



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - Public distribution

Date: 8/5/2008

GAIN Report Number: IN8077

India

Biotechnology

Annual

2008

Approved by:

Holly Higgins
U.S. Embassy

Prepared by:

Santosh K. Singh

Report Highlights:

In November 2007, the Government of India released the National Biotech Development Strategy that suggests establishment of a National Biotech Regulatory Authority. Recently, the Genetic Engineering Approval Committee (GEAC) approved new guidelines and protocols for conducting confined field trials and safety assessments of foods derived from biotech plants. The GEAC has also granted approval for a new Bt event that has been introduced for the first time in a varietal background. Area coverage under Bt cotton, the only commercially approved biotech crop, has surged to over 80 percent of total cotton area in the last six years. All sections of this report were updated on 7/15/08.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
New Delhi [IN1]
[IN]

Table of Contents

SECTION I: EXECUTIVE SUMMARY 3
SECTION II: BIOTECH PRODUCTION AND TRADE 3
SECTION III: BIOTECH POLICY 4
 Regulatory Framework..... 4
 GEAC Approves New Guidelines for Trials on Biotech Crops..... 5
 Field Testing of Biotech Crops 6
 Seed Policy..... 8
 Technology Fees 8
 Food Policy..... 9
 Trade Policy..... 9
 Cartagena Protocol 10
SECTION IV: MARKETING ISSUES 11
 Biotechnology Stakeholders 11
SECTION V: CAPACITY BUILDING AND OUTREACH 12

SECTION I: EXECUTIVE SUMMARY

Agricultural trade¹ between the United States and India reached a record \$1.6 billion in CY 2007, although the trade balance is 2.4:1 in India's favor. India's major agricultural exports to the U.S. include cashew, spices, processed horticultural products, dairy products, rice, tea and castor oil. Major U.S. agricultural exports to India are almonds, cotton, pulses, fresh fruits, processed horticultural products, and other consumer food products. India's trade policy stipulates that imports of all biotech food/agricultural products or products derived from biotech plants/organisms should receive prior approval from the apex regulatory body, the Genetic Engineering Approval Committee (GEAC). The only biotech food and agricultural product approved for commercial imports thus far is soybean oil derived from Round-up Ready soybeans for consumption after refining.

The Environmental Protection Act (EPA) of 1986 lays the foundation for India's biotechnology regulatory framework, which involves a hierarchy of monitoring committees (Annex 1). The government has laid out procedures and formats for the import of biotech products, both for research and commercial use (see Annex 2). The regulatory process is still evolving and thus commercialization of biotech crops and events is onerous and time consuming. The regulatory authorities are working towards harmonization of regulations with international standards. Recently, the GEAC approved new guidelines and protocols for conducting confined field trials and safety assessments of foods derived from biotech plants, which will be subsequently notified and implemented. In November 2007, the government released the National Biotech Development Strategy² that seeks to set up a National Biotech Regulatory Authority. Despite recent efforts by regulatory bodies to streamline the process, the biotechnology community feels there is a need for further reforms to facilitate faster growth in the sector.

Bt cotton is the only biotech crop approved for commercial cultivation in India. Recently, a new Bt cotton event was approved for commercial cultivation, taking the total number of approved events to five (see Annex-3). Private seed companies and public sector institutes are actively involved in developing various food and non-food biotech crops in India. Following concerns expressed by Indian rice exporters and farmers over the impact of biotech rice trials on basmati rice exports, the government has decided not to allow open field trials of biotech rice in major basmati rice growing states of north India. The legal issues pertaining to the pricing of Bt cottonseed continue to be unresolved, which is likely to be detrimental to technology transfer and foreign direct investment in India's biotechnology sector.

SECTION II: BIOTECH PRODUCTION AND TRADE

India has emerged as the second largest producer and exporter of cotton in the world, largely due to planting of Bt cotton - a major success story in India's agricultural biotechnology development. The Bt cotton coverage has surged in the last six years to over 80 percent of total cotton area in 2007. On May 2, 2008, the GEAC granted approval to a new Bt event developed by the Central Institute of Cotton Research, and incorporated in a popular cotton variety *Bikaneri Narma*. With this, Bt technology has been for the first time introduced in a varietal background whereby the farmers can save the seeds. As of now, the total number of approved Bt cotton events is five, and the number of approved hybrids/varieties is 263 (Annex 3). 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 and CICR

¹ Excludes fish and forest products; U.S. exports to India estimated at \$475 million and India's exports to the U.S. at \$1.16 billion.

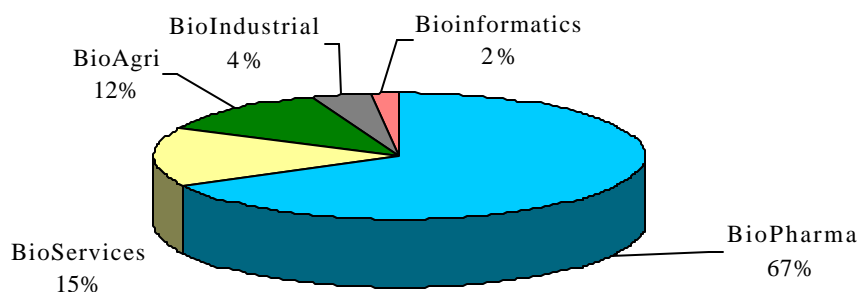
² <http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf>

event. For additional information on India's Bt cotton success story, please refer to the "Cotton Annual Report" (GAIN IN8049).

