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Report Highlights:

Ecuador maintains a number of anti-biotech laws and regulations, including a new Constitution passed in July 2008, but there is no enforcement and trade in corn and soybean products continues. However, this situation can change quickly. Ecuador's next National Assembly will decide whether to draft and approve a Law of Seeds, among other laws and regulations that could restrict trade. Efforts are needed to strengthen the institutional capacities to establish and enforce regulations based on sound science and international standards.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I. EXECUTIVE SUMMARY

Ecuador has a number of laws and regulations that could impact the importation, distribution and use of products derived from biotechnology, but it lacks a specific law that directly regulates biotechnology. Article 401 of the new Constitution declares Ecuador free of transgenic crops and seeds. However, the same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification. In February 2009, Ecuador's legislative body approved a Food Sovereignty Law aimed at regulating the use of biotechnology. The law was published in the national register on May 5, 2009. This law is very vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's next National Assembly will deal with at least one additional law or ruling regarding seeds and agricultural research. In the interim, imports have continued normally.

In April 2006, Ecuador enacted the Food and Nutrition Security law that invokes the precautionary principle and calls for prohibitions on the use, handling, trade or importation of any food products that are, or contain, genetically modified organisms (GMOs). The regulation initially created trade problems with soybean meal and soybean oil imports, but backlash from the industries that use these products as inputs led the government to drop any enforcement measures. As Ecuador imports almost 60 percent of its corn demand, 99 percent of cotton, and 90 percent of soybean meal and oil, these products have been entering with no restrictions or review.

Ecuador ratified the Cartagena Protocol on Biosafety in November 2002, and its general policies on biosafety are expressed in several existing laws, including the Constitution. Currently, Ecuador's Constituent Assembly and the Executive have conflicting views with regard to GMOs. A majority of the assembly opposes the use of GMOs, while the President defends the use of biotechnology for agriculture and medical applications.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

According to the Ecuadorian Institute for Agricultural Research (INIAP), given the incipient technology and infrastructure available, Ecuador does not have the capacity to conduct any GMO-related research; therefore it does not commercially produce any biotechnology crops. However, INIAP conducts genetic research to improve the quality of seeds through hybrids for cocoa, potatoes, tomato, corn, rice and soybeans.

Furthermore, given the nonexistence of specific biotechnology legislation, Ecuador does not allow the importation of seeds containing GMOs. According to the Ministry of Agriculture, all seeds used for corn, soybean and other plants are either hybrids developed by the INIAP or other certified imported seeds that do not contain GMOs, and which must have passed through a rigorous in-country certification process. Existing law, however, does not properly specify or authorize any government agency to conduct such certification process due to a typo in the text of the law appearing in the national register.

A growing proportion of the supply of corn, cotton, soybean meal and soybean oil for industrial use is of foreign origin. A brief description of the commercial situation of these products follows:

- Presently, Ecuador imports 24 percent of its corn demand. Imports reached 329,000 MT in 2008, 71 percent of which originated in the United States, with the remainder coming from Argentina and Uruguay.

- Ecuador purchased 75 percent (11,570 MT) of its cotton needs (15,435 MT) from the United States in 2008.
- Soybean meal and oil imports are also rising, with Argentina as the main supplier. However, depending on prices, in some years, Ecuador purchases important volumes of soybean meal from the United States. Overall, imports of soybeans, soybean meal and soybean oil reached 587,598 MT in 2008, 78 percent of which came from Argentina and 15 percent from the United States.

SECTION III. BIOTECHNOLOGY POLICY

Ecuador's 2008 New Constitution and Regulatory Framework Background

According to the Environmental Management Law, the Ministry of Environment of Ecuador is the entity in charge of regulating the production, propagation, research, use, trade and importation of genetically modified organisms (GMOs). The same law under article 8 establishes the coordination authority of the Ministry of Environment over the decentralized Environmental Management System, and allows for other institutions, such as the Ministries of Agriculture, Health and Foreign Trade to have direct authority over their own relevant issues.

Although the institutions are in place, there is no specific law or regulation on biotechnology and biosafety. The environmental management law is very broad and does not deal with specific issues of agricultural biotechnology and biosafety. However, a broad national policy on biosafety is clearly expressed in existing laws. In July 2008, Ecuador approved a new constitution. Article 401 of this Constitution declares Ecuador free of transgenic crops and seeds. However, the same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification. In February 2009, Ecuador's legislative body approved a Food Sovereignty Law that was aimed at regulating the use of biotechnology. This law is very vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's next National Assembly will deal with at least one additional law or ruling regarding seeds and agricultural research. In the interim, imports have continued normally. Interested private sector industries continue to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

The second section of Article 401 contains implications that might affect the development of biotechnology in Ecuador. This section states that the State will regulate under strict norms of biosafety, the use and development of modern biotechnology and its products, as well as biotechnology experimentation, use and commercialization. It further states that the application of risky or experimental biotechnology is forbidden. This last part has awakened a lot of controversy among Ecuador's scientific community as it is not clear at all who and under what parameters risky or experimental will be defined. Overall, the scientific community is concerned that the scope of work of highly trained scientists could be significantly reduced.

