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Report Highlights:

Cotton continues to be the only genetically engineered (GE) crop approved for cultivation and use. Regulatory uncertainty prevents life science companies from seeking approval for any other GE crops, and the National Biosafety Committee is still developing regulations on imports of GE commodities intended for food, feed, and processing. In 2020, Pakistan imported around 2.2 million tons of soybeans, with the United States having nearly 50 percent market share.

EXECUTIVE SUMMARY

Pakistan's agricultural biotechnology regulatory framework consists of 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, many of the corresponding implementing regulations have yet to be developed, and front-line Ministries lack sufficient technical staff to enforce existing regulations. First generation genetically engineered (GE) cotton events, approved for cultivation and use since 2010, are planted on about 95 percent of Pakistan's 2 million hectares seeded to cotton. Weak intellectual property enforcement hinders GE cotton seed development beyond the available first-generation traits. Meanwhile, lack of regulatory clarity prevents life science companies from applying for GE research and field trial permits for all other field 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 not yet established any rules or administrative protocols that would enable companies to legally register and import GE products for FFP purposes. Nonetheless, in 2020, Pakistan imported about 2.2 million tons of soybeans for further processing. Almost all of these soybean imports possessed GE content. The PBR's requirements for applying to the National Biosafety Committee (NBC) to conduct laboratory and field trials on GE food crops remain unclear. The Ministry of National Food Security and Research (MNFSR) finalized the PBRA's implementing rules and plant registry guidelines in 2018, but procedures for registering GE food crop seeds remain on hold. The absence of a fully operational agricultural biotechnology framework creates an uncertain trading environment for importers of GE-derived products intended for FFP and discourages technology providers from investing in Pakistan's cotton and food crop seed sectors.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

In March 2019, the Ministry of National Food Security and Research (MNFSR), in conjunction with National Biosafety Committee (NBC), suspended research and commercialization of GE hybrid corn, due to their assessment that local corn production, through the use of non-GE seeds, was sufficient to meet 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, which 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 approves GE seed for cultivation and issues GE product import permits. The NBC, under MOCC, reviews and approves laboratory procedures, monitors field trials, and regulates GE product trade and commercialization. Except for cotton, applications for research and development of GE crops has been put on hold pending clarifications of regulatory requirements.

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. NBC's preference for technology providers to conduct all their basic and primary research in-country, even if it has already been done previously in another country, is another factor causing multinational seed companies to be reluctant to invest in GE seed development.

The approval status of various GE traits is shown below:

Development of Biotech Crops in Pakistan

Crop	Trait	Approval Stage	Applicant	Status[1]

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

Crop	Trait	Approval Stage	Applicant	Status[1]
Cotton	Diamondback moth resistance with Bt gene	Field trials	CEMB	In process
	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 IBGE, IIUI,	On hold

Crop	Trait	Approval Stage	Applicant	Status[1]
			Peshawar	
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
	cry2Ab2 & cry1A.105 and cp4epsps	Field trials	Pioneer	On hold
	cry1F, cry1Ab and cp4epsps	Field trials	Pioneer	On hold
	cry1Ab x mESPSPS	Field trials	Syngenta	On hold
	mESPSPS	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	Applicant	Status[1]
Tobacco	Insect (Helicoverpaarmigera and Heliothesisvericens) resistance with a novel synthetic spider venom gene	Experimental	NIBGE	On hold
	Salt tolerance with yeast, Arabidopsis Na+/H+ 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 IBGE	On hold

Crop	Trait	Approval Stage	Applicant	Status[1]
	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 approved for planting in Pakistan. In 2021, farmers planted about 25 cotton seed varieties on 2 million hectares, with GE cotton accounting for 95 percent of Pakistan's total cotton planted area. Most of the approved biotech cotton seed varieties contain one of the two first generation events: MON 531 (Cry1Ac gene) or (Cry1Ab gene). Varieties with these events protect cotton from the larvae of lepidopterans (i.e., butterflies, moths). The CEMB developed five double gene transgenic cotton varieties that are now being marketed commercially. Regulatory uncertainty is hindering applicants from applying to conduct GE trials for any other crops besides cotton.

