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Biotechnology in South Africa

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Report Highlights:
The production area of Genetically Engineered (GE) corn, soybean and cotton in South Africa increased to 2.7 million hectares in 2016, a 17 percent increase from the 2.3 million drought-reduced hectares in 2015. As a result, South Africa remained the ninth largest producer of GE crops in the world and by far the largest in Africa. In December 2016, the Registrar of the "GMO" Act informed stakeholders, that all GE corn events causing asynchrony with the United States were approved and that applications for import permits was open. Since then, the United States exported 245,000 tons of corn to South Africa which made a difference in the food security status in southern Africa after drought hit the region during the 2015/16 production season. However, due to a record corn crop in 2017, South Africa returned to be a net exporter of corn with zero import demand.

EXECUTIVE SUMMARY

South Africa is a net exporter of agricultural products and exports are expected to reach about US$9 billion in 2017, up 10 percent from the previous year on better agricultural conditions. The Netherlands (nine percent of exports), United Kingdom (seven percent of exports), Botswana (six percent of exports) and Namibia (six percent of exports) are the four major destinations of South Africa's agriculture products. South Africa's exports of agricultural products to the United States are expected to reach US$270 million in 2017, a 12 percent increase from the previous year, and accounts for three percent of total agricultural exports by South Africa. Fresh fruit, macadamia nuts and wine are the major products exported to the United States.

South Africa imports agriculture products primarily from Swaziland (which accounts for nine percent of imports), Brazil (seven percent of imports), United States (six percent of imports), Argentina (five percent of imports) and Thailand (five percent of imports). South Africa mainly imports rice, poultry, wheat and palm oil. Imports from the United States are expected to increase by 25 percent to US$365 million in 2017, on higher poultry and grain imports.

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 continues to be the biotechnology leader on the Africa continent. The production area of GE corn, soybean and cotton increased to 2.7 million hectares in 2016, a 17 percent increase from the 2.3 million drought-reduced hectares in 2015. As a result, South Africa remained 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. In 2016, GE corn plantings represented approximately 81 percent of total biotechnology plantings in South Africa, while GE soybeans represented approximately 19 percent and GE cotton less than one percent. An estimated 90 percent of corn plantings, 95 percent of soybean plantings and all cotton plantings in South Africa are grown from GE seeds.

On December 5, 2016, the Registrar of the "GMO" Act informed stakeholders, that all GE corn events causing asynchrony with the United States were approved and that the applications for import permits was open. Due to the slow pace of approval by the South African government, the United States was not allowed to export GE corn to be used for food and feed to South Africa. According to the South African regulatory procedures, the application process for commodity import permits requires that the exporting country must have approved the same type and number of GE events that have been approved in South Africa. Since December 2016, South Africa imported 245,000 tons of corn from the United States which made a difference in the food security status in southern Africa after the worst drought in history. However, due to a record corn crop in 2017, South Africa returned to be a net exporter of corn with zero import demand.

PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

(a) PRODUCT DEVELOPMENT

All of the agriculture GE events currently produced commercially in South Africa were originally developed in the United States and approved by the Executive Council (EC) after a period of field trails in South Africa. Under South Africa's "GMO" Act, an EC, consisting of representatives of seven government departments is 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 to the environment and the health of humans and animals. If the EC approves the GE application, the "GMO" registrar will issue a permit. Permits may be issued for contained use, field trails or as a commercial commodity for trade (imports or exports). Most permits issued in 2015 and 2016 were for the importation of GE corn, mainly from Argentina, Brazil and the United States, due to the drought that hit South Africa in the 2015/16 production season. However, in 2017 most permits issued were for the export of GE corn, as South Africa produced a record corn crop in the 2016/17 production season.

Since 2014, 36 field and clinical trials permits were authorized from seven companies of which three events have been approved for general release (see also Table 4). Table 1 summarizes the event, trait, product and company involved for the permits issued for trail release since 2014 (please refer to the Biotechnology Gain Report 2014 for more detail on events that have been approved for trails prior to 2014). The products include corn, soybeans and cotton for evaluation of insect resistance and/or herbicide tolerance and drought tolerance in corn as well as clinical trial permits for HIV, Tuberculosis and melanoma vaccines.

Table 1: GE events approved for trial release since 2014

Company	Event	Crop/ product	Trait
Monsanto	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
	MON89034 x MON88017	Corn	Insect resistant Herbicide tolerance

	MON87460 x MON89034 x MON88017	Corn	Drought Tolerance Insect resistant Herbicide tolerance
	MON810 x MON89034	Corn	Insect resistant
	MON810 x MON89034 x NK603	Corn	Insect resistant Herbicide tolerance
Bayer	Twinlink x GlyTol	Cotton	Herbicide tolerance Insect resistant
	GlyTol x TwinLink x COT 102	Cotton	Herbicide tolerance Insect resistant
	GLTC	Cotton	Herbicide tolerance Insect resistant
	GL x LL	Cotton	Herbicide tolerance Insect resistant
Pioneer	TC1507 x MON810	Corn	Herbicide tolerance Insect resistant
	TC1507 x MON810 x NK603	Corn	Herbicide tolerance Insect resistant
	PHP37046	Corn	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
Syngenta	BT11x 1507 x GA21	Corn	Herbicide tolerance Insect resistant
	BT11 x MIR162 x GA21	Corn	Herbicide tolerance Insect resistant
	BT11 x MIR162 x 507 x GA21	Corn	Herbicide tolerance Insect resistant
	BT11x GA21	Corn	Herbicide tolerance Insect resistant
	GA21	Corn	Herbicide tolerance

	BT11	Corn	Insect resistant
Dow AgroScience	MON89034 x TC1507 x NK603	Corn	Herbicide tolerance Insect resistant
	DAS-40278-9	Corn	Herbicide tolerance
	NK603 x DAS-40278-9	Corn	Herbicide tolerance
	MON89034 x TC1507 x NK603 x DAS-40278-9	Corn	Herbicide tolerance Insect resistant
Triclinium	VPM1002	Vaccine	Tuberculosis
	ALVAC-HIV	Vaccine	HIV
Amgen	Talimogene laherparepvec (T-VEC)	Vaccine	Melanoma

Source: Department of Agriculture, Fisheries and Forestry (DAFF)

Agricultural Research Council's Biotechnology Platform

The Agricultural Research Council's Biotechnology Platform (ARC-BTP) was established in 2010 as a major strategic priority of the ARC. The role of the ARC-BTP is to create the high-throughput resources and technologies required for applications in genomics, quantitative genetics, marker assisted breeding and bioinformatics within the agricultural sector. The focus of the ARC-BTP is to establish itself as both a research and service driven institution, providing an environment to host and train highly skilled researchers. The technologies established within the platform are accessible as services to the ARC, collaborators, companies, science councils and researchers across the African continent.

