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Report Highlights:
The Government of India recently announced two new regulations that could adversely impact trade in agricultural biotechnology products. The current legal troubles in India regarding the pricing of Bt cottonseed could have serious implications for future technology transfer and foreign direct investment in India's biotechnology sector. Continuing its efforts to improve the regulatory mechanism for bio-engineered crops, the Ministry of Environment and Forests recently decided to simplify the clearance system for biotechnology crops by replacing the "case-by-case" approval process by an "event-based" approval system. Area coverage under Bt cotton, the only commercially-released biotechnology crop in the country, continues to grow. All sections of this report were updated on 07/15/06.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I: EXECUTIVE SUMMARY

The biotechnology sector in India is evolving, and the regulatory authorities are trying to streamline the regulatory process for biotech crops. However, the biotechnology community in India still feels that further reforms are needed for faster growth in their sector. The Government of India (GOI) recently announced two new regulations that could adversely impact trade in agricultural biotechnology products (GAIN reports IN6024 and IN6030). The current legal troubles in India regarding the pricing of Bt cottonseed could have ramifications on future technology transfer and foreign direct investment in India's biotechnology sector. Bt cotton remains the only transgenic crop approved for commercial cultivation in India. A number of other biotech crops are under development by private seed companies and public sector institutes. The next biotech crop in the pipeline for commercial release is expected to be Bt brinjal (eggplant) in 2007/08. Other transgenic crops approved for contained and limited field trials are cabbage, cauliflower, corn, cotton, peanut, mustard, okra, pigeon pea, rice, and tomato, for traits such as nutritional enhancement, pest resistance, and increased yields.

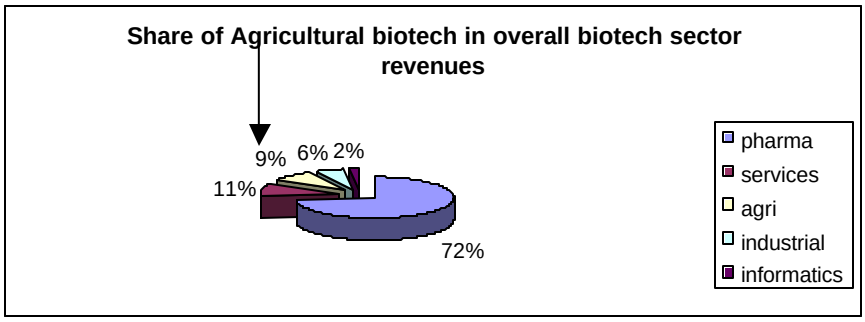
SECTION II: BIOTECH TRADE AND PRODUCTION

Bt cotton remains the only biotech crop released for commercial cultivation in India, spanning the country's major cotton growing regions. The crop itself has been a main focus for biotech research, with the number of approved biotech hybrids/varieties growing from three in 2002 to 59 in 2006, covering four events and involving 16 major seed companies. Details on the zonal spread of approved Bt cotton hybrids are in Annex I. Out of the 59 hybrids, 55 are from Monsanto technology. For specifics regarding India's cultivation of Bt cotton, please see Section III of Post's recent "Cotton Annual Report" (GAIN IN6040).

Bt brinjal is expected to be commercially released by 2007 or 2008. Other biotech crops approved for multi-location trials include cabbage, cauliflower, corn, peanut, mustard/rapeseed, okra, pigeon pea, rice, and tomato, and details are in Annex II.

The GOI recently announced two new regulations that could adversely impact trade in agricultural biotech products, both of which refer to existing GOI statutes (the 1989 Rules framed under the Environmental Protection Act of 1986). The Ministry of Commerce and Industry, on April 7, 2006, announced a supplement to the GOI's Foreign Trade Policy (2004-2009), which requires all imports containing products of modern biotechnology to receive prior approval via the Genetic Engineering Approval Committee (GEAC), as well as mandating a declaration stating that the product is "genetically modified." Importers would be responsible for providing this declaration, and likewise would be liable if the declaration is incorrect. Punitive action in a case where the consignment does not carry the correct declaration could be up to five times the value of the consignment. However, it is not clear how enforcement will be handled, since India does not have the ability to test products for bioengineering at its ports of entry. Inquiries regarding these new measures and their potential impact on trade have focused primarily on vegetable oil shipments, since India is the world's largest importer of vegetable oils. The impact on imports of everything from bulk corn for feed (which is not currently being traded due to a restrictive TRQ regime) to processed food products could be significant. Government sources tell Post that this regulation has come into force with effect from July 8, 2006.

