

**Required Report:** Required - Public Distribution

**Date:** November 04, 2024

**Report Number:** PE2024-0014

**Report Name:** Agricultural Biotechnology Annual

**Country:** Peru

**Post:** Lima

**Report Category:** Biotechnology and Other New Production Technologies

**Prepared By:** Miluska Camacho

**Approved By:** Robert Tuebner

**Report Highlights:**

Since 2011, Peru has continued its moratorium on biotechnology due to concern on its impact to the environment. The scientific community, however pledges to adopt it . In January 2021, Peru extended the previous ten-year biotechnology moratorium for another fifteen years. Like the previous moratorium, Peru has yet to notify the measure to the World Trade Organization. In general, biotechnology remains misunderstood by the public.. However, Peru carries out research at academic level institutions as part of its science, technology, and innovation plan. In 2024, the Ministry of Agriculture attempted to remove (without success) the moratorium on specific genetic engineering (GE) crops.

## ***EXECUTIVE SUMMARY***

Since 1999, Peru has had a biotechnology law aiming to regulate the use of genetically engineered (GE) products and their approval process. After more than 10 years of research, the Ministry of Agriculture published a dedicated biosafety regulation. However, Peru increased its moratorium on genetically engineering (GE) products until December 31, 2035. This measure reveals a complex and cumbersome governance system that limits GE domestic innovations at the plant, animal, and microbial level. All research with modern technologies is only kept at the academic level. All laboratory/research GE innovations cannot reach the market due to the moratorium that is in place.

The main goal of the moratorium is to not allow the entry of GE products into the country for environmental release. Peru's biotechnology moratorium contemplates three exceptions: 1) laboratory research; 2) use in pharmaceuticals and veterinary products; and 3) use in food, animal feed, and in food processing. The latter of these is required to go through a yet to be defined risk assessment process.

In the meantime, biotechnology is misunderstood by the Peruvian public and anti-biotechnology groups are well organized. While Peruvian academia and technical government bodies remain expectant and ready to embrace new technologies to target domestic challenges, Peru keeps the moratorium as a precautionary and environmental measure. Peru is concerned about its biodiversity and the polarized discussion is limiting Peru's opportunities in the global market. According to the Ministry of Environment GE corn is already in northern Peru coexisting with conventional and organic crops.

The Ministry of Environment (MINAM) is the lead agency responsible for regulating biotechnology and has also publicly expressed its concern about biotechnology and its impact on biodiversity. The Ministry of Agricultural Development and Irrigation (MIDAGRI) and its dependent agencies SENASA (Peru's sanitary and phytosanitary authority) and INIA (the National Agricultural Research Service) have secondary regulatory enforcement and research roles.

## TABLE OF CONTENTS

<b>CHAPTER 1: PLANT BIOTECHNOLOGY</b> .....	4
PART A: PRODUCTION AND TRADE.....	4
PART B: POLICY .....	5
PART C: MARKETING.....	11
<b>CHAPTER 2: ANIMAL BIOTECHNOLOGY</b> .....	12
PART D: PRODUCTION AND TRADE.....	12
PART E: POLICY .....	12
PART F: MARKETING .....	13
<b>CHAPTER 3: MICROBIAL BIOTECHNOLOGY</b> .....	14
PART G: PRODUCTION AND TRADE.....	14
PART H: POLICY .....	14
PART I: MARKETING .....	15

## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

- a) **RESEARCH AND PRODUCT DEVELOPMENT:** Peru produces important research in the plant biotechnology sector at the academic level which is aligned with its long-term strategy on promoting science, technology and innovation. Despite the work being done at the academic level, the GE moratorium poses doubt not only over Peru's future plant innovation and private investment but also on researchers having challenges and constraints to expand their knowledge.

Peru's National Agricultural Innovation Institute (INIA) is the lead agency for plant biotechnology. All genetically engineered (GE) developments remain at the research level due to the moratorium that's in place.

