

PREFACE

Now, using recombinant DNA techniques, scientists are able to genetically modify plants and animals by selecting individual genes that carry desirable traits from one organism and inserting them into another organism that can be raised for food, fiber, pharmaceutical or industrial uses. This new book examines the global policies, perspectives and issues relating to the biotechnology field today

Chapter 1- U.S. soybean, cotton, and corn farmers have rapidly adopted genetically engineered (GE) varieties of these crops since their commercialization in the mid-1990s. Over the last decade, GE varieties in the United States have increased from 3.6 million acres to 143 million acres. Worldwide, 25 countries planted GE crops on approximately 309 million acres in 2008. GE varieties now dominate soybean, cotton, and corn production in the United States, and they continue to expand rapidly in other countries. As adoption has spread, policy debates have continued over the costs and benefits of GE products.

Chapter 2- Animal agriculture is being transformed by rapid advances in biotechnology—a term that encompasses a variety of technologies, including genetic engineering (GE), genetic modification, transgenics, recombinant DNA techniques, and cloning, among others. Producers are interested in the application of biotechnology to improve productivity, consistency, and quality; to introduce new food, fiber, and medical products; and to protect the environment. Potential human health applications of transgenic animals include producing biopharmaceuticals and generating organs, tissues, and cells for xenotransplantation. Criticisms of such applications involve issues ranging from food safety and social resistance to potential negative impacts on animal welfare and on ecosystems. Questions also have arisen about the adequacy of the current regulatory structure to assess and manage any risks created by these technologies.

Chapter 3- The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of the impact this has on the ability of the U.S. to export to Australia. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over 1 percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own.

Chapter 4- Bosnia and Herzegovina (BiH) imports around two-thirds of its overall food needs. Its principal trading partners are neighboring countries such as Croatia, Serbia, and European Union (EU) countries. Imports of U.S. consumer products have been minor. However, a U.S. food donation program successfully imported U.S. bulk commodities, mostly wheat and sunflower seed oil. Although there has not been much trade between the two countries, reservations towards U.S.-origin foods has increased recently. Generally, these impressions seem to be tied to biotech applications, particularly to products containing either soy or corn.

Chapter 5- Bilateral agricultural trade between Brazil and United States reached US\$ 3.4 billion in CY 2009, of which Brazil exported to the United States US\$ 3 billion and imported from the United States US\$ 400 million. This represents a drop of nearly 19 percent from 2008 record trade due to the impact of the world financial crisis.

Chapter 6- Canada was ranked fifth in the world for hectares of land planted with biotech crops according to the International Service for the Acquisition of Agri-biotech Applications in 2009, behind the United States, Brazil, Argentina and India. Actual data on biotech production are limited; although estimates of area planted are available from Statistics Canada and the Canola Council of Canada and suggests 7.2 million hectares in 2010, up from about 6.6 million hectares in 2009. Major Canadian biotech crops remain canola, corn, soybeans and, most recently, sugar beets.

Chapter 7- Biotechnology remains a relatively new endeavor in the Caribbean with most research and applications limited to cell biology and diagnostic techniques. Consequently, the Caribbean has no regulatory system in place yet to govern the use of modern biotechnology and safeguard public health, animal health, or the environment. Because the region has very limited agricultural production, and research is limited to a small number of crops and animals in select islands, farm applications of biotechnology have been relatively few. The lack of any regulation has also meant unrestricted trade for biotech products. While consumer awareness of biotech issues is growing, it is still not widespread. The region relies on the United States as its main supplier of food and agricultural products.

Chapter 8- Under the current Chilean regulations, Chile can only propagate transgenic seeds for export. In food products, the Ministry of Health requires all events to be registered, and the product must be label only if substantially different from their conventional counterpart.

Despite two bills introduced in Congress to regulate biotechnology, one of them requiring mandatory labeling and the other to creating a biotechnology framework, the Bachel administration, which ended this past March, did not move forward to adopt this technology.

Chapter 9- Colombia has traditionally been the largest market 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.

