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# India

# Biotechnology

# Annual

# 2007

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**Report Highlights:**
On June 22, 2007, the Genetic Engineering Approval Committee approved imports of soybean oil derived from round-up-ready soybeans for consumption after refining, the only biotech food product approved for imports to date. The recent Supreme Court of India intervention in biotechnology regulations has hampered ongoing biotech crop field trials, but three new biotech cotton events were approved for commercial cultivation in 2006, taking the total approved events to four. Area planted to Bt cotton, the only biotech crop approved for commercial cultivation in India, continues to grow, reaching 70 percent of total cotton planted area in 2007.

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## SECTION I: EXECUTIVE SUMMARY

Agricultural trade[1] between the United States and India reached a record $1.4 billion in CY 2006, although the trade balance is almost 3:1 in India's favor. India's major agricultural exports to the U.S. include cashew, sugar, spices, essential oils, processed horticultural products, rice, tea and castor oil. Major U.S. agricultural exports to India are almonds, cotton, fresh fruits, pulses, soybean oil, 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 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 regulatory process, which is still evolving, is not entirely science based. Consequently, commercialization of biotech crops and events is onerous and time consuming. 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. The government has laid out procedures and formats for the import of biotech products, both for research and commercial use (see Annex 2).

Bt cotton is the only biotech crop approved for commercial cultivation in India. Three new Bt cotton events were approved for commercial cultivation in 2006, taking the total number of approved events so far to four. Private seed companies and public sector institutes are actively involved in developing various food and non-food biotech crops in India. Due to the recent intervention by the Supreme Court of India in biotech regulatory areas, field trials of several biotech crops and events have been hindered. Following concerns expressed by Indian rice exporters and farmers over biotech rice trials' impact on basmati rice exports, the government has decided not to allow open field trials of biotech rice in the farmers' field in major basmati rice growing states of north India. Continuing legal issues pertaining to the pricing of Bt cottonseed are likely to be detrimental to technology transfer and foreign direct investment in India's biotechnology sector.

## SECTION II: BIOTECH PRODUCTION AND TRADE

Bt cotton has emerged as a major success story of India's agriculture biotechnology. India's Bt cotton coverage has surged over the past five years to cover 70 percent of total cotton area in 2007. India has now emerged as the second largest cotton producer and third largest cotton exporter in the world. The GEAC approved three new Bt cotton events for commercial cultivation in the 2006 season, taking the total number of approved biotech events to four and the number of approved hybrids/varieties to over 141 in 2007 (Annex 3). Most of the approved Bt cotton hybrids are from the two Monsanto events that are approved in the U.S. Other approved events include the GFM event sourced from China and the locally developed Event 1. For additional information on India's Bt cotton success story, please refer to the "Cotton Annual Report" (GAIN IN7040).

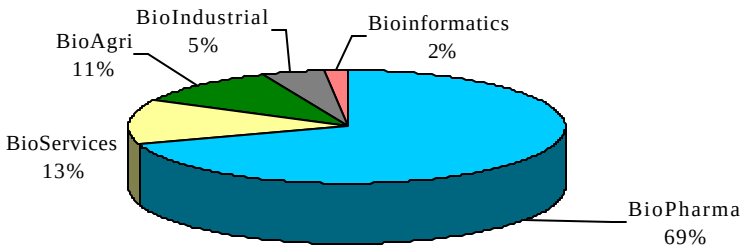
In addition to cotton, Indian private seed companies and public sector organizations (government research institutes and state agriculture universities) are working on the development of various biotech food crops such as brinjal (eggplant), cabbage, castor, cauliflower, corn, mustard, peanuts, okra, potato, rice, and tomato, mainly for traits such as

[1] Excludes fish and forest products; U.S. exports to India estimated at $365 million and India's exports to the U.S. at $1.04 billion.

pest resistance, nutritional enhancement, drought tolerance and yield enhancement (Annex 4 & 5). However, most of these 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 import into India is soybean oil derived from round-up ready soybean. 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 2006-07**
(million US$)




Source: BioSpectrum-ABLE Survey, 2007

Riding on the success of Bt cotton, agriculture biotechnology has emerged as one of fastest growing biotech industries in recent years. It is the third largest contributor among various biotech sectors, with total revenues of more than $229 million in Indian fiscal year 2006/07 (April-March), registering growth of 55 percent. Export revenue from agriculture biotechnology has grown to $11.6 million in 2006/07 from around $8 million last year.