c. EXPORTS

Pakistan exports small volumes of GE cotton. During marketing year (August/July) 2020/21, Pakistan exported 25,000 bales (375 lbs/bale) of raw cotton. 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 2020, Pakistan imported just over 1 million tons of cotton, mostly from the United States and Brazil. Pakistan also imports 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 2.2 million metric tons of soybeans in 2020, with about 43 percent of that coming from the United States and the rest from Brazil.

e. FOOD AID

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

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 FFP, 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. In October 2020, the NBC established a sub-committee to finalize the FFP import regulations.

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 tons of GE products (e.g., soybeans, canola, sunflower seeds, and DDGs) annually from the United States and other countries. Due to the lack of defined procedures and requirements in the NBG, these imports are occurring without any regulatory permits or approvals as required under the PBR. In the interim, the lack of clear guidance and the possibility of stricter measures threatens trade in GE products and causes increasing uncertainty for importers and 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 teaching and research at development institutes and/or private companies involved in the uses and applications of "genetically modified organisms" and products thereof;

- All work involved in field trials of genetically manipulated plants, animals (including poultry and marine life), micro-organisms, and cells;
- The import, export, sale and purchase of "living modified organisms," substances, or cells, and products thereof, for commercial purposes.

The PBR is supposed to be consistent with the Cartagena Protocol of Biosafety, which Pakistan ratified the (CPB) in 2009.

The PBR also established the following entities:

- The National Biosafety Committee (NBC), who reviews and approves laboratory procedures, monitors field trials, regulates trade and commercialization of GE crops and products. The NBC 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), who reviews applications for new GE crops and organisms and makes recommendations to the NBC on technical matters related to laboratory and field activities, and on placing GE crops and organisms on the market. The EPA's Director General chairs the TAC and committee members include representatives from Pakistan's provinces and territories.
- The Institutional Biosafety Committee (IBC), who conducts risk assessments, implements safeguards, and monitors and inspects 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.

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 allowed the private sector to import new seed technologies. It's regulations also helped to organized the seed industry and facilitated opportunities for all stakeholders to expand knowledge and resources on new 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, MNSFR finalized the implementing rules in May 2018, and established the seed registry in October 2018. The eventual complete implementation of this Act is will establish Pakistan's first-ever intellectual property protection for seeds and plant varieties and should attract investment in seed development and marketing. 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. So when fully implemented, this Act should accelerate agricultural biotechnology development in Pakistan, and incentivize seed research and development in both the public and private sector.

b. APPROVALS

The TAC and NBC meet irregularly. During the past two years, based on TAC recommendations, the NBC approved several GE applications, mainly involving cotton events. The committees are currently reviewing results of many cotton variety trials, including some with triple and double stacked traits.

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

Approvals for Commercialization				
S. No	**Institute**	**Crop**	**Trait**	**Status[2]**
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

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

Approvals for Commercialization				
S. No	**Institute**	**Crop**	**Trait**	**Status[2]**
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. Once regulatory officials receive an application for any event, a final decision is supposed to be 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

The PBR states that single or multiple gene transformations will be treated as a single, separate event. 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 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**	**Status[3]**
cp4epsps	Maize	Commercial	Bayer	On hold

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

Approval for Stacked Events				
Genes	**Crop**	**Approval Stage**	**Company**	**Status[3]**
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 mESPSPS	Maize	Field trials	Syngenta	On hold
mESPSPS	Maize	Field trials	Syngenta	On hold

d. FIELD TESTING

Currently, research institutes are only doing cotton field trials. There are more than 50 public sector research institutes doing trials in agriculture biotechnology. Among these, 28 have registered their IBCs with the NBC.

