USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 7/24/2009
GAIN Report Number: IN9098

India

AGRICULTURAL BIOTECHNOLOGY ANNUAL

2009

Approved By:
Holly Higgins
Prepared By:
Santosh Singh

Report Highlights:
Bt cotton is the only commercially approved biotech crop in India. The Genetic Engineering Approval Committee (GEAC), India's biotech regulatory body, has granted approval for six Bt cotton events. Over the last seven years, use of Bt cotton has grown to over 87 percent of the total cotton area under cultivation. In December 2008, the GEAC adopted new guidelines for field trials and food safety assessments.

Section I. Executive Summary:

Agricultural trade [1] between the United States and India reached a record $2.1 billion in CY 2008. However, the trade balance continues to remain skewed (3:1) in India's favor. India's major agricultural exports to the U.S. include cashew, spices, essential oils, rice, dairy products, processed fruits & vegetables, vegetable oils, and tea. Major U.S. agricultural exports to India are almonds, cotton, pulses, fresh fruits, and other consumer food products.

India's trade policy requires that imports of all biotech food/agricultural products or products derived from biotech plants/organisms should receive prior approval from the Genetic Engineering Approval Committee (GEAC). Refined soybean oil derived from Round-up Ready soybeans is the only biotech food/agricultural product currently approved for import. During

the first three months of the CY 2009, India imported $34 million of soybean oil from the United States.

The Environmental Protection Act (EPA) of 1986 lays the foundation for India's biotechnology regulatory framework (see Annex 1). The Indian biotech regulatory system adopts a precautionary approach for the assessment of biosafety of food and agricultural products. In December 2008, the GEAC adopted new guidelines for conducting confined field trials and safety assessments of foods derived from biotech plants. The EPA has procedures and formats for imports of biotech products, both for research and commercial release or consumption (See Annex 2).

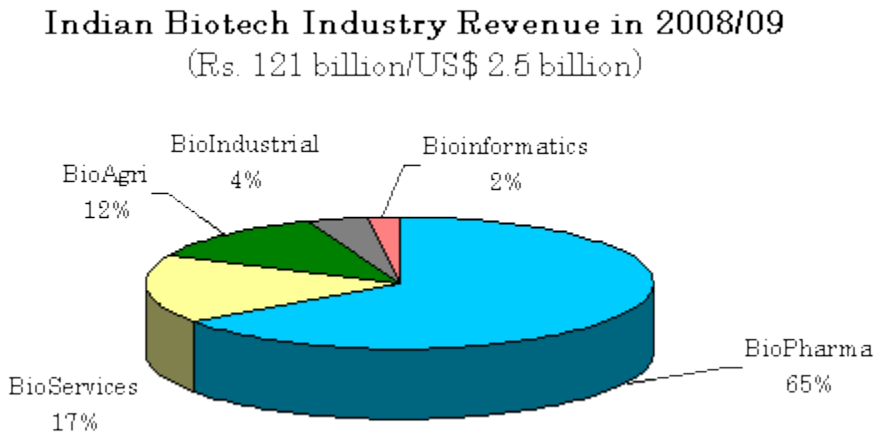
In November 2007, the Government of India released the National Biotech Development Strategy, [2] outlining a plan to set up a national biotech regulatory authority as an independent, autonomous and professionally led body that would provide a single window mechanism for biosafety clearance of genetically engineered products and processes. The Department of Biotechnology (DBT) under Ministry of Science and Technology (MST) has been given the responsibility to establish and operationalize the new Biotechnology Regulatory Authority of India (BRAI). The MST is expected to present a draft BRAI bill for parliamentary approval in 2009. The existing regulatory framework will continue to oversee biotechnology regulations until the BRAI is fully functional.

Bt cotton is the only biotech crop currently approved for commercial cultivation in India. Recently, a new Bt cotton event was approved, bringing the total number of approved events to six. Seed companies and public sector institutes are actively developing various food and non-food biotech crops. However, there are still some unresolved legal issues as various state governments continue to fix Bt cottonseed prices. This is likely to have dampen the prospects for further technology transfer and foreign direct investment in India's biotechnology sector.