Before the moratorium, the International Potato Center (i.e., Centro Internacional de la Papa – CIP), La Molina Agrarian University (UNALM), and the National University of the Centre (i.e., Universidad Nacional del Centro) developed a new biotechnology (Bt) potato variety that produces a toxin like the *Bacillus thuringiensis* bacteria. This Bt gene provides potato moth (i.e., *Phthorimaea operculella*) resistance. The “Revolutionary” Bt potato variety is naturally sterile, alleviating fears of unintentional crossbreeding with native (conventional) varieties. CIP has not been able to release this variety into the market due to Peruvian regulations governing the application of agricultural biotechnology. Additionally, Perricholi Bt and Unica Bt potatoes never hit the market due to the moratorium.

Specific agricultural industries in Peru, such as the coffee, cacao, banana, papaya, bell peppers, and mango industries, could benefit from access to GE crops already commercialized in other countries. Crops for domestic consumption (e.g., corn, potatoes, and cotton) could also benefit from biotechnology, particularly from the development of varieties that resist weather conditions associated with climate change, such as frost and drought.

Recent research on plant biotechnology include:

- Decreased absorption of cadmium in Peruvian cocoa by genetic editing of its transporters using CRISPR-Cas9 technology. National University Toribio Rodriguez de Mendoza and financed by National Fund for Scientific, Technological Development and Technological Innovation (FONDECYT).
- Development of technology for gene editing for the improvement of potato cultivation through the CRISPR Cas9 tool. The objective of the project is to develop increased tolerance to biotic and/or abiotic stresses, in commercial potato varieties, as well as to strengthen the capacities of the INIA technical team in gene editing technologies. This research is being conducted by INIA.
- Obtaining a new variety of *Lupinus* sp. with low alkaloid content and a new variety of *Chenopodium* sp. with low saponin content through gene editing with CRISPR/CAS. National University of Saint Agustin, Arequipa.

- Mutations found in the Asc1 Gene conferring susceptibility to the AAL-Toxin in ancestral tomatoes from Peru and Mexico, led by UNALM.
- Tools and computational resources for the design of CRISPR/Cas9 sgRNA for NPR3 gene knockout in sour orange (*Citrus aurantium L.*) by Jose Faustino Sanchez Carrion. The objective is to design *in silico* guide RNA (sgRNA) for CRISPR/Cas9-mediated inactivation of the Non-expression of Pathogenesis-Related genes 3 (*NPR3*) in sour orange (*CaNPR3*).
- Characterization of the complete chloroplast genome of a Peruvian landrace of *Capsicum chinenses* (Solanacea), arnaucho chili pepper.
- Draft genome and SSR data mining of a Peruvian landrace of *Capsicum chinenses*.
- Exploring disease resistance in pepper (*Capsicum spp.*) germplasm collection using fluidigm SNP genotyping.

b) **COMMERCIAL PRODUCTION:** Due to the extended moratorium on biotechnology cultivation, there is no commercial production of GE crops in Peru.

Some university researchers and non-governmental organizations have raised concerns about excessive pesticide use in Peru, which has led to increased (pest) resistance, environmental degradation, deforestation, and adverse health risks for consumers. GE crops could offer relief from these pressures. The farmer should choose the type of agriculture to use.

c) **EXPORTS:** None

d) **IMPORTS:** Peru imports GE crops such as soybeans, corn, and cotton. The country's major trading partners include Argentina, Bolivia, Paraguay, and the United States, all of which produce GE crops and imports are on the rise. Corn and soybeans are used in animal feed, direct consumption, and for processing into oil. Cotton is used as raw material for the garment industry with an export driven orientation.

e) **FOOD AID:** Peru is part of two regional Food for Progress programs. Both programs used soy oil products to fund their programming.

f) **TRADE BARRIERS:** To date, the biotechnology moratorium has not halted trade. However, the zero-tolerance threshold poses a potential threat to conventional seed trade due to the risk of false positives and subsequent steep fines.

