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Report Highlights:

South Africa is amongst the top-10 largest producers of genetically engineered (GE) crops in the world and has approved 32 GE plant events for commercial cultivation since 1997. South Africa's robust regulatory system for GE products, which started with the introduction of the Genetically Modified Organism ("GMO") Act of 1997, supported the country's leading position in regulatory policy regarding agricultural biotechnology. However, South Africa announced a decision to uphold an October 2021 declaration to regulate products derived through "New Breeding Techniques" (NBTs) under the current "GMO" Act, regardless of foreign DNA presence. This risk-disproportionate approach runs counter to international best practices.

Executive Summary:

Total bilateral agricultural trade between the United States and South Africa surged by 16 percent in 2022 to reach a record high of US\$997 million. Biotechnology related exports by the United States to South Africa included US\$48 million of processed products potentially containing biotech-derived food ingredients as well as corn planting seeds (US\$12 million) which are primarily biotech varieties. The United States imported US\$105 million of processed products that could contain biotech-derived food ingredients from South Africa in 2022. The United States did not import any GE agricultural commodities such as corn, cotton, or soybeans from South Africa.

South Africa possesses a highly advanced commercial agricultural industry based, *inter alia*, in biotechnology research 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. Several local and international regulations govern the use of GE products in South Africa. The goal of these regulations is to ensure that any activity involving GE products is assessed with regards to potential risks to human health and the environment prior to undertaking any such activity.

Thirty-two GE plant events have received general release approval for commercial cultivation since 1997 in South Africa, including five new events approved the past two years. These events are present in three crops, namely, corn, soybeans, and cotton. More than 80 percent of corn plantings, approximately 95 percent of soybean plantings, and virtually all cotton plantings in South Africa are from GE seeds. In fact, farmers in South Africa planted a record soybean area of 1.1 million hectares in marketing year 2023/24, an upsurge of 24 percent. South Africa is also a significant exporter of corn with average annual corn exports of more than 3.0 million metric tons over the past five years (also refer to GAIN report [South Africa Grain and Feed](#)).

After the introduction of innovative biotechnologies such as genome editing in many countries around the world, South Africa started internal deliberations to determine regulatory policies for “NBTs”, including genome editing and derived products. In October 2021, a public notice was sent to all stakeholders announcing South Africa’s regulatory approach for “NBTs as the same risk assessment framework that exists for GE products under South Africa’s 1997 “GMO” Act. This means all genome edited products will be treated the same as GE products under South Africa’s “GMO” Act, regardless of the presence of foreign DNA. The local industry launched an internal appeal against this one-sided ruling and requested that the Minister appoint an independent panel of experts to serve as the Appeal Board.

In December 2022, the Appeal Board found in favor of industry and recommended a science-based, case-by-case approach for the regulation of NBTs in South Africa. However, in an unanticipated decision, the Minister of the Department of Agriculture, Land Reform and Rural Development (DALRRD) announced on August 11, 2023, through a public notice ([Minister final decision on NBTs appeal](#)), that the decision to regulate “NBTs” under the “GMO” Act of 1997 would be upheld. According to the Minister, the “GMO” Act provides the appropriate framework to manage any potential risks associated with “NBTs.” The domestic industry is expected to continue to advocate for a risk-proportionate approach.

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PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

(a) RESEARCH AND 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. To date, South Africa has approved 32 GE plant events for commercial production, including five new events approved the past two years (see Table A1 in the appendix). These GE events are contained within three commodities, namely corn, soybeans, and cotton, and include herbicide tolerance, insect resistance and drought tolerance traits.

In the past 5 years, South Africa authorized 35 field trials permits. Table A2 in the appendix summarizes the events, traits, products, and companies involved with the permits issued for trial release clearance since 2018. To Post's knowledge, there are no GE plants used to produce antibiotics of pharmaceuticals for human or animal disease at this time.

In addition to the large multinational GE companies, like Bayer, Syngenta, BASF and Corteva, several parastatals, universities and agricultural industry organizations in South Africa are involved in innovative GE research. These include the following organizations:

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. For more information, please visit the following link: [ARC-BTP](#).

The Forestry and Agricultural Biotechnology Institute at the University of Pretoria

The Forestry and Agricultural Biotechnology Institute (FABI) is based at the University of Pretoria, South Africa. FABI promotes the broad field of plant biotechnology through an interdisciplinary approach and with close linkages to a wide range of academic departments. The institute has been operational since 1998. For more information, please visit the following link [FABI-UP](#).

The Institute for Wine Biotechnology at Stellenbosch University

The Institute for Wine Biotechnology (IWBT) was established at Stellenbosch University in 1995 (see also [IWBT-US](#)). The IWBT is an internationally recognized postgraduate training and research institute offering visionary training and innovative research to support the South

African wine and grapevine industries. The IWBT's research programs follows a globally unique, integrated, and multidisciplinary approach, combining cutting edge high-throughput and systems-based approaches derived from the core sciences of biology and chemistry with the traditional wine sciences of viticulture and oenology. Themes include grapevine ecophysiology and molecular biology, microbial diversity, physiology and molecular biology, analytical chemistry, and computational biology. Wine and related products make up a large part of South Africa's agricultural exports to the United States with an annual value typically exceeding US\$40 million.

The South African Sugarcane Research Institute

The South African Sugarcane Research Institute (SASRI) is a world-renowned agricultural research institute that contributes to the sustainability of the local sugar industry. Research at SASRI is clustered within four multidisciplinary programs, namely Variety Improvement, Crop Protection, Crop Performance and Management and Systems Design and Optimization. The Variety Improvement Program conducts research and implements strategies for the continual release of high yielding, adaptable, pest and disease resistant varieties that add value and enhance industry productivity. Modern biotechnological approaches are deployed for the commercial development of GE sugarcane for insect borer resistance and herbicide tolerance and to improve sugarcane drought stress tolerance. For more information, please visit the following link: [SASRI](#).

(b) COMMERCIAL PRODUCTION

South Africa cultivates three GE agricultural crops commercially, namely, corn, soybeans, and cotton. In marketing year (MY) 2022/23 a total of 3.6 million hectares (MHa) of these three crops were planted in South Africa, of which an estimated 3.1 MHa were planted with GE seeds. Of the total GE area, GE corn plantings represent about 71 percent or 2.2 MHa, followed by GE soybeans, representing approximately 28 percent or 880,000 ha and GE cotton representing approximately one percent or 18,000 ha. This places South Africa among the top-10 global producers of GE crops.

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 14.0 million metric tons (MMT). In 1997, the first GE corn event (insect resistant) was approved in South Africa. Since then, the country has seen a progressive and steady increase in GE corn plantings, leading to more than 80 percent of total corn plantings today. Table 1 illustrates the plantings of GE corn in South Africa over the past seven marketing years. Of the 2.6 MHa of corn planted in MY 2022/23, an estimated 2.2 MHa or 84 percent were planted with GE seeds.

White corn plantings in MY 2022/23 were 1.6 MHa, of which an estimated 91 percent or 1.4 MHa were planted with GE seed. Yellow corn plantings were approximately 1.0 MHa, of which an estimated 73 percent were planted with GE seed. A large proportion of non-GE yellow corn produced in South Africa is used in the beer brewery industry, while the rest is exported to non-GE markets. A traceability system and dedicated non-GE grain storage facilities allow for segregation for the local and international non-GE markets.

