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# South Africa - Republic of

# **Agricultural Biotechnology Annual**

# **Biotechnology in South Africa**

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# **Report Highlights:**

The production area of Genetically Engineered (GE) crops in South Africa was unchanged in 2014, at 2.9 million hectares, making South Africa the ninth largest producer of GE crops in the world and by far the largest in Africa. South Africa approved three new GE events for general release in 2014, which included two corn stacked events. Twenty-five field or clinical trials permits were also authorized in 2014, including the long-awaited drought tolerance in corn. The Water Efficient Maize for Africa (WEMA) project is expected to deliver its first biotech stacked drought tolerant corn with insect control in South Africa as early as 2017. There is still no finalization on GE labeling in South Africa.

**SECTION I: EXECUTIVE SUMMARY** 

South Africa is a net exporter of agricultural, fish and forestry products and exports reached US\$10 billion in 2014. The Netherlands (eight percent of exports), Namibia (seven percent of exports) and the United Kingdom (seven percent of exports) are the three major destinations of South Africa's agriculture, fish, and forestry products. South Africa's exports of agricultural, fish and forestry products to the United States were valued at US\$302 million in 2014, a four percent increase from the previous year, and accounts for three percent of total agricultural exports by South Africa. Fresh fruit (US\$54 million), Wine (US\$51 million) and nuts (US\$48 million), were the major items exported to the United States.

South Africa's major partners for importing agriculture, fish, and forestry products are Swaziland (which accounts for nine percent of imports), Indonesia (six percent of imports), China (five percent of imports) and Argentina (five percent of imports). Imports from the United States decreased by ten percent to US\$298 million in 2014 and represents four percent of South African imports of agriculture, fish, and forestry products. Nuts (US\$23 million), planting seed (US\$22 million) and wheat (US\$18 million) were the major products imported from the United States by South Africa in 2014.

South Africa possesses a highly advanced commercial agricultural industry based *inter alia* on first-generation biotechnologies and effective plant breeding capabilities. South Africa 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 area of GE crops in South Africa was unchanged in 2014, at approximately 2.9 million hectares, making South Africa the ninth largest producer of GE crops in the world and by far the largest in Africa. Most South African farmers have adopted plant biotechnology and the benefits thereof. GE corn plantings in 2014 represented approximately 79 percent of total biotechnology plantings in South Africa, down from 83 percent in 2013, due to a 37 percent increase in soybean plantings. GE soybeans in 2014 represented approximately 21 percent of total biotechnology plantings with GE cotton representing less than one percent of total biotechnology plantings. An estimated 87 percent of corn plantings, 90 percent of soybean plantings and all cotton plantings in South Africa are grown from GE seeds. The Water Efficient Maize for Africa (WEMA) project is expected to deliver its first biotech stacked drought tolerant maize with insect control in South Africa as early as 2017.

All of the GE events that are currently commercially produced in South Africa were developed in the United States. However, due to the fact that the United States has approved corn events that are not yet approved in South Africa, United States commercial corn cannot be exported to South Africa.

South Africa has a National Biotechnology Strategy in place. This strategy is a policy framework, which aims at creating incentives for the biotechnology research and facilitates the adoption of biotechnology. The strategy also guarantees a stringent biosafety regulatory system, which ensures that biotechnology is utilized in a manner that causes minimum disruption to the environment, while addressing South Africa's sustainable development goals and imperatives. The Genetically Modified Organisms Act of 1997 (GMO Act), is the regulating framework that enables authorities to conduct scientifically-based, case-by-case assessment of the potential risks that may arise from any activity involving a particular GE product. The GMO Act also requires applicants to notify the public of a proposed release of GE products prior to the application for a permit of such a release. Apart from the GMO Act, biotechnology is also regulated through environmental and health related legislation.

South Africa's new Consumer Protection Bill came into effect in 2011. The new act requires virtually every product label in South Africa's food and beverage industry to be changed to comply with mandatory GE labeling requirements. However, strong criticism from stakeholders in the food chains, due to the ambiguity and complexity of the issue, has resulted in the Department of Trade and Industry (DTI) appointing a task team to address the conflicts and confusion of the labeling regulation. A workshop that served as a consultative forum with stakeholders to finalize proposed amendments on GE labeling was held in July of 2014. However, new GE labeling regulations have not yet been published and the issues is still lingering.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

**CHAPTER 1: PLANT BIOTECHNOLOGY** 

# **PART A: PRODUCTION AND TRADE**

# (a) PRODUCT DEVELOPMENT

#### **Permits issued**

Under South Africa's GMO Act, an Executive Council (EC), consisting of seven departments within the South African government, was established. The EC reviews all GE applications submitted in terms of the GMO Act and uses a case-by-case and precautionary approach to ensure sound decision-making in the interest of safety of the environment and the health of humans and animals. Most applications considered by the EC involve GE corn, soybeans and cotton and in most cases represent modifications and refinements of existing traits. The EC also evaluate applications for vaccine trials involving biotechnology.

South Africa has seen an increase in the submission of comments on GE permit applications from a wider audience of stakeholders and interested parties in recent years. These organizations include academic institutions, consumer forums, commodity organizations, provincial departments, and other stakeholder organizations representing the anti- and pro-GE movements.

A total number of 402 permits were issued in 2014, compared to 413 in 2013 and 420 in 2012. The majority of permits being issued were for the import and export of GE crops (see also Table 1). Imports focused mainly on commercially approved corn, soybeans and cotton for activities relating to planting, contained use, food and feed. In addition, imports also include GE HIV and tuberculosis vaccines for contained use in South Africa. The main exports permits issued included GE corn and to a lesser degree GE cotton primarily for contained use, planting activities and GE corn and soybeans exported as commodities for human and animal use. Three new events were approved for general release in 2014, namely, TC1507 x MON810 and TC1507 x MON810 x NK603 corn from Pioneer (refer to Table 5) that has herbicide tolerance and insect resistant traits and a poultry vaccine, Innovax ILT, from Intervet. In 2013 no new event was released and in 2012, one stacked event was approved for general release, namely: TC1507 corn also from Pioneer. Six commodity clearances were also approved in 2014 (refer to Table 6), after safety assessments were completed. These approvals included corn and soybeans for importation and can be use as food, feed and processing.

Table 1: Summary of GE permits issues in South Africa from 2009

	2009	2010	2011	2012	2013	2014
Exports	167	225	197	237	256	244
Imports	150	128	131	154	124	120

Trials	35	33	32	23	17	25
Contained use	7	6	3	2	13	3
Commodity clearance	0	0	24	3	3	6
General release	0	4	0	1	0	3
Total	359	396	387	420	413	402

In 2014, 25 field, or clinical trials permits were authorized, eight more than in 2013. Table 2 summarizes the event, trait, product and company involved, of the permits issued for trail release in 2013 and 2014 (please refer to the <u>Biotechnology Gain Report of 2012</u> for more detail on events that have been approved for trails prior to 2013). The products include corn, soybeans and cotton for evaluation of insect resistance and/or herbicide tolerance and the long-awaited drought tolerance in corn as well as clinical trial permits for HIV vaccines.