[1] Excludes fish and forest products; India's exports to the U.S. estimated at $1.6 billion and U.S. exports to India estimated at $489 million.
[2] http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf

Section II. Biotechnology Trade and Production:

The adoption of Bt cotton has encouraged the development of agricultural biotechnology into one of fastest growing segments of the Indian biotech industry. Agricultural biotechnology is now the third largest sector in the domestic biotech industry, with total revenues of nearly Rs. 15 billion ($318 million) in FY 2008 (April-March), a 24 percent growth over the previous year [1]. Export revenue from agriculture biotechnology has grown to Rs. 610 million in 2008/09, up from Rs. 518 million in 2007/08.



Source: BioSpectrum-ABLE Survey, 2009

Bt cotton is a well-documented success story in Indian agriculture. Since the introduction of Bt cotton in 2002, area under Bt cotton has grown to over 86 percent of the total cotton area in 2008. At the same time, India has also emerged as the second largest producer, and one of the leading world exporters of cotton.

The GEAC has recently granted approval for a new Bt event expressing synthetic cry1Ac gene. This brings the total number of currently approved Bt cotton events to six, with the number of approved hybrids/varieties to 284 [2]. Most of the approved Bt cotton hybrids are from the two Monsanto events that are already approved in the United States. Other approved events include the GFM event sourced from China and the locally developed Event 1, CICR event and Event 9124. For additional information on Bt cotton in India, please refer to the "Cotton Annual Report" (GAIN IN9058).

In addition to cotton, Indian private seed companies and public sector research institutions (government research institutes and state agriculture universities) are working on the development of various biotech crops mainly for traits such as pest resistance, nutritional enhancement, drought tolerance and yield enhancement. The biotech crops 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 [3]. The private sector is focusing on cabbage, cauliflower, cotton, corn, rapeseed/mustard, okra, pigeon pea, rice and tomato. There are several new gene events in nine crops undergoing field trials for regulatory approval [4]. Of these, Bt eggplant, developed by MAHYCO, is expected to reach final approval by the end 2009 or in early 2010. This would be India's first biotech food crop, and the first transgenic eggplant globally.

The only biotech food product currently allowed for importation into India is soybean oil derived from Round-up Ready soybeans. Under the requisite GEAC approval, obtained in 2002, India imports some refined soybean oil from the United States. While India exports biotech cotton and cottonseed meal, biotech has not been a major trade issue. India does not export any significant quantity of cotton or cottonseed meal to the United States.

[1] Growth in US$ terms was only 6 percent due to the sharp appreciation in the value of US$ vis-à-vis Indian Rs. (Rs. 40 in 2007/08 to Rs. 47 in 2008/09).
[2] http://igmoris.nic.in/files/commercially%20released%20varieties%20of%20Bt%20cotton%20hybrids_31.07.08.pdf
[3] International Service for the Acquisition of Agri-biotech Application (ISAAA)

[4] http://igmoris.nic.in/field_trials.asp

Section III. New Technologies:
GENETICALLY ENGINEERED ANIMALS

Research on genetically engineered animals is at an infancy stage in India. Most of the research work is focused on the genomics of important livestock, poultry and fish species, which can be subsequently used in breeding programs [1] 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 there are no animals or products derived from genetically engineered animals in commercial production. The EPA 1986 governs the development, commercial use and /or import of genetically engineered animals or products (see Section IV). There are no separate or specific guidelines for approval, commercialization or import of genetically engineered animals.

[1] Identifying superior animals with required trait and/or development of genetically engineered animals for breeding purpose.

Section IV. Biotechnology Policy:

Regulatory Framework

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

In 1990, the Department of Biotechnology (DBT), in the Ministry of Science and Technology developed Recombinant DNA Guidelines, which were subsequently updated in 1994. Additionally, in 1998, the DBT issued separate guidelines for carrying out research of biotech plants and imports and shipment of biotech plants for research use. On May 28, 2008, the GEAC adopted new "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" The EPA Act of 1986, 1989 Rules, and all guidelines and protocols are available online at http://dbtbiosafety.nic.in/.

