

F. No. 1-2/2013/DFSC-II  
Government of Pakistan  
Ministry of National Food Security & Research  
\*\*\*\*

Islamabad the 3<sup>rd</sup> June, 2026

Subject: **REQUEST FOR DISSEMINATION AND IMPLEMENTATION OF NATIONAL AGRICULTURE BIOTECHNOLOGY POLICY (NABP) - 2025**

The undersigned is directed to refer to the subject noted above and to say that the Federal Cabinet has been pleased to approve the National Agricultural Biotechnology Policy (NABP)-2025, which provides a comprehensive national framework for promoting the safe, responsible and science-based application of biotechnology in agriculture to enhance food security, climate resilience, agricultural productivity and competitiveness. The Policy focuses on key strategic areas including plant tissue culture for disease-free planting material, bio-fertilizers and bio-pesticides, genetically modified crops, biotechnology-based livestock improvement, and facilitation of import/export of biotechnology products. The Policy further aims to strengthen research and innovation, promote public-private partnerships, streamline regulatory processes, support commercialization of biotechnology products, and facilitate the development of high-yielding, disease-resistant and climate-resilient crop varieties and livestock breeds while ensuring biosafety and environmental protection.

2. In view of the above, a **copy of the National Agricultural Biotechnology Policy (NABP)-2025** is enclosed herewith for information and necessary action. It is requested that the Policy may kindly be disseminated to all concerned departments, research institutions and relevant stakeholders under your administrative jurisdiction and for implementation in letter and spirit to achieve its objectives of sustainable agricultural development, enhanced agricultural productivity, food and nutritional security, and improved livelihoods of farming communities, please.

**Encl: as above.**



(MUHAMMAD ASIF)

Deputy Food Security Commissioner-II  
051-9208368

**Distribution:**

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18. Secretary Agriculture, Livestock, & Fisheries Department, GB.
19. Chairman, National Seed Development & Regulatory Authority (NSDRA), Islamabad.
20. Chairman, PARC, Islamabad.
21. D. G., FSC&RD, Islamabad.
22. Registrar, Plant Breeder Right Registry (PBRR), Islamabad.
23. Animal Husbandry Commissioner, MNFS&R, Islamabad.
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# National Agricultural Biotechnology Policy (NABP)-2025



Ministry of National Food Security and Research  
Government of Pakistan

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## List of Abbreviations

AARI	Ayub Agricultural Research Institute
ABRI	Agricultural Biotechnology Research Institute
BCH	Biosafety Clearance House
BSL	Biosafety Level
Bt.	<i>Bacillus thuringiensis</i>
CABB	Centre of Agricultural Biochemistry and Biotechnology
CBD	Convention of Biodiversity
CEMB	Centre of Excellence in Molecular Biology
CFTs	Confined Field Trials
CLCV	Cotton Leaf Curl Virus
CPB	Cartagena Protocol on Biosafety
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DNA	Deoxyribonucleic Acid
DUS	Distinctness, Uniformity and Stability
EU	European Union
FFP	Food, Feed and Processing
FSC&RD	Federal Seed Certification & Registration Department
GBS	Genotyping by Sequencing
GBTS	Genotyping by Targeted Sequencing
GEd	Gene Editing
GMO	Genetically Modified Organism
GPUs	Germplasm Units
GWAS	Genome wide Association Study
HEC	Higher Education Commission
IBC	Institutional Biosafety Committee

IBGE	Institute of Biotechnology and Genetic Engineering
IPO	Intellectual Property Rights Organization of Pakistan
ISAAA	The International Service for the Acquisition of Agri-biotech Applications
LMOs	Living Modified Organisms
MAS	Marker Assisted Selection
MNFS&R	Ministry of National Food Security & Research
MoCC	Ministry of Climate Change
MTDF	Medium Term Development Framework
NABP	National Agricultural Biotechnology Policy
NARC	National Agricultural Research Center
NBC	National Biosafety Committee
NBTs	New Breeding Technologies
NCVT	National Cotton Varietal Trial
NIAB	Nuclear Institute for Agriculture and Biology
NIBGE	National Institute for Biotechnology and Genetic Engineering
NIGAB	National Institute for Genomics and Advanced Biotechnology
NSDRA	National Seed Development and Registration Authority
NUYT	National Uniform Yield Trial
Pak-EPA	Pakistan Environmental Protection Agency
PARC	Pakistan Agricultural Research Council
PCCC	Pakistan Central Cotton Committee
PCR	Polymerase Chain Reaction
PNAC	Pakistan National Accreditation Council
R&D	Research and Development
RBC	Red Blood Cell
S&T	Science and Technology
SDN	Site Directed Nuclease

SLAF-seq	Specific locus Amplified Fragment Sequencing
SNP	Single Nucleotide Polymorphism
SSR	Simple Sequence Repeat
STIP	Science, Technology & Innovation Policy
TAC	Technical Advisory Committee
VEC	Variety Evaluation Committee
WBC	White Blood Cell

## **Executive Summary**

Agricultural biotechnology is playing a transformative role in global agriculture, with genetically modified (GM) crops now covering approximately 3% of the world's arable land. Pakistan holds considerable potential in this field, supported by a large pool of scientific talent, an established regulatory framework, and 54 fully operational biotechnology research centers equipped with state-of-the-art laboratories. Despite these strengths, the country has yet to fully capitalize on the benefits of agricultural biotechnology due to the absence of a clear strategic direction.

To bridge this gap, the Ministry of National Food Security and Research has formulated the National Agricultural Biotechnology Policy (NABP). This comprehensive policy sets out national priorities, targets, and streamlined regulatory mechanisms. Its vision is to make Pakistan self-sufficient, minimize risks associated with biotech products, and position the country as a global partner in biotechnology research, innovation, commercialization, and industrial development.

The policy distinguishes between regulated and non-regulated technologies. Regulated technologies include GMO development and commercialization, gene editing, import/export of GM products, and recombinant vaccines for animals. Non-regulated technologies primarily involve plant tissue culture and genomic research. Both areas have been given due importance, with priority research areas identified based on national needs.

Gene Editing (GE) is recognized as a breakthrough technology for genetic improvement in crops. While no formal guidelines currently exist in Pakistan, NABP introduces the country's first fast-track framework for GE R&D and commercialization, enabling national researchers and policymakers to utilize this emerging tool efficiently and safely, drawing on international experiences.

The policy also addresses confusion within the national research system regarding regulatory approval for GM crop varieties, biosafety data requirements, and the distinction between genetic engineering and conventional breeding. It offers practical guidance to clarify these issues and proposes simplified procedures within the existing regulatory structure to ensure faster and more effective implementation for commercialization of biotech seeds and other technologies.

The policy also emphasizes support for non-regulated biotechnology areas such as plant tissue culture and genomics, critical for innovation beyond GMOs. These areas are addressed with clearly defined priorities to promote research and development aligned with Pakistan's agricultural needs.

Thus, NABP provides a robust framework to enhance agricultural productivity, encourage innovation, attract investment, and ensure the responsible and efficient use of biotechnology. Its implementation will foster inclusive growth in both plant and animal sectors and position Pakistan as a partner in sustainable agricultural biotechnology.

**Note** *The contributions of Dr. Kauser Abdulla Malik, HI, SI, TI, President Pakistan Academy of Sciences and Former Federal Minister, Minister of Food Security and Research in developing agricultural biotechnology and endorsing the first draft of the policy are gratefully acknowledged.*

## **A. Introduction**

### **Background**

Biotechnology is a broader discipline encompassing natural sciences and bioengineering sciences to achieve the application of organisms and parts thereof for products and services. Biotechnology has had a significant impact on many areas of society, from medicine to agriculture to environmental sciences.

