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Approved by:
Michael Riedel
U.S. Embassy, New Delhi

Prepared by:
V. Shunmugam

Report Highlights:
India's biotechnology regulatory framework lacks clarity, and is at times perceived to be based on considerations other than those science-based. Despite recent and fairly promising efforts to improve the regulatory mechanism, a lack of policy direction regarding biosafety assessment and commercialization has led to delays in the commercial release of biotech crops.

Includes PSD Changes: No
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Table of Contents

SECTION I: EXECUTIVE SUMMARY

India's biotechnology regulatory framework, governed by the Environmental Protection Act (EPA) of 1986, lacks clarity, and at times is perceived to be based on considerations other than those science-based. It involves a hierarchy of monitoring committees with different functions. Despite recent efforts to improve the regulatory mechanism, a lack of direction regarding biosafety assessment and commercialization of biotech crops has led to delays in the commercial release of biotech crops. India's major agricultural trade interests include rice, wheat, pulses, sugar, cotton, castor oil, fruits and vegetables, and cashew nuts. US trade interests include cotton, almonds, pulses, and fresh fruits. Cotton is the only biotech crop produced and traded in India. Indian private seed companies and public sector institutes are actively involved in the development of various food and non-food biotech crops, which include corn, eggplant, tomato, and mustard, for traits such as nutritional enhancement, pest resistance, and increased yields.

SECTION II: BIOTECH TRADE AND PRODUCTION

The only biotech crop approved for commercial cultivation in India is cotton (event Cry 1Ac), which is also approved for commercialization in the United States. Apart from cotton, Indian private seed companies and public sector institutes and universities are involved in the development of various biotech food and non-food crops such as corn, eggplant, tomato, and mustard, for nutritional enhancement, pest resistance, and increased yields. However, most of these crops are still in the laboratory stage or in the contained field trial stage, and are three to five years away from commercialization.

Although India exports cotton and cottonseed meal, the biotech issue has not come to the forefront. Nor is there any domestic concern regarding their safety. The existing regulation ("Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989") states that importers of biotech crops and foods must apply to the Genetic Engineering Approval Committee (GEAC) with the necessary data. Such an application form is available at the website of the Department of Biotechnology under http://dbtindia.nic.in/policy/polimain.html.

Food aid received by India is confined these days to refined soybean oil from the United States under PL 480 Title II; the requisite GEAC approval was obtained in 2002.

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 Environment 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, 1990 Rules, and all Guidelines are available online at www.dbtindia.nic.in/thanks/biosafetymain.html.

A hierarchy of committees constituted under the 1989 Rules governs the commercialization of biotech crops (Annex I). Industry sources say that a lack of standard operating procedures is hindering timely clearance of biotech crops for commercialization and thereby increasing costs. Although imported Living Modified Organisms (for food/feed purposes) and biotech food products must undergo the same process of data vetting as is required for commercialization of biotech crops, it is unclear whether LMOs would be field-tested for their environmental safety.

Although the State Biotechnology Coordination Committees and the District Level Committees have the legal power to do so, there are no regular monitoring or enforcement programs for biotech crops/foods, including for imported products.

"Cry 1Ac" is the only GEAC approved event for cotton. Three cotton hybrids with the Bt cotton gene were approved for commercial cultivation in 2002. Since then, 15 more Bt hybrids have been approved for cultivation.

India has signed and ratified the Cartagena Biosafety Protocol (CBP). The Ministry of Environment and Forests (MOEF), the nodal Ministry for the implementation of the CBP, is building capacity to implement various provisions of the CBP and to strengthen the biosafety regulatory framework. Efforts, which are likely to be successful, are underway to set up a Biosafety Clearing House (BCH), which would inform the public of the GEAC approvals of biotech crops/foods in India and instill confidence regarding the government regulatory system.

SECTION IV: MARKETING ISSUES

Domestically-produced Bt cotton and its products (cottonseed, oil, and meal) are marketed along with non-biotech cotton, and there are no segregation norms nor acceptance issues.

Biotech-labeling laws would be enacted only after a consensus is reached in the ongoing Codex Alimentarius discussions regarding the labeling of bioengineered foods. The Indian government is not planning to implement a traceability-oriented marketing system, due to practical problems such as lack of appropriate segregation policies, existence of innumerable small farms, and the lack of a monitoring mechanism.

