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## Guatemala

### Biotechnology

### Country status and policies

### 2005

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**Report Highlights:** The Guatemalan Congress approved the Cartagena Protocol in September 2003, and the Protocol took effect in January 2005. The National Biosafety Framework law was drafted in August 2004 and has passed 2 of 3 votes before approval in the Legislature. This Framework is intended to reduce as much as possible the use of GMOs for any purpose, establishing a 270 day review process that involves citizen consultancy, and gives authorities the power to deny any related activity (research, production, commercialization) independent of the scientific evidence. At the moment there are no specific laws concerning commercialization of GMOs. GMOs that have entered the country have been approved at research and field trial levels. Guatemala imports GMO products as corn, soybeans, and oil derivatives. These products have been evaluated under conventional protocols that involve microbiological and composition analysis. There are no major issues regarding health and GMO food consumption. The focus has been on the environment since Guatemala is a designated center for biological diversity. Neither academia nor the private sector supports the proposed Framework. Attempts are underway to stop the Congress from approving the initiative on its third and final vote.

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**EXECUTIVE SUMMARY**

The U.S. Census Bureau reports \$ 1 million (YTD as of March 2004) on U.S. biotechnology products exported to Guatemala. Table 1 shows the main U.S. agricultural exports to Guatemala that may include deregulated biotech products.

Table 1  
US Exports to Guatemala  
CY 2004  
Source: BICO

<b>Commodity</b>	<b>Total Exports Value (In thousands of \$)</b>
Coarse grains	59,982
Soybeans	729
Cotton	33,897
Soybean Meal	36,359
Soybean Oil	8,691
Other Vegetable Oils	3,430

The Guatemalan Congress approved the Cartagena Protocol in September 2003 by Legislative Decree 44-03, which was published in the Official Newspaper, Volume CCLXXII N. 72, on 10/13/03. The Protocol took effect on January 2005.

By the end of 2003, the Technical Office for Biodiversity (OTECBIO) executed the project GUA-02-G21 "Development of the National Biosafety Framework for Guatemala", financed by the United Nations Environmental Program (UNEP) and the Global Environment Facility (GEF) through the National Council of Protected Areas (CONAP). The project ended in August 2004 with the creation of the National Committee for Biosecurity Coordination (CNCB), composed of various government representatives for the preparation of the National Biosafety Framework. Participants in drafting this framework were government officials, NGOs, PVO's consumer and indigenous organizations. The Framework is an over reaching law which seeks to regulate all aspects of biotechnology research and commercialization. The private sector and academia complained that they were not included in the drafting process and were only invited to the last meeting where the final document was presented. The initiative has a definite bias, greatly influenced by groups with extreme views. The framework includes a regulatory, an administrative, a decision-making system for risk assessment and management, and mechanisms for public participation and information. The Framework, at the time of this writing, is in the Legislature awaiting a third vote before approval.

**BIOTECHNOLOGY TRADE AND PRODUCTION**

Guatemala produces no biotechnology crops, but imports yellow corn and soybean products from the U.S. Guatemala is also a food aid recipient through USDA's Food For Progress and Food For Education programs. The country relies on corn and soybean meal for the animal feed industry. In the last three years, imports of commodities have increased at a constant rate of 25% and tariffs have been progressively reduced.

**BIOTECHNOLOGY POLICY**

## Current Regulations

Guatemala does not have an official system for testing or monitoring GMO products. The national norm in effect is Agreement 393-98 and its amendment 476-98, by which the Ministry of Agriculture (MAGA) through its Unit for Norms and Regulations (UNR) requires a phyto genetic or zoo genetic certificate for the importation of GMOs for research and field-testing. The Agreement establishes general guidelines for the handling and transport of GMOs in order to prevent their dissemination outside of their approved uses. The Agreement also establishes rules for labeling and approval of research trials. This Agreement assigns responsibilities for those who perform tests and for commercial companies that develop or supply transgenic products.

When considering whether to approve the import of transgenic materials, the Agreement allows MAGA to require a technical report from a Biosafety Committee composed of the Institute of Agricultural Science and Technology (ICTA), the Ministry of Environment through the National Committee of Environment (MARN), the UNR, the National Council of Science and Technology (CONCYT) and the Agronomy School of the National University (Universidad de San Carlos de Guatemala). It also allows authorized staff from the MAGA Sanitary Area to inspect GMOs at the warehouses and experimental sites.