Advances in biotechnology could transform the very nature of society itself by providing solutions to societal issues. Biotechnological transformation will encompass methods used for product R&D, as well as raw materials, manufacturing methods, and resource recycling. Taking advantage of biotechnologies in this way has the potential to cause industrial restructuring and to fundamentally alter the way societies obtain and use resources, energy, and food.

The framework for promoting and regulating biotechnology in Pakistan is established through key legislative measures, including the Pakistan Biosafety Rules 2005 (amended 2024) and, National Biosafety Guidelines 2005 (amended 2024). To commercialize the biotech varieties/hybrids, the Seed Amendment Act 2024 and Seed Rules 2016 were enacted.

### **Situation Analysis**

The first National Science and Technology (S&T) policy of Pakistan was formulated in 1984. The subjects of Molecular Biology and Genetic Engineering were placed in priority research areas. Later, in 1997, some modification was made, and the National Technology Policy was launched, maintaining an emphasis on biotechnology as one of the priority areas.

National Science, Technology & Innovation Policy (STIP) specially focuses on emerging and frontier technologies with emphasis on advancement in Biotechnology, which is vital to keep pace with the modern tech-world and to stay one step ahead of all. Other earlier policies (National Food Security Policy, Cotton Revival Plan-2025 etc.) do mention agricultural biotechnology in general but lack a clear road map. NABP-2025 is the first consensus effort to set a national road map for harnessing the immense benefits of modern biotechnology tools, especially fast emerging Gene Editing/Precision breeding technologies.

Plant tissue culture is a simple and well-established technology that is currently practiced on a small scale at various national centers across the country. However, apart from potato and to some extent, banana, there has been no significant economic impact of this technology so far. The agricultural sector has yet to fully benefit from the potential of tissue

culture, as research efforts in both the public and private sectors remain limited. The size of these efforts in terms of researchers and financial resources is still very small and unable to reach commercial scale. A reasonably good infrastructure exists for producing virus-free seed potatoes. However, despite an annual demand of 0.4 million tons of virus-free seed potatoes produced through tissue culture, local production currently meets only about 2% of this requirement. There is also significant potential to harness tissue culture technology for the micropropagation of date palm, temperate fruits (such as olive, kiwi, and strawberry), ornamental plants (including gerbera, lily, carnation, and gladiolus), as well as medicinal plants (such as ginger and turmeric). There are only sporadic and limited activities in this area, with little to no economic impact. Furthermore, these initiatives often lack sustainability.

The importance of modern biotechnology in Pakistan was formally recognized in 1981 when the first training course on recombinant DNA technology was organized at the Nuclear Institute for Agriculture and Biology (NIAB), Faisalabad. In 1983-84, the Centre of Excellence in Molecular Biology (CEMB) at the University of Punjab, Lahore was established. In 1986, the Government of Pakistan approved the establishment of the National Institute for Biotechnology and Genetic Engineering (NIBGE), which was formally inaugurated in 1994, and many more after that.

In the years 2001 and 2002, the establishment of the National Biotechnology Commission and the Higher Education Commission played an important role in the promotion of modern biotechnology. During the year 2007, at the Federal level, the National Institute for Genomics and Advanced Biotechnology (NIGAB) was established at the National Agricultural Research Centre (NARC), Islamabad. At the policy level, many important documents cover the sector of Biotechnology, especially S&T policy 2011 & 2024, MTDF, Pakistan Vision 2030, National Food Security Policy-2018 and National Seed Policy 2024. Huge investments have been made in the development of Biotechnology infrastructure in the country, and billions have been spent over the last few years on R&D.

Significant investments have been made in developing biotechnology infrastructure in the country. Over the past two decades, more than Rs. 20 billion have been allocated through the Higher Education Commission (HEC), the Ministry of Science & Technology, the Ministry of Agriculture (now the Ministry of National Food Security and Research), and national funding agencies such as the Pakistan Science Foundation, the PARC-Agricultural Linkage Program, the Planning Commission, as well as various international donors. These funds have supported infrastructure development and capacity building for research and development in

biotechnology, particularly in the agriculture and health sectors, across numerous universities and research institutes.

Through HEC funding, several hundred young researchers have been sent abroad to pursue PhDs or post-doctoral research at leading universities worldwide. Notably, *Bt*. (insect-resistant) cotton became the first biotech crop to receive approval for commercial cultivation in 2010. Despite considerable developments, the agricultural biotechnology sector is still facing challenges like,

- Institutional capacity deficit at the regulatory level for the commercialization of modern biotechnology
- No 2<sup>nd</sup> GM crop was released after cotton
- Lack of clarity regarding data requirements for different types of trials
- Both Event and Varietal approval by the National Biosafety Committee (NBC)
- Nontransparent and inconsistent decision-making, often lacking a scientific basis
- Unpredictable application processing timelines, the time frame mentioned in the rules is not being followed
- Industry representation is not reflected in regulatory committees (TAC & NBC)
- Lack of a clear policy for the commercialization of genetically modified crops.

## **B. Vision and Mission**

**Vision:** To harness the potential of agricultural biotechnology as a premier precision tool for national development and the well-being of society

**Mission:** To make Pakistan self-sufficient, safe from risks of biotech products, globally competitive in agricultural biotechnology research, innovation, translation, entrepreneurship, and industrial growth.

## **C. Objectives of the National Agricultural Biotechnology Policy**

It is the need of time that Pakistan must develop and adopt National Agricultural Biotechnology Policy to prioritize and set the road map to benefit from the advancements made in biotechnology to reduce productions costs, preserve biodiversity, improve environment, bolster food security, create alternative raw materials for industry, empowering farming communities and enhance exports.

### **Detailed Objectives**

These objectives aim to create a robust biotechnology industry that supports sustainable agriculture, enhances crop productivity, and ensures food and nutrition security through research and commercialization of innovative products. A periodic progress audit of these objectives should be conducted to allow for policy adjustments if necessary. The implementation of an effective and science-based National Agricultural Biotechnology Policy will ensure

- The Pakistani nation has access to, confidence in and benefits from safe and effective biotechnology-based products and services.
- An effective science-based strategic investment in local research and development.
- Position Pakistan as a responsible country in the development, commercialization, sale and use of biotechnology by protecting public health, safety, and the environment.
- Improve public awareness and understanding of biotechnology.
- Support the development of human resources in the sector.
- Implementation of science-based and globally harmonized regulations.
- To join global players for the development and deployment of new and emerging technologies

### **However, we need to focus on**

- Fixing priorities and targets to harness the benefits of agricultural biotechnology
- Strengthening the link between biotech research and commercialization.
- Sustaining required financial resources for target-based research and development in Agricultural Biotechnology.
- Predictable, science-based, transparent approvals and representation of the biotech industry in regulatory committees (TAC / NBC).

#### **D. Key Strategic Areas of National Agricultural Biotechnology Policy**

The Ministry of National Food Security and Research will be the custodian of the Policy. The biosafety regulatory domain for GMOs is under the control of the Ministry of Climate Change (MoCC) as the MoCC is the focal point of the UN-sponsored Cartagena Protocol on Biosafety, which is administered through the National Biosafety Centre.

In this context, Agricultural Biotechnology strategies/priorities have been proposed under the following focused areas:

1. Plant Tissue Culture
2. Bio-fertilizer and Bio-pesticide
3. Genetically Modified Crops
4. Gene Editing
5. Plant Genomics
6. Genetically Modified Products Export/Import
7. Animal Biotechnology

## **1. Plant Tissue Culture**

### **1.1 Policy Measures for the Production of Disease-free Potato Plants**

- 1.1.1 There is a big gap between demand and supply, which must be overcome by launching projects to enhance production capacity and to revive the sick units to reach the targets within the stipulated time. These projects should be sustainable once the project duration is over.
- 1.1.2 Development and strengthening of public-private partnerships. The public sector may produce pre-basic tubers. The private sector may be assigned the production of basic and certified tuber for farmers.
- 1.1.3 Potato seed production through tissue culture should be backed by Aeroponic culture for efficient seed production.
- 1.1.4 Programs/projects for the development of new potato varieties through somaclonal variations generated through tissue culture should be initiated.