Chapter 10- Transgenic varieties have been grown in Costa Rica for seed multiplication purposes since 1992, with all seeds being exported to the country of origin. Costa Rica has implemented legislation to regulate the import and cultivation of biotech crops. This legislation includes a labeling requirement for genetically modified organisms in agriculture, but there is currently no requirement that foods containing the products of biotechnology be labeled.

Chapter 11- Croatia is a net food importer and government policy is geared towards raising agricultural productivity and, to a lesser extent, limiting imports. EU membership is also a priority for the Croatian government, and new laws and agricultural policies increasingly mirror those of the EU.

Chapter 12- 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 2008 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 National Assembly will consider at least one additional law or ruling regarding seeds and agricultural research. In the interim, imports have continued normally.

Chapter 13- El Salvador is a net food importer. White corn, red kidney beans and rice are major staples. The U.S. is the main supplier of yellow corn for animal feed, rice, wheat, vegetable oil, tallow, soybean meal and cotton, among other products.

Chapter 14- There are currently two biotech products approved for cultivation in the European Union (EU). The first, MON810 corn, was approved in 1998, and its approval is currently subject to renewal. It has been planted on approximately 100,000 hectares (ha) each year since 2005. Estimated at 96,000 ha in 2010, MON810 corn is spread over six Member States (MS), including Spain, the Czech Republic, Portugal, Poland, Slovakia, and Romania. The second product is the A mflora starch potato. It was approved for cultivation in March 2010, and is estimated to be grown on about 225 ha in the Czech Republic, Sweden, and Germany in 2010.

Chapter 15- U.S. food exports to Ghana consist primarily of rice, poultry, and other consumer oriented food products. U.S. BICO data showed a decrease in total US agricultural exports in CY 2009, with exports at \$52 million, down from \$86 million in 2008. Although Ghana remains one of the largest U.S. rice markets in Sub-Saharan Africa, U.S. rice exports in CY 2009 were \$21 million, down from \$32 million in CY 2008. The United States is one of the largest suppliers of poultry in Ghana with its main competitor being Brazil. In CY 2009 U.S. poultry exports to Ghana remained strong at \$20.5 million, only slightly down from a record \$21 million in CY 2008. U.S. exports of high value products (HVP) including vegetable oils, fruit and vegetable juice, pulses, processed fruits and vegetables, sweeteners and other products also declined last year. At present, Ghana has no specific law governing agricultural biotechnology. The United Nations Environment Program and the Global Environment Facility (UNEP/GEF) provided financial and technical support towards the drafting of the Biosafety Framework for Ghana that was completed in July, 2004. The draft Biosafety Bill establishes the National Biosafety Authority as the administrative body responsible for all issues related to Biotechnology in Ghana. According to official sources, the Biosafety Bill now has now been sent to cabinet for review before it is sent to parliament to be passed into law. The process has been slow, and it is unclear as to when the draft bill will be passed.

Chapter 16- Major U.S. agricultural trade interests in Guatemala include animal feed and grains for human consumption. In 2009, Guatemala imported US\$120 million in coarse

grains, mainly yellow corn for feed purposes, but also white corn for human consumption. Guatemala has no restrictions on the importation of agricultural products for human and animal consumption. The main concern of some social groups and government institutions is that in their view, the planting of GE plants could pose a potential risk for the biodiversity. Guatemala has been declared by the United Nations as a center of biodiversity for many species, including corn.

Chapter 17- U.S. agribusiness has a strong economic interest in Hong Kong. In 2009, Hong Kong was the 4th largest market for U.S. high value food (HVF) exports totaling a record \$1.8 billion, a 32% increase. In the first 4 months of 2010, U.S. HVF exports to Hong Kong reached \$658 million, representing a growth of 52% over the same period in 2009. It is one of our fastest growing major markets.

Chapter 18- Agricultural trade¹ between the United States and India is estimated at \$1.9 billion in CV 2009. However, the trade balance continues to remain skewed (2:1) in India's favor. India's major agricultural exports to the U.S. include cashew, spices, rice, essential oils, processed fruits & vegetables, tea, vegetable oils and other consumer oriented products. Major U.S. agricultural exports to India are almonds, soybean oil, pulses, cotton, fresh fruits, and other consumer food products.