Table 2: GE events approved for trial release in 2013 and 2014

Company	Event	Crop/product	Trait
<u>Monsanto</u>	MON87460	Corn	Drought Tolerance
	MON87460 x MON89034	Corn	Drought Tolerance Insect resistant
	MON87460 x MON89034 x NK603	Corn	Drought Tolerance Insect resistant Herbicide tolerance
	MON87460 x NK603	Corn	Drought Tolerance Herbicide tolerance
	MON87460 x MON810	Corn	Drought Tolerance Insect resistant
<u>Bayer</u>	Twinlink x GlyTol	Cotton	Herbicide tolerance Insect resistant
	GlyTol x TwinLink x COT 102	Cotton	Herbicide tolerance Insect resistant
<u>Pioneer</u>	TC1507 x MON810	Corn	Herbicide tolerance Insect resistant
	TC1507 x MON810 x NK603	Corn	Herbicide tolerance Insect resistant
	PHP37046	Corn	Insect resistant
	DP-32138-1	Corn	Male fertility Pollen infertility
	PHP37050	Corn	Herbicide tolerance Insect resistant
	TC1507 x NK603	Corn	Herbicide tolerance Insect resistant
	305423 x 40-3-2	Soybeans	Modified oil/fatty acid Herbicide tolerance

	305423	Soybeans	Modified oil/fatty acid Herbicide tolerance
	PHP36676	Corn	Herbicide tolerance Insect resistant
	PHP36682	Corn	Herbicide tolerance Insect resistant
	PHP34378	Corn	Insect resistant
	PHP36827	Corn	Insect resistant
Wits	ALVAC	Vaccine	HIV
Syngenta	BT11x 1507 x GA21	Corn	Herbicide tolerance Insect resistant
	BT11 x MIR162 x GA21	Corn	Herbicide tolerance Insect resistant
	BT11 x MIR162 x 1507 x GA21	Corn	Herbicide tolerance Insect resistant
Dow AgroScience	MON89034 x 1507 x NK603	Corn	Herbicide tolerance Insect resistant

## **Grapevines**

The Institute for Wine Biotechnology at Stellenbosch University (IWBT) is the only research institute in South Africa that focuses on studying the biology of grapevine and wine microorganisms, and cooperates very closely with the wine and table grape industries of South Africa.

The IWBT's research theme is the understanding of the biology of wine-associated organisms, including the ecology, physiology, molecular and cellular biology of grapevine, wine yeast and wine bacteria to promote the sustainable, environmentally friendly and cost-effective production of quality grapes and wine. The Institute continually integrates the latest technologies in the biological, chemical, molecular and data analytical sciences to achieve these aims.

The specific research portfolio consists of three programs. The first focuses on a better understanding and exploitation of wine associated microbial biodiversity, and the physiological, cellular and molecular characterization of Saccharomyces and non-Sacharomyces yeasts, as well as the genetic improvement of wine yeast strains. A second program is concerned with lactic acid and other bacteria, including their impact on wine, metabolic characterization and improvement of malolactic fermentation. The third program focuses on the physiology, cellular and molecular biology and genetic improvement of grape cultivars.

Wine is one of the major agricultural products exported to the United States by South Africa, with an annual value worth around US\$50 million.

#### Cassava

The Agricultural Research Council (ARC) received authorization for field trials of a starch enhanced cassava variety in 2012. The main goal of this crop is to produce an industrial starch crop, as a means to improve jobs and income for South Africa and the region. USAID/South Africa obligated \$800,000 over two years to this research and the initial focus was on further development and roll-out of a transgenic pest-resistant variety of cassava for use as industrial starch. The project is being managed by Michigan State University in collaboration with the CGIAR.

## Sugar cane

The Variety Improvement Program of the South African Sugarcane Research Institute (SASRI) encompasses operational and research activities that facilitate the development and release of varieties with sucrose, yield, pest and disease, agronomic and milling characteristics that are desirable to both millers and growers.

Currently, modern biotechnological approaches are deployed in research projects that include:

- Drought tolerance induced in sugarcane by genetic modification.
- Overcoming transgenic silencing in sugarcane.
- Unlocking genetic variation in sugarcane for disease resistance.
- Improved nitrogen use efficiency through GE technology.
- Medium and long-term conservation of strategically-important transgenic germ plasma.
- Characterization and isolation of mutates ALS gene with tolerance to *imazapyr* in sugarcane.
- Tissue specific transgene expression.

## Other Research

Research is continuing on corn, soybeans and cotton for evaluation of insect resistance and/or herbicide tolerance and the long-awaited drought tolerance in corn. The Biotechnology Division of the ARC specializes in GE research on vegetables, ornamental plants and indigenous crops. Research projects have been identified and implemented by the division with the aim of developing new cultivars better suited to South African conditions.

## (b) COMMERCIAL PRODUCTION

## Corn

Corn is the main field crop produced in South Africa and is used for both human consumption (mainly, white corn) and animal feed (mainly, yellow corn). In 1997, the first GE corn event (insect resistant) was approved in South Africa and since then there was a progressive and steady increase in GE corn plantings. Table 3 illustrates the plantings of GE corn in South Africa over the past 8 years. GE corn plantings increased from 28 percent of total corn planted in the 2005/06-production year to an estimated 87 percent in the 2014/15 production year. Of the estimated 2.3 million hectares of corn planted with GE seed in the 2014/15-production year, single insect resistant comprised of an estimated 25 percent, herbicide tolerant of 17 percent and the stacked variety (insect resistant and herbicide tolerant) of an estimated 58 percent (see also Table 4). White corn plantings in the 2014/15

production year were 1.4 million hectares of which an estimated 84 percent or 1.2 million hectares were planted with GE seed. Yellow corn plantings were 1.2 million hectares of which an estimated 90 percent were planted with GE seed.

Table 3: Planting of GE corn in South Africa over the past 10 years

	Area planted '000 ha					
Production years	White corn	Yellow corn	Total corn			
2005/06						
Total	1,033	567	1,600			
Biotech	281	175	456			
% of total	27%	30%	28%			
<u>2006/07</u>						
Total	1,625	927	2,552			
Biotech	851	528	1,379			
% of total	52%	56%	54%			
2007/08						
Total	1,737	1,062	2,799			
Biotech	975	588	1.563			
% of total	56%	55%	56%			
2008/09						
Total	1,489	939	2,428			
Biotech	1,046	642	1.688			
% of total	70%	68%	70%			
2009/10						
Total	1,720	1,023	2,742			
Biotech	1,212	666	1,879			
% of total	71%	65%	69%			
2010/11						
Total	1,418	954	2,372			
Biotech	1,007	696	1,704			
% of total	71%	73%	72%			
2011/12						
Total	1,636	1,063	2,699			
Biotech	1,126	747	1,873			
% of total	69%	70%	69%			
2012/13						
Total	1,617	1,164	2,781			
Biotech	1,316	1,055	2,371			
% of total	81%	91%	85%			
2013/14						
Total	1,580	1,139	2,719			
Biotech	1,323	1,041	2,364			
% of total	84%	91%	87%			

