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Report Highlights:

South Africa has a robust and experienced regulatory system for genetically engineered (GE) products, which started with the publication of its "GMO" act in 1997. This enabled South Africa to be placed in the top-10 of largest producers of GE crops in the world and by far the largest in Africa. The production area of GE corn, soybean, and cotton in South Africa is estimated at around 3.0 million hectares. Almost 90 percent of corn plantings, 95 percent of soybeans plantings, and all cotton plantings in South Africa are with GE seeds. This year's report includes a section on microbial biotechnology derived products used as ingredients in the food sector of South Africa.

Executive Summary:

South Africa is a net exporter of agricultural products and exports are expected to reach about US\$10.0 billion in 2020. South Africa's exports of agricultural products to the United States are expected to be around US\$400 million in 2020, on the same level as the previous year. The United States accounts for about 4 percent of South Africa's total agricultural exports. Citrus, macadamia nuts, and wine are the major products exported to the United States. South Africa's agricultural imports from the United States are expected to decline by 20 percent to US\$320 million in 2020, due to the impact of the COVID-19 pandemic on the South African economy. The major agricultural products South Africa imports from the United States are poultry, wheat, corn seed, almonds, food ingredients and enzymes.

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 African continent. South Africa cultivates three GE agricultural crops commercially, namely corn, soybeans and cotton. In the 2019/20 production season, a total of 3.3 million hectares of these three crops were planted in South Africa of which an estimated 3.0 million hectares where planted with GE seeds. This places South Africa in the top-10 of largest producers 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. An estimated 90 percent of corn plantings, 95 percent of soybean plantings, and all cotton plantings in South Africa are grown from GE seeds.

Twenty GE plant events have received general release approval since 1997 in South Africa. This means these events can be used for commercial plantings, for food and/or feed, and the import and export of these events are allowed. These events are present in three crops namely, corn, soybeans, and cotton. Three animal vaccines were also approved.

South Africa is a net exporter of corn in most years, except when drought limits production. Post estimates South Africa should be able to export about 2.5 million tons of corn in the 2019/20 marketing year (MY) (May 1, 2020 – Apr 30, 2021), after farmers produced the second highest corn crop on record. Corn exports continue amidst a COVID-19 lockdown that started on March 27, 2020, as the South Africa government labeled the food supply system as an essential sector that needs to remain uncompromised and functional. Much of the white corn exports in the 2019/20 MY will be destined to South Africa's neighboring countries, especially Zimbabwe. Zimbabwe is in need of at least 1.0 million tons of corn to meet local demand after drought conditions impacted negatively on crop yields. Zimbabwe also lifted restrictions on the importation of GE corn, supporting increased corn imports from South Africa. With excess corn available, South Africa is also in a position to export corn, especially yellow corn, beyond its neighboring countries to other markets such as Taiwan, South Korea and Japan. South Africa did not export or import any corn to or from the United States the past three seasons.

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PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

(a) PRODUCT DEVELOPMENT

South Africa has been involved with biotechnology research and development for over 30 years and continues to be the biotechnology leader on the African continent. Up to date, South Africa approved 20 GE plant events for commercial production (see Table A1 in the appendix) and in the past 6 years, 44 field trials permits were authorized from 10 companies (see Table A2). Table A2 in the appendix summarizes the event, trait, product, and company involved for the permits issued for trail release clearance since 2014. The commodities included corn, soybeans, and cotton for evaluation of insect resistance, herbicide tolerance and drought tolerance.

Several parastatals, universities and agricultural industry organizations in South Africa are involved in innovative GE research. For example:

The 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 in which highly skilled researchers can be hosted and trained. 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. Research projects have been identified and implemented by the division 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.

Wine is one of the major agricultural products exported to the United States by South Africa, with an annual value worth around 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

South Africa at present cultivates three GE agricultural crops commercially, namely corn, soybeans and cotton. In the 2019/20 production season, a total of 3.3 million hectares of these three crops were planted in South Africa of which an estimated 3.0 million hectares where planted with GE seeds. This places South Africa in the top-10 of largest producers of GE crops in the world and by far the largest in Africa. GE corn plantings represent about 77 percent or 2.3 million hectares of the 3.0 million hectares GE plantings in South Africa, followed by GE soybeans, representing 22 percent or approximately 670,000 hectare and GE cotton representing only 1 present.

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) with an annual average production of more than 12.0 million tons. In 1997, the first GE corn event (insect resistant) was approved in South Africa and since then there has been progressive and steady increase in GE corn plantings to almost 90 percent of total corn plantings today. Table 1 illustrates the plantings of GE corn in South Africa over the past 7 years. Of the 2.6 million hectares of corn planted with GE seed in the 2019/20 production season, an estimated 2.3 million hectares were planted with GE seeds. The 2019/20 production season corn crop at

15.5 million tons is the second highest commercial corn crop ever produced in South Africa at a national average yield of 5.9 tons per hectare. The commercial white corn crop is estimated at 9.1 million tons, an increase of 64 percent from the previous season, while the commercial yellow corn crop is estimated at 6.4 million tons, 12 percent higher than the previous season.

White corn plantings in the 2019/20 production season were 1.6 million hectares, of which an estimated 89 percent or 1.4 million hectares were planted with GE seed. Yellow corn plantings were almost 1.0 million hectares, of which an estimated 87 percent were planted with GE seed. More than 80 percent of GE seed planted in South Africa consists of stacked varieties (insect resistant and herbicide tolerant, while single insect resistant and herbicide tolerant events in total comprised of less than 20 percent of total GE corn plantings.

