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Prepared By: Waqas Farooq Sheikh

Approved By: Christopher Rittgers

Report Highlights:

The Department of Plant Protection (DPP) stopped imports of genetically engineered (GE) soybeans and canola in late October 2022. DPP said that importers needed an import license from the Ministry of Climate Change (MOCC). However, MOCC had no system to process import licenses for GE commodities destined for food, feed, or processing (FFP). Despite attempts to amend the National Biosafety Rules and Guidelines to create a system for importers to obtain a license, as of November 2023, the GE commodity import ban remains. Prior to the ban, Pakistan had been annually importing 2.5 to 3 million tons of GE oilseeds for FFP.

EXECUTIVE SUMMARY

In late October 2022, without providing trading partners any prior notice, Pakistan's Department of Plant Protection (DPP) began requiring importers to present an import license from the Ministry of Climate Change (MOCC) as a condition for releasing genetically engineered (GE) soybean and canola arrivals. However, MOCC had no system for receiving and/or processing import licenses for oilseeds destined for food, feed, and processing (FFP). As a result, since October 2022, DPP has banned GE oilseed imports. The National Biosafety Committee (NBC) has completed draft amendments to the Pakistan Biosafety Rules (PBR) that would potentially create a system for importers to obtain an import license for GE oilseeds destined to FFP. However, as of October 2023, the Federal Cabinet had still not approved the amendment. MOCC is unlikely to implement a functioning licensing system for GE oilseed imports before second-half 2024.

Pakistan's agricultural biotechnology regulatory framework consists of four key laws, the 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 have been approved for cultivation and use since 2010. About 95 percent of cotton crop area is BT cotton. Weak intellectual property enforcement hinders GE cotton seed development beyond the available first-generation traits. Citing sufficient domestic production using conventional non-GE varieties, regulatory authorities halted GE corn commercialization in 2019. Meanwhile, lack of regulatory clarity prevents life science companies from investing in and pursuing GE field crop research and development. In the absence of IP protection, breeders lack incentive to invest in the seed business.

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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 NBC, suspended research and commercialization of GE hybrid corn. MNFSR determined that GE corn seed was unnecessary to meet domestic demand.

In 2023, NBC approved both public and private sector entities to do laboratory work using a variety of biotechnology techniques, including genome editing, CRISPR and genetic engineering. This laboratory work includes trait development on potatoes, wheat, soybeans, sesame, and cotton. The NBC approved confined field trials for GE cotton (stacked traits) and sugarcane. In 2023, the only new GE events NBC approved for commercialization were GE cotton varieties with multiple traits.

Several GE cottons seed varieties are approved every year. Cotton is an important cash crop in Pakistan and exports of cotton products account for 60 percent of all foreign exchange earnings. 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 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. When/if amendments to the PBR are approved, MOCC will be responsible for reviewing and issuing import licenses for GE commodities for FFP.

Institutional Biosafety Committees (IBCs) from public and private sector entities regularly communicate with regulatory authorities to track the status of approvals. 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, leads multinational seed companies to be reluctant to invest 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 ¹
	Diamondback moth resistance with Bt gene	Field trials	CEMB	In process
Cotton	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

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

	interference (RNAi)			
	AVP1-H+ for salt and	Field trials	NIBGE	In process
	drought tolerance			1
	Cry1Ac and Cry2Ab	Field trials	CEMB/NIBGE + 4 Domestic Seed	In process
			Companies	
	Cry1Ac + Cry2Ab and Glyphosate	Field Trials	CEMB/NIBGE + 4 Domestic Seed Companies	In process
	Fiber improvement	Experimental	CEMB	In process
	Rust, drought, and salt tolerance	Experimental/Field Trial	NIBGE	On hold
Wheet	Bio-fortified wheat for increased iron and zinc bioavailability	Field Trial	FCCU/AARI	On hold
Wheat	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
	Insect Resistance (Cry1Ac+Cry2A)	Field trials	CEMB/ NIGAB	On hold
	CEMB-GTGene	Field trials	CEMB	On hold
	CEMB-AFP	Field trials	CEMB	On hold
Maize	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
	Insect resistance with Cry gene	Experimental	NIBGE	On hold
Sugarcane	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	Experimental	CEMB	On hold
	VIP3+ASAL	Experimental	CLMD	On noid
	Herbicide tolerant	Experimental	CABB	On hold
	sugarcane	Experimental	CIDD	On noid
	Biotic stress tolerant	Experimental	CABB	On hold
	sugarcane using	Experimental	CIDD	On noid
	SUGARWIN 2 gene			
	Abiotic stress tolerant	Experimental	CABB	On hold
	sugarcane using scdr1	1		
	gene			
	Antifungal sugarcane	Experimental	CEMB, IBGE	On hold
	virus resistance	1	,	
<u>Claistan</u>	Insect resistance (Bt	Experimental	CEMB/NIGAB	On hold
Chickpeas	gene)			
	Insect	Experimental	NIBGE	On hold
	(Helicoverpaarmigera			
	and			
	Heliothesisvericens)			
	resistance with a			
	novel synthetic spider			
	venom gene			
	Salt tolerance with	Experimental	NIBGE	On hold
	yeast, Arabidopsis			
Tobacco	Na+/H+ antiporter			
	genes			
	Salt tolerance with	Experimental	CABB	On hold
	ArDH chloroplast			
	transformation			
	(Biosafe GM)			
	Non-edible vaccine	Experimental	CABB	On hold
	development against			
	Bursal and Newcastle			
	diseases of poultry			
	Virus (PLRV, PLXV,	Experimental	NIBGE	On hold
	PVY) resistance,			
	Chitinase gene for			
	fungal disease			
D	resistance			
Potato	Insect-resistant	Experimental	CABB	On hold
	transplastomic potato			
	- chloroplast			
	transformation	Emperiment 1		$O_{re} = 1 \cdot 1$
	Fungal resistance	Experimental	CABB	On hold
	using glucanase gene			