In addition to cotton, Indian private seed companies and public sector organizations (government research institutes and state agriculture universities) are working on the development of various biotech food crops such as brinjal (eggplant), cabbage, castor, cauliflower, corn, mustard, peanuts, okra, potato, rice, and tomato, mainly for traits such as pest resistance, nutritional enhancement, drought tolerance and yield enhancement (Annex 4 & 5). Industry sources expect Bt eggplant to be approved by 2009, which will be India's first biotech food crop. The other crops are still in the development or field trial stages, and are three to five years away from commercialization.

The only biotech food product allowed for importation into India is soybean oil derived from Round-up Ready soybeans. Although India exports cotton and cottonseed meal, the biotech issue has not come to the forefront. India does not export any significant quantity of cotton or cottonseed meal to the United States. Food aid received by India is now mostly confined to refined soybean oil from the United States under PL 480, Title II for which the requisite GEAC approval was obtained in 2002.

Indian Biotech Industry Revenue in 2007/08 (2.5 billion US\$)



Source: BioSpectrum-ABLE Survey, 2008

Riding on the success of Bt cotton, agricultural biotechnology has emerged as one of the fastest growing biotech industries in recent years. In addition to cotton, there are over 10 transgenic crops that are in the process of regulatory approval for commercial cultivation. It is the third largest contributor among various biotech sectors, with total revenues of more than \$300 million in Indian fiscal year 2007/08 (April-March), registering growth of 30 percent over last year. Export revenue from agriculture biotechnology has grown to \$13 million in 2007/08 from \$11.6 million in 2006/07.

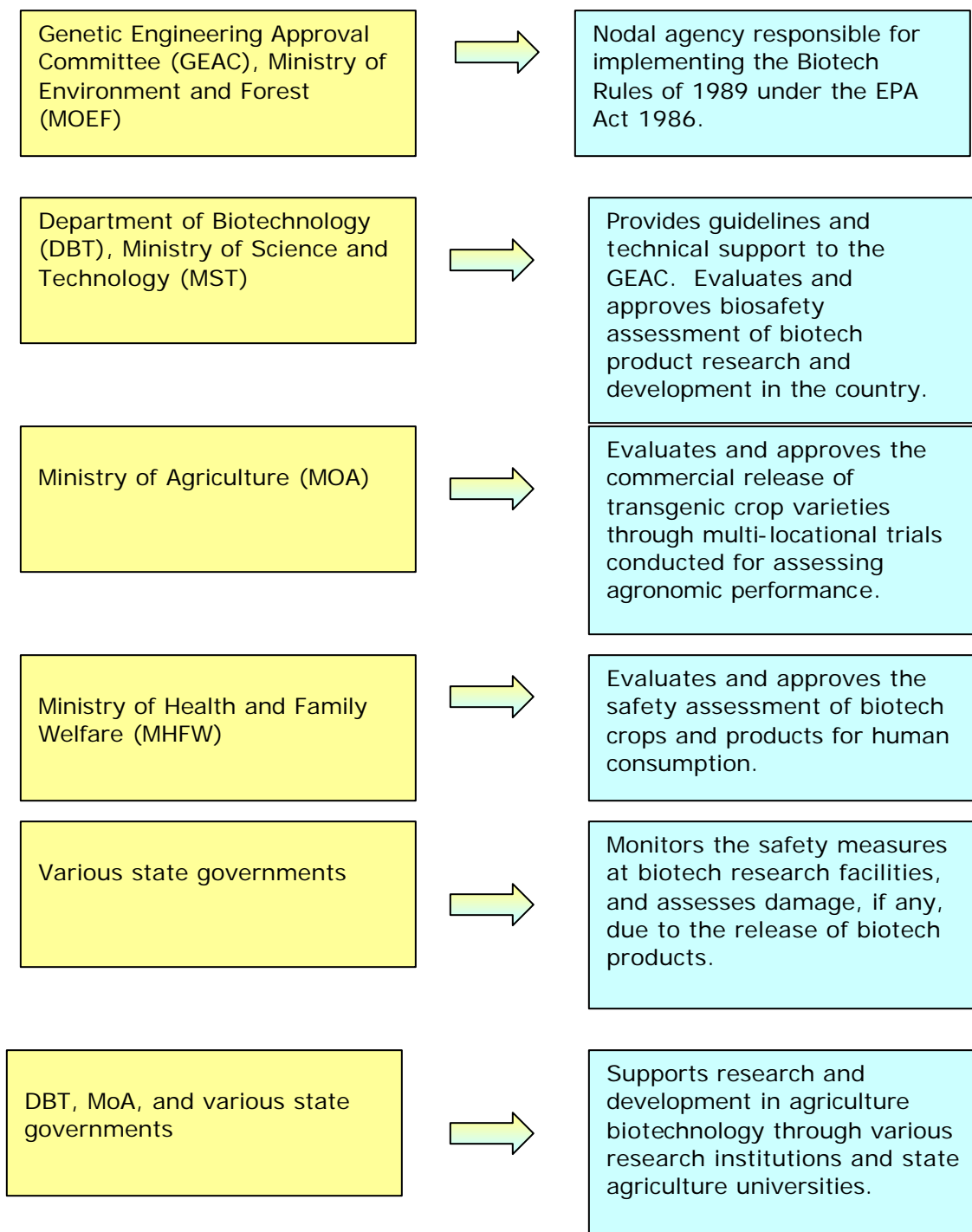
SECTION III: BIOTECH POLICY

Regulatory Framework

The regulatory framework for biotech crops 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, 1986. These rules cover areas of research, development, large-scale use, and imports of biotech organisms and their products, and have identified six competent