Table 1: Planting of GE corn in South Africa over the past 7 years

	Area planted (1,000 ha)				
Production years	White corn	Yellow corn	Total corn		
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	1,643	985	2,629		
Biotech	1,580	885	2,465		
% of total	96%	90%	94%		
2017/18					
Total	1,268	1,050	2,318		
Biotech	1,215	955	2,170		
% of total	96%	91%	94%		
2018/19 (estimate)					
Total	1,298	1,002	2,300		
Biotech	1,140	870	2,010		
% of total	88%	87%	87%		
2019/20 (estimate)					
Total	1,616	995	2,611		
Biotech	1,435	865	2,300		
% of total	89%	87%	88%		

Source: GrainSA and ISAAA

The long-term trend in corn production indicates that 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 South Africa's average corn yield more than doubled over the past 20 years. Indications are that this trend of producing more corn on fewer hectares will continue in the future.

Figure 1: The area planted and production of commercial corn in South Africa the past 100 years

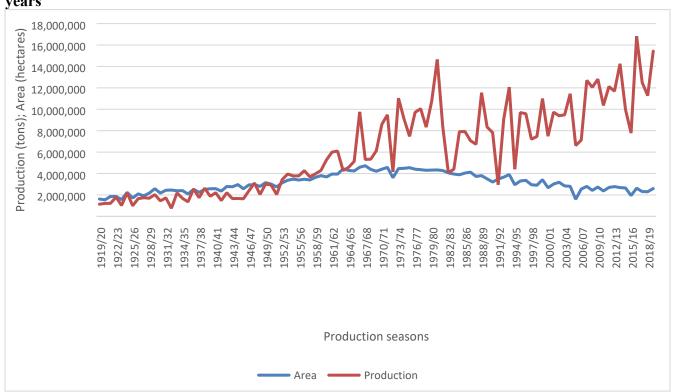
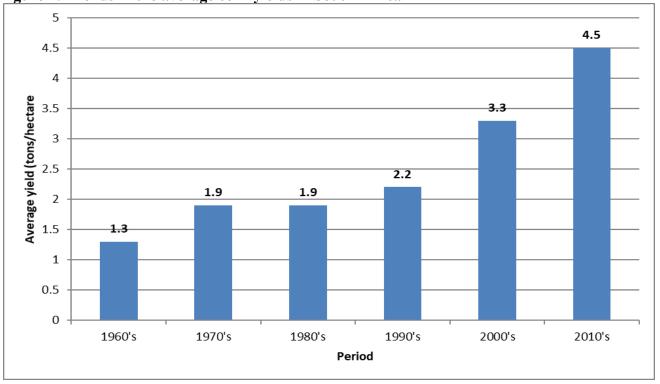


Figure 2: Trends in the average corn yields in South Africa



Soybeans

South Africa demonstrates a positive trend in soybeans production over the past 10 years, mainly driven by an expansion in soybean processing capacity to replace soybean meal imports and the adoption of GE soybeans (see Figure 3). In addition, many producers have realized the positive attributes of soybeans if used in a rotational system with corn. As a result, the area planted with soybeans in South Africa more than doubled over the past 10 years. GE soybeans were first approved for commercialization in South Africa in 2001 and by 2006, 75 percent of the soybean crop grown was GE. Estimates are that currently more than 95 percent soybeans are planted with GE seeds.

In the 2019/20 production season, producers planted 705,000 hectares of soybeans, producing 1.3 million tons. Post believes the positive trend will continue in the 2020/21 production season and producers will plant 750,000 hectares with soybeans.

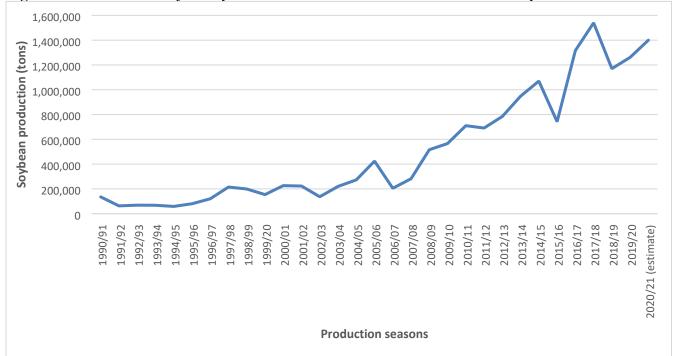


Figure 3: The trend in soybean production in South Africa since the 1990/91 production season

Cotton

Cotton area planted decreased by 32 percent to 28,350 hectares in the 2019/20 production season. The decrease in hectares planted was mainly due to seed availability, restructuring of ginning capacity and unfavorable growing conditions at the beginning of the planting season. All cotton plantings in South Africa are GE.

(c) EXPORTS

South Africa is a net exporter of corn in most years, except when drought limits production. Post estimates South Africa should be able to export about 2.5 million tons of corn in the 2019/20 MY (May 1, 2020 – Apr 30, 2021) on a bumper crop. In the first three months of the 2019/20 MY, South Africa exported 1.1 million tons of corn (839,796 tons of yellow corn and 290,762 tons of white corn). Corn exports continue amidst a COVID-19 lockdown that started on March 27, 2020, as the South Africa government designated the food supply system to be an essential sector that needs to remain uncompromised and functional. Much of the white corn exports in the 2019/20 MY will be destined for South Africa's neighboring countries, especially Zimbabwe. Zimbabwe needs at least 1.0 million tons of corn to meet local demand after drought conditions negatively impacted crop yields. South Africa is in a perfect position to supply Zimbabwe with corn, after producing a bumper commercial corn crop of more than 15.5 million tons. In order to receive South African corn, Zimbabwe temporarily lifted restrictions on the importation of GE corn. Moreover, a large commercial corn crop enables South Africa to export corn, especially yellow corn, beyond its neighboring countries to other markets such as Taiwan, South Korea and Japan (see Table 2).

