USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 7/10/2015

GAIN Report Number: IN5088

India

Agricultural Biotechnology Annual

2015

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Report Highlights:

Bt cotton continues to remain the only biotech crop approved for commercial cultivation in India, with six events and nearly 1,200 Bt hybrids currently under cultivation. Although India's biotechnology regulatory system showed strong signs of life in early 2014, it dithered during the latter months of 2014 and thus far in 2015 because of political backsliding. Indian animal biotechnology research is in its infancy, except for some successes in animal cloning. There are no genetically engineered (GE) animals currently in commercial production.

Section I. Executive Summary:

Agricultural trade between the United States and India was estimated at about $5.9 billion in calendar year (CY) 2014, although the balance of ag trade was skewed roughly 4 to 1 in India's favor. Soybean oil derived from GE soybeans (select events) remains the only biotech food/agricultural product currently approved for import. In CY 2010, U.S. soybean oil exports to India reached a record $132.9 million, but trade has since declined significantly.

Bt cotton is the only GE crop currently approved for commercial cultivation in India. Since 2002, the Government of India (GOI) has approved six Bt cotton events and nearly 1,200 Bt cotton hybrids and varieties for commercial cultivation. India does not commercially produce GE animals, including cloned animals, and/or products derived from GE animals.

The 1986 Environmental Protection Act (EPA) provides the foundation for India's biotechnology regulatory framework (see Annex 1) for GE plants, animals, and their respective products. Current Indian regulations stipulate that the Genetic Engineering Appraisal Committee (GEAC), India's apex regulatory body, must conduct an appraisal of all biotech food/agricultural products, or products derived from biotech plants and/or other biotech organisms prior to commercial approval or importation. Annex 2 of the EPA outlines the procedures for importing biotech products, including products used for research. On April 22, 2013, the Ministry of Science and Technology's (MOST) Department of Biotechnology (DBT) submitted the "Biotechnology Regulatory Authority of India Bill 2012" (BRAI) to the Parliament of India, but the bill was never brought to the floor for discussion and approval. The BRAI bill proposed to establish an independent and autonomous national biotech regulatory authority for biosafety clearance of GE products and processes. The 2013 BRAI bill lapsed in May 2014 following the dissolution of the 15th Lok Sabha, subsequent to the last Parliamentary election. To date, the current National Democratic Alliance (NDA) government has not reintroduced any version of the BRAI bill (with or without modifications from 2013) to the Parliament.

The Food Safety and Standards Act of 2006 include specific provisions for regulating GE food products, including processed foods. However, the apex food safety regulatory body identified by the Act, the Food Safety and Standard Authority of India (FSSAI), is still in the process of formulating specific regulations for overseeing GE food products. Consequently, the GEAC continues to regulate processed food products (containing GE ingredients) under the 1989 Rules.

India's biotech regulatory policy environment from 2010 through early-2014 severely hampered approvals for new events, many of which had achieved advanced stages within the regulatory approval process. On February 9, 2010, the Ministry of Environment and Forest (MOEF) announced a moratorium on the approval of Bt *brinjal* (eggplant). On July 6, 2011, the GEAC introduced new procedures for authorizing biotech crop field trials, requiring applicants (technology developers) to obtain a 'no objection certificate' (NOC) from the relevant state government. The decision has hampered GE crop field trials as very few states have issued NOCs due to various political reasons. The functioning of GEAC was effectively suspended for nearly two years from April 2012 through March 2014. The previous government revived the GEAC by reconvening it again on March 21, 2014, by the monthly meetings in April and May approving field trials of several crop events.

The GEAC reconvened for the first time under the new NDA government on July 17, 2014, and approved several GE crop field trials. This led to strong opposition from some of the ideologically-based organizations affiliated to the Bharatiya Janata Party (BJP)-led NDA government. Although the

government allowed the approved GE crop field trials to proceed, subject to the issuance of NOCs from the various state governments, no new approvals were granted during subsequent GEAC meetings held in September 2014 and February 2015. While no new GE crop field trials have been approved for the upcoming 2015/16 crop season, the ongoing multi-season GE field trials (already approved in 2013 and 2014) are likely to continue during the upcoming crop season.

