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Report Highlights:

Peru continues to enforce the extended biotechnology moratorium. In February 2021, Peru extended the previous ten-year biotechnology moratorium for another fifteen years. Similar to the previous moratorium, Peru has yet to notify the measure to the World Trade Organization. In general, biotechnology remains misunderstood by the public in Peru. However, there are a several research studies using gene editing that are being carried out with many financed by government agencies.

EXECUTIVE SUMMARY

The Ministry of Environment published Ministerial Resolution 028-2021-MINAM on February 12, 2021, which established the implementing regulation for a 15-year biotechnology moratorium. The moratorium extension was approved by Peru's Congress through Law 31111 dated January 6, 2021.

Biotechnology is generally misunderstood by the Peruvian public. Anti-biotechnology groups are well organized in Peru. On December 9, 2011, Peru established a ten-year moratorium on the cultivation of genetically engineered (GE) organisms. The Ministry of Environment (MINAM) is the lead agency responsible for regulating biotechnology and has also publicly been an opponent to the adoption of biotechnology. 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.

On November 14, 2012, Peru passed implementing regulations to enforce the original moratorium on the planting of GE crops. Peru has yet to notify the regulation to the WTO, asserting it is an environmental law aimed at protecting national biodiversity. The implementing regulation does not define tolerances for adventitious presence of GE components in conventional planting seeds. 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.

On July 20, 2016, Peru signed Executive Decree N° 006-2016-MINAM which establishes a procedure and plan for surveillance and early detection of GE organisms. Peru's Ministries of Agricultural Development and Irrigation, Environment, and Production enforce the moratorium on biotechnology. On July 24, 2016, Peru listed specific commodities restricted under the moratorium (Executive Decree N° 011-2016-MINAM). These regulations do not change any requirements for producers or importers; but operationalize the biotechnology moratorium and related legislation already in place. To date, these regulations have not significantly affected agriculture or trade.

The Ministry of Environment randomly tests seed shipments upon arrival for the presence of GE organisms. This is of concern to conventional seed traders as the test, which uses reactive strips, reportedly has a high risk of producing false positives. As the Peruvian regulation has a zero-tolerance standard, the risk of adventitious presence and a steep fine is relatively high. To date, Peru has made no detection from any source. The 2011 Consumer Defense Code legislates for GE labeling. However, as no implementing regulation has been approved to operationalize this law, it remained unenforced until July 2019, when the Government of Peru's Consumer Defense Authority (INDECOPI) fined several companies for failure to label GE content in their processed food products.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **RESEARCH AND PRODUCT DEVELOPMENT:** Peru's National Agricultural Innovation Institute (INIA) has developed a GE virus-resistant papaya in the laboratory. However, INIA has not been able to test this variety in the field due to restrictions on planting GE crops in non-contained areas. Confined field trials are also not permitted.

The International Potato Center (i.e., Centro Internacional de la Papa – CIP) successfully transferred a biotech (Bt) gene (that produces a toxin similar to that produced by the *Bacillus thuringiensis* bacteria) to a new potato variety. This Bt gene confers potato moth (i.e., *Phthorimaea operculella* - potato tuber moth) resistance. The “Revolution” Bt potato variety is naturally sterile, allaying 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.

Specific agricultural industries in Peru, such as the papaya 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, at INIA, the CRISPR/Cas 9 tool for increasing tolerance to biotic and/or abiotic stresses, in commercial potato varieties, as well as to strengthen the capacities of the INIA technical team for the development of gene editing technology. This research is being conducted by the National Agricultural Innovation Institute (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 St. Agustin, Arequipa.