On March 10, 2006, the Ministry of Health and Family Welfare (MHFW) published a proposed amendment to the "Prevention of Food Adulteration Rules," which pertains to the labeling and sale of foods derived from biotechnology. This amendment would require the labeling of "genetically modified foods." For additional details, please refer to the "Marketing Issues" Section.



Source: Biospectrum-ABLE survey, June, 2006

During the Indian Fiscal year (IFY) 2005-06, the agricultural biotech sector is reported to be the third largest contributor among the different sectors of the biotech industry, with total revenues of more than $130 million. It is also the fastest growing sector in the biotech industry, registering a revenue growth of 81% from IFY 2004-05 to 2005-06. The revenue figures for exports and the domestic market were around $8 million and $122 million, respectively.

SECTION III: BIOTECH POLICY

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 the gamut of activities relating to research, development, use, and imports of biotech organisms and their products. Guidelines were first issued in 1990, and were updated in 1994 and 1998. The EPA Act of 1986, 1989 Rules, and all Guidelines are available online at www.dbtindia.nic.in/thanks/biosafetymain.html.

The Format for filing clearance applications for imports of biotech products are detailed in Annex III. The Steps involved in commercializing a transgenic event are provided in Annex IV.

A plethora of committees constituted under the 1989 Rules govern the commercialization of biotech crops (Annex V). The procedure for government approval of biotechnology crops in India is shown in Annex VI.

The Review Committee on Genetically Modified Crops (RCGM), one of the regulatory bodies, was "reconstituted" in January 2006 in order to broaden its membership by involving expert members from relevant backgrounds and organizations. See http://dbtindia.nic.in/biosafety/New%20RCGM%20OM.doc for more details.

In a similar development, the Genetic Engineering Approval Committee (GEAC) was reshuffled in March 2006. A list of members of the new committee is available at www.envfor.nic.in/divisions/csurv/geac/comp.doc.

India ratified the Cartagena Protocol on Biosafety on January 17, 2003 (see Annex VII). A Biosafety Clearing-House (BCH) exists within the Ministry of Environment and Forests to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs). The BCH facilitates the protocol implementation by functioning as an internet-based system.

On June 30, 2006, the Ministry of Environment and Forests (MOEF) simplified and shortened the clearance system for biotech crops. This decision was based on a GEAC-approved report by one of its subcommittees. According to the new modus operandi, the "case-by-case" approval process previously followed by the GEAC will be replaced by an "event-based" approval system, designed specifically to speed up the approval process for Bt cotton hybrids. Under the old system, a biotech hybrid or variety had to endure a minimum of three years of extensive trials in order to qualify for approval. Now, any seed with the Cry 1Ac gene should require only one year of trials to gain GEAC clearance, mainly to test the agronomic trait value of hybrids and to confirm the presence of the gene. The Indian Council of Agricultural Research (ICAR) trials for Bt cotton (with the Cry 1Ac gene and the Mon 531 event) have been made optional. The roles of state agricultural universities (SAUs) and state agricultural departments have been enhanced by making them responsible for the pre-release field monitoring of biotech crops. The responsibilities have been transferred to the SAUs, because agriculture is considered to be a state subject.

The Seed Policy, 2002, which is non-binding, 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. The Seed Policy also advocates "protection," which remains undefined, of transgenic varieties under the Plant Variety Protection (PVP) legislation.

Considering perceived flaws in the present seed legislation (Seed Act, 1966), a new Seed Bill was introduced in Parliament in 2004. Clause 15 of the draft Bill covers specific provisions for the registration of transgenic varieties.

