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Colombian is developing a stronger biotechnology market

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Report Highlights:

Biotechnology in Colombia has continued to develop over the last year. In fact, LMO (living modified organism) soybeans were approved in 2010. Although hectares planted with LMO corn have increased by 58.6 percent with respect to 2009, a LMO cotton issue late in 2010 has created some negative information for biotechnology adoption. Regarding the biotechnology regulatory framework, there is a resolution that is expected to be released late in 2011 establishing the guidelines for LMO product labeling. Small attempts to use animal biotechnology in human and animal health are underway by both the academic and the private sectors.

Section I. Executive Summary:

Colombia has traditionally been one of the largest markets for U.S. agricultural products in Central and South America and is one of the top seven markets in the world for U.S. corn. To date, Colombian

biotechnology regulations are not impeding commercial U.S. exports.

The Colombian legal framework for mandating biotechnology regulations for agricultural products is under continual review. Colombia approved the Cartagena Protocol on Biosafety in 2002. In 2005, Decree 4525 was published to implement the Protocol, and since then, several other Ministerial resolutions were published to outline specific requirements and procedures for approving and using LMO (living modified organisms) products. To some extent, Colombia's biotechnology regulations are still a work in progress, which provides an opportunity to continue developing training activities that will facilitate the adoption of science-based regulations. Colombia has created three technical biotechnology committees to analyze the environmental, biosafety and food safety impact of biotechnology products (see section IV). Regarding labeling, the GOC (Government of Colombia) is still working on a resolution that is expected to be released in the coming months establishing the guidelines for LMO product labeling.

Prior to 2006, the only LMO products planted on a non-restricted commercial basis in Colombia were Bollgard and Roundup-Ready cotton varieties. In February 2007, the Colombian Government approved Bollgard/Roundup-Ready cotton, the first stacked LMO product. In addition, the GOC also approved plantings of LMO corn for limited commercial use. In 2010, LMO soybean was approved for commercial plantings which has stimulated the biotechnology market. Biotech blue carnations and blue petal roses continue to be approved for commercial production, but only for export. Regarding area planted, Colombia planted 76,550 hectares of LMO commodities in 2010, an increase of about 40,879 hectares with respect to 2009. This was due to cotton and corn hectares planted that increased by 18,783 and 22,103 respectively. Although both cotton and corn areas increased, cotton yields have been severely affected in the Northern Coast area by the flooding situation the country has faced since the end of 2010 and Monsanto's LMO cotton seed failure, according to farmers. In addition to this issue, there is still a dispute because of Monsanto's alleged lack of stewardship to cotton farmers since 2008 which has not yet been resolved. There are pending license applications for several other crops that are in varying phases of approval (see appendices A and B).

Regarding animal biotechnology, Colombia continues to do some work on animals aimed at developing cattle and sheep as well as laboratory research for human health. LMO vaccines for poultry and swine diseases continue to be imported (see appendix C).

Section II. Plant Biotechnology Trade and Production:

Areas planted for LMO cotton increased steadily from 2,000 hectares in 2002 to 28,000 hectares in 2008. However, in 2009, there was a dramatic drop of nearly 10,000 hectares when 18,874 hectares were planted, a decrease of 32 percent because of the Monsanto's stewardship issue and the increase in rice prices. In 2010, area planted increased again to 37,657 hectares, but the outlook for 2011 is somehow negative even though the issue on the Monsanto cotton seed was resolved in favor of the multinational. The interagency committee that was created to conduct a study and determine the performance of Monsanto's seed concluded that there was no seed failure, but it was rather the increased rains during the cotton capsule blossoming that affected crops, thus causing negative effects for both transgenic and conventional seeds. It is worth mentioning that cotton stacked events (resistant to some lepidopterous insects and tolerant to Roundup herbicide) continue to be the most planted variety. As opposed to the LMO cotton difficult situation, LMO corn adoption has increased