authorities for handling these tasks (Annex 1). In 1990, the Department of Biotechnology (DBT), in the Ministry of Science and Technology formulated Recombinant DNA Guidelines that were further 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. The EPA Act of 1986, 1989 Rules, and all guidelines are available online at <http://dbtbiosafety.nic.in/>

Role of Various Ministries/State Governments:



GEAC Approves New Guidelines for Trials on Biotech Crops

On May 28, 2008, the GEAC approved the draft guidelines³ and standard operating procedures⁴ for the conduct of confined field trials, and draft guidelines⁵ for safety assessment of toxicity and assessment of toxicity and allergenicity of genetically engineered crops prepared by the DBT.

The GEAC also approved the draft Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants prepared by the Indian Council of Medical Research (ICMR). The ICMR, in its capacity as the scientific and technical advisory body to the MHFW, formulated the guidelines taking into consideration 'International Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC 2003b)'. These new guidelines, SOPs and protocols will be incorporated in the guidelines for research in transgenic crops. The changes do not have any direct trade implications as they are applicable to research on transgenic crops.

GOI Initiates Steps to Establish National Biotech Regulatory Authority

In 2005, the Task Force on "Application of Agriculture Biotechnology" set up by the Ministry of Agriculture (MoA) under the Chairmanship of India's leading agricultural scientist, Dr. M.S. Swaminathan suggested setting up an autonomous National Biotech Regulatory Authority (<http://agricoop.nic.in/TaskForce/tf.htm>). On November 13, 2007, the Minister of Science and Technology released the "National Biotechnology Strategy" prepared by the Department of Biotechnology (DBT). One of the cornerstones of the strategy is 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 of biotech products and processes. The DBT was entrusted with the responsibility of setting up the authority, which will require promulgation of a new law.

On May 27, 2008, the DBT issued the "Draft National Biotechnology Regulatory Bill, 2008" and "Draft Establishment Plan for Setting up of National Biotechnology Regulatory Authority" for public comments⁶. The DBT has meanwhile organized a series of national consultations on the two drafts with stakeholders. After the comment period, DBT will review the two drafts, and present the 'National Biotechnology Regulatory Bill, 2008 in the Parliament for approval. The proposed bill will be enacted after parliamentary approval, and the DBT will subsequently initiate steps for setting up the NBRA. However, this process of setting up of the NBRA and the rule making process may take a few years. Until the proposed NBRA is fully functional, the existing regulatory mechanism under the EPA 1986 and Rules of 1989 will continue to be in force.

Field Testing of Biotech Crops

The Rules for the Manufacture, Use/Import/Export and Storage of hazardous Microorganisms/Genetically Engineered Organism or Cell, 1989, describe procedures for government approval of biotechnology crops as shown in Annex 6. The Review Committee on Genetic Manipulation (RCGM) has the authority to give approval for contained field trials (Green House, Strip Field, Multi-location, etc) whereas GEAC has the authority to give approval for large-scale field trials. The state agricultural universities (SAUs) and state agricultural departments are responsible for the pre-release and post-release field monitoring

³ http://igmoris.nic.in/field_trials_guidelines/cft_guidance_23mar08.pdf

⁴ http://igmoris.nic.in/field_trials_guidelines/SOP.htm

⁵ <http://igmoris.nic.in/Copy%20of%20Protocols9.htm>

⁶ <http://igmoris.nic.in/default1.asp>

of biotech crops. A stacked event, even if consisting of already approved events, is treated as a new event for approval purposes.

Recently, the GEAC decided to follow an 'event based' process instead of the 'case-by-case' process for the approval of new hybrids derived from all the five approved Bt cotton events⁷. However, the present system will continue until the new procedure is formally notified⁸. Under the event based process, all new Bt hybrid and variety seed with any of the five approved Bt events requires only a one-year trial to receive GEAC clearance, mainly to test the agronomic trait value and to confirm the presence of the gene. Under the earlier 'case-by-case' process, a biotech hybrid or variety had to undergo a minimum of three years of extensive field trials (including environmental and biosafety trials) to qualify for approval.

Interventions by the Supreme Court in GM Crop Field Trials: In 2005, a case went to the Supreme Court with a petition against the government alleging that sufficient bio-safety precautions are not being taken while allowing and conducting field trials.

- On May 1, 2006, the Supreme Court of India instructed the GOI that approval of all field trials (contained and large-scale) should be approved by the GEAC instead of RCGM.
- On September 22, 2006, the court asked the GEAC to withhold new approvals of field trials of biotech crops and events until further notice. However, ongoing field trials that were approved by GEAC before September 22, 2006 were allowed to continue.
- On May 8, 2007, the court allowed the GEAC to approve the commercial release of hybrids of the already approved four Bt cotton events, and field trials of new biotech crops/events to be conducted under specified new conditions⁹.
- On February 13, 2008, the court ruled that the GEAC is permitted to consider applications for any open field trials of GM crops in accordance with the law (EPA 1986 and Rules 1989) and take an appropriate decision after considering all aspects including biosafety aspects¹⁰.