Other major highlights of the draft are import and export regulations of seeds, and an exemption for farmers to save, use, exchange, share, or sell their seed without registration. The full text of the draft Seed Bill is available at: http://agricoop.nic.in/seeds/seeds_bill.htm.

The Food Safety and Standards Bill, 2005, was introduced by the Ministry of Food Processing Industries with the basic aim of integrating the existing multitude of food laws in the country. Existing acts or orders like the Prevention of Food Adulteration (PFA) and the sections related to food under the EPA, 1986, and the Environment Protection Rules, 1989, will be moot once the Bill becomes functional. The Bill has a provision to address biotech-related issues through a separate scientific panel, which will be composed of independent scientific experts. The provisions prohibit the manufacture, processing, export, import or sale of biotech food products that are not in compliance with the Act's regulations.

The import of biotech seeds is 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.

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)

A draft "National Biotechnology Strategy, 2005," prepared by the 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 so far in India. This may change, however, depending on the ultimate outcome of the regulations discussed below. Monsanto, the pioneer of Bt cotton seed technology in India, is having legal problems regarding the pricing of its Bt cotton seed.

A biotech declaration has been made mandatory for imported food, feed, bioengineered organisms, or LMOs, via a notification issued by the Director General of Foreign Trade, Ministry of Commerce and Industry, on April 7, 2006 (http://164.100.9.245/exim/2000/not/not06/not0206.htm). Ministry of Commerce sources state that this regulation was implemented on July 8, 2006. For additional details, please refer to the "Trade and Production" section of this report.

The Ministry of Health and Family Welfare (MHFW) issued a draft amendment on the labeling of biotech foods via a notification published in the Official Gazette of India on March 10, 2006. The amendment proposes to add two rules (37-E and 48-F) to the PFA Rules, 1955, and seeks compulsory labeling of foods derived from biotechnology (to include those obtained by primary or secondary processing, any ingredient of food, food additives), whether produced domestically or imported. It also mandates specifying that such categories of products have been subjected to genetic manipulation. Additionally, the proposition requires the food label of biotech foods to specify that the product has been cleared for marketing and use in its country of origin. The new rule also restricts the sale, manufacture, import, transport, storage, and distribution of biotech foods without the approval and fulfillment of the criteria imposed by the GEAC, whatever those are at that moment. The MHFW has constituted an expert group to review comments received from various stakeholders; this group is expected to meet in late July or early August 2006, after which it will likely take at least six months to implement the amendment. The draft amendment can be accessed at http://mohfw.nic.in/152.pdf.

SECTION V: CAPACITY BUILDING AND OUTREACH

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, and many others, is deeply involved in these activities. Representatives from various agriculturally-oriented private and public organizations are currently being processed for training in agricultural biotechnology in the United States. Conferences, workshops, and other events are also planned. Please see www.fas.usda.gov/icd/india_knowl_init/india_knowl_init.asp for more information on the AKI.

A conference between US and Indian regulatory officials was conducted in February 2005 to help both sides share and learn from each other's regulatory experiences. USAID-India is working closely with various public and private sector research organizations to develop and commercialize biotech crops that may be commercially "unattractive," but which would have a significant stakeholder impact (example: Bt Brinjal; resistant to fruit borer). In 2003/2004, the State Department funded and coordinated two Speakers' tours, which were aimed at developing confidence in biotechnology among consumers and other stakeholders. Additionally, the State Department's Senior Advisor for Agricultural Biotechnology visited with

key stakeholders in India in early 2006. USDA/FAS' Director of Biotechnology Group visited India in May 2006.

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.

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 the training needs for food, feed, and environmental safety assessments.