GE research by the ARC focuses on vegetables, ornamental plants and indigenous crops. The ARC-BTP has identified and implemented research projects with the aim of developing new cultivars better suited to South African conditions.

The Institute for Wine Biotechnology at Stellenbosch University

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-Saccharomyces 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.

For South Africa wine is one of the major agricultural products exported to the United States by South Africa, with an annual value worth close to US$30 million.

The South African Sugarcane Research Institute

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 plasm.
- Characterization and isolation of mutates ALS gene with tolerance to *imazapyr* in sugarcane.
- Tissue specific transgene expression.

(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 has been a progressive and steady increase in GE corn plantings. Table 2 illustrates the plantings of GE corn in South Africa over the past 6 years. GE corn plantings soared from 28 percent of total corn planted in the 2005/06 production season to an estimated 90 percent in the 2016/17 production season. Of the estimated 2.6 million hectares of corn planted with GE seed in the 2016/17 production season, single insect resistant and herbicide tolerant comprised an estimated 20 percent and 19 percent, respectively. The stacked varieties (insect resistant and herbicide tolerant) accounted for an estimated 61 percent (see also Table 3 and Figure 1). White corn plantings in the 2016/17 production season were 1.6 million hectares of which an estimated 91 percent or 1.5 million hectares were planted with GE seed. Yellow corn plantings were 985,000 hectares of which an estimated 88 percent were planted with GE seed.

Table 2: Planting of GE corn in South Africa over the past 6 years

	Area planted '000 ha		
Production years	**White corn**	**Yellow corn**	**Total corn**
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	1,572	1,139	2,711
Biotech	1,323	1,041	2,364
% of total	***84%***	***91%***	***87%***
2014/15			
Total	1,448	1,205	2,653
Biotech	1,324	1,055	2,380
% of total	***91%***	***88%***	***90%***
2015/16			
Total	1,015	932	1,947
Biotech	914	821	1,735
% of total	***90%***	***88%***	***89%***
2016/17			
Total	1,615	985	2,600
Biotech	1,470	870	2,340
% of total	***91%***	***88%***	***90%***

Source: GrainSA and ISAAA

Table 3: Percentage of the GE corn crop planted with the different traits the past 6 years

Production year	Percentage GE corn plantings
2011/12	
% Insect Resistant	45
% Herbicide Tolerant	14
% Stacked	41
2012/13	
% Insect Resistant	34
% Herbicide Tolerant	15
% Stacked	51
2013/14	
% Insect Resistant	29
% Herbicide Tolerant	17
% Stacked	54
2014/15	
% Insect Resistant	29
% Herbicide Tolerant	17
% Stacked	54
2015/16	
% Insect Resistant	31
% Herbicide Tolerant	16
% Stacked	53
2016/17 (estimate)	
% Insect Resistant	20
% Herbicide Tolerant	19
% Stacked	61

Source: GrainSA

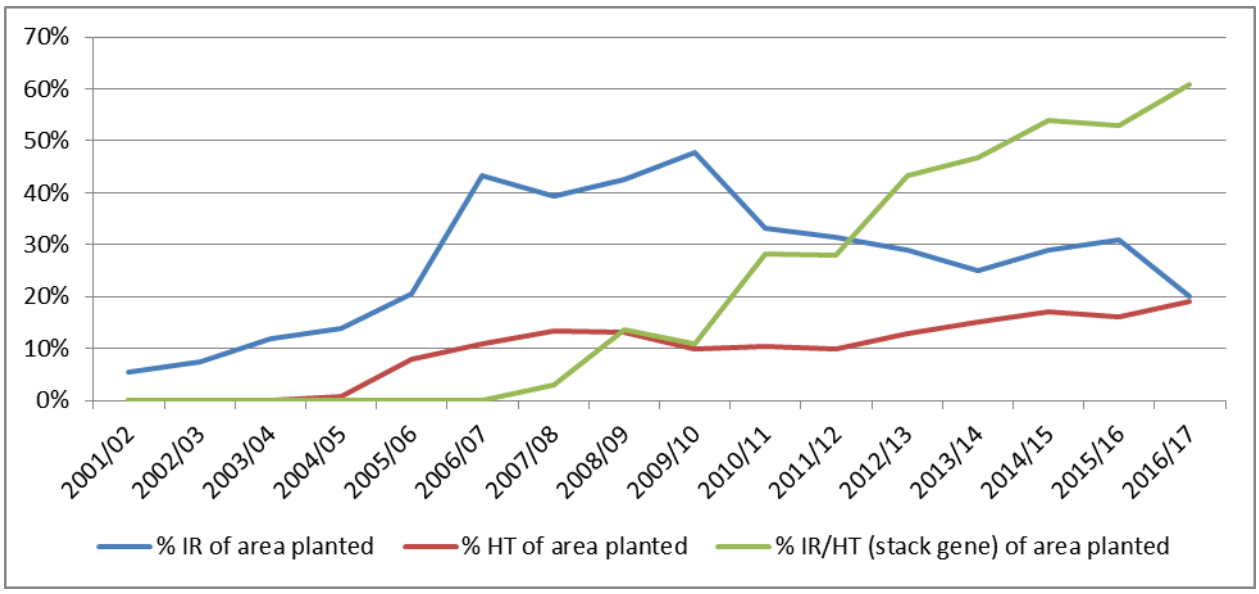

Figure 1: Corn area planted with different GE traits

The long term trend in corn production indicates South Africa is producing more corn on less area (see Figure 2). 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 3 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 the future.