Subsequent to the May 2007 Supreme Court ruling, GEAC had given approval to several new biotech crop/events subject to the specified conditions. The GEAC further stipulated that the biotech field trials should be conducted in either the applicant's own farm or the SAU research farm, and not in a farmer's field. The GEAC formed a committee to review new field trial conditions stipulated by the court order, which recommended that the Supreme Court's condition of isolation distance and the level of detection (LOD) should be removed¹¹. After the February 2008 ruling, GEAC approvals for field trials of new biotech crop/events continued to be subject to the May 2007 conditions. However, GEAC plans to submit the recommendation of the committee to the Supreme Court in the next hearing seeking the removal of the isolation distance and LOD requirements.

Biotech Rice Field Trials Restricted: On January 10, 2007, the GEAC decided not to allow any multi-locational biotech rice field trials in basmati rice growing areas, especially in the states of Punjab, Haryana and Uttaranchal. This was in response to a petition by Indian rice

⁷ Based on the recommendations of the Subcommittee on Bt cotton
http://www.envfor.nic.in/divisions/csurv/geac/mayee_report.pdf

⁸ The GEAC will constitute a committee for (i) drafting a notification empowering the State Department of Agriculture and SAUs to monitor and evaluate Bt cotton hybrids expressing approved events in cotton crop. (ii) drafting the guidelines to be followed by the State Agriculture Departments and SAUs and (iii) drafting the contents of the Affidavit including legal implication in case of non compliance / submission of wrong information.

⁹ (i) Trials to be conducted under the supervision of a designated scientist, (ii) maintain a 200 meter isolation distance, and (iii) approved organization to submit a validated event specific test protocol at a level of detection (LOD) of 0.01 percent. Industry experts believe that the 200 meter isolation distance is unwarranted as this may vary from crop to crop, and validated protocol of 0.01 percent LOD is not followed by any country in the world.

¹⁰ http://www.envfor.nic.in/divisions/csurv/geac/Hon'ble_SC_order_13.2.2008.pdf

¹¹ http://www.envfor.nic.in/divisions/csurv/Sub_Committeeel.pdf

exporters and farmers to the GEAC, who are apprehensive of the negative impact of such trials on India's basmati rice exports. Last year, there were a few isolated incidents of the uprooting of biotech rice crops under field trials in some northern states and Andhra Pradesh by farmers, instigated by anti-biotech activists. The Ministry of Commerce is also supportive of the exporters'/farmers' concerns about biotech rice trials being conducted in basmati growing areas.

Seed Policy

The Seed Policy, 2002¹² issued by the MoA includes issues related to transgenic crops. Accordingly, all biotech crops and varieties should be tested for environmental and bio-safety before their commercial release, in line with the regulations and guidelines of the EPA, 1986. The National Bureau of Plant Genetic Resources (NBPGR) is the designated agency to import 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 trait value. The Seed Policy advocates "protection," of transgenic varieties under the Protection of Plant Variety and Protection Right Rules, 2003¹³. The Seeds Act, 1966¹⁴, regulates the quality of certified seeds and the Seeds Control Order, 1983¹⁵, regulates and licenses the sale of seed, including transgenic seeds.

A new Seeds Bill of 2004 (http://agricoop.nic.in/seeds/seeds_bill.htm) was introduced in the parliament in December 2004, but has not yet been passed. Clause 15 of the draft bill covers specific provisions for the registration of transgenic varieties. Recently, the Cabinet Committee on Economic Affairs (CCEA) approved amendments to the proposed Seed Bill of 2004. The Ministry of Agriculture must present the revised Seed Bill again in the parliament for approval.

Technology Fees

India does not have a policy or regulation regarding 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, Mahyco Monsanto Biotech Limited (MMBL), the major biotech cotton event provider in India, and several other biotech cottonseed companies are currently facing problems from various state governments with regard to seed pricing and technology fees.

In January 2006, the State Government of Andhra Pradesh filed a complaint with the Monopolies and Restrictive Trade Practices Commission (MRTPC) alleging that the technology fee for biotech event Mon 531 (called Bollgard I) charged by MMBL was too high. In May 2006, the MRTPC asked MMBL to review technology fee pricing and make it reasonable for the farmers. Based on the MRTPC order, the Andhra government immediately issued a directive to all biotech seed companies not to price Bollgard I seed at more than Rs. 750 per packet (450 gm Bt seeds and 150 gm non-Bt seeds). Several other state governments also issued similar orders. The MMBL challenged the pricing orders issued by the state governments in the Supreme Court, and the case is still pending.