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

ANNEX I: Bt Cotton Hybrids approved to-date

	2002	2003	2004	2005	2006
NORTH ZONE (23%)*				**6 hybrids**	**7 hybrids**
Haryana				RCH 134, RCH 317,	MRC 6026, MRC 6029,
Punjab				MRC 6304	NCS-913, NCS-138,
Rajasthan				MRC 6301, Ankur 651,	NCEH-6RCH-308RCH-314
				Ankur 2534	
CENTRAL ZONE (58%)	**3 hyb**	**3 hyb**	**4 hyb**	**12 hybrids**	**11 hybrids**
Gujarat	Mech 12	Mech 12	Mech 12	Mech 12, Mech 162,	ACH-33-1, ACH 155-1,
Madhya Pradesh	Mech 162	Mech 162	Mech 162	Mech 184, RCH 2,	Brahma Bt, GK 205
Maharashtra	Mech 184	Mech 184	Mech 184	RCH 118, RCH 138,	NCEH-2, PRCH-102,
			RCH 2	RCH144, Ankur 09,	RCH 377, Tulasi-4, VICH-5
				Ankur 651, MRC 6301	VICH-9, VICH-111
				NCS-145 Bunny,	
				NCS-207 Mallika	
SOUTH ZONE (19%)	**3 hyb**	**3 hyb**	**4 hyb**	**9 hybrids**	**15 hybrids**
Andhra Pradesh	Mech 12	Mech 12	Mech 12	Mech 162, Mech 184,	ACH-33-1, Brahma Bt, GK
Karnataka	Mech 162	Mech 162	Mech 162	RCH 2,	207, GK 209, KDCHH-
Tamil Nadu	Mech 184	Mech 184	Mech 184	RCH 20, RCH 368,	9632, NCS-913, NCEH-3,
			RCH 2	MRC 6322,	RPCH-2270, PRCH-102,
				MRC 6918	PRCH-103, RCH-111,
				NCS-145 Bunny	RCH-371, RCHB-708,
				NCS-207 Mallika	VICH-5, VICH-9
TOTAL	**3**	**3**	**4**	**20**	**25**

*Figures given in percentage denote the contribution of each zone in the development of new hybrids

Source: ISAAA via Monsanto India

ANNEX II: Transgenic crops approved for contained, limited field trials, including multi-locational field trials, during 2005

SL. No.	CROP	INSTITUTE/INDUSTRY	EVENT
1.	Brinjal	Mahyco, Mumbai Sungro Seeds Ltd., New Delhi IARI, New Delhi	cry1Ac cry1Ac cry1F
2.	Cabbage	Sungro Seeds Ltd., New Delhi	cry1Ac
3.	Cauliflower	Sungro Seeds Ltd, New Delhi	cry1Ac
4.	Corn	Monsanto, Mumbai Metahelix Life Sciences, Bangalore Modified Mu-element (Turbo-Mu)	cry1Ab
5.	Cotton	Ajeet Seeds, Aurangabad Ankur Seeds P. Ltd., Nagpur M/s Bioseed Research India Pvt. Ltd., Hyd M/s Emergent Genetics India P. Ltd., Hyd Ganga Kaveri Seeds Ltd., Hyderabad Green Gold Seeds Ltd., Aurangabad JK Agri Genetics, Hyderabad M/s Kaveri Seeds Co. P. Ltd, S'bad Krishidhan Seeds, Jalna Mahyco, Mumbai Metahelix Life Sciences, Bangalore Nandi Seeds, Aurangabad Namdhari Seeds Pvt. Ltd., Bangalore Nath Seeds, Aurangabad Nuziveedu Seeds, Hyderabad Prabhat Agri Biotech Ltd., Hyderabad Pravardhan Seeds Pvt. Ltd, Hyderabad Proagro Seeds Co. Ltd., Hyderabad Rasi Seeds Ltd., Attur Syngenta India Ltd., Pune Tulsi Seeds, Guntur UAS, Dharwad Vibha Agrotech Ltd., Hyderabad Vikki's Agrotech, Hyderabad Vikram Seeds Ltd., Ahmedabad Zuari Seeds Ltd., Bangalore	cry1Ac, cryX cry1Ac, cryX cry1Ac, cryX cry1Ac, cryX cry1Ac GFM cry1A cry1Ac cry1Ac cry1Ac, cryX cryX cry1Ac cry1Ac cry1Ac GFM cry1A cry1Ac, cryX cry1Ac cry1Ac cry1Ac cryX Vip-3A cry1Ac, cryX cry1Ac cry1Ac cry1Ac cry1Ac GFM cry1A
6.	Groundnut	ICRISAT, Hyderabad	Coat protein of IPCV Nucleo Capsid Protein of PBNV
7.	Mustard	UDSC, New Delhi	Barnase & barstar
8.	Okra	Mahyco, Mumbai	cry1Ac
9.	Pigeonpea	ICRISAT, Hyderabad	cry1Ac
10.	Rice	 Mahyco, Mumbai Metahelix Life Sciences, Bangalore	cry1Ac, cry1Aa + cry1B cry1Ac NHX gene
11.	Tomato	IARI, New Delhi Mahyco, Mumbai	Antisense replicase gene of tomato leaf curl virus Cry1Ac

