

Required Report: Required - Public Distribution

Date: February 18,2021

Report Number: PK2020-0020

Report Name: Agricultural Biotechnology Annual

Country: Pakistan

Post: Islamabad

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Shafiq Rehman

Approved By: Lisa Anderson

Report Highlights:

The Government of Pakistan has put on hold genetically engineered (GE) trials on all crops except cotton since March 2019. Regulatory approval for cultivation, use, and commercialization of GE cotton has been granted since 2010, with new varieties added into the system each year. In Pakistan, agricultural biotechnology laws exist, but many of the implementing rules and guidelines have yet to be established and technical staff have yet to be hired. National regulatory bodies are in different stages of promulgating rules and administrative procedures, which need to be synchronized in order for Pakistan's legal system that governs agricultural biotechnology to operate effectively. The National Biosafety Committee, under the Ministry of Climate Change, is currently in the process of developing regulations governing the importation of GE food intended for food, feed, and processing. Intellectual property protections remain weak, limiting access to the cotton industry of the latest generations of GE cotton seed.

EXECUTIVE SUMMARY

Pakistan's agricultural biotechnology framework is dependent on four key laws: the Pakistan Biosafety Rules (PBR) of 2005; the Intellectual Property Organization of Pakistan Act of 2012; the Seed Amendment Act of 2015; and the Plant Breeders Rights Act (PBRA) of 2016. However, despite the passage of these laws, many of the corresponding implementing regulations have not been developed, nor sufficient technical staff hired to enforce those regulations that are on the books. Pakistan approved the cultivation and use of genetically engineered (GE) cotton in 2010, but in March 2019, it put on hold GE trials of all other crops.

The 2005 PBR require GE-derived products used for food, feed, and processing (FFP) to be approved by the National Biosafety Committee (NBC). However, to date, the NBC has yet to promulgate rules or establish administrative protocols that would enable companies to legally register and import their GE products for FFP purposes. Despite the passage of the PBRA in 2016 and the finalization of its implementing rules and plant registry in 2018, the Ministry of National Food Security and Research lacks staff to enforce the rules. The absence of a fully operational agricultural biotechnology framework creates an uncertain trading environment for exporters of GE crops intended for FFP and discourages technology providers from investing in Pakistan's cotton industry.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY 2

PART B: POLICY 8

PART F: MARKETING 17

PART I: MARKETING 18

Not applicable. 18

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

The present administration of the Government of Pakistan (GoP) took office in August 2018 with a call for broad reforms. Since then, Pakistan’s agricultural and food policies have been under review. In March 2019, the Ministry of National Food Security and Research (MNFSR), in conjunction with National Biosafety Committee (NBC), issued a moratorium to suspend the commercialization of

genetically engineered (GE) hybrid corn,¹ due to a determination by the present administration that corn production, through the use of non-GE seeds, was sufficient to meet Pakistan’s domestic demand.

Pursuant to this determination, GE trials on all crops, except for cotton, were also put on hold. Since then, NBC has not approved any applications for laboratory, green house or field trials for corn and other food crops submitted by either public research institutes or private companies. Regulatory approval for the cultivation and commercialization of GE cotton, which was granted in 2010, remains unaffected and several GE cotton seed varieties are approved every year. Cotton is the most important cash crop in Pakistan and exports of cotton products account for 60 percent of all foreign exchange earnings of the country. Cotton serves as the raw material for the textile industry, the country’s largest agro-industrial sector, employs 17 percent of the labor force, earns precious foreign exchange, and contributes 8.5 percent to the gross domestic product.

The MNFSR and Ministry of Climate Change (MOCC) are the two main ministries involved in the approval and regulation of GE products. The MNFSR is the ministry responsible for approving the cultivation of GE plants and issuing import permits for GE products, while MOCC’s NBC is the body responsible for reviewing and approving laboratory procedures, monitoring of field trials, regulation of trade, and the commercialization of GE crops and GE-derived products. Except for cotton, ongoing research and development on all other crops has been put on hold pending further review.

The Institutional Biosafety Committees (IBCs) from public and private sector entities and research and development organizations are in continuous dialogue with Pakistani regulatory authorities regarding the status of approvals. However, the March 2019 moratorium on further approvals for all crops except cotton is slowing ongoing research and development activities and may adversely impact the future food security dynamics in Pakistan. Multinational seed technology providers are reassessing their plans to invest in main crops like cotton and corn, for example.

The details of GE traits for different crops in the trial phase from public sector institutes and private sector companies as of March 2019 is shown below:

Development of Biotech Crops in Pakistan

Crop	Trait	Approval Stage	Institute	Status²
	Diamondback moth resistance with Bt gene	Field trials	CEMB	In process

¹ In the 1990s, Pakistan shifted to non-GE hybrid corn technology using DuPont-Pioneer/Corteva and Monsanto/Bayer corn hybrid seed, even though GE hybrid corn technology is now available.

² GE trials on all crops, except for cotton, were put on hold in March 2019.