In the 2018/19 MY (May 1, 2019 – Apr 30, 2020), South Africa exported 1.4 million tons of corn consisting of 1.0 million tons of white corn and 410,000 tons of yellow corn. The major markets for South African corn were mainly its neighboring countries, with Zimbabwe, Botswana, Namibia, Mozambique, Eswatini (Swaziland) and Lesotho representing almost 90 percent of total corn exports (see Table 2). After Zimbabwe lifted restrictions on the importation of GE corn late in 2019, South Africa increased corn exports to Zimbabwe to such an extent that Zimbabwe emerged as South Africa's main corn export market in the 2018/19 MY. South Africa did not export any corn to the United States.

Table 2: South Africa's exports and imports of corn in the 2018/19 MY and 2019/20 MY

	2018/19				2019/20 MY ¹			
May	1, 2019 – A		0	Mag		- Apr 30,	2021	
	(1,000 to			(1,000 tons)				
Countries	White	Yellow	Total	Countries	White	Yellow	Total	
	corn	corn			corn	corn		
<u>Export</u>				<u>Export</u>				
Destinations				Destinations				
Zimbabwe	268	72	340	Taiwan	0	323	323	
Botswana	191	85	276	South Korea	0	258	258	
Namibia	181	66	247	Zimbabwe	118	25	143	
Mozambique	162	50	212	Japan	0	102	102	
Eswatini	45	109	154	Botswana	73	18	91	
Ethiopia	74	0	74	Vietnam	0	55	55	
Lesotho	52	13	65	Mozambique	38	11	49	
Somalia	23	0	23	Eswatini	14	29	43	
Tanzania	23	0	23	Namibia	12	17	29	
Uganda	20	0	20	Ethiopia	20	0	20	
North Korea	0	9	9	Lesotho	16	2	18	
South Korea	0	6	6					
TOTAL				TOTAL				
EXPORTS	1,039	410	1,449	EXPORTS	291	840	1,131	
<u>Import</u> suppliers								
Argentina	0	460	460					
Brazil	0	50	50					
TOTAL IMPORTS	0	510	510	TOTAL IMPORTS	0	0	0	

Source: SAGIS

Note: 1. Preliminary export and import data from May 1, 2020 to August 7, 2020

South Africa's exports of soybeans are relatively small as most local production is processed locally to produce oil and protein meal. Soybean exports in the 2018/19 season totaled a mere 5,336 tons, all destined for Zimbabwe. Post expects exports of soybeans will continue to be limited in the near future as local crushing plants have enough capacity to process most of the locally produced soybeans.

(d) IMPORTS

South Africa allows the importation of GE crops and GE processed products as long as synchronized approvals exist. Table A3 in the appendix list the 57 GE events that received commodity clearance in South Africa. This means these GE events received approval to be imported into South Africa to be used for food and/or feed.

South Africa is normally not a major importer of corn, but imported about 510,000 tons of yellow corn from Argentina and Brazil in the 2018/19 MY to augment local production (see Table 2). Due to the bumper crop, South Africa will not import any corn in the 2019/20 MY.

In the 2018/19 MY, South Africa imported a small number of soybeans (9,098 tons), mainly from Zambia and Mozambique. Imports of soybeans from these countries is not expected in the 2019/20 MY due to increased local production.

(e) FOOD AID

South Africa is not a recipient of food aid even in years of drought. However, international food aid destined for Lesotho, Swaziland, Zambia, and Zimbabwe ordinarily passes through the South Africa's major port of Durban. In order for shipments containing GE commodities to pass through South Africa, the "GMO" Registrar's office requires several measures, including an advance notification to ensure that proper containment measures can be taken. A letter from the recipient country stating that it accepts the food aid consignment and that it contains GE products is also required.

(f) TRADE BARRIERS

Department of Agriculture, Land Reform and Rural Development (DALRRD) (previously Department of Agriculture, Forestry and Fisheries) 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 that the exporting country must have approved the same type and number of GE events that have been 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 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.

In the past, 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 all corn GE events that had caused asynchrony with the United States had been approved by the Executive Council. As a result, South Africa imported almost 300,000 tons of corn from the United States.

PART B: POLICY

(a) REGULATORY FRAMEWORK

In South Africa, GE agricultural plant product development is regulated by the "GMO" Amendment Act of 1997 (Act 15 of 1997). The "GMO" Act is administered by DALRRD. The Act uses a system under which any party conducting activities with GE products must apply for permit approval. Under South Africa's "GMO" Act, an Executive Council (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 a GE application is approved, the "GMO" registrar will issue a permit. Permits may be issued for contained use, field trails, commodity clearance (importation for use as food or feed) and general release for commercial use within South Africa.

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 was 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, 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 under the "GMO" Act of 1997.

The "GMO" Act of 1997

The "GMO" Act of 1997, and its accompanying Regulations, is administrated by DALRRD. Under the "GMO" Act, a decision-making body (the Executive Council (EC)), an advisory body (the Advisory Council (AC)), and an administrative body (the "GMO" Registrar) were established. The main functions of these bodies are 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.

The "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. These amendments to the "GMO" Act were published Aon 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.