Meanwhile, Bt cottonseed companies have been forced to sell their Bollgard 1 cottonseed to farmers at below the Rs. 750 per packet price. The MMBL, as the technology provider, is forced to negotiate with 'seed multiplier' companies for technology fees within the ceiling

¹² <http://seednet.gov.in/Material/National%20Seed%20Policy,%202002.pdf>

¹³ http://seednet.gov.in/Material/farmers_right_rule_2003/index.pdf

¹⁴ <http://agricoop.nic.in/seedsact.htm>

¹⁵ <http://agricoop.nic.in/seedsconord.htm>

price of Rs. 750 per packet. Cottonseed companies using the new approved events have also been forced to sell seed around Rs. 750 per packet. Although the Supreme Court ruling is still pending, unwarranted interference by state governments in seed pricing could act as a disincentive to introduce new biotech traits/events into India.

Food Policy

On August 24, 2006, the GOI enacted the integrated food law, namely the "Food Safety and Standards Act, 2006", to bring all existing food laws under one single authority (Food Safety and Standard Authority) that seeks to establish science-based standards for articles of food and align Indian food standards with international standards. The new Act has provisions to regulate genetically engineered food products, including processed products. The MHFW is currently in the process of establishing the Food Safety and Standard Authority, which in turn will initiate the rule making process. It will be a monumental task to integrate under one single authority all existing food laws, rules and orders that are currently being implemented by several ministries and authorities, and it may take one to three years to complete the rule making process.

Food Labeling: On March 10, 2006, the Ministry of Health and Family Welfare issued a draft amendment to the Prevention of Food Adulteration (PFA) Rules, 1955, pertaining to the labeling of 'Genetically Modified' foods¹⁶. Ministry of Health sources report that an expert committee has reviewed the comments submitted by various stakeholders, but the final regulation has been deferred and may be brought under the new Food Safety and Standard Act.

Industry sources are unsure how effective enforcement of the biotech food labeling rule will be when the rule comes into effect, as the country lacks adequate testing facilities for biotech products. The Ministry of Health is focusing on building capacity, but it will take three to five years to develop adequate biotech food testing facilities. Meanwhile, the government may try to ensure compliance through selective sampling and testing of suspected food products. This can lead to increased monitoring of domestic food processors and importers by food inspectors.

India supports mandatory labeling of GM foods in the Codex. From the two options being considered by Codex, India supports the more stringent option that requires declaration of food and food ingredients composed of or containing genetically modified or engineered organisms obtained from modern biotechnology, and food ingredients produced from but not containing genetically modified or engineered organisms. Although the Ministry of Health argues that mandatory GM labeling is for consumer information and choice, there is very little awareness or concern about GM food products among Indian consumers.

Trade Policy

On June 22, 2007, the GEAC approved importation of soybean oil derived from Roundup Ready soybeans for consumption after refining. No other biotech food products are officially permitted for commercial importation or are awaiting approval for import to date.

Effective July 8, 2006, the GOI's Foreign Trade Policy (2004-2009) specified that all imports containing products of modern biotechnology must have prior approval from the GEAC. The policy also made a biotech declaration mandatory¹⁷. The procedures and format for filing clearance applications for the import of biotech products with the GEAC are detailed in Annex

¹⁶ For more information on the proposed regulation, refer our gain reports IN6024 and IN6060.

¹⁷ <http://164.100.9.245/exim/2000/not/not06/not0206.htm>

2. As India is one of the leading importers of vegetable oils, including soybean oil, the government gave a special exemption to commercial imports of soybean oil derived from Roundup Ready soybeans while GEAC reviewed the industry's application for importation. On June 22, 2007, the GEAC gave a permanent approval for importation of soybean oil derived from Roundup Ready soybeans for consumption after refining.

Currently, effective enforcement of the above regulation at the port of entry is limited due to lack of facilities to test biotech products. There are a few labs in the country that have the capability to test biotech products. In the event customs officials suspect that import consignments contain biotech products, they can refer samples for testing to these labs. Thus, the regulation could potentially impact imports of several biotech products including corn, soybean, and corn and soy based processed food products. Although corn is not currently imported due to high world prices, there is future potential due to growing demand from the poultry and starch industries.

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 a living modified organism (LMO), do not require approval from GEAC for production, marketing, importation and use in India¹⁸. Since the processed food products derived from biotech products can not be replicated in the environment, they are not an environmental safety concern under the EPA 1989. Processed biotech food products may have health and human safety concerns, and thus should be reviewed by the MHFW under the Food Safety and Standard Act. However, the MHFW is in the process of establishing the Food Safety and Standard Authority, and currently there are no PFA regulations on approval of biotech food products. Consequently, the MOEF issued a notification in February 2008 wherein the August 2007 notification has been kept in abeyance until September 30, 2008 or until further notification by the MHFW regarding regulation of biotech processed food products¹⁹. Thus, GEAC continues to regulate imports of processed biotech food products until the FSS Authority takes over the responsibility. The imports of biotech food products that are LMO will continue to be under the purview of GEAC.

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

Cartagena Protocol

India ratified the Cartagena Protocol on Biosafety on January 17, 2003, and has established rules in place for implementing the provisions of most of the articles (see Annex 7). A Biosafety Clearing-House (BCH)²⁰ 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 has been a vocal advocate of strict liability and redress related to the trans-boundary movement of LMOs, a position that may expose India to legal repercussions resulting from the movement of Bt cotton seed to its neighboring countries.