Table 1*Planting of GE corn in South Africa over the past seven years*

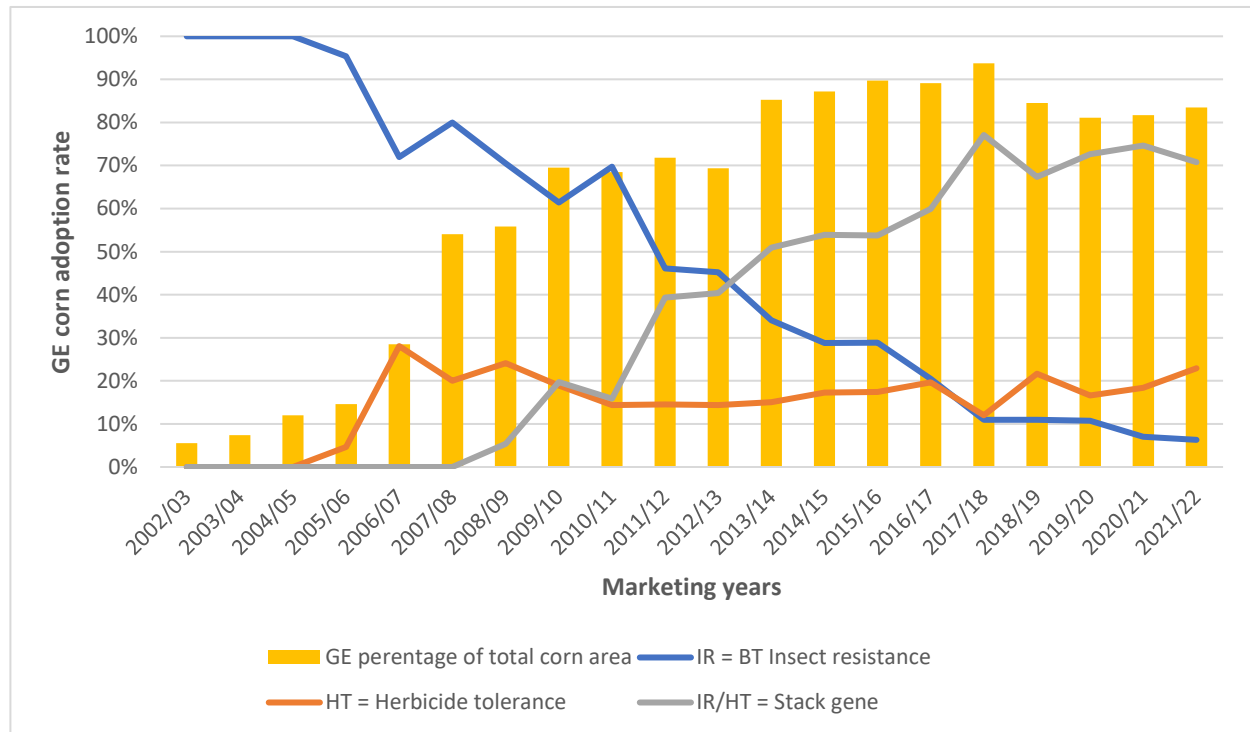
Marketing years	Area planted (1,000 ha)		
	White corn	Yellow corn	Total corn
<u>2016/17</u>			
Total area	1,015	932	1,947
GE area	914	821	1,735
GE area % of total area	90%	88%	89%
<u>2017/18</u>			
Total area	1,643	985	2,629
GE area	1,580	885	2,465
GE area % of total area	96%	90%	94%
<u>2018/19</u>			
Total area	1,268	1,050	2,318
GE area	1,103	856	1,959
GE area % of total area	87%	81%	85%
<u>2019/20</u>			
Total area	1,298	1,002	2,300
GE area	1,175	690	1,865
GE area % of total area	91%	69%	81%
<u>2020/21</u>			
Total area	1,616	995	2,611
GE area	1,365	769	2,134
GE area % of total area	84%	77%	82%
<u>2021/22</u>			
Total area	1,692	1,063	2,755
GE area	1,535	765	2,300
GE area % of total area	91%	72%	83%
<u>2022/23*</u>			
Total area	1,575	1,048	2,623
GE area	1,435	765	2,200
GE area % of total area	91%	73%	84%

Source: Bureau for Food and Agricultural Policy (BFAP), GrainSA**Note:** *Post/Pretoria estimate

In MY 2021/22 (information for MY 2022/23 is not yet available), approximately 70 percent of GE seed planted consisted of stacked varieties (insect resistant and herbicide tolerant), while single insect resistant (7 percent) and herbicide tolerant (23 percent) events in total comprised of about 30 percent of total GE corn plantings (see also Figure 1).

Figure 1

The adoption trends of GE corn in South Africa

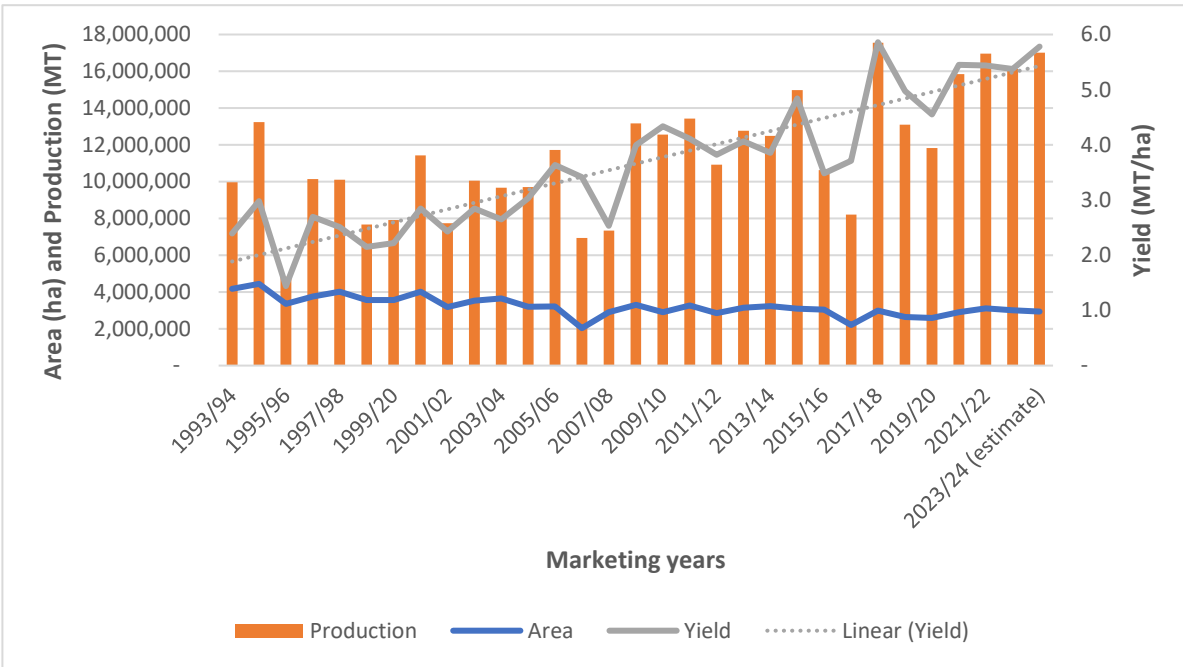


Source: BFAP

The long-term trend in corn production indicates that South Africa is producing more corn on less area. In fact, South Africa's five largest corn crops on record were produced in the past seven years, driven mainly by improved yields and favorable weather conditions, while planted area declined (see Figure 2). South Africa's corn yields have more than doubled in the past 30 years (see Figure 3) with the use of new production technologies, such as genetically engineered seed and more efficient and effective farming practices, including precision and conservation farming. Indications are that this trend of producing more corn on fewer hectares will continue in the future.

Figure 2

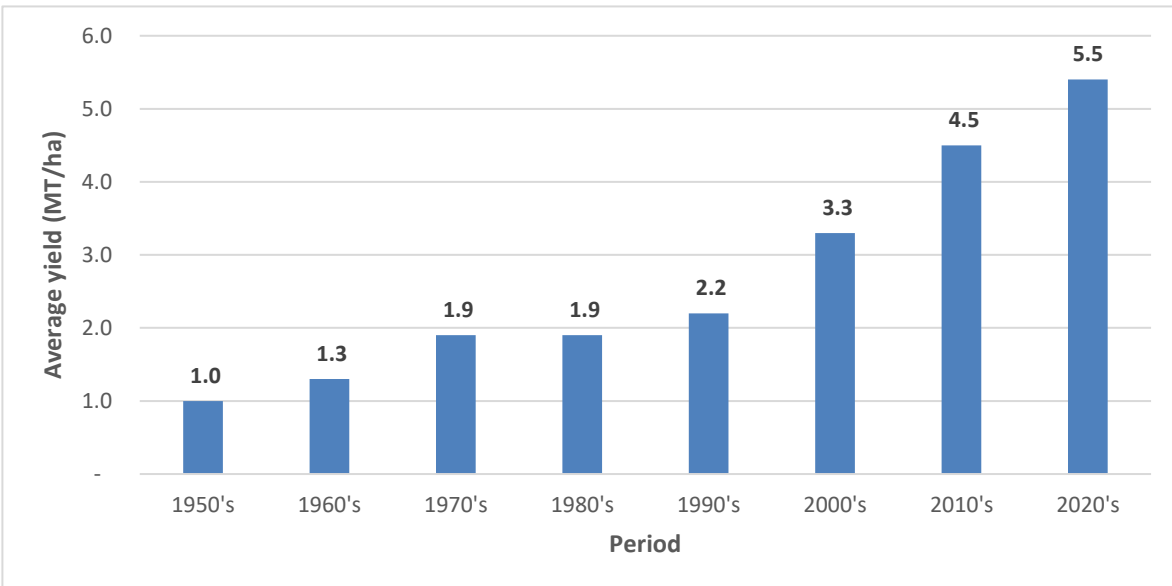
Area Planted, Production and Yields of Corn in South Africa over the Past 30 Years