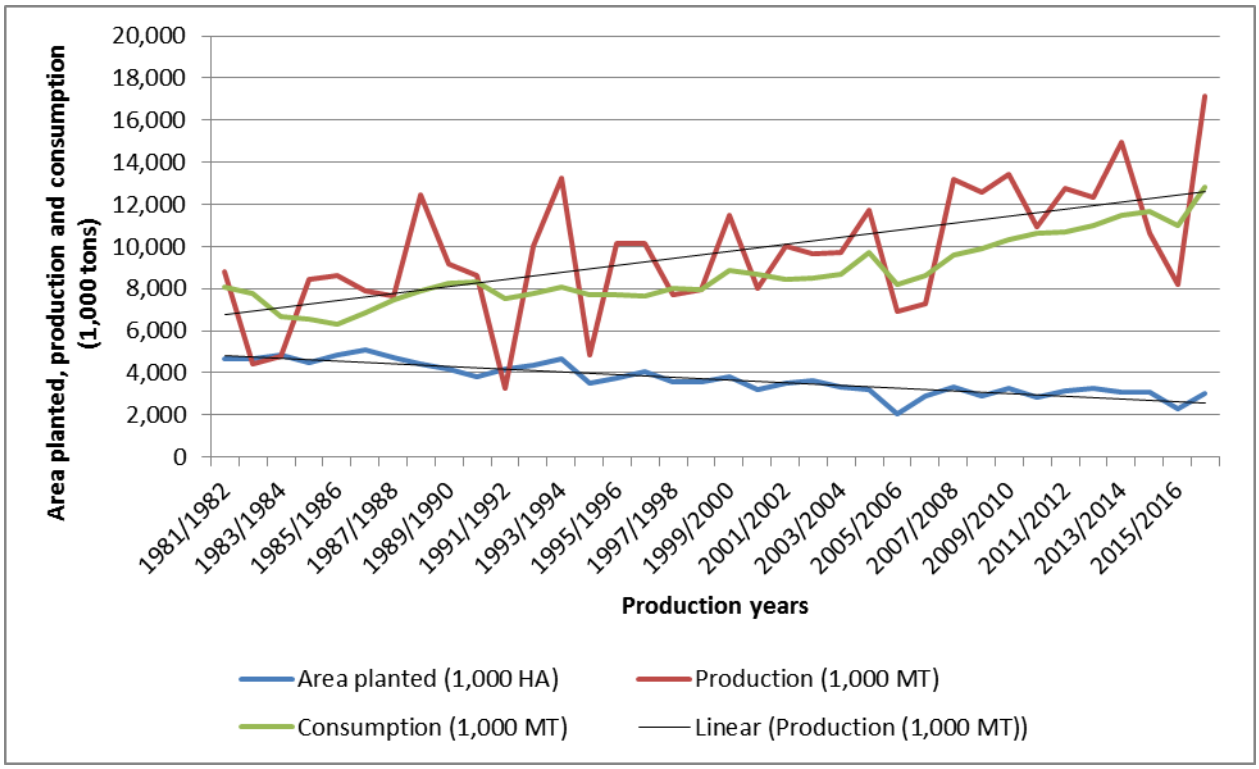

Figure 2: The trend in corn production and consumption in South Africa since the 1980's

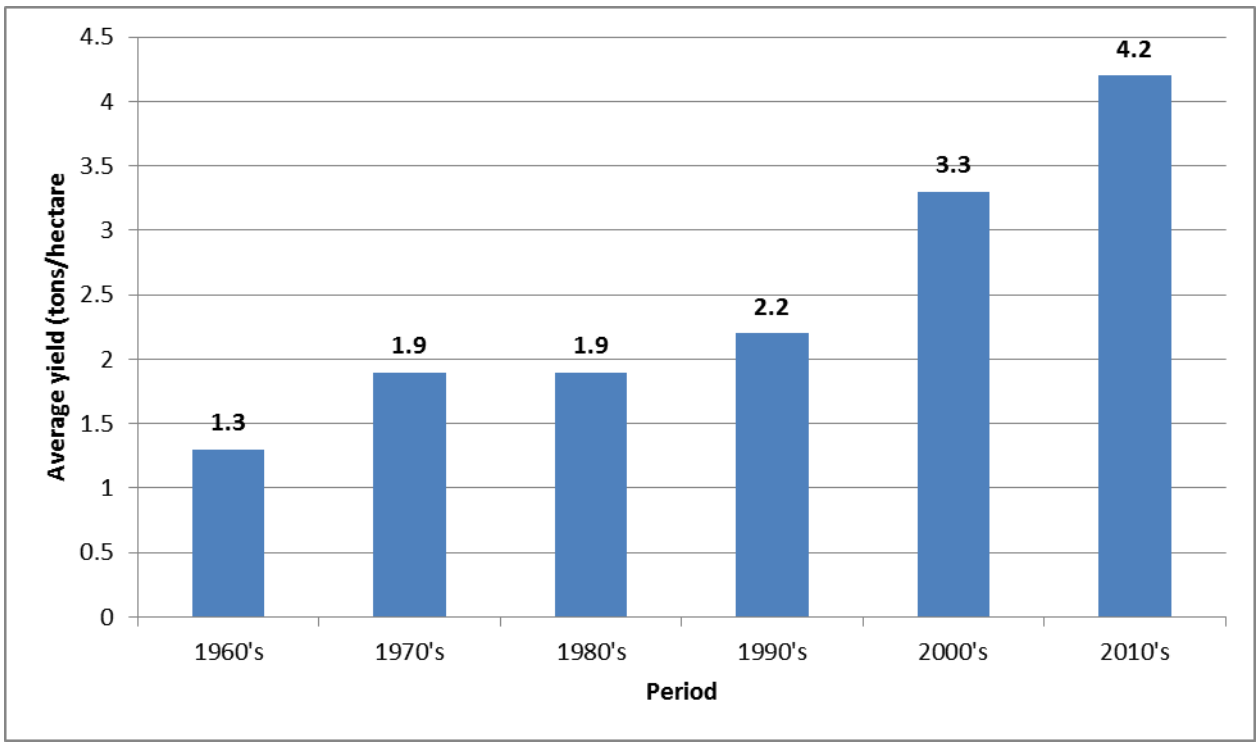

Figure 3: Trends in the average corn yields in South Africa

Soybeans

South Africa has seen a positive trend in the planting of oilseeds the past 10 years (see also Figure 4), mainly driven by an increase in soybean plantings. South Africa invested an estimated R1 billion (US$100 million) the past few years on expanding its soybean processing capacity to replace soybean meal imports. Due to the demand pull and good weather, South Africa produced a record soybean crop of 1.3 million tons in the 2016/17 production season. This represents an increase of 77 percent from the 2015/16 production season's drought reduced crop of 742,000 tons. In the 2016/17 production season the area planted with soybeans reached 573,950 hectares of which an estimated 95 percent were planted with GE seeds. GE soybean seeds were first approved for commercialization in South Africa in 2001 and by 2006, 75 percent of the soybean crop grown was GE.

