybean oil exports to India were estimated at a record \$132 million, but declined sharply in CY 2011 to \$94,000 due to market conditions.

In November 2007, the Government of India (GOI) introduced a National Biotech Development Strategy, outlining a plan to set up an independent and autonomous national biotech regulatory authority that would provide a single window mechanism for biosafety clearance of genetically engineered products and processes. The Department of Biotechnology (DBT) under the Ministry of Science and Technology (MST) has the responsibility to establish and operationalize the new Biotechnology Regulatory Authority of India (BRAI). After a consultative process involving interdisciplinary and inter-ministerial experts, state governments and other stakeholders, the DBT submitted a draft BRAI bill 2012 for parliamentary approval. Pending action by the Indian Parliament, the existing regulatory framework will continue to oversee biotechnology regulation.

Bt cotton is the only biotech crop currently approved for commercial cultivation in India. Since 2002, the GOI has approved six Bt cotton events and more than 1100 Bt cotton hybrids for commercial cultivation. In October 2009, the GEAC recommended the approval of commercial cultivation of Bt *brinjal* (eggplant). However, on February 9, 2010, following a series of public consultations, the Ministry of Environment and Forest (MoEF) announced a moratorium on the approval of Bt eggplant until the regulatory system could ensure food and environmental safety. More than two years have passed since the moratorium announcement, but there has been little progress on either biosafety assessment or approval of Bt eggplant.

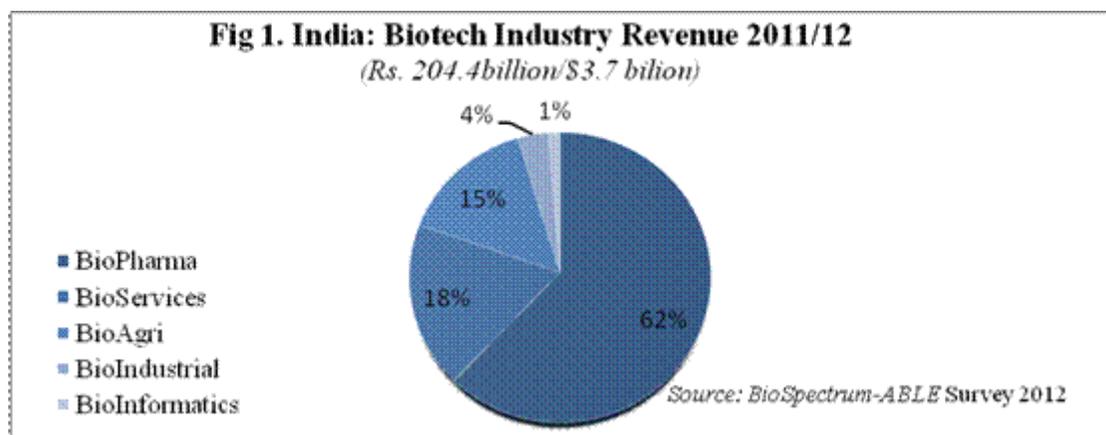
On July 6, 2011, the GEAC introduced new procedures for authorizing biotech crop field trials, requiring applicants (technology developers) to obtain a "no objection certificate (NOC)" from the relevant state government. The GEAC decision has hampered ongoing field trials as only a few states have issued NOCs.

On May 10, 2012, the Supreme Court of India instituted a six-member Technical Expert Committee to

review and recommend biosafety risk assessment studies for genetically modified (GM) crops. The Technical Expert Committee was given two months to develop recommendations that may affect the current/existing biotech regulatory system/processes.

## Section II. Plant Biotechnology Trade and Production:

Based solely on the success of Bt cotton, agricultural biotechnology is one of the fastest growing segments of the Indian biotech industry. With approximately 64 seed companies selling Bt cotton hybrid seeds across various agro-climatic zones, agricultural biotechnology is the third largest component in India's domestic biotech industry, accounting for 15 percent of the industry's total revenues of Rs. 30.5 billion (\$545 million) in FY 2011/12 (April-March). While over the past five years the revenue share of agricultural biotechnology has grown from less than five percent to 15 percent, this growth rate is slowing due to an overdependence on Bt cotton. With close to 90 percent of cotton farmers already having adopted Bt cotton, there is limited scope for growth in coming years.