In May 2012, the Supreme Court of India appointed a Technical Expert Committee (TEC) to review and recommend biosafety risk assessment studies for GE crops. On July 18, 2013, five members of the six-member TEC submitted its final report and recommended a ban on all GE crop field trials until the gaps in the existing biosafety regulatory system are addressed.
However, one member of the TEC submitted a separate report recommending the continuation of field trials while the GOI addresses regulatory shortcomings. The GOI and industry stakeholders strongly contested the five-member TEC's recommendation immediately following its issuance, as well as during subsequent hearings in August 2013, April and May 2014. Although the case has not been heard since April 2014, it remains pending with the Supreme Court.

Prime Minister Narendra Modi and other senior GOI officials have stated support for adopting new agriculture technologies, including biotechnology. Most local biotech stakeholders remain cautiously optimistic that the GOI will continue to allow biotechnology research and field trials.

Section II. Author Defined:

CHAPTER 1: PLANT BIOTECHNOLOGY

PRODUCTION AND TRADE

a. Product Development

Several Indian seed companies and public sector research institutions are working to develop a variety of GE crops, mainly for pest resistance, herbicide tolerance, nutritional enhancement, drought tolerance, and yield enhancement. The crops being developed by public sector institutions include banana, cabbage, cassava, cauliflower, chickpea, cotton, eggplant, rapeseed/mustard, papaya, pigeon pea, potato, rice, sugarcane, tomato, watermelon and wheat. The private seed companies are more focused on cabbage, cauliflower, chickpea, corn, rapeseed/mustard, okra, pigeon pea, rice, tomato, and next generation technologies (stacked events) for cotton. Despite the GEAC approvals for field trials of 21 events in eight crops, problems in obtaining permission (in the form of NOCs) from state governments have limited field trials to only few events (chickpea, corn, cotton, mustard and rice) in the crop year 2014/15.

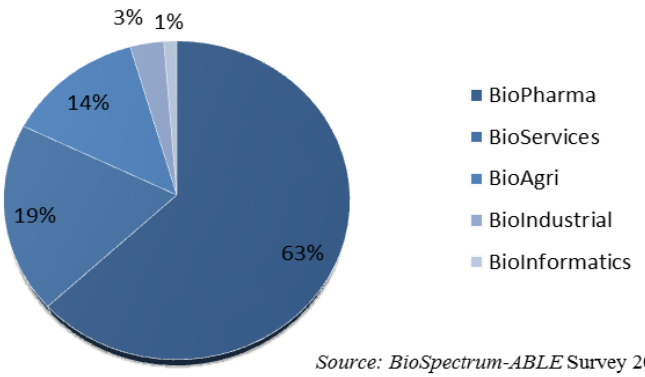
On October 14, 2009, the GEAC recommended the approval of commercial cultivation of Bt eggplant, which was forwarded to the MOEF for a final decision. After a series of public consultations, on February 9, 2010, the MOEF announced a moratorium on the approval until the GOI's regulatory system could ensure human and environmental safety through long-term studies. More than five years later, the GEAC has not undertaken any steps, or issued any decisive way forward for the approval of Bt eggplant. Industry sources report that there are at least 2-3 other GE crop events that are at advanced stages of product appraisal and could feasibly be ready for approval in the next 1-2 years.

b. Commercial Production

Bt cotton is the only GE crop approved for commercial cultivation in India since 2002. In a period of 13 years, Bt cotton area has grown to about 95 percent of total cotton area and has led to a huge surge in cotton production. India's cotton production in 2014 was estimated at 29.5 million bales (480 lbs) from 12.7 million hectares, compared to 10.6 million bales from 7.6 million hectares in 2002. As a result, India has emerged as the world's second largest producer and exporter of cotton. To date, the GOI has approved six cotton events and nearly 1,200 hybrids for cultivation in different agro-climatic zones. Most of the approved Bt cotton hybrids are produced from two Monsanto events (Mon 531 and Mon 15985). The commercial cultivation of Bt cotton events is approved for seed, fiber, and feed production/consumption.