## 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) formulated Recombinant DNA Guidelines that were further updated in 1994. Further in 1998, the DBT issued separate guidelines for carrying out research in 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 www.dbtindia.nic.in/thanks/biosafetymain.html.

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

| | |
|---|---|
| Genetic Engineering Approval Committee (GEAC), Ministry of Environment and Forest (MOEF) | Nodal agency responsible for implementing the Biotech Rules of 1989 under the EPA Act 1986. |
| Department of Biotechnology (DBT), Ministry of Science and Technology (MST) | Provides guidelines and technical support to the GEAC.<br>Evaluates and approves biosafety assessment of biotech product research and development in the country. |
| Ministry of Agriculture (MOA) | Evaluates and approves the commercial release of transgenic crop varieties through multi-locational trials conducted for assessing agronomic performance. |
| Ministry of Health and Family Welfare (MHFW) | Evaluates and approves the safety assessment of biotech crops and products for human consumption. |
| Various state governments | Monitors the safety measures at biotech research facilities, and assesses damage, if any, due to the release of biotech products. |
| DBT, MoA, and various state governments | Supports research and development in agriculture biotechnology through various research institutions and state agriculture universities. |

**Field Testing of Biotech Crops**

The 1989 Rules describe procedures for the 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. A stacked event, even if consisting of already approved events, is treated as new event for approval purposes.

Based on the recommendation of the sub-committee on Bt cotton[2], the GEAC has decided to follow an 'event based' process instead of the 'case-by-case' process for the approval of new hybrids derived from the Bt cotton event Cry1Ac (Mon 531). Now, any seed with the Cry1Ac gene would require 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 old system, a biotech hybrid or variety had to undergo a minimum of three years of extensive field trials in order to qualify for approval. Other approved Bt cotton events will be considered for 'event based' approval after analyzing the bio-safety performance during the initial three-year approval period. The GEAC has also accepted the recommendation of enhancing the roles of state agricultural universities (SAUs) and state agricultural departments by making them responsible for the pre-release and post-release field monitoring of biotech crops.

Recent Interventions by the Supreme Court in Field Trial Approvals: In 2005, an anti-biotech activist 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 order. 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 ongoing field trials of new biotech crops/events[3] to be conducted under specified new conditions[4]. Industry experts feel that most of these conditions are not based on sound science and will be difficult to adhere to. The GEAC has formed a committee to review new field trial conditions stipulated by the court order and to recommend valid science based alternatives for submission in the next court hearing in August. Meanwhile, the GEAC has given approval for field trials of several new biotech crop/events subject to meeting the Supreme Court conditions (Annex 5). Industry sources believe that most biotech crop event applicants are unlikely to conduct field trials in current fall season. With field trials virtually on hold since September 2006, approval of most new biotech crop events has been pushed back by one to two years. It has further delayed India's commercial approval of its first biotech food crop, Bt brinjal (eggplant), possibly next in the pipeline for approval[5].

Biotech Rice Field Trials: On January 10, 2007, the GEAC decided not to allow any multi-locational biotech rice field trials in farmers' fields[6] in basmati rice growing areas, especially

[2] http://www.envfor.nic.in/divisions/csurv/geac/mayee_report.pdf

[3] field trials of new hybrids developed from the already approved four Bt cotton events were exempted from these conditions.

[4] (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 an 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.

[5] Prior to the Supreme Court interventions, industry sources expected Bt brinjal to be approved in 2007.

[6] Contained field trials (including green house, field trial on research farms) exempted.

in the states of Punjab, Haryana and Uttaranchal. This was in response to a petition by Indian rice exporters and farmers to the GEAC, 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 was also supportive of the exporters'/farmers' concerns of biotech rice trials being conducted in basmati growing areas.

**Seed Policy**

The Seed Policy, 2002, 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 will be tested by the Indian Council of Agricultural Research (ICAR) for at least two seasons to determine their agronomic trait value. The Seed Policy also advocates "protection," of transgenic varieties under the Plant Variety Protection (PVP) legislation.