## PART B: POLICY

a) **REGULATORY FRAMEWORK**

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
-----------------------------------	-------------------------	---	-------------------------------

Biología Moderna	Modern Biotechnology	<a href="#">Executive Decree 012-2023-MINAM</a>	Modern biotechnology: In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or the fusion of cells beyond the taxonomic family, which overcome natural physiological barriers to reproduction or recombination, and which are not techniques used in traditional breeding and selection.
Organismo vivo modificado (OVM)	Living Modified Organism (LMO)	<a href="#">Executive Decree 012-2023-MINAM</a>	Living Modified Organism (LMO): Any living organism that possesses a new combination of genetic material that has been obtained through the application of modern biotechnology.

b) APPROVALS/AUTHORIZATIONS: On May 12, 1999, Peru approved [Law 27,104](#), aiming to regulate the safety of biotechnology use with a risk prevention approach, also known as, Biotechnology Law. The Law allows research, sets applicable ways of biotechnology use, looks to prevent risks, and deploys surveillance actions under controlled conditions. Peru's Biotechnology Law contemplates: 1) To protect human health, the environment and biological diversity, 2) To promote safety in research and development of biotechnology, in its applications for the production and provision of services, 3) To regulate, manage and control the risks arising from the contained use and intentional release of LMOs, and 4) To regulate the exchange and trade, within the country and with the rest of the world, of LMOs, facilitating international technological transfer in accordance with the international agreements signed and to be signed by the country.

On October 28, 2002, Peru passed the Executive Decree N° [108-2002-PCM](#) regulating Law 27,104. The regulation set the mechanisms for biotechnology safety and development for Living Modified Organisms (LMOs) protocols. Also, established three responsible agencies for biosecurity:

- On agricultural issues: the National Institute of Agrarian Innovation (INIA).
- On fisheries issues: the Vice Ministry of Fisheries and Aquaculture; and

- On health issues: the General Directorate of Environmental Health and Food Safety (DIGESA).

In 2004 and 2010, Peru ratified the Cartagena Protocol on Safety of Modern Biotechnology and approved the Nagoya-Kuala Lumpur Protocol on Liability and Compensation Supplementary to the Cartagena Protocol on Biosafety, respectively.

On April 15, 2011, Peru approved Executive Decree N° [003-2011-AG](#) the Biosafety Regulation for activities related to Agricultural and Forestry Living Modified Organisms and derived products (RISBA). The RISBA was rescinded and put on hold due the extended moratorium. In 2020, an attempt to approve it, ended on the 15-year extended moratorium. Until today, RISBA is still pending.

On December 9, 2011, Peru approved [Law 29,811](#), establishing a ten-year moratorium on the cultivation of GE organisms. The Ministry of the Environment is tasked with coordinating policy issues with Peru's Technical Group on Biotechnology (which includes INIA, the National Agrarian Health Service (SENASA), and representatives from the Ministries of Agriculture and Health). The National Committee of Biological Diversity (CONABID) is the main discussion forum for biotechnology issues; participants include regulatory agencies, the private sector, academia, and international organizations (e.g., the International Potato Center).

On November 14, 2012, Peru passed Executive Decree N° [008-2012-MINAM](#) establishing the implementing regulation for enforcing a ten-year moratorium on the cultivation of GE crops. The stated purpose of the law was to strengthen national capacities and infrastructure on biotechnology and to study the impacts on native biodiversity. The regulation aims at developing a nationwide inventory of animals, plants, insects (target and non-target) and soil microorganisms (fungi and bacteria) that could be affected by GE crops. This inventory also encompasses a survey of organic farms and biodiversity areas. Government sources indicate that this survey is nearly impossible to fully execute and complete and lacks scientific justification. The regulation is based on non-scientific justifications other than biodiversity protection. Despite the challenges, these goals have been reached within the scientific and agricultural sectors; however public perception remains a hurdle according to many proponents of biotechnology within Peru.