Agricultural biotechnology is the third largest component in India's domestic biotech industry with revenues of INR 33.5 billion ($734 million) in Indian fiscal year (IFY) 2012/13 (April/March), accounting for about 14 percent of the total revenue. With Bt cotton being the only GE product approved and area under Bt cotton nearly at its maximum, growth of agriculture biotechnology has slipped down to 4.3 percent in 2013/14 (5 percent in 2012/13), and is likely to weaken further for the foreseeable future unless the GOI approves other biotech crop events.

Figure 1. India Biotech Industry Revenue 2013/14
(Rs. 252 billion/$4.1 bilion)



Source: BioSpectrum-ABLE Survey 2014

c. Exports

India is the one of the world's leading cotton exporters and occasionally exports small quantities of cotton seed and cotton seed meal, which are derived from Bt cotton. India exported about 4.1 million bales (480 lbs) in 2014 and had exported a record 11.1 million bales in 2011. Market sources report that export documentation for cotton as a fiber product (cellulose) does not require any GE declaration, as it has no protein content. India does not export significant quantities of cotton or cottonseed meal to the United States.

d. Imports

The only GE food product currently authorized for import into India is soybean oil derived from GE

soybeans (glyphosate tolerant and four other events). India imports significant quantities of soybean oil (2.1 million metric tons in 2014) from Argentina, Brazil, Paraguay, and Ukraine.

e. Food Aid

India is not a food aid recipient from the United States and is not likely to be in the near future.

POLICY

a. Regulatory Framework

The regulatory framework for GE crops, animals, and products in India is governed by the EPA of 1986 and the "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989." These rules govern research, development, large-scale use, and import of GE organisms and their products. The rules identify six competent authorities (see Annex 1).

On August 24, 2006, the GOI enacted an integrated food law, namely the Food Safety and Standards Act of 2006, which has specific provisions for regulating GE food products, including processed foods. Under the Act, FSSAI is cited as the single authority responsible for establishing and implementing science-based standards for food, including GE foods. However, as noted above, FSSAI has still not developed the institutional capacity to fulfill this function.

Table 1. India: Role of Various Ministries/State Governments:

Authority	**Role/Responsibility**
MOEF, GOI.	Houses the GEAC, the nodal agency responsible for the implementation of Biotech Rules of 1989 under the EPA Act.
DBT, MOST, GOI.	Provides guidelines and technical support to the GEAC. Evaluates and approves biosafety assessment of GE product research and development in the country.
Ministry of Agriculture (MOA)	Evaluates and approves the commercial release of transgenic crop varieties after conduction field trials for assessing agronomic performance.
FSSAI, Ministry of Health and Family Welfare, GOI.	Evaluates and approves the safety assessment of GE crops and products for human consumption. FSSAI has not yet establish regulations and the GEAC continues to oversee this responsibility.
Various state governments.	Monitors the safety measures at biotech research facilities, and assess damage, if any, due to the release of GE products. Approve field trials and commercial cultivation of GE crops finally approved by the GEAC in their respective states.
DBT, MOA, and various state governments.	Supports, research and development of agriculture biotechnology through various research institutions and state agriculture universities.

In 1990, the DBT developed the Recombinant DNA Guidelines, which were subsequently amended in 1994. In 1998, the DBT issued separate guidelines for biotech plant research, including the import and shipment of GE plants for research use. In 2008, the GEAC adopted "Guidelines and Standard

Operating Procedures for the Conduct of Confined Field Trials." The GEAC also adopted new "Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants". All guidelines and protocols, including the EPA Act of 1986 and the 1989 Rules, are available online at http://dbtbiosafety.nic.in/.

GEAC Staggers….

From April 2012 through March 2014, the GEAC, which falls under the administrative umbrella of the MOEF, did not make any decisions regarding GE events in the regulatory pipeline, and for all intents and purposes ceased to function as an organization. The previous government reconvened the GEAC on March 21, 2014, followed by additional meetings on April 25, 2014, and May 12, 2014.