A new Seed Bill was introduced in the Parliament in 2004 but has not yet been passed. Clause 15 of the draft bill covers specific provisions for the registration of transgenic varieties. The full text of the draft Seed Bill is available at: http://agricoop.nic.in/seeds/seeds_bill.htm.

**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 have been 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. 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 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 awaited, state governments unwarranted interference with seed pricing could act as a disincentive to introduce new biotech traits/events into India.

**Trade Policy**

On June 22, 2007, the GEAC approved imports of soybean oil derived from roundup ready soybeans for consumption after refining. No other biotech food products are officially permitted for commercial import 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 have to receive prior approval from the GEAC and made a biotech declaration mandatory[7]. The procedures and format for filing clearance applications for the import of biotech products with the GEAC are detailed in Annex 2. As India is one of the leading importers of vegetable oils, including soybean oil, concerns about high domestic vegetable oil prices forced the government to give a special exemption to commercial imports of soybean oil derived from roundup ready soybeans for imports until December 31, 2007. On June 22, 2007, the GEAC gave permanent approval for imports of soybean oil derived from roundup ready soybeans for consumption after refining.

Currently, effective enforcement of the 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 the 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 a potential to import corn due to growing demand from the poultry and starch industries.

The import of biotech seeds is 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 will be authorized to issue import permits. The complete text of the order is available at http://agricoop.nic.in/gazette/gazette2003.htm.

**Food Policy**

Food Labeling: On March 10, 2006, the Ministry of Health and Family Welfare notified in the Gazette a draft amendment to the Prevention of Food Adulteration (PFA) Rules, 1955, pertaining to the labeling of 'Genetically Modified' foods[8]. Ministry of Health sources report that an expert committee has reviewed the comments submitted by various stakeholders, but the final regulation is yet to be notified.

Industry sources are unsure about effective enforcement of the biotech food labeling rule 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, Ministry of Health may try to ensure compliance through selective sampling and testing of suspected food products. This can lead to increased harassment of domestic food processors and importers by food inspectors. It is unclear how the government will handle labeling of biotech food products used in processing.

India supports mandatory labeling of GM foods in the Codex. Of 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

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

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

organisms obtained from modern biotechnology, and food and food ingredients produced from but not containing genetically modified or engineered organisms. Although the Ministry of Health argues that the mandatory GM labeling is for consumer information and choice, there is very little awareness or concern about GM food products among Indian consumers.

New Food Law in Place: On August 24, 2006, the GOI enacted the integrated food law, namely the "Food Safety and Standards Act, 2006"[9], in order to bring all existing food laws under one single authority and to establish science-based standards for articles of food and to align Indian food standards to international standards. In late 2006, the GOI designated the Ministry of Health and Family Welfare (MHFW) with the responsibility of the new Food Safety and Standard Act. The Ministry is currently in the process of establishing a Food Safety and Standard Authority, which in turn will initiate the rule making process. However, it will be a monumental task to integrate under one single authority the existing food laws, rules and orders that are currently being implemented by several ministries and authorities, and it may take two to five years to complete the rule making process. It is still unclear whether the new Authority would simply consolidate the existing multitude of laws and rules without any change in implementation, or would formulate new rules and procedures.

**Cartagena Protocol and Environment Policy**

India ratified the Cartagena Protocol on Biosafety on January 17, 2003 (see Annex 7). 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 MOEF issued the "Draft National Environment Policy, 2004," which reviews the regulatory processes for Living Modified Organisms (LMOs) in order to address any health, ecological, and economic concerns. (www.envfor.nic.in/nep/nep.pdf)

**Biotechnology Development Policies**

The Task Force on "Application of Agriculture Biotechnology" set up by the MoA under the Chairmanship of India's leading agricultural scientist, Dr. M.S. Swaminathan, submitted its report in 2005 (http://agricoop.nic.in/TaskForce/tf.htm). Among other recommendations, the task force suggested setting up an autonomous National Biotech Regulatory Authority. The DBT has initiated steps to form such an authority.