Source: South African Grain Information Services (Sagis)

Figure 3

Trends in the Average Corn Yields in South Africa



Source: Sagis

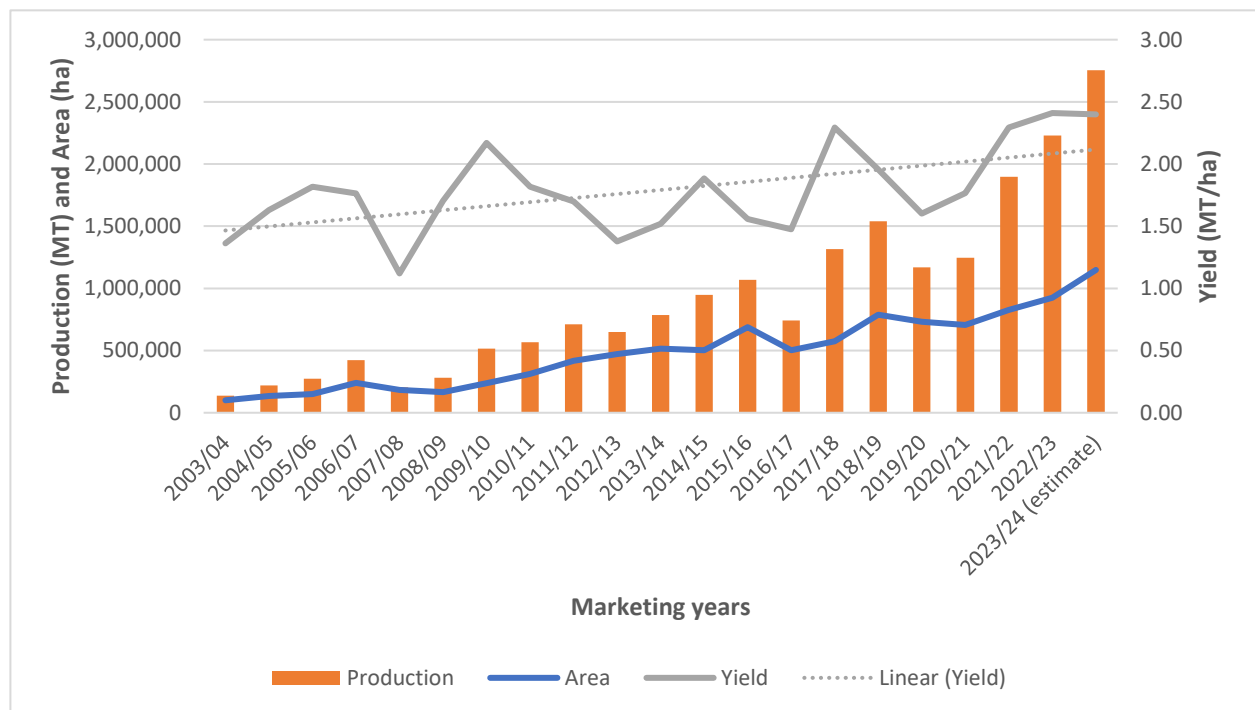
Note: *Include only the first three years of the 2020's

Soybeans

South Africa expanded soybean area by almost 11-fold during the past 20 years (see also Figure 4). In fact, farmers in South Africa planted a record soybean area of 1.1 MHa in MY 2023/24, an upsurge of 24 percent from the previous marketing year, surpassing yellow corn area for the first time. Twenty years ago, South African farmers planted a mere 100,000 ha with soybeans. As a result, soybeans now represent more than 25 percent of the area planted with summer rainfall field crops, while 20 years ago it was only four percent. This surge has been driven by farmers' growing interest in using soybeans as a rotational crop with corn, a growing local demand for soybeans through extensive investments in oilseed processing plants and the adoption of GE soybeans. GE soybeans were first approved for commercialization in South Africa in 2001. By 2006, 75 percent of the soybean crop grown was GE. Today, Post estimates that more than 95 percent of soybeans are planted with GE seeds.

Figure 4

Trends in Area Planted, Production and Yields of Soybeans in South Africa



Source: Sagis

Cotton

In 1997, the first GE cotton event (insect resistance) was approved in South Africa and currently all local cotton plantings are from GE seeds. However, cotton production is relatively small in South Africa as farmers opt to plant more profitable crops like corn and soybeans. Cotton area stayed flat in the 2022/23 production season at approximately 18,000 ha.

(c) EXPORTS

Exporters of GE products in South Africa must apply for a GE export permit according to the “GMO” Act of 1997. Permit applications should be accompanied by a permit/letter of authority from the importing countries’ Competent Authority permitting GE imports.

Corn

South Africa is a net exporter of corn in most years, except when drought limits production. Post/Pretoria estimates South Africa will export 4.0 MMT of corn in MY2023/24 (May 1, 2023 – Apr 30, 2024) after producing the second largest corn crop on record. In the first 15-weeks of MY 2023/24, South Africa already exported 1.4 MMT of corn, primarily to Taiwan, South Korea, Vietnam, and Japan (see also Table 2).

In MY 2022/23, South Africa exported 3.7 MMT of corn to nearly 20 countries, keeping exports on the same level as MY 2021/22. South Africa exported almost 2.2 MMT of yellow corn and 1.5 MMT of white corn. The top seven markets were Taiwan, Japan, Vietnam, Mexico, Italy, Botswana, and South Korea. These countries represented 75 percent of South Africa’s corn exports. Exports to the Asian countries consisted mainly of yellow corn, while corn exports to Mexico, Italy, and Botswana were largely white corn.

Table 2*South Africa's Exports of Corn in MY 2022/23 and MY 2023/24*

Countries	MY 2022/23 (1,000 MT)			Countries	MY 2023/24* (1,000 MT)		
	White corn	Yellow corn	Total		White corn	Yellow corn	Total
Taiwan	0	720	720	Japan	0	364	364
Japan	0	605	605	Taiwan	0	350	350
Vietnam	0	353	353	South Korea	0	350	350
Mexico	337	0	337	Vietnam	0	127	127
Italy	262	4	266	Botswana	80	3	83
Botswana	211	28	239	Kenya	52	0	52
South Korea	95	130	225	Mozambique	16	14	30
Namibia	101	36	137	Eswatini	12	16	28
Zimbabwe	119	10	129	Zimbabwe	17	2	19
Eswatini	37	87	124	Namibia	1	15	16
China	0	108	108	Lesotho	10	0	10
Mozambique	52	51	103	Ghana	2	0	2
Kenya	87	0	87				
Lesotho	76	9	85				
Portugal	53	0	53				
Honduras	47	0	47				
Guatemala	22	0	22				
Angola	0	6	6				
Saudi Arabia	0	6	6				
TOTAL	1,499	2,153	3,652	TOTAL	190	1,241	1,431

Source: Sagis**Preliminary export data from May 1 to August 11, 2023***Soybeans**

In the past, South Africa's trade in oilseeds was generally limited, as the bulk of production was destined for local crushing. As a result, exports and imports were directed to oils and meals. However, with the surge in the local production of soybeans and crushing capacity reaching optimal levels, South Africa's soybean exports reached a historical high level on 277,504 MT in MY 2022/23. Malaysia (144,473 MT), Thailand (52,393 MT) and Vietnam (27,531 MT) were the major markets for South Africa's soybeans. So far in MY 2023/24 (March 2023 to June 2023), South Africa exported 195,551 MT of soybeans with Malaysia, Vietnam, and Thailand the main markets. Post expects South Africa's exports of soybeans will continue in the future on higher production and global demand. At the end of 2022, South Africa completed export protocols with China, opening the world's largest soybean market for local producers.