Peru's biotechnology moratorium contemplates three exceptions: 1) laboratory research; 2) use in pharmaceuticals and veterinary products; and 3) use in food, animal feed, and in food processing.

On July 4, 2013, the Ministry of Environment issue Resolution [191-2013-MINAM](#) listing 222 products restricted under the moratorium. These include harmonized system code of livestock, seafood, grains, seeds, nuts, spices, etc. Also listed six restricted products subject to sampling and analysis at Peru's eight points of entry (ports).

On March 14, 2015, by the Environmental Oversight and Enforcement Office (known by its Spanish acronym OEFA) assumed the competence of MINAM on oversight and surveillance for GE organisms. On the same day, OEFA established a scale of fines by Rule [012-215-OEFA/CD](#).

OEFA is a decentralized and financially independent agency under the umbrella of the Ministry of Environment. The fine scale for non-compliance with the moratorium, i.e., farming GE crops on Peruvian soil ranges from \$67,000 to \$1.3 million but must not exceed 10 percent of the company's annual revenues.

On July 20, 2016, Peru signed Executive Decree N° [006-2016-MINAM](#) establishing an early detection surveillance plan for GE organisms, by the Ministries of Agriculture and Irrigation, Environment, and Production with the goal of enforcing the ten-year moratorium on biotechnology. On July 24, 2016, Peru prioritize 36 specific commodities to be restricted under the biotechnology moratorium (Executive Decree N° [011-2016-MINAM](#)). To date, these regulations have not significantly affected agriculture or trade due the feed and food exception.

However, on July 27, 2016, Peru updated the list to include seven new products that would be required to undergo GE sampling and analysis at the points of entry. According to seed importers, it takes 30 calendar days, imposing difficulties and higher costs.

Table 1. List of seven restricted imported products for sampling and analysis.

	<b>Harmonized System Code (HS)</b>	<b>Description</b>
1	0301.11.00.00	Ornamental Fish, Live, Freshwater
2	1005.10.00.00	Corn seeds ( <i>Zea mays convar. vulgaris</i> o <i>Zea mays var. indurata</i> )
3	1201.10.00.00	Soy seeds
4	1205.10.10.00	Rape or colza seeds low erucic acid
5	1205.90.10.00	Other rape and colza seeds, whether broken
6	1207.21.00.00	Cotton seeds
7	1209.21.00.00	Alfalfa seeds

Source: Ministerial Resolution [195-2016-MINAM](#)

On January 6, 2021, Peruvian congress published [Law 31111](#), modifying Law 29811, establishing a 15-year biotechnology ban, extending the current moratorium to December 31, 2035.

On December 29, 2023, Peru passed Executive Decree N° [012-2023-MINAM](#) (published in 2021 for public comments) establishing oversight and enforcement responsibilities to non-Ministry of Environment agencies, including SUNAT (Customs), INIA, SENASA, and the Ministry of Production's Fisheries Sanitary Authority (SANIPES). Peru requires that importers of the 36 restricted commodities file an affidavit declaring the presence GE product regardless of the quantity, origin, and use. While the exception for food, animal feed, and food processing still in place, it is unknown how the rule is enforced. For the additional seven restricted products, SENASA and SANIPES will conduct random sampling and testing to enforce compliance. The regulation does not define sampling size or clarify sampling procedures or address adventitious presence, but it does impose steep fines on importers found to be in violation. Seed importers argue that it is scientifically impossible to ensure zero presence of GE material due to the possible occurrence of false positives.



In May 2024, the Peruvian Minister of Agriculture (known as MIDAGRI) proposed to end the moratorium on biotechnology via a legislative initiative. MIDAGRI was looking to allow GE corn and cotton along the Coastal areas of Peru with the hopes of tackling the year-over-year decline in domestic production.

