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Absence of Low Level Presence Policy a Concern for Conventional Seed Shipments

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Report Highlights:
Peru maintains implementation of its 10-year moratorium on genetically engineered (GE) crops and a zero tolerance for GE events. 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.

Executive Summary:

Bilateral agricultural trade between the United States and Peru reached a record of $3.5 billion in calendar year (CY) 2017, up 6 percent from the previous year. Peru exported a record $2.2 billion in food and agricultural products to the United States, while importing $1.3 billion of U.S. food and agricultural products. The top U.S. agricultural exports to Peru are bulk commodities, including corn ($515 million), wheat ($94 million), cotton ($97 million), and soybeans and products ($132 million)[1].

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 (MINAM) as the lead agency responsible for biotechnology. On November 14, 2012, Peru passed Supreme Decree 008-2012-MINAM establishing the implementing regulations for enforcing the moratorium on the planting of genetically engineered crops. Peru did not notify the regulation to the WTO, asserting it is an environmental law aimed at protecting national biodiversity.

Biotechnology remains largely misunderstood by the public. Anti-biotechnology groups are well organized in Peru. The Ministry of Environment is 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. 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 with 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. FAS Lima anticipates that these regulations will not significantly affect agriculture or trade.

The Ministry of Environment has begun testing some seed shipments upon arrival for the presence of genetically engineered organisms, which has raised concerns from conventional seed traders. The analysis, using reactive strips, is only qualitative and reportedly has a high risk of producing false positives. Since 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.

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[1] 2017 calendar year trade figures.

CHAPTER 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 local consumption (e.g., corn, potatoes and cotton) could benefit as well from biotechnology, particularly from 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 the conventional seed trade given the steep fines and the zero tolerance standard.

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 micro-organisms (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 accomplish 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 named as the agency responsible for the oversight and enforcement of the moratorium on 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. Fines range from $62,000 to $1.2 million, but must not exceed 10 percent of the company's annual revenues. These fines would be levied against entities cultivating GE crops on Peruvian soil.

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. As a result, FAS Lima anticipates that the 2016 Executive Decrees will have little impact on 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:** The Ministry of Environment on April 30, 2014, issued Ministerial Resolution 117-2014-MINAM – Sampling Guidelines for Detecting Genetically Engineered Crops in Non-Confined Areas.

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:** 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 seven 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 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 administration. No substantive response to these concerns has been received by the Administration. 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 poor 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 TREATIE & 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. **INNOVATIVE BIOTECHNOLOGIES:** None.

c. **LABELING AND TRACEABILITY:** None.

d. **INTELLECTUAL PROPERTY RIGHTS (IPR**): None.

e. **INTERNATIONAL TREATIES & FORUMS:** None.

f. **RELATED ISSUES:** None

PART F: MARKETING

a. **PUBLIC/PRIVATE OPINIONS:** None.

b. **MARKET ACCEPTANCE/ STUDIES:** None.