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Report Highlights:

In 2022, after a Technical Advisory Committee (TAC) completed the draft, the National Biosafety Committee (NBC) reviewed a policy on regulating imports of genetically engineered (GE) commodities for food, feed, and processing (FFP). The NBC sent the draft FFP policy to relevant Ministries for further review. Cotton remains the only GE crop approved for cultivation. The underdeveloped and loosely enforced regulatory framework governing advanced agricultural technology continues to hinder life science companies' investment in GE seed research and development. In 2022, Pakistan imported around 2 million tons of GE soybeans, with the United States having about 40 percent market share.

EXECUTIVE SUMMARY

After receiving it from the Technical Advisory Committee (TAC), in June 2022, the National Biosafety Committee (NBC) reviewed a draft policy on regulating imports of genetically engineered (GE) commodities for food, feed, and processing (FFP). The NBC then sent the draft policy to relevant technical Ministries for review and input. It is still unclear when the Ministries will conclude the review of the draft and when NBC will forward it to the Cabinet for approval. Even though the policy could have implications for soybean imports, the NBC has not shared the draft policy with trading partners.

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 GE cotton events, approved for cultivation and use since 2010, account for about 95 percent of seeded cotton crop area and are all BT traits. Weak intellectual property (IP) enforcement hinders GE cotton seed development beyond the available first-generation traits. Furthermore, lack of regulatory clarity prevents life science companies from applying for GE research and field trial permits for all other field crops. In the absence of IP protections, life science companies have no incentive to invest in the GE cotton seed business.

The Ministry of National Food Security and Research (MNFSR) is finalizing new regulations on seed imports, which, inter-alia, include requirements for company registration, a performance contract,¹ and a performance bond.² In addition, developers are required to produce 10 percent of the seed locally the first year, and 50 percent by the 5th year after import approval is granted.

¹ A performance contract listing obligations will be signed by company with the Federal Seed Registry.

² The performance bond is a bank guarantee from the seed company in favor of FSC&RD to cover contractual default.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

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, using non-GE seeds, was sufficient to meet domestic demand. As a result, GE trials on all crops, except for cotton, were put on hold. Since then, NBC has not approved any applications for laboratory, green house, or field trials for corn or other food crops.

Regulatory approval for the cultivation and commercialization of GE cotton, which was granted in 2010, remains unaffected and several GE cottons 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.

MNFSR and the Ministry of Climate Change (MOCC) are the two main ministries involved in regulating GE products. 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, GE crop research and development is largely at a standstill due to the regulatory uncertainty.

The Institutional Biosafety Committees (IBCs) from public and private sector entities and research and development organizations regularly communicate with regulatory authorities regarding product 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 hindering multinational seed company investment in GE seed development.

The approval status of various GE traits is shown below:

Table1: Development of Biotech Crops in Pakistan

Crop	Trait	Approval Stage	Applicant	Status ³
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	Field trials	CEMB & NIBGE	In process

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

	interference (RNAi)			
	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
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 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
Tobacco	Insect (Helicoverpaarmigera and Heliothisvericens) 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 yield	Experimental	AARI IBGE	On hold

- 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

Commercial Production

GE cotton is the only crop currently approved for planting. In 2022, 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. Lack of IP protections and regulatory uncertainty are hindering private sector investment in GE cotton seed development. MNFSR has not yet approved commercial production of any other GE crops, even though several GE corn events passed all the regulatory testing and trial requirements in 2019.

Exports

Pakistan exports small volumes of cotton fiber, but no cotton seed from its GE cotton crop. 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 using both domestic and imported cotton fiber derived from GE cotton. The textile sector comprises a major share of Pakistan's economy, with around 60 percent of total exports dependent on this sector.

Imports

In 2022, Pakistan imported over 1.2 million tons of cotton, mostly from the United States and Brazil. Pakistan also imports 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 million metric tons of soybeans in 2022, with about 40 percent of that coming from the United States and the rest from Brazil.

Food Aid

There are no known issues or restrictions affecting food aid imports produced from GE crops.