Table 3*South Africa's Exports of Soybeans in MY 2022/23 and MY 2023/24*

Countries	MY 2022/23 (1,000 MT)	MY 2023/24* (1,000 MT)
Malaysia	145	106
Vietnam	28	55
Thailand	52	33
Zimbabwe	19	1
Bangladesh	29	0
Mozambique	5	0
Total	278	195

Source: Sagis**Preliminary export data from March 1 to June 30, 2023***Cotton**

South Africa's exports of cotton are relatively small at around 5,000 MT annually with Vietnam, Bangladesh, and Lesotho as the most important markets.

(d) IMPORTS

South Africa allows the importation of GE crops and GE processed products that have been approved by South African regulators for food and feed purposes (approval for cultivation is not required to import). Table A3 in the appendix lists the 106 GE events that received commodity clearance in South Africa since 2001 (see also [Commodity Clearance Approvals](#)). Commodity clearance means that South Africa allows the importation of these events for the use as food and/or feed. Typically, this means seeds that will not be planted, but rather processed in a way that will leave them non-viable. A complete food safety assessment is required, but the environmental assessment is not necessary in line with the limited environmental exposure. Currently, commodity clearance approvals cover seven crops, namely, corn, soybeans, canola, cotton, rice, wheat, and rapeseed. One new event in corn received commodity clearance so far in 2023. In 2022, three events received commodity clearance in corn, soybeans, and wheat.

(e) FOOD AID

South Africa is not a recipient of food aid even in years of drought. However, international food aid destined for Lesotho, Eswatini, Zambia, and Zimbabwe ordinarily passes through the South African ports. 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 acknowledging that the consignment contains GE products is also required.

(f) TRADE BARRIERS

DALRRD mandates that only approved GE events are allowed into South Africa under the “GMO” Act. According to the South African regulatory procedures: “Import permits are issued for the import of GE consignments, irrespective of the crop and country, provided the exporting country has approved the same or less number and type of events as 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 can pose significant risks to trade since South Africa applies only one percent tolerance for unintentional presence of GE even in food and feed.

The stakeholders in the South African grain and oilseeds industry continue to monitor for asynchronous GE approvals to ensure trade between South Africa and its trading partners, including the United States, is not unnecessarily interrupted. As a result of this efforts to establish synchronous approvals, the United States was able to export 53,000 MT of soybeans to South Africa in 2021.

PART B: POLICY

(a) REGULATORY FRAMEWORK

Several local and international regulations govern the use of GE products in South Africa. The goal of these regulations is to ensure that any activity involving GE products is assessed with regards to potential risks to human health and the environment prior to undertaking any such activity.

Locally, GE agricultural plant product development is regulated by the “GMO” Amendment Act of 1997 (Act 15 of 1997) and administrated by DALRRD (see also [Genetically Modified Organisms Amendment Act.pdf](#)). Additional regulations, specifically pertaining to GE products, are also contained under legislation in other departments of the South African government, namely:

- Department of Health, e.g., food safety and labelling requirements,
- Department of Forestry, Fisheries, and Environment e.g., post-release monitoring and triggers for environmental impact assessments and
- the Department of Trade and Industry, e.g., labelling.

Internationally, South Africa is a party to two agreements regarding GE products, the Cartagena Protocol on Biosafety (with an environmental focus) and the CODEX Alimentarius (with a food safety focus). Collectively, these regulations establish South Africa’s National Biosafety Framework (see Table 4). Table 5 lists specific definitions related to the regulation of GE plants in South Africa.

Table 4

South Africa's National Biosafety Framework

	“GMO” Act of 1997 <i>(Provides for measures to promote the responsible development, use and application of GE products)</i>	<u>National</u>	<u>International</u>
<u>Health</u>		Foodstuffs, Cosmetics & Disinfectants Act, 1972 <i>Defines labelling requirements for GE containing foods (Regulation 25, 2004)</i>	CODEX Alimentarius
<u>Environment</u>		National Environmental Management Act, 1998 <i>Provides general guidance with regards to the criteria that may trigger an Environmental Impact Assessment for GE products</i> National Environmental Management Biodiversity Act, 2004 <i>Regulates possible impacts of GE products on biodiversity and introduces minimum monitoring requirements, implemented through the South Africa National Biodiversity Institute (SANBI)</i>	Cartagena Protocol on Biosafety
<u>Socio-Economic</u>		Consumer Protection Act, 2008 <i>Introduced mandatory labeling requirements for all GE products (Regulation 293, 2008)</i>	

Source: Biosafety South Africa

Table 5*Specific Definitions Related to the Regulation of GE Plants in South Africa*

Legal Term	Laws and Regulations where term is used	Legal definition
Accident	“GMO” Act	Means any - (i) incident involving an unintentional environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment or on human or animal health within the Republic; or (ii) unintentional transboundary movement of genetically modified organisms that is likely to have an immediate or a delayed adverse impact on the environment or on human or animal health.
Biosafety	“GMO” Act	Means the level of safety when risk management measures must be taken to avoid potential risk to human and animal health and safety and to the conservation of the environment, because of exposure to activities with genetically modifies organisms.
Commodity clearance	“GMO” Act	Means the authorization to use a genetically modified organism as a food and feed, or for processing, but excludes the planting of a genetically modified organism as a release into the environment.
General release	“GMO” Act	Means the release of a genetically modified organism into the environment by whatever means, where the organism is no longer contained by any system of barriers.
Environment	National Environmental Management Act	Means the surroundings within which humans exist and that are made up of— (i) the land, water and atmosphere of the earth; (ii) micro-organisms, plant, and animal life; (iii) any part or combination of (i) and (ii) and the interrelationships among and between them; and (iv) the physical, chemical, aesthetic, and cultural properties and conditions of the foregoing that influence human health and well-being.
Environmental	“GMO” Act	Means the process used to assess the potential

impact assessment		impact of an activity on the environment by collecting, organizing, analyzing, interpreting, and communicating information on such activity.
Genetically modified organism	“GMO” Act	Means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both.

The “GMO” Act of 1997

In 1979, the South African government established the Committee on Genetic Engineering (SAGENE). SAGENE comprised of a group of South African scientists and was commissioned to act as scientific advisory body to the government. SAGENE paved the way for the uptake of biotechnology in food, agriculture, and medicine in South Africa, and laid the groundwork for implementation of the “GMO” Act of 1997. For more historical information on SAGENE and implementation of the “GMO” Act, see [SF2020-0056](#).

The “GMO” Act of 1997, along with its accompanying regulations, is administrated by DALRRD. The “GMO” Act of 1997 was modified by the South African government in 2005 to bring it in line with the Cartagena Biosafety Protocol and again in 2006 to address some economic and environmental concerns. These amendments to the “GMO” Act were approved 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. This encompasses the entire pipeline of GE product development, including, research (contained use and field trail activities), production (general release activities), imports and exports, transport, and the use of GE products. All activities with GE products are monitored through the “GMO” act and its regulations according to permits issued, including permits for imports, exports, commodity clearance, general release, field trails and contained use.

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 health, and 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 amendments to the “GMO” Act make it clear that a scientifically based risk assessment is a prerequisite for decision making and 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 scientific assessments 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 and more importantly is the decision-making body that approves or rejects GE product applications. The EC is also empowered to appoint 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 Forestry, Fisheries and Environment.
- Department of Health.
- Department of Trade, Industry and Competition.
- Department of Science and Innovation.
- Department of Employment and Labor.
- Department of Water and Sanitation.

Before deciding on 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 based on consensus by all the members. When 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 DALRRD. The EC advises the Minister on the appointment of members of the AC. The role of the AC is to advise the EC 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 DALRRD, is responsible for administration of the “GMO” Act. The Registrar acts on the instructions and conditions laid down by the EC. The Registrar is 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 5 illustrates the GE application process in South Africa.

The National Environmental Management Act of 1998

The National Environment Management Act is administered by the Department of Forestry, Fisheries, and the Environment (DFFE) and provides established general principles for decision making with regards to activities that affect the environment. The Act and relevant amendments include:

- National Environmental Management Act (Act no. 107 of 1998)
- National Environmental Management Act Amendment Act (Act no. 8 of 2004)

The Act provides general guidance with regards to the objectives of an Environmental Impact Assessment (EIA) of GE products, the criteria that may trigger an EIA and the administrative procedure to follow should the trigger requirements be met.