Peanut	Herbicide resistance, Tikka disease	Experimental	NIGAB	On hold
	resistance			
	Glyphosate resistance,	Experimental	AARI	On hold
	FAEI gene for		IBGE	
	reduced erucic acid			
Brassica	and MAX1 gene for			
	maximum axillary			
	branches to enhance			
	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

Commercial Production

GE cotton is the only crop currently approved for planting. In 2023, GE cotton accounted for about 95 percent of the 2.6 million hectares in cotton 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. Seed companies are very interested in marketing GE corn varieties, but MNFSR's current policy of no GE corn production prevents that.

Exports

Pakistan exports a small volume of GE cotton. During marketing year (August/July) 2022/23, Pakistan exported 50,000 bales (480 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 the economy, with textiles accounting for more than 60 percent of total exports.

Imports

In October 2022, Pakistan banned imports of GE oilseeds. Prior to that, Pakistan had been importing 2.5 to 3 million tons of GE oilseeds annually. In 2022/23, Pakistan imported over 1 million tons of cotton, mostly from the United States and Brazil.

Food Aid

There are no known issues or restrictions affecting the importation of food aid.

Trade Barriers

In late October 2022, without providing trading partners any prior notice, the DPP began requiring that importers present an import license from MOCC as a condition for releasing genetically engineered soybean and canola arrivals. However, MOCC had no system for receiving and/or processing import licenses for oilseeds destined to FFP. As a result, GE oilseed imports have been effectively banned since October 2022. From 2015 until DPP began enforcing the MOCC import license requirement last October, DPP approved and cleared nearly 14 million tons of GE soybean imports; importers did not have MOCC import licenses for any of those imports.

Since the GE import ban went into effect last October, the NBC has considered ways to amend the PBR and Guidelines to create a system for importers to obtain MOCC import permits for GE oilseeds destined to FFP. NBC took several months to finalize proposed changes to existing regulations due to disagreements on whether in-country risk analysis should be required or if original research conducted where an event was originally developed could be used. The question of who should submit the import license request (developer or commodity importer) was also a point of contention. Also, MNFSR leadership, which holds an influential position on the NBC, publicly announced opposition to GE commodity imports.

In mid-2023, NBC completed draft amendments to the Rules that would allow import license applicants to provide existing risk analysis information from third countries, rather than requiring new research to be done in Pakistan. However, the amended guidelines still require the importer to submit the import license request through a third-party Institutional Biosafety Committee. This means that the commodity importer would still need to obtain risk analysis data from life science companies who developed the individual events. This type of coordination between the life science companies and commodity importers, including sharing of proprietary information, will likely be difficult.

MOCC still must submit the amended rules to the federal Cabinet for approval, and it is uncertain when that will happen. Even if the cabinet would approve the amended rules allowing for third country risk assessments, it will still take some time for MOCC to implement a workable import licensing system. Due this uncertainty, it will likely be no sooner than second-half 2024 before GE oilseed imports resume.

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 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 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 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.
- Institutional Biosafety Committees (IBC), which conduct risk assessments, implement safeguards, and monitor and inspect 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.
- According to the draft PBR amendments on imports of GE commodities for FFP, importers must apply for import licenses through a public sector IBC.