Crop	Trait	Approval Stage	Institute	Status ²
Cotton	Virus (CLCV) resistance with Tr AC gene	Field trials/ready to release	CEMB	In process
	Virus (CLCV) resistance with RNA interference (RNAi)	Field trials	CEMB & NIBGE	In process
	AVP1-H+ for salt and drought tolerance	Field trials	NIBGE	In process
	Cry1Ac and Cry2Ab	Field trials	CEMB/NIBGE + 4 Domestic Seed Companies	In process
	Cry1Ac + Cry2Ab and Glyphosate	Field Trials	CEMB/NIBGE + 4 Domestic Seed Companies	In process
	Fiber improvement	Experimental	CEMB	In process
Wheat	Rust, drought, and salt tolerance	Experimental/Field Trial	NIBGE	On hold
	Bio-fortified wheat for increased iron and zinc bioavailability	Field Trial	FCCU/AARI	On hold
	Increased phosphorus use efficiency	Field Trial	FCCU+ 1 Domestic Seed Company	On hold
	Rust resistance markers	Experimental	AARI	On hold
Rice	Bacterial blight resistance with Xa21 gene (through molecular assisted breeding)	Experimental	NIBGE	On hold
	Insect resistance with Cry1Ac & Cry2A genes	Experimental	CEMB IIUI NIBGE, IIUI, Peshawar	On hold

Crop	Trait	Approval Stage	Institute	Status ²
Maize	Insect Resistance (Cry1Ac+Cry2A)	Field trials	CEMB/ NIGAB	On hold
	CEMB-GTGene	Field trials	CEMB	On hold
	CEMB-AFP	Field trials	CEMB	On hold
	cp4epsps	Field trials	Monsanto	On hold
	cry2Ab2 & cry1A.105 and cp4epsps	Field trials	Pioneer	On hold
	cry1F, cry1Ab and cp4epsps	Field trials	Pioneer	On hold
	cry1Ab x mESPPS	Field trials	Syngenta	On hold
	mESPPS	Field trials	Syngenta	On hold
Sugarcane	Insect resistance with Cry gene	Experimental	NIBGE	On hold
	Chloroplast transformation	Experimental	CEMB	On hold
	Drought tolerance	Experimental	AARI	On hold
	SIG1+SIG2+SIG3	Experimental	CEMB	On hold
	CHiA+CHiB+CHiC	Experimental	CEMB	On hold
	Insect resistance with VIP3+ASAL	Experimental	CEMB	On hold
	Herbicide tolerant sugarcane	Experimental	CABB	On hold
	Biotic stress tolerant sugarcane using SUGARWIN 2 gene	Experimental	CABB	On hold
	Abiotic stress tolerant sugarcane using scdr1 gene	Experimental	CABB	On hold
Antifungal sugarcane virus resistance	Experimental	CEMB, IBGE	On hold	
Chickpeas	Insect resistance (Bt gene)	Experimental	CEMB/NIGAB	On hold

Crop	Trait	Approval Stage	Institute	Status ²
Tobacco	Insect (<i>Helicoverpa armigera</i> and <i>Heliothis virescens</i>) resistance with a novel synthetic spider venom gene	Experimental	NIBGE	On hold
	Salt tolerance with yeast, <i>Arabidopsis Na⁺/H⁺</i> antiporter genes	Experimental	NIBGE	On hold
	Salt tolerance with ArDH chloroplast transformation (Biosafe GM)	Experimental	CABB	On hold
	Non-edible vaccine development against Bursal and Newcastle diseases of poultry	Experimental	CABB	On hold
Potato	Virus (PLRV, PLXV, PVY) resistance, Chitinase gene for fungal disease resistance	Experimental	NIBGE	On hold
	Insect-resistant transplastomic potato – chloroplast transformation	Experimental	CABB	On hold
	Fungal resistance using glucanase gene	Experimental	CABB	On hold
Peanut	Herbicide resistance, Tikka disease resistance	Experimental	NIGAB	On hold
Brassica	Glyphosate resistance, FAEI gene for reduced erucic acid and MAX1 gene for maximum axillary branches to enhance	Experimental	AARI NIBGE	On hold

Crop	Trait	Approval Stage	Institute	Status ²
	yield			

- CEMB Centre of Excellence in Molecular Biology, University of the Punjab, Lahore
- NIBGE National Institute for Biotechnology and Genetic Engineering, Faisalabad
- FCCU Forman Christian College University, Lahore
- AARI Ayub Agriculture Research Institute, Faisalabad
- NARC National Agriculture Research Center, Islamabad
- CABB Centre of Agricultural Biochemistry and Biotechnology, University of Agriculture, Faisalabad
- NIGAB National Institute for Genomics and Advanced Biotechnology, NARC, Islamabad
- IBGE Institute of Biotechnology and Genetic Engineering, Ag. Univ. Peshawar
- IIUI International Islamic University, Islamabad

b. COMMERCIAL PRODUCTION

GE cotton is the only crop currently under commercial production in Pakistan. Most of the approved biotech cotton seed varieties contain one of the two released events: MON 531 (Cry1Ac gene) or (Cry1Ab gene). Varieties with these events protect cotton from the larvae of lepidopterans (i.e., butterflies, moths) and were introduced for cultivation in Pakistan a few years ago. The CEMB developed five double gene transgenic cotton varieties that are now being marketed commercially. In 2020, farmers used more than 25 cotton seed varieties to plant 2.4 million hectares of GE cotton – an acreage that comprises over 95 percent of Pakistan’s total cotton planted area. For crops intended for food use, MNFSR and MOCC has put on hold regulatory approvals for GE trials.

