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Colombia Continues to Offer Biotechnology Market Opportunities

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Report Highlights:

Biotechnology in Colombia has continued to develop over the last year. LMO corn adoption has surpassed LMO cotton adoption by increasing the area planted in 52 percent. Regarding the biotechnology regulatory framework, the Ministry of Social Protection issued resolution 4254 on September, 2011, establishing the requirements for labeling foods derived from modern biotechnology. 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. The recent implementation of the Free Trade Agreement between Colombia and the US on May 15 opens up the

market for increased trade and opportunities between the two countries.

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 environmental, biosafety and food safety impact of biotechnology products (see section IV). Regarding labeling, the Colombian Ministry of Social Protection issued resolution 4254 establishing the requirements for labeling foods derived from modern biotechnology. The resolution entered into force at the end of June, 2012. In addition to the resolution, the Colombian government is working on a Technical Annex which supplements the resolution and it is expected to be issued in late 2012.

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 planting although there have not been any areas planted. Biotech blue carnations and blue petal roses continue to be approved for commercial production, but only for export. Regarding area planted, Colombia planted 108,577 hectares of LMO commodities in 2011, an increase of about 32,027 hectares with respect to 2010. This was due to cotton and corn hectares planted which increased by 11,677 and 20,343 respectively. (See chart 1 below). Although both cotton and corn areas increased, corn adoption has grown tremendously since 2007, taking the lead in Colombia's biotechnology crops. 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).

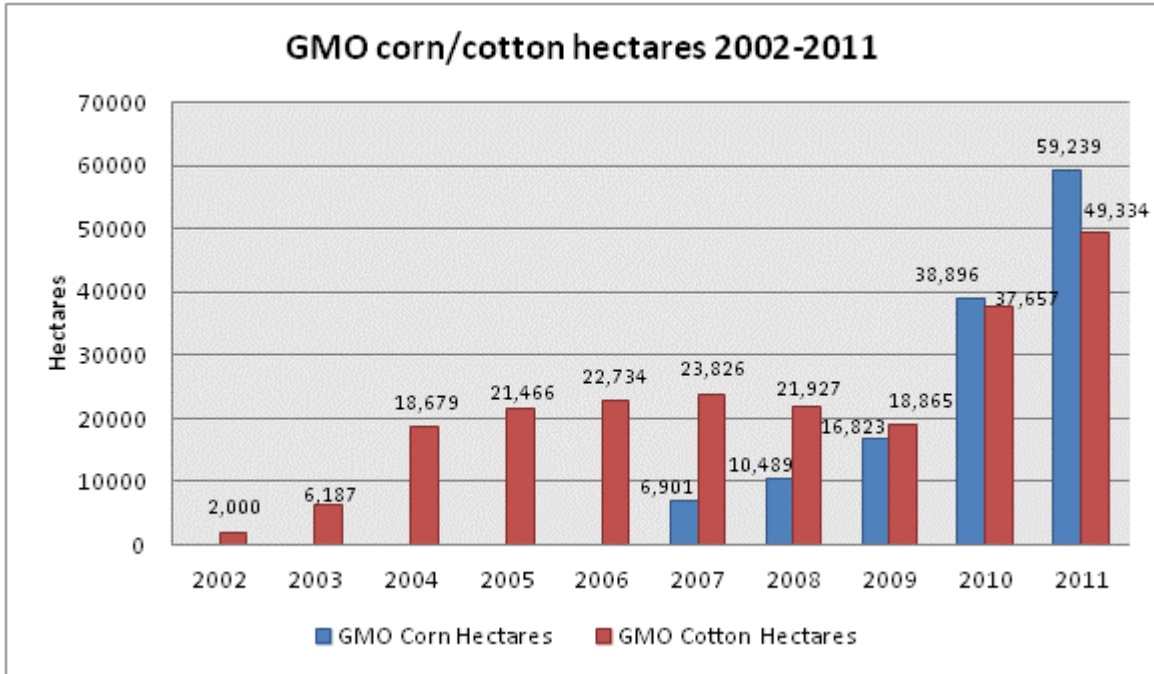


Chart 1
Data provided by ICA

Section II. Plant Biotechnology Trade and Production:

Areas planted for LMO cotton increased steadily from 2,000 hectares in 2002 to 21,927 hectares in 2008. However, in 2009, there was a dramatic drop of nearly 3,000 hectares when 18,865 hectares were planted, mainly due to Monsanto's stewardship issues and the increase in rice prices. In 2010, area planted increased again to 37,657 hectares, and it continued to increase to 49,334 hectares in 2011, thus showing a major recovery after the 2008 crisis. Both Antioquia and Cundinamarca joined LMO cotton adoption by planting 84,8 and 107,54 hectares, respectively (See chart 2 below). In spite of this growth, the outlook for 2012 is somehow negative for GMO cotton in Cordoba as farmers do not seem to be satisfied with the technology because of the alleged cotton seed failure under increased rain conditions in late 2011. In fact, the cotton association, Conalgodon, has mentioned cotton farmers' interest to go back to planting conventional seeds as it is their perception that such seeds adapt better to the country's climate change conditions. It is worth mentioning that cotton stacked events (resistant to some lepidopterous and tolerant to Roundup herbicide) continue to be the variety mostly planted. LMO corn adoption has surpassed LMO cotton adoption by increasing the area planted to 59,239 hectares, which represented an increase of 52 percent with respect to 2010. Farmers' interest on the benefits of LMO corn has grown so much that it is now being planted in two additional states: Boyaca and Vichada with 2,1 and 29 hectares, respectively. 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 2011, area planted remained the same, 4 hectares for each ornamental crop. The production of blue petal roses will continue to be destined to 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. It is expected that hectares planted to genetically modified corn will continue to surpass hectares planted to GMO cotton, which up to 2010, had been the main GMO crop planted.