After the NDA government formed in May 2014, the first GEAC meeting under the new government was held on July 17, 2014, wherein approvals were granted for field trials of several GE crop events. This was strongly opposed by several ideological organizations affiliated with the ruling BJP-led NDA government. Consequently, the GEAC did not consider any new applications for GE crop field trials during subsequent meetings held in September 2014 and February 2015. To date, no GEAC meetings have been convened since February 2015 and no new GE event applications have been approved for field trials in the upcoming 2015/16 crop season. However, industry sources remain hopeful that the government will reinvigorate the GEAC functioning to continue GE crop field trials as well as examine additional GE event approvals.

Supreme Court Case in Limbo

On May 10, 2012, the Supreme Court of India appointed a six-member TEC to review and recommend risk assessment studies (for health and environmental safety) for all GE crops before they can be released for open field trials. The Court's action was in response to a petition filed in 2005 which alleged that field trials of GM crops were being allowed without proper scientific evaluation of biosafety concerns. (NOTE: For more information on the 2005 SC case, please refer to GAIN report IN8077, page 7).

The TEC submitted an interim report on October 7, 2012, to the Court which recommended a ban on ongoing GE crop field trials until gaps in the existing biosafety regulatory system are addressed. On November 9, 2012, the TEC report was discussed in a Supreme Court hearing, wherein the GOI and various industry stakeholders expressed their strong opposition the TEC's recommendation. Consequently, the Court asked the TEC to consider the objections when making its final recommendations. The Supreme Court also nominated a senior agriculture scientist in place of one of the earlier nominated member who declined to be part of the TEC. On July 18, 2013, the five members of the TEC submitted their final report recommending a ban on field trials until the gaps in the existing regulatory system are properly addressed. However, the sixth nominated member (agriculture scientist) in the TEC submitted a separate report dissenting against the TEC recommendation. On April 1, 2014, the GOI submitted an affidavit to the Court against the five-member TEC report. The five-member TEC report has been strongly opposed by the GOI and biotech industry stakeholders in the court hearings on April 22, 2014 and May 7, 2014. The discussion is likely to continue in the next hearing, which has not been scheduled till date.

FSSAI Still Not Ready to Regulate GE Food

Subsequent to the enactment of the 'Food Safety and Standard Act of 2006, the MOEF issued a notification on August 23, 2007, stating that processed food products derived from GE products (where the end-product is not an LMO - a living modified organism) do not require approval from GEAC for production, marketing, import and use in India. As processed food products are not replicated in the environment, they are not considered to be an environmental safety concern under the 1989 EPA. However, imports of LMOs continue to be under the purview of GEAC and the 1986 EPA.

Although technically the FSSAI has regulatory authority over GE food products in India, there are no specific regulations in place for FSSAI to approve GE food products. Consequently, the Ministry of Health and Family Welfare (MHFW) requested that the GEAC continue to regulate processed, GE-derived food products under the 1989 Rules. Thus, the MOEF notification on processed food products has been deferred and the GEAC continues to regulate imports of processed GE food products. On May 21, 2010, the FSSAI circulated a "Draft on Operationalizing the Regulation of Genetically Modified Foods in India." (See GAIN report IN1044). However, there has not been any official notification from the FSSAI on the proposed regulations on GE food till date. Until new regulations are in place, the 1986 EPA remains the cornerstone of India's biotech regulatory system.

Biotechnology Regulatory Authority Bill Lapses

On November 13, 2007, the MOST unveiled a "National Biotechnology Strategy" to strengthen the regulatory framework, instituting a National Biotechnology Regulatory Authority of India (NBRAI) that would provide a single window mechanism for biosafety clearance. In 2008, the DBT issued a draft "National Biotechnology Regulatory Bill," together with a draft "Establishment Plan for Setting up the National Biotechnology Regulatory Authority." Following inter-ministerial consultations with different stakeholders, the DBT subsequently revised the BRAI, which was submitted to the Parliament of India for approval on April 22, 2013. Subsequently, the bill was referred to the Parliamentary Standing Committee on Science, Technology, Environment and Forests. On June 11, 2013, the standing committee sent a notice seeking comments on the proposed bill from the stakeholders. Meanwhile, the BRAI bill lapsed in May 2014 with the dissolution of the 15th Lok Sabha after the last Parliamentary elections. The ruling National Democratic Alliance government will have to reintroduce the BRAI bill to the Parliament of India for approval in near future. The NDA government will have to decide on whether to present the proposed bill in its current form, or conduct further consultations and make additional changes before presenting it to the Parliament for approval. Pending parliamentary approval of the BRAI, India's regulatory mechanisms continue to be governed by the EPA 1986 and the Rules of 1989.

b. Approvals

Bt cotton is the only GE crop approved for cultivation in India.