2014/15 (estimate)			
Total	1,448	1,205	2,653
Biotech	1,210	1,085	2,295
% of total	84%	90%	87%

Source: FoodNCropBio supported by the Corn Trust

Table 4: Percentage of the GE corn crop planted with the different traits the past 10 years

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Production year	White corn	Yellow corn	Total corn
<u>2005/06</u>			
% Insect Resistant	79	61	72
% Herbicide Tolerant	21	39	28
% Stacked	0	0	0
2006/07			
% Insect Resistant	84	72	80
% Herbicide Tolerant	16	28	20
% Stacked	0	0	0
2007/08			
% Insect Resistant	71	69	71
% Herbicide Tolerant	22	27	24
% Stacked	6	4	5
2008/09			
% Insect Resistant	66	63	64
% Herbicide Tolerant	17	18	17
% Stacked	19	19	19
2009/10			
% Insect Resistant	81	49	70
% Herbicide Tolerant	10	23	14
% Stacked	9	28	16
<u>2010/11</u>			
% Insect Resistant	50	39	46
% Herbicide Tolerant	9	21	13
% Stacked	41	41	41
2011/12			
% Insect Resistant	46	44	45
% Herbicide Tolerant	10	20	14
% Stacked	44	36	41
2012/13			
% Insect Resistant	36	34	35
% Herbicide Tolerant	9	24	16
% Stacked	55	42	49
2013/14			
% Insect Resistant	31	26	29

% Herbicide Tolerant	13	23	17
% Stacked	56	51	54
2014/15 (estimate)			
% Insect Resistant	27	22	25
% Herbicide Tolerant	13	23	17
% Stacked	60	55	58

**Source:** FoodNCropBio supported by the Corn Trust

The long term trend in corn production indicates South Africa is producing more corn on less area (see Figure 1). The main reasons for this trend are more efficient and effective farming methods and practices, the use of less marginal land in the corn production systems, better seed cultivars, and the adoption of biotechnology. Figure 2 illustrates another remarkable trend, where the average corn yield almost doubled over the past 20 years in South Africa. Indications are that this trend of producing more corn on fewer hectares will continue in future.

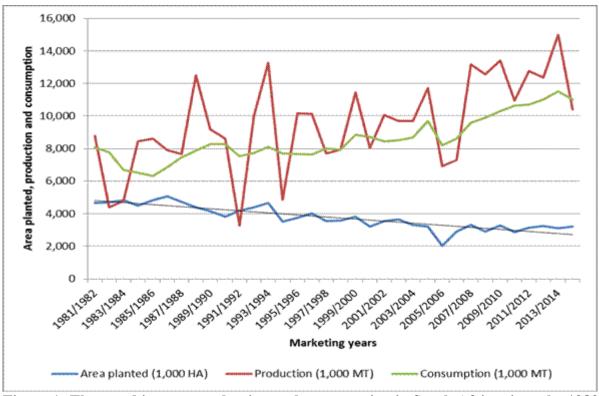


Figure 1: The trend in corn production and consumption in South Africa since the 1980's

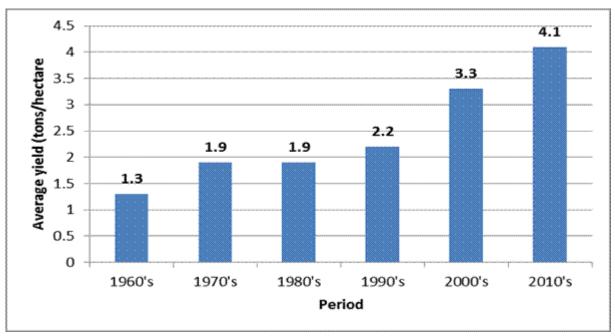


Figure 2: Trends in the average corn yields in South Africa

# **Soybeans**

South Africa planted a record of 1.3 million hectares of oilseeds in the 2014/15 MY, up 14 percent from the 1.2 million hectares planted in the 2013/14 MY. This positive trend in oilseeds area planted (see also Figure 3) was mainly driven by an increase in soybean plantings. In the 2014/15 production season the area planted with soybeans reached a record 687,300 hectares of which an estimated 90 percent were planted with GE seeds. GE soybeans were first approved for commercialization in South Africa in 2001; by 2006, 75 percent of the soybean crop grown was GE. The area planted with soybeans in South Africa increased almost 5-fold the past ten years. Many South African producers are now recognizing the value of soybeans in a crop rotation system with corn and, in addition, the production of soybeans is made relatively easier with the GE cultivars that are available in South Africa. With the increase in soybean crushing capacity, indications are that this upward trend in soybean plantings will continue in the future. South Africa invested an estimated R1 billion (US\$100 million) the past few years on expanding its soybean processing capacity, due to increased soybean production and to replace soybean meal imports. As a result, about 1.2 million tons of additional oilseed processing capacity has been created, bringing South Africa's current total oilseed capacity to an estimated 2.2 million tons per annum.

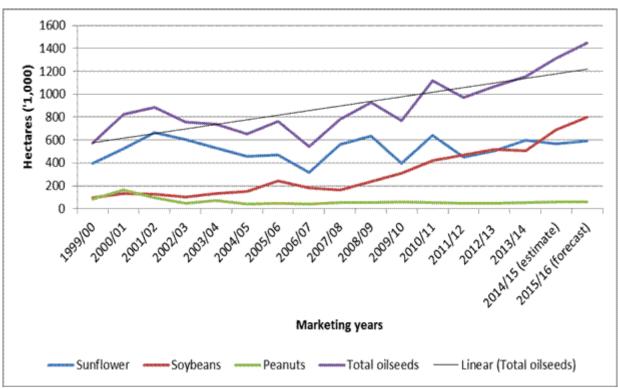


Figure 3: Trends in the area planted with oilseeds in South Africa since the 1999/00 marketing vear

#### Cotton

Bt cotton was the first GE crop variety to be grown commercially in sub-Saharan Africa. Early adopters were small-scale farmers in the Makhatini Flats in Kwazulu-Natal, South Africa, who have been growing the crop since 1998. Cotton planting increased to 16,000 hectares in the 2014/15 production season, from 7,500 hectares in the 2013/14 production season. The increase in hectares planted was mainly due to positive movement in cotton prices. All cotton plantings in South Africa are GE with the stacked variety representing more than 95 percent of total cotton planting.

## (c) EXPORTS

South Africa is the major exporter of corn on the Africa continent and a large percentage of South African corn exports are destined for countries in Africa. South Africa exported 2.0 million tons of corn in the 2014/15 MY South Africa exported both white corn and yellow corn, with Taiwan (679,185 tons yellow corn), Korea (214,474 tons yellow corn and 3,875 tons white corn) and Japan (198,197 tons yellow corn) being the largest deep-see export markets in the 2014/15 MY. Almost a million tons of corn was exported to South Africa's neighboring countries e.g. Botswana, Zimbabwe, Lesotho, Mozambique, Swaziland and Namibia in the 2014/15 MY.