Since its introduction in 2002, India's Bt cotton area has grown to over 90 percent of the total cotton area, accounting for over 95 percent of cotton production in 2011. As a result, India has emerged as the second largest producer and exporter of cotton in the world. To date, the GOI has approved six cotton events and more than 1100 hybrids for cultivation in different agro-climatic zones. Most of the approved Bt cotton hybrids are produced from two Monsanto events (Mon 531 and Mon 15985). Other approved events include the GFM event (developed by Nath Seeds) sourced from China and the locally developed Event 1 (J.K. AgriGenetics), Event MLS-9124 (Metahelix Life Sciences) and Event BNLA-601 (Central Institute of Cotton Research and University of Agriculture Sciences).

In addition to cotton, several Indian seed companies and public sector research institutions are working on the development of various biotech crops, mainly for pest resistance, herbicide tolerance, nutritional enhancement, drought tolerance and yield enhancement. The crops currently being developed by public sector institutions include banana, cabbage, cassava, cauliflower, chickpea, cotton, eggplant, rapeseed/mustard, papaya, pigeon pea, potato, rice, tomato, watermelon and wheat. Indian seed companies are also focusing on cabbage, cauliflower, corn, rapeseed/mustard, okra, pigeon pea, rice and tomato, and next generation technologies (stacked events) for cotton. In 2011, field trials were conducted for castor bean, cotton, corn, rice, mustard, peanut, potato, and sorghum.

On October 14, 2009, the GEAC recommended the approval of commercial cultivation of Bt *brinjal* (eggplant), which was forwarded to the MoEF for a final decision. The Ministry of Environment and Forest (MoEF) subsequently held a series of public consultations on the approval of Bt eggplant, and on February 9, 2010, announced a moratorium on the approval until the government regulatory system could ensure human and environmental safety through long term studies. On April 27, 2011, the [GEAC held a consultation](#) with experts and scientists on the regulatory process for genetically modified crops. The GEAC has, however, deferred its decision, and as a result more than two years have now passed without a clear indication of next steps or additional studies that need to be undertaken for the approval of Bt egg plant.

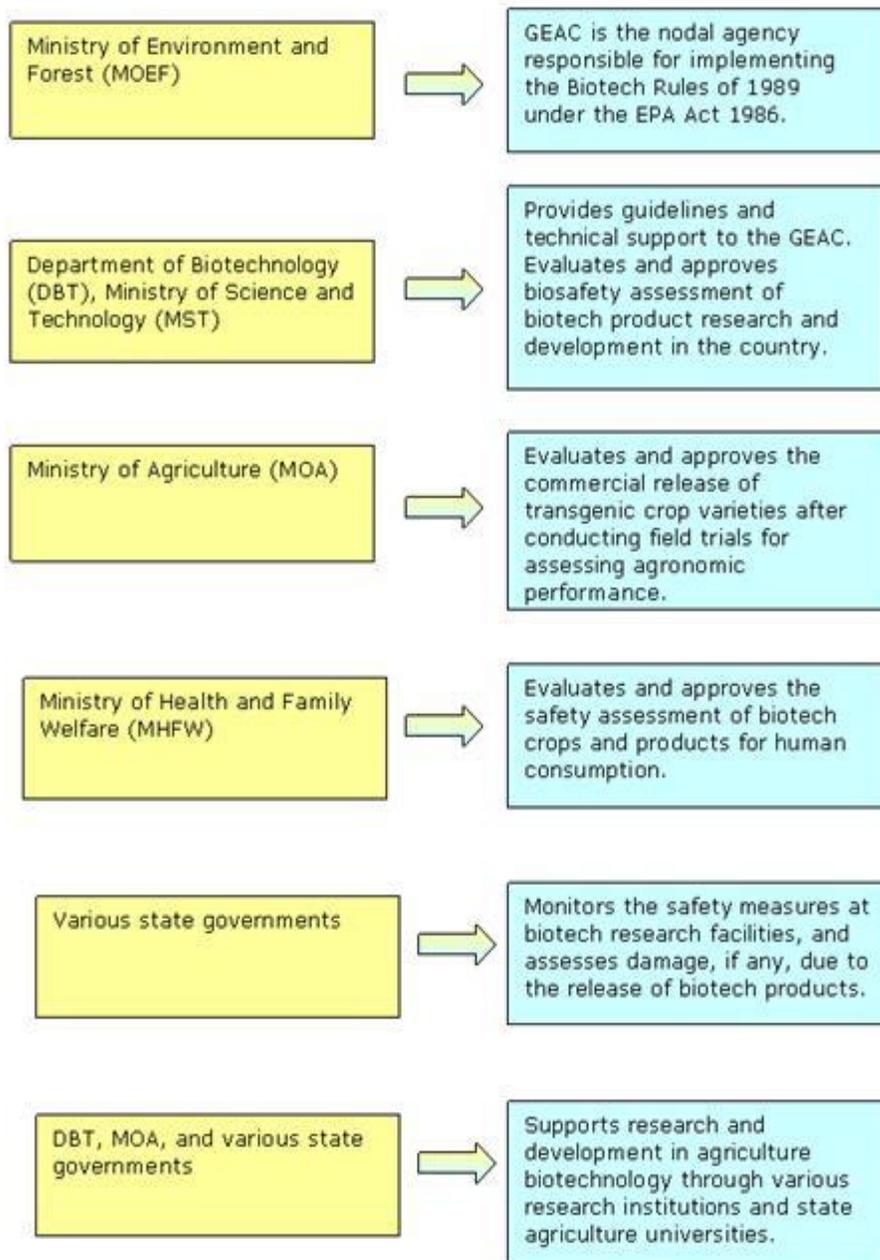
The only biotech food product currently authorized for import into India is soybean oil derived from glyphosate-tolerant soybeans. India has imported soybean oil from several countries, including Brazil, Argentina and the United States. India exports biotech cotton and cottonseed meal, but does not export any significant quantity of cotton or cottonseed meal to the United States.