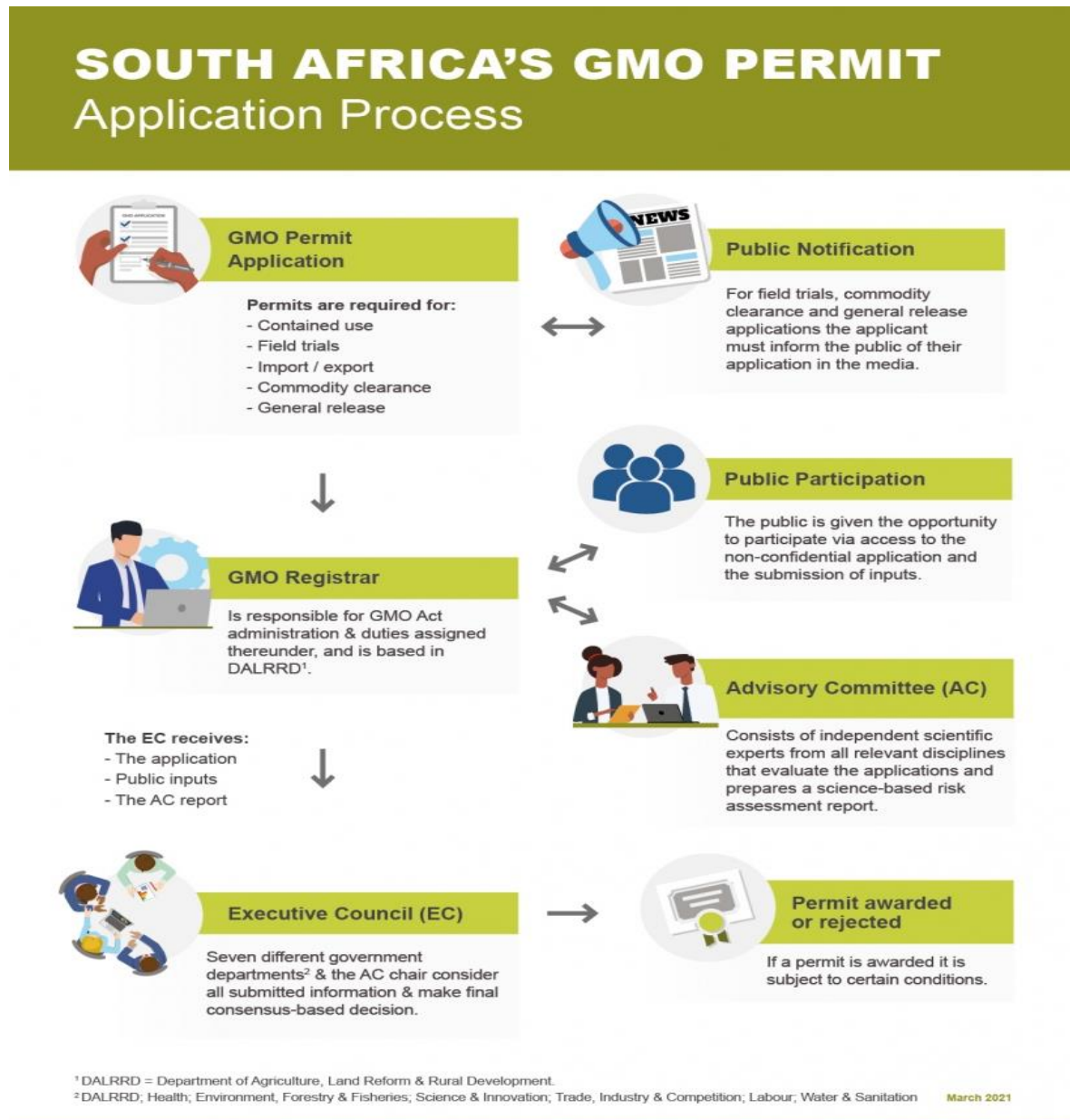
The National Environmental Management Biodiversity Act of 2004

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 DFFE 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 DFFE 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.

Figure 5

The GE application process in South Africa



The National Environmental Management Act of 1998

The National Environment Management Act is administered by the Department of Forestry, Fisheries, and the Environment (DFFE) and provides established general principles for decision making with regards to activities that affect the environment. The Act and relevant amendments include:

- National Environmental Management Act (Act no. 107 of 1998)
- National Environmental Management Act Amendment Act (Act no. 8 of 2004)

The Act provides general guidance with regards to the objectives of an Environmental Impact Assessment (EIA) of GE products, the criteria that may trigger an EIA and the administrative procedure to follow should the trigger requirements be met.

The National Environmental Management Biodiversity Act of 2004

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 DFFE 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 DFFE 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.

Foodstuffs, Cosmetic and Disinfectants Act of 1972

The Foodstuffs, Cosmetic and Disinfectants Act (Act No. 54 of 1972) of the Department of Health (DoH) controls the sale, manufacture and importation of foodstuffs, cosmetics, and disinfectants to ensure their quality and safety. The DoH accepts the Codex Alimentarius principles and guidelines for the food/feed safety requirements of GE products as policy for South Africa.

The DoH also published mandatory GE food labelling regulations in 2004 under the Foodstuffs, Cosmetic and Disinfectants Act. Regulation 25 states that foodstuffs produced through genetic modification – where they differ significantly from existing foodstuffs in terms of their composition, nutritional value, mode of storage, preparation, or cooking, allergenicity or genes with human or animal origin – must be labelled.

Consumer Protection Act of 2008

In 2008 the Consumer protection Act (Act No. 68 of 2008) was promulgated under the Department of Trade, Industry and Competition which asserts that labelling is required for all GE goods. Draft amendments to the GE labelling regulations were published in October 2012 that triggered serious concerns regarding the limitations of the Act on GE labeling by the business community in South

Africa. 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.




(b) APPROVALS

Table A1 in the appendix indicates all the GE events that have been approved for general release in South Africa under the “GMO” Act of 1997 (see also [General Release Approvals](#)). 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. Thirty-two 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 (see Table 6 for a summary).

In the past two years, five new GE events received general release approval, namely, Corteva’s pollination control technology (DP-056113-9) that is used in hybrid planting seed production and Corteva’s stacked insect resistant and herbicide tolerant events for corn and soybeans. Syngenta released an insect resistant event for corn in 2022. Corteva’s DP-056113-9 is not a commercial trait and there is no intent for it to enter the grain commodity supply chains. Rather it is used to ease the hybrid corn seed production process.

Table 6

The Traits and Companies Involved in South Africa’s 32 Approved GE Plant Events for Cultivation

<u>Crop</u>	<u>Traits</u>			
Corn	Insect resistance (IR)	2	2	
	Herbicide tolerance (HT)	1	1	2
	Drought tolerance	1		
	Stacked (IR & HT)	3	3	6
	Pollination control			1
Soybeans	Herbicide tolerance	1		1
	Stacked (IR & HT)	1		1
Cotton	Insect resistance	2		
	Herbicide tolerance	2		
	Stacked (IR & HT)	2		

Source: DALRRD

As already mentioned, Table A3 in the appendix lists the 103 GE events that received commodity clearance in South Africa since 2001 (see also [Commodity Clearance Approvals](#)). Commodity clearance means that South Africa allows the importation of these events for the use as food and/or feed and that are not intended for environmental release.

(c) STACKED OR PYRAMIDED EVENT APPROVALS

South Africa requires separate approval for GE planting seeds for general release 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. The EC confirmed that each stacked event must undergo a separate safety assessment as per the “GMO” Act. Currently, 16 stacked events (insect resistant and herbicide tolerant) have been approved for general release in South Africa: 12 for corn and two each for cotton and soybeans.

(d) FIELD TESTING

South Africa allows for field-testing of GE crops under the “GMO” Act of 1997. Please refer to Table A2 in the appendix for GE events that have been approved for confined field trails. 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

After the introduction of innovative biotechnologies worldwide, South Africa started internal deliberations to determine regulatory policies for “NBTs”, including genome editing and derived products. On October 27, 2021, a public notice (see also [Notice SA's regulatory approach for NBT's](#)) was sent to all stakeholders announcing South Africa’s regulatory approach for “NBTs.” According to the notice, the same risk assessment framework that exists for GE products under South Africa’s current “GMO” Act will apply to “NBTs.” South Africa’s “GMO” Act defines a “GMO” as “an organism, the genes, or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both.” Based on this definition under the “GMO” Act, the EC concluded that the current risk assessment framework that exists for GE products would apply to all products produced using innovative biotechnologies.