Approvals for Field Trials				
S. No	**Institute**	**Crop**	**Trial**	**Status[4]**
1	NIBGE	Wheat	Increased salinity and heat tolerance	On hold
2	NIBGE	Cotton	Abiotic stress tolerance, insect resistance (IR-NIBGE+8)	In process
3	NIBGE	Cotton	NIAB Bt-1 +NIAB Bt2	In process
4	CEMB	Cotton	CEMB Klean Cotton	In process

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

Approvals for Field Trials				
S. No	**Institute**	**Crop**	**Trial**	**Status[4]**
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. Biotechnology research funding is very limited, but preference is given to gene editing in microbial and crop plants.[5]

f. COEXISTENCE

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

g. LABELING AND TRACEABILITY

[5] 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.

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

h. MONITORING AND TESTING

Although monitoring and testing requirements are outlined in the PBR, neither is occurring. However, Pakistan is developing guidelines on imports of GE crops, and these may contain monitoring and testing protocols. A possible monitoring scenario could be that GE product imports require an import permit from MNSFR's Department of Plant Protection (DPP) and GE certification from the NBC.

i. LOW LEVEL PRESENCE (LLP) POLICY

Pakistan does not yet have an 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 IPOP, the PBRA, and their implementing regulations, once finalized, should establish Pakistan's first-ever intellectual property protection for seeds and plant varieties. Enforcement of the IPOP 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 enforcement remains lax.

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). Pakistan is a founding member 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 GE technology. However, the lack of regulations governing the GE certification and FFP approval processes is creating uncertainty in the trade of GE products. This ambiguity is also making multinational technology providers reluctant to invest in GE seed development. Patent laws were modified in 2001 to be consistent with WTO guidelines, but enforcement, especially on agricultural products (e.g., seeds, cuttings), is weak. Piracy and imitation are common.

Consumer attitudes on GE technology are mixed, but they are nonetheless generally accepting of GE products in the marketplace. Consumers are generally unaware of the regulatory landscape.

b. MARKET ACCEPTANCE/ STUDIES

There are two PhD theses 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 papers on the development of agriculture biotechnology in Pakistan.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

No commercial production or sale of 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 has been research on developing a recombinant vaccine for Newcastle disease in Pakistan's poultry industry. Research and development work on producing this vaccine is occurring 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

While there is no regulatory framework for animal biotechnology, GE animals and related product imports would likely be restricted. Imports must first receive a "No Objection Certificate" from the relevant ministry, where 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 occurring 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 currently no labeling policy.

e. ADDITIONAL REGUALTORY REQUIREMENTS

None.

f. INTELLECTUAL PROPERTY RIGHTS (IPR)

There are no 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.

RELATED ISSUES

None.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS

General awareness is limited.

b. MARKET ACCEPTANCE/STUDIES

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.

