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## **Report Name:** Agricultural Biotechnology Annual

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### **Report Highlights:**

Peru's 10-year moratorium on genetically engineered (GE) crops and zero tolerance for GE events is scheduled to expire in 2021. The Ministry of Environment tests conventional imported seed shipments upon arrival, raising concerns amongst seed traders. The detection of a GE event in seeds, including adventitious presence, results in steep fines. Peru imports GE crops such as soybeans, corn, and cotton for consumption and processing. The United States is a major supplier of these commodities, as are other South American countries. In 2019, Peru, for the first time, imposed fines on several products that were not labeled as having GE content. The 2011 Consumer Defense Code legislated for GE labeling, however to date there is no implementing regulation to operationalize this law.

## **Executive Summary:**

Bilateral agricultural trade between the United States and Peru reached a record of \$3.9 billion in calendar year 2018, up 11 percent from the previous year. Peru exported a record \$2.5 billion in food and agricultural products to the United States, while importing \$1.4 billion of U.S. food and agricultural products. The top U.S. agricultural exports to Peru are bulk commodities, including corn (\$507 million), wheat (\$54 million), cotton (\$113 million), and soybeans and soy products (\$153 million)

Biotechnology remains largely 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 organisms. The Ministry of Environment (MINAM) is the lead agency responsible for regulating biotechnology. It is also the main opponent to the adoption of biotechnology. The Ministry of Agriculture and Irrigation (MINAGRI) and its dependent agencies SENASA (Peru's sanitary and phytosanitary authority) and INIA (the National Agricultural Research Service) have a secondary regulatory enforcement and research role.

On November 14, 2012, Peru passed implementing regulations to enforce the moratorium on the planting of genetically engineered 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 genetically engineered 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 that establishes a procedure and plan for surveillance and early detection of genetically engineered organisms. Peru's Ministries of Agriculture and Irrigation, Environment, and Production 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. 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 genetically engineered 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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# 1: PLANT BIOTECHNOLOGY

## PART A: PRODUCTION AND TRADE

- a. **PRODUCT DEVELOPMENT:** Peru's National Agricultural Innovation Institute (INIA) has developed a genetically engineered 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.

Specific export crops in Peru such as papayas and mangos could benefit from 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 climate change conditions, such as frost. 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.

- b. **COMMERCIAL PRODUCTION:** Due to the ten-year moratorium on biotechnology cultivation there is no commercial production of genetically engineered crops in Peru.

Concerns have been raised about excessive pesticide use, leading to increased (pest) resistance, environmental degradation, and adverse health effects for growers and consumers. Genetically engineered crops could offer relief from these pressures.

- c. **EXPORTS:** None.
- d. **IMPORTS:** Peru imports genetically engineered 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 genetically engineered crops. Peruvians utilize soybeans in animal feed, direct consumption, and for processing into oil.
- e. **FOOD AID:** Peru will be included in a new regional Food for Progress program focusing on cacao and coffee value chains. No barriers are expected.
- 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:** On December 9, 2011, Peru approved Law 29,811, establishing a ten-year moratorium on the cultivation of genetically engineered 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 Ministry of Environment has 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 supposed to coordinate policy issues with Peru’s Technical Group on Biotechnology (which includes INIA, 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 genetically engineered crops. This inventory also encompasses a survey of organic farms and biodiversity areas. Government sources indicate that this survey is practically 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 genetically engineered 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. Supreme Decree 008-2012-MINAM requires that seed importers file an affidavit declaring that their imported seed does not contain genetically engineered 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 genetically engineered 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 live animals, 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 genetically engineered 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 July 2016, Peru signed Executive Decree N° 006-2016-MINAM that established a procedure and plan for surveillance and early detection of genetically engineered 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 genetically engineered seeds into Peru. The United States and other important players submitted comments.

**b. APPROVALS:** Not applicable.

**c. STACKED or PYRAMIDED EVENT APPROVALS:** 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 Genetically Engineered 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 new breeding techniques.

**f. COEXISTENCE:** Not applicable.

**g. LABELING AND TRACABILITY:** Article 37 of the Consumer Defense Code (March 2011) mandates the labeling of genetically engineered content in processed products. The code's implementing regulation, which should be published within 180-days, is still pending after eight

years. Reportedly, INDECOPI (Peru's consumer defense body) has encountered problems drafting an implementing regulation that does not restrict trade.

In July 2019, Peru's Consumer Defense and Intellectual Property Right Institute (INDECOPI) fined companies selling six processed products available on the Peruvian market for failure to include a warning label for GE content on package labeling. INDECOPI's sanction resulted from a complaint filed by the Peruvian Society for Consumers and Users (ASPEC), a consumer defense NGO. The total fine is about \$61,800 (207,000 soles). The companies have appealed this Resolution.

**h. MONITORING AND TESTING:** Peru has begun ad hoc testing of conventional seed imports for genetically engineered 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 are not very accurate since the test is event specific. This has caused some concern among seed importers who have raised it 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 genetically engineered 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. The Ministry of Environment has also been monitoring corn production in the field and has found some GE corn planted in northern Peru. Since the farms where GE corn was found are small and owned by small-holder farmers, no action has been taken against them to date.

**i. LOW-LEVEL PRESENCE POLICY (LLP):** Peru maintains a zero tolerance for the presence of genetically engineered seeds in imported shipments of conventional seeds.

**j. ADDITIONAL REGULATORY REQUIREMENTS:** Not applicable.

**k. INTELLECTUAL PROPERTY RIGHTS (IPR):** Not applicable.

**l. CARTEGENA PROTOCOL RATIFICATION:** Peru has signed and ratified the Cartagena Protocol on Biosafety. Peru's biotechnology moratorium however contradicts the protocol's risk management approach. Under the Humala administration, the Ministry of Environment was advocating signing the Nagoya-Kuala Lumpur supplementary Protocol on Liability. The current administration, which took office in March 2017, has made no move to date to sign this Protocol.

**m. INTERNATIONAL TREATIES & 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 implemented, labeling would be the main marketing issue for biotechnology.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

- a. PRODUCT DEVELOPMENT:** Not applicable.
- b. COMMERCIAL PRODUCTION:** None.
- c. EXPORTS:** None.
- d. IMPORTS:** None.
- e. TRADE BARRIERS:** None.

### **PART E: POLICY**

- a. REGULATORY FRAMEWORK:** None.
- b. APPROVALS:** None.
- c. INNOVATIVE BIOTECHNOLOGIES:** None.
- d. LABELING AND TRACEABILITY:** None.
- e. INTELLECTUAL PROPERTY RIGHTS (IPR):** None.
- f. INTERNATIONAL TREATIES & FORUMS:** None.
- g. RELATED ISSUES:** None

### **PART F: MARKETING**

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

**Attachments:** No Attachments