c. EXPORTS

Pakistan exports small volumes of GE cotton produced in the country. During Marketing Year (MY) (August/July) 2019/20, Pakistan exported 75,153 bales (375 lbs/bale) of raw cotton valuing around USD\$17 million to Vietnam, Indonesia, Bangladesh, Thailand, and China. Pakistan also exports cotton yarn, cotton fabric, and other items derived from both domestic and imported GE cotton. The textile sector comprises a major share of Pakistan’s economy, with around 60 percent of total exports from Pakistan dependent on this sector.

d. IMPORTS

In Calendar Year (CY) 2019, Pakistan imported around 3.73 million bales (375 lbs/bale) of cotton, mostly from the United States and Brazil. Pakistan is also an importer of soybeans, soybean meal, soybean oil, canola, and distillers dried grains (DDGs) derived from GE grains from the United States, Brazil, Canada, and Argentina. Pakistan imported around 1.92 million metric tons of soybeans during CY 2019, valued at around \$690 million. Of this, approximately 60 percent, were from the United States.

e. FOOD AID

There are no known issues or restrictions affecting the importation of food aid produced from GE crops. Pakistan imported U.S. soybean oil under the Food for Progress (FfP) development program. Currently, Winrock is implementing an FfP funded project in Punjab and Sindh provinces. In recent years, Pakistan has provided food aid to Afghanistan and certain African countries.

f. TRADE BARRIERS

Pakistan authorities are currently in the process of developing measures to regulate GE trade, specifically the importation of products intended for FFP use. Although the Pakistan Biosafety Rules (PBR) stipulate that import approval is required for GE-derived products intended for food, feed, and processing (FFP) use, the National Biosafety Guidelines (NBG) lack specific details on how to obtain an import permit for GE products or the process of obtaining legal recognition for imported GE products. To address this issue, the NBC is developing policy and procedural recommendations to regulate the import of GE products intended for FFP use in Pakistan.

While development of these measures and their inclusion into the NBG should provide a level of trade certainty, the exact nature of the measures being developed is unclear. At present, Pakistan imports around four million metric tons (MMT) of GE products (e.g., soybeans, canola, sunflower seeds, and DDGs) annually from the United States and other countries without any regulatory permits or approvals as required under the PBR, due to the absence of a clearly defined process in the NBG. In the interim, the lack of clear guidance and the possibility of stricter measures governing trade in GE products is causing increasing uncertainty for Pakistani importers and third country exporters of these products.

PART B: POLICY

a. REGULATORY FRAMEWORK

In 2005, Pakistan established its federal biotechnology regulatory structure for approving new technologies under the provisions of the Environmental Protection Act of 1997. Under this Act, Pakistan created the PBR in April 2005. The PBR is the first of four foundational laws of the country's agricultural biotechnology framework and govern the following:

- the manufacture, import and storage of micro-organisms and gene technological products for research whether conducted in laboratories of teaching and research, research and development institutes or private companies involved in the uses and applications of genetically modified organisms and products thereof;
- all work involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), micro-organisms and cells;
- the import, export, sale and purchase of living modified organism, substances or cells and products thereof for commercial purposes.

The PBR is consistent with the Cartagena Protocol of Biosafety (CPB), which was ratified by Pakistan in 2009. The CPB allows for the production, sale and use of GE products on transparent scientific principles and guidelines that have been developed by each sovereign state that is a party to this protocol under the United Nation's Convention of Biodiversity. In accordance with CPB protocol, it is obligatory to make decisions on sound scientific knowledge acceptable to global community.

The PBR also established the following entities:

- The National Biosafety Committee, whose responsibilities include the review and approval of laboratory procedures, the monitoring of field trials, the regulation of trade, and the commercialization of GE crops and products. The NBC is governed by the PBR and is located within Pakistan's Environmental Protection Agency (EPA) under the MOCC. There are fifteen members of the NBC, which include representatives from the ministries of National Food Security and Research (1), Health (2), Education (3), Science and Technology (4), Commerce and Textiles, (5), Planning and Development (6), the Pakistan Agricultural Research Council (7); the Pakistan Atomic Energy Commission (8); and representatives from Pakistan's four provinces (9-12) and three territories (13-15).
- The Technical Advisory Committee (TAC) is responsible for examining applications for new GE crops and organisms and makes recommendations to the NBC on technical matters related to laboratory manipulation, field work, and the commercialization of GE crops and organisms. The TAC is chaired by the EPA's Director General and committee members include representatives from Pakistan's provinces and territories.
- The Institutional Biosafety Committee (IBC) is responsible for undertaking risk assessments, implementing safeguards, and monitoring and inspecting all regulated research and product development that has been authorized by the NBC. The IBCs' findings are forwarded to the TAC for review and to formulate recommendations to the NBC. To date, the EPA has notified 44 IBCs, which include 16 IBCs from multinational corporations and Pakistan's private sector, with the remainder from Pakistan's public universities and research organizations.