Trade Barriers

MOCC and MNFSR are currently in the process of developing measures to regulate GE trade, specifically GE commodity imports for FFP. 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 October 2020, the NBC established a sub-committee to finalize the FFP import regulations. The technical sub-committee completed the draft policy and sent it to the NBC in 2022. After reviewing the draft, the NBC referred it to relevant Ministries for technical review. As of October 2022, the front-line Ministries had still not responded to the NBC with input on the draft. While development of these measures and their inclusion into the NBG should provide a level of trade certainty, the NBC has not shared the draft with trading partners, and the exact nature of the measures being developed is uncertain.

Pakistan imports around three 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

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 GE products for teaching and research at development institutes and/or private companies involved in the use and application of “genetically modified organisms” and products thereof.
- All work involved in field trials of GE 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 (CPB), which Pakistan ratified in 2009.

The PBR also established the following entities:

- The National Biosafety Committee (NBC), which reviews and approves laboratory procedures, monitors field trials, regulates trade and commercialization of GE crops and products. The NBC is located within the 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), which reviews new GE crop applications 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), which 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. IP laws include the copyright, patent, and trademark laws.

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.

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, and MNSFR finalized the implementing rules in May 2018, and established the seed registry in October 2018. The full implementation of this Act would establish Pakistan’s first-ever IP protection for seeds and plant varieties and should attract investment in seed development and marketing. The PBRA provides 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 can sell IP rights to agricultural firms to raise funds for their research and development. In addition, plant breeders in public research facilities have a much greater incentive to develop innovative seed technologies. 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.

Links to the above cited regulations are in appendix 4. The regulations are in English.

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 cottons variety trials, including some with triple and double stacked traits.

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

Table 2: Approvals for Commercialization

S. No	Institute	Crop	Trait	Status ⁴
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

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

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.

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, each new genetic trait is protected separately.

Table 3: Details for commercial approvals and field trials for stacked events are as follows:

Genes	Crop	Approval Stage	Company	Status ⁵
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

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.

Table 4: 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
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

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

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 Eagle 1-6	In process
13	CABB, UAF	Wheat	Salinity and drought tolerance	On hold
14	CABB, UAF	Sugarcane	Herbicide tolerance and borer-resistance	On hold

Innovative Biotechnologies

A few Pakistani academic and research institutions have been working on gene editing technology, such as CRISPR-Cas9. Biotechnology research funding is very limited, but preference is given to microbe and plant gene editing.

Coexistence

There is no policy governing how GE and non-GE crops will coexist in cultivation.

Labeling And Traceability

Pakistan has no labeling requirements for bulk imports of foods, seeds, fibers, oils, or feeds that are derived from GE crops.

Monitoring And Testing

Although monitoring and testing requirements are outlined in the PBR, neither is occurring. However, the policy on imports of GE commodities for FFP, currently being reviewed by the NBC, 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.

Low Level Presence (LLP) Policy

Pakistan does not yet have an LLP policy.

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. The Seed Amendment Act of 2015 requires this seed registration step.

Provincial seed councils and all federally funded agriculture research require NBC approval prior to funding of any GE-research proposal.

Intellectual Property Rights

The IPO, the PBRA, and their implementing regulations, once fully enforced, should provide IP protection for seeds and plant varieties. Enforcement of the IPO 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.

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.

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.

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 complete set of implementing regulations nor sufficient technical staff to make them fully operational.

PART C: MARKETING

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 GE certification and FFP approval processes has created uncertainty about imports 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.

Market Acceptance/ Studies

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, International Life Sciences Institute, and some universities have published papers on the development of agriculture biotechnology in Pakistan.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

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. 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.

Commercial Production

None.

Exports

None.

Imports

None.

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

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.

Approvals

The approval process has not yet started as no production or trade of GE animals is occurring. Only in-vitro experiments are occurring at some research institutes.

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.

Labeling And Traceability

There is currently no labeling policy.

Additional Regulatory Requirements

None.

Intellectual Property Rights (IPR)

There are no existing IP protection provisions for animal biotechnology.