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. A new definition of "accident" was 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

The EC functions as an advisory body to the Minister of DALRRD 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 consists of representatives of different departments within the South African government. These include:

- DALRRD
- Department of Environment, Forestry and Fisheries
- Department of Health
- Department of Trade and Industry
- Department of Higher Education, Science and Technology
- Department of Employment and Labor
- Department of Sports, 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 declined. For this reason, it is essential that all representatives on the EC have significant knowledge of biotechnology and biosafety.

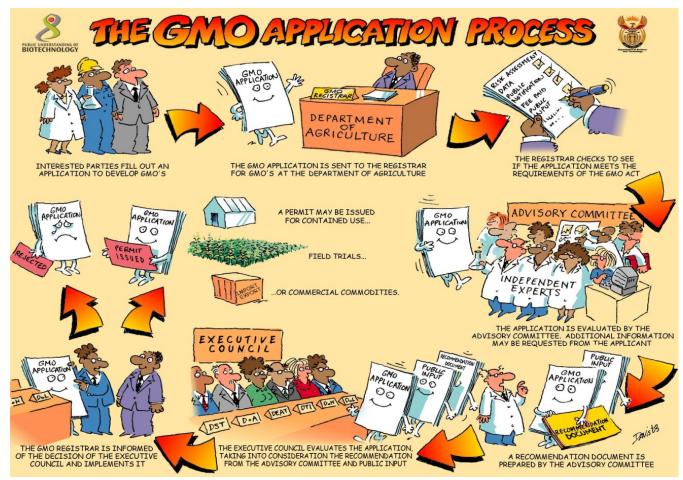
The Advisory Council

The AC consists of ten scientists who are appointed by the Minister of Agriculture, Land Reform and Rural Development. 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 the evaluation of 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 Land Reform and Rural Development 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 trial release sites. Figure 4 illustrates the GE application process in South Africa.

Figure 4: The GE application process in South Africa



Other regulations that impact 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 Environment, Forestry and Fisheries 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.

(b) APPROVALS

Table A1 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 import and export of these events are allowed. Twenty GE plant events have received general release approval since 1997 in South Africa. These events are present in three crops namely, corn, soybeans, and cotton. The last event that got general release approval was in 2018, namely, DowAgroSciences SA's stack insect resistant and herbicide tolerant event for corn. No new GE events have been approved for general release in 2019 and 2020.

In Table A3 in the appendix, GE events that have received commodity clearance are indicated. The events cover six crops, namely, corn, soybeans, canola cotton, rice, and rapeseed. Commodity clearance means that South Africa allows the importation of these events for the use as food and/or feed. So far in 2020, 3 new events received commodity clearance. In 2019, no new events received commodity clearance, while 13 new events received commodity clearance in 2018.

(c) STACKED EVENT APPROVALS

South Africa requires an additional approval for GE planting seeds that combine two or more 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. This requirement is delaying the approvals of new stacked events in South Africa. The EC reconfirmed in its first meeting of 2012, that each stacked event must undergo a separate safety assessment as per the "GMO" Act. Currently, ten stacked events (insect resistant and herbicide tolerant), eight for corn and two for cotton, have been approved for general release in South Africa.

(d) FIELD TESTING

South Africa allows for field-testing of GE crops under the "GMO" Act of 1997. Please refer to Table A1 in the appendix 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 of the "GMO" Act. A separate application must be logged with the registrar for 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 activities within the facility, and
- the 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 modifications to genomes in South Africa. However, in 2015, 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 (NBTs) in South Africa. The study concluded that South Africa has a robust and experienced regulatory system for GE products, which can without much change be applied to also effectively regulate the products of NBTs. The basic elements for allowing this is that the current "GMO" Act has a product-based trigger and sets genetic variations beyond that which may also occur naturally as the threshold for regulation.

(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 AND TRACEABILITY

South Africa has had compulsory labelling regulations in place since 2004 when the Department of Health (DOH) introduced labelling regulations under the Foodstuffs, Cosmetics and Disinfectants Act (1972) – Regulation 25 (see also Regulations relating to the labelling of foodstuffs obtained through certain techniques of genetic modification (R25/2004). This regulations mandates labeling of GE foods only in certain cases, including when allergens or genes with human or animal origin are present, and when a GE food product differs significantly from a non-GE equivalent in terms of their composition, nutritional value, mode of storage, preparation or cooking. 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. As all current GE foods are considered substantially equivalent, i.e. do not differ from the conventional counterpart, these regulations have never been triggered.

In contrast, the Consumer Protection Act from the Department of Trade and Industry that has been in force since April 1, 2011 states that all GE goods must be labelled. The primary purpose of the law is to prevent exploitation or harm of consumers and to promote their social well-being. As a result, the 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".
- Products containing less than one percent GE content may be labeled as "does not contain genetically modified organisms".

Regulation 25 is based on health and food safety concerns, while the Consumer Protection Act is purely value-based, hinging on the consumer's intrinsic right to information to make an informed choice or decision about food.

Draft amendments to the Act's GE regulations were published in October 2012, in essence only changing the wording from "labelling genetically modified organisms" to "labelling genetically modified ingredients or components." A significant implication of this change is that ingredients will have to be labelled individually as "containing GMO's" and not the whole product.

Serious concerns were raised regarding the limitations of the Act on GE labeling by the business community in South Africa, but no further productive action has been taken by the Department to develop more practical guidelines. As a result, new GE labeling regulations under the Consumer Protection Act have not yet been published, precluding any required GE labeling by stakeholders in the food supply chains of South Africa.