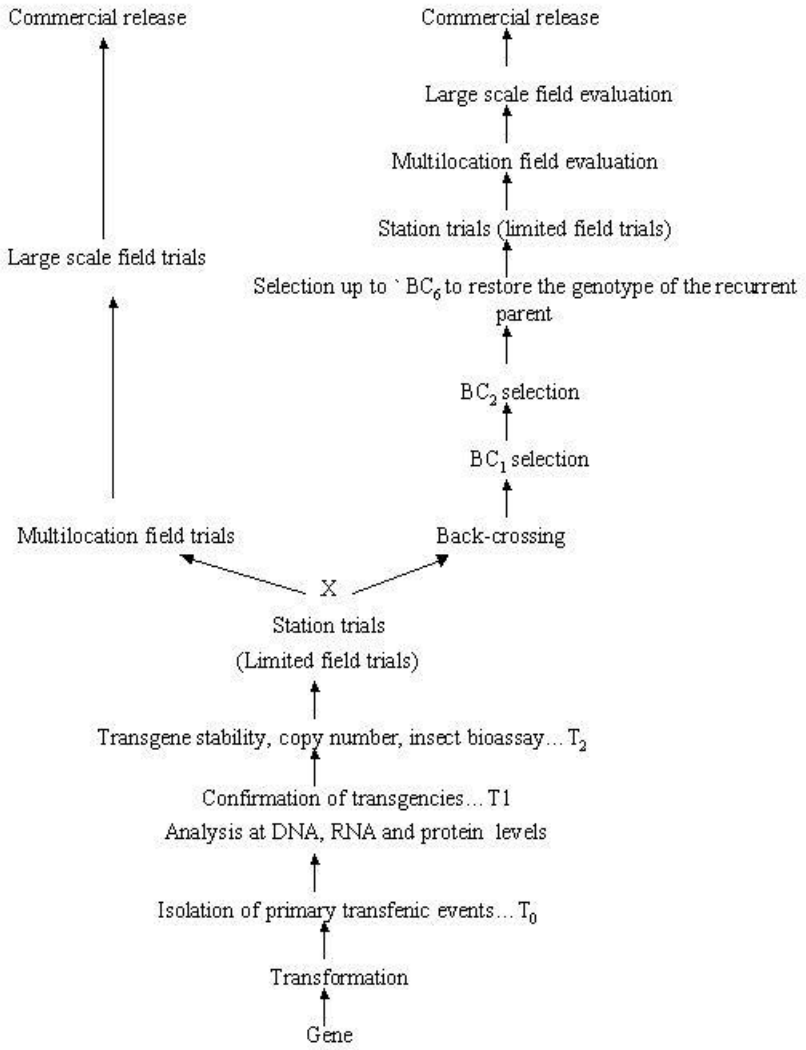
Source: Department of Biotechnology Annual Report 2005-06