For the 2015/16 MY, South Africa will have to import about 500,000 tons of corn, due to the drop in corn production as the result of the current drought conditions. South Africa will, however, continue to export corn to its neighboring countries, which should amount to about 600,000 tons

South Africa's trade in oilseeds is mainly directed to the imports of oil and protein meal, however, in the 2014/15 MY, South Africa exported a small amount of 2,000 tons of soybeans and 2,000 tons of sunflower seeds, destined mainly for South Africa's neighboring countries. Exports of soybeans and sunflower seeds are expected to drop to zero in the 2015/16 MY as total local production will be used locally.

## (d) IMPORTS

South Africa is not a major importer of corn and only imported around 65,250 tons of corn from Argentina in the 2014/15 MY. However, due to the drought, South Africa will have to import about 500,000 tons of corn and 100,000 tons of soybeans in the 2015/16 MY. Due to the fact that countries such as the United States and Brazil have approved corn events that are not yet approved in South Africa, imported corn from these countries is not authorized to enter into South Africa. South Africa is not opposed in principle to these events, but any events that have not made it through the regulatory approval process of South Africa cannot be imported. As a result, South Africa, if needed, imports corn from countries that do not produce GE crops, such as, Zambia and certain countries in Europe.

# (e) FOOD AID RECIPIENT COUNTRIES

South Africa is not a recipient of food aid and is expected to stay a net exporter of agricultural products in the future. However, any international food aid destined to Lesotho, Swaziland, Zambia and Zimbabwe ordinarily passes through the port of Durban, South Africa's major port. In order for the shipment to pass through South Africa, the GMO Registrar's Office requires several measures, including, an advance notification so that proper containment measures can be taken and a letter from the recipient country stating that it accept the food aid consignment and that it is known that it contains GE products.

#### **PART B: POLICY**

# (a) REGULATORY FRAMEWORK

#### **Historical context**

In 1979, the South African government established the Committee on Genetic engineering (SAGENE). SAGENE comprised of a group of South African scientists and was commissioned to act as scientific advisory body to the government and paved the way for the uptake of GE in food, agriculture, and medicine. In 1989, on the advice of SAGENE, the first GE experiments in open field trials took place. In January 1994, a few months before South Africa's first democratic elections, SAGENE was given legal powers to "advise any Minister, statutory or government body on any form of legislation or controls pertaining to the importation and/or release of GE products". As a result, SAGENE was tasked to draft a GMO Act for South Africa. A draft GMO bill was published for public comment in 1996 and passed by the Parliament in 1997. Nevertheless, the GMO Act only came into effect in December 1999, after regulations to bring the Act into effect were promulgated. In this interim period, SAGENE continued to act as the key "regulatory body" for GE products, and under its auspices granted permits to allow Monsanto to commercialize GE cotton and GE corn seed. In addition, 178 permits were granted for a variety of open field GE trials. Once the GMO Act came into effect, SAGENE ceased to exist and was replaced by an Executive Council, established by the GMO Act of 1997.

## The GMO Act of 1997

The GMO Act of 1997, and its accompanying Regulations, is administrated by DAFF. Under the GMO act a decision-making body (the EC), an advisory body (the Advisory Council (AC)) and administrative body (the GMO Registrar) was established to:

- Provide measures to promote the responsible development, production, use and application of GE products;
- Ensure that all activities involving the use of GE products be carried out in such a way as to limit possible harmful consequences to the environment, human, as well as, animal health;
- Give attention to the prevention of accidents and the effective management of waste;
- Establish mutual measures for the evolution and reduction of the potential risks arising from activities involving the use of GE products;
- Lay down the necessary requirements and criteria for risk assessments;
- Establish appropriate procedures for the notification of specific activities involving the use of GE products.

This GMO Act of 1997 was modified by the cabinet in 2005 to bring it in line with the Cartagena Biosafety Protocol (CBP) and again in 2006 in order to address some economic and environmental concerns. These amendments to the GMO Act were published and gazetted on April 17, 2007 and came into effect in February 2010, after the Regulations were published. The GMO Act, as amended, does not change the pre-existing preamble, which establishes the general ethos of the legislation namely, to subsume the need for biosafety with the imperative to promote GE development.

The amendments to the GMO act make it clear that a scientifically based risk assessment is a prerequisite for decision-making and also authorizes the EC to determine if an environmental impact assessment is required under the National Environmental Management Act. The amendments also added specific legislation to allow socio-economic considerations to factor into decision-making and make those considerations significantly important in the decision-making process.

The amendments also create at least eight new provisions dealing with accidents and/or unintentional transboundary movement. These provisions have been motivated by the spate of contamination incidents that have occurred worldwide involving unapproved GE products. A new definition of "accident" has been created to capture two types of situations: one dealing with unintentional transbondary movements of GE products and the other, unintentional environmental release within South Africa.

In summary: The existence and application of the GMO Act and its amendments provides South Africa with a decision-making tool that enables authorities to conduct scientifically-based, case-by-case assessment of the potential risks that may arise from any activity involving a particular GE product.

## The Executive Council

The EC functions as an advisory body to the Minister of Agriculture, Forestry and Fisheries on matters relating to GE products, but more important is the decision-making body that approves or rejects GE applications. The EC is also empowered to co-opt any person knowledgeable in the field of science to serve on the EC to provide advice.

The EC is made up of representatives of different departments within the South African government. These include:

- DAFF
- Department of Water and Environmental Affairs
- Department of Health
- DTI
- Department of Science and Technology
- Department of Labor
- Department of Arts and Culture

Before making a decision regarding GE applications, the EC is obliged to consult with the AC. The AC is represented on the EC through its chairperson. Decision-making by the EC is on the basis of consensus by all the members and where no consensus is reached, the application before the EC will be considered as having been refused. For this reason it is essential that all representatives on the EC have significant knowledge on biotechnology and biosafety.

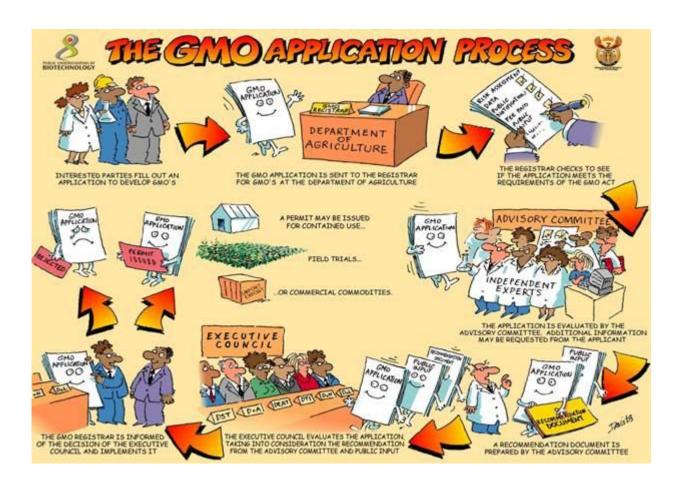
# The Advisory Council

The AC consists of ten scientists who are appointed by the Minister of Agriculture, Forestry and Fisheries. The EC has input in the appointment of members of the AC and has recently changed a number of the members, following protest by civil society that some members of the AC were also members of the pro-GMO lobby group, Africabio and ex-SAGENE members.