(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 considered to have health considerations. However, routine inspections by authorized inspectors are allowed under the "GMO" act to examine commodities and take samples to test if unapproved GE are 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 are usually no importation problems. South Africa's 2016 effort to bring their approval in to synchrony with the United States and other producers was a proactive step toward avoiding LLP situations. Rather than testing for unapproved events, South Africa compares the number and type of events approved in the exporting country to its own.

(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 World Trade Organization (WTO). 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.

Intellectual property right enforcement for Soybeans is more complicated. 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 self-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. As a result, the Minister of Agriculture, Land Reform and Rural Development approved a statutory levy on soybeans on 22 June 2018, according to which seed companies can be compensated for their performance in the soybean seed market in South Africa. The Breeding and Technology levy on soybeans has been approved for 2 years and took effect on March 1, 2019. The levy has been set at R65 (\$4.40) per ton for the first year and R80 (\$5.40) per ton for the second year. These values are calculated at 1.2 percent of the previous marketing year's average soybean price and will be payable when producers sell their soybeans. The soybean levy will be administered by the SA Cultivar and Technology Agency (SACTA) and paid to seed companies according to their market share. SACTA is a non-profit company established to administer seed levies for all self-pollinated crops. Levies on wheat and barley for this purpose have already been collected and paid by SACTA for a second year.

(I) CARTAGENA PROTOCOL RATIFICATION

South Africa has signed and ratified the Cartagena Protocol on Biosafety (CPB). South Africa, under the leadership of DALRRD's "GMO" Regulatory Office, has modified its "GMO" Act to align with the CPB.

(m) INTERNATIONAL TREATIES and FORUMS

South Africa is a signatory member of the following relevant treaties:

- 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):
- The Convention on Biological Diversity;
- International Grains Agreement.

South Africa does not actively participate in discussions related to GE plants within these international organizations.

(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

A 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 and the use of biotechnology in daily life. The research also investigated participants' sources of information regarding 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 favour 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 favouring the purchase of GE food. The proportion of the public that said they would purchase GE foods taking health considerations into account 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 from 50 percent to 68 percent. However, the South African public are strongly in favour of labelling GE foods.

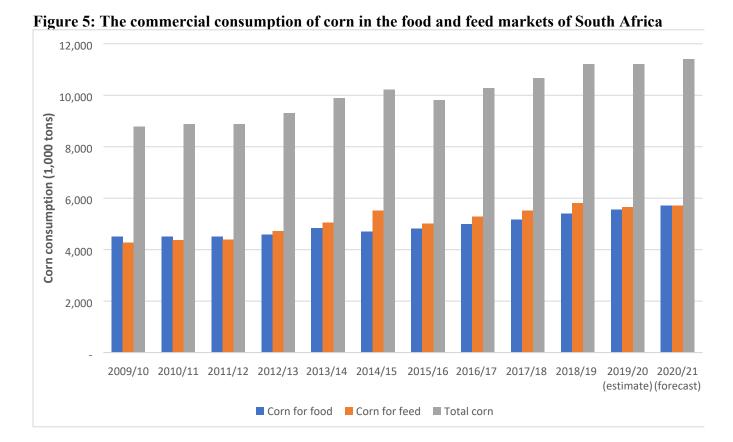
About half of the public is aware that GE crops are legally grown in South Africa. This mostly applies to corn, while the awareness of GE cotton and GE soya crops is very low. The public felt that the governance of biotechnology should be most strongly influenced by commercial farmers, university scientists, and environmental groups. The least favoured 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 and small-scale/emerging farmers. GE products have a wide appeal with both groups with almost 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. Small-scale farmers also find GE crops easier to manage than traditional or conventional hybrid varieties.

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. In fact, white corn is the staple food for many South Africans, especially for the lower to middle income group, and per capita consumption is estimated at around 90kg per annum. Yellow corn is mainly used for animal feed. The commercial demand for corn for food increased on average by 1.5 percent per year the past 20 years, while the commercial demand for feed corn increased on average by two percent per year (see also Figure 5). Projections are that these increases in demand for corn will continue in the future.



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 product has 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 animals.

(e) TRADE BARRIERS

Not applicable

PART E: POLICY

(a) REGULATORY FRAMEWORK

As already mentioned, animal biotechnology falls under the GMO Act of 1997. The Directorate of Biosafety in DALRRD has proactively developed 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).

Animal cloning is not included in the Animal Improvement Act. The act, currently, regulates only for artificial insemination and embryo transfer. However, the act is under review and after the process amendments will be published to address cloning.

The National Health Research Ethics Council (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 the 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) Approvals

There are no GE animals approved for production in South Africa.

(c) INNOVATIVE BIOTECHNOLOGIES

Not applicable

(d) LABELING AND TRACEABILITY

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. However, if implemented, GE labeling regulations under the Consumer Protection Act would apply to GE animals.

Currently, the label requirements for GE products under the Foodstuffs, Cosmetics and Disinfectant Act would apply to GE animal products only in certain cases when the product differs significantly from a non-GE equivalent.

(e) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable

(e) INTELLECTUAL PROPERTY RIGHTS

South Africa is a signatory to the Trade-Related Aspects of International Property Rights (TRIPS) agreement of the WTO; hence Intellectual Property Rights are supported by the government.

(f) INTERNATIONAL TREATIES and FORUMS

South Africa is a signatory member of the following relevant treaties:

- The Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS);
- Codex Alimentarius Commission (Codex);
- The World Organization for Animal Health (OIE)

South Africa does not actively participate in discussions related to GE plants within these international organizations.