Guatemala has not provided a list of biotechnology crops approved for use in food, processing, feed, or for release to the environment. Guatemala's law includes the FAO International Treaty on Phyto Genetic Resources, intended to govern preservation and sustainable use of agricultural resources (Ministerial Agreement 177-95). The conventional law is applied in general to all food (there are no specifications for GMOs) and requires that the Health National Laboratory (LUCAM) analyze food to verify quality and safety. Imported processed food products should have a "sanitary registry" of reference, which should be processed in the Ministry of Health (MSPAS) Registry and Food Control Department. The requirements are general "to show the product's original label (product name), and its qualitative composition".

At an environmental level, there is an article requiring foreign companies or institutions to ask for a permit at the Institute of Agricultural Science and Technology (ICTA) for germplasm collections. In 1989 a law of Protected Areas created CONAP, responsible for the conservation of biological diversity (Global Agreement on Biological Diversity, Legislative Decree 5-95, Published in the Official Newspaper, Volume CCLIII, N. 10, on 1/12/96). CONAP has the authority to decide restricted areas. A list of protected areas where GMOs are not allowed is available at <http://www.conap.online.fr/primera.htm>

## Biotechnology Framework Proposal/Initiative

Guatemala modeled its biotechnology framework using as a reference norms from Mexico, Colombia, Panama, Nicaragua, Peru, España, Cuba, and Argentina. The Framework intends to rule "all activities related to research, experiments, submission, experimental and commercial release, production, commercialization, distribution, use, storage, import, export, transit and transport of GMOs". The Framework includes the creation of the National Commission for Modern Biotechnology (CONASBIO), the Consultative Council and three Technical-Scientific Committees to cover wild life, food, agriculture and livestock.

CONASBIO's main attribution is to provide orientation and advise for decision makers. Representatives of MAGA, Ministry of Economy (MINECO), MSPAS, MARN, universities, CONCYT, and two Consultative Council representatives must compose CONASBIO. The Consultative Council functions as an assistant office to address opinions from different

sectors of the civil society. The Technical-Scientific Committees are proposed to study the risk evaluation document submitted by the applicant.

The Framework includes a general procedure to be followed when handling modified living organisms and their products. Deadlines are set in accordance to those established in the Cartagena Protocol. The proposed system for the authorization of GMOs is the following:

1. The person interested in importing GMOs should complete a request for a phyto genetic or zoo genetic certificate.
2. The request will be submitted to government officials from MAGA.
3. Government officials will review the request and attached documents. If the request is complete, it will be provisionally accepted and a technical file opened. If the request is not complete, it will be returned to the applicant.
4. Upon acceptance, the request will be filed with CONASBIO for technical assessment and recommendation. The Technical Scientific Committee will perform an analysis and risk study and the opinions from the Consultative Council will be considered at this time.
5. If approved, the government will require the applicant to publish a summary of the submitted application in the two largest national newspapers to inform the population and get opinions within a 20-day period from publication date.
6. CONASBIO will send the application to the Consultative Council who will then have 20 days to respond. CONASBIO will also send the file to the Scientific Technical Committees to analyze the request and the corresponding risk study, based on scientific procedures.
7. CONASBIO will notify the applicant of the final resolution within a period no longer than 270 calendar days.

The request for acquiring a phyto genetic or zoo genetic certificate, according to Title III, Article 31, establishes that "on the information required in case of GMOs and their products for human consumption and animal feed, the national authorities can require, at a minimum, the following information in relation to GMOs and their products intended as direct use for human food or animal feed, or for processing":

1. Name and nature of the business.
2. Name and signatures of the authorities in charge.
3. Name and identity of the GMO.
4. Description of the gene modification, technique, resulting characteristics of the GMO.
5. Any exclusive identification of the GMO.
6. Taxonomic condition, common name, place of origin, characteristics of the receptor organism, or the parental organisms that may have relation with biotechnology security.
7. Origin centers and genetic diversity centers, if known, of the receptor organisms and/or parental organisms, and habitat description where the organisms may persist or proliferate.
8. The approved uses of the GMO.
9. Quantity or volume of the GMO.
10. A risk assessment report, attaching other countries' studies.
11. Suggested methods for the manipulation, storage, transport, safe use, including packaging, labeling, documentation, and elimination procedures under emergency situations, according to each situation.
12. Planned dates for the transnational movement.
13. Legal status of the GMO in the exporting country with detailed information on its prohibition in other countries if applicable.