The public notice caused discontent amongst international stakeholders, the local industry and academia. As a result, the local industry, launched an internal appeal, in terms of the “GMO” Act, against this one-sided ruling and requested that the Minister appoint an independent panel of experts to serve as the Appeal Board. The industry based its appeal on a defective consultation procedure, incorrect interpretation of the definition of a “GMO” in terms of the “GMO” Act, and international

best practice.

In December 2022, the Appeal Board found in favor of industry in respect of all the grounds of the appeal. The Board therefore recommended that the decision of the Executive Council regarding “NBTs” be set aside and that a consultative process be initiated and concluded within 12 months from the Minister’s decision on this matter to develop a new regulatory framework for “NBTs.” The Appeal Board recommended a science-based, case-by-case approach for the regulation of “NBTs” in South Africa.

However, the Minister of DALRRD announced on August 11, 2023, through a public notice ([Minister final decision on NBTs appeal](#)), that the EC decision to regulate “NBTs” under the “GMO” Act of 1997 would be upheld. According to the Minister, the “GMO” Act provides the appropriate framework to manage any potential risks associated with “NBTs”.

(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 GE 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. This regulation 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. To date these requirements have not been triggered for any of the GE products/foods on the South African market and as a result none of these had to be labelled – i.e., these foods are considered equivalent to their conventional counterparts.

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 [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 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 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 applies to living GE organisms and processed commodities. 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. Rather than testing for unapproved events, import permits are issued for the import of GE consignments, irrespective of the crop and country, provided the exporting country has approved the same or less number and type of events as South Africa.

(j) ADDITIONAL REGULATORY REQUIREMENTS

No additional seed registration is required in South Africa after GE seed is approved for general release. Seed Certification is 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 buy new GE hybrid 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 every year. Also, farmers often use soybeans for on-farm feed so it might never enter commercial circulation. As a result, the Minister of DALRRD approved a statutory levy on soybeans in 2018, according to which seed companies can be compensated for their performance in the soybean seed market of South Africa. The seed levy is payable to the South African Cultivar and Technology Agency (SACTA) on an annual basis. SACTA was formed as a non-profit company, to guarantee that breeding and technology levies are paid to seed breeding companies and plant breeder rights holders, ensuring continuous research and cultivar development (see also [Sactalevy](#)). Levies on wheat and barley for this purpose have been collected and paid by SACTA for several years.

(l) CARTAGENA PROTOCOL RATIFICATION

South Africa has signed and ratified the Cartagena Protocol on Biosafety in 2003. As a result, revisions made in the “GMO” Amendment Act of 2006 included changes to ensure compliances with the provisions of the Cartagena Protocol.

(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

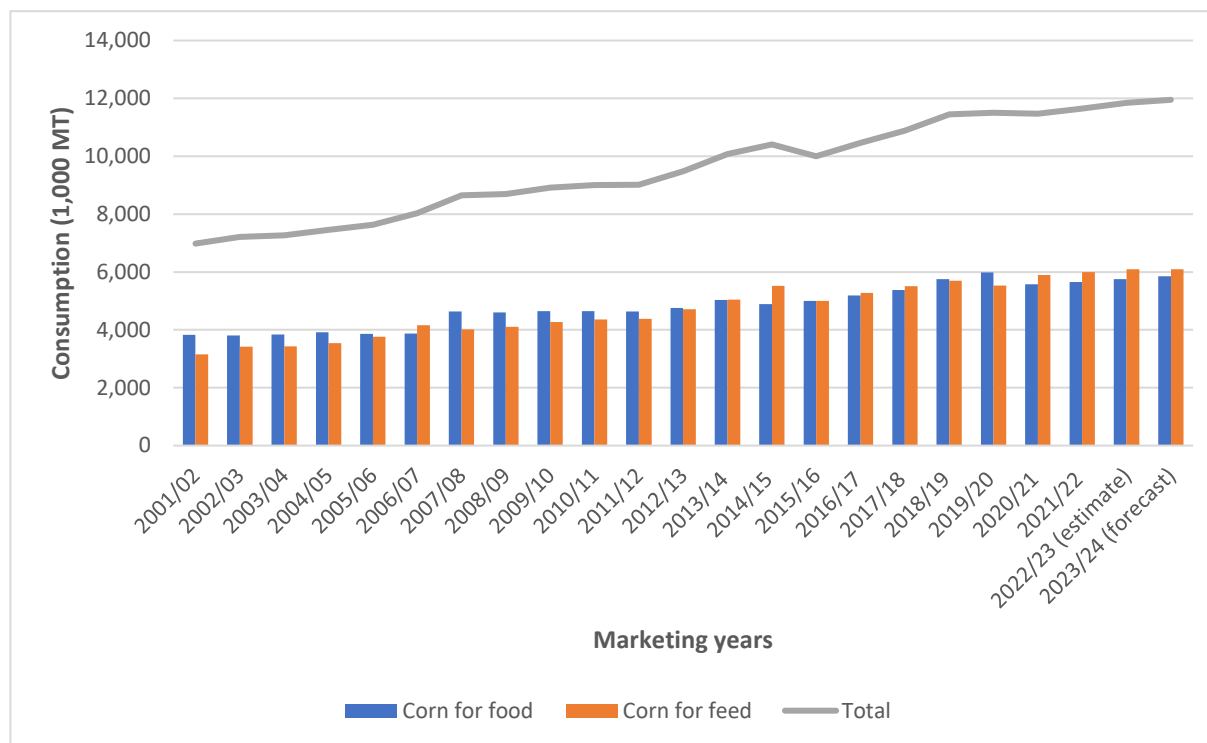
On the production side, South African farmers can be divided into two categories, namely, commercial, and small-scale/emerging farmers. GE products have a wide appeal with both groups with more than 80 percent of corn, 95 percent of soybeans, and all cotton being planted with GE seeds. Each group appreciates that GE crops use fewer inputs and have generally higher yields. Small-scale farmers also find GE crops in terms of pest and weed management easier than traditional or conventional hybrid varieties.

On the consumption side, South Africa uses almost 12 million tons of corn commercially on an annual basis, of which about half (mainly white corn) is used for human consumption. During the past 10 years, South Africa maintained an average marginal growth rate of about two percent per annum in the consumption of corn (refer to Figure 6). This trend is mainly driven by the increase in demand through population growth and expansion in the local broiler industry to serve the local market. Yellow corn is used as the primary ingredient for animal feed, especially in the broiler industry. Chicken meat has grown to be the most important protein source in the diet of the majority of South Africans over the past 20 years. White corn, in the form of a meal, is the staple food for many South African households as it is a relatively inexpensive source of carbohydrates. The per capita consumption of white corn is estimated at around 90kg per annum.

The bulk of soybeans produced in South Africa are crushed to produce both edible oil for human consumption and protein meal for inclusion in animal feed rations. South Africa crushed a record 2.5 MMT of oilseeds in MY 2021/22 on higher production. On the other hand, soybean demand for food is relatively small in South Africa as it is not traditionally consumed as part of the diet.

Figure 6

The Consumption of Corn in South Africa



Source: Sagis

(b) MARKET ACCEPTANCE/STUDIES

The most recent study evaluating public perceptions of biotechnology in South Africa was released by the Human Science Research Council (HSRC) in November 2016. The results of the study clearly indicated that the South African public can be broadly described as “less informed, but more positive” about biotechnology, and specifically GE products. South Africans are more than twice as likely as Europeans to believe that GE food is safe to eat and are also significantly more likely to see GE foods as good for the economy. The study also indicated major shifts in the public awareness of biotechnology and attitudes that favor the purchasing of GE food from 2004 to 2015. Public familiarity with the term ‘biotechnology’ more than doubled during this period, from 21 percent of the population to 53 percent. Public awareness that GE foods form a part of their diet more than tripled, from 13 percent to 48 percent (for more information see [Public perceptions of biotechnology in South Africa](#)).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

(a) RESEARCH AND PRODUCT DEVELOPMENT

In South Africa, animal biotechnology is also regulated by the “GMO” Act of 1997 and any application for research or product development will have to be approved by the EC. However, to date no animal biotechnology product has applied for review in South Africa. 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 as no commercial production is currently taking place.