(g) RELATED ISSUES

Not applicable

PART F: MARKETING

(a) PUBLIC/PRIVATE OPINIONS

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

(b) MARKET ACCEPTANCE/STUDIES

Not applicable

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

(a) COMMERCIAL PRODUCTION

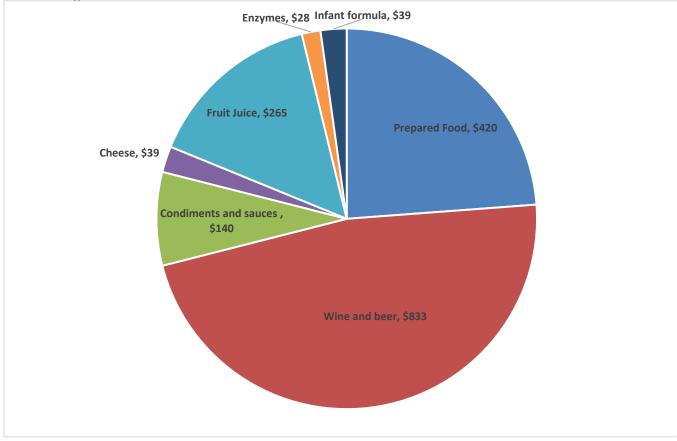
Various companies in South Africa are involved in the commercial production of food ingredients. Many of these companies use microbial biotechnology in the production process for enzymes, additives, flavorings, colorings, vitamins and seasonings. Food ingredient manufacturers in South Africa are represented by two associations, namely, the South Africa Association of Food Science and Technology (https://www.saafost.org.za/) and the South Africa Association of the Flavor and Fragrance Industry (https://saaffi.co.za/). Many research institutions are also involved in microbial biotechnology, such as: The Institute for Microbial Biotechnology at the University of the Western Cape; Microbial, Biochemical and Food Biotechnology Department at the University of the Free State and the Institute of Biomedical and Microbial Biotechnology at the Cape Peninsula University of Technology.

b) EXPORTS

South Africa exported almost US\$1.8 billion of processed products that might contain microbial biotech derived ingredients in 2019 (see also Figure 6). Most of the trade in microbial biotech derived products is from value-added products such as wine and beer and prepared food, but South Africa also exported microbial biotech derived enzymes worth US\$28 million in 2019. The United States represent a small portion of South Africa's export markets of these products at US\$66 million or less than 4 percent.

Figure 6: South Africa's exports of processed products that could contain microbial biotech



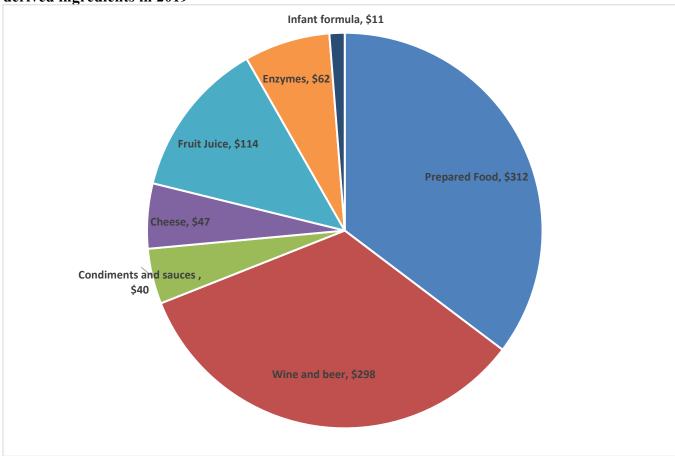


c) IMPORTS

South Africa imported US\$884 million worth of microbial biotech-derived food ingredients, such as enzymes, or processed products that could contain microbial biotech-derived food ingredients in 2019 (see also Figure 7). These imports include US\$58million of processed products containing microbial biotech-derived food ingredients from the United States. South Africa also imported US\$62 million worth microbial biotech derived enzymes in 2019 of which US\$20 million were imported from the United States.

Figure 7: South Africa's imports of processed products that could contain microbial biotech





d) TRADE BARRIERS

Post is not aware of any specific trade barriers that hinder the trade in processed products containing microbial biotech derived ingredients.

PART H: POLICY

a) REGULATORY FRAMEWORK

South Africa has to date not employed a "process-based" review approach for food ingredients from microbial biotechnology sources. As a result, food ingredients from microbial biotechnology are not regulated under the South Africa's "GMO" act as in described in Chapter One, Section A of this report. Food ingredients, however, are regulated under the Foodstuffs, Cosmetics and Disinfectants Act no. 54 of 1972 (Foodstuffs, Cosmetics and Disinfectants Act) with specific regulations for food additives, food colorants and microbiological standards. As a result, South Africa's food additives food colorants and microbiological standards regulations are developed and administered by the Ministry of Health, under the Food Control Division. This Division also represents the Department of Health on the Executive Council of the "GMO" Act and serves as the Codex point of contact.

Table 3 stipulates the list of applicable additives food colorants and microbiological standards regulations in South Africa. These regulations also specify the requirements on the use of additives including how they should be labelled.