The role of the AC is to provide the EC advice on GE applications. The AC is further supported by subcommittee members representing an extended pool of scientific expertise from various disciplines. The AC together with the subcommittee members is responsible for the evaluation of risk assessments of all applications as it relates to food, feed and environmental impact and submit recommendations to the EC.

# The Registrar

The Registrar, who is appointed by the Minister of Agriculture, Forestry and Fisheries, is in charge of the day-to-day administration of the GMO act. The Registrar acts on the instructions and conditions laid down by the EC. The Registrar is also responsible for examining applications to ensure conformity with the Act, issuing of permits, amending and withdrawing of permits, maintaining a register and monitor all facilities that are used for contained use and trail release sites. Figure 4 illustrates the GE application process in South Africa.



# Figure 4: The GE application process in South Africa

**Source:** *DAFF* 

## Other regulations that impact on GE products in South Africa

# The National Environmental Management Biodiversity Act

The National Environmental Management Biodiversity Act (Biodiversity Act) of 2004 was established to protect South Africa's biodiversity from specific threats and includes GE products as one of those threats. Section 78 of the act gives the Minister of Environmental Affairs the power to deny a permit for general or trial release applied for under the GMO Act, if the GE product may pose a threat to any indigenous species or the environment.

Under the Biodiversity Act a South African Biodiversity Institute (SANBI) was also established. SANBI is tasked to monitor and report regularly to the Minister of Environmental Affairs on the impacts of any GE product that has been released into the environment. The legislation requires reports on the impact of non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture.

#### **Consumer Protection Act**

Health regulations published in 2004, largely follow Codex Alimentarius scientific guidelines. These regulations mandate labeling of GE foods only in certain cases, including when allergens or human/animal proteins are present, and when a GE food product differs significantly from a non-GE equivalent. The rules also require validation of enhanced-characteristic (e.g., "more nutritious") claims for GE food products. The regulations do not address claims that products are GE-free.

However, on April 24, 2009, the President of South Africa signed a new Consumer Protection Bill into law. Implementation of the Act, however, was delayed for some time as the legislation generated significant comments from the private sector over the basis of many provisions and uncertainty over how the Act would be enforced. The new Consumer Protection Bill required virtually that every product label in South Africa's food and beverage industry had to change.

On April 1, 2011, DTI published regulations in the Gazette that brought the Consumer Protection Act (68/2008) into force. The regulation came into effect six months (October 1, 2011) after the commencement of the act. The primary purpose of the law is to prevent exploitation or harm of consumers and to promote the social wellbeing of consumers.

However, the approved Consumer Protection Act has the following section which states that all products containing GE material must be labeled [Section 24(6)]:

(6) Any person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the packaging of those goods, a notice in the prescribed manner and form that

discloses the presence of any genetically modified ingredients or components of those goods in accordance with applicable regulations.

# According to the act:

- All food containing more than five percent GE ingredients, whether produced in South Africa or elsewhere, needs to carry the declaration which states, "contains at least five percent genetically modified organisms" in a conspicuous and easily legible manner and size.
- Those products that contain less than five percent of GE ingredients may be labeled "Genetically modified content is below five percent".
- If it is impossible or not feasible to test goods for the presence of GE traits, the product must be labeled "may contain GMO ingredients".
- Less than one percent maybe labeled as "does not contain genetically modified organisms".

The DTI views the labeling of GE products solely within the context of the consumer's right to obtain the facts needed to make an informed choice or decision about food. Thus, it is not about human health, safety or quality issues.

In May, 2012, Business Unity South Africa (BUSA) organized a meeting with the Commissioner of the Consumer Protection Act to discuss the current challenges pertaining to the regulations of the Act. The intention was also to initiate the establishment of future dialogues and collaboration to address pertinent limitations of the regulations, including GE labeling.

The BUSA delegates tabled the following concerns regarding GE labeling to the Commissioner:

- The inclusion of GE labeling in the Consumer Protection Act is not necessary as it is already covered by regulations No. R25 of the Foodstuffs, Cosmetics and Disinfectant Act, Act No. 54 of 1972, administrated by the Department of Health;
- To adhere to the current regulations regarding GE labeling will increase the cost of food and impact negatively on the consumer and household food security;
- The current regulations referred to "genetically modified organisms" as defined in Section 1 of the GMO Act, Act No. 15 of 1997. The current commercially approved "genetically modified organisms" in terms of the latter are corn, soybeans and cotton. Inevitably, downstream products are not covered and therefore the existing regulations might not be applicable;
- The regulations are vague and pose interpretation challenges. There are varying degrees of interpretations by various industries in an attempt to solicit compliance mechanisms;
- There are currently only a few laboratories in the country and these would be unable to absorb the pressure of testing every batch from the farm gate and throughout the value chain.

The Commissioner replied by acknowledging the inherent challenges pertaining to definitions and interpretations of the existing GE regulations, as well as, disparities leading to the final draft. As a result, the Commission has been collaborating with the Departments of Health, Agriculture, Forestry and Fisheries, Trade and Industry and Science and Technology in an effort to develop more sensible guidelines on GE labeling. A task team to address the conflicts and confusion of the labeling regulations was then appointed. A workshop that served as a consultative forum with stakeholders to finalize proposed amendments on GE labeling was held on July, 25, 2014. However, new GE

labeling regulations have not yet been published and the issues is still lingering.

# (b) APPROVALS

Table 5 illustrates all the GE events that have been approved for general release in South Africa under the GMO Act of 1997. This means these events can be used for commercial plantings, for food and/or feed and the importation and exportation of these events are allowed. All the GE events that are currently commercially available in South Africa were developed in the United States. These events are present in three crops namely, corn, soybeans and cotton. Three new events were approved for general release in 2014, namely, TC1507 x MON810 and TC1507 x MON810 x NK603 corn from Pioneer that has herbicide tolerance and insect resistant traits and a poultry vaccine, Innovax ILT, from Intervet. In 2013 no new event was released and in 2012, one stacked event was approved for general release, namely: TC1507 corn also from Pioneer.