A draft "National Biotechnology Strategy, 2005," prepared by Department of Biotechnology, Ministry of Science and Technology, enumerates various amendments being made to policies, procedures, and protocols by the departments regulating biotech products and processes. Another aspect of the strategy attempts to resolve various conflicting issues related to the regulation of biotech activities in research and development, import, export, commercial releases etc. See: http://dbtindia.nic.in/biotechstrategy.htm

**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.

[9] For more information, please refer http://mofpi.nic.in/fsnstds.pdf
[10] www.indbch.nic.in

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 starts implementing the proposed biotech food product labeling regulations, some concerns could develop.

Biotechnology Stakeholders:

Several anti-biotech, environmental and consumers groups have been running aggressive and sustained campaigns against the use of biotechnology crops and products in India. These groups are very pro-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 the new tool for tackling the emerging food crisis. Unfortunately, India's public sector research system has so far been unable to commercially release even a single biotech crop event. Most of the biotechnology crop events that have been approved or are under approval 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.

Since biotechnology is a relatively new development, Indian regulators and policymakers are cautious in their approach towards the biosafety aspect of biotechnology crops and products, and prefer to be very regressive on biosafety assessment.

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 were 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 agriculture 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.

## SECTION V: CAPACITY BUILDING AND OUTREACH[11]

Capacity building and outreach activities undertaken by USG agencies have focused on streamlining the Indian regulatory mechanism and spreading the message regarding the safety of biotech foods.

Biotechnology is one of the prime focus areas under the US-India Agricultural Knowledge Initiative (AKI). Post, with active support from the FAS/Biotech team, the Cochran program,

[11] Also refer IN6060 for information on previous activities.

and other programs, is actively involved in biotech outreach efforts. Some biotech activities under the AKI are:

Harnessing the Benefits of Biotechnology (USDA): A workshop planned for November 2007 that will promote the application of biotechnological tools to solve important agricultural constraints, address the continuum from molecular research to applied product development and commercialization, with a focus on delivering benefits to farmers.

Agricultural Biotechnology Training Program: Sponsored by the U.S. Trade Development Agency (USTDA), the program is designed to provide additional support for biosafety capacity building and policy development, which will support India's development of its regulatory system for agricultural biotechnology.

Biotechnology Patent Examiner Training Program: USTDA has partnered with the U.S. Patent and Trademark Office to design a program that will support an agricultural and pharmaceutical biotech-training program for patent examiners in India's Patent Office.

Pigeon Pea Genomics: The University of California-Davis (funded by competitive research grants from various USG sources) will partner with the National Research Centre on Plant Biotechnology, New Delhi, and the International Crops Research Institute for the Semi-Arid Tropics, Patancheru, to carry out biotechnology research that will lead to improved marker-assisted breeding of pigeon pea.

Please see www.fas.usda.gov/icd/india_knowl_init/india_knowl_init.asp for more information on other AKI biotechnology activities.

A USAID sponsored South Asia Biosafety Program (SABP) was initiated in early 2004 to support capacity building in safety issues related to biotech food crops. SABP is an ongoing program that aims to work with Indian partners to respond to training needs for food, feed and environment safety assessments.

The ongoing Agricultural Biotechnology Support Project (ABSP)-II, initiated in October 2002, focuses on South Asia to aid the development of expertise in agricultural biotechnology, with the aim of reducing hunger and poverty. Details on the program can be accessed at www.absp2.cornell.edu/aboutabsp2/index.cfm.