ANNEX III: Application formats for imports 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; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; Recombinant DNA safety guidelines,1990; Revised guidelines for research in transgenic seeds, plant & plant parts,1998, & Guidelines for import of germplasm, 2004 by NBPGR	I	www.envfor.nic.in/divisions/csurv/geac/gecform-I.doc, http://dbtindia.nic.in, http://nbpgr.delhi.nic.in
Import of 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/gec_form-II-B.doc
Import of GM food / feed as LMOs per se	GEAC	Biosafety & Food safety studies, Compliance with the Biosafety protocol	III	www.envfor.nic.in/divisions/csurv/geac/gec_form-III.doc
Import of GM processed food derived from LMOs	GEAC to follow "Event based approval" in a given crop	One time approval required & following information needs to be furnished – List of genes/events approved in the crop species for commercial production in the country of export/country of origin; Approval of product for consumption in countries other than producing countries; Food safety study conducted in the country of origin; Analytical/compositional report from the country of export/origin; Details on further processing envisaged after import; Details on commercial production, marketing and use for feed/food in the country of export/origin; Details on the approval of genes / events from which the product is derived	IV	www.envfor.nic.in/divisions/csurv/geac/gec_form-IV.doc

Source: MOEF Website

ANNEX IV: Steps involved in processing a transgenic event into a commercial variety



Source: Handbook of Agriculture, Indian Council of Agricultural Research, 2006

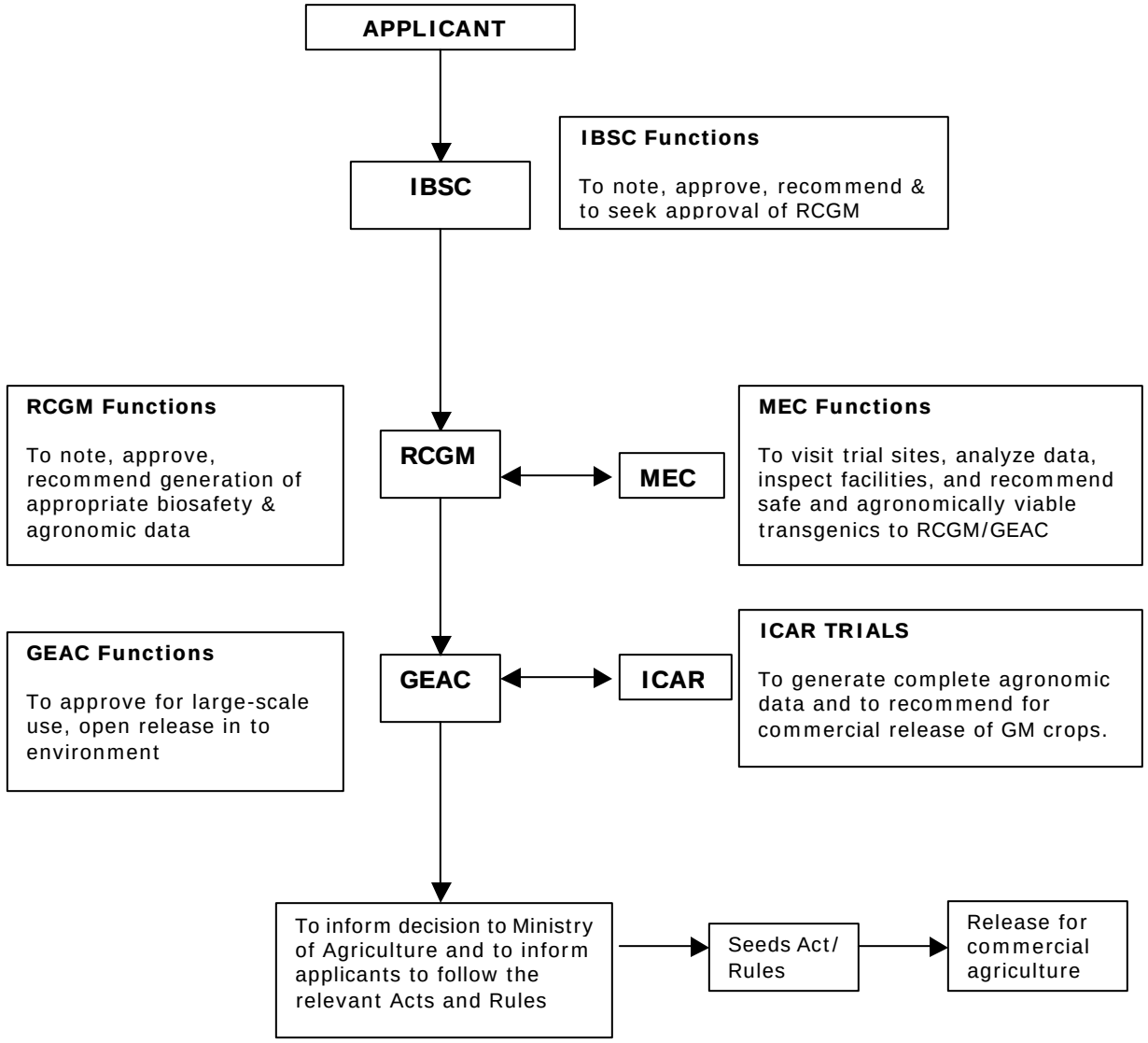
ANNEX V: Composition and Functions of Indian Biotech Regulatory Authorities