### **1.2 Policy Measures for the Production of Disease-free Banana Plants**

- 1.2.1 Establishment of Banana germplasm GPUs for approved varieties
- 1.2.2 Production of certified disease-free plants of approved banana varieties.
- 1.2.3 Public-private partnerships and capacity-building programs should be strengthened to meet demand.
- 1.2.4 Self-sustained projects for banana plant production.

### **1.3 Policy Measures for Other Horticultural Crops/ Ornamentals, etc.**

- 1.3.1. Tissue culture-based R&D should be strengthened in horticulture, ornamental & medicinal plants (Table 1).
- 1.3.2. Capacity-building programs focusing on plants (Table 1) should be launched, involving both national and international expertise.

**Table 1: Proposed Horticultural/Ornamental Plants for Tissue Culture**

<b>Area</b>	<b>Plants</b>
Temperate fruits	Olive Grapes, Kiwi, Strawberry
Ornamentals Plants	Cut flowers, Lilly, Carnation, Gladiolus, Gerbera etc.
Medicinal Plants	Ginger, Kalvanji, Turmeric
Others	Date Palm, Pistachio, Chilgoza, Avocado

## **2. Bio-Fertilizers and Bio-pesticides**

### **Policy Measures**

The following policy measures are proposed to support research and development and ensure the efficient utilization of biofertilizers and biopesticides:

- 2.1 Development and production of multi-strain bio-fertilizers with enhanced shelf life
- 2.2 Biofilm producing biofertilizers
- 2.3 High temperature-tolerant formulations of bio-fertilizers
- 2.4 Laboratory-raised cultivable mycorrhizal fungi
- 2.5 Development of dsRNAi-based bio-pesticides
- 2.6 Transgenic sterile insect technology (e.g., pink bollworm control)

### 3. Genetically Modified (GM) Crops Research and Development

Genetically Modified crops are grown on 201.5 million hectares globally, which accounts for 3% of the world's cultivated area (Table 2). A total of 71 countries have adopted biotech crops with 29 countries cultivating them, and another 42 countries (including 16 individual nations and 26 EU member states) importing GM grains such as maize, soybean, canola for food, feed, and processing. Biotech crops have expanded beyond the big four (maize, soybeans, cotton, and canola) offering greater options for consumers and food producers worldwide. These biotech crops include alfalfa (1.3 million hectares), sugar beets (473,000 hectares), sugarcane (20,000 hectares), papaya (12,000 hectares), safflower (3,500 hectares), potatoes (2,265 hectares), eggplant (1,931 hectares), and less than 1,000 hectares of squash, apples, and pineapple. Additionally, biotech crop research conducted by public sector institutions involves rice, banana, potato, wheat, chickpea, pigeon pea, and mustard with various economically important and nutritional quality traits beneficial to food producers and consumers in developing countries.

In Pakistan, CEMB (Lahore) and NIBGE (Faisalabad) are the pioneer Biotech institutes. CEMB ([www.cemb.edu.pk](http://www.cemb.edu.pk)) employs locally cloned genes of *CryIAc*, herbicide resistance *EPSPS*, and many other genes for abiotic stress tolerance. A group in NIBGE has transformed *CryIAc*, *Cry2A*, and *EPSPS* into cotton. Field trial permission has been granted for insect-resistant sugarcane to the Centre for Agricultural Biotechnology and Biochemistry (CABB), UAF.

Gene cloning and transformation for several other traits is being carried out by many other institutes, including public (NIGAB, ABRI, IBGE) and private sectors (4-Bothers Ltd, Tara Group, and others)

#### Policy Measures

##### 3.1 Phase I: Immediate Action

**3.1.1.** Under this category, development work and commercialization of genetically modified crops should be allowed that are not novel and which have shown significant economic and environmental benefits globally, with a safe history of use. The following crops have target traits for which natural genetic diversity is absent or limited, and genetic engineering can help the farming community by overcoming these genetic barriers (Table 2).

**Table 2: Crops and Target Traits for Immediate Action Plan**

S. No.	Crops	Target Traits
1	Cotton	Insect resistance, CLCV resistance, Drought tolerance, Herbicide resistance, Fiber and oil quality, Heat tolerance
2	Sugarcane	Insect resistance, red rot, Herbicide tolerance, Low sugar content
3	Oil seeds (Canola, mustard and Rapeseed)	Herbicide resistance, Male sterile for hybrid development, Shattering resistance.
4	Soybean	Herbicide resistance, Virus resistance, Photoperiod sensitivity, improved oil quality, insect and disease resistance
5	Alfalfa	Low lignin contents
6	Potato	Blight resistance, Reduced browning, Virus resistance
7	Tomato	Delayed Ripening, Drought tolerance, Heat tolerance, Cold tolerance
8	Wheat	Aphids' resistance, Heat tolerance, Herbicide resistance, Drought tolerance, Bio-fortification
9	Maize (Yellow)	Insect resistance, Herbicide resistance, Drought tolerance, Bio-fortification, Bio-Pharming.

\*Not an exhaustive list; taking note of rapid technological developments, any technology developed in the above-mentioned crops will fall into this category even if the trait is not mentioned here.

**3.1.2.** The representation of private /industrial involved in biotechnology R&D sector in the regulatory committees (TAC, NBC) will be made.

**3.1.3.** Collaboration with international public and private sector will be strengthened through PPP mode.

**3.1.4.** Ministry of Climate Change and Environmental Coordination and Ministry of National Food Security and Research will conduct public awareness workshops/conferences on GMOs developments and misconceptions jointly with national research institutes/universities at least 1-2 in year.

3.1.5. MoCC & EC will review the current Pakistan Biosafety Guidelines and Rules and update according to current international standards and developments, strengthen the roles and responsibilities of regulatory Committees (IBC, TAC & NBC).

### **3.2 Phase II: Genetic Modification of other Crops (Case by Case)**

This category covers crops developed using GM technology, which has demonstrated success worldwide in improving crop productivity, enhancing climate resilience, and strengthening plant protection. Alongside biological and biosafety aspects, it is essential to take trade and commercial implications into account adopting GM crops. Therefore, Pakistan should carefully weigh its trade interests and economic benefits before approving the cultivation of any GM variety. To ensure a balanced and strategic approach, a Ministerial Committee comprising relevant ministries, the Ministry of National Food Security and Research, Ministry of Climate Change, Ministry of Industries and Production, Ministry of Commerce and SIFC should be established to assess and approve GM crop cultivation on a case-by-case basis, considering the economic value of the biotech traits for Pakistan and subject to fulfillment of the statutory requirements outlined in Biosafety, Seed, Quarantine and other applicable Acts / Laws / Rules / SOP's. The crops include white maize, sugar beet, eggplant, poplar, pineapple, papaya, squashes, apple, safflower, chickpea, and other vegetables and fruits.

### **3.3 Phase III: Prohibited Genetic Modification**

This category comprises crops that are of prime importance from a historical and geographical indication point of view in Pakistan. The crops such as Rice, Kinnow, Mango, Kasuri Methi, Hunza Peaches, Date palm (Dhakki, Halawai, Bejum Jangi), Guava, and other crops that have been and will be registered as National GIs in the list of Intellectual Property Rights Organization of Pakistan (IPO) from time to time. Genetic modification through genetic engineering will not be allowed in these crops unless a further decision is taken by the Pakistan government, purely due to economic considerations and export value.