For the 2017/18 production season, Post forecasts that a record area of 1.4 million hectares will be planted with oilseeds in South Africa. The bumper corn crop in the 2016/17 production season and resulting lower local corn price levels will put downward pressure on the areas to be planted with corn in the 2017/18 production season. Post forecasts that around 2.4 million commercial hectares of corn will be planted in the 2017/18 production season, which is nine percent less than the areas planted in the 2016/17 production season. Many of these unplanted corn areas will shift to oilseed plantings, especially to soybeans and sunflower. In addition, the area under oilseeds has increased on average by more than 10 percent per annum over the past ten years, due to the demand pull from the investments that have grown the oilseed processing capacity in South Africa. Hence, post forecasts a 13 percent growth in the areas planted with soybeans in the 2017/18 production season to 650,000 hectares. Based on average yields, post forecasts that South Africa will produce 2.1

million tons of oilseeds in the 2017/18 production season.

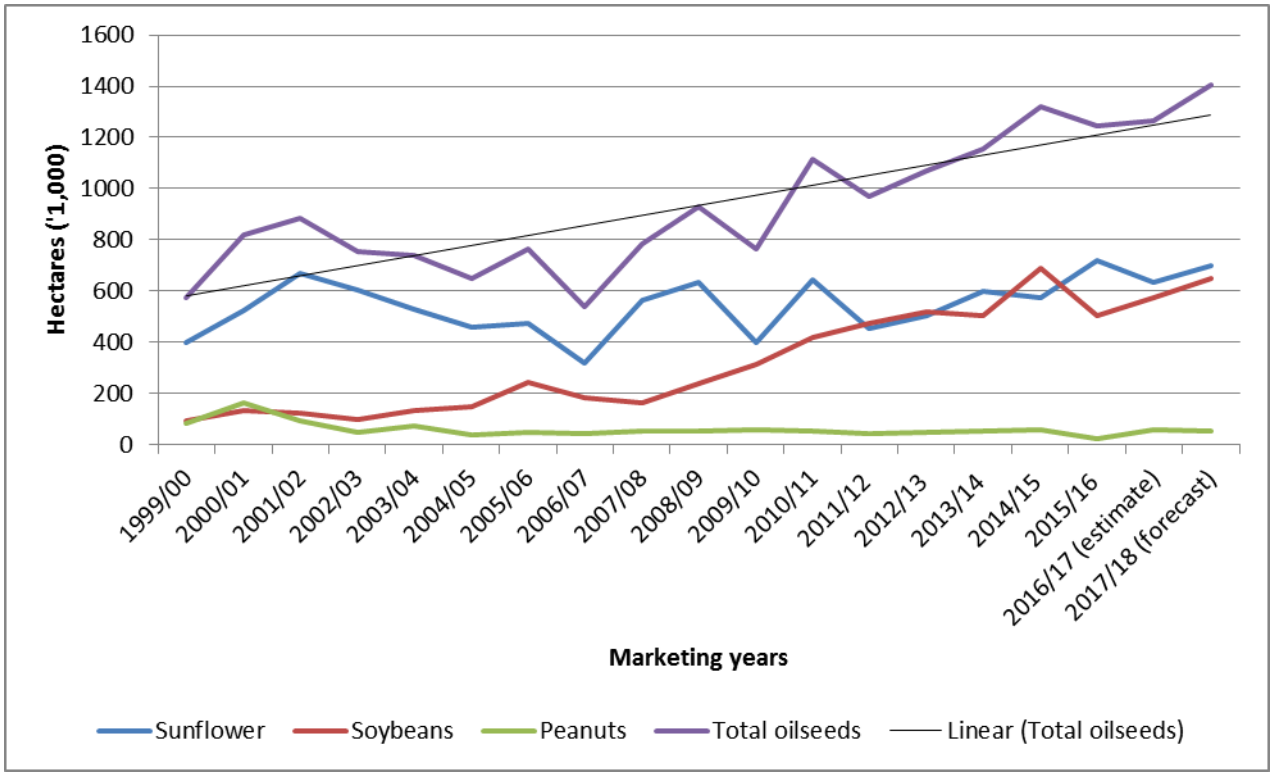

Figure 4: Trends in the area planted with oilseeds in South Africa since the 1999/00 marketing year

Cotton

Bt cotton was the first GE crop variety to be grown commercially in sub-Saharan Africa. Cotton area planted soared by 120 percent to 18,341 hectares in the 2016/17 production season, from 8,353 hectares in the 2015/16 production season. The increase in hectares planted was mainly due to better climatic conditions and positive movement in cotton prices. All cotton plantings in South Africa are GE.

(c) EXPORTS

As a result of the historically high corn crop, South Africa returned to being a net exporter of corn in the 2016/17 MY, after the drought in the previous marketing year forced South Africa to import more than 2.2 million tons. In the first 24 weeks of the 2016/17 MY (May 1, 2017 to October 13, 2017), South Africa has already exported 1.4 million tons of corn, which included 479,749 tons of white corn and 906,750 tons of yellow corn (see also Figure 5). This means South Africa is exporting almost 60,000 tons of corn per week. White corn is mainly exported to Kenya (247,250 tons), as many parts of Kenya have been impacted by drought. The major markets for South Africa's yellow corn are Japan (509,307 tons), Taiwan (213,926 tons) and South Korea (107,241 tons). Post estimates South Africa's exports will slow down through the remainder of the 2016/17

MY and will total at about 2.5 million tons. An oversupplied regional market after a favorable agricultural season and a weak global market for white corn, limits South Africa's export opportunities, which will leave a relatively large carry-over stock, especially in white corn, for the next marketing year.