**Annex 1: Biotech Regulatory Authorities – Functions and Composition**

| Committee | Members | Functions |
|---|---|---|
| Genetic Engineering Approval Committee (GEAC); function under Ministry of Environment and Forests (MOEF). | Chairman-Additional Secretary, Ministry of Environment and Forests (MOEF)<br>Co-Chairman - Nominee of Department of Bio-technology<br>Members: Representatives of concerned agencies and departments namely Ministry of Industrial Development, Department of Biotechnology, and the Department of Atomic Energy<br>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.<br>Member Secretary: An official from the MOEF | Approve the use of bio-engineered products for commercial applications.<br>Approve activities involving large-scale use of bio-engineered organisms and recombinants in research and industrial production from an environmental safety angle.<br>Consult RCGM on technical matters relating to clearance of bio-engineered crops/products.<br>Approve imports of bio-engineered food/feed or processed product derived thereof.<br>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:<br>Department of Biotechnology (DBT)<br>Indian Council of Medical Research (ICMR)<br>Indian Council of Agricultural Research (ICAR)<br>Council of Scientific and Industrial Research (CSIR)<br>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.<br>Monitor and review all ongoing GM research projects up to the multi location restricted field trial stage.<br>Undertake visits to trial sites to ensure adequate security measures.<br>Issue clearance for import of raw materials needed in GM research projects.<br>Scrutinize applications made to the GEAC for the import of bioengineered products.<br>Form Monitoring and Evaluation Committee for biotech crop research projects.<br>Appoint sub-groups when required in topics of interest to the committee. |

| | | |
|---|---|---|
| Recombinant DNA Advisory Committee (RDAC); function under DBT | Scientists of the Department of Biotechnology | Take note of developments in biotechnology at the national and international level.<br>Prepare suitable guidelines for safety in research and applications of GMOs.<br>Prepare other guidelines as may be required by the GEAC. |
| Institutional Biosafety Committee (IBC); function at research institution/ organization. | Head of the Institution, Scientists engaged in biotech work, Medical Expert, and Nominee of the Department of Biotechnology | Develop manual of guidelines for the regulatory process on bio-engineered organisms in research, use and application to ensure environmental safety.<br>Authorize and monitor all ongoing biotech projects until the controlled multi location field stage.<br>Authorize imports of bio-engineered organisms/transgenes for research purposes.<br>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 review safety and control measures in institutions handling bio-engineered products.<br>Inspect and take punitive action through the State Pollution Control Boards or the Directorate of Health in case of violations.<br>Nodal agency at 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.<br>Investigate compliance with rDNA guidelines and report violations to SBCC or GEAC.<br>Nodal agency at district level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures. |

Source: Ministry of Environment and Forests (MOEF), GOI.

**Annex 2: Application procedure/formats for the import of biotech products**

(R&D/contained use, intentional release & biotech food)

| AGENDA | APPROVAL ACCORDING AGENCY | GOVERNING RULES | FORM NO. | LINKS FOR DOWNLOADING |
|---|---|---|---|---|
| Import of GMOs / LMOs for R&D | IBSC/RCGM/ NBPGR | Rules 1989[12]; Biosafety guidelines of 1990 and 1998[13]; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; and Guidelines for import of germplasm, 2004 by NBPGR | I | http://www.envfor.nic.in/divisions/csurv/geac/geac_form-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/csurv/geac/geac_form-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/csurv/geac/geac_form-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/csurv/geac/geac_form-IV.htm |

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

[12] http://www.dbtindia.nic.in/policy/rules.html

[13] http://www.dbtindia.nic.in/thanks/biosafetymain.html

**Annex 3: Bt Cotton Events / Hybrids Approved for Commercial Cultivation**

| Year | Gene/Event | No. of Hybrid Varieties |
|---|---|---|
| 2002 | Cry1Ac (Mon 531)[14] | 3 |
| 2003 | Cry1Ac (Mon 531) | 3 |
| 2004 | Cry1Ac (Mon 531) | 4 |
| 2005 | Cry1Ac (Mon 531) | 20 |
| 2006 | Cry1Ac (Mon 531)<br>Cry1Ac (Mon 531) & Cry2Ab (Mon 15985)[15]<br>Cry1Ac (Event 1)[16]<br>Cry1Ab and Cry1Ac (GFM Event)[17] | 50<br>7<br>2<br>3 |
| 2007 | Cry1Ac (Mon 531)<br>Cry1Ac (Mon 531) & Cry2Ab (Mon 15985)<br>Cry1Ac (Event 1)<br>Cry1Ab and Cry1Ac (GFM Event) | 105<br>21<br>7<br>8 |

Source: GEAC, MOEF, GOI.

[14] Developed by Mahyco Monsanto Biotech Ltd., and sourced from Monsanto.
[15] Stacked gene event developed by Mahyco Monsanto Biotech Ltd., and sourced from Monsanto.
[16] Developed by J.K. Agri Genetics Seeds Ltd., and sourced from Indian Institute of Tech., Kharagpur,
[17] Developed by Nath Seeds, and sourced from China featuring fused genes.