### **3.4 Phase IV: Status of Known Genes/Known Genetic Events**

This category of Policy defines the status of known genes that have been transformed into different crops and have a well-established biosafety and commercialization history. Chapter 13 of National Biosafety Guidelines, 2005 (amended 2024) provides specific exempt status for GMO technologies/genes if there are sufficient grounds/information available to consider them risk-free. In this regard, the policy measures are as follows:

3.4.1 Institutional Biosafety Committees (IBCs) will examine Exempt Status regarding risk analysis for Laboratory work/field/commercialization work with GMOs/genes based

on sufficient grounds available to consider the work having no risk. The final approval will be granted by TAC/NBC.

3.4.2 The National Biosafety Committee will grant approval for such cases for commercial release on a priority basis and will notify to IBC within thirty (30) days.

3.4.3 TAC and NBC can accept a risk assessment done in the country of origin or can do a Risk Assessment based on the studies provided by the applicant, done internationally and in Pakistan.

3.4.4 The following genes for various economic traits have well-established biosafety data history and have been commercialized in the world. These genes/technologies will be considered for the grant of exempt status (Table 3).

3.4.5 For other genes in the future, IBCs and the TAC may consider granting exempt status on a case-by-case basis.

**Table 3: Known Genes/Technologies for various Traits**

S. No.	Genes/Technologies	Traits	Data Source
1	<i>aad-12, cym, aad-1</i> and <i>ft_t</i>	2,4-D herbicide tolerance	ISAAA
2	<i>pg</i> (sense or antisense)	Delayed fruit softening	ISAAA
3	<i>dmo</i>	Dicamba herbicide tolerance	ISAAA
4	<i>Hahb-4</i>	Drought stress tolerance	ISAAA
5	<i>Rpi-vnt1</i>	Foliar Late Blight Resistance	ISAAA
6	<i>bar, pat</i>	Glufosinate herbicide tolerance	ISAAA
7	<i>cp4 epsps (aroA: CP4), gat4621, gat4601, goxv247, 2mepsps, mepsps, epsps (Ag), epsps grg23ace5</i>	Glyphosate herbicide tolerance	ISAAA
8	<i>cryIF, cryIAc, vip3A(a), cryIAb, cry2Ab2, cryIAb-Ac, cry2Ae, cryIC, cryIA, cryIAb (truncated), cryIFa2, vip3Aa20, cryIA.105, cry9C, pinII, cryIDa_7, cryIB.868, mocryIF, vip3Aa19</i>	Lepidopteran insect resistance	ISAAA

9	<i>barnase, zm-aa1, dam</i>	Male sterility	ISAAA
10	<i>PGAS PPO</i> suppression gene	Non-Browning	ISAAA
11	<i>ecry3.1Ab</i>	Coleoptera insects	ISAAA
12	<i>amy797E</i>	Bioethanol production	ISAAA
13	<i>mcry3A(MIR604)</i>	Beetles resistance	ISAAA
14	<i>Ecry1Gb.1lg</i>	Lepidopteran resistance	ISAAA
15	<i>GA20ox_SUP suppression cassette</i>	Short stature Corn	ISAAA

### 3.5 Varietal Approval System for new and already approved Event/s

A harmonized approach should be adopted to regulate the varieties and hybrids having NBC-approved biotech EVENT/S. The National Biosafety Committee is responsible for granting approvals for genetically engineered organisms under the Pakistan Biosafety Rules 2005 / 2024.

For commercialization as per 12.1.9 of Pakistan Biosafety Guidelines 2005 (amended 2024), Mendelian inheritance data and Chi-square analysis for at least 2 generations will be submitted to demonstrate.

The transfer (trait introgression) of NBC-approved Biotech EVENT from one germplasm to another variety/hybrid through conventional breeding will be carried out as per Standard Operating Procedures notified by NBC(Annexure-II).

#### 3.5.1 Approval of Crop Variety / Hybrid with new EVENT/S

There will be a requirement for two years or seasons of CFTs for biosafety risk assessment of biotech events related to health and environmental concerns, with data requirements specified in Annexure-III.

After the biosafety clearance of the new event for commercialization issued by NBC for the new event, the variety will be subjected to other existing Rules/Act applicable for the cultivation and commercial release of seed (Annexure-I).

NSDRA/ VECs will approve SOPs for National Uniform Yield Trials of each specific crop as required for variety approval by VEC and Provincial Seed Council.

### **3.6 Stewardship requirement of GM Crops allowed for Commercial Cultivation**

Product stewardship is a concept that requires each person in the product life cycle including innovators, regulators, and technology users to share responsibility. Product stewardship is the legal, ethical, and moral obligation to assess products and technologies to ensure that they are safe as well as socially and environmentally responsible.

There must be a focus on adoption of product stewardship for post-release management of GM crops which encompasses trait performance, product integrity throughout the product's life cycle, resistance management, integrated pest management (IPM), good agricultural practices, high-quality seeds and planting material, intellectual property management, labeling, identity preservation, consumer acceptance, and effective marketing.

#### **Insect-Resistant Crops**

Being a biological organism, insects have the potential to develop cross-resistance against insect-resistant transgenic crops. Crop refugia is one of the strategies being implemented for managing cross-resistance. The idea behind a crop refuge is that it supports a population of *Bt*-susceptible insects that have not been exposed to selection pressure from the *Bt* protein. The goal is to dilute the resistant genes in the insect population.

#### **Herbicide-Tolerant (HT) Crops**

It is well understood that the challenges with herbicide resistance in key weed species is largely attributed to overreliance on a single weed control strategy for example herbicide applications with the same mode of action. As the cultivation of herbicide-tolerant crops goes hand in hand with the application of herbicides such as glyphosate, the use of diverse weed control strategies is crucial for reducing weed resistance and ensuring the sustainability of HT crops.

#### **Policy Measures**

- 3.6.1 Each insect-resistant crop is approved with a predetermined refuge requirement based on the data generated for this purpose by the technology developer.
- 3.6.2 The Insect Resistance and Weed Resistance monitoring committee shall be constituted by TAC/NBC with representation of provincial governments. The committees should guide technology providers and growers based on the data generated specifically for this purpose.
- 3.6.3 GMO seed pack must be properly labeled with the EVENT name, its purpose and spectrum of activity.

3.6.4 Technology / GMO seed providers must provide instructions about the product and its usage to farmers, such as:

- Key benefits of technology/s
- Herbicide recommendation and its safety on the Crop
- Planting timing and agronomy practices

#### **4. Gene Editing**

Targeted genome editing using artificial nucleases has the potential to accelerate basic research as well as plant breeding by providing the means to modify genomes rapidly in a precise and predictable manner.

The technology of gene editing has been employed by more than 40 countries in the world for the genetic improvement of crops and animals, mainly using the Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR)/CRISPR-associated protein 9 (Cas9) system, a recently developed tool for the introduction of site-specific double-stranded DNA breaks. Commercial products of gene editing include GABA tomato (Japan), rice (India), and a number of success stories are in the pipeline.

GM (Genetically Modified) crops now cover about 3% of world cultivated area and provide more than 10% of the world's food, but unlike conventional or mutation breeding, both of which are forms of genetic manipulation, the commercial growth of GM crops has been highly regulated, and this has increased the costs of their development.

Over the last ten years, so-called 'New Breeding Technologies' (NBTs) have also emerged, based on the development of targeted mutations using gene editing (GE) approaches. Realizing the importance of NBTs, the **Precision Breeding Act-2023** passed in the UK, which is a major step in unlocking the growth and innovation in new technologies, reinforcing food security in the face of climate change, and ensuring that England becomes a world leader in agri-food innovation. This act has removed unnecessary barriers to research into gene editing, providing ease in the application of precision breeding techniques that will not need to go through the restrictive rules for genetically modified (GM) crops, since the resulting plants could have been a product of natural selection or conventional breeding.

#### **Scientific Basis of Edited Changes**

In gene editing using the CRISPR/Cas9 system, a spontaneous repair at a double-strand break (dsB) site that does not introduce external DNA is typically classified as Site-Directed Nuclease 1 (SDN-1). If a repair oligonucleotide is incorporated at the dsB site, it

is referred to as Site-Directed Nuclease 2 (SDN-2). When an entirely new gene cassette is inserted at the dsB site, it is known as Site-Directed Nuclease 3 (SDN-3).