(d) IMPORTS

South Africa allows the importation of products from GE animals that have been approved by South African regulators for food and feed purposes (commodity clearance). Commodity clearance means that South Africa allows the importation of these GE events for the use as food and/or feed and that are not intended for environmental release. South Africa’s regulators have not yet received any application for the importation of products from GE animals.

(e) TRADE BARRIERS

Not applicable

PART E: POLICY

(a) REGULATORY FRAMEWORK

As mentioned, animal biotechnology is regulated by the “GMO” Act of 1997 (see Chapter 1, Part B, sub paragraph a). 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 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 organizations.

(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.

(f) 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.

(g) INTERNATIONAL TREATIES and FORUMS

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

- 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 animals within these international organizations.

(h) RELATED ISSUES

Africa's first cultivated meat company, based in South Africa, has initiated the process of producing cell-cultured protein products, moving away from the traditional methods of harvesting livestock for meat. Founded in 2020, the Mzansi Meat Company seeks to use cellular agriculture technology to grow meat from cells. Another South African company, WildBio (previously Mogale Meat) seek to provide affordable healthy and nutritious cell cultivated meat products to a growing population through advanced biotechnologies. However, consumer acceptance, production costs and regulatory restrictions are major challenges to overcome.

South Africa's current food regulations do not provide for any classification regarding lab-grown meat. Without concerted government effort to update regulations, it could take years before lab-grown meat can legally be sold in South Africa. Labelling could also be an issue, as the makers of vegan and vegetarian products discovered recently. DALRRD demanded goods such as plant-based meatballs, vegan nuggets and vegan BBQ ribs be removed from shelves and re-labelled, for using names commonly associated with processed meat.

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

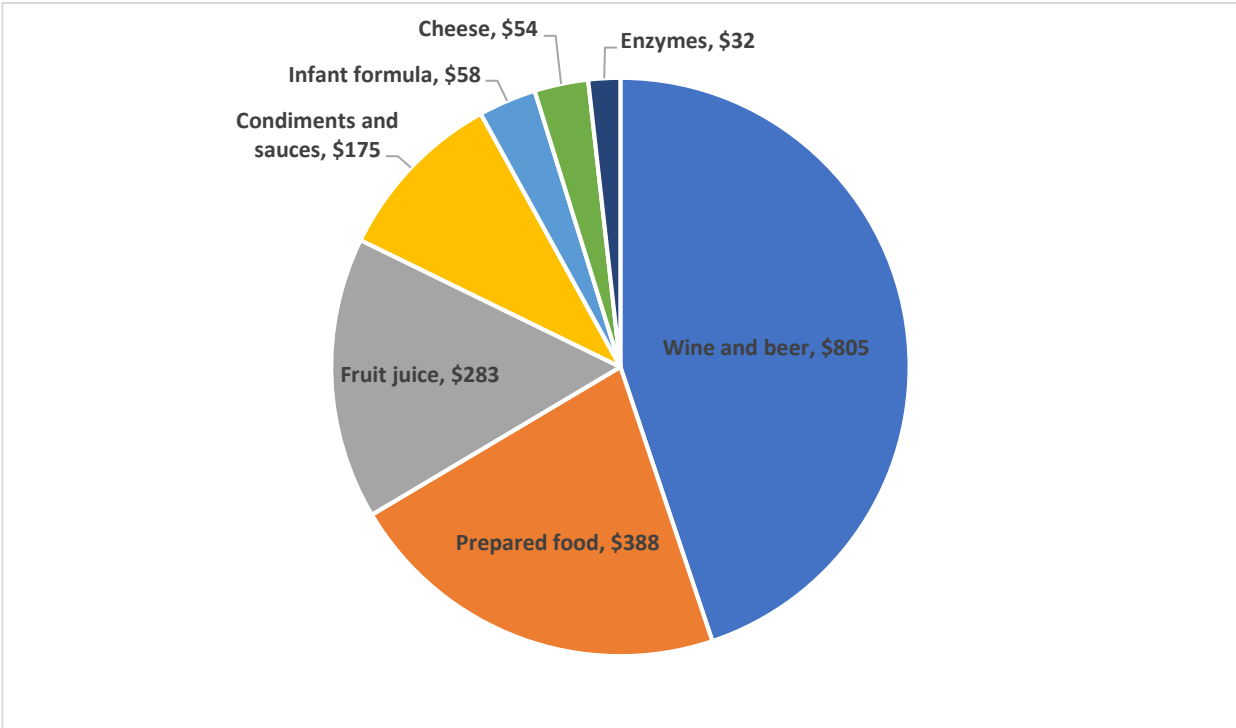
Various companies in South Africa are involved in the commercial production of food ingredients. Many of these companies use microbial biotechnology in the production process for enzymes, additives, flavorings, colorings, vitamins, and seasonings. Food ingredient manufacturers in South Africa are represented by two associations, namely, the South Africa Association of Food Science and Technology (<https://www.saafof.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 (see [Institute for microbial biotechnology and metagenomics](#)); Microbial, Biochemical and Food Biotechnology Department at the University of the Free State (see [Microbiology and biochemistry](#)) and the Institute of Biomedical and Microbial Biotechnology at the Cape Peninsula University of Technology (see [Research technology and innovation](#)).

b) EXPORTS

There are no official statistics on exports of microbial biotechnology products. However, South Africa exported US\$1.8 billion of processed products that might contain microbial biotech derived ingredients in 2022 (see Figure 7). Most of the trade in microbial biotech derived products are from value-added product categories, such as (1) wine and beer and (2) prepared food. The United States represents a relatively small portion of about six percent or US\$105 million of South Africa's export markets of these products.

Figure 7

South Africa's Exports of Processed Products that Could Contain Microbial Biotech Derived Ingredients in 2022 (millions of USD)



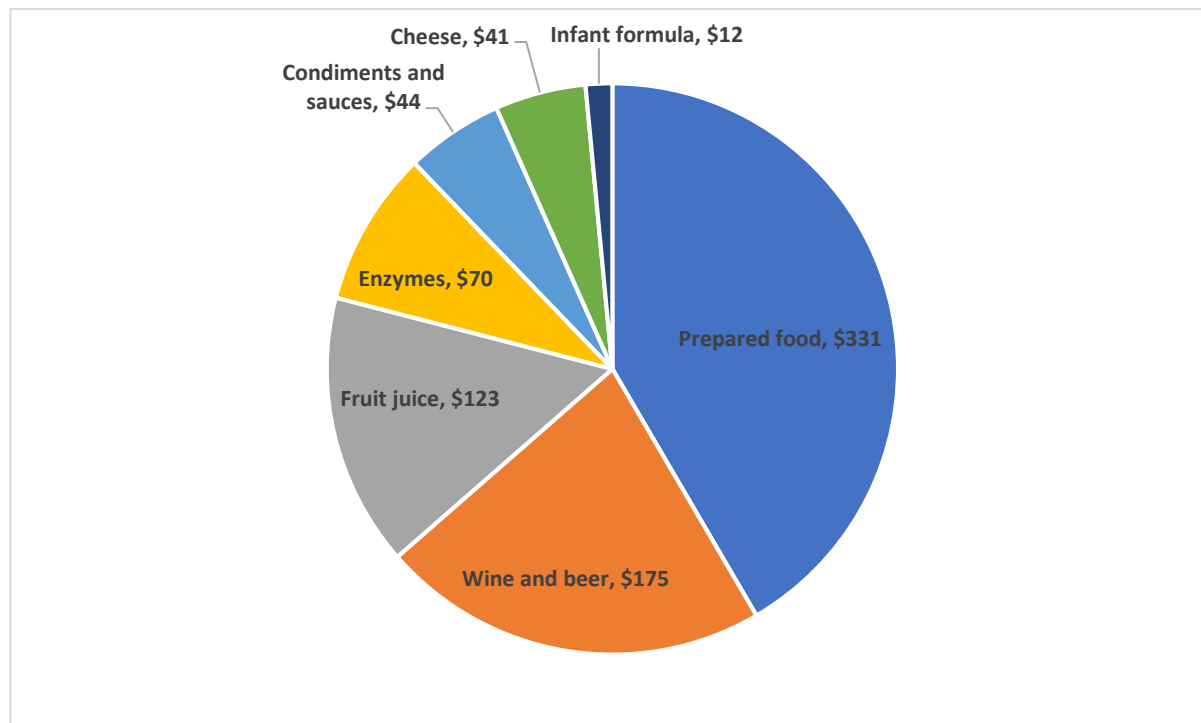
Source: Trade Data Monitor LLC

c) IMPORTS

South Africa imported US\$796 million worth of food ingredients, such as enzymes, or processed products that could contain microbial biotech-derived food ingredients in 2022 (see Figure 8). These imports include US\$48 million of processed products, potentially containing microbial biotech-derived food ingredients from the United States. South Africa also imported US\$70 million worth of microbial biotech derived enzymes in 2022, of which US\$10 million were imported from the United States.