Table 2. India: Bt cotton events approved

Gene/Event	Developer	Usage
Cry1Ac (Mon 531) [1]	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed
Cry1Ac & Cry2Ab (Mon 15985) [2]	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed

Cry1Ac (Event 1) [3]	JK Agrigenetics	Fiber/Seed/Feed
Cry1Ab and Cry1Ac (GFM Event) [4]	Nath Seeds	Fiber/Seed/Feed
Cry1ac (BNLA1)	Central Institute of Cotton Research	Fiber/Seed/Feed
Cry1C (Event MLS 9124)	Metahelix Life Sciences Private Limited	Fiber/Seed/Feed

Source: IGMORIS, GOI.
[1] Gene sourced from Monsanto.
[2] Stacked gene event sourced from Monsanto.
[3] Gene sourced from Indian Institute of Tech., Kharagpur.
[4] Gene sourced from China featuring fused genes.

c. Field Testing

The GEAC is responsible for approving all open field trials on the recommendation of RCGM. In 2008, the GEAC adopted an "event based" approval system, reviewing the efficacy of the event/trait, and focusing on biosafety, particularly on environmental and health safety. Before any GE event can be approved for commercial use, it must undergo extensive agronomic evaluation through field trials under the supervision of an Indian Council of Agricultural Research (ICAR) institution or a state agriculture university (SAU) for at least two crop seasons. Product developers can also conduct agronomic trials in conjunction with the biosafety trials, or do so separately after the GEAC recommends environmental clearance and the GOI gives final authorization.

In early 2011, some state governments objected to authorization of GE crop field trials without state permission. On July 6, 2011, the GEAC amended the procedures for field trial authorization, which now require the applicant (the technology developer) to obtain an NOC from the relevant state government. Applications that had previously received approval from the GEAC now also require an NOC from the state government before commencing the field trials. Industry sources report that only the states of Andhra Pradesh, Delhi, Gujarat, Haryana, Punjab, Karnataka and Maharashtra have issued NOCs for GE field trials of select events in the Indian crop year 2014/15 (July-June), and some of the states have restricted the trials to non-food crops only.

Since March 2014, the GEAC has approved field trials of 21 applicants for several new GE crop events for planting in Indian crop year 2014/15 (July/June). In addition, some of prior approved events for multi-year field trial may also be planted in 2014/15 season.

d. Additional Requirement

Once an event is approved for commercial use, the applicant can register and market seeds in various states according to the provisions of the 2002 National Seed Policy and other relevant seed regulations specific to each state. Following the commercial release of a GE crop, the Ministry of Agriculture, together with the various state departments of agriculture, monitors field performance for 3-5 years.

e. Stacked Events

For approval purposes, a stacked event, even if consisting of already approved events, is essentially

treated as a new event.

f. Coexistence

The GOI has no specific regulations on coexistence of GE and non-GE crops. On January 10, 2007, the GEAC decided against allowing multi-location GE crop field trials in basmati rice growing areas, particularly in the GI states of Punjab, Haryana and Uttaranchal.

g. Labeling

In March 2006, the Ministry of Health and Family Welfare issued a draft amendment to the 1955 Prevention of Food Adulteration (PFA) Rules, extending a labeling requirement to "Genetically Modified foods" (For more information on the proposed regulation, refer to GAIN reports IN6024 and IN6060). The FSSAI has been consulting with various stakeholders on the draft amendment to consider labeling options under the new Food Safety and Standard Act 2006, but no decision has been taken on labeling of GE food products to date.

