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Global Agricultural Information Network

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## India

### Agricultural Biotechnology Annual

#### 2014

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**Report Highlights:**

Bt cotton remains the only commercially approved biotech crop in India, with six events and nearly 1,100 Bt hybrids approved for commercial cultivation. India's biotechnology regulatory system was reanimated in early 2014 following a two-year hiatus. Indian animal biotechnology research is in its infancy, despite some successes in animal cloning. There are no genetically engineered (GE) animals in commercial production.

## Section I. Executive Summary:

Agricultural trade between the United States and India was estimated at about \$5.6 billion in calendar year (CY) 2013, although the balance of ag trade balance was skewed roughly 5.5 to 1 in India's favor. Soybean oil derived from glyphosate-tolerant soybeans is 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. However, this trade has since declined significantly and reached only \$28.3 million in CY 2013.

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 1,100 Bt cotton hybrids and varieties for commercial cultivation. India does not commercially produce GE animals, to include cloned animals, and/or products derived from GE animals for commercial production.

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. Per current Indian regulations, all biotech food/agricultural products, or products derived from biotech plants and/or other organisms must receive formal approval from the Genetic Engineering Appraisal Committee (GEAC) prior to commercialization or imports (the GEAC is India's apex biotech regulatory body). Annex 2 of the EPA outlines the procedures for importing biotech products, including products used for research. On April 22, 2013, the DBT submitted the "Biotechnology Regulatory Authority of India Bill 2012" (BRAI) to the Parliament of India, which has been subsequently referred to the Parliament's Standing Committee on Science, Technology, Environment and Forests for review and consultations with stakeholders. However, to date the BRAI bill still has not been formally introduced to the Parliament for approval. The BRAI bill proposes setting up an independent and autonomous national biotech regulatory authority for biosafety clearance of genetically engineered products and processes.

The Food Safety and Standards Act of 2006 includes specific provisions for regulating GE food products, including processed foods. However, the apex regulatory body under the Act, the Food Safety and Standard Authority of India, 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 were at advanced stages of regulatory approval. 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. This decision has hampered ongoing field trials as only a few states (Punjab, Haryana, Gujarat, Andhra Pradesh and Maharashtra) have issued NOCs.

The functioning of GEAC was effectively suspended for nearly two years from April 2012 through March 2014. After the resignation of the former Minister of Environment and Forest in December 2013, and the subsequent appointment of her successor, the GEAC was revived and reconvened on March 21, 2014. During its first official meeting, it approved field trials for several new crop events, followed by subsequent monthly meetings, and additional approvals, in April and May. Although the

GEAC was not convened in June following the formation of the newly elected National Democratic Alliance (NDA) Government, it is scheduled to reconvene on July 17, 2014. Post expects that that India's new government is likely to continue with the regular monthly GEAC meetings.

In May, 2012, the Supreme Court (SC) 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. The next SC hearing on the case is scheduled for July 15, 2014, but the Court's final verdict may take additional time (perhaps months) after the July reconvening.

Most local biotech stakeholders remain cautiously optimistic that ongoing field trials are likely to continue. Moreover, the newly elected NDA Government has stated support of adopting new agricultural technologies. While the SC verdict may ultimately foment changes to India's biotech regulatory system, the pendulum seems to be swinging back towards a more progressive regulatory environment.