Table 5: GE events approved for general release in South Africa

Company	Event	Crop/product	Trait	Year approved
Intervet	Innovax ILT	Poultry vaccine		2014
Pioneer	TC1507 x MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2014
Pioneer	TC1507 x MON810	Corn	Insect resistant Herbicide tolerant	2014
Pioneer	TC1507	Corn	Insect resistant Herbicide tolerant	2012
Syngenta	BT11xGA21	Corn	Insect resistant Herbicide tolerant	2010
Syngenta	GA21	Corn	Herbicide tolerant	2010
Monsanto	MON89034xNK603	Corn	Insect resistant Herbicide tolerant	2010
Monsanto	MON89034	Corn	Insect	2010

			resistant	
Monsanto	Bollgard II x RR flex (MON15985 x MON88913)	Cotton	Insect resistant Herbicide tolerant	2007
Monsanto	MON88913	Cotton	Herbicide tolerant	2007
Monsanto	MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2007
Monsanto	Bollgard RR	Cotton	Insect resistant Herbicide tolerant	2005
Monsanto	Bollgard II, line 15985	Cotton	Insect resistant	2003
Syngenta	Bt11	Corn	Insect resistant	2003
Monsanto	NK603	Corn	Herbicide tolerant	2002
Monsanto	GTS40-3-2	Soybeans	Herbicide tolerant	2001
Monsanto	RR lines 1445 & 1698	Cotton	Herbicide tolerant	2000
Monsanto	Line 531/Bollgard	Cotton	Insect resistant	1997
Monsanto	MON810/Yieldgard	Corn	Insect resistant	1997

In Table 6, GE events that have received commodity clearance are indicated. The events cover five crops, namely, corn, soybeans, cotton, rice and rape seed. Commodity clearance means the importation of these events for the use as food and/or feed are allowed. In 2014, six new events from Syngenta received commodity clearance.

**Table 6: GE events with commodity clearance** 

Company	Event	Crop	Trait	Year
Company	F3 ( C110	O-OP		_ 041

				approved
Syngenta	SYHT0H2	Soybeans	Herbicide tolerant	2014
Syngenta	BT11 x 59122 x MIR604 x TC1507 x GA21	Corn	Insect resistant Herbicide tolerant	2014
Syngenta	BT11 x MIR604 x TC1507 x 5307 x GA21	Corn	Insect resistant Herbicide tolerant	2014
Syngenta	BT11 x MIR162 x MIR604 x TC1507 x 5307 x GA21	Corn	Insect resistant Herbicide tolerant	2014
Syngenta	MIR162	Corn	Insect resistant	2014
Monsanto	MON89034 x MON88017	Corn	Insect resistant Herbicide tolerant	2014
Monsanto	MON87701 x MON89788	Soybeans	Insect resistant Herbicide tolerant	2013
Monsanto	MON89788	Soybeans	Herbicide tolerant	2013
DowAgrowScience	DAS-44406-6	Soybeans	Herbicide tolerant	2013
DowAgrowScience	DAS-40278-9	Corn	Herbicide tolerant	2012
BASF	CV127	Soybeans	Herbicide tolerant	2012
DowAgrowScience/ Monsanto	MON89034 x TC1507 x NK603	Corn	Insect resistant Herbicide tolerant	2012
Syngenta	MIR604	Corn	Insect resistant	2011
Syngenta	BT11 x GA21	Corn	Insect resistant Herbicide tolerant	2011
Syngenta	BT11 x MIR604	Corn	Insect resistant	2011

			Herbicide tolerant	
Syngenta	MIR604 x GA21	Corn	Insect resistant Herbicide	2011
			tolerant	
Syngenta	BT11 x MIR604 x GA21	Corn	Insect resistant Herbicide tolerant	2011
Syngenta	BT11 x MIR162 x MIR604 x GA21	Corn	Insect resistant Herbicide tolerant	2011
Syngenta	BT11 x MIR162 x GA21	Corn	Insect resistant Herbicide tolerant	2011
Syngenta	BT11 x MIR162 x TC1507 x GA21	Corn	Insect resistant Herbicide tolerant	2011
Pioneer	TC1507 x NK603	Corn	Insect resistant Herbicide tolerant	2011
Pioneer	59122	Corn	Insect resistant	2011
Pioneer	NK603 x 59122	Corn	Insect resistant Herbicide tolerant	2011
Pioneer	356043	Soybean	Herbicide tolerant	2011
Pioneer	305423	Soybean	Higher oleic acid content Herbicide tolerant	2011
Pioneer	305423 x 40-3-2	Soybean	Higher oleic acid content Herbicide tolerant	2011
DowAgroScience	TC1507 x 59122	Corn	Insect resistant Herbicide	2011

			tolerant	
DowAgroScience	TC1507 x 59122 x NK603	Corn	Insect resistant Herbicide tolerant	2011
Bayer	LLRice62	Rice	Herbicide tolerant	2011
Bayer	LLCotton25	Cotton	Herbicide tolerant	2011
Monsanto	MON863	Corn	Insect resistant	2011
Monsanto	MON863 x MON810	Corn	Insect resistant	2011
Monsanto	MON863 x MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2011
Monsanto	MON88017	Corn	Insect resistant	2011
Monsanto	MON88017 x MON810	Corn	Insect resistant	2011
DowAgroScience & Monsanto	MON89034 x TC1507 x MON88017 x 59122	Corn	Insect resistant Herbicide tolerant	2011
Monsanto	MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2004
Monsanto	MON810 x GA21	Corn	Insect resistant Herbicide tolerant	2003
Pioneer Hi-Bred	TC1507	Corn	Insect resistant Herbicide tolerant	2002
Monsanto	NK603	Corn	Herbicide tolerant	2002
Monsanto	GA21	Corn	Herbicide tolerant	2002
Syngenta	Bt11	Corn	Insect resistant	2002
AgrEvo	Т25	Corn	Herbicide tolerant	2001

Syngenta	Bt176	Corn	Insect resistant	2001
AgrEvo	Topas 19/2, Ms1Rf1,	Oilseed	Herbicide	2001
rigitivo	Ms1Rf2, Ms8Rf3	rape	tolerant	2001
AgrEvo	A2704-12	Soybean	Herbicide tolerant	2001

**Notes:** Excludes events that have obtained general release clearance before commodity clearance; the events can be used for importation as food or feed

# (c) FIELD TESTING

Please refer to Table 2.

# (d) STACKED EVENT APPROVALS

South Africa requires an additional approval for GE seeds that combines two already approved traits, such as herbicide tolerance and insect resistance. This requirement means that companies effectively need to start from the beginning of the approval process for stacked events, even when the individual traits have already been approved. The EC has reconfirmed in its first meeting of 2012, that each stack event must be subjected to a separate safety assessment as per the GMO Act. Currently, eight stacked events (insect resistant and herbicide tolerant), six for corn and two for cotton, have been approved for general release in South Africa.

# (e) ADDITIONAL REQUIREMENTS

No additional seed registration is required in South Africa after GE seed was approved for general release. Seed Certification is also voluntary, except for specific varieties listed in the Plant Improvement Act and on request of the breeder or owner thereof.

## (f) COEXISTENCE

Coexistence has not been an issue that has necessitated the introduction of specific guidelines or regulations in South Africa. The government leaves the management of the approved GE field crops to the farmers. South Africa also does not currently have a National Organics Standard in place.

# (g) LABELING

The mandatory labeling of GE products as stipulated in South Africa's Consumer Protection Act that came into law on April 1, 2011, is on hold. Strong criticism from stakeholders in the food chains, due to the ambiguity and complexity of the issue, has resulted in DTI appointing a task team to address the conflicts and confusion of the labeling regulation. A workshop that served as a

consultative forum with stakeholders to finalize proposed amendments on GE labeling by the task team was held on July, 25, 2014. However, new GE labeling regulations have not yet been published and the issues are still lingering.