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 law is supposed to protect the proprietary work of individuals and businesses from unauthorized use or exploitation by third parties. By utilizing intellectual property laws, seed developers are supposed to be able to protect and recoup their investment in GE products.

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 organize 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 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 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.

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 NBC approved events for commercialization:

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

Table 2: Approvals for Commercialization

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

5	Corteva Pakistan	Maize	Maize 1507xNK603; MON	On hold
			810xNK603	

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, Pakistan's regulatory officials have confirmed that each new genetic trait will be protected separately.

Genes	Crop	Approval Stage	Company	Status ³
cp4epsps	Maize	Commercial	Bayer	On hold
cry2Ab2 & cry1A.105 and	Maize	Commercial	Bayer	On hold
cp4epsps				
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

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

Field Testing

Research institutes are only doing cotton and sugar cane field trials. There are more than 50 public sector research institutes doing laboratory work in agriculture biotechnology, but NBC has approved only a few of them do field trials.

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

S. No	Institute	Сгор	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
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

Table 4: Approvals for Field Trials

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.

Coexistence

At present, Pakistan has not developed a 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 amended guidelines on GE imports might contain monitoring and testing protocols.

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 in line with the requirements of the Seed Amendment Act of 2015. Similarly, provincial seed councils and all national research funding agencies require NBC approval prior to providing funding for any GE-research.

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.

Cartagena Protocol Ratification

Pakistan ratified the Cartagena Protocol on Biosafety on March 2, 2009.

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 the full suite of implementing regulations or the deep bench of technical staff needed to make them fully operational.

PART C: MARKETING

Public/Private Opinions

The previous MNFSR leadership was opposed to GE commodities. 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 GE technology. The ban on GE imports for FFP and the moratorium on GE corn commercialization are 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 and International Life Sciences Institute and Agriculture

universities / Research Institute have published papers on the development of agriculture biotechnology in Pakistan.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

Product Development

There is no commercial production or sale of animals derived from biotechnology. 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.

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 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.

Innovative Biotechnologies

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 IPR 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

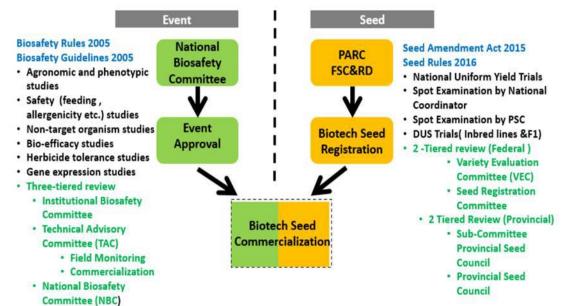
There is no production or sale of GE animals in Pakistan.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

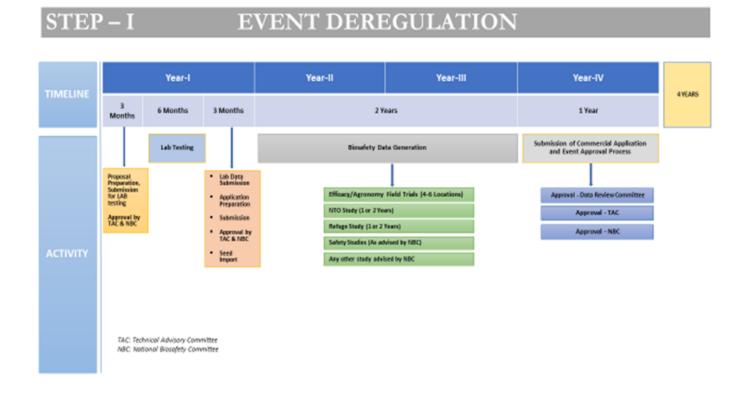
PART G: PRODUCTION AND TRADE Not applicable. *PART H: POLICY* Not applicable.

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
C		

Source – FSC&RD

Annex – IV

Cotton Imports (1000 MT)

Marketing Year	August - July	August -July
	2021/2022	2022/23
United States	351	426
Brazil	190	187
Australia	24	91
Cote d'Ivoire	126	55
Afghanistan	74	46
Argentina	33	13
Turkey	28	52
Tanzania	27	18
Benin	14	6
Greece	14	15
Togo	13	8
EU 27 External Trade	13	49
Others	64	12
Total	982	978

Source: (Trade Data Monitor LLC)

Soybean Import (1000 MT)

Marketing Year	2020/21	2021/22	2022/23				
	(Oct-Sep)	(Oct-Sep)	(Oct-Sep)				
United States	700	770	70				
Brazil	1,600	1,240	57				
Total	2,300	2,010	127				

Source: (Trade Data Monitor LLC)

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1. Pakistan Biosafety Rules, 2005

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Attachments:

No Attachments