- 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, and adverse health effects for growers and consumers. GE crops could offer relief from these pressures.
- 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. Peruvians utilize soybeans in animal feed, direct consumption, and for processing into oil.
- e) **FOOD AID:** Peru is part of the regional Food for Progress program focusing on cacao and coffee value chains. Soy oil products have been utilized to fund this 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)
Biotecnología Moderna	Modern Biotechnology	Ministerial Resolution 028-2021-MINAM	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	Ministerial Resolution 028-2021-MINAM	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 December 9, 2011, Peru approved Law 29,811, establishing a ten-year moratorium on the cultivation of GE organisms. The law designates the Ministry of Environment as the lead agency responsible for regulating biotechnology. On November 14, 2012, Peru passed Supreme Decree 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. 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.

The Ministry of Environment proposed declaring Peru "free of GMO products" to "protect native production," as well as to promote the development of the organic and "natural" food product industries. 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). The Minister of Environment's Supreme Decree 008-2012-MINAM is aimed 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 also lacks clear objectives and performance indicators to measure progress on building capabilities and developing infrastructure.

The implementing regulations of the moratorium do not define tolerances for adventitious presence of GE components in conventional planting seeds. Supreme Decree 008-2012-MINAM requires that seed importers file an affidavit declaring that their imported seed does not contain GE content. SENASA is tasked with conducting 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 2014, the Ministry of Environment issued Resolution 191-2013-MINAM (July 4, 2013) that lists the products that are restricted under the moratorium. These include livestock, fish, and seeds. On March 14, 2015, the Environmental Oversight and Enforcement Office (known by its Spanish acronym OEFA) was designated responsibility for the oversight and enforcement of the moratorium of the cultivation of GE organisms. OEFA is a decentralized and financially independent agency under the umbrella of the Ministry of Environment. On the same date, OEFA approved the fine scale for non-compliance with the moratorium, i.e., cultivating GE

crops on Peruvian soil. Fines range from \$62,000 to \$1.2 million but must not exceed 10 percent of the company's annual revenues.

The implementing regulation for the moratorium also assigns oversight and enforcement responsibilities to non-Ministry of Environment agencies, including SUNAT (Customs), SENASA, INIA, and the Ministry of Production's Fisheries Institute (ITP). The regulation did not provide funding for these agencies, but it did require them to adapt their procedures and enter into compliance within 120 days of its publication.

On July 20, 2016, Peru signed Executive Decree N° 006-2016-MINAM that established a procedure and plan for surveillance and early detection of GE organisms, by which Peru's Ministries of Agriculture and Irrigation, Environment, and Production will enforce the ten-year moratorium on biotechnology. On July 24, 2016, Peru listed specific commodities restricted under the biotechnology moratorium (Executive Decree N° 011-2016-MINAM). These regulations do not change any requirements for producers or importers but operationalize the biotechnology moratorium and related legislation already in place in Peru. To date, these 2016 Executive Decrees have not significantly affected agriculture or trade. In June 2017, the Environmental Enforcement Agency (OEFA) published the proposed regulation to control and fine the entrance of GE seeds into Peru. The United States and other interested parties submitted comments.

On February 12, 2021, the Ministry of Environment published Ministerial Resolution 028-2021-MINAM establishing the implementing regulation for a continued 15-year biotechnology ban, extending the current moratorium to December 31, 2035.

- 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 nine years. Reportedly, INDECOPI (Peru's consumer defense body) has encountered problems drafting an implementing regulation that does not restrict trade. The Peruvian food industry is proposing a minimum 3 percent labeling threshold.

- 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. The testing is done using reactive strips that show poor accuracy since the test is event specific. This has caused some concern among seed importers who have raised the issue with the Government of Peru. No substantive response to these concerns has been received from the government. 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.
- 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:** None

PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Biotechnology is largely misunderstood by the general public, which has developed a negative opinion of GE products due to newspaper coverage, NGOs, and prominent Peruvian chefs' opposition to this plant breeding technology.
- 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:** There are three registered research studies on animal biotechnology:

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. National University of Agriculture – La Molina.

- 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	Ministerial Resolution 028-2021-MINAM	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.
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- 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)
NA	NA	NA	NA

- 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: None

PART I: MARKETING

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

Attachments:

No Attachments