In July 2024, the Peruvian congress rejected MIDAGRI's request to end the moratorium. The rejection was based on protecting biodiversity and preserving traditional agricultural practices, an essential part of the Peru's cultural and economic identity. Also, congress raised concerns on environmental and health risks associated with GEs and emphasized the need for more independent, long-term studies. The MIDAGRI technical approach was focused on not for human consumption crops and to strengthen small agriculture with tailor-made technical solutions.

Since the moratorium, Peru has published [14 baseline studies](#) to develop the mechanisms for their conservation. According to Ministry of Environment, baselines are the main input for the risk assessment when requesting an authorization for the release of GE products into the environment. Peru's biggest concern is about its biodiversity. As presented, GE poses a threat not a solution for Peruvian biodiversity but might be a tool for Peruvians to acknowledge and embrace innovations and preserve it, at the same time.

- c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS: Not applicable.
- d) FIELD TESTING: Restrictions in place for the planting of GE crops in non-contained areas are applied to field tests. The Ministry of Environment issued Ministerial Resolution [117-2014-MINAM](#) – “Sampling Guidelines for Detecting Living Modified Organisms in Crops in Non-Confined Areas,” on April 30, 2014.
- e) INNOVATIVE BIOTECHNOLOGIES: Limited research is being conducted on innovative biotechnologies because field-testing is not possible. There is also regulatory uncertainty regarding crops developed using genome editing. It is still unclear how Peru's government will interpret the regulatory status of genome edited crops, but there is interest within the scientific community.
- f) COEXISTENCE: Not applicable.
- g) LABELING AND TRACEABILITY: [Article 37](#) of the Consumer Defense Code (March 2011) mandates the labeling of GE content in processed products. The code's implementing regulation, which should be published within 180-days, is still pending after thirteen years. Reportedly, INDECOPI (Peru's Consumer Defense Body) has encountered problems drafting an implementing regulation that does not restrict trade.
- h) MONITORING AND TESTING: Peru regularly tests conventional seed imports for GE traits. No budget has been allocated to implement regular testing responsibilities that were given to SENASA at ports of entry. Currently only seed imports are being tested for GE traits at the port of entry. FAS Lima understands that if a GE trait is detected during testing at the port of entry, the option of re-export will be the first option offered to the owner of the shipment, as it is not

considered to be on Peruvian soil until it passes through customs. Fines will not be levied unless detected outside of customs.

Since 2016, Peru has implemented a national surveillance program for the cultivation of GE products. It was documented that the Ministry of Environment identified that 93 percent of GE crops are in northern Peru.

Table 2. Number of inspections performed on the field (2016-2022)

	Analyzed	LMO presence	%
Corn fields	2,201	327	15
Cotton fields	266		
Alfalfa fields	84		
Soy fields	45	4	9
Corn seed at point of sale	61		
Corn at point of sale	24		17

Source: [2022 Ministry of Environment Report to Peruvian congress](#)

- i) **LOW LEVEL PRESENCE (LLP) POLICY:** Peru maintains a zero tolerance for the presence of GE seeds in imported shipments of conventional seeds.
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** Not applicable.
- k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Not applicable.
- l) **CARTAGENA PROTOCOL RATIFICATION:** Peru has signed and ratified the Cartagena Protocol on Biosafety.
- m) **INTERNATIONAL TREATIES AND FORUMS:** Not applicable.
- n) **RELATED ISSUES:** Peru has 27 technical standards on GE products at INDECOPI (Peru’s Consumer Defense Body). Also, Peru is investing \$13 million in a 12,000 square meter Technological and Innovation Park, located at UNALM. The project will have five units: a business development and entrepreneurship center, an incubator, laboratories with state-of-the-art technology for agricultural and livestock research, and residencies for scientists and teachers.