SECTION V: CAPACITY BUILDING AND OUTREACH

The USDA, USAID, and State Department are actively coordinating various biotechnology capacity-building measures and outreach activities in India. Post, with active support from the FAS/Biotech team and the Cochran program, is involved in these activities, including the training of Indian personnel regarding biosafety assessment. In 2003, Post and FAS/Washington held a digital video conference between US and Indian regulators to understand and learn from each other's experiences on biotech food safety issues. A conference between US and Indian regulatory officials was conducted in February 2005, in order to help both sides share and learn from each other's regulatory experiences. USAID-India is also closely working with various public and private sector research organizations to develop and commercialize biotech crops, which may be commercially unattractive but would have maximum stakeholder impact (example: Bt Brinjal-resistant to fruit borer). The State Department funded and coordinated two Speakers' tours in 2003 and 2004, which were aimed at developing confidence in biotechnology among consumers and other stakeholders.

Capacity building and outreach activities undertaken by USG agencies have been focused on streamlining the Indian regulatory mechanism and spreading the message regarding safety of biotech foods. However, the crucial issue of training the regulators to effectively communicate risk issues with all stakeholders has been left out of most USG efforts. The importance of public-private partnerships is another important area mostly absent from past USG activities. A workshop to create awareness about the US-model of public-private collaboration would help the GOI design the respective partnerships to benefit from each other's skills in biotech product development and commercialization.

SECTION VI: REFERENCE MATERIAL

- Annexure III provides a list of crops approved for contained and multi-location field trials.

- The minutes of GEAC are periodically published at www.envfor.nic.in/divisions/csurv/geac/archive.html

Annex I: Composition and Functions of Biotech Regulatory Authorities

Committee	Members	Functions
Institutional Biosafety Committee (IBC)	➢ Head of the GM 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 bioengineered 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	➢ 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

	➢ 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	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.

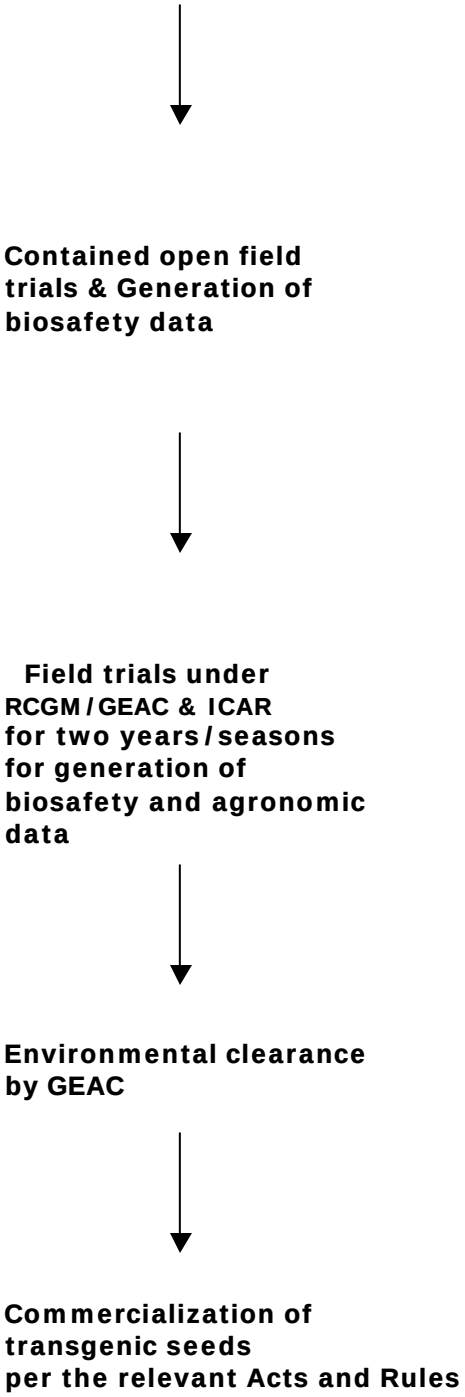
Annex II: Procedures to Develop Transgenic Crops with a Gene* in a Gene Cassette**