As a result, the only label requirement currently for GE products is South Africa falls under the Foodstuffs, Cosmetics and Disinfectant Act. This Act mandates labeling of GE foods only in certain cases, including when allergens or human/animal proteins are present, and when a GE food product differs significantly from a non-GE equivalent. The rules also require validation of enhanced-characteristic (e.g., "more nutritious") claims for GE food products. The regulations do not address claims that products are GE-free.

## (h) TRADE BARRIERS

DAFF mandates that only approved GE events are allowed into South Africa under the GMO Act. The South African regulatory procedures for approving GE plants sometimes take longer than those in supplier countries. Differences in the speed of authorizations lead to situations where products are approved for commercial use outside South Africa but not within South Africa. These asynchronous approvals result in severe risks of trade disruption since South Africa applies only one percent tolerance for the presence of unauthorized (in South Africa) biotech events in food and feed.

# (i) INTELLECTUAL PROPERTY RIGHTS

Biotechnology companies operating in South Africa follow essentially the same procedure for collecting technology fees as in the United States. This policy generally works because South Africa is a signatory to the Trade-Related Aspects of International Property Rights (TRIPS) agreement of the WTO. Trade sources relate that cotton and corn are such that farmers have to buy new seed every year. Farmers sign a one-year licensing agreement, and the technology fee is included in the price of the bag of seed for these crops. Soybeans are more difficult. Technology developers try to collect the fee from the farmers when they deliver the harvest to the terminal. This fee can be difficult to collect because soybeans are open-pollinated so seed need not be purchased each year. Also farmers often use soybeans for on-farm feed so it might never enter commercial circulation. This challenge is not unique to South Africa, but rather is due to the intrinsic nature of the soybean.

## (j) CARTAGENA PRODTOCOL RATIFICATION

South Africa has signed and ratified the Cartagena Biosafety Protocol (CBP). The primary responsibility for implementing the CBP has shifted from the Department of Environmental Affairs to DAFF. CBP implementation is meant to be gradual, and accordingly DAFF's implementation will be in phases, with the most significant issues being handled first. South Africa, under the leadership of DAFF's GMO Regulatory Office, has modified its GMO Act to comply with the CBP.

# (k) INTERNATIONAL TREATIES/FOR A

South Africa is a signatory member of *inter alia*:

- The <u>Agreement on the Application of Sanitary and Phytosanitary Measures</u> of the <u>World Trade Organization</u> (WTO-SPS)
- Codex Alimentarius Commission (Codex)
- <u>International Plant Protection Convention (IPPC)</u> of the <u>Food and Agricultural Organization</u> (FAO)

South Africa as a member of the IPPC undertakes to:

- Implement common and effective measures on national and international level to prevent the importation and distribution of pests of plants and plant products
- Promote the methods for the control of pests
- Establish legal, technical and administrative measures necessary to achieve the goals of the Convention.

# (I) RELATED ISSUES

There are no other issues related to plant biotechnology that are not captured under the current headings.

## (m) MONITORING AND TESTING

In South Africa, approved GE commodities are imported through a permit system under the GMO Act (1997). This system only applies to living GE organisms and processed commodities are not regulated unless considered to have health considerations. However, no routine GE detection is performed on GE imports or non-GE imports to ensure that unapproved events are not present.

## (n) LOW LEVEL PRESENCE POLICY

South Africa hosted the annual multi-national LLP meeting on September, 19 and 20, 2013. Countries represented included, Brazil, Australia, Korea, Paraguay, Canada, Columbia, China and the United States. The number and complexity of genetically engineered crops being developed and cultivated worldwide is increasing annually. This situation threatens to increase the number of asynchronous and asymmetric approvals worldwide and, consequently, increase the risk of trade disruptions resulting from LLP of unapproved events in commercial channels. Hence, there is an immediate need to address the risk to trade arising from LLP occurrences as it can impact global food security. Recognizing the need for action the annual LLP meetings by concerned countries begin the development of a practical approach for the management of LLP globally that are science-based, predictable and transparent.

At the meeting, Foreign Agricultural Services (FAS) Administrator, Phil Karsting, reiterated that to ensure global food security agriculture production would need to increase through an increase in productivity and that biotechnology is going to play a critical role in that. He also emphasized the importance of international trade in agriculture commodities to combat global food security and that governments and the private sector need to work collaboratively to address the impact of LLP on trade.

South Africa's regulation for Low Level Presence (LLP) is only one percent. However, if the product is milled or otherwise processed there is usually no importation problem.

# **PART C: MARKETING**

# (a) MARKET ACCEPTANCE

On the production side, South African farmers can be divided into two categories, namely, commercial and small/emerging farmers. GE products have a wide appeal with both groups with an estimated 87 percent of corn, 90 percent of soybeans and all cotton being planted with GE seeds. Each group appreciates that GE crops use fewer inputs and have generally higher yields. Subsistence farmers also find GE crops easier to manage than traditional or conventional hybrid varieties. On the consumption side, South Africa uses about 11 million tons of corn annually, of which about half (mainly white corn) is used for human consumption. Yellow corn is mainly used for animal feed. The commercial demand for corn for food increased on average by two percent per year the past 15 years, while the commercial demand for feed corn increased on average by three percent per year (see also Figure 5). Projections are that this increase in demand for corn will continue in the future.

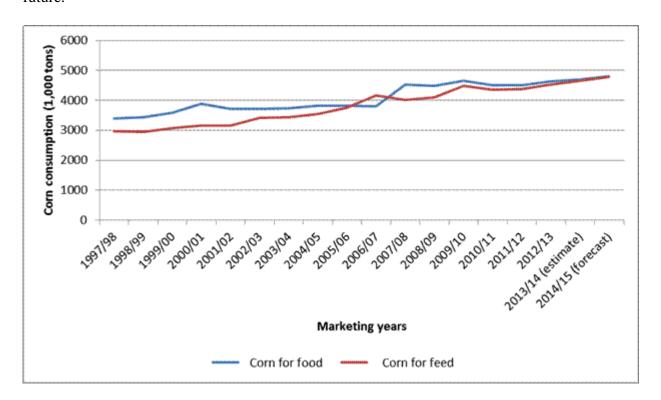


Figure 5: The commercial consumption of corn in the food and feed markets of South Africa since the 1997/98 MY.

## (b) PUBLIC/PRIVATE OPINIONS

A survey conducted by the Department of Science and Technology's Public Understanding of Biotech organization, shows that most South Africans have no knowledge of biotechnology. This finding is not surprising given that most South Africans are more concerned with the price of food than with how it was grown. What is interesting is that despite this lack of understanding, an average of 57 percent indicated that different applications of biotechnology should continue. Although South African scientists are the leaders in biotechnology on the African continent, the survey showed that the term "biotechnology" means nothing to 82 percent of the general public. A similar proportion is unaware of the meanings of 'genetic engineering', 'genetic modification', and 'cloning'. The study, in which researchers interviewed 7,000 people in the language of the participant's choice, was designed to be representative of the adult population of South Africa. It reveals that even among the few South Africans who were aware of biotechnology, most were indifferent to it.