Early January 2024, the Ministry of Environment started a potato seed bank run by farmers. Forty families in 4 communities along with an alliance of 11,410 families from 72 farming communities began working with 248 varieties of 10 native crops, including 106 varieties of native potatoes in the following locations 60 in Apurimac, 30 in Cusco, 6 in Huancavelica and 10 in Puno. The goal is to triple native potato production for 2025. For the Ministry of Environment, traditional Andean agriculture is key to fighting against climate change and biodiversity loss. According to experts, this practice can be enhanced using GE products.

## PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Biotechnology is largely misunderstood by the public, which has developed a negative opinion of GE products due to press coverage, NGOs, and prominent Peruvian chefs' opposition to this plant breeding technology. Peruvian academia and experts have not been able to explain GE benefits, science and evidence due a polarized and politized debate.
- b) **MARKET ACCEPTANCE/STUDIES:** If and when is fully implemented, labeling would be the main marketing issue for biotechnology.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

#### a) RESEARCH AND PRODUCT DEVELOPMENT:

Recent research on animal biotechnology include:

- Genomic editing in the “white shrimp” *Litopenaeus vannamei* using CRISPR/Cas9 system targeting the LvYY1 gene involved in white spot virus infection. The National University of Tumbes is responsible for this study.
- Genetic editing of tilapia on increase productivity. University Federico Villareal.
- Silencing of the myostatin gene by CRISPR/Cas9 in guinea pig (*Cavia porcellus*) to increase muscle mass. UNALM.
- Alpaca genome study for fiber improvement. UNALM. Peru has a long-term study lead by INIA to preserve the genetics of South American camelids.
- Genetic diversity and population structure of a Peruvian cattle herd using SNP data.

b) COMMERCIAL PRODUCTION: None

c) EXPORTS: None

d) IMPORTS: None

e) TRADE BARRIERS: None

### PART E: POLICY

#### a) REGULATORY FRAMEWORK

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Biotecnología Moderna	Modern Biotechnology	<a href="#">Executive Decree 012-2023-MINAM</a>	Modern biotechnology: In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;

			or the fusion of cells beyond the taxonomic family, which overcome natural physiological barriers to reproduction or recombination, and which are not techniques used in traditional breeding and selection.
--	--	--	--

- b) APPROVALS/AUTHORIZATIONS: None
- c) INNOVATIVE BIOTECHNOLOGIES: None
- d) LABELING AND TRACEABILITY: None
- e) ADDITIONAL REGULATORY REQUIREMENTS: None
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): None
- g) INTERNATIONAL TREATIES AND FORUMS: None
- h) RELATED ISSUES: None

**PART F: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: None
- b) MARKET ACCEPTANCE/STUDIES: None

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

- a) COMMERCIAL PRODUCTION: None
- b) EXPORTS: None
- c) IMPORTS: None
- d) TRADE BARRIERS: None

### PART H: POLICY

#### a) REGULATORY FRAMEWORK

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Biotecnología Moderna	Modern Biotechnology	<a href="#">Executive Decree 012-2023-MINAM</a>	Modern biotechnology: In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or the fusion of cells beyond the taxonomic family, which overcome natural physiological barriers to reproduction or recombination, and which are not techniques used in traditional breeding and selection.

- b) APPROVALS/AUTHORIZATIONS: None
- c) LABELING AND TRACEABILITY: None
- d) MONITORING AND TESTING: None

- e) ADDITIONAL REGULATORY REQUIREMENTS: None
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): None
- g) RELATED ISSUES: La Molina Agrarian University UNALM is leading a genome editing program on fungus to improve production of enzymes for lignocellulosic biomass. The method used is CRISPR/Cas on *Saccharomyces cerevisiae*, *Aspergillus fumigatus* LMB-35Aa, *Trametes polyzona* LMB-TM5, and *Talamyces wortmannii* LMB-HP14. Attached published article.

PART I: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: None
- b) MARKET ACCEPTANCE/STUDIES: None

**Attachments:**

No Attachments