In regional and other countries like Japan, India, Bangladesh, Thailand, Australia, USA, Philippine, GEd products with SDN-1 change do not undergo normal regulatory process and products with SDN-3 are considered as GMOs in most of the jurisdictions. However, the product with SDN-2 are reviewed case by case to decide NON-GMO or GMO status

### **Pakistan Scenario (Gene Editing)**

Pakistan will require technologies such as Gene editing (GEd) to enhance the yield, quality, and nutritional value of food and fiber crops, which are the mainstay of its economy. To date, different institutions in Pakistan are working in collaboration with researchers' other countries to improve important crops such as wheat, rice, cotton, potato, oilseed brassicas, soybean, and tomato using various GEd tools. Under the Pakistan Biosafety Rules, 2005 (amended 2024), gene-edited organisms are currently classified as GMOs. In contrast, if a foreign gene is absent or segregated out, then the edited plant should not be subject to GMO regulations.

### **Policy Measures**

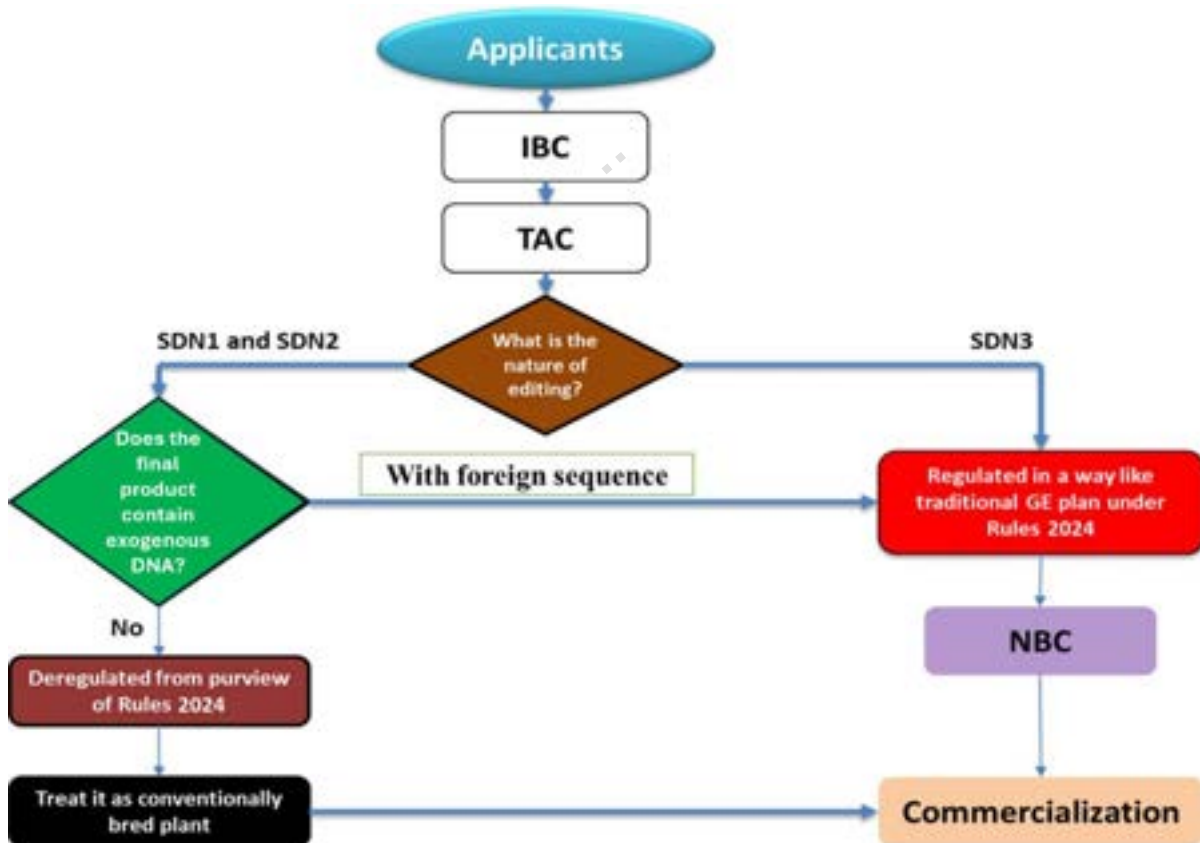
The policy and regulatory framework for gene-edited products, particularly those generated through SDN1 and SDN2, should be streamlined as follows:

- 4.1 The proposed road map for approval of gene-edited organisms/plants in Pakistan is shown in Figure 1.
- 4.2 The Institutional Biosafety Committee (IBC) will consider all GEd cases, define the nature of edited change (SDN-1, SDN-2 or SDN-3) and submit recommendations on the status of projects or research outcomes as GMO or NON-GMO to the TAC and NBC.
- 4.3 Relevant Standard Operating Procedures for research and development on gene-edited plants/animals should be formulated along the following lines:

The organisms developed using gene-editing tools will be categorized based on the type of edit

- a) Products generated through SDN-1 (which do not contain any foreign nucleotide sequences) and SDN-2 (which do not contain foreign sequences other than those from a sexually compatible donor) will not be regulated as GMOs.
- b) The presence of exogenous DNA templates in final products, except for sequences derived from a sexually compatible donor, will not be permitted under SDN-2.

- c) Whereas when a foreign gene/exogenous DNA of any size is present, the product will be treated as a GMO (SDN-3).
- d) Researchers must provide evidence or data demonstrating that the gene-edited plant(s) are free from any introduced exogenous DNA to obtain NON-GMO status from the IBCs.
- e) Relevant certificate for gene-edited change will be issued by the National Biosafety Committee, whether GMO or NON-GMO".



**Figure 1: Proposed Roadmap for GEd Crops Approval System in Pakistan**

## 5. Plant Genomics

Genomics research has influenced all aspects of agricultural research. It evolved from basic information generated by molecular biologists, chemists, and computational scientists. The first era deals with developing DNA markers for the crop of choice. During the same time, various techniques of DNA fingerprinting using Single Nucleotide Polymorphism (SNPs) have developed at an astonishing pace. This technology has many applications in varietal identification, seed purity, breeders' rights, phylogenetic relationship, assessing diversity and genome-based selection of plants and animals of choice.

## Policy Measures

Genomic research, being a modern tool of agricultural biotechnology, is non-regulated. The following areas need to be focused on for agricultural research using modern tools of genomics.

- 5.1 The development of reference genome chips for indigenous crop varieties is essential for further sequencing-based genomic applications.
- 5.2 DNA fingerprinting for crop varieties using SSRs should be recommended as a short/medium-term strategy. SNP-based approach, Genotype by Sequencing, should be recommended once genomic platforms are available for particular crops.
- 5.3 High throughput phenotyping of crops using ground and unmanned aerial vehicles (e.g. drones) equipped with hyperspectral sensors and Artificial Intelligence tools for phenomics data collection and analysis.
- 5.4 Accelerating the Breeding through pre-breeding using GWAS based on GBTS, SLAF-seq, and exome capture for the discovery of new genes as well.
- 5.5 To reduce the linkage drag in MAS, the application of Speed cloning based on K-mer-based association genetics.
- 5.6 Implementation of genome-based 'breeding by design' strategy in important crops.
- 5.7 Integration of genomics techniques supplemented with speed breeding projects based on the above thematic area should be launched, involving global and private partnerships.

## 6. Genetically Modified Products Export/Import

This part of the policy defines guidelines for export and import of genetically modified products (seed, seedlings, cutting, grains) meant for cultivation, Food, Feed, and Processing (FFP).