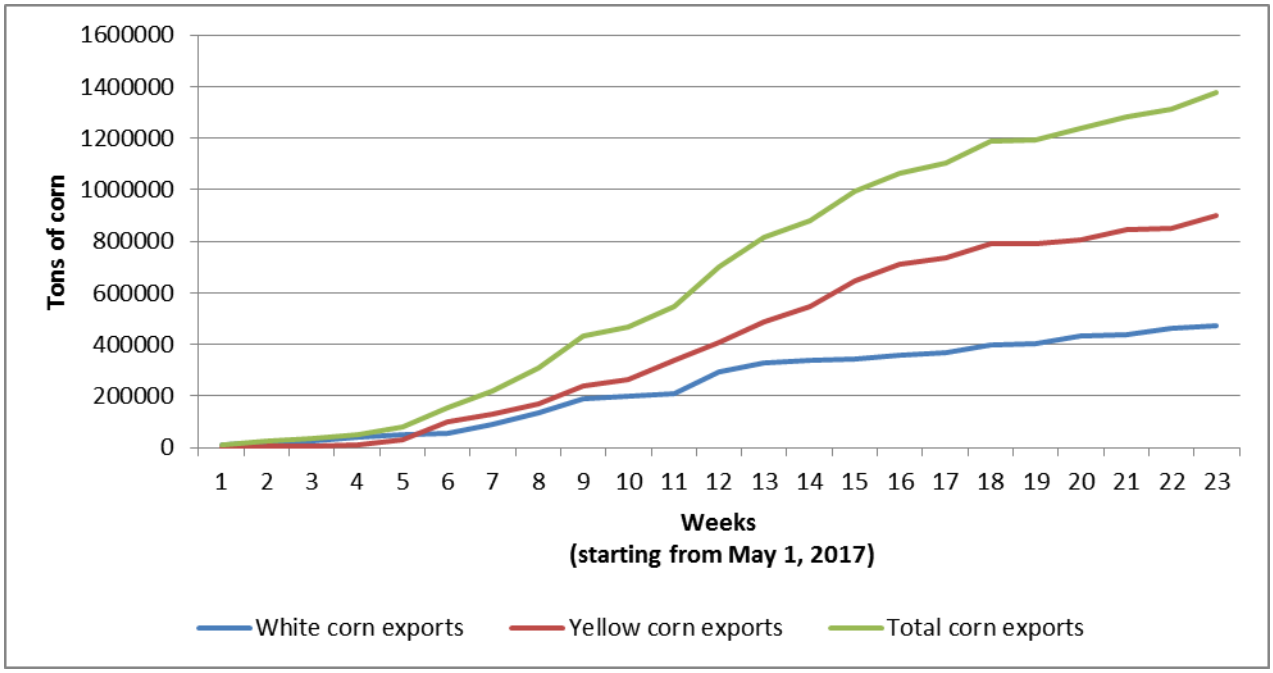

Figure 5: Acceleration of South Africa's corn exports in the midst of a record crop

(d) IMPORTS

South Africa is normally not a major importer of corn, but due to the drought, South Africa had to import 2.2 million tons of corn in the 2015/16 MY, mainly from Argentina (989,783 tons), Mexico (499,596 tons), Ukraine (371,559 tons) and the United States (244,961 tons).

For much of the season, the United States was not allowed to export corn to South Africa due to unsynchronized GE approvals. However, on December 5, 2016, the Registrar of the GMO Act informed stakeholders that the Executive Council approved all corn GE events that had caused asynchrony with the United States and invited applications for permits from importers. Due to the slow pace of approval by the South African government, the United States was not allowed to export GE corn to be used for food and feed to South Africa. All of the corn GE events currently commercially produced in South Africa were developed in the United States. Nonetheless, United States commercial corn cannot be exported to South Africa as South Africa and the United States are not synchronous in terms of certain GE event approvals for corn. According to the South African regulatory procedures, the application process for commodity import permits requires that the exporting country must have approved the same type and number of GE events that have been approved in South Africa. Since December 2016, South Africa imported almost 245,000 tons of corn from the United States. Argentina, Brazil and Paraguay can also export GE corn to South Africa. However, due to a record corn crop in 2017, South Africa returned to be a net exporter of corn with zero import demand.

(e) FOOD AID

South Africa was not a recipient of food aid despite the recent drought and return to be a net exporter of agricultural products in the current season. 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 shipment containing GE commodities 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 knowingly accepts the food aid consignment containing GE products.

(f) TRADE BARRIERS

DAFF mandates that only approved GE events are allowed into South Africa under the "GMO" Act. According to the South African regulatory procedures, the application process for commodity import permits requires the exporting country to have approved the same type and number of GE events approved in South Africa. The South African regulatory procedures for approving GE events sometimes take longer than those in supplier countries. Differences in the speed of authorizations have led 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.

PART B: POLICY

(a) REGULATORY FRAMEWORK

Historical context

In 1979, the South African government established the Committee on Genetic engineering (SAGENE). SAGENE was comprised of a group of South African scientists and commissioned to act as scientific advisory body to the government. It has paved the way for the uptake of GE in food, agriculture, and medicine in South Africa. 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, SAGENE granted 178 permits for a variety of open field GE trials. Once the "GMO" Act became effective, SAGENE ceased to exist and was replaced by an Executive Council, established under the "GMO" Act of 1997.

The "GMO" Act of 1997

The "GMO" Act of 1997, and its accompanying Regulations, is administrated by Department of Agriculture, Forestry and Fisheries (DAFF). Under the "GMO" act, a decision-making body the Executive Council (the EC), an advisory body (the Advisory Council (AC)) and an administrative body (the "GMO" Registrar) were 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 South Africa government 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 product development.

Notably, 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 a 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, namely, dealing with unintentional transboundary movements of GE products and the 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 (EC)

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

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

- DAFF
- Department of Water and Environmental Affairs
- Department of Health
- Department of Trade and Industry
- 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; where no consensus is reached, the application in question will be considered declined. For this reason it is essential that all representatives on the EC have significant knowledge of biotechnology and biosafety.

The Advisory Council (AC)

The AC consists of ten scientists who are appointed by the Minister of Agriculture, Forestry and Fisheries. The EC also has input in the appointment of members of the AC. 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 evaluating risk assessments of all applications as it relates to food, feed and environmental impact and for submitting 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 permits, amending and withdrawing permits, maintaining a register and monitoring all facilities that are used for contained use and trail release sites. Figure 6 illustrates the GE application process in South Africa.