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

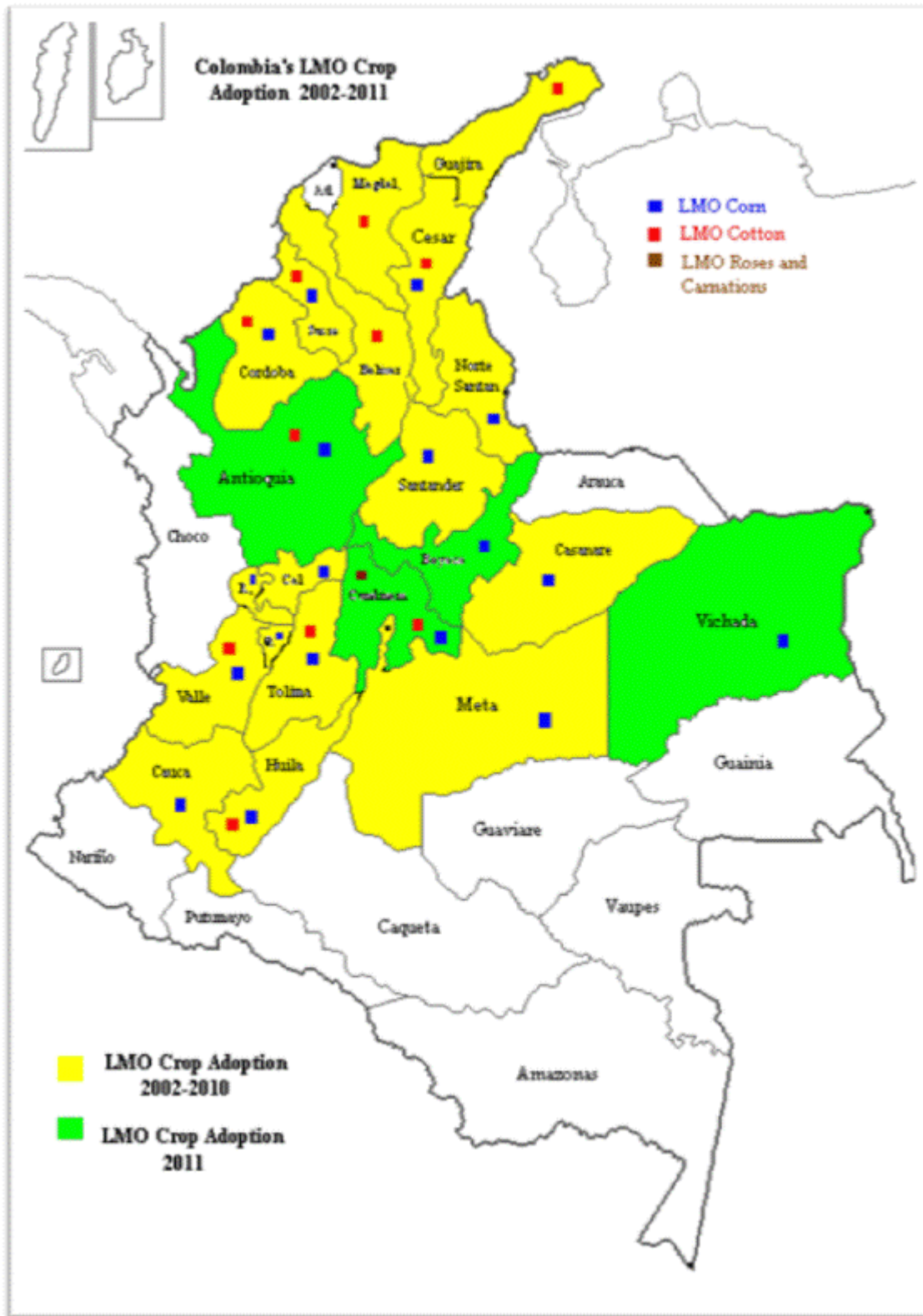


Chart 2

Data provided by ICA

Due to the fact that Colombia has not developed any biotechnology 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 such as rice and potatoes. There seems to be an increasing interest to develop biotechnology 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. However, once it is released, it would have to go through the standard approval process in case it is intended for human consumption and/or for feed.

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 the two 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. 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 continues to take long to issue resolutions. However, the outlook for next year may be more positive as the industry and the US Government are pressing the Ministry to streamline their processes, thus creating room for a predictable timetable for issuing resolutions. Regarding labeling, the Ministry issued resolution 4254 establishing the requirements for labeling foods derived from modern biotechnology which only requires 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. In addition to the resolution, the Colombian government is working on a Technical Annex which supplements the resolution and it is expected to be issued in late 2012. Commodity exporters and industry that deal with biotechnology commodities will have to comply with the new requirements to ensure shipments entering Colombia are approved for human consumption. In fact, the documentation of raw material requires a list of single identifiers of all GMO that the shipment may contain, or, in case the list may not be available, a statement stating that the shipment of grain does not contain genetically modified organisms that are not approved in Colombia for intended use as human food. Industry and commodity exporters have expressed their concern as GMO events in the US have not all been approved in Colombia for human consumption which may delay any imports for human food channels. 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 handling LMO corn which outlines the role for farmers and LMO seed companies. Both resolutions have completed the road map for the two main LMO crops in Colombia to ensure the technology continues to be effective.

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 not voiced any 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 LMO cotton have greatly impacted the adoption of biotechnology by farmers and provided grounds to NGO's opposing biotechnology. In fact, the outcome for 2012 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:

- 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 Bogota 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 a couple of 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.
- In 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.
- July, 2011: FAS and State partnered with Agrobio, a NGO in charge of promoting biotechnology, and coordinated a visit of a biotechnology expert to conduct a media tour with Colombian journalists to Palmira, Villavicencio, Montería, Ibagué and Bogota.
- August, 2011: FAS coordinated with State a voluntary program on biotechnology and intellectual property rights for a group of 9 Colombian representatives from academia and associations to St. Louis, Davis, and Washington D.C

Section VI. Animal Biotechnology:

Colombia has done some work on animal biotechnology for developing pharmaceuticals and vaccines to be used for humans and animals (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 the area.

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. 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.