## **Section II. Author Defined:**

### **CHAPTER 1: PLANT BIOTECHNOLOGY**

#### ***PRODUCTION AND TRADE***

##### **a. Product Development**

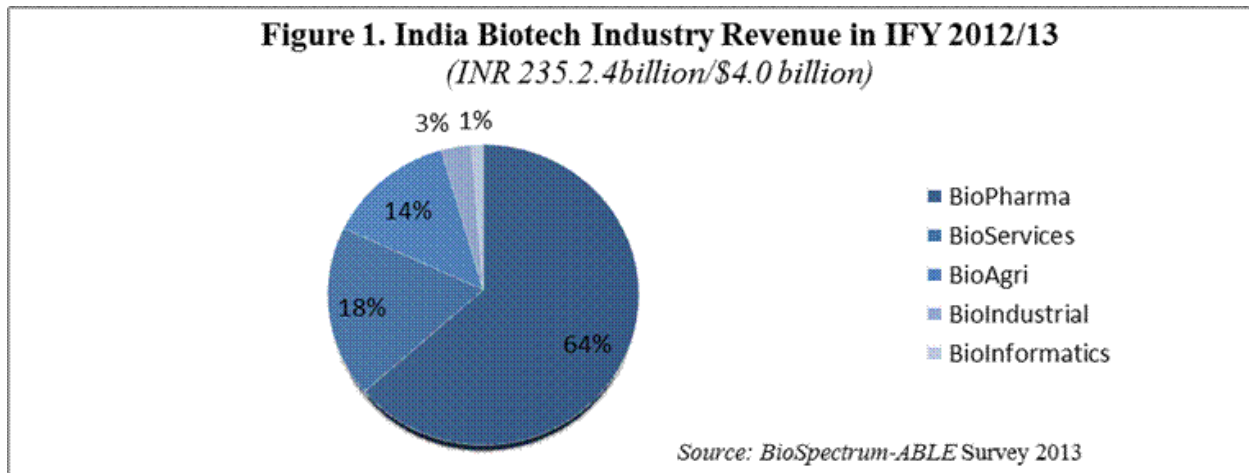
Several Indian seed companies and public sector research institutions are working on the development of various GE crops, mainly for pest resistance, herbicide tolerance, nutritional enhancement, drought tolerance and yield enhancement ([http://igmoris.nic.in/status\\_gmo\\_products.asp](http://igmoris.nic.in/status_gmo_products.asp)). The crops being developed by public sector institutions include banana, cabbage, cassava, cauliflower, chickpea, cotton, eggplant, rapeseed/mustard, papaya, pigeon pea, potato, rice, tomato, watermelon and wheat. The private seed companies are focusing on cabbage, cauliflower, corn, rapeseed/mustard, okra, pigeon pea, rice and tomato, and next generation technologies (stacked events) for cotton. Due to the nearly two-year inactivity of the GEAC, and problems with obtaining permission from the state governments, field trials for new GE events were conducted only for [corn and cotton in 2013](#).

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 government regulatory system could ensure human and environmental safety through long term studies. More than four years later, the GEAC has not undertaken next steps or studies, or issued any decisive ways forward for the approval of Bt eggplant.

## b. Commercial Production

Bt cotton is the only GE crop approved for commercial cultivation in India since 2002. In a period of 12 years, Bt cotton area has grown to about 95 percent of total cotton area and has led to a huge jump in cotton production. India's cotton production in 2013 was estimated at a record 30.5 million bales (480 lbs) from 11.7 million hectares compared to 10.6 million bales from 7.6 million hectares in 2002. As a result, India has emerged as the second largest producer and exporter of cotton in the world. To date, the [GOI has approved](#) six cotton events and nearly 1,100 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.

Riding on the success of Bt cotton, agricultural biotechnology has emerged as the third largest component in India's domestic biotech industry with revenues of INR 43.3 billion (\$734 million) in Indian fiscal year (IFY) 2012/13 (April/March), accounting for more than 18 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 slowed to five percent in 2012/13 (15 percent in 2011/12), and is likely to slow further for the foreseeable future.



## c. Exports

India is one of the world's leading cotton exporters and occasionally exports small quantities of cotton seeds and meal, which are derived from Bt cotton. India exported a record 11.1 million bales (480 lbs/bale) in 2011, and export in 2013 was estimated at 9.0 million bales. Market sources report that export documentation for cotton as a fiber product (cellulose) does not require GE declaration as it has no protein content. India does not export a significant quantity 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 glyphosate-tolerant soybeans. India imports significant quantity of soybean oil (1.6 million metric tons

in 2013) from several countries, including Brazil, Argentina and the United States.

**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 Environmental Protection Act (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, the Food Safety and Standards Authority of India (FSSAI) has been entrusted as the single authority responsible for establishing and implementing science-based standards for food, including GE foods,

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

<b>Authority</b>	<b>Role/Responsibility</b>
MOEF, GOI.	Houses the Genetic Engineering Appraisal Committee (GEAC), the nodal agency responsible for the implementation of Biotech Rules of 1989 under the EPA Act.
Department of Biotechnology (DBT), Ministry of Science and Technology (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 in the MOST developed 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 Resumes Functioning

During 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 all intents and purposes ceased to be a functional organization. Throughout this period, the GEAC did not provide any approvals for GE crops for field trials or commercial cultivation. In December 2013, the previous Minister of Environment and Forest resigned. Subsequently, her successor rejuvenated the GEAC in late February 2014 by approving the proceedings of the last GEAC meeting (March 22, 2013). This action by the new Minister cleared the way for resumption of the regular monthly GEAC meetings. The GEAC reconvened on March 21, 2014, followed by meetings on April 25, 2014 and May 12, 2014 and resulted in the approval of about 21 new applications for field trials of GE crop events. The GEAC was not convened during the formation of the new NDA Government in June 2014. As of the date of publication, the next GEAC meeting is scheduled on July 17, 2014. Industry sources are optimistic that the normal monthly GEAC meetings will enable ongoing GE crop field trials to continue, as well as to expedite additional GE event approvals, some of which have been in limbo for over two years.