On June 5, 2012, the Department of Consumer Affairs (DCA), Ministry of Consumer Affairs, Food and Public Distribution, issued notification G.S.R. 427 (E) amending the Legal Metrology (Packaged Commodities) Rules, 2011, effective January 1, 2013, which stipulates "every package containing genetically modified food shall bear at the top of its principal display panel the word "GM." The DCA stated that the "GM" labeling requirement is for consumers' right to know. Industry sources report that there has been no enforcement of the labeling requirement by DCA. As the FSSAI is still in the process of establishing labeling regulations for GM foods, the future status of the DCA GM labeling regulation remains uncertain (see GAIN report IN2078).

h. Trade Barriers

On July 8, 2006, the Ministry of Commerce and Industries issued a notification specifying that all imports containing GE products must have prior approval from the GEAC. This directive requires a GE declaration at the time of import. In 2006, the MOEF published the Procedure for GEAC Clearance for Imports of GM Products. The specific procedure for filing an import application for a GE product is found in Annex 2 of this report.

Industry sources report that the procedure for GEAC clearance for import of GE products is very cumbersome and not science based, which effectively prohibit imports. Nevertheless, on June 22, 2007, the GEAC granted permanent approval for importation of soybean oil derived from glyphosate-tolerant soybeans for consumption after refining. On July 17, 2014, the GEAC also approved importation of soybean oil derived from four other GE events. No other GE food products, bulk grains, semi-processed or processed foods are currently authorized for import.

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

i. Intellectual Property Rights

In 2001, India enacted the Protection of Plant Varieties and Farmers' Rights Act to protect new plant varieties, including transgenic plants. The Protection of Plant Varieties and Farmers' Right Authority was established in 2005, and to date has notified 88 crops for registration, including Bt cotton hybrids.

j. Cartagena Protocol Ratification

On January 17, 2003, India ratified the Cartagena Protocol on Biosafety, and has since established rules for implementing the provisions of the articles (see Annex 3). A Biosafety Clearing-House (BCH) has been set up within the MOEF to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs). The GEAC has the responsibility of approving trade of GE products, including seed and food products. India has traditionally advocated strict liability and redress to the trans-boundary movement of LMOs, a position that could complicate the movement of Bt cotton seed to neighboring countries.

k. International Treaties/Fora

In Codex Alimentarius discussions, India has supported mandatory labeling of GM foods, requiring a compulsory declaration whenever food and food ingredients contain genetically modified organisms.

l. Related Issues

Not applicable.

m. Monitoring and Testing

The Ministry of Agriculture does monitor the approved GE crop events for three years for agronomic performance and environmental implications. However, there is no regular monitoring program for GE food products. In case of suspicion of an unapproved GE food product in the market, the FSSAI and food safety authorities in the state governments can draw samples for testing at various government and private food testing labs with facilities for identifying events and taking penal action in case found containing unapproved GE events.

n. Low Level Presence

India has a zero tolerance policy for unapproved GE food and crop events.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PRODUCTION AND TRADE

a. Biotechnology Product Development

Indian research on animal biotechnology is in its infancy, except for some successes in animal cloning. On February 6, 2009, scientists of the National Dairy Research Institute delivered the first cloned buffalo heifer calf through the advanced hand guided cloning technique, but the calf died shortly after birth. Subsequently, two cloned heifer calves were born on June 6, 2009, and August 22, 2010, and a bull calf was born on August 26, 2010. While the second cloned heifer died two years later, the third heifer and the cloned bull calf are alive (see below). On January 25, 2013, the cloned heifer calved after being bred by a progeny tested bull. On December 27, 2014, the first cloned buffalo delivered its second calf using the 'hand-guided cloning technique', which is the eighth cloned calf by the institute. On March 9, 2012, scientists from the Sher-e-Kashmir University of Agricultural Sciences and Technology at Srinagar claimed to have delivered a cloned pashmina goat by the same cloning technique. Scientists from NDRI reported that the cloning research is still experimental and it may take another 3-5 years before they can standardize the technique for commercial production.

Cloned Buffalo Cow

Cloned Buffalo Bull

Most animal biotechnology research in India is currently focused on the genomics of important livestock, poultry and marine species for identifying genes for heat/cold tolerance, disease resistance and economically important production factors. The bovine genomics program focuses on characterizing and identifying genes for heat tolerance, disease resistance, and economic factors like duration between calving, length of lactation, and milk yield. The ongoing genomics studies can be used in the future breeding programs for incorporating important traits through traditional breeding or future genetic engineering.