The Framework also includes general guidelines for monitoring GMO related work under the supervision of MAGA. The Framework mandates that even if there is not enough scientific evidence to deny an import request, if the organism is deemed to potentially possess a risk for biodiversity or may have a negative social impact, the government officials can prohibit the import of the GMO. The Framework also allows government officials to revoke a previously granted license if the GMO or derived product may possess a potentially negative impact. Additional information can be found at [www.unep.ch/biosafety/development/devcountries/Gtctrypage.htm](http://www.unep.ch/biosafety/development/devcountries/Gtctrypage.htm) and <http://www.congreso.gob.gt/archivos/iniciativas/registro3105.pdf>.

Guatemala's biosafety framework focuses on the environment taking into consideration that Guatemala is a designated center for biodiversity. A study on biological diversity and potential risk by the introduction and manipulation of GMOs can be found at <http://www.unep.ch/biosafety/development/Countryreports/GTNBFPriorizacion%20.pdf>. The Framework does not consider coexistence between traditional agriculture (including organic) with biotechnology agriculture. Protected areas are considered biodiversity regions and no GMOs are allowed (Title IV Article 36). The Framework does not allow genetic manipulation of local flora and fauna without a license or permit (Title VIII, Article 58).

In practice, the Framework has a biased "green tint" based largely on assumptions and misinformation. If approved, this Framework may signal the country's isolation from a modern and viable agriculture system. The inclusion of citizen consultancy for each and every possible GMO to be introduced into the country, besides the time frame for authorization, would practically be a mechanism of discouraging any future work or commercialization with GMOs.

### **Field Trials and Research**

The private sector is concerned about the opportunity to commercialize their biotech products. These companies want to work with GMO lines because they understand their higher yield and productivity, reduced cost on chemical control, and direct environmental benefit. The private sector has approached the Agriculture Minister to make known their disapproval of the Framework.

In the past MAGA has allowed field-testing of biotechnology crops from transnational companies. Semillas, S.A., in cooperation with Monsanto, worked on a field trial with Yielgard gene in corn for Lepidopteron resistance. This company foresees testing other biotechnology with insect, herbicide, and water stress resistance. They have two projects awaiting approval at Norms and Regulations (UNR) and would like to evaluate corn, soybean and cotton. Algodones Mayas S.A., also in cooperation with Monsanto, established a field trial with Liberty gene to develop glufosinate resistant cotton.

Two universities are working with GMOs. Universidad del Valle de Guatemala (UVG) has 2 laboratories where ring spot virus resistant native papaya has been developed in collaboration with Cornell University. The Biology Department of Universidad de San Carlos de Guatemala has an Applied Entomology and Parasitology Laboratory (LENAP) that is producing taq polimerase, using a recombinant E. coli. Both UVG and LENAP are well equipped for working DNA cloning, transformation, gene transference to other organisms, and field tests with GMOs.

Guatemala has two government institutions with the potential to work with Modern Biotechnology. ICTA has Molecular Markers and Tissue Culture laboratories. ICTA is responsible for authorizing studies and reference collections of crop species (Ministerial Agreement 177-98). ICTA is also in charge of approving field trials with GMOs (Ministerial

Agreement 476-98). Central America and Panama Nutrition Institute (INCAP) has Microbiology and Virology laboratories. INCAP has a program to evaluate the social impact of a GMO introduction into the country.

In total, including the above universities and government institutions, the country has 27 laboratories related to Biotechnology, half of them working on Agriculture and the other half with Human Health. These institutions are staffed by a total of 56 professionals of which 9 have master degree and 7 have PhD. The working space of any of these laboratories is at most half the area of an average US laboratory. Most of the research is not at the molecular level but with basic biotechnology dealing with germplasm conservation and tissue culture propagation for sugar cane and vegetable production for local and export markets. Appendix 1 lists the Agricultural programs running in the country.