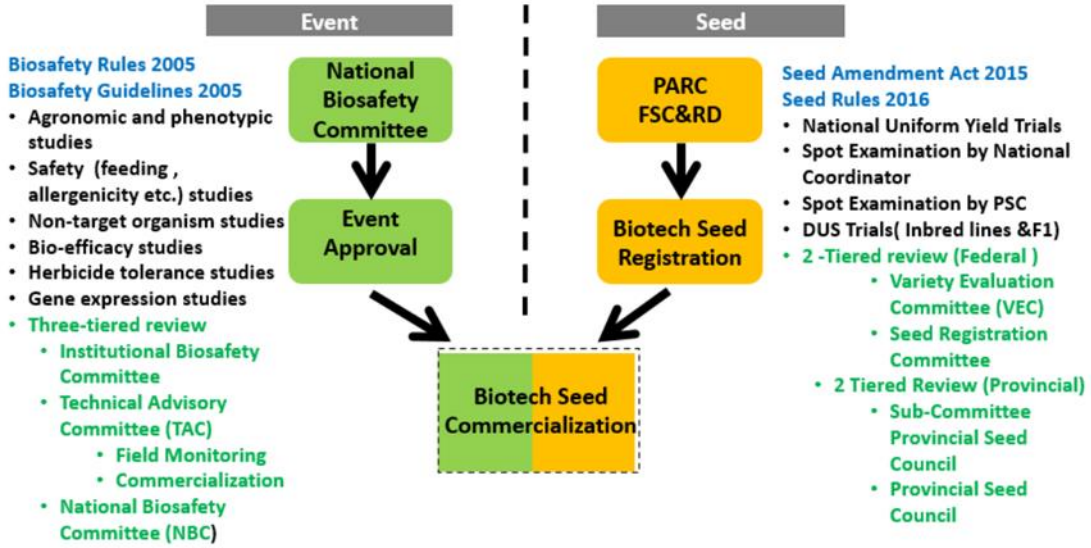
PART I: MARKETING

Not applicable.

Annex I

BIOTECH APPROVAL PROCESS IN PAKISTAN:

REGULATORY FRAMEWORK FOR BIOTECH CROPS:



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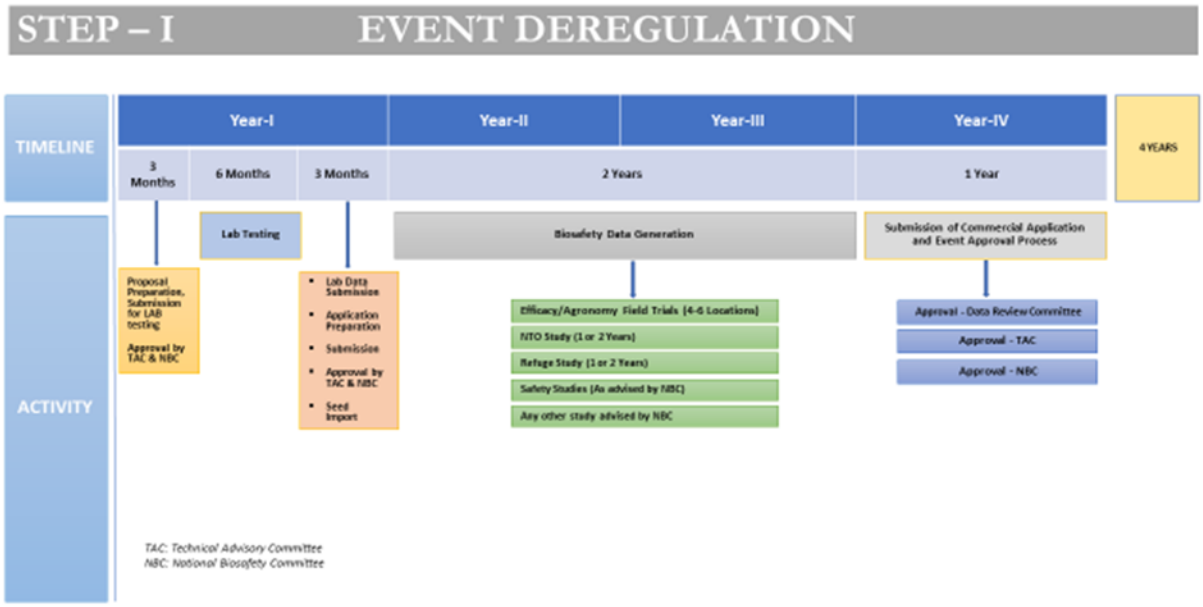