### **Section III. Plant Biotechnology Policy:**

#### **Regulatory Framework**

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

#### **Role of Various Ministries/State Governments:**



In 1990, the Department of Biotechnology (DBT), in the Ministry of Science and Technology developed Recombinant DNA Guidelines, which were subsequently amended in 1994. In 1998, the

DBT issued separate guidelines for biotech plant research, including the import and shipment of biotech plants for research use. In 2008, the GEAC adopted “Guidelines and Standard Operating Procedures for the Conduct of Confined Field Trials.” The GEAC also adopted new “Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants” All guidelines and protocols, including the EPA Act of 1986 and the 1989 Rules are available online at <http://dbtbiosafety.nic.in/>.

### **Status of the Proposed Biotechnology Regulatory Authority**

On November 13, 2007, the Ministry of Science and Technology unveiled a “National Biotechnology Strategy” to strengthen the regulatory framework, instituting a National Biotech Regulatory Authority (NBRA) that would provide a single window mechanism for biosafety clearance. In 2008, the DBT issued a draft “National Biotechnology Regulatory Bill,” together with a draft “Establishment Plan for Setting up the National Biotechnology Regulatory Authority.” Following inter-ministerial consultations with different stakeholders, the DBT subsequently drafted a revised “Biotechnology Regulatory Authority of India Bill 2012” (BRAI), which has now been submitted to the Parliament of India for approval. Pending parliamentary approval of the BRAI, India’s regulatory mechanisms continue to be governed by the EPA 1986 and the Rules of 1989.

### **Field Testing of Biotech Crops**

The GEAC is ultimately responsible for approving all field trials. In 2008, the GEAC adopted an “event based” approval system, reviewing the efficacy of the event/trait, and focusing on biosafety, particularly on environmental and health safety. Before any biotech event can be approved for commercial use, it must undergo extensive agronomic evaluation through field trials under the supervision of an Indian Council of Agricultural Research (ICAR) institution or a state agriculture university (SAU) for at least two crop seasons. Product developers can also conduct agronomic trials in conjunction with the biosafety trials, or can also do so separately after the GEAC recommends environmental clearance and the GOI gives final authorization. For approval purposes, a stacked event, even if consisting of already approved events, is essentially treated as a new event.

The GOI does not have any specific regulations on coexistence between biotech and non-biotech crops. On January 10, 2007, the GEAC decided against allowing multi-location biotech field trials in basmati rice growing areas, particularly in the states of Punjab, Haryana and Uttaranchal.

In early 2011, some state governments objected to authorization of biotech crop field trials without state permission. On July 6, 2011, the GEAC amended the procedures for field trial authorization, which now require the applicant (the technology developer) to obtain a “no objection certificate (NOC)” from the relevant state government. Applications that had previously received approval from the GEAC now also require an NOC from the state government before commencing the field trials. Industry sources report that only a few states (Punjab, Haryana, Gujarat and Andhra Pradesh-cotton only) have issued NOCs for biotech field trials. As a result, a number of field trials already approved by the GEAC could not be [conducted in 2011](#). A few states (Maharashtra, Rajasthan, and Delhi National Capital Region) are in the process of developing their own approval system, and could still be in a position to issue NOCs for the 2012 *kharif* season planting.