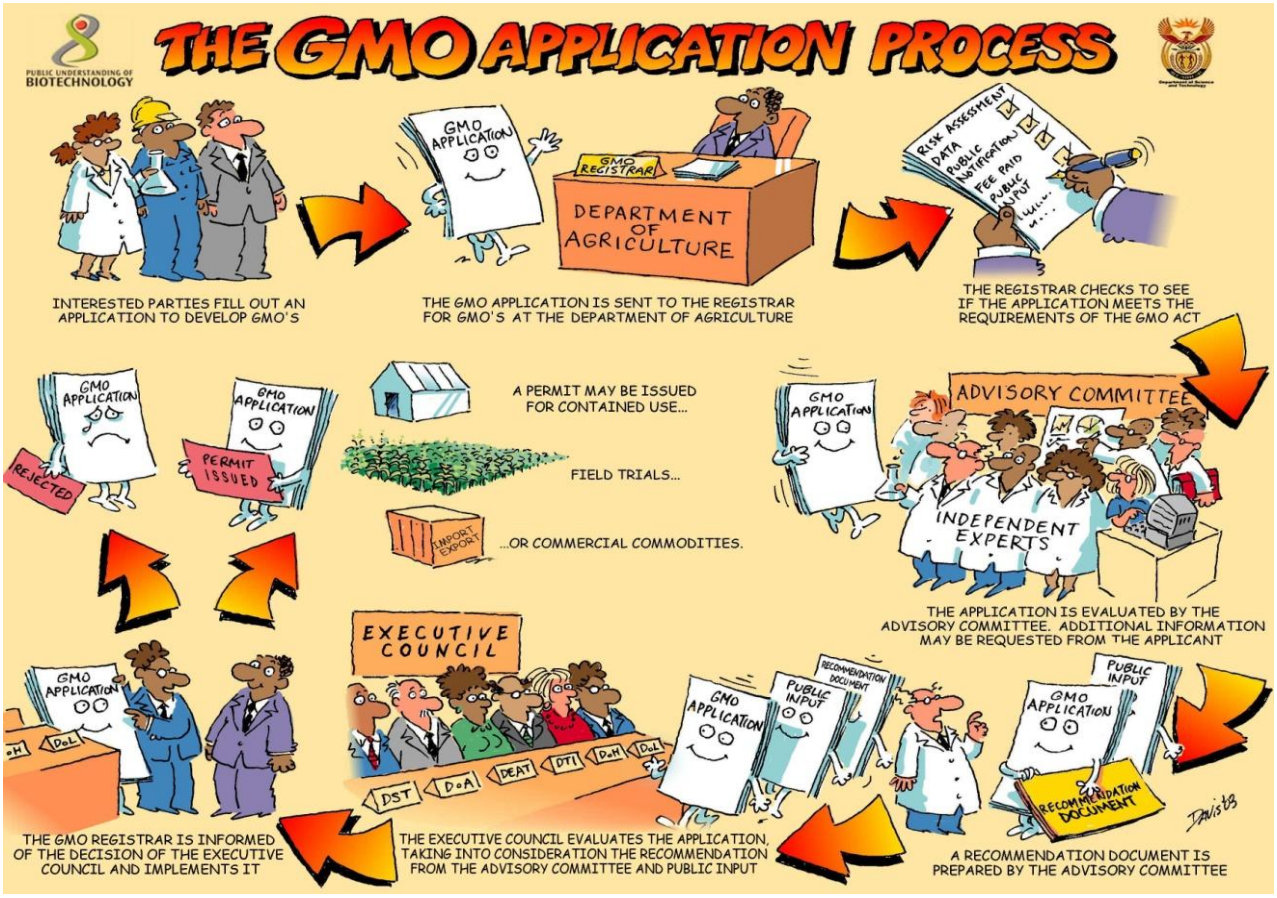

Figure 6: The GE application process in South Africa
Source: DAFF

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 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.

On April 24, 2009, the President of South Africa signed a new Consumer Protection Bill into law. Implementation of the Act 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 that virtually every product label in South Africa's food and beverage industry had to change.

On April 1, 2011, DTI published regulations 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 well-being of consumers.

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, the GE labeling

regulations are 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 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 to serve 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 4 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. Twenty-two GE events have received general release approval since 1997 in South Africa. These events are present in three crops namely, corn, soybeans and cotton. Three animal vaccines were also approved. Three new events were approved for general release in 2015, namely, the long awaited drought tolerance trait from Monsanto, MON87460, and two animal vaccines, from Intervet and Ceva Animal Health. So far in 2017, no new GE events have been approved for general release.

Table 4: GE events approved for general release in South Africa

Company	Event	Crop/product	Trait	Year approved
Intervet	Innovax-ND	Vaccine		2015
Ceva Animal Health	Vectromune HVT NDT & Ripens	Vaccine		2015
Monsanto	MON87460	Corn	Drought tolerance	2015
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 resistant	2010
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 5, GE events that have received commodity clearance are indicated. The events cover six crops, namely, corn, soybeans, canola cotton, rice and rape seed. Commodity clearance means the importation of these events for the use as food and/or feed are allowed. In 2016, 26 new events received commodity clearance to allow imports of GE commodities to supplement local production after the drought.

Table 5: GE events with commodity clearance

Company	**Event**	**Crop**	**Trait**	**Year approved**
Monsanto	MON87705 x MON89788	Soybean	Herbicide tolerant Modified oil/fatty acid	2017
Monsanto	MON87708 x MON89788	Soybean	Herbicide tolerant	2016
Bayer	FG72	Soybean	Herbicide tolerant	2016
Bayer	A5547-127	Soybean	Herbicide tolerant	2016
DowAgroSciences	DAS68416-4 x MON89788-1	Soybean	Herbicide tolerant	2016

DowAgroSciences	DAS81419-2	Soybean	Insect resistant	2016
Syngenta SA	3272 x BT11 x MIR604 x GA21	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x MON810 x MIR162	Corn	Insect resistant Herbicide tolerant	2016
Syngenta SA	BT11 x TC1507 x GA21	Corn	Insect resistant Herbicide tolerant	2016
Monsanto	MON87427 x MON89034 x MIR162 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Monsanto	MON87427 x MON89034 x 1507 x MON88017 x 59122	Corn	Insect resistant Herbicide tolerant	2016
Monsanto	MON87460 x NK603	Corn	Drought tolerance Herbicide tolerant	2016
Monsanto	MON87427 x MON89034 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x MON810 x MIR162 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x MIR604 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x MON810 x MIR604 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x 59122 x MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	TC1507 x 59122 x MON810 x MIR604 x NK603	Corn	Insect resistant Herbicide tolerant	2016
DowAgroSciences	DAS81910-7	Cotton	Herbicide tolerant	2016
DowAgroSciences	DAS-24236-5 x DAS-21023-5	Cotton	Insect resistant	2016
DowAgroSciences	MON89034 x TC1507 x MON88017 x DAS-59122-7 x DAS-40278-9	Corn	Insect resistant Herbicide tolerant	2016
DowAgroSciences	MON89034 x TC1507 x NK603 x DAS-40278-9	Corn	Insect resistant Herbicide tolerant	2016
Syngenta	3272 x BT11 x MIR604 x TC1507 x 5307 x GA21	Corn	Insect resistant Herbicide tolerant	2016
Du Pont Pioneer	DP4114	Corn	Insect resistant Herbicide tolerant	2016