Other national laws such as the Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Law of Seeds, and the Plant and Animal Health Law are of general applicability but do not provide specific guidance on biosafety issues.

On the international front, as a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, Ecuador is obliged to issue policies and regulations in accordance with the precepts of these international agreements. Also, as a member of the

Andean Community of Nations, Ecuador is subject to Andean Decision 523, which states an Andean Strategy on Biodiversity that must be taken into account by all members in issuing their regulations on biosafety.

Until April 2005, there was a proposed text for a "Law of Conservation and Sustainable Management of the Biodiversity" (Biodiversity Law) that would have served as a framework for Ecuador's regulations on biosafety and biotechnology. The text aimed at providing technical standards and a comprehensive regulatory system that would have ensured proper control of products derived from biotechnology and would not unjustifiably block trade.

This proposed bill was first submitted to Congress in April of 2002 and later debated without consensus. A second debate was scheduled for February of 2003, but it never happened. This time, political parties controlled by indigenous, environmentalists and leftist groups in the Ecuadorian congress used filibusters to delay a decision. Finally, the proposal was filed away and these groups counter-attacked by adding two articles to a controversial Food and Nutrition Security bill that banned any production, use, import or trade of biotech foods in Ecuador.

Specific Laws dealing with Biosafety and Biotechnology

Labeling: The Law for Protection of Consumer's Rights

This law, enacted on July 10 of 2000, regulates the supplier-consumer relations by promoting knowledge and protection of consumer's rights. It has a clause by which ambiguous dispositions should be interpreted to favor the consumer. The public entity in charge of enforcing this law is the Office of the Ombudsman. However, little or nothing has been done to exercise such enforcement.

On regards to Biotechnology, article 13 of this law states clearly that "in the case of products sold for human or animal consumption had been produced using biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters". Despite this specific regulation, there are no products in the Ecuadorian market, whether imported or locally produced, that contain such warning. Article 14 furthers the explanation of labeling by declaring minimum labeling requirements for food, which should include the biotech process.

As to health and safety, this law has a supplemental character by leaving room for specific laws dealing with health protection matters to regulate specific issues. However, the non-existence of a law on biosafety and biotechnology provides that this law is currently the only one in place dealing specifically with biotechnology labeling.

An inter-institutional working group that includes Ecuador's Standardization Institute and the Ministry of Health was formed to prepare new standards for food labeling. The proposed text is still waiting to be submitted to the WTO for comment, in part due to changes in Ecuador's legislative body. Based on the provision of article 13 of the Consumer Rights law, this proposed standard would set a requirement for biotech foods to be labeled as to contain GMOs, and for foods containing GMO ingredients to declare the percentage of such GMOs in their composition.

Imports of Vegetable Materials and Animals: Laws of Animal and Vegetable Health

Article 4 of the Vegetable Health law establishes that any import of vegetable materials for propagation, including those used for research must obtain a previous authorization from the

Ministry of Agriculture. In the case of animals used for genetic improvement, the Animal Health law provides requirements and authorizations from the Ministry of Agriculture, and establishes the obligation to comply with Andean regulations.

Authorized Biotech Foods: Rules for Sanitary Registration and Control

This regulation deals with the sanitary registration of national and imported food and beverage products for human consumption in Ecuador. Article 50 of this regulation makes reference to fines and penalties, which will be applied according to the dispositions of the Consumers Rights Protection law.

Furthermore, article 54 mentions that biotech and/or GMO foods will only be authorized to enter Ecuador when such products comply with the requirements of the Ministry of Health, which would issue a positive list of transgenic products authorized for import. Such a list does not exist. It is not apparent when Ecuador's new National Assembly will address the issue.

Food Sovereignty Law 2009

The main objective of this law is to promote and provide access for the population of Ecuador to food and nutrition and agricultural land. It declares food security as a primary national policy and creates the inter-ministerial "National System of Food Sovereignty and Nutrition" and the National Food Sovereignty Conference. The law is based on Constitutional principles that guarantee people's rights. This is not a technical law and limits its ruling to broad and vague principles.

Article 26 declares Ecuador free of GMOs. It continues to mention that the introduction of seeds and crops genetically modified will only be possible in the case of national interest properly recognized by the office of the Presidency. The state is given the authority to regulate under strict biosafety norms the use and development of modern biotechnology and its products, as well as experimentation, use and commercialization. The use of risky or experimental application of biotechnology is forbidden, although no definition of risky or experimental is given.

Article 26 also mentions that raw materials that contain transgenic ingredients can be imported and processed, only when they fulfill health and safety requirements, and that they are not capable to reproduce, while respecting the precautionary principle so that they do not threaten human health, food sovereignty and the ecosystems. It adds that products processed using transgenics must be labeled according to the law that regulates consumers' protection rights. This is the most controversial part of this law. On the one hand it requires importers to bring in only material that cannot be reproduced, but on the other it also requires to take food sovereignty and the ecosystems into consideration. Requiring importers to for example grind the grains would only increase their costs and act against food sovereignty. Similarly, the genetic manipulation of seeds so that they cannot reproduce can also be seen as threatening the ecosystems. Additional laws and regulations on agri-biodiversity, biotechnology, usage and commercialization of biotechnology products, animal health, plant health are mentioned as the set of norms that will establish the mechanisms of food safety and the instruments that will guarantee respect to the rights of Nature and the production of safe foods while establishing preferred treatment to micro-entrepreneurs, microenterprises or micro and small and medium size producers.