Once an event is approved for commercial use, the applicant can register and market seeds in various

states according to the provisions of the 2002 National Seed Policy and other relevant seed regulations specific to each state. Following the commercial release of a biotech crop, the the Ministry of Agriculture, together with the various state departments of agriculture, monitor field performance for 3-5 years.

### **Supreme Court Appoints Technical Committee To Review Biosafety Assessment**

On May 10, 2012, the [Supreme Court of India appointed a six-member Technical Expert Committee](#) to review and recommend risk assessment studies (for health and environmental safety) for all bioengineered crops before they can be released for open field trials. The Supreme Court has given the Technical Expert Committee three months to submit a report, which will be discussed in the next case hearing on August 6, 2012. The Supreme Court action is in response to a petition filed in 2005 which alleged that field trials of GM crops were being allowed without proper scientific evaluation of bio-safety concerns. [For more information on the 2005 Supreme Court case, please refer to GAIN report [IN8077](#), page 7].

### **Seed Policy**

India's [seed policy](#), developed by the Ministry of Agriculture in 2002, notes that all biotech crops must be tested for environmental and bio-safety concerns prior to commercial release, per the regulations and guidelines of the EPA 1986. The National Bureau of Plant Genetic Resources (NBPGR) is the designated agency responsible for reviewing and approving the import of biotech seeds for research purposes. Biotech crops must be tested by the Indian Council of Agricultural Research (ICAR) for at least two seasons to determine the agronomic potential. India's seed policy advocates "protection" of transgenic varieties under the [Protection of Plant Variety and Farmers Right Rules, 2003](#).

The [Seeds Act of 1966](#), regulates the quality of certified seeds, while the [1983 Seeds Control Order](#) regulates and licenses the sale of seed, including transgenic seeds. A new seed bill ([http://agricoop.nic.in/seeds/seeds\\_bill.htm](http://agricoop.nic.in/seeds/seeds_bill.htm)) was introduced in December 2004, but the proposed legislation has not received final parliamentary approval.

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 (PPVFRA) was established in 2005, and to date has [notified 57 crops species](#) for registration. The PPVFRA is planning to gradually expand the list of crop species to be notified for registration.

### **Cotton Seed Pricing/Technology Fee**

India does not regulate seed pricing or set technology fees. Seed companies are free to fix seed prices, and a technology provider can set its own technology fees. Nevertheless, several biotech companies have faced seed pricing and technology fee challenges with individual state governments.

In January 2006, the State Government of Andhra Pradesh filed a complaint with the Monopolies and Restrictive Trade Practices Commission (MRTPC) contending that the technology fees were too high. The MRTPC asked the technology provider to review technology fees, and urged a more modest pricing structure for sales to farmers. Following the MRTPC order, the Andhra state government issued a

directive to all biotech seed companies not to price Bt cotton seeds above Rs. 750 per packet (450 gm Bt seeds and 150 gm non-Bt seeds). Subsequently, several other state governments issued similar orders. The pricing order directives have been challenged in the Supreme Court, and these cases are still pending.

## **Food Policy**

On August 24, 2006, the GOI enacted an integrated food law, namely the “Food Safety and Standards Act of 2006”, which has specific provisions to regulate genetically engineered food products, including processed foods. Under the Act, the Food Safety and Standard Authority of India (FSSAI) has been entrusted as the single authority responsible for establishing and implementing science-based standards for food, and align these with international standards.

On August 23, 2007, the [MoEF issued a notification](#) stating that processed food products derived from genetically engineered products (where the end-product is not an LMO - a living modified organism) do not require approval from GEAC for production, marketing, import and use in India. As processed food products are not replicated in the environment, they are not considered to be an environmental safety concern under the 1989 EPA. However, imports of products that are LMOs continue to be under the purview of GEAC and the 1986 EPA.

As FSSAI does not have specific regulations for biotech food products, the Ministry of Health and Family Welfare (MHFW) has requested that the GEAC continue to regulate processed food products (containing biotech ingredients) under the 1989 Rules. Thus, the MoEF notification on processed food products has been deferred and the GEAC continues to regulate imports of processed biotech food products. On May 21, 2010, the FSSAI circulated a “Draft on Operationalizing the Regulation of Genetically Modified Foods in India.” Stakeholders have been invited to comment. (See GAIN report [IN1044](#)). However until new regulations are in place, the 1986 EPA remains cornerstone of India’s biotech regulatory system.