Table 3: Existing food additives, food colorant and microbiological standards regulations in South Africa (with website link)

Name	of	regu	<u>lation</u>	

Miscellaneous additives

Regulations relating to food colourants (R1055/1996)

List of permissible sweeteners referred to in Regulation 4 of the regulations relating to the use of sweeteners in foodstuffs

Regulations relating to the use of sweeteners in foodstuffs (R733/201)

Codex General Standards for Food Additives

Regulations relating to the use of sweeteners in foodstuffs (R733/201)

Regulations Governing Microbiological Standards for Foodstuffs and Related Matters (R692/1997)

Source: Department of Health: Food Control Division

In the absence of a regulation pertaining to a specific additive, South Africa normally adopts the General Standard for Food Additives (GSFA) of the Codex Alimentarius Commission (CAC). If an additive is not available under the South African positive list or covered by Codex, an exporter may request for permission from the Department of Health to use such an additive. Notably, this may be a long process as the Department of Health may request supporting evidence that the additive is safe for consumption.

b) APPROVALS

Lists of permitted additives and colorants are included in the specific regulations as specified in Table 3.

c) LABELING AND TRACEABILITY

Labelling of GE-derived products in South Africa is regulated under the Foodstuffs, Cosmetics and Disinfectants Act (1972) – Regulation 25, and under the 2011 Consumer Protection Act. For a description of these laws, see Chapter 1, section G.

General labeling regulations for processed foodstuffs and liquor also falls under the Foodstuffs, Cosmetics and Disinfectant Act. Inspectors under the Ministry of Health at the ports of entry are responsible for ensuring compliance with labeling regulations. According to the current regulations it is not mandatory to include nutritional information tables on labels. However, should a label contain

nutritional information it has to comply with the existing labeling regulations (also see <u>Regulations on labelling and advertising</u>).

d) MONITORING AND TESTING

Not applicable

e) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

South Africa is a signatory to the Trade-Related Aspects of International Property Rights (TRIPS) agreement of the WTO; hence Intellectual Property Rights are supported by the government.

g) RELATED ISSUES

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

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Post is not aware of any research that was done to determine the public's opinion regarding microbial biotech in South Africa.

b) MARKET ACCEPTANCE/STUDIES

South Africa has a well-developed and advanced food sector, which is a key driver in the use and demand for food ingredients. See also reports done by FAS/Pretoria on the topic (for example Food Processing Ingredients - Pretoria, South Africa (03/30/2020). an assessment of market acceptance issues relating to the sale and use of microbial biotech derived food ingredients in South Africa, it is safe to assume it is widely accepted in the food sector.

APPENDIX

Table A1: GE events approved for general release in South Africa

Company	ts approved for general release Event	Crop/product	Trait	Year approved
Dow AgroSciences SA	MON89034xTC1507xNK603	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87460	Corn	Drought tolerance	2015
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

Table A2: GE events approved for trial release since 2014

Company	Event	Crop/ product	Trait	Year approved
<u>Monsanto</u>	MON87460	Corn	Drought Tolerance	2014
	MON87460 x MON89034	Corn	Drought Tolerance Insect resistant	2014
	MON87460 x MON89034 x NK603	Corn	Antibiotic Insect resistant Herbicide tolerance	2014
	MON87460 x NK603	Corn	Drought Tolerance Herbicide tolerance	2014
	MON87460 x MON810	Corn	Drought Tolerance Insect resistant	2014
	MON89034 x MON88017	Corn	Insect resistant Herbicide tolerance	2015
	MON87460 x MON89034 x MON88017	Corn	Drought Tolerance Insect resistant Herbicide tolerance	2015
	MON810 x MON89034	Corn	Insect resistant	2015
	MON810 x MON89034 x NK603	Corn	Insect resistant Herbicide tolerance	2015
	MON87427 x MON89034 x MIR162 x NK603	Corn	Insect resistant Herbicide tolerance	2017
	MON87701 x MON89788	Soybeans	Insect resistant Herbicide tolerance	2017

	MON87427-7	Corn	Herbicide tolerance	2019
<u>Bayer</u>	Twinlink x GlyTol	Cotton	Herbicide tolerance	2014
	GlyTol x TwinLink x COT 102	Cotton	Insect resistant Herbicide tolerance	2016
	GLTC	Cotton	Insect resistant Herbicide	2015
	GL x LL	Cotton	Insect resistant Herbicide	2016
	OL X LL	Cotton	tolerance Insect resistant	2010
	GHB614 x LLCotton25	Cotton	Herbicide tolerance	2018
<u>Pioneer</u>	TC1507 x MON810	Corn	Herbicide tolerance Insect resistant	2014
	TC1507 x MON810 x NK603	Corn	Herbicide tolerance Insect resistant	2014
	PHP37046	Corn	Insect resistant	2014
	TC1507 x NK603	Corn	Herbicide tolerance Insect resistant	2014
	305423 x 40-3-2	Soybeans	Modified oil/fatty acid Herbicide tolerance	2014
	305423	Soybeans	Modified oil/fatty acid Herbicide tolerance	2014
	PHP36676	Corn	Herbicide tolerance Insect resistant	2014
	PHP36682	Corn	Herbicide tolerance Insect resistant	2014
	PHP34378	Corn	Insect resistant	2014
	PHP36827	Corn	Insect resistant	2014

	TC1507 x MIR162 x NK603	Corn	Herbicide tolerance Insect resistant	2019
	MON89034 x TC1507 x MIR162 x NK603 x DAS40278- 9	Corn	Herbicide tolerance Insect resistant	2019
	DP-0561139	Corn		2019
Syngenta	BT11x 1507 x GA21	Corn	Herbicide tolerance Insect resistant	2014
	BT11 x MIR162 x GA21	Corn	Herbicide tolerance Insect resistant	2014
	BT11 x MIR162 x 1507 x GA21	Corn	Herbicide tolerance Insect resistant	2014
	BT11 x MIR162 x MON89034 x GA21	Corn	Herbicide tolerance Insect resistant	2018
	BT11 x GA21	Corn	Herbicide tolerance Insect resistant	2018
Dow AgroScience	MON89034 x TC1507 x NK603	Corn	Herbicide tolerance Insect resistant	2014
	DAS-40278-9	Corn	Herbicide tolerance	2015
	NK603 x DAS-40278-9	Corn	Herbicide tolerance	2015
	MON89034 x TC1507 x NK603 x DAS-40278-9	Corn	Herbicide tolerance Insect resistant	2015
BASF	GHB614 x LLCotton25	Cotton	Herbicide tolerance	2019
<u>Genective</u>	VCO-1981-5	Corn	Herbicide tolerance	2017
PSI CRO South Africa	BWN 270		Gene Therapy Vector	2018
UniQure Biophar ma	AMT-061		Enhanced Vector for Gene Transfer	2019