Committee	Members	Functions
Institutional Biosafety Committee (IBC)	Head of the Biotech Research Project Scientists Medical Expert Nominee of the Department of Biotechnology	Training GM project personnel for safety. Help the applicant to prepare an on-site emergency plan. Coordinate with district and state level biotechnology committees. Instituting health monitoring program for lab personnel. Carry out periodical medical checks on lab personnel.
Review Committee on Genetic Manipulation (RCGM)	Representatives from: Department of Biotechnology (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.	Review all ongoing GM research projects. Undertake visits to trial sites to ensure adequate security measures. Issue clearance for import of raw materials needed in GM research projects. Scrutinize applications made to the GEAC for import of bioengineered products. Form Monitoring and Evaluation Committee for bio-engineered crop research projects. Appoint sub-groups as and when required in topics of interest to the committee.
Genetic Engineering Approval Committee (GEAC)	Chairman-Additional Secretary, Ministry of Environment and Forests (MOEF) Co-Chairman - Nominee of Department of Bio-technology Members: Representatives of concerned agencies and departments namely Ministry of Industrial Development, Department of Biotechnology, 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 activities involving large-scale use of potential hazardous micro-organisms and recombinants in research and industrial production from the point of view of environmental safety. Approve proposals relating to release of genetically engineered organisms and products into the environment, including field trials. Take punitive actions on those found violating the GM rules under EPA, 1986. Consult RCGM on technical matters relating to clearance of bioengineered crops/products. Approve bioengineered foods for commercial sales/distribution.
Recombinant DNA Advisory Committee (RDAC)	Scientists of Department of Biotechnology	Take note of developments in biotechnology at 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.
State Biotechnology Coordination committee (SBCC) (in states 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 in handling biotech products. Inspect and take punitive action through the State Pollution Control Boards or the Directorate of Health in case of violations.

		Take on-site control measures.
District-Level Committee (DLC)	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.	To monitor safety regulations in research and production installations Investigate compliance with rDNA guidelines and report violations to SBCC or GEAC.

Source: Environmental Protection Act, 1989.

ANNEX VI: Procedure for Approval of Biotech Crops in India



Source: Department of Biotechnology, GOI

ANNEX VII: Present Status of India's Compliance and Capacity Building Needs for Various parts of the Cartagena Protocol

Article	Provisions	Present Status	Capacity Building Needs	Stakeholders
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 notified. Border control through NBPGR only for contained use. Projects initiated to strengthen DBT and MOEF's capabilities to identify LMOs.	Customs and border control procedures, mainly for import/export of LMOs for food, feed and processing; documentation and inspection systems for LMO shipments; development of methods and systems of identification of LMOs.	Scientists, regulators, customs and border control officials, traders (importers, exporters), food/feed processing industry.
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.	Harmonization of rules with the requirements of the protocol. Incorporating the information requirements for regulating status of LMOs/GMOs in the documentation for export/import Training customs/port officials, such as plant quarantine, etc. to review the information requirements.	Regulators, border control officials, industry, importers/exporters
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, i.e. GEAC, in place	Strengthening of domestic regulatory framework to meet the timelines and access to data requirements.	Regulators (Members of GEAC and other officials working in the relevant ministries)