Chapter 19- Japan is the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology (also known as 'biotech' or GMO'). Japan annually imports about 16 million metric tons of corn and four million metric tons of soybeans, approximately three quarters of which are 'biotech'. Japan also imports billions of dollars worth of processed foods that contain biotech- derived oils, sugars, yeasts, enzymes, and other ingredients.

Chapter 20- Jordan has recently introduced new regulations on biosafety of biotechnology products, but Jordan still lacks the technical ability to enforce laws on biotechnology.

Chapter 21- Kenya's parliament passed a Bill, now known as the "Biosafety Act 2009," in December 2008 and President Kibaki signed the Bill into Law, when it became an "Act" in February 2009. Under terms of the Act, the National Council of Science and Technology (NCST) spearheaded initial development of the biotechnology regulations that may soon guide research and trade in biotechnology. The regulation-development role will reportedly now be taken up by the newly formed National Biosafety Authority (NBA).

Chapter 22- Mexico was the United States' second largest agricultural trading partner in 2009, while the United States was Mexico's principal agricultural trading partner with nearly 80 percent of Mexico's agricultural exports going to its northern neighbor. In 2009, U.S. agricultural exports to Mexico were valued at \$13.9 billion, while U.S. imports of Mexican agricultural products were valued at a record \$11.9 billion. The impact of the North American Free Trade Agreement (NAFTA) has been substantial, with U.S. agricultural exports to Mexico increasing by \$9.3 billion between 1994 and 2009 and Mexican agricultural exports to the United States increasing by \$8.5 billion in the same time frame. Mexico is the largest market for U.S. soy-meal, sorghum, dry beans, rice, apples, beef, dairy, swine, and turkey.

Chapter 23- Biotechnology products are tolerated in Morocco although officially banned, but the issue remains very sensitive politically. Morocco's proximity to the EU results in high dependence on the EU as a market for Moroccan agricultural exports and also results in many restrictive and fearful EU perceptions of biotechnology being shared by Moroccans. Imports

of biotechnology seeds are prohibited and a "GMO-free" certificate is required for customs clearance. Certificates provided by breeders and unofficial bodies are accepted.

Chapter 24- GM technology remains a highly charged political issue in New Zealand with strong opposition from the Green Party and GE Free NZ. Even some commodity organizations and farmers oppose the use of genetic modification (GM) technology out of concern that it will tarnish New Zealand's "clean and green" image and negatively impact on the ability to market products overseas. However, there are signs that attitudes toward GM technology are beginning to change. Press articles have touted the need to rethink New Zealand's restrictive stance on GM technology expressing concern that the New Zealand agricultural sector will fall behind competitor countries if it doesn't embrace GM technology. Other articles have highlighted the benefits of genetic engineering in addressing environmental issues.

Chapter 25- Yellow corn for animal feed is the main biotechnology crop exported from the United States to Nicaragua. The GON is implementing the provisions of the Cartagena Protocol. It requires notifications of imports of biotechnology products and risk analysis for such imports. The Commission for Risk Analysis of Genetically Modified Organisms (CONARGEN) has performed risk analyses on all genetic events approved by United States for yellow corn destined for processing and feed use. Yellow corn imports from the United States have continued without delays. The Ministry of Agriculture and Forestry (MAGFOR) makes biotechnology import requirements available to the public upon request. Concerning biotechnology Nicaragua is in compliance with the WTO.

Chapter 26- Nigeria, Africa's most populous nation (148 million), is a food deficit country. Formally a net food exporter, Nigeria's subsistence agriculture can no longer supply the needs of its growing population. According to trade sources, Nigeria imported about \$3.4 billion worth of agricultural commodities in 2009. Nigeria is largely a bulk commodity market and imports wheat, soybean products, tallow, rice and high value products. In CV 2009, U.S. agricultural exports to Nigeria reached \$834 million, primarily wheat. Nigeria became the largest buyer of U.S. wheat in the world in 2009/10.

