USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network



Required Report - public distribution

**Date:** 8/6/2015
**GAIN Report Number:** PK1536

# Pakistan

# Agricultural Biotechnology Annual

# Agricultural Biotechnology Annual 2015

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**Report Highlights:**

Pakistan's biotech regulatory system is currently on hiatus as the courts work to determine whether the provinces or federal government should regulate biotech crops. A federal system was implemented in 2005, but its role has not been clear since Pakistan "devolved" a number of federal powers to the provinces in 2010. Pakistan has only approved two biotech traits, both for use in cotton to control lepidopterans. Nevertheless, over 90 percent of Pakistan's cotton crop is produced from biotech seeds and cottonseed oil is Pakistan's largest domestically produced vegetable oil. Pakistan is also a significant importer of products derived from biotech soybeans and canola. The Biosafety Act, if approved, would return oversight to the sector to the federal government. Similarly, approval of the Plant Breeders' Rights Act would create intellectual property protection that would help spur investment and development of the sector.

## Chapter 1: PLANT BIOTECHNOLOGY

## PART A: PRODUCTION AND TRADE

### a) PRODUCT DEVELOPMENT:

Federal approval of new events and products stopped in 2012. In 2010, the Government of Pakistan "devolved" most federal powers to the provinces via the 18th Amendment to the Constitution. The Amendment cast doubt as to whether the federal or provincial governments were in charge of regulating biotechnology. Federal approvals continued through 2012, but halted when the province of Punjab began to develop its own regulatory system and announced its intent to approve biotech seeds. The matter is now before the courts and the process of introducing new products has stopped. Nevertheless, domestic development and testing of various crop traits continues. At present, over 100 field trial results and proposals to commercialize are pending before the National Biosafety Committee in the Ministry of Climate Change. For additional information about the structure of Pakistan's regulatory system see the relevant sections of this report.

The following table lists the ongoing public and commercial testing. Acronyms are defined at the bottom of the table.

**Table 1: DEVELOPMENT OF BIOTECH CROPS IN PAKISTAN**

| Crop | Trait | Status | Institute |
|---|---|---|---|
| Cotton | Diamondback moth resistance with Bt gene | Field trials | CEMB |
| | Virus (CLCV) resistance with Tr AC gene | Field trials/ ready to release | CEMB |
| | Virus (CLCV) resistance with RNA interference (RNAi) | Field trials | CEMB & NIBGE |
| | AVP1-H+ for salt and drought tolerance | Field trials | NIBGE |
| | Cry1Ac and cry2Ab | Field trials | CEMB and Ali Akbar |
| Wheat | Rust, drought and salt tolerance | Experimental/ Field Trial | NIBGE |
| | Bio-fortified Wheat for increased Iron and Zinc bioavailability | Field Trial | FCC/AARI |
| | Rust resistance markers | experiments | ABRI, AARI |

| | | | |
|---|---|---|---|
| Rice | Bacterial blight resistance with Xa21 gene (through Molecular Assisted Breeding)<br><br>Insect resistance with Cry1Ac & Cry2A genes | Experimental<br><br>Experimental | NIBGE<br><br>CEMB |
| Maize | Insect Resistance<br><br>cp4epsps<br><br>cry2Ab2 & cry1A.105 and cp4epsps<br><br>cry1F, cry1Ab and cp4epsps<br><br>cry1Ab x mESPSPS | Field trials<br><br>Field trials<br><br>Field trials<br><br>Field trials<br><br>Field trials | CEMB, NIGAB<br><br>Monsanto<br><br>Monsanto<br><br>Pioneer<br><br>Syngenta |
| Sugarcane | Insect resistance with Cry gene<br><br>Chloroplast Transformation<br><br>Drought tolerance | Experimental<br><br>Experimental<br><br>Experimental | NIBGE<br><br>CEMB<br><br>AARI |
| Chickpeas | Insect resistance (Bt gene) | Experimental | CEMB |
| Tobacco | Insect( Helicoverpaarmigera and Heliothesisvericens) resistance with a novel synthetic spider venom gene<br><br>Salt Tolerance with Yeast, Arabidopsis Na+/H+ antiporter genes<br><br>Salt Tolerance with ArDH Chloroplast transformation ( Biosafe GM) | Experimental<br><br>Experimental<br><br>Experimental | NIBGE<br><br>NIBGE, CABB<br><br>CABB |
| Potato | Virus (PLRV, PLXV, PVY)resistance, Chitinase gene for fungal disease resistance | Experimental | NIBGE |
| Groundnut | Herbicide resistance, Tikka disease resistance | Experimental | NIGAB |