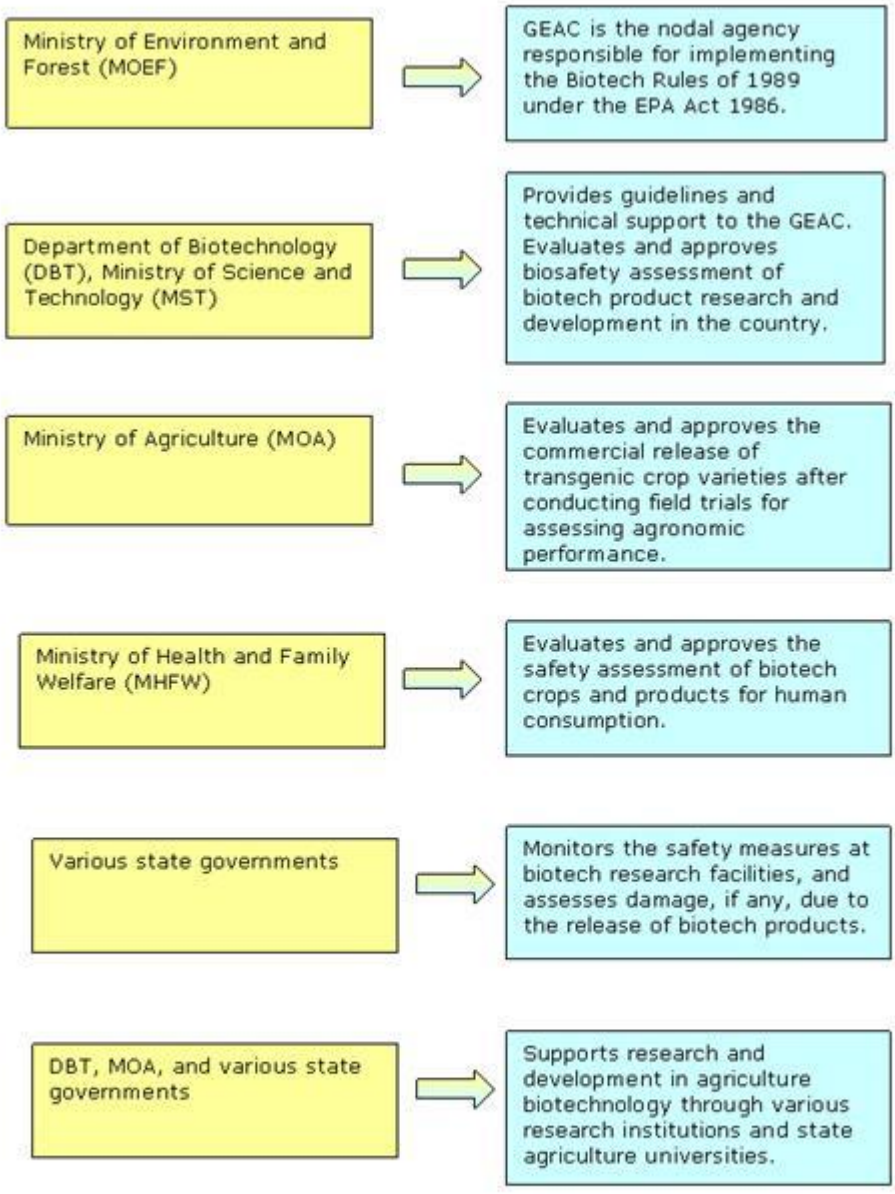
Status of the Proposed Biotechnology Regulatory Authority

On November 13, 2007, the Minister of Science and Technology released the "National Biotechnology Strategy [1] " prepared by the Department of Biotechnology (DBT). One of the cornerstones of the strategy was to reinforce India's biotech regulatory framework by setting up a National Biotech Regulatory Authority (NBRA) that would provide a single window mechanism for biosafety clearance. The DBT was entrusted with the responsibility of setting up the authority.

In May 2008, the DBT issued a draft "National Biotechnology Regulatory Bill" and a draft "Establishment Plan for Setting up the National Biotechnology Regulatory Authority [2] ." Following inter-ministerial consultations with different stakeholders, the DBT subsequently drafted a revised "Biotechnology Regulatory Authority of India Bill [3] ", to be submitted for approval in Parliament. Until the proposed BRAI becomes fully functional, the existing regulatory mechanisms under the EPA 1986 and Rules of 1989 will continue to be in force.