Syneos Health SA FLT 180A	Gene therapy	2019

Table A3: GE events with commodity clearance

Company	Event	Crop	Trait	Year approved
Monsanto	MON87427 x MON87419 x NK603	Corn	Insect resistant Herbicide tolerant	2020
Monsanto	MON87427 x MON89034 x MIR162 x MON87419 x NK603	Corn	Insect resistant Herbicide tolerant	2020
Monsanto	MON87427 x MON89034 x MON810 x MIR162 x MON87411 x MON87419	Corn	Insect resistant Herbicide tolerant	2020
Monsanto	MON87427 x MON89034 x MON87419 x NK603	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87427 x MON89034 x TC1507 x MON87411 x DAS59122-7 x MON87419	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87751 x MON87701 x MON87708 x MON89788	Soybeans	Insect resistant Herbicide tolerant	2018
Bayer	FG72 x A5547-127	Soybeans	Herbicide tolerant	2018
DowAgroSciences	MON89034 x TC1507 x MIR162 x NK603	Corn	Insect resistant Herbicide tolerant	2018
Syngenta	BT11 x MIR162 x MIMR604 x 5307 x GA21	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87705 x MON87708 x MON89788	Soybeans	Herbicide tolerant	2018
Monsanto	MON87427 x MON87460 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Corn	Insect resistant Herbicide tolerant Drought tolerance	2018
Monsanto	MON87427 x MON89034 x MIR162 x MON87411	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87427 x MON89034 x TC1507 x MON87411 x DAS-	Corn	Insect resistant Herbicide	2018

	59122-7		tolerant	
Monsanto	MON87427 x MON87460 x MON89034 x MIR162 x NK603	Corn	Insect resistant Herbicide tolerant Drought tolerance	2018
Monsanto	MON87708 x MON89788 x A5547-127	Soybeans	Herbicide tolerant	2018
Syngenta	BT11 x MIR162 x MON89034	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87427 x MON89034 x MON88017	Corn	Insect resistant Herbicide tolerant	2017
Monsanto	MON89034 x MIR162	Corn	Insect resistant	2017
Syngenta	BT11 x MIR162 x MON89034 x GA21	Corn	Insect resistant Herbicide tolerant	2017
Du Pont Pioneer	DP114 x MON810 x MIR604 x NK603	Corn	Insect resistant Herbicide tolerant	2017
Monsanto	MON87705 x MON89788	Soybean	Herbicide tolerant Modified oil/fatty acid	2016
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	2016

			tolerant	
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	2016
C .	MATICALO		tolerant	2016
Syngenta	MZHG0JG	Corn	Herbicide	2016
			tolerant	
Du Pont Pioneer	DP73496	Canola	Herbicide	2016
			tolerant	
Monsanto	MON87460 x MON89034 x	Corn	Drought	2015
	NK603		tolerance	
			Insect resistant	
			Herbicide	
			tolerant	
Syngenta	BT11 x MIR162	Corn	Insect resistant	2015
•			Herbicide	
			tolerant	
Monsanto	MON87460 x MON89034 x	Corn	Abiotic	2015
1VIOIISMITTO	MON88017	Com	resistance	2013
	14101400017		Insect resistant	
			Herbicide	
			tolerant	
Creamonata	GA21 x T25	Carre	Herbicide	2015
Syngenta	GA21 X 123	Corn		2013
Q .	CYLLEDOLIO.	G 1	tolerant	2014
Syngenta	SYHT0H2	Soybean	Herbicide	2014
			tolerant	
Syngenta	BT11 x 59122 x MIR604 x	Corn	Insect resistant	2014
	TC1507 x GA21		Herbicide	
			tolerant	
Syngenta	BT11 x MIR604 x TC1507 x	Corn	Insect resistant	2014
	5307 x GA21		Herbicide	
			tolerant	
Syngenta	BT11 x MIR162 x MIR604 x	Corn	Insect resistant	2014
•	TC1507 x 5307 x GA21		Herbicide	
			tolerant	
Syngenta	MIR162	Corn	Insect resistant	2014
Monsanto	MON89034 x MON88017	Corn	Insect resistant	2014
Tylonsumo			Herbicide	201.
			tolerant	
Monsanto	MON87701 x MON89788	Soybeans	Insect resistant	2013
		Soyucans	Herbicide	2013
			tolerant	
N	MON89788	Carl	Herbicide	2013
Monsanto	TATOTA 00	Soybeans		2013
D 4 C:	D 4 C 4440 C C	0 1	tolerant	2012
DowAgrowScience	DAS-44406-6	Soybeans	Herbicide	2013
			tolerant	
DowAgrowScience	DAS-40278-9	Corn	Herbicide	2012
			tolerant	

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 Herbicide tolerant	2011
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	2011

			Herbicide 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 of 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	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

Attachments:

No Attachments