CEMB Centre of Excellence in Molecular Biology, University of the Punjab, Lahore
NIBGE National Institute for Biotechnology and Genetic Engineering, Faisalabad
FCC Forman Christian College University, Lahore
AARI Ayub Agriculture Research Institute, Faisalabad
ABRI Agricultural Biotechnology Research Institute, Faisalabad
CABB Centre of Agricultural Biochemistry and Biotechnology, University of Agriculture, Faisalabad

NIGAB National Institute for Genomics and Advanced Biotechnology, National Agriculture Research Centre, Islamabad.

**PRODUCTION**:

Biotech cotton is the only crop approved for commercial production in Pakistan. Approved seed varieties contain one of the two released events MON 531(Cry1AC gene) and Cry1Ab, both of which protect cotton from lepidopterans. In 2014 farmers planted 2.6 million hectares of biotech cotton (over 90 percent of total cotton area) using more than twenty seed varieties (including one hybrid).

The 2012 halt in the federal government's approval process coupled with ongoing delays in the implementation of a federal intellectual property system for plant breeders has effectively halted the introduction of new biotechnology products from both the private and public sectors. While there are draft proposals that would address this situation that have been pending for some time, at this stage it is not clear when those proposals will be implemented. See the relevant sections of this report for additional background on the regulatory issues.

**c) EXPORTS:**

Pakistan exports significant volumes of biotech cotton to China, Bangladesh, Indonesia, Thailand, Vietnam and Turkey. Exports were valued at $210 million during the most recent complete cotton marketing year. Pakistan also exports cotton yarn, cotton fabric, and other items manufactured from both domestic and imported biotech cotton. The textile sector comprises a major share of Pakistan's economy and exports.

**d) IMPORTS:**

In 2014, Pakistan imported around 1.2 million 480 lb bales of biotech cotton valued at approximately $587 million mostly from India and the United States. Pakistan is also a major importer of canola and soybean oil derived from biotech seeds in countries such as Canada, Australia, Brazil, and Argentina. Over the past 12 months, Pakistan has begun to import much larger volumes of soybean meal and soybeans from major producers of biotech soybeans such as the United States, Brazil, and Argentina.

**e) FOOD AID:**

There are no known issues or restrictions affecting the importation of food aid produced from biotech crops.

**PART B: POLICY:**

**a) REGULATORY FRAMEWORK**:

Pakistan's federal biotechnology regulatory system has faced challenges since the passage of the 18$^{th}$ Amendment to the Constitution which "devolved" many federal roles and responsibilities to the provinces in 2010. At the time, it was not clear if oversight of the seed and biotechnology sector would fall to the federal or provincial governments and the federal system continued to operate until 2012.

However, the role of the federal government was challenged in 2012 when the Government of Punjab announced its plans to approve several new biotechnology products. Since that time, Pakistan's federal biosafety regulatory structure has effectively ceased to function as the courts review the matter.

While not currently functioning, the federal regulatory structure was established in 2005 and created a three-tiered system under the provisions of the Environmental Protection Act of 1997. Under this Act, Pakistan created the National Biosafety Rules (NBR) and established the National Biosafety Committee (NBC) as the apex body responsible for review and approval of laboratory procedures, monitoring of field trials, regulation of trade, and facilitation of the commercialization of biotech crops and products. The NBC is governed by the 2005 National Biosafety Guidelines and is housed within Pakistan's Environmental Protection Agency in the Ministry of Climate Change. The National Biosafety Rules are consistent with the Cartagena Protocol of Biosafety which was ratified by Pakistan in 2009.