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

| No. | CROP | INSTITUTE/INDUSTRY | GENE/EVENT |
|---|---|---|---|
| 1. | Brinjal | Mahyco, Mumbai<br>Sungro Seeds Ltd., New Delhi<br>Indian Agricultural Research Institute (IARI), New Delhi | cry1Ac<br>cry1Ac<br>cry1Aa and Cry1Aabc |
| 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<br>Nunhems India Pvt Ltd., Gurgaon | cry1Ac<br>cry1Ba and cry1Ca |
| 5. | Corn | Monsanto, Mumbai | cry1Ab (Mon 810) |
| 6. | Cotton[18] | Central Institute of Cotton Research (CICR), Nagpur<br>CICR, Nagpur<br>CICR, Nagpur<br><br>Deltapine India Seed Pvt Ltd, Hyderabad<br>Dow Agro Science, Mumbai | cry1Ac<br><br>cry1Ac, cry1Aa3, cry1F<br>Antisense coat protein, sense coat protein & antisense replication protein gene<br>vip3Aa (COT 102x COT67B)<br>cry1Ac & cry1F (Event 3006-210-23 & Event 281-24-236) |
| 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<br>Tamil Nadu Agric University<br><br>IARI, New Delhi | Cry1Ac<br>Rice chitinase (chi11) or tobacco osmotin gene<br>Cry1B-cry1Aa fusion gene |
| 11. | Tomato | IARI, New Delhi<br>Mahyco, Mumbai | Antisense replicase gene of tomato lcv<br>Cry2Ab |

**Source: GEAC, MOEF, GOI**

[18] Lists only new gene events that have not been approved for commercial cultivation.

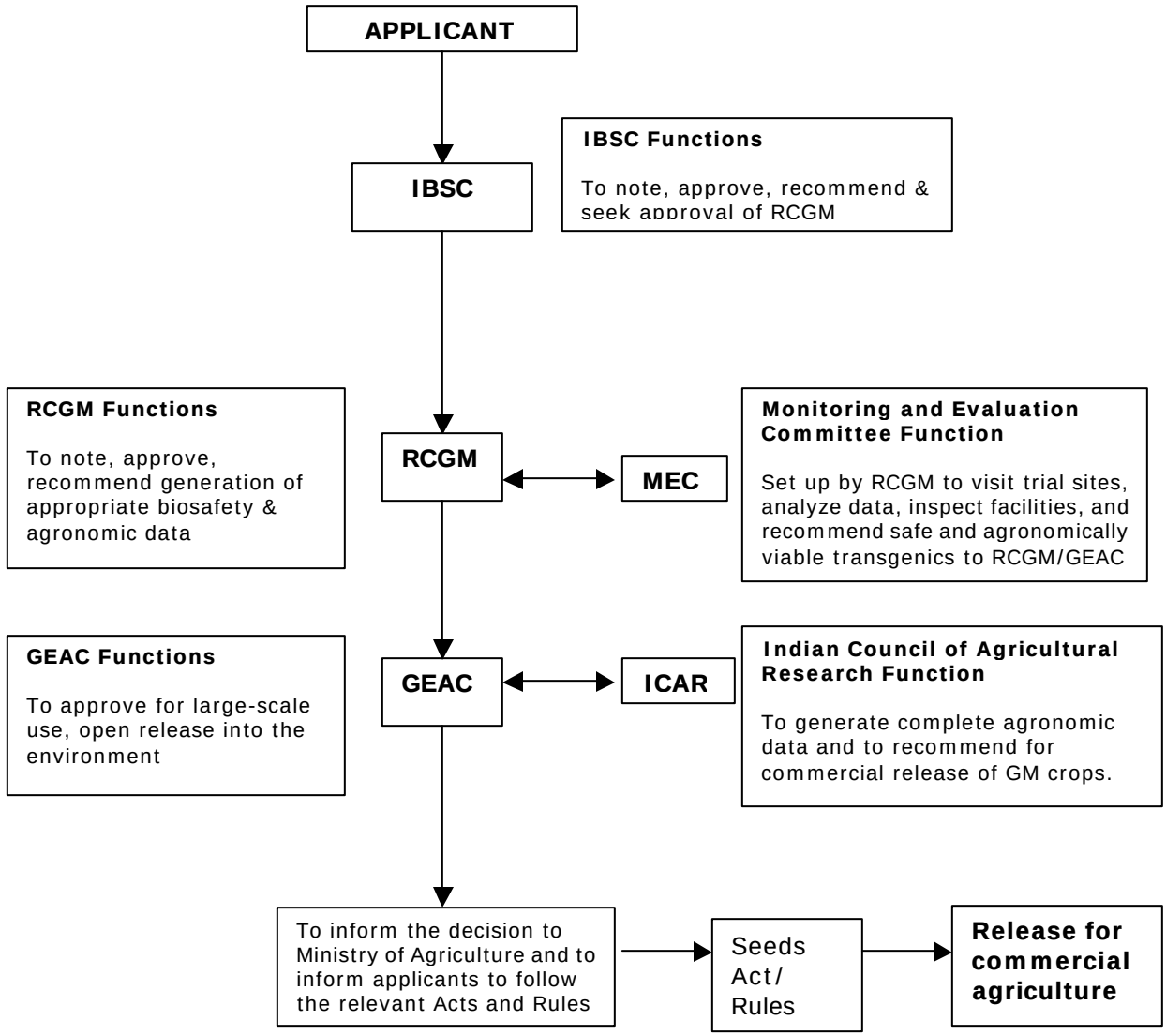
**Annex 5: Transgenic crops with new gene events[19] approved for field trials during 2007[20]**