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**Public/Private Opinions**

General awareness is limited.

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.

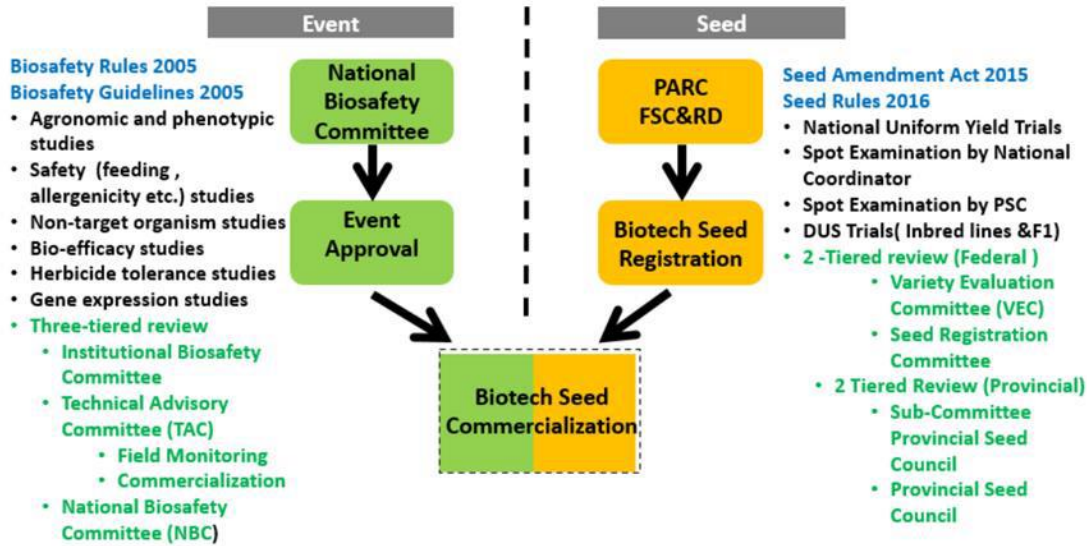
PART I: MARKETING

Not applicable

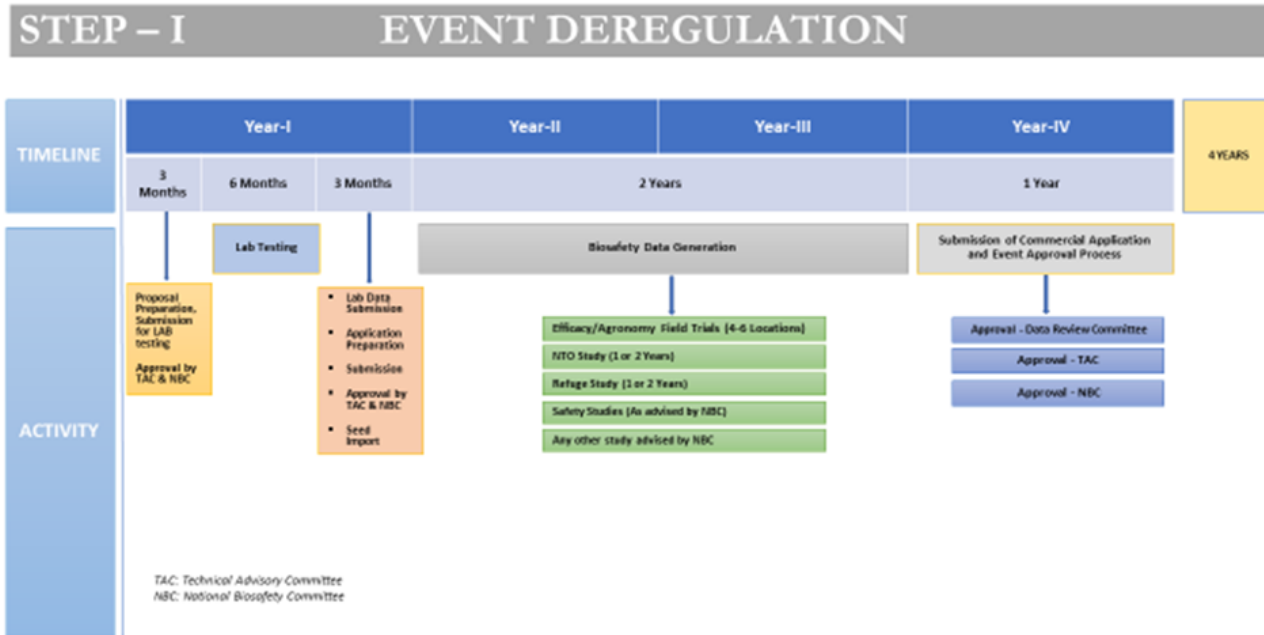
Annex I

BIOTECH APPROVAL PROCESS IN PAKISTAN:

1.Regulatory Framework for Biotech Crops:



2.Timeline for Biotech Approval Process:



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

Pakistan's legal framework regulating the Seed Sector Evolution and Amendment

S.No	Statute	Year
1	The Seed Act	1976
2,	The Seed (Amendment) Act	2015
3,	The Plant Breeders' Rights Act	2016
4	The Seed (Business Regulation) Rules,	2016
5	The Plant Breeders' Rights Rules,	2018
6	The Seed (Registration) Rules 1987 amended in	1998
7	The Seed (Truth-in-Labeling) Rules 1991, amended in	1993 and 1998
8	The Pakistan Fruit Plants Certification Rules	1998
9	Pakistan Environmental Protection Act (PEPA)	1997
10	Pakistan Plant Quarantine Act	1976
11	Plant Quarantine Rules	1967
12	Pakistan Biosafety Rules	2005
13	Patent Ordinance 2000 as amended up to	2016

Source – FSC&RD

Annex – IV

Cotton Imports (Tons)

	2017	2018	2019	2020	2021	2022 (Jan-July)
United States	171,752	344,980	374,585	508,000	436,979	374,231
Brazil	48,839	36,873	113,029	285,000	281,536	190,386
India	127,503	288,192	34,949	-		
Argentina	100	26,788	21,635	54,000	57,682	34,543
EU 28	14,453	13,538	17,771	21,000	34,584	12,926