This is not the first time that a law like this issued. In May 2005, after the passage of a similar law, the Ministry of Agriculture of Ecuador stopped for three weeks imports of soybean meal and soybean oil. This caused great difficulties to the poultry, animal feed, cooking oil and tuna canning industries. Even though the provisions of this law were initially enforced, a technical error found in the text gave Ecuador's Attorney General enough reason to declare this bill as unenforceable. Since then, trade has flowed normally and there have not been any reports of shipments being stopped or import permits being denied as a result of this regulation. Post expects that industry groups will put an enormous pressure at assuring that the additional set of norms addresses their concerns and trade will not be disrupted, and if so, not permanently.

The Health Code

As a continuation of the anti-biotechnology policy, Ecuador's Congress passed a new Health Code law in December 2006. This is a general law dealing with the protection of human health, and includes provision on matters of food safety. This bill literally reintroduced the provisions of the Food and Nutrition Security law and corrected its technical errors. However, it does not resolve the issue of Ecuador's lack of capacity to determine the safety of food products derived from biotechnology. The law also leaves the implementation of its biotechnology-related dispositions to the application rules that are still to be issued.

The Ministry of Health of Ecuador has the lead in writing draft application rules for this law, which cannot be fully enforced without them. For this reason, imports of food products have continued normally, and the Ministry of Agriculture has not issued a position on the matter. Application rules are not likely to be available anytime soon. Affected private sector industries plan to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

SECTION IV. MARKETING ISSUES

The use of biotechnology in food is a new and intricate topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with abundant patches of food insecure regions, this may not be an issue of major concern to the poor and struggling majority. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence of the implications of biotechnology, they have been successful in keeping any biotech-related products either labeled or advertised as such from entering Ecuador, as a requirement to preserve this country's mega-biodiversity. In addition, continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies.

There is no specific information related to the market acceptance of biotech foods. However, the Post's perspective is that if biotech products are required special labels "alerting" of presumable harmful characteristics, a considerable portion of Ecuadorian consumers will certainly reject them.

Another concern arises when Ecuador currently purchases high percentages from its corn, cotton and soybean imports to fulfill its meal needs – basically from the United States and Argentina – without any specific biotechnology requirements. The animal feed as well as the poultry, pork, cooking oil, tuna canning and snacks industries currently use these products in their formulations, and it is unlikely that Ecuador would have the capacity to supply this demand in the near future. Therefore, the issuance of additional restrictive rules would not only hurt U.S. export interests, but would also complicate the survival of large local

industries further jeopardizing Ecuador's efforts to achieve food security and combat malnutrition.

It needs to be emphasized that currently no organization or government agency is either legally authorized or asked to perform analysis of food products entering the country to assess the presence of genetically modified ingredients. Post is also aware that appropriate protocols for testing have not been either adopted or created locally.

In addition, Ecuador does not have either the resources or the scientific capacity to conduct high-level research on agricultural biotechnology, so it must rely on foreign technologies and research results. Although, this might change quickly as efforts to properly equip research labs by leading universities and Ecuador's INIAP are highly visible. In the meantime, Ecuador remains incapable of submitting enough scientific evidence about the possible risks of the use of biotechnology as a way to justify restrictive trade measures against biotech foods. However, it is clear that Ecuadorian authorities are worried about the issue of "dependence" from foreign technologies and imports of certain products, such as planting seeds and oilseeds. There is also an increased fear from farmers that allowing biotech seeds will hurt their plantations, and that using these products will turn their production capacity into a dependency relationship with multinational corporations. Nevertheless, Post understands that producers are highly aware of the benefits of improved seeds brought illegally into the country from Argentina and Brazil that have been planted by several farmers.

SECTION VI. CAPACITY BUILDING AND OUTREACH

Even with the lack of accurate information about biotechnology among consumers and policymakers in Ecuador, a few activities related to biotech capacity building and outreach have been carried out by government institutions and industry. The U.S. Agricultural Affairs Office in Quito has also been active in the past few years on issues related to promoting biotechnology and agricultural research. In October 2008, Post attended a special conference on Agricultural Biotechnology presented by world-renowned scientists and experts, which was intended to start defining a strategy to address biotechnology and environmental issues on agriculture. Post has also made use of Cochran resources so that policymakers, key players and journalists can take part in short training courses on biotechnology, food safety and biosafety issues in Hawaii and Michigan for the last several years. Post is planning the visit of a highly respected academician to address Ecuadorian researchers, industry contacts and government officials in 2009. Further efforts are being made to continue with this type of assistance by using USDA's food aid programs to improve Ecuador's trade capacity by providing funds for international agricultural training and in-country research.