[1] http://dbtindia.nic.in/biotech_strategy.htm
[2] http://igmoris.nic.in/default1.asp
[3] The document is not available in the public domain. While the revised draft bill and establishment plan for setting up the regulatory authority have undergone revisions since May 2008, industry sources report that the basic structure remains largely the same.

Role of Various Ministries/State Governments:



Field Testing of Biotech Crops

In 2008, the GEAC adopted an "event based approval system," wherein the focus of the field testing is on biosafety issues, particularly the environmental and health safety, and efficacy of the event/trait.

The responsibility of the agronomic evaluation is with the National Agricultural Research System consisting of Indian Council of Agricultural Research institutions and state agriculture universities. A stacked event, even if consisting of already approved events, is treated as a new event for approval purposes. The GOI does not have any specific regulations on coexistence between biotech and non-biotech crops.

Due to the various interventions by the Supreme Court of India in an ongoing case against the Government [1] , the GEAC continues to be the authority that gives approval to all field trials. The GOI maintains a policy that the biotech field trials should be conducted in either the applicant's own farm or in the SAU research farm. On January 10, 2007, the GEAC decided not to allow multi-location biotech rice field trials in basmati rice growing areas, especially in the states of Punjab, Haryana and Uttaranchal.

Before any biotech event can be approved for commercial use, it must undergo extensive field trials for agronomic evaluation under the supervision of an ICAR institutions or a state agriculture university for at least two crop seasons Product developers can conduct agronomic trials in conjunction with biosafety trials, or they can conduct separate trials after the GEAC approves environmental clearance. Once an event is approved for commercial use, the applicant can register and market the seeds in various states following the provisions of the National Seed Policy 2002 and the other relevant seed acts specific to a state. Following the commercial release of a biotech crop, the performance in the field is monitored for 3-5 years by the Ministry of Agriculture and by the various state departments of agriculture.

New Procedures for Confined Field Trials: In December 2008, the GEAC implemented the (i) Guidelines and Standard Operating Procedures (SOPs) for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants, 2008 and (ii) Guidelines for Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008.

Under the new guidelines and SOPs, field trials of biotech crops with new gene events are redefined as Biosafety Research Level - BRL–I, and BRL-II. These define the various food and environmental safety studies that must be undertaken at each stage of the process. The guidelines require three years of mandatory field trials for the environmental release of a new event. BRL-I trials are conducted in the first crop season, and can potentially continue into the second crop season. BRL-II trials may begin in the second season, but are typically concluded by the end of the third crop season. RCGM and GEAC also have the authority of recommending additional studies or trials on case by case basis. The new guidelines set out various food safety assessment tests to be undertaken before and during the BRL-I and BRL-II trials. On this basis, the GEAC approves (or denies) the environmental clearance of the particular event (see Annex 5).

New Procedures for Release of Hybrids of Approved Bt Cotton Events: On April 17, 2009, the GEAC issued the new procedures [2] for commercial release of Bt cotton hybrids with the events that have been approved by 2007 or earlier (see Annex 3). The GEAC has set up a Standing Committee which will evaluate the applications for commercial release of Bt cotton hybrids expressing these approved events, and approve commercial release to various state departments of agriculture. Newly approved Bt cotton hybrids will have to follow the same process as those used for commercial release of conventional (non Bt) cotton seeds in a particular state. The new procedures will apply only after a Bt cotton event completes three seasons of commercial cultivation. Until then, the new biotech hybrid or variety is subject to the minimum three years of extensive field trials (including environmental and biosafety trials) to qualify for commercial approval.

Seed Policy

India's Seed Policy [3] issued by the Ministry of Agriculture in 2002, covers seed use issues relating to

transgenic crops. According to the seed policy, all biotech crops must be tested for environmental and bio-safety concerns prior to their commercial release as 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 importation 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 their agronomic potential. The Seed Policy advocates "protection," of transgenic varieties under the Protection of Plant Variety and Farmers Right Rules, 2003 [4] .

The Seeds Act of 1966 [5] , regulates the quality of certified seeds, while the 1983 Seeds Control Order [6] regulates and licenses the sale of seed, including transgenic seeds. A new Seeds Bill (http://agricoop.nic.in/seeds/seeds_bill.htm) was introduced in December 2004, but is still awaiting final approval.