	Description	Steps
1.	R&D Institution/Industry constitutes IBSC per the DBT Guidelines and makes request for DBT nominee.	**Constitution of Institutional Biosafety Committee (IBSC)**
		↓
		Nomination of DBT nominee
		↓
		Formation of IBSC
		↓
2.	Per the DBT's 1998 Guidelines, IBSC approves category I & II experiments up to the green house level with notice to RCGM. If applicable, IBSC recommends RCGM allow lab & green house studies. IBSC also recommends whether to allow import transgenic seeds for research purposes.	**Applications to IBSC**
		↓
3.	IBSC should meet twice yearly and should send six monthly reports to RCGM. Category III experiments at all levels and the import/exchange of transgenic germplasm needs the recommendation of IBSC. All open-field experiments (biosafety studies, seed increase experiments, agronomic studies, etc) need the approval of RCGM.	**IBSC meetings**
		↓
4.	The following information should be generated by the applicant before going into open-field trials: Rationale for the development of transgenic plants in terms of agronomic, nutritional, and other benefits; source and sequence of transgene; cloning strategy; characteristics of expression vector(s); characteristics of inserted genes with detailed sequences; characteristics of gene(s); genetic analysis including copy number of inserts, stability, level of expression of transgene, characterization of expressed gene product; mode of action of gene product; compositional analysis; description of the host plant; centers of origin of the host plant; geographical distribution of the host-plant in the country of development; back-crossing duration; seed-setting characteristics; germination rates; phenotypic characteristics; target-gene efficacy tests; observations on the implications of toxicity and allergenicity, if any, during handling.	**Lab & Green House Experiments & Generation of relevant target data**
		↓
	The above points are indicative only of the general	

procedures. Depending on the nature and characteristics of the transgenic crop, additional information may be required.

5. The following information should be generated by the applicant during the contained open field trials: Comparison of germination rates and phenotypic characteristics; study of gene flow; invasiveness studies; possibility of weed formation; possibility of gene-transfer to nearby relatives through out-crossing; implications of out-crossing; susceptibility to diseases and pests; toxicity and allergenicity implications of plants/fruits/seeds and any other plant parts; food/feed safety evaluation in animals; handling procedures for allergenic substances. The information may be generated by conducting controlled, open-field trials in one or two locations.

If RCGM approves the multi-location field trials of the transgenic crop, requests the Monitoring and Evaluation Committee (MEC) to monitor and evaluate the same for its intended agronomic advantage and safety aspects. The minimum number of locations per agro-climatic crop zones are five in one crop season, not to exceed one acre at a single location, or per the plot-size recommended by the All India Co-ordinated Project (AICP) of the Indian Council of Agricultural Research (ICAR). ICAR conducts field trials at different locations under AICP for two consecutive years/seasons.



Notes:

Gene* = A functional gene responsible for imparting a new character or enhancing an existing character in transgenic plants.

Gene cassette** = Consisting of promoter sequence(s), poly-A signal sequences, marker sequence(s), target genes, etc.

Source: Review Committee on Genetic Manipulation (RCGM)

Annex III: Crops approved for contained field trials and multi-location field trials in India

Table-7.1

Transgenic crops approved for conducting contained limited field trials including multi-location field trials during 2004.

Sl #	Crop	Institute/Industry	Transgene
1.	Brinjal	Mahyco, Mumbai	*cry1Ac*
2.	Cotton	Mahyco, Mumbai	*cry1Ac cryX*
		Rasi Seeds Ltd., Attur	*cry1Ac, cryX*
		Mahendra Hybrid Seeds Ltd., Hyderabad	*cry1Ac, cryX*
		Ajeet Seeds, Aurangabad	*cry1Ac, cryX*
		Ankur Seeds P.Ltd., Nagpur	*cry1Ac*
		JK AgriGenetics, Hyderabad	*cry1Ac*
		Syngenta India Ltd., Pune	*Vip-3A*
		Krishidhan Seeds, Jalna	*cry1Ac*
		Nath Seeds, Aurangabad	*cryX*GFM *cry1 Aa*
		Nuziveedu Seeds, Hyderabad	*cry1Aa*
		Tulsi Seeds, Guntur	*cry1Ac, cryX*
		Ganga Kaveri Pvt. Ltd., Hyderabad	*cry1Ac*
		Vikki's Agrotech, Hyderabad	*cry1Ac*
		Pravardhan Seeds, Hyderabad	*cry1Ac*
		Prabhat Agri Biotech Ltd., Hyd.	*cry1Ac*
3.	Chickpea	ICRISAT, Hyderabad	*cry1Ac* and *cry1Ab*
4.	Groundnut	ICRISAT, Hyderabad	coat protein of *IPCV*
5.	Maize	Monsanto, Mumbai	CP4 EPSPS
6.	Mustard	IARI, New Delhi	Osmotin
		TERI, New Delhi	β-carotenoids
		UDSC, New Delhi	*barnase & barstar*
7.	Pigeonpea	ICRISAT, Hyderabad	*cry1Ab + SBTI*
8.	Rice	Mahyco, Mumbai	*cry1Ac*
		MSSRF, Chennai	cytosolic Cu/ Zn SOD gene from mangrove species *Avicennia marina*
		Osmania University, Hyderabad	*gna* gene
9.	Tomato	IARI, New Delhi	*Osmotin*

Source: DBT Annual Report 2004-05.