### SC Technical Committee Report on Biosafety Assessment

On May 10, 2012, the SC of India appointed a six-member TEC) to review and recommend risk assessment studies (for health and environmental safety) for all bioengineered 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 SC hearing, wherein the GOI and various industry stakeholders expressed their strong opposition the TEC recommendation. Consequently, the SC asked the TEC to consider the objections when making its final recommendations. The SC 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 SC 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, and the discussion is likely to continue in the next hearing on July 15, 2014.

## FSSAI Still Does Not 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.

## Proposed Biotechnology Regulatory Authority Bill Still Pending

On November 13, 2007, the Ministry of Science and Technology 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. 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**

<b>Gene/Event</b>	<b>Developer</b>	<b>Usage</b>
Cry1Ac (Mon 531) <sup>[1]</sup>	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed
Cry1Ac & Cry2Ab (Mon 15985) <sup>[2]</sup>	Mahyco Monsanto Biotech Limited	Fiber/Seed/Feed
Cry1Ac (Event 1) <sup>[3]</sup>	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 four states (Punjab, Haryana, Gujarat and Andhra Pradesh) have issued NOCs for GE field trials, which has adversely affected the ongoing GE crop field trials.

The GEAC permitted field trials of about seven events in cotton and corn for the Indian crop year 2013/14 (July/June). Since March 2014, the GEAC has approved field trials of 21 applicants for several new GE crop events in the last three meetings 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 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 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. 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 79 crop species](#) 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 clear 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. However, in case of reports 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**

In India research on animal biotechnology is in its infancy, except for some success 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 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 is 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 genomics studies can be subsequently used in 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**

As yet 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**

<b><i>Committee</i></b>	<b><i>Members</i></b>	<b><i>Functions</i></b>
Genetic Engineering Appraisal Committee (GEAC); functions under Ministry of Environment and Forests (MOEF).	Chairman-Additional Secretary, Ministry of Environment and Forests (MOEF) Co-Chairman - Nominee of Department of Biotechnology (DBT) Members: Representatives of concerned agencies and departments namely Ministry of Industrial Development, DBT, and the Department of Atomic Energy Expert members: Director General-ICAR, Director General-ICMR; Director General-CSIR; Director General of Health Services; Plant Protection Adviser; Directorate of Plant Protection; Quarantine and storage; Chairman, Central Pollution Control Board;	Review and recommend the use of bio-engineered products for commercial applications. Approve activities involving large-scale use of bio-engineered organisms and recombinants in research and industrial production from an environmental safety angle. Consult RCGM on technical matters relating to clearance of bio-engineered crops/products. Approve imports of bio-

	and few outside experts in individual capacity. Member Secretary: An official from the MOEF	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 Department of Biotechnology (DBT).	Representatives from: DBT, Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR) Other experts in their individual capacity.	Develop guidelines for the regulatory process for research and use of bio-engineered products from a bio-safety angle. Monitor and review all ongoing 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: Department of Biotechnology (DBT) and Ministry of Environment and Forest (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	<a href="#">GEAC Form I</a>
GMOs / LMOs for intentional release	IBSC/RCGM/ GEAC /ICAR	Rules 1989; Biosafety guidelines of 1990 & 1998	II B	<a href="#">GEAC Form II B</a>

(including field trials)				
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	<a href="#">GEAC Form III</a>
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	<a href="#">GEAC Form IV</a>
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	<a href="#">GEAC Form IV B</a>

Source: MOEF Website [http://www.envfor.nic.in/divisions/csurv/geac/gmo\\_lmo.htm](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 <sup>[1]</sup> , DGFT Notification No. 2(RE-2006) / 2004-2009 <sup>[2]</sup>
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, 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 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 ( <a href="http://www.indbch.nic.in">http://www.indbch.nic.in</a> ) 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 <sup>[3]</sup> , GEAC <sup>[4]</sup> , DBT Biosafety <sup>[5]</sup> , etc.
Article 24	Non-Parties (transboundary movements of LMOs between Parties and non-Parties)	1989 rules in place for all import and export
Article 25	Illegal transboundary movements	--
Article 26	Socio-economic considerations	Socioeconomic analysis is an integral part of decision making
Article 27	Liability and redress	National Consultation ongoing

Source: MOEF and Industry Sources.

<sup>[1]</sup> See Annex 2

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

<sup>[3]</sup> <http://igmoris.nic.in/>

<sup>[4]</sup> [http://www.envfor.nic.in/divisions/csurv/geac/geac\\_home.html](http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html)

<sup>[5]</sup> <http://dbtbiosafety.nic.in/>