Chapter 27- The administration and farmers in Pakistan are generally pro-biotech. In May 2010 eight Bt cotton (MON 531) varieties were finally approved by the Government of Pakistan (GoP) for general cultivation. A number of Genetically Modified (GM) crops are currently under development with public/ private / multinational seed companies in Pakistan.

Chapter 28- Panama is a net food importer and the U.S. by far, is its main supplier. During Calendar Year 2009, exports of U.S. agricultural, fish & forestry products to Panama exceeded \$378.2 million of dollars. The increase of 27% over the last year can be attributed to the entry into force of the U.S. - Panama Agreement regarding certain Sanitary and Phytosanitary Measures and Technical Standards affecting trade in agricultural products, signed in February 22, 2007.

Chapter 29- The Government of Peru (GOP) has not made a decision on whether to support the use, research and production of bioengineered products. For the past five years, and despite the fact that there is comprehensive regulation and a biosafety plan drafted, the GOP has been unable or unwilling to move forward and approved the legislation. The lack of leadership within the Ministry of Agriculture has allowed anti-biotech groups, led by the Ministry of Environment, to stop these initiatives and to win the media battle thus far. Proposed Law N°12033, called "Law to Promote the Use of Modern Biotechnology in Peru" has been up for the debate for the past five years; however, due to the lack of political

support, the Peruvian Congress has not been interested in initiating such debate. The proposed law asserts that biotechnology and its applications are fundamental factors in improving Peru's competitiveness in the agricultural sector and overall economic development.

Chapter 30- The Philippine biotechnology regulatory system continues to evolve but remains science-based. Under the current regulatory regime as provided for by the Philippine Department of Agriculture's Administrative Order No. 8 (DA-AO 8), 31 transformation events (TEs) and 22 stacked-trait products have been approved for direct use as food, feed or propagation. There remains to be five (5) biotech crop varieties approved for propagation while 11 field tests have been allowed since 2004. Guided by DA-AO 8, the first genetically enhanced (GE) crop being developed locally, *Bacillus thuringiensis* (Bt) eggplant, will likely be commercialized by the second semester of 2011 or early 2012.

Chapter 31- On July 1, 2010, changes to the Russian customs legislation were introduced as a result of the new Customs Union between Russia, Belarus and Kazakhstan. While the Union is currently in effect, much of the corresponding legislation required for its implementation is still being drafted. Frustration and confusion has resulted for many exporters as they continue to operate with uncertainty under previous regulations. As of July 2010, Russia's biotechnology registration requirements and procedures have not changed from last year. The mechanism of registering events and their use in all three countries in the Customs Union has not been developed yet. For Russia, only the previous Russian registrations are currently valid. While the adoption of the Customs Union has created a cloud of uncertainty it also provides an opportunity for change. In the process of harmonizing technical regulations, provisions will be examined, revised and finally adopted.

Chapter 32- In January 2004 and December 2001, M OA and M OCI implemented biotech-labeling decrees on animal feed and processed foodstuffs respectively. The decrees require positive biotech labeling if a product contains more than 0.9 percent of genetically engineered (GE) vegetable (plant) ingredients. GE grains such as corn and soybean meal are being imported from the U.S. and other suppliers. According to Saudi importers, U.S. high value food products declared biotech free have tested negative and companies whose products test negative will not be tested again for another six months. In May 2009, all responsibilities of inspecting imported high value products at the 27 Saudi ports of entry and implementing standards were passed to the Saudi Food and Drug Authority (SFDA). The SFDA will take charge of setting food standards in the next few months. Currently, food standards are set by the Saudi Arabian Standards Organization (SASO) while imported foodstuffs were tested before May 2009 by M OCI. The SFDA will take over inspections of imported animal feed, fruits, and vegetables from MOA within a year.