Monsanto	NK603 x T25	Corn	Herbicide tolerant	2016
Syngenta	MZHG0JG	Corn	Herbicide tolerant	2016
Du Pont Pioneer	DP73496	Canola	Herbicide tolerant	2016
Monsanto	MON87460 x MON89034 x NK603	Corn	Drought tolerance Insect resistant Herbicide tolerant	2015
Syngenta	BT11 x MIR162	Corn	Insect resistant Herbicide tolerant	2015
Monsanto	MON87460 x MON89034 x MON88017	Corn	Abiotic resistance Insect resistant Herbicide tolerant	2015
Syngenta	GA21 x T25	Corn	Herbicide tolerant	2015
Syngenta	SYHT0H2	Soybean	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 tolerant	2011
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 tolerant	2011
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	2004

			Herbicide tolerant	
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	T25	Corn	Herbicide tolerant	2001
Syngenta	Bt176	Corn	Insect resistant	2001
AgrEvo	Topas 19/2, Ms1Rf1, Ms1Rf2, Ms8Rf3	Oilseed rape	Herbicide 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) STACKED EVENT APPROVALS

South Africa requires an additional approval for GE seeds that combine two or more already approved traits, such as herbicide tolerance and insect resistance known as stacked events. 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 at its first meeting of 2012, that each stacked event must be subjected to a separate safety assessment as per the "GMO" Act. Currently, eight stacked events, six for corn and two for cotton, have been approved for general release in South Africa.

(d) FIELD TESTING

South Africa does allow for field-testing of GE crops and the process is regulated by the "GMO" Act of 1997. Please refer to Table 1 for GE events that have been approved for confined field trails. According to the act, all facilities conducting GE activities must be registered with the registrar. A separate application much be lodged with the registrar in respect of each facility and applications must include:

- the name of the person taking responsibility for the facility,
- a map of the facility that indicates the different units within the facility,
- a locality map that clearly indicates where the facility is situated, including its geographic coordinates,
- a science-based risk assessment of the activity(ies) within the facility, and
- proposed risk management mechanisms, measures and strategies.

After receiving the application, the registrar approaches the AC for consideration of the application

and a recommendation. Upon registration of a facility, the registrar furnishes the applicant with proof of registration and information on relevant guidelines. The registration of a facility is valid for a period of three years, before an application for renewal must be submitted.

(e) INNOVATIVE BIOTECHNOLOGIES

Currently, the "GMO" Act (1997) regulates all non-human modifications to genomes in South Africa. However, last year the Department of Science and Technology commissioned the Academy of Science of South Africa to develop an expert report on the regulatory implications of new breeding techniques. The study was completed in 2017. The concept recognizes that new techniques may be more accurate and precise, and may thus need a lower/different level of regulatory scrutiny. After analyzing the report, the Department of Science and Technology will investigate the need for possible regulatory amendments.

(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 evaluate 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.

Currently, the only label requirement for GE products in 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) 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, and is not regulated unless determined 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.

(i) LOW LEVEL PRESENCE POLICY

South Africa has a Low Level Presence (LLP) tolerance of only one percent. However, if the product is milled or otherwise processed there is usually no importation problem.

(j) ADDITIONAL REGULATORY REQUIREMENTS

No additional seed registration is required in South Africa after GE seed is 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.

(k) 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. For cotton and corn 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.

(l) CARTAGENA PROTOCOL 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.

(m) INTERNATIONAL TREATIES/FORA

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

- The Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS);
- Codex Alimentarius Commission (Codex);
- International Plant Protection Convention (IPPC) of the Food and Agricultural Organization (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 pest; and
- Establish legal, technical and administrative measures necessary to achieve the goals of the Convention.

(n) RELATED ISSUES

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

PART C: MARKETING

(a) PUBLIC/PRIVATE OPINIONS

The newest report on the Public Perceptions of Biotechnology in South Africa was released by the Human Science Research Council (HSRC) on November 1, 2016. The report investigated *inter alia* South Africans knowledge about biotechnology, attitudes towards biotechnology, the use of biotechnology in daily life, sources of information about biotechnology and perceptions about the governance of biotechnology.

According to the report more than half of South Africa's population believes that biotechnology is good for the economy and many are in favor of purchasing GE food. The survey showed that 48 percent of South Africans were aware that they were eating GE food, and 49 percent believed that it was safe to do so. The first survey, conducted in 2004, indicated that only 21 percent of the public were familiar with the word "biotechnology", and only 13 percent of those surveyed were aware of consuming GE food. The latest survey indicated that these figures have increased significantly, to 53 percent and 48 percent, respectively.

The HSRC said these changes signified a major shift in public awareness due to increased levels of education, increased access to information, and greater prominence of biotechnology in the public discourse since the first survey in 2004. There had also been a major increase in attitudes favoring the purchase of GE food. The proportion of the public that said they take health considerations into account when purchasing GE foods increased from 59 percent to 77 percent. Those who would do it on the basis of cost considerations increased from 51 percent to 73 percent, and those who would do so on the basis of environmental considerations rose from 50 percent to 68 percent. However, the South African public is strongly in favor of labeling GE foods.

About half of the public is aware that GE crops are legally grown in South Africa. This mostly applies to corn, while the awareness of GE cotton and GE soya crops is very low. The public felt that the governance of biotechnology should be most strongly influenced by commercial farmers, university scientists, and environmental groups. The least favored institutions for this purpose are seen to be international corporations, the general public, the media and religious organizations.