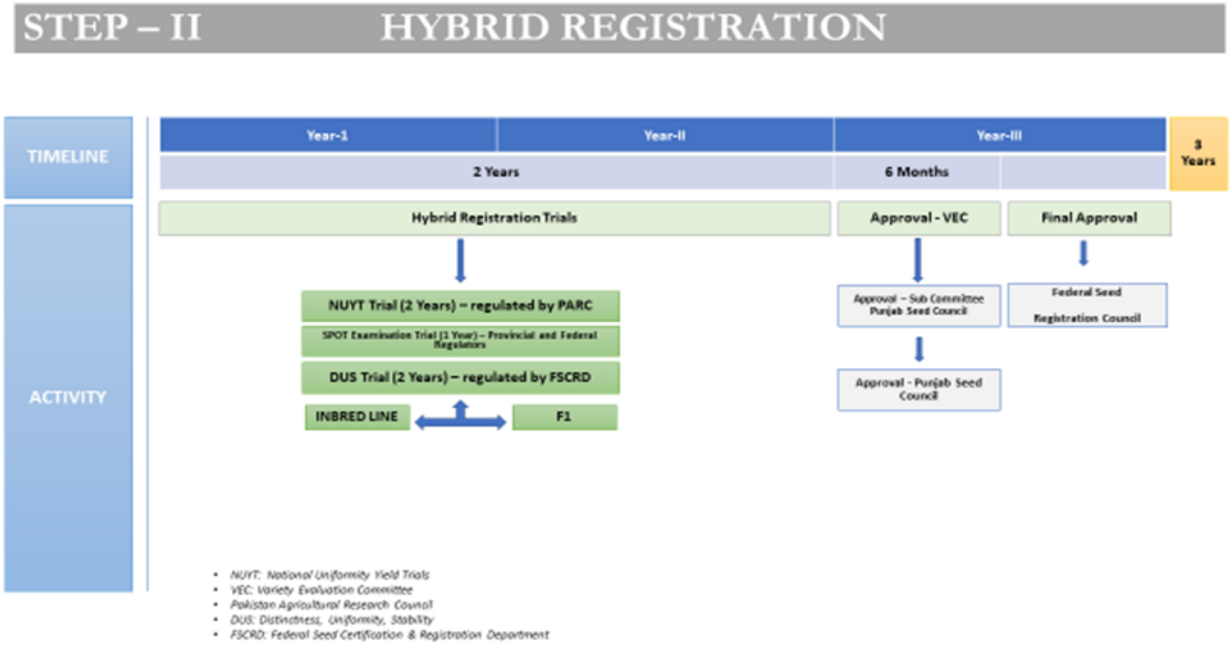

Annex - II

APPROVED GE COTTON EVENTS

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 PRODUCT IMPORTS

Source	**Cotton Imports (tons)**					
	2015	**2016**	**2017**	**2018**	**2019**	**2020**
Total	**504,906**	**440,089**	**435,784**	**777,896**	**634,576**	**1,014,000**
United States	72,636	129,455	171,752	344,980	374,585	508,000
Brazil	54,368	69,789	48,839	36,873	113,029	285,000
India	342,223	189,997	127,503	288,192	34,949	-
Argentina	-	-	100	26,788	21,635	54,000
EU 28 External Trade	5,324	6,358	14,453	13,538	17,771	21,000
Mexico	-	2,055	6,225	13,089	16,527	47,000
Cote d'Ivoire	2,990	7,554	27,889	8,458	15,512	51,000
Turkey	1,351	2,714	1,957	7,565	14,687	-
Egypt	5,614	3,388	5,750	8,236	13,764	-
Malaysia	-	4,359	554	296	6,054	-
Australia	1,334	11,148	5,548	4,263	4,448	-
China	278	505	-	1,794	924	-
Azerbaijan	-	-	-	69	235	-
Benin	18,602	4,426	2,409	842	224	-
Others	186	8,342	22,803	22,913	234	48,000

SOYBEAN IMPORTS (Tons)

	2015	**2016**	**2017**	**2018**	**2019**	**2021**
Source	**672,830**	**863,403**	**2,094,938**	**2,380,070**	**1,916,668**	**2,207,000**
United States	314,363	322,744	1,138,302	1,733,277	1,130,977	953,000
Brazil	125,989	476,428	955,599	644,072	785,691	1,200,000
Canada	79,708	64,208	-	-	-	54,000
Argentina	152,760	-	-	-	-	-
Others	9	23	1,037	2,721	-	-

Source: Trade Data Monitor (TDM)

Annex - IV

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Attachments:

No Attachments