Mexico	6,225	13,089	16,527	47,000	25,097	
Cote d'Ivoire	27,889	8,458	15,512	51,000	91,823	132,230
Turkey	1,957	7,565	14,687	-	39,083	28,365
Egypt	5,750	8,236	13,764	-		
Malaysia	554	296	6,054	-		
Australia	5,548	4,263	4,448	-	5,308	24,557
China	-	1,794	924	-		

Azerbaijan	-	69	235	-		
Benin	2,409	842	224	-	17,300	13,900
Others	22,803	22,913	234	48,000	112,000	68,300

Source: (Trade Data Monitor, LLC)

Soybean Imports (Tons)

	2018	2019	2020	2021	2022
United States	1,733,277	1,130,977	1,196,714	745,678	699,469
Brazil	644,072	785,691	1,219,154	1,607,822	1,127,856
Canada	-	-	54,000	65,674	

Source: (Trade Data Monitor, LLC)

Annex - IV

REFERENCES:

1. Pakistan Biosafety Rules, 2005

<https://environment.gov.pk/Detail/MDUzMDI1OGItYWYzZC00NzQ0LTlhZWItZjYzY2RkOTkyZGVh>

2. Pakistan Biosafety Guidelines, 2005

<https://environment.gov.pk/Detail/Nzk4N2ZhMmQtM2VIYy00NWNjLWE4NzUtOTZkYmMyMmIyY2E2>

3. Seed Act 1976

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

4. Seed (Amendment) Act 2015

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

5. Plant Breeders Rights Act 2016

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

6. Pakistan Intellectual Rights Act 2012

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

7. Food and Agricultural Import Regulations and Standards Export Certificate Report

<https://www.fas.usda.gov/data/pakistan-food-and-agricultural-import-regulations-and-standards-export-certificate-report>

Attachments:

No Attachments