### Current Scenario in Pakistan

Pakistan has been importing GM Canola as well as GM soybean for many years for Food, Feed and Processes (FFP) and meeting over 90% of the **soft edible oil** needs of the food industry. Currently, at the domestic level, cottonseed derived from 90% of the GM cotton grown in the country is also used by the local processing industry.

Pakistan is a party to the UN-sponsored Cartagena Protocol on Biosafety of the Convention of Biodiversity (CBD). For Trade, Labelling & Traceability, Pakistan lately (2023) established Biosafety Clearing House (BCH) Pakistan which is linked to CBD-Montreal and all GMOs

related activities at any level are given at the BCH platform. It is mandatory to get approval for “import, export, sale and purchase of living modified organisms (LMO), substances or cells and products thereof for commercial purposes in the country, **for cultivation and direct use as food or feed or for processing**. The import of GM soybean/Canola was the main issue under the Trade & Investment Framework Agreement (TIFA) between Pakistan and the USA. The GM soybean issue was resolved under trade diplomacy; however, the GM Canola issue is under review. The whole business of export/import related to genetically modified products needs to be clarified, facilitated, and eased.

### **Policy Measures**

- 6.1 The import of seeds/seedlings/cuttings for cultivation and grains for FFP will be regulated according to Rule 14(2) and Rule (14)2A of Pakistan Biosafety Rules-2005 (amended-2024), **case by case**.
- 6.2 If sufficient information and risk assessment data is available for genetic events meant for export/import related to Food, Feed and Processing, Institutional Biosafety Committees should be empowered to review the exempt status as per Chapter 13 of National Biosafety Guidelines-2005. As in other cases, the IBC assessment and project proposal shall be forwarded to TAC and NBC for award of exempt status.
- 6.3 Pakistan Biosafety Clearing House (BCH) (GMO data storage house) and National Biosafety Centre should be strengthened with regular staff and infrastructure.

## **7. Animal Biotechnology**

In Pakistan, adopting biotechnology and genomics can result in the livestock genetic improvement in a rapid way. However, the country has to address various issues related to trained human resources, infrastructure, and funding opportunities in research and development, etc.

### **Policy Measures**

The biotechnology-oriented research aimed to improve animal production, health and nutrition that would not only generate new opportunities for knowledge creation but also new options for handling emerging problems. The main areas as policy measures that should be focused on for the improvement of livestock productivity via animal biotechnology are as follows (Table 4):

**Table 4: Priority Research Areas for Animal Biotechnology in Pakistan**

Area	Research Area
Livestock Genomics (buffalo, cattle, goat, sheep, yak, camel and poultry)	<ul style="list-style-type: none"><li>• Genetic Diversity studies</li><li>• Candidate gene analysis for economic traits</li><li>• Genome Wide Association Studies (GWAS) for new gene discover</li><li>• Genotyping by Sequencing (GBS)</li><li>• Transcriptomic Analysis</li><li>• Selection of true-to-type pure breeds</li><li>• Creation of indigenous reference genome of important breeds (Buffalo, cattle)</li><li>• Indigenous livestock genomic chip development for targeted sequencing</li><li>• Genomic selection</li><li>• Breed-specific SNP markers</li></ul>
Animal Reproductive Biotechnology (buffalo, cattle, goat, sheep, yak, camel and poultry)	<ul style="list-style-type: none"><li>• Artificial Insemination</li><li>• Embryo transfer</li><li>• Ovum pick-up</li><li>• Somatic Cell Cloning</li><li>• Cryopreservation of ova and embryos</li></ul>
Animal Health and Feed Products	<ul style="list-style-type: none"><li>• Characterization / epidemiology of emerging pathogens,</li><li>• Disease diagnostic development</li><li>• Research on quality of meat for export.</li></ul>
Vaccine Development	<ul style="list-style-type: none"><li>• Vaccine candidate identification/matching</li><li>• Recombinant vaccine development</li><li>• Cell culture purified viral vaccines</li></ul>
Fish Biotechnology	<ul style="list-style-type: none"><li>• Genetic characterization /improvement of local fishes</li><li>• Development of Quantitative Trait Loci (QTLs) /markers development</li><li>• Production of Gene edited fish for enhanced growth and disease resistance</li></ul>
Microbial Biotechnology	<ul style="list-style-type: none"><li>• Functional food / Nutraceuticals development</li><li>• Neutrigonomics</li><li>• Next Generation probiotics for animal feed/ therapeutics development</li><li>• Development of biofertilizers</li><li>• Preserving Meat with Bacteriophage-Encapsulated techniques</li></ul>

- 7.1 The policy covers R&D areas in animal biotechnology only.
- 7.2 Pakistan has no reference genome for any of its indigenous breeds. There is a dire need for reference genomes for local high-quality breeds of buffalo, cattle, sheep, goat, yak, and camel.
- 7.3 A livestock genome bank should be established to support research and development.
- 7.4 Projects on the above research area should be launched involving public-private, national-international partnerships.
- 7.5 DNA-based IPRs protection of indigenous breeds of yak, camel, buffalo, goat, sheep and cattle should be strengthened.
- 7.6 The national coordination mechanism on animal biotechnology research and development should be strengthened at the Platform of the Pakistan Agricultural Research Council.

## **E. Socio-Economic Impact Assessment (SEIA) Framework of NABP**

SEIA framework is integrated into the policy to ensure that technological advancements in biotechnology lead to tangible, inclusive, and measurable benefits for society, while also promoting environmental sustainability, economic viability, and public accountability. To ensure policy coherence and alignment with national and international commitments, the framework is integrated with Pakistan's Vision 2025, Science, Technology & Innovation Policy 2022, National Food Security Policy 2018, and the amended Pakistan Biosafety Rules (2005/2024).

### **Objectives and Scope**

The SEIA Framework aims to guide decision-making at all stages of biotechnology development from research to commercialization and post-market surveillance by assessing the social, economic, environmental, and institutional impacts.

### **Core Dimensions, Indicators, and Implementation Mechanisms**

SEIA evaluations will address key dimensions aligned with NABP-2025 goals, including technology classification and stewardship, farm-level viability, socioeconomic and environmental outcomes, trade and market impacts, equity and inclusion, and institutional readiness, ensuring responsible adoption, regulatory coherence, and inclusive benefits.

### **Linkages with Regulatory and Trade Systems**

SEIA findings can be used by Institutional Biosafety Committees (IBCs), Technical Advisory Committee (TAC), and National Biosafety Committee (NBC) in decision-making.

### **Implementation Mechanism**

A dedicated SEIA Unit shall be established within the Social Sciences Division of PARC. This unit will be responsible for:

- Developing SEIA methodologies, SOPs, and standardized reporting templates.
- Coordinating SEIA evaluations across biotech projects.
- Managing a national SEIA data repository.

- Supporting biotech developers, regulators, and stakeholders with socio-economic analysis.

## **Conclusion**

The Government of Pakistan is confident that the National Agricultural Biotechnology Policy of Pakistan 2025 will receive strong support from Provincial Governments, Agricultural Universities, plant breeders, seed producers, the seed industry, technology developers and all other stakeholders. It is anticipated that this policy will act as a catalyst in achieving the objectives of sustainable agricultural development, ensuring food and nutritional security for the population, and raising living standards for farming communities.

The implementation of the National Agricultural Biotechnology Policy of Pakistan 2025 is poised to play a pivotal role in boosting food production and striving towards a hunger-free Pakistan. By establishing an efficient system for the supply of high-quality, disease, insect-resistant, herbicide-resistant seeds and high-quality animals to farmers, this policy is expected to inject momentum into agricultural production.