There are fifteen members of the NBC which include representatives from the ministries of National Food Security and Research; Health; Education; Science and Technology; Commerce; Planning and Development; and Textiles. Other members include the Pakistan Agricultural Research Council, the Pakistan Atomic Energy Commission, and representatives from the provinces and territories.

In addition to the apex NBC, the NBR created two additional bodies that provide technical support to the review and approval process:

i) The Technical Advisory Committee (TAC), which is responsible for examining applications for new biotech crops and organisms and makes recommendations to the NBC on technical matters related to laboratory work, field work, and the commercialization of the organisms.

ii) The Institutional Biosafety Committee (IBC) is responsible for undertaking risk assessment, implementing safeguards, and monitoring and inspecting all regulated research and product development that has been authorized by the NBC. The IBC's findings are forwarded to the TAC for review and to formulate recommendations to the NBC.

The federal government is currently reviewing the 2015 Biosafety Act which would reassert the federal regulatory structure that was in effect prior to the devolution of federal powers in 2010 and resolve the current impasse over whether the federal or provincial governments should regulate biotechnology. The rationale for such a move stems from Pakistan's status as a signatory to the Cartagena Protocol on Biosafety. The Protocol outlines certain requirements that are best implemented and regulated at the federal level rather than at the provincial level. If approved for introduction in the Parliament or for approval via a Federal decree, the Biosafety Act would re-establish federal oversight of the biotechnology sector; thereby, eliminating the need for the provinces to develop independent regulatory structures. At this stage, it is too early to predict how the pending cases before the courts in Punjab would be affected by such a move.
The lack of certainty within the regulatory system has prevented both foreign, domestic, and government organizations from introducing new technologies that would boost yields and improve the livelihoods of farmers.

**APPROVALS:**

Only a single cotton technology product has been approved for commercial cultivation. The trait was introduced unofficially in 2002 and spread rapidly across Pakistan as the trait was incorporated into seeds domestically. In 2010, the Government of Pakistan officially approved the cotton trait and which remains the only trait approved for use in Pakistan. In December 2013, the Punjab Seed Council (PSC) approved 15 new biotech seed varieties for cultivation in 2014 (all contained either the Cry1AC or Cry1Ab genes). Many of these varieties had been reviewed by the PSC in 2013 but were not approved due to directions from the National Biosafety Committee stating that product commercialization is a federal undertaking. However, as spring planting approached in 2014, officials were concerned that some of the PSC seeds could become available through unofficial channels. At the same time, the European Union had decided to grant Generalized System of Preferences Plus status to Pakistan, a significant opportunity for Pakistan's textile exporters. However, provincial officials were concerned that the presence of unapproved cotton varieties in textile products might jeopardize textile exports and decided to move ahead with provincial approval and officially release of the new varieties. The courts are now reviewing the matter to determine which government authority should regulate the biotech sector. Several local and multinational seed companies and government institutes have submitted new biotech crop applications to the federal Technical Advisory Committee for review, but all are on hold pending a decision determining whether the federal or provincial governments have the authority to regulate the biotechnology sector.

The Pakistan Biosafety Rules 2005 provides a time line for the approval process. It maintains that in response to an application submitted, a final decision shall be made and communicated to the applicant within:

- 60 days for work bearing low risk and work bearing considerable level of risk for lab work, green house and field testing
- 90 days for experimental release
- 120 days for commercialization

**b) FIELD TESTING**

Pakistan is actively conducting field trials as illustrated in Table 1. The Government has agreed to provide compensation to third parties negatively affected by any unapproved biotech material release during field trial testing. However, FAS Islamabad is not aware of any claims or payments made under this provision.