India enacted the Protection of Plant Varieties and Farmers' Rights Act 2001 to protect the new plant varieties, including transgenic. The Protection of Plant Varieties and Farmers' Right Authority (PPVFRA) was established in 2005, which is currently registering 14 notified crops including transgenic cotton hybrids and varieties. 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 have a policy or regulations on seed pricing or technology fees. Seed companies are free to fix seed prices, and a technology provider is free to establish its technology fees. Nevertheless, several biotech cottonseed companies have faced seed pricing and technology fee difficulties with various 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) in the 2006 season. Several other state governments issued similar orders. The pricing order directives have been challenged in the Supreme Court, and while the case is still pending, some observers worry that state government interference in seed pricing could deter investment in new technologies.

Food Policy

On August 24, 2006, the GOI enacted an integrated food law, namely the "Food Safety and Standards Act of 2006." The Act brings all existing food laws under one single authority the Food Safety and Standard Authority of India (FSSAI). FSSAI's mandate is to establish science-based standards for articles of food, and align Indian food standards with international standards. The new FSSAI also has specific provisions to regulate genetically engineered food products, including processed foods. The Indian Ministry of Health and Family Welfare is in the process of finalizing implementation of the Act. [7] However, the existing regulatory system under the EPA 1986 continues to remain in place until the FSSAI completes and implements rules on biotech foods.

On August 23, 2007, the Ministry of Environment and Forests (MOEF) issued a notification 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 [8] . As processed food products are not replicated in the environment, they are not considered to be an environmental safety concern under the 1989 EPA. Processed biotech foods may have health and human safety concerns, and thus should be reviewed under the Food Safety

and Standard Act. However, the MHFW requested GEAC to continue to regulate biotech processed food products under Rules 1989 as the FSSAI do not have any rules in place regarding biotech food products. Thus, GEAC continues to regulate imports of processed biotech food products until the FSSAI takes over the responsibility. The imports of biotech food products that are LMO will continue to be under the purview of GEAC under the EPA 1986.

Food Labeling: In March 2006, the Ministry of Health and Family Welfare issued a draft amendment to the 1955 Prevention of Food Adulteration (PFA) Rules, extending a labeling requirement for "Genetically Modified' foods." [9] Although the draft amendment has not been finalized, the Ministry of Health is consulting with various stakeholders to consider options under the new Food Safety and Standard Act.

Cartagena Protocol and Other International Agreements

India ratified the Cartagena Protocol on Biosafety on January 17, 2003, and has established rules for implementing the provisions of the articles (see Annex 3). A Biosafety Clearing-House (BCH) [10] has been set up within the Ministry of Environment and Forests to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs). The regulatory body, GEAC, has the responsibility of approving trade of biotech products, including seed and food products. India is traditionally a vocal advocate of strict liability and redress related to the trans-boundary movement of LMOs, a position that may lead to some difficulty with the movement of Bt cotton seed to neighboring countries.

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

Trade Policy

In 2006, the Ministry of Environment and Forests published the Procedure for GEAC Clearance for Imports of GM Products [11] . The GOI's Foreign Trade Policy (2004-2009), which took effect on July 8, 2006, specifies that all imports containing biotech products must have prior approval from the GEAC. This policy also requires a biotech declaration at the time of import. [12] On June 22, 2007, the GEAC gave a permanent approval for importation of soybean oil derived from Roundup Ready soybeans for consumption after refining. No other biotech food products, bulk grain, semi-processed or processed, are officially permitted for commercial importation.

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 authorizing authority to issue import permits. A complete text of the order is available at http://agricoop.nic.in/gazette/gazette2003.htm.