tremendously to a total of 38,896 hectares, which represented an increase of 58.6 percent with respect to 2009. Dutch blue carnations continue to be produced under greenhouse conditions for export to Europe as well as blue petal roses for exports to Japan. In 2010, planted area remained the same, 4 hectares for each ornamental crop. The production of blue petal roses will continue to be destined fot the Japanese market where a rose of this kind will be sold for $40-$50 each. Given the current situation, biotechnology in Colombia will continue to develop over the next year. However, there will be a major change in trends as it is expected that hectares planted to genetically modified corn will surpass hectares planted to LMO cotton, which up to 2010, had been the main LMO crop planted. Also, the fact that LMO soybean has been approved for commercial plantings in the eastern plains, it may open up an new area for agricultural potential development: The Colombian Altillanura. (see GAIN report: The Altillanura-Colombia's Next Agricultural Frontier, dated 11/13/2009).

In addition to the above-mentioned LMO events, Colombia is currently working on several biotechnology crops for regulatory approval. (see appendices A and B).

Due to the fact that Colombia has not developed any biotech crops to date, LMO seeds are imported mostly from the United States and occasionally from South Africa, Argentina and Australia (see appendices A and B for more details). There are several Colombian organizations conducting specific research projects. The sugar cane research center (Cenicana) is looking to develop a sugar cane variety resistant to the yellow leaf virus; the International Center for Tropical Agriculture (CIAT) is working on rice and cassava; the Coffee Research Center (Cenicafe) is working on a coffee variety that is resistant to coffee borer (broca); and the International Corporation for Biological Research (CIB) is doing research on potatoes resistant to some lepidopterous insects. It is important to mention that both associations and universities are working together to develop some biotechnology events for rice and potatoes. There seems to be an increasing interest to develop such events that may contribute to benefit crops that are sensitive to the Colombian market. Actually, biotech potatoes seem to be the ones which may be released first as other research projects do not seem to be moving at the same pace.

Section III. Plant Biotechnology Policy:

The Ministry of Agriculture is a strong supporter of agricultural biotechnology and as such, is developing a regulatory framework to implement the Cartagena Biosafety Protocol. The Cartagena Protocol specifically focuses on trans border movement of any LMO resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. Colombia approved the Biosafety Protocol, Law 740 in 2002, which became into force in September 2003. As of today, regulations to implement the above mentioned law are outlined in decree 4525 of December 6, 2005; Colombian Agricultural Institute (ICA) resolution 1063 of March 22, 2005; ICA resolution 000946 of April 17, 2006; Ministry of Social Protection resolution 0227 of February 1, 2007 and Ministry of Environment resolution 957 of May 19, 2010. The following entities are responsible for biotechnology risk assessments:

1. Ministry of the Environment, Housing and Territorial Development.
2. Ministry of Social Protection.
3. Ministry of Agriculture and Rural Development.
4. Colciencias (Colombian Entity for the Development of Science and Technology).
5. National Institute for the Surveillance of Food and Medicines (INVIMA).

6. Colombian Agricultural Institute (ICA).

Decree 4525 of December 6, 2005, established three interagency committees composed of the above-mentioned entities that are responsible for evaluation and approval of biosafety issues:

National Technical Committee for Agriculture, Fishery, Forestry and Agro-industry (CTN-Bio): This committee's role is to assess LMO events for the listed sectors. Although the committee has been approving new-to-market LMO products, the Ministry of Environment has voiced their concerns regarding the environmental impact the events may have. In order to be approved, each variety with a specific gene must go through a lengthy approval process with rigid step-by-step procedures. Colombia allows field-testing for biotechnology crops (see appendix A) after a risk assessment is submitted to CTN-Bio. The time taken to conduct the risk assessment varies since all dissenting concerns by the different ministries must be resolved before a product is approved.