¹⁸ <http://www.envfor.nic.in/divisions/csurv/geac/1519E.pdf>

¹⁹ <http://www.envfor.nic.in/divisions/csurv/geac/411.pdf>

²⁰ <http://www.indbch.nic.in>

SECTION IV: MARKETING ISSUES

Current marketing issues relating to biotech crops are confined mainly to Bt cotton, the only biotechnology crop commercially released thus far in India. Monsanto, the pioneer of Bt cottonseed technology in India, and other Bt cottonseed companies are experiencing legal problems regarding the pricing of Bt cottonseed.

Currently, there are no restrictions on the marketing of domestically produced biotech cottonseed oil and meal for consumption. The government also allows the import of soybean oil produced from round up ready soybeans. There are no serious concerns about these biotech products among consumers. However, when the Ministry of Health and Family Welfare begins implementing the proposed biotech food product labeling regulations, some confusion could develop. Consumers may misinterpret that GM identification labels refer to health and safety concerns.

Biotechnology Stakeholders:

Several anti-biotech, environmental and consumer groups have been running aggressive and sustained campaigns against the use of biotechnology crops and products in India. These groups are very active in the mass media, but have limited influence among biotech product producers and consumers.

Given India's stagnating agricultural production, agricultural policy makers and the scientific community in India believe that biotechnology is possibly their most beneficial new tool for tackling the emerging food crisis. India's public sector research system has only recently been able to commercially release one biotech crop event. Most of the biotechnology crop events that have been approved or are under consideration are by private sector and multinational seed companies. Consequently, Indian policy makers and scientists are hesitant in coming out in support of biotechnology in public as that may be construed as favoring the interests of the private sector and multinational biotech companies.

Indian farmers have been generally neutral on the issue of biotechnology due to lack of awareness and absence of any significant biotech crops except cotton. However, in the case of Bt cotton, farmers are generally very appreciative of its benefits. Major concerns of farmers regarding biotech crops are:

- Most biotechnology crops in the pipeline for approval have traits like pest resistance, etc whereas farmers are more interested in traits for yield enhancement.
- All biotech crop events have been introduced in hybrid seeds by private companies, which are higher priced and have to be replaced every year. Indian farmers are used to varietal seeds developed from public sector research that are available at reasonable prices and can be reused.
- Farmers producing exportable crops like basmati rice, soybean, tea, etc have concerns about biotech contamination spoiling their export markets, especially to the E.U. market. India's major industry associations are generally supportive of agricultural biotechnology and biotech crop and food products. Biotech industry associations in India are also proactive and play a key role in liaising with various regulatory bodies and farmers' organizations.

Since biotechnology is a relatively new development, Indian regulators and policymakers are cautious in their approach towards the bio-safety aspect of biotechnology crops and products, and prefer to be very incremental on bio-safety assessment. Recently, the government has been proactive in adopting more rationale regulatory procedures such as moving to 'event-based' approvals, and issuing revised guidelines for confined field trials and safety assessments of food derived from genetically engineered plants, etc. Given the

significance of the biotechnology sector, there will likely be continued intense engagement in the policy process by all stakeholders.

SECTION V: CAPACITY BUILDING AND OUTREACH²¹

Capacity building and outreach activities undertaken by USG agencies have focused on streamlining the Indian regulatory mechanism and creating awareness regarding the safety of biotech foods. Biotechnology is one of the focus areas under the US-India Agricultural Knowledge Initiative (AKI). Post, with active support from the FAS/Biotech team, the Cochran program, and other programs, is actively involved in biotech outreach efforts.

²¹ Also refer IN6060 and IN7062 for information on previous activities.

Annex 1: Biotech Regulatory Authorities – Functions and 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 three 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 of the DBT	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); functions under DBT.	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

<p>Institutional Biosafety Committee (IBC); functions at research institution/ Organization level.</p>	<p>Head of the Institution, Scientists engaged in biotech work, Medical Expert, and Nominee of the Department of Biotechnology</p>	<p>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/transgenes for research purposes. Coordinate with district and state level biotechnology committees.</p>
<p>State Biotechnology Coordination Committee (SBCC); functions under the state government where biotech research occurs.</p>	<p>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.</p>	<p>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.</p>
<p>District-Level Committee (DLC); functions under the district administration where biotech research occurs.</p>	<p>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.</p>	<p>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.</p>

Source: Department of Biotechnology and Ministry of Environment and Forest, GOI.

Annex 2: Application procedure/formats for the import of biotech products
(R&D/contained use, intentional release & biotech food)

Item	APPROVAL ACCORDING AGENCY	GOVERNING RULES	FORM NO.	LINKS FOR DOWNLOADING
Import of GMOs / LMOs for R&D	IBSC/RCGM/NBPGR	Rules 1989 ²² ; Biosafety guidelines of 1990 and 1998 ²³ ; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; and Guidelines for the import of germplasm, 2004 by NBPGR	I	http://www.envfor.nic.in/divisions/cs/urv/geac/geac_for_m-I.htm
Import of GMOs / LMOs for intentional release (including field trials)	IBSC/RCGM/GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	http://www.envfor.nic.in/divisions/cs/urv/geac/geac_for_m-II-B.htm
Import of 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	http://www.envfor.nic.in/divisions/cs/urv/geac/geac_for_m-III.htm
Import of 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	http://www.envfor.nic.in/divisions/cs/urv/geac/geac_for_m-IV.htm