When asked who they most trust to tell the truth about biotechnology, 24 percent of interviewees said universities, 19 percent said the media, and 16 percent said the government. Respondents were even less likely to trust consumer groups, environmental organizations, religious groups, or the biotechnology industry. The survey concluded that South Africa needs better science communication about biotechnology so that people can have a clearer picture of how it affects their lives.

# (c) MARKETING STUDIES

Please refer to the following studies:

http://csis.org/files/publication/100701\_Cooke\_AfricaGMOs\_WEB.pdf;

http://upetd.up.ac.za/thesis/available/etd-11222005 110807/unrestricted/00dissertation.pdf;

http://etd.uovs.ac.za/ETD-db/theses/available/etd-10042011-094627/unrestricted/MarxGM.pdf;

The first study was conducted in 2010 and studied the difference in debate in Zambia, Kenya and South Africa on GE crops, while the second study looked at consumer perceptions and market segmentation of GE white corn in South Africa. The third study investigated the monitoring of GE food products in South Africa.

## PART D: CAPACITY BUILDING AND OUTREACH

# (a) ACTIVITIES

Below, the activities that have been carried out by FAS/Pretoria in South Africa in 2014 are listed. These activities are implemented usually through AfricaBio. AfricaBio is a non-governmental, non-political and non-profit biotechnology organization based in South Africa that advocates for stakeholders in the research and development, production, processing and consuming sectors. The bulk of its funding comes from the private sector. USAID and other United States organizations also provide periodic funding to Africabio for training and capacity building activities and for the production of biotechnology informational materials.

Biotechnology outreach to the South African Parliament (February 25 -27, 2014): FAS/Pretoria Senior Agricultural Attaché, Pickelsimer, presented on the benefit of biotechnology to smallholder farmers as part of a State Department funded biotechnology outreach activity. The biotechnology outreach came on the heels of a petition by the African Center for Biosafety (ACB) to overturn South Africa's approval of the importation of 2,4-D corn, a decision made in 2012. The tone of the outreach was notably more positive than an earlier FAS/Pretoria presentation to parliament, which was considered a huge success, in spite of speaking immediately after the ACB petition, which could have artificially raised concerns about biotechnology.

SADC conference on biotechnology and biosafety (March 3 – 5, 2014): AfricaBio, in collaboration with South Africa's Department of Agriculture, Forestry, and Fisheries (DAFF), the United States Department of Agriculture (USDA), and other international partners, co-hosted the Southern African Agri-Biotech and Biosafety Conference. The event focused on Smart and Sustainable Agriculture in Southern Africa: Meeting Future Food Needs. The three-day event brought together government and academic representatives in the biotech and biosafety sectors from 14 SADC members. In addition, regional economic communities like Common Market for Eastern and Southern Africa (COMESA) and the New Partnership for Africa's Development (NEPAD) attended the event to discuss the importance of biotech harmonization in the region. The conference recognized the role of biotechnology in ensuring food security, using South Africa as a case study after more than 15 years of biotechnology adoption. The conference also reached consensus that there is an urgent need for the harmonization of biosafety policies in the SADC region. However, a number of critical issues still need to be addressed by the SADC Secretariat, which remains a huge challenge.

**Farmer information day (March 3, 2014):** AfricaBio in collaboration with FAS/Pretoria and the Limpopo Department of Agriculture held a farmer' information day on the 3rd March 2014 at Mr Frans Malela's farm, in Matlerekeng. Approximately 120 people attended the event, and they

included the keynote speaker, Prof Moloney (Group Executive, Food, Health and Life Science Industries, CSIRO, Australia); Biosafety Regulators from Angola, DRC, Lesotho, Malawi, Zimbabwe, Zambia, Swaziland, Namibia, Botswana, Tanzania, Mozambique, Mauritius, and Seychelles – attending the Biotech and Biosafety Conference; SA biotech stakeholders; officials from Limpopo Department; extension officers; seed representatives; officials from DAFF; grade 11 science students from Matlerekeng High School; the Chief; and other famers of Matlerekeng. The information day was used to create awareness and demonstrate the benefits of using biotech crops to the visiting SADC regulators; as well as to build capacity and increase the adoption of this promising agricultural technology by small-holder farmers. This seeing-is-believing outreach program is an initiative of AfricaBio and has served as a useful tool to showcase the benefits of biotechnology in South Africa to the region.

AfricaBio Business Breakfast meeting (October, 24, 2014): FAS/Pretoria supported the event financially and Senior Agricultural Attaché, Justina Torry, was the key note speaker. Participants at the business breakfast meeting included government officials, farmers, and delegates from seed companies, academics and other stakeholders. More than 60 people attended the function. Justina presented the United States perspective on the labeling of food derived from modern biotechnology. The discussion took place during a time when South Africans are waiting for the government to publish new GE labeling regulations. In her presentation, Justina mentioned that in the United States labeling criteria depends on the objective characteristics and intended use of the food and not on method used to produce the food. Judged by the positive and constructive discussion and feedback afterwards the presentation and event was a huge success.

# (b) STRATEGIES AND NEEDS

The South African government generally supports the use of biotechnology products. Transgenic varieties of cotton, corn, and soybeans are approved for commercial planting. Agricultural biotechnology holds wide appeal for South African small scale and commercial farmers as they recognize the financial benefits of fewer inputs and potentially higher yields.

FAS/Pretoria's program uses South Africa as an example of a country that accepts and uses agricultural biotechnology successfully when doing outreach activities in the region. South Africa's GE adoption story is key in FAS/Pretoria's regional biotechnology strategy. The participation of South African researchers, officials, and experts in USDA funded outreach activities as speakers and participants, adds a type of credibility to the biotechnology picture that the United States story alone could not attain. To continue strengthening the South African agricultural biotechnology position by implementing a sustained and deliberate outreach strategy will contribute significantly to harmonizing the regional biotechnology system and lead to less trade disruptions overall. FAS/Pretoria's short term goals for biotechnology in Southern Africa include:

- To seek opportunities for additional resources through the State EB biotech program, EMP funding, and other available funding sources to raise awareness of the benefits of biotechnology and the development of science-based regulatory systems in Southern Africa.
- To improve USDA-DAFF coordination within the like-minded group, including within

SADC, to promote harmonized and science-based rule-making on innovative agricultural technologies.

• To continue to facilitate the harmonization of biotechnology rule-making in the SADC region.

Regulatory stabilization and streamlining should be a focal point to capacity building activities in South Africa. These activities could include:

- Regular interaction and information exchange with regulators on GE issues.
- Regular interactions with portfolio committees in parliament.

Additionally, outreach to small scale farmers on the benefits of biotechnology should also be a focus. Expanding this outreach to include consumer groups and the general public could achieve greater understanding and acceptance of biotechnology.

# **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

Animal biotechnology also falls under the GMO Act of 1997, and any application will have to be approved by the EC. However, no animal biotechnology has been applied for review, in South Africa, at this stage. The Directorate of Biosafety in DAFF is proactive and is in the process of developing a framework for risk assessments regarding animal biotechnology.