Furthermore, the policy is set to lay the groundwork for liberalizing the biotech sector and initiating necessary legal reforms to introduce tools like gene engineering and editing for modern agriculture. This strategic move will cater to the evolving needs of the rapidly expanding modern agriculture industry. With a focus on broadening the scope of the domestic biotech institutions, enhancing their technological capabilities, and promoting investment in research and development programs, the National Agricultural Biotechnology Policy aims to facilitate the production of local high quality biotech seeds by fostering an environment also conducive to biotech seed exports, this policy will contribute significantly to national agricultural production and create employment opportunities for professionals, skilled workers, and small farmers in the competitive global trade landscape and will significantly reduce cost of production and enhance productivity.

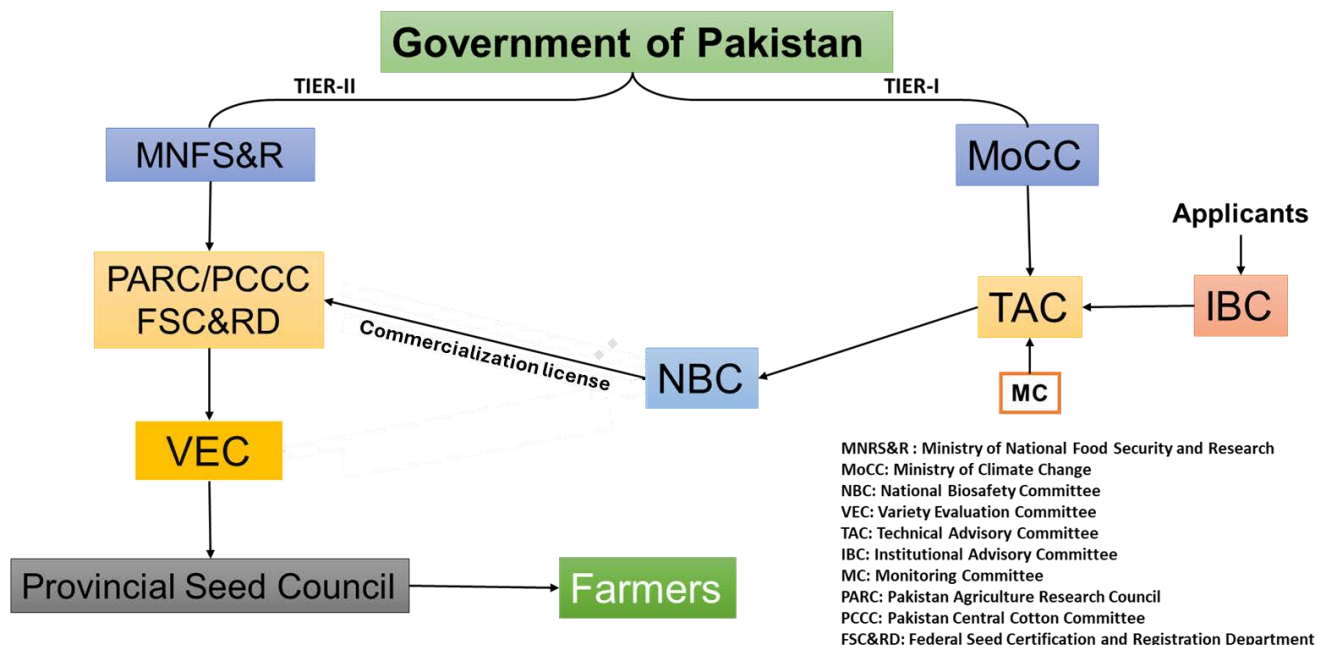
## **Institutional Arrangement**

- i. Ministry of National Food Security and Research (MNFS&R)
- ii. Ministry of Climate Change and Environmental Coordination (MOCC&EC)
- iii. Pakistan Agricultural Research Council (PARC)
- iv. Pakistan Environment Protection Agency (PAK EPA)
- v. National Seed Development and Regulatory Authority (NSDRA)
- vi. Federal Seed Certification and Registration Department (FSC&RD)
- vii. Department of Plant Protection (DPP)
- viii. Plant Breeders' Rights Registry (PBRR)
- ix. Pakistan Atomic Energy Commission (PAEC)
- x. Provincial Agriculture Departments
- xi. Provincial Agriculture Research Institutes
- xii. Agricultural Universities
- xiii. Crop Life Pakistan Association (CLPA)
- xiv. Hi-Tech Hybrid Seed Association
- xv. Seed Association of Pakistan
- xvi. Civil Society and Farmers

## **Legal and Regulatory Framework**

Approval of the National Agricultural Biotechnology Policy of Pakistan 2025 by the Federal Government

## GM variety Approval System in Pakistan



The Genetically Modified variety system consists of inter-ministerial coordination with two tiers.

**Tier-I:** Tier-1 is regulated by the Ministry of Climate Change and Environment Coordination under Pakistan Biosafety Rules and Guidelines-2005 through the National Biosafety Centre. This process is composed of three committees, i.e. IBC, TAC, and NBC. Research and development related to GM variety development is regulated at three work stages, i.e. laboratory work, confined field trial, and commercialization permissions. Depending upon the work stage, the applicant submits its application to TAC through the respective IBC. NBC grants final approval for a period of two years for laboratory work, confined field trials (CFTs), and commercialization. After two years of CFTs, NBC will give commercial approval and forward the GM variety case to PARC for National Uniform Yield Trial in multi-locations.

**Tier-II:** This is regulated by the Ministry of National Food Security and Research under the Seed Act-2015. This process is the same for NON-GM and GM varieties. PARC will conduct a year's multi-environment National Uniform Yield Trial (NUYT) for all crops, coupled with Distinctness, Uniformity and Stability (DUS) test by FSC&RD for agronomic traits, gene expression etc. evaluation. Based on successful NUYT results for GM variety and recommendation of the Variety Evaluation Committee (VEC), the variety will be finally approved by the Provincial Seed Council for farmer field cultivation.

**Standard Operating Procedures (SOPs) for Cross-Bred Genetically Modified Variety Approval**

**Step 1: Prior approval from NBC**

- a) The applicant will submit the case of crossbreeding/stack-breeding to the concerned IBC, providing the pedigree of the cross-bred GM line under development. IBC will thoroughly review the case and submit recommendations to Pak-EPA/TAC.
- b) If the applicant is not the developer of GM technology for which biosafety clearance has been issued by NBC, the applicant will have to submit a copy of the agreement/authorization made with the developer/license holder.
- c) The Technology developer/license holder will intimate Pak-EPA/NBC regarding the agreements made with public/private organizations for the use of technology as per Rule-11 of Pakistan Biosafety Rules, 2005 (amended 2024) before the initiation of work on crossbreeding/stack-breeding.

**Step 2: NBC approval**

- a) TAC will evaluate the case and submit recommendations to NBC.
- b) NBC will approve cross-bred/stack-breeding in compliance with Pakistan Biosafety Rules, 2005 (amended 2024).

**Step 3: GMOs confirmation**

The authenticity of the cross-bred line will be ensured by the developer and verified from at least one of the following designated public sector laboratories, which may include more public and private sector Labs with the approval of NBC.

- a) National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad.
- b) National Centre of Excellence in Molecular Biology (CEMB), Lahore.
- c) Agriculture Biotechnology Research Institute (ABRI), Ayub Agriculture Research Institute (AARI), Faisalabad.
- d) National Institute for Genomics and Advanced Biotechnology (NIGAB), Islamabad.

**Step 4: Exemption from Confined Field Trials (CFT)**

- a) Cross-bred lines will be exempt from CFT if risk assessments for one or both parents are already conducted and well established, cleared by NBC, as per Chapter 13 of the Pakistan Biosafety Guidelines, 2005 (amended 2024).

- b) Data for the inheritance and transfer of transgenic traits will be recorded in segregating generations by applicants.

#### **Step 5: National Uniform Yield Trial (NUYT)/National Cotton Varietal Trial (NCVT)**

The GM lines developed through crossbreeding/stack-breeding will undergo a two-year evaluation in the National Uniform Yield Trial (NUVT)/National Cotton Varietal Trial (NCVT) to assess agronomic traits, gene expression, and impacts on non-target pests, along with a Distinctness, Uniformity, and Stability (DUS) test. Prior notification will be provided to the National Biosafety Committee (NBC) through the respective Institutional Biosafety Committee (IBC).