While the survey reveals a significant improvement in the public's understanding and awareness of biotechnology, the levels of understanding remain broadly linked to living standards measures,

demographics, and levels of education. If compared to public perceptions of biotechnology studies in developed countries, the results of this study clearly show that the South African public can be broadly described as less informed, but more positive about biotechnology and specifically GE foods.

(b) MARKET ACCEPTANCE/STUDIES

On the production side, South African farmers can be divided into two categories, namely, commercial famers and small/emerging farmers. GE products have a wide appeal with both groups with an estimated 90 percent of corn, 95 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. However, the adoption rate remains relatively low amongst subsistence farmers.

On the consumption side, South Africa uses more than 10 million tons of corn commercially on an annual basis, 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 1.5 percent per year over the past 20 years, while the commercial demand for feed corn increased on average by two percent per year (see also Figure 7). Projections are that these increases in demand for corn will continue in the future.

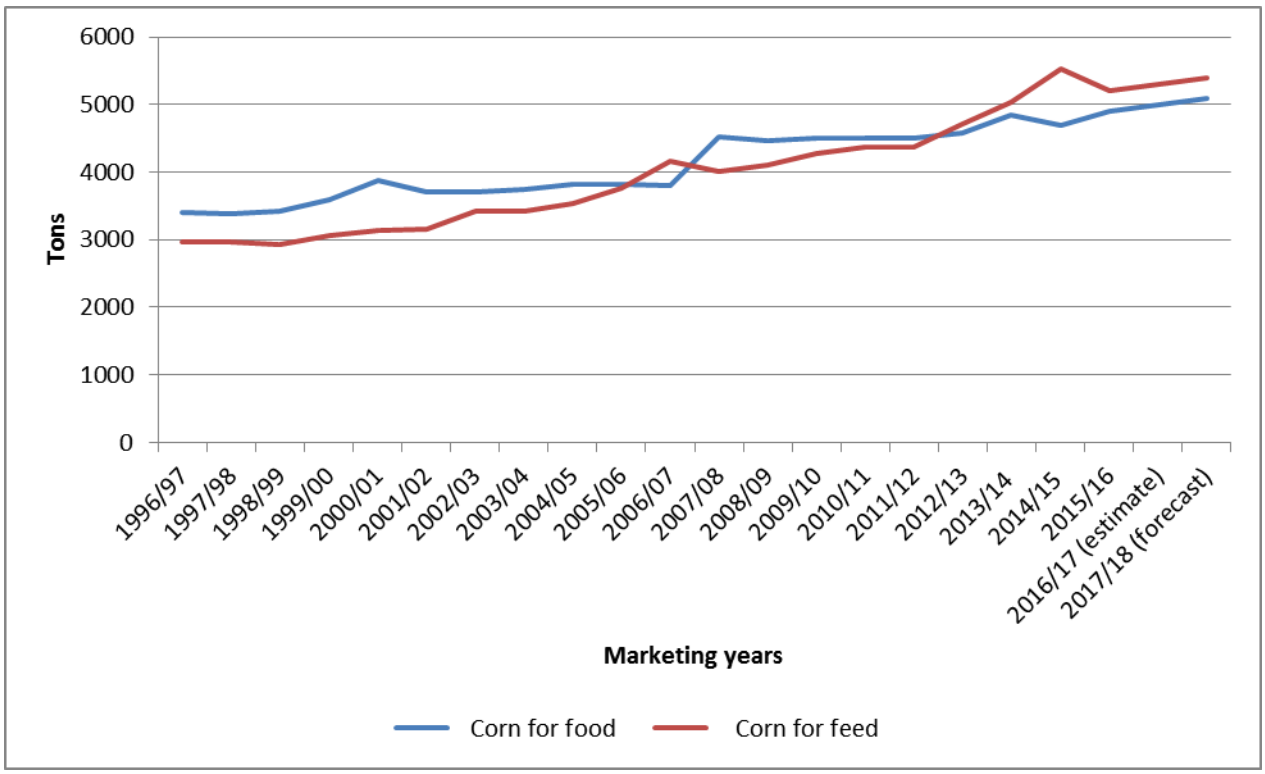

Figure 7: The commercial consumption of corn in the food and feed markets of South Africa since the 1996/97 MY.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

(a) PRODUCT DEVELOPMENT

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. Post is also not aware of any animal clones that are under development in South Africa.

(b) COMMERCIAL PRODUCTION

There is no commercial production of GE or cloned animals in South Africa.

(c) EXPORTS

South Africa does not export products from GE or cloned animals.

(d) IMPORTS

South Africa does not import products from GE or cloned animals.

(e) TRADE BARRIERS

Not applicable

PART E: POLICY

(a) REGULATORY FRAMEWORK

As mentioned above, animal biotechnology falls under the GMO Act of 1997. The "GMO" Act of 1997, and its accompanying Regulations, is administrated by Department of Agriculture, Forestry and Fisheries (DAFF). Under the "GMO" act a decision-making body (the EC), an advisory body ((AC) and an administrative body (the "GMO" Registrar) were 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 South African government 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. The Directorate of Biosafety in DAFF is proactive and is in the process of developing a framework for risk assessments regarding animal biotechnology.

On the other hand, animal cloning is not specifically regulated in South Africa, although related regulations and Research and Development ethics guidelines are applicable, including the Animal Improvement Act and the guidelines of the National Health Research Ethics Council (NHREC).

The Animal Improvement Act does not currently cover animal cloning. At the moment, the act regulates for artificial insemination and embryo transfer. However, the act is under review and after the process amendments will be published to address cloning.

NHREC is a statutory body established under the National Health Act No 61 of 2003. The Act mandates the Minister of Health to establish the Council and it sets out NHREC's functions, which in short involves giving direction on ethical issues relating to health and to develop guidelines for the conduct of research involving humans and animals. The Council observes and advises on international developments in health ethics issues through liaison with relevant international

organisations.

(b) INNOVATIVE BIOTECHNOLOGIES

Not applicable

(c) LABELING AND TRACEABILITY

Not applicable

(d) INTELLECTUAL PROPERTY RIGHTS

Not applicable

(e) INTERNATIONAL TREATIES/FORUMS

Not applicable

(f) RELATED ISSUES

Not applicable

PART F: MARKETING

(a) PUBLIC/PRIVATE OPINIONS

Post is not aware of any research that was done in South Africa to determine the public's opinion regarding livestock clones or GE animals in South Africa.

(b) MARKET ACCEPTANCE/STUDIES

Not applicable