In May 2005, the EPA followed up with the issuance of the NBG, which provides guidelines on laboratory research, field trials, and the release of GE organisms.

The Intellectual Property Organization of Pakistan Act (IPOP) of 2012 is the second of four foundational laws of the country's agricultural biotechnology framework. Intellectual property laws of Pakistan include the copyright laws, patent laws and trademark laws. This area of law protects the proprietary work of individuals and businesses from unauthorized use or exploitation by third parties. By utilizing intellectual property laws, seed developers can fully protect and recoup their investment from their GE products. As a signatory to World Trade Organization (WTO), Pakistan is bound to a mutual recognition of intellectual property rights at a higher level of protection. Pakistan's intellectual property laws take into account the provisions of the WTO.

The Seed Amendment Act of 2015 is the third of four foundational laws of the country's agricultural biotechnology framework. This amended act breaks the government's monopoly on the country's seed sector, allowing the private sector to import new technologies. It also provides for much-needed regulation in organizing the seed industry and provides opportunities for all stakeholders to expand knowledge and resources related to new gene technology.

The Plant Breeders Rights Act (PBRA) of 2016 is the fourth of four foundational laws of the country's agricultural biotechnology framework. The PBRA was passed in 2016, its implementing rules were finalized in May 2018 by MNSFR, and a plant registry was established in the Ministry by October 2018. However, the Ministry is still in the process of recruiting specialized technical staff for its plant registry office. Until staff is hired, MNSFR will be in a weak position to enforce the implementing rules of the PBRA. Nevertheless, the eventual implementation of this Act will establish Pakistan's first-ever intellectual property protection for seeds and plant varieties and is a step toward modernizing and attracting investment in agriculture. The PBRA will provide 20 to 25 years of legal protection to firms who register their seeds, granting them exclusive rights to conduct all facets of seed production and commercialization. Pakistan's public sector research institutes will be able to sell intellectual property rights (IPR) to agricultural firms to raise funds for their research and development. In addition, plant breeders in public research facilities will have a much greater incentive to develop innovative seed technologies. In short, this Act is going to facilitate the commercialization of agricultural biotechnology and will provide incentives to both public and private seed companies.

b. APPROVALS

The TAC and NBC do not hold regular meetings nor adhere to the meeting time schedule outlined in the PBR. Since April 2006, the TAC has held 30 meetings while the NBC has met 22 times. During the past two years, based on TAC recommendations, the NBC approved several GE applications mainly involving cotton events. Applications for all other events have been put on hold as the MNFSR, under the current GoP administration, has opposed the use of GE technology for crops falling directly in food value chain. With regard to cotton, the results of trials of 92 cotton varieties are currently under review. Among them are 16 varieties with triple gene traits, 22 varieties with double gene traits, and the rest with a single gene trait.

The following are details of approved commercialized events granted by the NBC:

Approvals for Commercialization				
S. No	Institute	Crop	Trait	Status³
1	CEMB NIBGE NARC	Cotton	More than 40 cases of Bt cotton approved	Commercialized
2	Cotton Research Institute (CRI) Faisalabad	Cotton	Bt cotton variety FH- Lalazar, MNH- 988, BH-184	Commercialized
3	Auriga, Lahore	Cotton	Bt cotton Variety Sayban -202	Commercialized
4	Bayer Pakistan	Maize	Roundup Ready corn® (NK603) Genuity VT Double Pro (MON89034XNK603)	On hold
5	Corteva Pakistan	Maize	Maize 1507xNK603; MON 810xNK603	On hold

The PBR specifies a timeline for the approval process (i.e. laboratory work, field trial or for commercialization) for each event. The TAC and NBC are supposed to hold regular meetings every 45 days and 90 days, respectively. Once regulatory officials receive an application for any event, a final decision shall be made and communicated to the applicant within:

- 60 days for work bearing either low or considerable level of risk for laboratory work, green house, and field testing.
- 90 days for experimental release; or
- 120 days for commercialization.

c. STACKED OR PYRAMIDED EVENT APPROVALS

When introducing a new technology, the PBR states that single or multiple gene transformations will be treated as a single, separate event. The biosafety approval of stacked traits is based on an event in a specific crop. Thus, approval of an event is crop specific. For example, a seed with multiple GE genes would be treated as a single event in the approval process. With the passage of the IPOP in 2012 and the

³ GE approvals on all crops, except for cotton, were put on hold in March 2019

PBRA in 2016, Pakistan’s regulatory officials have confirmed that each new genetic trait will be protected separately.