Chapter 33- Guinea Bissau joined in May 2010, one of the few countries that has adopted the Cartagena Protocol on Biosafety in West Africa. Important progress is being made in Burkina Faso which is planning to produce Bt cotton large scale. Harvested area is expecting to increase from 115,000 ha to 400,000 ha from 2009 to 2010. In response to significant progress made in biotech development in Burkina Faso and recent initiative to harmonize WAEM U¹ and ECOWAS² regional Biosafety regulations, more governments in the region have become interested in developing biosafety regulations and are actively participating in biotech capacity building programs.

Chapter 34- As a result of the Law on GMO, adopted in May 2009, Serbia strictly prohibits all imports, production and commercial growing of GM O crops or products containing GM O. This law was adopted without any scientific basis and represents one of the

main obstacles for Serbia's WTO accession process. Beside a ban on trade and commercial cultivation of GMO products, law is extremely problematic in the compliance with WTO rules.

Chapter 35- South Africa possesses a highly advanced agricultural industry based *inter alia* on first-generation biotechnologies and effective plant breeding capabilities. The country has been involved with biotechnology research and development for over 30 years and will continue to be the biotechnology leader on the Africa continent. The production of biotech crops in South Africa continued to expand in 2009 to reach 2.1 million hectares. This increase in biotech production has enable South Africa to retain its position as the eighth largest producer of biotech crops in the world, illustrating that South African farmers have adopted biotech and the benefits thereof. Genetically Modified (GM) corn plantings represent 89 percent of total biotech planting in South Africa, followed by GM soybeans (approximately 10 percent) and GM cotton. All of the GM events that are currently commercially produced in South Africa were developed in the United States. However, due to the fact that that the United States has approved corn events that are not yet approved in South Africa, United States commercial corn is not authorized to enter into South Africa.

Chapter 36- On December 2007, the Thai Cabinet revoked the ban on biotech field trials, however little progress has occurred in allowing the commercial use of biotech crops in Thailand. This is a result of the restrictive controls and surveillance required for field trials, which include confining trials to government properties and the need to conduct public hearings prior to initiating any new field trials.

Chapter 37- Tunisia currently has no legal framework dealing with the use and release of products of agricultural biotechnology. New legislation on biotech products were expected to be finalized and adopted by the parliament before the end of 2010. However, it seems that this legislation will be further delayed due to the lack of consensus among Tunisian policy-makers, influenced by the EU position on GMO issues. Until the adoption of a legal framework, the imports of biotech products into Tunisia continue to be treated the same way as the conventional agricultural products. Tunisian officials recognize the existence of GM O materials in imported animal feed, however the dependence of Tunisian agriculture on these imports, as well as the Tunisian consumer's lack of awareness of international GMO acceptance issues, has allowed this situation.

Chapter 38- Commercial agriculture in the GCC-5 countries covered by ATO Dubai (Bahrain, Kuwait, Oman, Qatar and the UAE) is limited due to the harsh desert climate and limited water resources. While dates are a major crop, other agricultural production consists of limited amounts of forage, fruits, vegetables, poultry, dairy and a moderate livestock industry comprised principally of sheep. Consequently, the GCC-5 is reliant on imports of raw, semi- and fully processed foods to meet an estimated 85-90 percent of domestic food needs. In view of this situation, none of the GCC-5 governments have legislated any regulations concerning the production of GMO crops and animals. The Gulf Standards Organization (GSO) which establishes standards for all six members of the Gulf Cooperation Council (GCC) has formed a subcommittee to draft a set of standards related to the testing and regulation of foods containing biotech ingredients. The subcommittee was established in 2008 and has met few times.

Chapter 39- Despite significant interest in biotechnology by researchers and farmers to meet growing food demand and protect the environment, there is no commercial adoption. Research is being done, but the lack of implementing regulations hinders real progress. A

fairly extensive list of international treaties and domestic laws provide the basic legal framework for agricultural biotechnology, but the regulatory system is imprecise.

There are no commercial animal or plant biotechnology events under development in Venezuela, and the Bolivarian republic has not granted approval for animal biotechnology events or plant biotechnology crops from any source.