Figure 8

South Africa’s Imports of Processed Products that Could Contain Microbial Biotech Derived Ingredients in 2022 (millions of USD)



Source: Trade Data Monitor LLC

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 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 described in Chapter One, Part B 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 7 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 labelling requirements.

Table 7

Existing Food Additives, Food Colorant and Microbiological Standards Regulations in South Africa (with website link)

<u>Name of regulation</u>

Miscellaneous additives

Regulations Relating to Food Colorant

Regulations - Additives - Sweeteners - List of Permissible Sweeteners

Regulations Relating to the Use of Sweeteners in Foodstuffs (R733/201)
--

Codex General Standards for Food Additives
--

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 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 7.

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, Part B, sub-paragraph g (Labeling and Traceability).

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 [Foodstuffs, Cosmetics and Disinfectants Act: Regulations: Labeling and advertising of foodstuffs](#)).

d) MONITORING AND TESTING

South Africa does not actively test for evidence of genetic engineering in imports and exports of processed products.

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 microbial 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. However, as the public, in general, is relatively uninformed about the use of microbial biotechnology, neither strongly positive nor negative opinions have been formed.

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 [South Africa Food Processing Ingredients](#)). Although no studies could be found focusing on 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 plant events approved for general release in South Africa

Company	Event	Crop/product	Trait	Year approved
Corteva	DP-056113-9	Corn	Pollination Control System	2023
Corteva	MON89034xTC1507xMIR162xNK603xDAS-40278-9	Corn	Insect resistant Herbicide tolerant	2023
Corteva	DAS-44406-6xDAS-81419-2	Soybean	Insect resistant Herbicide tolerant	2022
Corteva	DAS-44406-6	Soybean	Herbicide tolerant	2022
Syngenta	MIR162	Corn	Insect resistant	2022
Bayer	MON87701xMON89788	Soybeans	Insect resistant Herbicide tolerant	2021
Syngenta	BT11xMIR162xGA21	Corn	Insect resistant Herbicide tolerant	2021
Syngenta	BT11xMIR162xMON89034xGA21	Corn	Insect resistant Herbicide tolerant	2021
Bayer	MON87427xMON89034xMIR162xNK603	Corn	Insect resistant Herbicide tolerant	2020
Dow AgroSciences SA	DAS40278-9	Corn	Herbicide tolerant	2019
Dow AgroSciences SA	MON89034xTC1507xNK603xDAS40278-9	Corn	Herbicide tolerant	2019
Dow AgroSciences SA	DAS40278-9xNK603	Corn	Insect resistant Herbicide tolerant	2019
Dow AgroSciences SA	MON89034xTC1507xNK603	Corn	Insect resistant Herbicide tolerant	2018
Monsanto	MON87460	Corn	Drought tolerance	2015
Du Pont Pioneer	TC1507 x MON810 x NK603	Corn	Insect resistant Herbicide tolerant	2014
Du Pont Pioneer	TC1507 x MON810	Corn	Insect resistant Herbicide tolerant	2014
Du Pont 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

Source: DALRRD

Table A2

GE plant events approved for trial release since 2018

Company	Event	Crop	Trait	Year approved
<u>Monsanto</u>	MON87427xMO89034xMIR162xNK603	Corn	Insect resistant Herbicide tolerance	2018
	MON87701 x MON89788	Soybean	Insect resistant Herbicide tolerance	2018
	MON87460xMON810	Corn	Insect resistant Drought tolerance Antibiotic resistant	2019
	MON87701 x MON89788	Soybeans	Insect resistant Herbicide tolerance	2019
<u>Bayer</u>	GHB614 x LLCotton25	Cotton	Herbicide tolerance	2018
	MON87427 x MON89034 x MIR162 x NK603	Corn	Herbicide tolerance Insect resistant	2020

	MON87460 x MON810	Corn	Insect resistant Abiotic resistant	2020
	MON87701 x MON89788	Soybeans	Herbicide tolerance Insect resistant	2020
	MON87460xMON810	Corn	Insect resistant Drought tolerance Antibiotic resistant Abiotic tolerance	2021
<u>Bioceres</u>	HB4	Soybean	Herbicide tolerance Abiotic tolerance	2022
	HB4 x GTS-40-3-2	Soybean	Herbicide tolerance Abiotic tolerance	2022
<u>Dow</u>	DAS40278-9	Corn	Herbicide tolerance	2018
<u>AgroSciences</u>	NK603 x DAS40278-9	Corn	Herbicide tolerance	2018
	MON89034 x 1507 x NK603	Corn	Herbicide tolerance Insect resistant	2018
	MON89034 x 1507 x NK603 x DAS40278-9	Corn	Herbicide tolerance Insect resistant	2018
	DAS-44406-6	Soybeans	Herbicide tolerance	2020
	DAS-81419-2 x DAS-44406-	Soybeans	Herbicide tolerance Insect resistant	2020
<u>Pioneer</u>	DP-0561139	Corn		2019
	NK603 x T25 x DAS-40278-9	Corn	Herbicide tolerance	2020
	DP-056113-9	Corn		2020
	TC1507 x MIR162 x NK603	Corn	Herbicide tolerance Insect resistant	2020
	MON89034xTC1507xMIR162xNK603x DAS40278-9	Corn	Herbicide tolerance Insect resistant	2020
<u>Syngenta</u>	BT11 x MIR162 x GA21	Corn	Herbicide tolerance Insect resistant	2018
	BT11xMIR162xMON89034xGA21	Corn	Herbicide tolerance Insect resistant	2018
	BT11 x MIR162 x GA21	Corn	Herbicide tolerance Insect resistant	2019
	BT11xMIR162xMON89034xGA21	Corn	Herbicide tolerance Insect resistant	2019
	MIR162	Corn	Insect resistant	2020
	BT11xMIR162xGA21	Corn	Herbicide tolerance Insect resistant	2020
	BT11xMIR162xMON89034xGA21	Corn	Herbicide tolerance Insect resistant	2020

	MIR162	Corn	Insect resistant	2021
	BT11xMIR162xGA21	Corn	Herbicide tolerance Insect resistant	2021
	BT11xMIR162xMON89034xGA21	Corn	Herbicide tolerance Insect resistant	2021
<u>BASF</u>	GHB614xLLCotton25	Cotton	Herbicide tolerance	2020
	GHB614xLLCotton25	Cotton	Herbicide tolerance	2021
<u>Sensako</u>	HB4	Soybeans	Abiotic Resistant Herb tolerance	2020

Source: DALRRD

Table A3

GE events with commodity clearance

Company	Event	Crop	Trait	Year approved
Corteva	DP202216	Corn	Enhanced grain yield, Herbicide tolerance	2023
Bioceres	HB4	Soybean	Abiotic resistance, Herbicide tolerance	2022
Trigall Genetics	HB4	Wheat	Abiotic resistance, Herbicide tolerance	2022
Syngenta	3272 x Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21	Corn	Insect resistance, Herbicide tolerance	2022
Corteva	NK603 x T25 x DAS-40278-9	Corn	Herbicide tolerance	2021
Pioneer Hi-Bred RSA (Pty) Ltd	DAS-81419-2 x DAS-44406-6	Soybean	Insect resistance, Herbicide tolerance	2021
BASF	GMB151	Soybean	Insect resistance, Herbicide tolerance	2021
BASF	GHB811	Cotton	Herbicide tolerance	2021
Pioneer Hi-Bred RSA (Pty) Ltd	MON89034 x TC1507 x MIR162 x NK603 x DAS- 40278- 9	Corn	Insect resistance, Herbicide tolerance	2020
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	Corn	Insect resistant Herbicide tolerant	2020

	MON87411 x MON87419			
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- 59122-7	Corn	Insect resistant Herbicide tolerant	2018
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 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	2015

			Herbicide tolerant	
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 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 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 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

Source: DALRRD

Attachments:

No Attachments