Details for commercial approvals and field trials for stacked events are as follows:

Approval for Stacked Events				
Genes	Crop	Approval Stage	Company	Status⁴
cp4epsps	Maize	Commercial	Bayer	On hold
cry2Ab2 & cry1A.105 and cp4epsps	Maize	Commercial	Bayer	On hold
cry1F, cry1Ab and cp4epsps	Maize	Commercial	Corteva	On hold
Cry1Ac + Cry2Ab + Glyphosate	Cotton	Commercial	CEMB	In use
Insect Resistance	Maize	Field trials	CEMB, NIGAB	On hold
cry1F, cry1Ab and cp4epsps	Maize	Field trials	Corteva	On hold
cry1Ab x mESPPS	Maize	Field trials	Syngenta	On hold
mESPPS	Maize	Field trials	Syngenta	On hold

d. FIELD TESTING

Pakistani agricultural biotechnology research institutes are only engaged in conducting cotton field trials. There are more than 50 research institutes/departments in the public sector which claim to be working on biotechnology. Among these, 28 have registered their IBCs with the NBC. Field trials on all other GE events have been put on hold as the current administration opposes the use of GE technology on crops which fall directly in the food value chain.

Approvals for Field Trials				
S. No	Institute	Crop	Trial	Status⁵
1	NIBGE	Wheat	Increased salinity and heat tolerance	On hold
2	NIBGE	Cotton	Abiotic stress tolerance, insect resistance	In process

⁴ GE approvals on all crops, except for cotton, were put on hold in March 2019

⁵ GE approvals on all crops, except for cotton, were put on hold in March 2019

Approvals for Field Trials				
S. No	Institute	Crop	Trial	Status⁵
			(IR-NIBGE+8)	
3	NIBGE	Cotton	NIAB Bt-1 +NIAB Bt2	In process
4	CEMB	Cotton	CEMB Klean Cotton	In process
5	CEMB	Cotton	CEMB-77, CEMB-88	In process
6	CEMB	Potato	By transmission of Multiple genes	On hold
7	AARI	Cotton	Bt cotton variety 181	In process
8	AARI	Cotton	Synthetic Bt gene Cry 1Ac & Cry 2Ab	In process
9	FCCU	Wheat	Bio fortified wheat for increased bioavailability of iron and zinc	On hold
10	FCCU	Wheat	Increased phosphorus use efficiency	On hold
11	CRI Faisalabad	Cotton	Bt cotton CIM 600 & 616; Cyto-177	In process
12	CRI Faisalabad	Cotton	Bt cotton Variety Eagle1-6	In process
13	CABB, UAF	Wheat	Salinity and drought tolerance	On hold
14	CABB, UAF	Sugarcane	Herbicide tolerance and borer-resistance	On hold

e. INNOVATIVE BIOTECHNOLOGIES

A few Pakistani academic and research institutions have been working on gene editing technology, such as CRISPR-Cas. The CRISPR-Cas9 is the technology most in-demand and has become an integral part of research and development in the life sciences. Biotechnology research funding is very limited, but preference is given to gene editing in microbial and crop plants.⁶

f. COEXISTENCE

At present, the GoP has not developed a policy governing how GE and non-GE crops will coexist in cultivation.

⁶ Biotechnology refers to the use of microbial, animal or plant cells or enzymes to synthesize, breakdown or transform material for production of goods and services.

g. LABELING AND TRACEABILITY

Pakistan has no labeling requirements for bulk imports of foods, seeds, fibers, oils, or feeds that are derived from GE crops. The government may be considering rules for labeling certain products.

h. MONITORING AND TESTING

Pakistan is in the process of changing import requirements for GE crops and is in the initial stage of monitoring GE products. A possible scenario could require that any imported GE products have an import permit from MNSFR's Department of Plant Protection (DPP) and GE certification from the NBC. Although the mechanisms for monitoring and testing are outlined in the PBR, currently there is no clear and transparent process in the NBC to register GE events. Absent such guidelines governing the trade of GE products intended for FFP, Pakistan appears to be out of compliance with its own law. The NBC is responsible for overseeing all laboratory work, field trials, and the approval of the commercial release of GE crops.

i. LOW LEVEL PRESENCE (LLP) POLICY

Pakistan does not yet have a LLP policy.

j. ADDITIONAL REGULATORY REQUIREMENTS

Once a GE seed is approved by the NBC, the applicant must register the product with the Federal Seed Certification and Registration Department (FSC&RD) of MNFSR before it can be commercialized in line with the requirements of the Seed Amendment Act of 2015. Similarly, provincial seed councils and all national funding agencies like the Agriculture Linkages Program (ALP), which is administered by the Pakistan Agricultural Research Council; the National Science Linkages Program (NSLP), which is administered by the Pakistan Science Foundation; as well as funding through the Higher Education Commission, require NBC approval prior to the authorization of the funding of any GE-research proposal.

k. INTELLECTUAL PROPERTY RIGHTS (IPR)

The IPOPOP and the PBRA and their implementing regulations will establish Pakistan's first-ever intellectual property protection for seeds and plant varieties, thereby creating the necessary environment for attracting investment in agriculture. Enforcement of the IPOPOP and its implementing regulations falls under the Ministry of Commerce. The FSC&RD of MNFSR finalized the PBRA implementing regulations and established the plant registry in 2018, but currently lacks the technical staff needed for enforcement. Pakistan is among the top 34 founding members of WTO. Under the WTO's IP regime, Pakistan adopted *Sui-Genres* system under which this enactment was made by Parliament in 2016.

l. CARTAGENA PROTOCOL RATIFICATION

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

m. INTERNATIONAL TREATIES AND FORUMS

Pakistan is a member of the International Plant Protection Convention and the Codex Alimentarius (Codex) and actively participates in discussions on biotechnology. Pakistan is one of the founding members of the World Trade Organization (WTO) and has a permanent representative in Geneva.

n. RELATED ISSUES

Pakistan's agricultural biotechnology framework is dependent on four key laws: the 2005 PBR, the IPOP Act of 2012, the Seed Amendment Act of 2015, and the 2016 PBRA. None of these laws have the full suite of implementing regulations or the deep bench of technical staff needed to make them fully operational.