| No. | CROP | INSTITUTE/INDUSTRY | GENE/EVENT |
|---|---|---|---|
| 1. | Brinjal | University of Agric Sciences, Dharwad<br>**Sungro Seeds Ltd., New Delhi** | cry1Ac<br>cry1Ac |
| 2. | Corn | Monsanto, Mumbai<br>**Monsanto, Mumbai** | cry1Ab (Mon 810)<br>Roundup Ready(NK 603) |
| 3. | Cotton | CICR, Nagpur<br>CICR, Nagpur<br>CICR, Nagpur<br><br>Deltapine India Seed Pvt Ltd, Hyderabad<br>Dow Agro Science, Mumbai<br><br>Mahyco, Mumbai<br><br>Metahelix Life Sciences, Bangalore | cry1Ac<br>cry1Ac, cry1Aa3, cry1F<br>Antisense coat protein, sense coat protein & antisense replication protein gene<br>vip3Aa (COT 102x COT67B)<br>cry1Ac & cry1F (Event 3006-210-23 & Event 281-24-236)<br>cry1Ac, cry2Ab & CP4epsps (Mon 88913)[21]<br>cry1Ac (E 9124) |
| 4. | Mustard | Delhi University, New Delhi | Barnase & barstar |
| 5. | Okra | Mahyco, Mumbai | Cry1Ac(Mon 531), cry2Ab (Mon15985) & CP4epsps (Mon88913) |
| 6. | Potato | CPRI, Shimla | RB Transgenic Katahdin lines (SP904/SP905) |
| 7. | Rice | **Mahyco, Mumbai** | Cry1Ac |

Source: GEAC, MOEF, GOI.

[19] Lists new gene events that have not been approved for commercial cultivation.
[20] Approved by GEAC subject to meeting the Supreme Court Conditions (200 meter isolation distance and protocol ensuring 0.01 percent LOD.
[21] 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[22] |
| 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, include Global Environment Facility (GEF)-World Bank funded Capacity Building project, USAID-sponsored SABP, IGMORIS[23] |
| Article 23 | Public awareness and participation | Ongoing, include GEF-World Bank funded Capacity Building Project, SABP, IGMORIS, GEAC website, 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 initiated and ongoing |

Source: Capacity Building on Biosafety: Training Needs Assessment, Project Coordination and Monitoring Unit, MOEF, 2006.

[22] http://164.100.9.245/exim/2000/not/not06/not0206.htm
[23] http://www.igmoris.nic.in