Regarding "stacked" events, CTN-Bio requires running the field testing again as if the seed is a completely new variety. Even though the individual traits were already accepted, the "stacked" variety has to begin the process all over again. In addition, the coexistence between biotechnology and non-biotechnology crops in Colombia does not have a written regulation. However, ICA has carried out an evaluation of cross-pollination on cotton and found that both LMO and non-LMO crops may coexist. Nevertheless, farmers continue to use buffer areas (a natural barrier of fallow terrain between plantings). On labeling, ICA resolutions 3492 of December 22, 1998 and 2935, October 23, 2001 were superseded by ICA resolution 946 of April 17, 2006, which requires labeling imported biotechnology materials (seeds or other plant reproductive materials and animal products). It should read in Spanish: "ORGANISMO MODIFICADO GENETICAMENTE". The requirement is justified as being needed consumer information.

National Technical Committee for Environment (CTN-Environment): This committee's function is to assess biotechnology events for introduction of LMO events that impact the environment. The CTN has not received any requests for assessment of LMO events yet. However, in May, 2010, the Ministry of Environment issued resolution 957 establishing procedures on what companies must submit for evaluation and what the Ministry has to do to carry out the assessment of LMO events. Thus, the committee is now fully operational.

The National Technical Committee for Health and Human Nutrition (CTN-Health): CTN-Health's function is to assess the impact of genetically modified events in LMO products and by-products on human health. On February 1, 2007, the Ministry of Social Protection issued resolution 227 to establish the functions of the committee making it fully operational. In fact, CTN-Health has submitted a number of recommendations for approval to the Ministry of Social Protection which has taken long to issue resolutions. Thus, the Ministry of Social Protection is not keeping pace with the CTN Health. However, in the second semester of 2011, there will be some staff adjustments at the Ministry that may help improve the approval process. Regarding labeling, CTN-Health has not implemented any labeling requirement on finished packaged foods or feed as of this date. However, there is a proposed law on labeling that may come into effect in September, 2011 which will only require labeling in case it provides information that consumers need to know for health, potential allergenicity and safety aspects, functionality, or use of the food as well as for identifying significant differences in essential characteristics of the food. Thus, the proposed law seems to be in agreement with CODEX guidelines. Both the Ministry of Social Protection and INVIMA are currently working on strengthening their

technical capabilities at ports and laboratories to implement the labeling law once it is enforced.

Although Colombia's approach to biotechnology has been favorable, some environmental groups are pressing government officials to reject biotech products. In addition, some indigenous groups have been inspired by NGOs to oppose the introduction of LMOs based on biodiversity concerns. The GOC's structure for biotechnology regulations is based on science-based decisions of accepting or rejecting new biotechnology events. The basic principle is to adopt the technologies that may help the economic/social development of Colombia. The Ministry of Environment has been the most controversial voice on biotechnology approvals.

In 2009, the GOC issued resolution 682 requiring LMO seed companies to adopt a life cycle stewardship approach to accompany producers which had only been applied to cotton crops. A year later, in September 2010, a resolution was issued for implementing a biosafety plan for handling LMO corn which outlines the role for farmers and LMO seed companies. Both resolutions have completed the biosafety road map for the two main LMO crops in Colombia**.**

Section IV. Plant Biotechnology Marketing Issues:

Biotechnology has existed in Colombia for the last 15 years, but regulation is a relatively new issue. Most press coverage is favorable to biotechnology. To date, consumers have voiced limited concerns about biotechnology products or products containing biotechnology raw materials. There are no commercial barriers related to biotechnology products. Regarding biotechnology fees, the Government of Colombia does not have legislation in place to collect technology fees. The incidents with Monsanto LMO cotton have greatly impacted the adoption of biotechnology by farmers and provided grounds to NGO's opposing biotechnology. In fact, the outcome for 2011 seems to be more positive for LMO corn than LMO cotton. Regarding market share, Monsanto continues to be the lead LMO company followed by Syngenta, Dupont, Dow and Bayer. However, Monsanto downsized its operation in Central America and the Andean Region. The administrative areas are being handled from Mexico.