**c) STACKED EVENT APPROVAL**

The National Biosafety Committee allowed field testing of stacked gene (Cry 1Ac and Cry 2Ab) in cotton developed by the Center of Excellence in Molecular Biology (CEMB) in Lahore. Four stacked gene products are reportedly awaiting approval.

**d) ADDITIONAL REQUIREMENTS**

Once a biotech seed is approved by the National Biosafety Committee, it must be registered with the Federal Seed Certification Department of the Ministry of National Food Security and Research before it can be commercialized.

## e) COEXISTENCE

At present, the Government of Pakistan has not formulated a policy on coexistence between biotech and non-biotech crops.

## f) LABELING

There are no labeling requirements for foods, seeds, fibers, oils, or feeds that that are derived from biotech crops. However, there is a possibility that regulators will seek to develop a system at some point in the future.

## g) TRADE BARRIERS

There are no laws prohibiting or restricting the importation of foods, seeds, fibers, oils or feeds that are derived from biotech crops. Pakistan is a regular importer of seeds and products derived from biotech cotton, soybeans, and canola.

## h) INTELLETUAL PROPERTY RIGHTS (IPR)

Currently, there is no IPR protection system in place which has hindered investment in the seed sector and the introduction of the latest products that biotechnology sector has to offer. The still-to-be implemented and enforced Plant Breeders' Rights Act is the key federal regulation for establishing IPR protection. As a member of the World Trade Organization since 1995 (and a founding member of its predecessor, the General Agreement on Tariffs and Trade in 1947), Pakistan is obligated to make changes to its biotechnology laws in order to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement requires Pakistan to develop a "sui generis" system (a unique law or regulation) for plant protection. The Pakistan Patents Ordinance of 2000 specifically excludes a provision for plants, leaving the Government of Pakistan to develop a protection system. The Plant Breeder's Right Act, if implemented, would provide IPR protection and provide 20 or 25 years of legal protection to firms that register their seeds, granting exclusive rights to conduct all facets of seed production and commercialization.

Pakistan's Intellectual Property Organization (IPO), a federal agency that reports directly to the Prime Minister has oversight of a number of IPR sectors and would be charged with enforcing plant IPR protection. The Prime Minister has approved the Act, but it has not yet been introduced to the legislative National Assembly for approval. While the Act has not been implemented, firms are registering their biotechnology products with the IPO with the expectation that enforcement will begin at some point in the future. Until protections are in place, seed firms are expected to limit the introduction of new seeds to hybrids and seeds containing the currently-approved trait.

## i) CARTAGENA PROTOCOL RATIFICATION:

Pakistan ratified the Cartagena Protocol on Biosafety on March 2, 2009, and the National Biosafety Rules provide a framework for the trans-boundary movement, transit, handling, and use of living modified organisms.

## j) INTERNATIONAL TREATIES/FORA

Pakistan is a member of the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) and actively participates in discussions on biotechnology.

## k) RELATED ISSUES

On July 23, 2015 Pakistan's President approved the amendments to the 1976 Seed Act. The amendments have been awaiting approval for a number of years and passage is considered an important step to facilitating the growth of the seed sector. Key provisions include:

- The amendments would bring the private sector under the purview of the Seed Act. Currently, the Act makes little mention of the private sector, leaving private companies, which have formed under other regulatory statutes (the 1984 companies act for example), largely unregulated.
- Anyone seeking to participate in the seed industry would have to have a seed processing plant or work as a registered seed dealer.
- Selling seed without proper registration and selling misbranded seed would be subject to jail time or a fine.
- Biotech seeds may not contain the "terminator gene," a gene that prohibits the replanting of a crop, but is not deployed in commercial crop crops.
- Biotech seed must have approval from the National Biosafety Committee stating that the seeds will not have an adverse effect on the environment, human, animal, or plant life and health.