### CAPACITY BUILDING AND OUTREACH

A scientist of Universidad del Valle de Guatemala (UVG) participated in USDA's Cochran Program in 2001 to receive training in transforming papaya for ring spot virus resistance. There is a great need to continue support and assistance for the evaluation and acceptance of GMO products exported from the United States. The majority of the Guatemalan population is illiterate; communities are easily manipulated according to the desires of special interest groups. Green groups promote anti-biotech movements in communities who are recipients of food aid programs with no concern for the conditions of severe hunger.

The most important strategy that must be implemented with urgency is to convince the Guatemalan Legislature not to approve the Biotechnology Framework. Embassy's Economic Section and FAS are participating and working with GOG officials to educate key leaders. A systematic delivery of newspaper articles and radio diffusion on GMO related information would also aid in the education of the broader community. Training programs on FDA, APHIS, and EPA protocols used to study the safe use of transgenic products would also provide a basis to assess Guatemala's needs in the area of biotechnology, as well as deepen the understanding of the meticulous U.S. process to approve new biotech products.

### APPENDIX 1: BIOTECHNOLOGY-RELATED PROGRAMS RUNNING IN GUATEMALA

PROGRAM	PROJECT	FINANCIAL SOURCE
Molecular markers	Enhancement of Gemini virus resistant plants. Genetic resistance to diseases with economic impact in tomato.	FAUSAC – USAID  FAUSAC - AGROCYT
Micro propagation	Banana, plantain, pony, izote, loroco, fir tree, potato, Persian lemon, sarsaparilla, blackberry, strawberry, orchid.	FAUSAC
Germplasm conservation	Yucca, sweet potato, sarsaparilla, sugar cane, chrysanthemum, African violet, Rabinal orange, Persian lemon	FAUSAC

Virus cleaning	Garlic, potato	ICTA - AGROCYT
Micro propagation	Fir tree Potato greenhouse acclimatizing	ICTA – FODECYT ICTA
Biotechnology	Sugar cane micro propagation Sugar cane varietal characterization using micro satellites	CENGICAÑA CENGICAÑA – ICTA
Vegetable protection	Virus resistance in papaya (RFLP, ADN cloning and transformation, gene transference, field trials)  Citric species evaluation for determining presence of virus and viroids with economic relevance, cleaning and characterization previous to its propagation  Determination of the causal agent for the “chocolate disease” in tomato (ELISA, PCR).  Epidemiology surveillance for the coconut lethal yellowing; local measures for its control (monitoring).  Coconut lethal yellowing study and search for native seed.  Pest insect and disease evaluations, integrated pest management, and establishment of virus resistant Hawaiian papaya.  Immunoimpression for detection of viral psorosis in citric production areas in Guatemala (ELISA).	UVG - US Universities (including North Carolina)  UVG – AGROCYT  UVG – AGROCYT  UVG – AGROCYT  UVG – FACYT  UVG – IPM/CRSP  UVG - FODECYT
Biological control	Metarrizum and parasitoid production for insect control  Insect virus production Nematodes for virus control	Ingenio Pantaleon Ingenio La Union  Ingenio Santa Ana
Germplasm conservation and Micro propagation	Sugar cane micro propagation	CENGICAÑA

	<p>Germplasm conservation and hybrid evaluation in coffee.</p> <p>Micro propagation of pineapple, cactus, papaya, pithaya, sweet potato, anthurius, vanilla, orchids, garlic, artichoke.</p> <p>Black berry micro propagation</p>	<p>ANACAFE – PROMECAFE, BIOFONTAGRO</p> <p>ICTA</p> <p>URL</p>
Molecular markers	<p>Corn germplasm characterization (SSR)</p> <p>Corn selection of lines with high protein quality (SCAR)</p> <p>Garlic germplasm characterization (AFLP)</p> <p>Black beans varietal characterization (AFLP)</p> <p>Black beans characterization of varieties and mutants (SSR)</p>	<p>ICTA – AGROCYT</p> <p>ICTA – FODECYT</p> <p>ICTA</p>

Source: "Actual situation of the Biotechnology in Guatemala". 2004. CONAP Technical Bulletin N. 17 (06-2004).