[1] See Gain Report India Biotechnology Annual 2008 (IN8077) page 7.
[2] http://www.envfor.nic.in/divisions/csurv/geac/New%20procedure%20under%20EABM.pdf
[3] http://seednet.gov.in/Material/National%20Seed%20Policy,%202002.pdf
[4] http://seednet.gov.in/Material/farmers_right_rule_2003/index.pdf
[5] http://agricoop.nic.in/seedsact.htm
[6] http://agricoop.nic.in/seedsconord.htm
[7] The composition of the FSSAI is available at: http://www.fssai.gov.in/about.html
[8] http://www.envfor.nic.in/divisions/csurv/geac/1519E.pdf
[9] For more information on the proposed regulation, refer our gain reports IN6024 and IN6060.
[10] http://www.indbch.nic.in
[11] http://www.envfor.nic.in/divisions/csurv/geac/gmo_lmo.htm

The procedures and format for filing an import application for a biotech product is detailed in Annex 2.
[12] http://164.100.9.245/exim/2000/not/not06/not0206.htm

Section V. Marketing:

Marketing of biotech crops in India is currently confined to Bt cotton. There are no restrictions in marketing domestically produced biotech cottonseed oil and meal. Imported soybean oil is also authorized for domestic marketing.

Biotechnology Stakeholders*:*

Aside from the exceptional case of Bt cotton, Indian farmers are generally unaware of the potential benefits of biotechnology. Some farmers have expressed their concern over the role of private companies in introducing hybrid seeds that are higher priced and have to be replaced every year. Indian farmers are traditionally used to varietal seeds that have been developed by public sector research institutions, and that are therefore available at reasonable prices and can easily be reused year after year. Export oriented farmers producing crops like basmati rice and soybean are also very concerned that biotech products could adversely affect their ability to export, particularly to markets like the EU.

Within India's scientific community, and among various farm associations, the general public is largely favorably disposed to agricultural biotechnology. While there may be some reservations over the private interests of multinational companies, there is an increasing public awareness of the benefits of herbicide tolerance, insect resistance and drought tolerance. Aggressive anti-biotech campaigns generate a lot of attention in the media, but uninformed opinion and factual distortions fail to persuade many producers and consumers that champion progress and education.

Section VII. Author Defined:

Annex 1: Existing Biotech Regulatory Authorities – Function/Composition

Committee	***Members***	***Functions***
Genetic Engineering Approval 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	Approve 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);	District Collector; Factory Inspector; Pollution Control Board Representative;	Monitor safety regulations in research and production installations.

functions under the district administration where biotech research occurs.	Chief Medical Officer; District Agricultural Officer, Public Health Department Representative; District Microbiologists/Pathologists; Municipal Corporation Commissioner; other experts.	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	www.envfor.nic.in/divisions/csurv/geac/geac_form-I.htm
GMOs / LMOs for intentional release (including field trials)	IBSC/RCGM/ GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	www.envfor.nic.in/divisions/csurv/geac/geac_form-II-B.htm
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	www.envfor.nic.in/divisions/csurv/geac/geac_form-III.htm
GM processed food derived from LMOs	GEAC	One time 'event based' approval given based on importer providing the following information: i. List of genes/events approved in the crop species for commercial production in the country of export/country of origin; ii. Approval of the product for consumption in countries other than producing countries; iii. Food safety study conducted in the country of origin; iv. Analytical/compositional report from the country of export/origin; v. Details on further processing envisaged after import; vi. Details on commercial production, marketing and use for feed/food in the country of export/origin; vii. Details on the approval of genes / events from which the product is derived	IV	www.envfor.nic.in/divisions/csurv/geac/geac_form-IV.htm

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	www.envfor.nic.in/divisions/csurv/geac/geac_form-IV.htm

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

Annex 3: India's Compliance on 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 [1] , DGFT Notification No. 2(RE-2006) / 2004-2009 [2]
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 17	Unintentional transboundary movements and emergency measures	1989 rules
Article 18	Handling, transport, packaging and identification	1989 Rules, guidelines to be developed
Article 19	Competent National Authorities and National Focal Point	Ministry of Environment and Forests designated as competent authority and national focal point

Article 20	Information sharing and the Biosafety Clearing House	Biosafety Clearing House (www.indbch.nic.in) has been set up.
Article 21	Confidential information	--
Article 22	Capacity building	Ongoing capacity building activities by DBT, MOEF, USTDA and USAID-sponsored SABP
Article 23	Public awareness and participation	Ongoing, MOEF and DBT have specific websites on biotech developments and regulatory system including website of IGMORIS [3] , GEAC [4] , DBT Biosafety [5] , etc
Article 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.

[1] See Annex 2

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

[3] http://igmoris.nic.in/

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

[5] http://dbtbiosafety.nic.in/