Article	Provisions	Present Status	Capacity Building Needs	Stakeholders
Article 10	Decision Procedure- Decision taken by the Party of import shall be in accordance with Article 15	Regulatory body, GEAC, is in place	Strengthening of the decision-making procedures including access to databases (in terms of enforcement, inspection, and risk assessment)	Regulators and associated scientists, Information Technology managers
Article 11	Procedure for LMOs intended for direct use as food or feed, or for processing	1989 Rules, procedures to be detailed	Capacity building for methods and systems of detection of LMOs	Regulators, officers from concerned ministries, i.e. Ministry of Health, Ministry of Commerce etc.; importers/traders; researchers and technicians
Article 13	Simplified Procedure to ensure the safe intentional transboundary movement of LMOs	1989 rules	No information available	No information available
Article 14	Bilateral, regional and multilateral agreements and arrangements	No information available	Regional harmonization of biosafety-related sectoral laws/policies, and synchronizing with other international agreements such as WTO and IPPC.	No information available
Article 15	Risk assessment	DBT Guidelines for research in plants	Laws/guidelines/policies to be developed for biotech food/feed and products thereof. Environmental risk assessment procedures to be streamlined, including baseline information.	Policy makers, regulators, scientists, industry
Article 16	Risk Management	DBT Guidelines for research	Laws/guidelines to be developed, particularly for food/feed crops; harmonization with the existing procedures.	Policy makers, regulators, scientists, industry

Article	Provisions	Present Status	Capacity Building Needs	Stakeholders
Article 17	Unintentional transboundary movements and emergency measures	1989 rules	Detection, testing and quantitative analysis of LMOs; Border control and inspection facilities; development of emergency plans.	Scientists, technicians, and custom and port officials
Article 18	Handling, transport, packaging and identification	Detailed guidelines to be developed	Customs and border control procedures, Documentation and inspection systems for LMO shipment, Methods and systems of identification of LMOs, including traceability and technologies for safe handling, packaging and transporting of LMO shipments.	Scientists, technicians, and custom and port officials
Article 20	Information sharing and the Biosafety Clearing House	Biosafety Clearing House (BCH) in place. A separate website on capacity building activities hosted by MoEF.	Web based databases; Non-internet based electronic exchange material (e.g. CD ROMS, etc), publications and documents; handbooks; newsletters etc.	IT managers, scientists
Article 21	Confidential information	No information available	Harmonization with Right to Information Act	Regulators
Article 22	Capacity building	Ongoing, including Global Environment Facility (GEF)-World Bank funded Capacity Building project	Institutional capacity building (including national regulatory frameworks), Human resources development and training, Public awareness, education and participation, information exchange and data management	All stakeholders, including interest groups such as farmers and consumers industry associations.
Article 23	Public awareness and participation	Ongoing, including GEF-World Bank funded Capacity Building Project	Biosafety awareness activities (workshops, seminars, training programmes, etc.) and materials (newsletter, bulletins, newspapers etc.), Risk communication skills and strategies	All stakeholders

Article	Provisions	Present Status	Capacity Building Needs	Stakeholders
Article 24	Non-Parties (transboundary movements of LMOs between Parties and non-Parties)	1989 rules in place for all import and export	No information available	No information available
Article 25	Illegal transboundary movements	No information available	Methods and mechanisms for detecting unintentional or illegal LMO movement, border control and inspection facilities, compliance mechanisms to be strengthened.	No information available
Article 26	Socio-economic considerations	Socioeconomic analysis is an integral part of decision making	Mechanism to determine added value to specific socio-economic groups/sectors; Mechanism to review case-by case cost benefit analysis	Regulators, economists, NGOs, social groups
Article 27	Liability and redress	National Consultation initiated and ongoing	Deliberations on approach for Article 27 negotiations.	Regulators and legal experts, particularly on international law.

Source: Report on Capacity Building on Biosafety: Training Needs Assessment, Project Coordination and Monitoring Unit, Ministry of Environment and Forests, January 2006.