#### **Step 6: Application for Commercialization License**

- a. Based on successful NUYT results, the applicant will apply for a commercialization license to Pak-EPA/NBC.
- b. NBC will issue a biosafety clearance certificate for commercialization.

#### **Step 7: Provincial Seed Council Approval**

- a) After receiving recommendations from the Variety Evaluation Committee (VEC) and subsequent approval from the Provincial Seed Council, the variety will be released for commercial cultivation.

*These SOPs ensure compliance with Pakistan Biosafety Guidelines, 2005 (amended 2024) and Pakistan Biosafety Rules, 2005 (amended 2024) while facilitating the development and approval of cross-bred GM varieties.*

**Minimum Biosafety Considerations for Local Confined Field  
Trial of Genetically Modified Varieties**

**1- Health Safety Assessment (BSL-1+)**

A- Compositional analysis: It may be provided for leaf and seed tissue in comparison with the non-transgenic counterpart.

B- Toxicity-based assessment

i- Acute toxicity

a- Acute oral toxicity in laboratory rodents (rats, rabbits) is required to confirm the lack of toxicity

b- A single high dose is given, and observations are made for 2 weeks to ascertain no adverse effects, and

c- During this period, different parameters of different systems are monitored daily.

Blood CP/Hematological parameters (Hemoglobin, Total RBC, Total WBC, Neutrophils, Lymphocytes, monocytes, Basophils, Platelet count, etc.)

**2- Environmental Safety Assessment (BSL- 1)**

A- Weediness Potential

i- Speed of seed germination (Number of days)

ii- Shattering capability (%)

B- Cross-ability and Gene Glow

i- Extent of crossing with related species (PCR-based may be made)

ii- Extent of crossing with other seasonal species (PCR-based may be made)

C- Effect on Soil Flora

i- Gene leakages (PCR-based)

ii- Alteration in abundance (Sequencing-based)

- *Parameters will be notified by MOCC/NBC*
- *Health Safety Risk Assessment will be carried out in contained conditions*
- *Environment Risk Assessment will be conducted under confined conditions of Document.*

## Annexure-IV

### NAPB-Consultation and Feedback Timeline

S. No.	Timeline	Actions
1.	18 <sup>th</sup> & 27 <sup>th</sup> October 2023	MNFS&R issued directives to PARC to formulate Policy draft.
2.	20 <sup>th</sup> November 2023	1 <sup>st</sup> drafted submitted to Federal Minister Dr. Kausar Abdullah Malik for review
3.	2 <sup>nd</sup> December 2023	2 <sup>nd</sup> Draft circulated to 13 different Provincial and Federal stakeholders (including MoCC & MoST) for review/comments
4.	1 <sup>st</sup> March 2024	Comments received from 11 Stakeholders
5.	29 <sup>th</sup> March 2024	3 <sup>rd</sup> Draft submitted to MNFS&R
6.	15 <sup>th</sup> August 2024	Comments received from MoCC again
7.	16 <sup>th</sup> September 2024	4 <sup>th</sup> Draft submitted in the light of MoCC comments
8.	7 <sup>th</sup> January 2025	Constitution of Working Group by MNFS&R for finalization of Policy.
9.	14 <sup>th</sup> January 2025	Meeting of Working Group in PARC
10.	3 <sup>rd</sup> March 2025	Revised draft submitted
11.	7 <sup>th</sup> May 2025	Meeting at NSDRA (On-line)
12.	9 <sup>th</sup> May 2025	Revised Draft
13.	2 <sup>nd</sup> June 2025	Consultation and Feedback session at MNFSR
14.	5 <sup>th</sup> June 2025	Consultation and Feedback session-Animal Biotechnology
15.	27 <sup>th</sup> June 2025	Consultation and Feedback Session-Private Sector
16.	2 <sup>nd</sup> July 2025	Meeting at NSDRA to finalize the draft after incorporating Plant and Animal Biotechnology Stakeholders inputs.

## Definitions

Conventional Biotechnology	Conventional biotechnology uses classical techniques like selective breeding and fermentation to improve organisms for agriculture and food production.
CFTs	Controlled outdoor experiments to test genetically modified crops under regulatory and environmental guidelines before commercial release.
Crop Refugia	Areas planted with non-GM crops near GM crops to slow the development of pest resistance
CRISPR/cas system	A gene-editing tool that uses a guide RNA and Cas protein to cut DNA at precise locations for targeted genetic modifications.
Cartagena Protocol on Biosafety (CPB)	The Cartagena Protocol on Biosafety establishes international rules and procedures to regulate the transboundary movement, handling, and use of living modified organisms to protect biodiversity and human health.
dsRNAi	A biological process where double-stranded RNA silences specific genes by degrading their corresponding messenger RNA (mRNA).
Foreign/exogeneous Gene	A gene introduced into an organism's genome that originates from a different species or external source.
Genetic Engineering	Genetic engineering is a process that uses laboratory-based technologies to alter the DNA makeup of an organism.
Genetic Event	A specific, stable genetic modification in a plant or organism resulting from the insertion of foreign DNA or genome editing.
GM Crops	GM crops are those crop plants in which foreign genes have been inserted into their genome through genetic engineering to produce desirable characteristics.
Gene Editing	Gene editing is a group of technologies that enable scientists to change an organism's DNA by adding, removing, or altering genetic material at particular locations in the genome.
GPUs	High-quality, certified seeds or propagative materials with uniform genetic and physical characteristics for crop production.
Gene Cloning	The process of creating identical copies of a specific gene or DNA sequence.
Gene Transformation	The process of introducing foreign DNA into a host organism's genome to alter its genetic makeup.
GIs	Specific DNA sequences introduced into an organism's genome through genetic engineering.

Genotype By Sequencing	GBS is a next-generation sequencing (NGS)-based method that allows rapid discovery and genotyping of genetic variants across the genome by sequencing subsets of genomic fragments.
Modern Biotechnology	Modern biotechnology deals with advanced molecular techniques such as genetic engineering and genome editing for precise improvement of plants, animals, and microorganisms.
New Breeding Technologies (NBTs)	Innovative molecular breeding techniques, including genome editing and cisgenesis for precise crop improvement.
Plant Tissue Culture	A technique of growing plant cells, tissues, or organs under sterile conditions on a nutrient medium to produce clones or regenerate whole plants.
Plant Genomics	The study of the structure, function, evolution, and mapping of plant genomes to understand and improve plant traits.
Recombinant DNA	DNA molecules formed by joining DNA fragments from different sources, often used to introduce new traits into organisms.
Recombinant Vaccine	A recombinant vaccine is made using recombinant DNA technology to produce antigens that trigger an immune response and provide protection against disease.
Site Directed Nuclease (SDN)	Site-directed nucleases are customized enzymes designed to create breaks at specific positions in DNA, which the cell then repairs, allowing precise genetic modifications.
SDN-1	SDN-1 refers to genome edits that involve cutting the DNA at a specific site, which is repaired naturally by the cell, leading to small changes without adding any external genetic material.
SDN-2	SDN-2 edits are made by introducing a targeted double-strand break and providing a small homologous DNA template, resulting in precise nucleotide substitutions or small sequence changes.
SDN-3	SDN-3 edits involve inserting foreign DNA sequences at a targeted site following a nuclease-induced double-strand break, similar to classical genetic modification but at a precise genomic location.
Somaclonal variation	Somaclonal variation refers to the genetic variation that is observed among plants regenerated from somatic cells cultured in vitro.
Technology Stewardship	Responsible management of agricultural biotechnology to ensure sustainable use, compliance with regulations, and environmental safety.

**End of Document**

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