In March 2006, the Ministry of Health and Family Welfare issued a draft amendment to the 1955 Prevention of Food Adulteration (PFA) Rules, extending a labeling requirement to “Genetically Modified foods” (For more information on the proposed regulation, refer to GAIN reports [IN6024](#) and [IN6060](#)). While the draft amendment has not been finalized, the FSSAI has been consulting with various stakeholders to consider options under the new Food Safety and Standard Act.

On June 5, 2012, the Department of Consumer Affairs (DCA), Ministry of Consumer Affairs, Food and Public Distribution, issued notification G.S.R. 427 (E) amending the [Legal Metrology \(Packaged Commodities\) Rules, 2011](#), effective January 1, 2013, which stipulates “every package containing genetically modified food shall bear at the top of its principal display panel the word “GM.” Sources report that the DCA did not conduct prior consultations with other government agencies or domestic stakeholders before introducing the notification. As the FSSAI is still in the process of establishing labeling regulations for GM foods, the future status of the DCA GM labeling regulation remains uncertain (see GAIN report [IN2078](#)).

## **Cartagena Protocol and Other International Agreements**

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

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

### **Trade Policy**

In 2006, the MOEF published the [Procedure for GEAC Clearance for Imports of GM Products](#). The specific procedure for filing an import application for a biotech product is found in Annex 2 of this report.

On July 8, 2006, the Ministry of Commerce and Industries issued a [notification](#) specifying that all imports containing biotech products must have prior approval from the GEAC. This directive requires a biotech declaration at the time of import. On June 22, 2007, the GEAC gave a permanent approval for importation of soybean oil derived from glyphosate-tolerant soybeans for consumption after refining. No other biotech food products, bulk grain, semi-processed or processed food are authorized for import.

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

### **Section IV. Plant Biotechnology Marketing Issues:**

Bt cotton is currently the only biotech crop authorized for marketing in India. There are no restrictions in marketing domestically produced biotech cottonseed oil and meal. Imported soybean oil is also authorized for domestic marketing without any restrictions or labeling requirements.

### **Section VI. Animal Biotechnology:**

Animal biotechnology is very much at an infancy stage in India. Most of the research work focuses on the genomics of important livestock, poultry and fish species, which can be subsequently adopted into breeding programs for important traits - production (milk/meat), reproductive, drought/heat tolerance and pest/disease resistance. Research is generally conducted by public sector research organizations like ICAR institutions, Council of Scientific and Industrial Research (CSIR) institutions, SAUs, and other research organizations supported by DBT.

Currently, no animal products derived from genetically engineered animals are in commercial

production, nor has there been any request for regulatory approval for commercial production. The EPA 1986 governs the development, commercial use and /or import of genetically engineered animals and products.

**Section VII. Author Defined:**

**Annex 1: Existing Biotech Regulatory Authorities – Function/Composition**

<b>Committee</b>	<b>Members</b>	<b>Functions</b>
Genetic Engineering Appraisal Committee (GEAC); functions under Ministry of Environment and Forests (MOEF).	Chairman-Additional Secretary, Ministry of Environment and Forests (MOEF) Co-Chairman - Nominee of Department of Biotechnology (DBT) Members: Representatives of concerned agencies and departments namely Ministry of Industrial Development, DBT, and the Department of Atomic Energy Expert members: Director General-ICAR, Director General-ICMR; Director General-CSIR; Director General of Health Services; Plant Protection Adviser; Directorate of Plant Protection; Quarantine and storage; Chairman, Central Pollution Control Board; and few outside experts in individual capacity. Member Secretary: An official from the MOEF	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 GM rules under EPA, 1986.
Review Committee on Genetic Manipulation (RCGM); function under Department of Biotechnology (DBT).	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 GM 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 GM research projects. Scrutinize applications made to the GEAC for the import of bioengineered products. Form Monitoring and Evaluation Committee for biotech crop research projects. Appoint sub-groups when required in topics of interest to the committee.
Recombinant DNA Advisory Committee (RDAC); function under DBT	Scientists from DBT and other public sector research institutions	Take note of developments in biotechnology at the national and international level. Prepare suitable guidelines for safety in research and applications of GMOs. Prepare other guidelines as may be required by the GEAC.
Monitoring Cum Evaluation Committee (MEC)	Experts from ICAR institutes, State Agricultural Universities (SAUs) and other agricultural/crop research institutions and representatives from DBT.	Monitor and evaluates trial sites, analyze data, inspect facilities and recommend safe and agronomically viable transgenic crops/plants for approval to RCGM/GEAC

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

Source: Department of Biotechnology (DBT) and Ministry of Environment and Forest (MOEF), GOI.