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

²² <http://www.dbtindia.nic.in/policy/rules.html>

²³ <http://www.dbtindia.nic.in/thanks/biosafetymain.html>

Annex 3: Bt Cotton Events/Hybrids Approved for Commercial Cultivation
(As on June 30, 2008)

Year	Gene/Event	No. of Hybrid Varieties
2002	Cry1Ac (Mon 531) ²⁴	3
2003	Cry1Ac (Mon 531)	3
2004	Cry1Ac (Mon 531)	4
2005	Cry1Ac (Mon 531)	20
2006	Cry1Ac (Mon 531)	44
	Cry1Ac & Cry2Ab (Mon 15985) ²⁵	7
	Cry1Ac (Event 1) ²⁶	8
	Cry1Ab and Cry1Ac (GFM Event) ²⁷	3
2007	Cry1Ac (Mon 531)	100
	Cry1Ac & Cry2Ab (Mon 15985)	20
	Cry1Ac (Event 1)	12
	Cry1Ab and Cry1Ac (GFM Event)	6
2008 (until June 30, 2008)	Cry1Ac (Mon 531)	140
	Cry1Ac & Cry2Ab (Mon 15985)	83
	Cry1Ac (Event 1)	18
	Cry1Ab and Cry1Ac (GFM Event)	21
	Cry1Ac ²⁸ (CICR Event)	1

Source: GEAC, MOEF, GOI.

²⁴ Developed by Mahyco Monsanto Biotech Ltd., and sourced from Monsanto.

²⁵ Stacked gene event developed by Mahyco Monsanto Biotech Ltd., and sourced from Monsanto.

²⁶ Developed by J.K. Agri Genetics Seeds Ltd., and sourced from Indian Institute of Tech., Kharagpur,

²⁷ Developed by Nath Seeds, and sourced from China featuring fused genes.

²⁸ Developed by Central Institute of Cotton Research, Nagpur and incorporated in a Bikanari Narma cotton variety.

Annex 4: Transgenic crops Under Development and Field Trials in 2006 & 2007

No.	CROP	INSTITUTE/INDUSTRY	GENE/EVENT
1.	Brinjal	Mahyco, Mumbai Sungro Seeds Ltd., New Delhi Indian Agricultural Research Institute (IARI), New Delhi University of Agric Sciences, Dharwad Tamil Nadu Agric University, Coimbatore	cry1Ac cry1Ac cry1Aa and Cry1Aabc cry1Ac cry1Ac
2.	Cabbage	Nunhems India Pvt Ltd., Gurgaon	cry1Ba and cry1Ca
3.	Castor	Directorate of Oilseeds, Hyderabad	Cry1Aa, and cry1Ec
4.	Cauliflower	Sungro Seeds Ltd, New Delhi Nunhems India Pvt Ltd., Gurgaon	cry1Ac cry1Ba and cry1Ca
5.	Corn	Monsanto, Mumbai	cry1Ab (Mon 810)
6.	Cotton ²⁹	Central Institute of Cotton Research (CICR), Nagpur CICR, Nagpur CICR, Nagpur Deltapine India Seed Pvt Ltd, Hyderabad Dow Agro Science, Mumbai JK Agri Genetics Ltd., Hyderabad Mahyco, Mumbai	cry1Ac cry1Ac, cry1Aa3, cry1F Antisense coat protein, sense coat protein & antisense replication protein gene vip3Aa (COT 102x COT67B) cry1Ac & cry1F (Event 3006-210-23 & Event 281-24-236) cry1Ac and cry1EC cry1Ac(Mon 531), cry2Ab (Mon15985) & CP4epsps (Mon88913)
7.	Groundnut	ICRISAT, Hyderabad	Chitinase gene from rice (Rchit)
8.	Okra	Mahyco, Mumbai	Cry1Ac(Mon 531), cry2Ab (Mon15985)
9.	Potato	CPRI, Shimla	RB Transgenic Katahdin lines (SP904/SP905)
10	Rice	Mahyco, Mumbai Tamil Nadu Agric University IARI, New Delhi	Cry1Ac Rice chitinase (chi11) or tobacco osmotin gene Cry1B-cry1Aa fusion gene
11.	Tomato	IARI, New Delhi Mahyco, Mumbai	Antisense replicase gene of tomato lcv Cry2Ab

Source: GEAC, MOEF, GOI

²⁹ Lists only new gene events that have not been approved for commercial cultivation.

Annex 5: Transgenic crops with new gene events³⁰ approved for field trials in 2008
(As on June 30, 2008)