Most animal biotechnology research is conducted by public sector research organizations like ICAR institutions, Council of Scientific and Industrial Research (CSIR) institutions, state agricultural universities and other research organizations supported by the DBT.

b. Commercial Production

To date, India does not commercially produce GE animals, including cloned animals or products

derived from GE animals for commercial production.

c. Biotechnology Exports

Not applicable.

d. Biotechnology Imports

Currently India does not allow imports of any GE animals or products derived from GE animals.

POLICY

a. Regulation

The EPA 1986 also governs the research, development, commercial use and imports of GE animal and animal products. However, research on cloning of animals and genomic research on animals does not come under the purview of EPA. With the cloning of animal still at research stage, currently there is no regulation of commercial production or marketing of cloned animals.

b. Labeling and Traceability

India does not regulate labeling or traceability of GE animals and products, including cloned animals.

c. Trade Barriers

The trade barriers applicable to plant products are also applicable for animal GE products.

d. Intellectual Property Rights

There are no specific regulations on IPR for GE animals.

e. International Treaties/Fora

Post is not aware if India has taken any position on GE animals in international fora.

ANNEXURES

Annex 1: Existing Biotech Regulatory Authorities – Function/Composition

Committee	***Members***	***Functions***
Genetic Engineering Appraisal Committee (GEAC); functions under Ministry of	Chairman-Additional Secretary, MOEF Co-Chairman - Nominee of Department of Biotechnology (DBT) Members: Representatives of concerned agencies and	Review and recommend the use of bio-engineered products for commercial applications. Approve activities involving

Environment and Forests (MOEF).	departments namely Ministry of Industrial Development, DBT, and the Department of Atomic Energy Expert members: Director General-ICAR, Director General-ICMR; Director General-CSIR; Director General of Health Services; Plant Protection Adviser; Directorate of Plant Protection; Quarantine and storage; Chairman, Central Pollution Control Board; and few outside experts in individual capacity. Member Secretary: An official from the MOEF	large-scale use of bio-engineered organisms and recombinants in research and industrial production from an environmental safety angle. Consult RCGM on technical matters relating to clearance of bio-engineered crops/products. Approve imports of bio-engineered food/feed or processed product derived thereof. Take punitive actions on those found violating GE rules under EPA, 1986.
Review Committee on Genetic Manipulation (RCGM); function under DBT.	Representatives from: DBT, Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR) Other experts in their individual capacity.	Develop guidelines for the regulatory process for research and use of bio-engineered products from a bio-safety angle. Monitor and review all ongoing GE research projects up to the multi-location restricted field trial stage. Undertake visits to trial sites to ensure adequate security measures. Issue clearance for the import of raw materials needed in GE research projects. Scrutinize applications made to the GEAC for the import of bioengineered products. Form Monitoring and Evaluation Committee for biotech crop research projects. Appoint sub-groups when required in topics of interest to the committee.
Recombinant DNA Advisory Committee (RDAC); function under DBT	Scientists from DBT and other public sector research institutions	Take note of developments in biotechnology at the national and international level. Prepare suitable guidelines for safety in research and applications of GMOs. Prepare other guidelines as may be required by the GEAC.
Monitoring Cum Evaluation Committee (MEC)	Experts from ICAR institutes, State Agricultural Universities (SAUs) and other agricultural/crop research institutions and representatives from DBT.	Monitor and evaluates trial sites, analyze data, inspect facilities and recommend safe and agronomically viable transgenic crops/plants for approval to RCGM/GEAC
Institutional Biosafety Committee (IBC); functions at research institution/ Organization level.	Head of the Institution, Scientists engaged in biotech work, Medical Expert, and Nominee of the Department of Biotechnology	Develop a manual of guidelines for the regulatory process on bio-engineered organisms in research, use and application to ensure environmental safety.