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS

The MNFSR, MOCC and the ministries of Health, Education, Science and Technology, Commerce and Textiles, Planning and Development, as well as Pakistan's agricultural industry are generally supportive of the expanded utilization of GE technology. However, the apparent reformist bent of the current administration, along with the lack of regulations governing the GE certification and FFP approval processes, are creating uncertainty in the trade of GE products. This ambiguity is also making multinational technology providers reluctant to invest in Pakistan due to the lack of legal protections. Pakistan's patent laws were modified in 2001 to be consistent with WTO guidelines, but implementation, especially on agricultural products (e.g., seeds, cuttings), is weak. Piracy and imitation are common activities.

Consumer attitudes on GE technology are mixed, but they are nonetheless generally accepting of GE products in the marketplace. Consumers are generally unaware of shifts in the regulatory landscape, given the slow pace of development and introduction of new GE crops and products. Pakistan is one of the world largest producers (cotton) and importers (soybeans) of GE crops.

b. MARKET ACCEPTANCE/ STUDIES

FAS Islamabad is unaware of any marketing studies. However, there are two PhD thesis on Bt cotton in Pakistan from the University of Melbourne in Australia and the University of Guelph in Canada. The Australian study focused on the commercialization of GE cotton in Pakistan; while the Canadian one focused on farmers' well-being in Pakistan. In addition, the International Food Policy Research Institute and International Life Sciences Institute have published valuable documents on the development of agriculture biotechnology in Pakistan.

The regulations concerning GE products intended for FFP use in Pakistan are currently under review by the relevant regulatory authorities. See "Trade Barriers" section for further details.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

No commercial production or sale of cloned animals derived from biotechnology is currently occurring in Pakistan. Research for cloning mice embryos is in progress, but there are no commercial applications yet.

There are recent efforts to develop recombinant animal vaccines for Newcastle disease in Pakistan's poultry industry. Research and development work on producing this vaccine is going on at NARC's NIBGE in Faisalabad and Islamabad, CABB, and the University of Agriculture in Faisalabad. A limited number of cattle embryos are produced in the embryo transfer center of a military dairy farm but are mainly used at the center. CEMB has developed some interferon products, but the Drug Regulatory Authority of Pakistan (DRAP) did not register them because no efficacy and safety studies were provided.

b. COMMERCIAL PRODUCTION

None

c. EXPORTS

None.

d. IMPORTS

None

e. TRADE BARRIERS

Given the absence of a regulatory framework for animal biotechnology, FAS Islamabad believes that importation of GE animal and related products would likely be restricted. For example, the pharmaceutical compound "Heparin" could not be approved by DRAP, due to it being porcine in nature. Similarly, animal gelatin is a banned item in Pakistan. Imports must first receive a "No Objection Certificate" from the relevant ministry, but officials would likely raise concerns if the products were significantly unique or substantially different from conventional animals or their products.

PART E: POLICY

a. REGULATORY FRAMEWORK

The PBR mentions organisms (e.g., animal, plants, insects, fungi, and microbes) and it includes separate chapters on animals and plants. These rules would be the basis for any regulation of GE animals, livestock clones or their products, with the NBC the likely entity to be charged with the responsibility of reviewing any new product applications.

b. APPROVALS

The approval process has not yet started on a commercial scale as no production or trade of GE animals or activity in animal cloning is taking place in Pakistan. Only in vitro experiments are in process at some research institutes.

c. INNOVATIVE BIOTECHNOLOGIES

The mice embryo cloning was done in the University of Veterinary and Animal Sciences (UVAS) in Lahore as an academic model for animal cloning in milking cattle especially buffalo, goats, and sheep.

d. LABELING AND TRACEABILITY

There is no labeling policy at this time.

e. INTELLECTUAL PROPERTY RIGHTS (IPR)

FAS Islamabad is unaware of any existing IPR provisions for animal biotechnology.

f. INTERNATIONAL TREATIES AND FORUMS

Pakistan is a member of the WTO member and, as such, participates in WTO fora and relevant associated bodies such as the World Organization for Animal Health and Codex. FAS Islamabad is unaware of participation by Pakistan in discussions related to animal biotechnology.

g. RELATED ISSUES

None.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS

General awareness is limited.

b. MARKET ACCEPTANCE/STUDIES

FAS Islamabad is unaware of any studies related to the market acceptance of GE animals and livestock clones. There is no production or sale of GE animals in Pakistan.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

Not applicable.