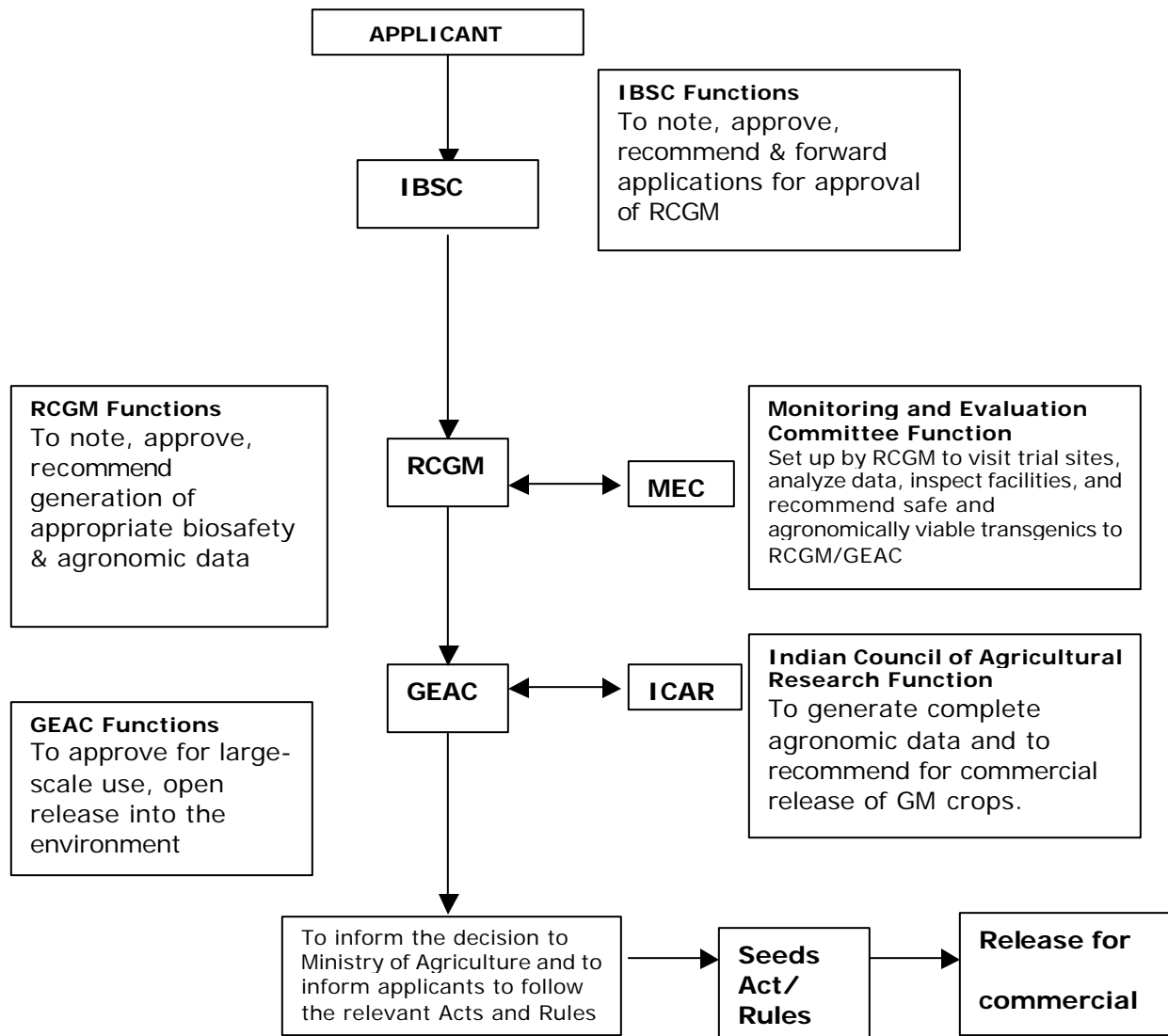
No.	CROP	INSTITUTE/INDUSTRY	GENE/EVENT
1.	Brinjal	University of Agric Sciences, Dharwad Mahyco, Mumbai	cry1Ac cry1Ac
2.	Cabbage	Nunhems India Pvt Ltd, Gurgaon	cry1B and cry1C
3.	Cauliflower	Sungro Seeds Research Ltd., New Delhi Nunhems India Pvt Ltd, Gurgaon	cry1Ac cry1B and cry1C
4.	Cotton	CICR, Nagpur Dow Agro Science, Mumbai Mahyco, Mumbai Metahelix Life Sciences, Bangalore JK Agri Genetics Ltd., Hyderabad*	cry1Ac cry1Ac & cry1F (Event 3006-210-23 & Event 281-24-236) cry1Ac, cry2Ab & CP4epsps (Mon 88913) ³¹ synthetic cry1C (E 9124) cry1Ac and cry1EC
5.	Okra	Mahyco, Mumbai	cry1Ac(Mon 531), cry2Ab (Mon15985) & CP4epsps (Mon88913)
6.	Peanut	ICRISAT, Patancheru*	coat protein gene (<i>cp</i>) of <i>Tobacco Streak Virus</i> (TSV)
7.	Rice	Mahyco, Mumbai Avesthagen Ltd., Bangalore	cry2Ab male sterile rice lines (unedited NAD9) and its restorers (Antisense unedited NAD9)
8.	Tomato	Mahyco, Mumbai Avesthagen Ltd., Bangalore	cry2Ab unedited NAD9

Source: GEAC, MOEF, GOI.

³⁰ new gene events that have not been approved for commercial cultivation.

³¹ Round-up ready flex cotton hybrids

Annex 6: Procedure for Approval of Biotech Crops in India



Source: Department of Biotechnology, GOI

Annex 7: 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, DGFT Notification No. 2(RE-2006) / 2004-2009 ³²
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
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 ³³ , GEAC ³⁴ , DBT Biosafety ³⁵ , 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.

³² <http://164.100.9.245/exim/2000/not/not06/not0206.htm>

³³ <http://igmoris.nic.in/>

³⁴ http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html

³⁵ <http://dbtbiosafety.nic.in/>