The amendments to the Seed Act are likely to have several important effects, including increased access by farmers to regulated and high quality seeds, increased financial and technological investments by large seed companies in research and development, punitive measures and enhanced fines have been instituted to deter the illegal and substandard sale of seed in the market. This should result in higher levels of agricultural production and the creation of new jobs in the agricultural sector.

## l) MONITORING AND TESTING

While not currently functioning, the mechanisms for monitoring and testing are outlined in the 2005 Biosafety Guidelines, the National Biosafety Committee and its two supporting technical committees are responsible for overseeing all lab work, field trials, and approval of the commercial release of biotech crops.

## m) LOW LEVEL PRESENCE POLICY

Pakistan has not considered a low-level presence policy.

# PART C: MARKETING

## a) MARKET ACCEPTANCE

Pakistan's agricultural community is generally supportive of the expanded utilization of biotechnology. Consumer acceptance is more mixed, but the production and consumption of biotech crops is generally accepted. However, consumer sentiment has not really been tested given the lack of progress in

regulating and introducing new biotech crops and products. Pakistan is both a producer (cottonseed oil) and importer (oilseeds, meals, and oils) of biotech crops and products.

Biotech cotton, while limited to a single approved trait, accounts for nearly 90 percent of cotton production.

b) **PUBLIC/ PRIVATE OPINIONS**

See "Market Acceptance" above.

**c) MARKETING STUDIES**

FAS Islamabad is not aware of any marketing studies.

**PART D: CAPACITY BUILDING AND OUTREACH**

**a) RECENT U.S. GOVERNMENT or USDA-FUNDED ACTIVITIES**

The Embassy in Islamabad has supported a number outreach activities related to agricultural biotechnology. For more details, please contact the Office of Agricultural Affairs at agislamabad@fas.usda.gov.

**b) STRATEGIES AND NEEDS**

The key steps for further development of the sector are approval and implementation of the Biosafety Act and the Plant Breeders' Rights Act. Additionally, policy makers and leaders will likely continue to benefit from "lessons learned" in other countries where there is a longer history of biotech regulation. While Pakistan is already a major producer and consumer of biotech crops, consumer awareness is limited. Consumer issues such as labeling, product safety, and transparency could become more prominent if Pakistan takes additional steps to facilitate the importation and production of biotech seeds and crops.

## Chapter 2: ANIMAL BIOTECHNOLOGY

**PART E: PRODUCTION AND TRADE**

No production or trade of animal biotechnologies or cloning is happening in Pakistan

**a) PRODUCT DEVELOPMENT:**

None.

**b) COMMERCIAL PRODUCTION:**

None.

**c) EXPORTS:**

None.

**d) IMPORTS**

None.

**PART F: POLICY**

a) **REGULATION:**

The 2005 Biosafety Rules of Government of Pakistan would likely be the basis for any regulation of genetically engineered animals or their products and National Biosafety Committee would like be charged with reviewing any new product application.

b) **LABELING AND TRACEABILITY:**

There is no labeling policy at this time.

c) **TRADE BARRIERS:**

Given the absence of a regulatory framework, FAS Islamabad believes that imports of animal biotechnology and its products would likely be restricted. Imports must first receive a "No Objection Certificate" from the relevant ministry and officials would likely raise concerns if the products were significantly unique or substantially different from conventional animals or their products.

d) **INTELLECTUAL PROPERTY RIGHTS (IPR):**

FAS Islamabad is not aware of any existing IPR provisions for animal biotechnology.

e) **INTERNATIONAL TREATIES/FORA:**

While Pakistan is a WTO member and participates in fora related to the WTO and its reference bodies such as the World Organization for Animal Health and Codex Alimentarius, FAS Islamabad is not aware of participation in discussions related to animal biotechnology.

**PART G: MARKETING**

a & b) **MARKET ACCEPTANCE, PUBLIC/PRIVATE OPINIONS:**

General awareness appears to be very limited.

c) **MARKET STUDIES:**

FAS Islamabad is not aware of any studies.