PART H: POLICY

Not applicable

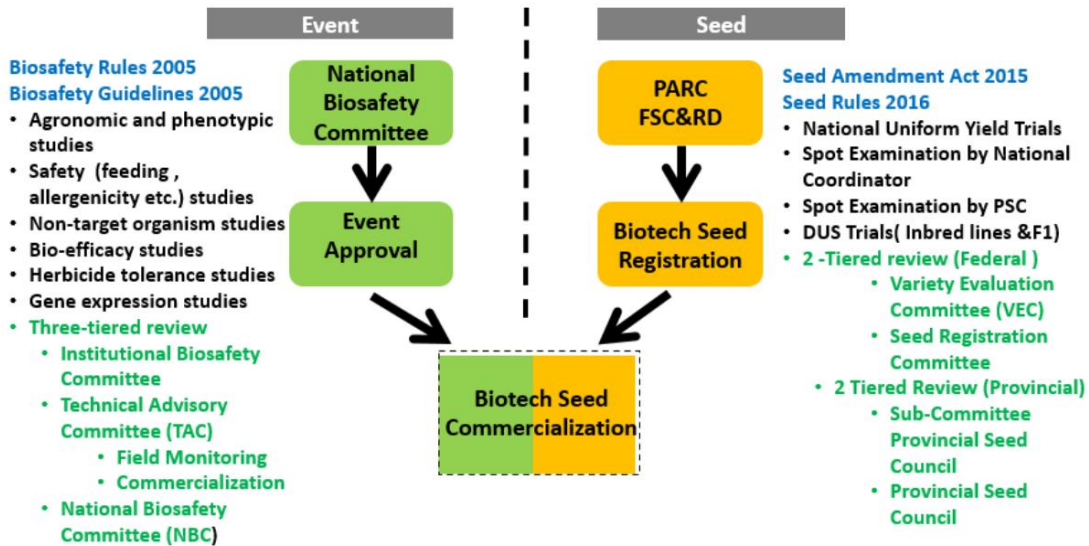
PART I: MARKETING

Not applicable.

Annex I

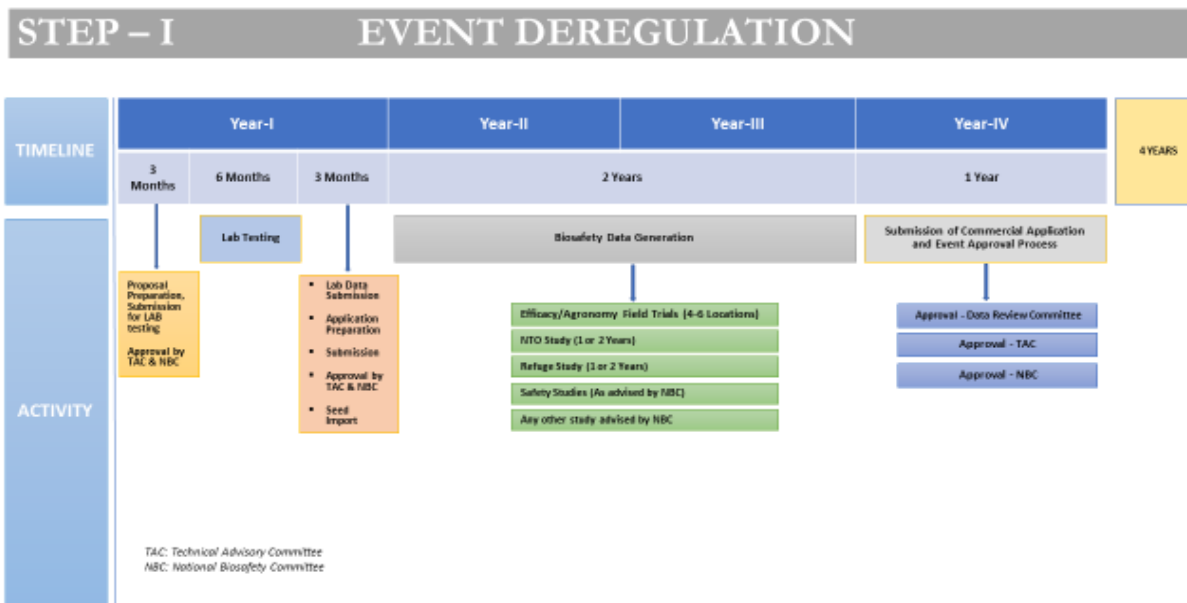
BIOTECH APPROVAL PROCESS IN PAKISTAN:

REGULATORY FRAMEWORK FOR BIOTECH CROPS:

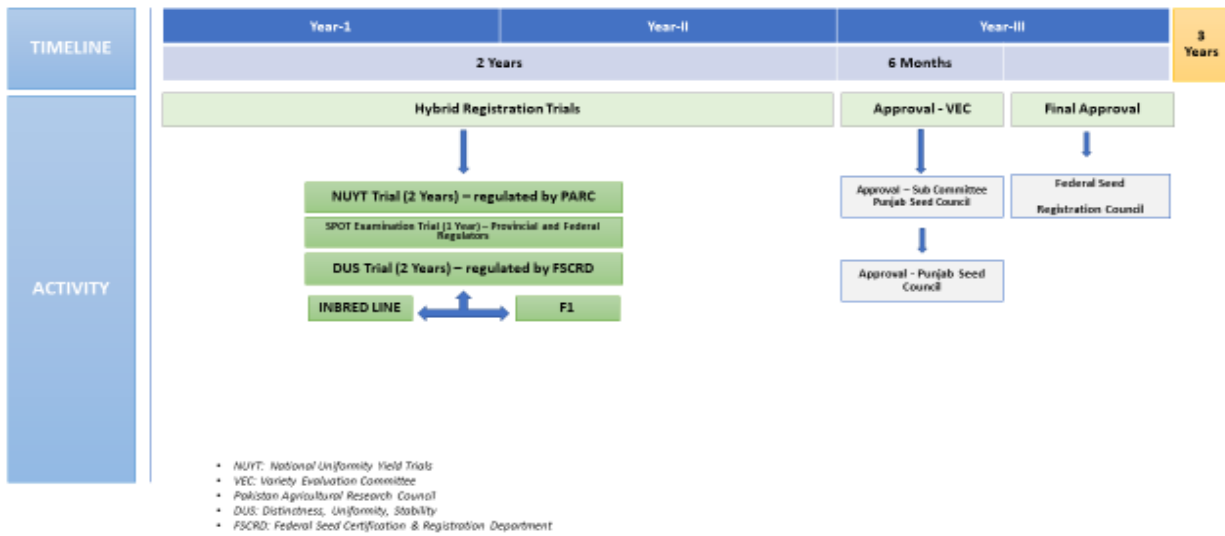


Source: FSC&RD and CLP

TIME-LINE FOR BIOTECH APPROVAL PROCESS:



STEP – II HYBRID REGISTRATION



Source: FSC&RD and CLP

Annex - II

BIOTECH APPROVED GENES USED IN PAKISTANI COTTON VARIETIES

The following are the genes currently approved for commercial use; they are only in cotton crop varieties. Approval for commercialization (deregulation) was granted by the National Biosafety Committee in the Ministry of Climate Change.

1. Cry 1Ac---- maximum cases
2. Cry 1Ac+ Cry 2A
3. Cry1Ac+ Cry 2A+ GTG (local equivalent to glyphosate).

Annex - III

BIOTECH PRODUCTS TRADE IN PAKISTAN:

PAKISTAN COTTON IMPORTS (CY)

Reporter	Figures in Metric Tons					
	2014	2015	2016	2017	2018	2019
Total	226,640	504,906	440,089	435,784	777,896	634,576
United States	39,359	72,636	129,455	171,752	344,980	374,585
Brazil	29,034	54,368	69,789	48,839	36,873	113,029
India	134,488	342,223	189,997	127,503	288,192	34,949
Argentina	546	-	-	100	26,788	21,635
EU 28 External Trade	4,941	5,324	6,358	14,453	13,538	17,771
Mexico	-	-	2,055	6,225	13,089	16,527
Cote d'Ivoire	1,274	2,990	7,554	27,889	8,458	15,512
Turkey	996	1,351	2,714	1,957	7,565	14,687
Egypt	2,765	5,614	3,388	5,750	8,236	13,764
Malaysia	790	-	4,359	554	296	6,054
Australia	8,911	1,334	11,148	5,548	4,263	4,448
China	199	278	505	-	1,794	924
Azerbaijan	-	-	-	-	69	235
Benin	3,067	18,602	4,426	2,409	842	224
Others	270	186	8,342	22,803	22,913	234

Source: Trade Data Monitor (TDM)

PAKISTAN SOYBEAN IMPORTS (CY)

Reporter	Figures in Metric Tons					
	2014	2015	2016	2017	2018	2019
Total	11,731	672,830	863,403	2,094,938	2,380,070	1,916,668
United States	-	314,363	322,744	1,138,302	1,733,277	1,130,977
Brazil	-	125,989	476,428	955,599	644,072	785,691
Canada	20	79,708	64,208	-	-	-
Argentina	-	152,760	-	-	-	-
Others	11,710	9	23	1,037	2,721	-

Source: Trade Data Monitor (TDM)

Annex - IV

REFERENCES:

1. Pakistan Biosafety Rules, 2005

<http://www.environment.gov.pk/images/PDF/Biosftyrules-2005.pdf>

2. Pakistan Biosafety Guidelines, 2005

<http://www.environment.gov.pk/images/guidelines/BiosftyGlines2005.pdf>

3. Cartagena Protocol on Biosafety

<http://bch.cbd.int/protocol>

4. Seed Act 1976

<http://extwprlegs1.fao.org/docs/pdf/pak16066.pdf>

5. Seed (Amendment) Act 2015

<https://pakistanlawyer.com/2016/07/03/seed-amendment-act-2015/>

6. Plant Breeders Rights Act 2016

http://www.na.gov.pk/uploads/documents/1485437584_777.pdf

7. Pakistan Intellectual Rights Act 2012

http://www.na.gov.pk/uploads/documents/1355912657_971.pdf

Attachments:

No Attachments