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

Item	APPROVAL ACCORDING AGENCY	GOVERNING RULES	FORM NO.	LINKS FOR DOWNLOADING
GMOs / LMOs for R&D	IBSC/RCGM/ NBPGR	Rules 1989; Biosafety guidelines of 1990 and 1998; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; and Guidelines for the import of germplasm, 2004 by NBPGR	I	<a href="#">GEAC Form I</a>
GMOs / LMOs for intentional release (including field trials)	IBSC/RCGM/ GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	<a href="#">GEAC Form II B</a>
GM food /feed as LMOs per se	GEAC	Provide biosafety & food safety studies, Compliance with the Rules 1989 and Biosafety guidelines of 1990 & 1998	III	<a href="#">GEAC Form III</a>
GM processed food derived from LMOs	GEAC	One time “event based” approval given based on importer providing the following information:	IV	<a href="#">GEAC Form IV</a>

		<p>i. List of genes/events approved in the crop species for commercial production in the country of export/country of origin;</p> <p>ii. Approval of the product for consumption in countries other than producing countries;</p> <p>iii. Food safety study conducted in the country of origin;</p> <p>iv. Analytical/compositional report from the country of export/origin;</p> <p>v. Details on further processing envisaged after import;</p> <p>vi. Details on commercial production, marketing and use for feed/food in the country of export/origin;</p> <p>vii. Details on the approval of genes / events from which the product is derived</p>		
Processed food containing ingredients derived from GMO	GEAC	If the processed food contains any ingredient derived from category 2 and 3 mentioned above, and if the LMO / product thereof has been approved by the GEAC, no further approval is required except for declaration at the port of entry. In case it does not have the approval of GEAC, the procedure mentioned in category 3 above to be complied.	IV , if required	<a href="#">GEAC Form IV B</a>

Source: MOEF Website [http://www.envfor.nic.in/divisions/csurv/geac/gmo\\_lmo.htm](http://www.envfor.nic.in/divisions/csurv/geac/gmo_lmo.htm)

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

Article	Provisions	Present Status
Article 7	Application of the Advanced Informed Agreement procedure prior to the first transboundary 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 transboundary movement of LMOs that falls within the scope of Article 7	Rules 1989 and competent authorities in place.
Article 9	Acknowledgement of receipt of notification-The Party of import shall acknowledge receipt of the notification, in writing to the notifier	Point of contact notified, the regulatory body (GEAC) in place
Article 10	Decision Procedure-Decision taken by the Party of import shall be in accordance with Article 15	Regulatory body (GEAC) in place
Article 11	Procedure for LMOs intended for direct use as food or feed, or for processing	1989 Rules <sup>[1]</sup> , DGFT Notification No. 2(RE-2006) / 2004-2009 <sup>[2]</sup>
Article 13	Simplified Procedure to ensure the safe intentional transboundary 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	Unintentional transboundary movements and emergency	1989 rules

17	measures	
Article 18	Handling, transport, packaging and identification	1989 Rules, guidelines to be developed
Article 19	Competent National Authorities and National Focal Point	Ministry of Environment and Forests designated as competent authority and national focal point
Article 20	Information sharing and the Biosafety Clearing House	Biosafety Clearing House ( <a href="http://www.indbch.nic.in">http://www.indbch.nic.in</a> ) has been set up.
Article 21	Confidential information	--
Article 22	Capacity building	Ongoing capacity building activities by DBT, MOEF, USTDA and USAID-sponsored SABP
Article 23	Public awareness and participation	Ongoing, MOEF and DBT have specific websites on biotech developments and regulatory system including website of IGMORIS <sup>[3]</sup> , GEAC <sup>[4]</sup> , DBT Biosafety <sup>[5]</sup> , etc
Article 24	Non-Parties (transboundary movements of LMOs between Parties and non-Parties)	1989 rules in place for all import and export
Article 25	Illegal transboundary movements	--
Article 26	Socio-economic considerations	Socioeconomic analysis is an integral part of decision making
Article 27	Liability and redress	National Consultation ongoing

Source: MOEF and Industry Sources.

<sup>[1]</sup> See Annex 2

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

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

<sup>[4]</sup> [http://www.envfor.nic.in/divisions/csurv/geac/geac\\_home.html](http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html)

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