Section V. Plant Biotechnology Capacity Building and Outreach:

Since Colombia is in the process of developing LMO regulations, FAS/Bogota has been working together with different groups to disseminate information on the benefits and to expand the application of agricultural biotechnology. Keeping this in mind, FAS has carried out the following activities in the previous years:

- September 2003: Three leading Colombian journalists attended a biotechnology tour in the United States.
- July 2004: Two Colombian officials attended a two-week "Biotech Short Course" on regulatory and trade issues at Michigan State University.
- August 2004: Farmer-to-Farmer Biotechnology Workshop was held at the University of Zamorano in Honduras, which a leading Colombian cotton producer and agricultural leader attended.
- February, 2006: a Cochran candidate attended a tailor-made program in the United States on biotechnology.
- July 23-25, 2007: FAS and State jointly sponsored a biotechnology conference for Government

officials held in Bogotá followed by meetings with research organizations in Cali.

- September, 2007: 2 Cochran candidates from INVIMA attended biotechnology training in Washington, St. Louis and Texas A&M.
- September, 2008: FAS and State jointly sponsored a seminar for government officials, private sector, academia and producers associations to address issues regarding labeling of LMO products, the implementation of the Cartagena Biosafety Protocol and environmental concerns.
- September, 2008: FAS supported Agrobio (an association of private companies producing biotechnology products) in an effort to educate Latin American researchers on LMO monitoring and detection.
- September, 2009: FAS and the US Grains Council took two Colombian regulators one from the Ministry of Environment and the other one from Colciencias to visit regulators in Washington, D.C. for two days and then visited Iowa, to see biotechnology risk-management practices in the field.
- September 2009: A Colombian official from the Von Humboldt Institute attended a two-week "Biotech Short Course" on regulatory and trade issues at Michigan State University.
- July, 2010: FAS and State jointly sponsored a visit from a scholar to speak on biotechnology during a three-day program in Bogota and Medellin. While in Bogotá, he addressed an audience on biotechnology and nutrition, gave a presentation to some media representatives and held a side meeting with the CTN Health to discuss policy issues. The itinerary in Medellin included two presentations at Agrofuturo, an annual event sponsored by the Ministry of Agriculture, where the speaker was able to discuss the benefits of biotechnology and food security.
- July, 2010: 3 Colombian officials from the Ministry of Environment, ICA and the Ministry of Social Protection attended the Biosafety short course in Michigan State University under the Cochran program.
- September, 2010: 3 Colombian officials from ICA, the National University and Colciencias attended the Biotechnology short course in Michigan State University under the Cochran program.

Section VI. Animal Biotechnology:

Colombia has done some work on animal biotechnology for developing pharmaceuticals and vaccines to be used for humans and animals. Resolutions have continued to be issued to approve imports of vaccines for animal diseases, poultry and swine, (see appendix C). Reportedly, research is in the initial stages according to Government officials who have informed that there has only been an informal request of information for submitting a proposal on bovine production of lactose free milk. With respect to human health, academia has submitted 3 proposed research projects on the use of LMO mice for health purposes. There is one pending for approval (see appendix B). There are other private sector research groups that are working on this issue.

The Government of Colombia has established a regulatory framework for plant biotechnology that applies to animal biotechnology as well. The three interagency committees that are responsible for evaluation and approval of plant biosafety issues are the ones dealing with animal issues.

Biotechnology is mostly related to plants. Thus, animal biotechnology is not well known to the public

and therefore is not an issue of controversy.

Section VII. Author Defined:

While Colombia has made significant progress in opening its markets to biotechnology products, it can still greatly benefit from additional collaborations in the areas of developing risk assessment policies and procedures and developing biotech-friendly regulations. In July, 2010, FAS and State will sponsor a visit from a scholar to conduct a media tour with Colombian journalists. In August, 2011, FAS will send a group of representatives from academia on an intellectual property rights program through the voluntary program that is State funded.