		Authorize and monitor all ongoing biotech projects to the controlled multi location field stage. Authorize imports of bio-engineered organisms/transgenic for research purposes. Coordinate with district and state level biotechnology committees.
State Biotechnology Coordination Committee (SBCC); functions under the state government where biotech research occurs.	Chief Secretary, State Government; Secretaries, Departments of Environment, Health, Agriculture, Commerce, Forests, Public Works, Public Health; Chairman, State Pollution Control Board; State microbiologists and pathologists; Other experts.	Periodically reviews the safety and control measures of institutions handling bio-engineered products. Inspect and take punitive action through the State Pollution Control Boards or the Directorate of Health in case of violations. Nodal agency at the state level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.
District-Level Committee (DLC); 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. Investigate compliance with rDNA guidelines and report violations to SBCC or GEAC. Nodal agency at district level to assess damage, if any, due to release of bio-engineered organisms and take on-site control measures.

Source: DBT and MOEF, GOI.

Annex 2: Procedure and Application Formats for Import of Biotech Products

Item	Approval According Agency	Governing Rules	Form No.	Links for Downloading
GMOs / LMOs for R&D	IBSC/RCGM/ NBPGR	Rules 1989; Biosafety guidelines of 1990 and 1998; Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by NBPGR; and Guidelines for the import of germplasm, 2004 by NBPGR	I	GEAC Form I
GMOs / LMOs for intentional release (including field trials)	IBSC/RCGM/ GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	GEAC Form II B
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	GEAC Form III
GM processed	GEAC	One time “event based” approval given based on	IV	GEAC Form

food derived from LMOs		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
Processed food containing ingredients derived from GMO	GEAC	If the processed food contains any ingredient derived from category 2 and 3 mentioned above, and if the LMO / product thereof has been approved by the GEAC, no further approval is required except for declaration at the port of entry. In case it does not have the approval of GEAC, the procedure mentioned in category 3 above to be complied.	IV , if required	GEAC Form IV B

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

Annex 3: India's Compliance with Various Articles of the Cartagena Protocol

Article	Provisions	Present Status
Article 7	Application of the Advanced Informed Agreement procedure prior to the first transboundary movement of LMOs intended for direct use as food or feed, or for processing.	Competent authority (GEAC) notified. Border control through NBPGR only for contained use. Projects initiated to strengthen DBT and MOEF's capabilities to identify LMOs.
Article 8	Notification – The Party of export shall notify, or require the exporters to ensure notification to, in writing, the competent authority of the Party of import prior to the intentional transboundary movement of LMOs that falls within the scope of Article 7	Rules 1989 and competent authorities in place.
Article 9	Acknowledgement of receipt of notification-The Party of import shall acknowledge receipt of the notification, in writing to the notifier	Point of contact notified, the regulatory body (GEAC) in place
Article 10	Decision Procedure-Decision taken by the Party of import shall be in accordance with Article 15	Regulatory body (GEAC) in place
Article 11	Procedure for LMOs intended for direct use as food or feed, or for processing	1989 Rules [1], DGFT Notification No. 2(RE-2006) / 2004-2009 [2]
Article 13	Simplified Procedure to ensure the safe intentional trans-boundary movement of LMOs	1989 rules
Article 14	Bilateral, regional and multilateral agreements and arrangements	--
Article 15	Risk assessment	DBT Biosafety Guidelines for research in plants, guidelines for confined field trials guidelines for safety assessment of foods derived from GE plants.
Article 16	Risk Management	DBT Guidelines for research

Article 17	Unintentional trans-boundary 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 **(http://www.indbch.nic.in**) has been set up.
Article 21	Confidential information	--
Article 22	Capacity building	Ongoing capacity building activities by DBT, MOEF, USTDA and USAID-sponsored SABP
Article 23	Public awareness and participation	Ongoing, MOEF and DBT have specific websites on biotech developments and regulatory system including website of IGMORIS [3] , GEAC [4] , DBT Biosafety [5] , etc.
Article 24	Non-Parties (trans-boundary movements of LMOs between Parties and non-Parties)	1989 rules in place for all import and export
Article 25	Illegal trans-boundary movements	--
Article 26	Socio-economic considerations	Socioeconomic analysis is an integral part of decision making
Article 27	Liability and redress	National Consultation ongoing

Source: MOEF and Industry Sources.

[1] See Annex 2

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

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

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

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