



THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 7/15/2010

GAIN Report Number:

South Africa - Republic of

Biotechnology - GE Plants and Animals

Enter a Descriptive Report Name

Approved By:

Linston Terry

Prepared By:

Dirk Esterhuizen

Report Highlights:

South Africa's new Consumer Protection Bill will require virtually every product label in South Africa's food and beverage industry to be changed by March 1, 2011 to comply with mandatory GMO labeling requirements. The intent of the law is to prevent exploitation or harm of consumers and to promote the social well being of consumers. Post expects mandatory GMO labeling for all domestic and imported GMO food products and liability clauses in this bill will directly affect U.S. companies with food and agricultural interests in South Africa.

Section I. Executive Summary:

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

South Africa is a net exporter of agricultural, fish and forestry products. The United Kingdom (\$609 million) is the major destination of South Africa's agriculture, fish, and forestry products and represents 10.22 percent of total exports. Exports of agricultural, fish and forestry products to the United States were \$200 million in 2009, 2.7 percent less than in 2008, and accounts for 3.3 percent of exports by South Africa. Fruit (\$40.3 million), wine (\$39.9 million), seafood products (\$24 million) and sugar (\$21.1 million) were the major items exported to the United States. South Africa's major partner for importing agriculture, fish, and forestry products is Argentina, which accounts for 13.28 percent or \$622 million of imports. Imports from the United States decreased by 56.65 percent to \$182 million in 2009 but still represents 3.8 percent of South African imports of agriculture, fish, and forestry products. The decline in imports from the United States was due to a decrease in wheat imports, vegetable oils, and dairy products. Planting seeds (\$13 million), forest products (\$12 million) and processed fruit and vegetables (\$11 million) were the major products imported from the United States by South Africa.

The amendments to the GMO Act of 1997 published and gazetted in April 2007 came into effect in February 2010. The amendments now make it clear that a scientifically based risk assessment is a prerequisite for decision making related to and Genetically Modified Organism (GMO). The Amendments also authorizes the Executive Council to determine if an environmental impact assessment is required under the National Environmental Management Act. The amendments also add specific legislation to allow socio-economic considerations to factor into decision making and makes those considerations significantly important in the decision making process.

South Africa's new Consumer Protection Bill require virtually that every product label in South Africa's food and beverage industry to be changed by March 1, 2011 and requires mandatory GMO labeling. The primary purpose of the law is to prevent exploitation or harm of consumers and to promote the social well being of consumers. Mandatory GMO labeling for all domestic and imported GMO food products and liability clauses in this bill will directly affect United States companies with food and agricultural interests in South Africa.

Section II. Plant Biotechnology Trade and Production:

1. Biotechnology Trade and Production

1.1 Current Status

Table 1 shows all the GMO events that have been approved for commercial use in South Africa. South Africa *does not commercially produce any biotechnology crops were the events were developed outside of the United States*. These events is present in three crops namely, corn, soybeans and cotton.

Table 1: GMOs approved for general release in South Africa

| Company | Event | Crop | Trait | Year approved |
|----------------|---|-------------|--|----------------------|
| 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 |

1.1.1 Corn

Corn is the main field crop produce in South Africa and is use for both human (mainly white corn) and animal (mainly yellow corn) consumption. The first GM corn event (insect resistant) approved in South Africa was in 1997 and since then there was a progressive and steady increase in GM corn plantings. Table 2 illustrates the plantings of GM corn in South Africa the past 5 years. GM corn plantings increased from 28.5 percent of total South African corn planted in the 2005/06 production year to 78.2 percent in the 2009/10 production year. In the 2008/09 production season GM corn plantings represented 62.0 percent of total corn plantings. Of the 1.536 million hectares of white corn planted in the 2009/10 season, 78.9 percent or 1.212 million hectares was

biotech. The Bt insect resistant (986,366 hectares) variety was planted most followed by the herbicide-tolerant (117,159 hectares) and combined (“stacked”) traits (111,187 hectares) seed (see also Table 3).

Of the 864,000 hectares yellow corn planted in the 2009/10 season, 77.0 percent or 666,403 hectares was biotech. Again the Bt insect resistant (326,865 hectares) variety was planted most followed by the combined (“stacked”) traits (186,973 hectares) and the herbicide-tolerant (153,565 hectares) seed.

Table 2: Planting of GM corn in South Africa the past 5 years

| | Area planted '000 ha | | |
|-------------------------|-----------------------------|--------------------|-------------------|
| Production years | White corn | Yellow corn | Total corn |
| <u>2005/06</u> | | | |
| Total | 1.033 | 567 | 1.600 |
| Biotech | 281 | 175 | 456 |
| % of total | 27.2% | 30.9% | 28.5% |
| <u>2006/07</u> | | | |
| Total | 1.625 | 927 | 2.552 |
| Biotech | 851 | 408 | 1.259 |
| % of total | 52.3% | 44.0% | 49.3% |
| <u>2007/08</u> | | | |
| Total | 1.737 | 1.062 | 2.799 |
| Biotech | 975 | 587 | 1.562 |
| % of total | 56.1% | 55.2% | 55.8% |
| <u>2008/09</u> | | | |
| Total | 1.600 | 1.000 | 2.600 |
| Biotech | 892 | 720 | 1.612 |
| % of total | 55.7% | 72.0% | 62.0% |
| <u>2009/10</u> | | | |
| Total | 1.536 | 864 | 2.400 |
| Biotech | 1.212 | 666 | 1.878 |
| % of total | 78.9% | 77.0% | 78.2% |

Source: FoodNCropBio supported by the Maize Trust

Table 3: Percentage of the biotech corn crop that was planted with the different traits the past 5 years

| Production year | White corn | Yellow corn | Total corn |
|-----------------------------|-------------------|--------------------|-------------------|
| 2005/06 | | | |
| % Insect Resistant | 78.6 | 61.1 | 71.9 |
| % Herbicide Tolerant | 21.4 | 38.9 | 28.1 |
| % Stacked | 0 | 0 | 0 |
| 2006/07 | | | |
| % Insect Resistant | 83.7 | 71.6 | 79.8 |
| % Herbicide Tolerant | 16.3 | 28.4 | 20.2 |
| % Stacked | 0 | 0 | 0 |
| 2007/08 | | | |
| % Insect Resistant | 71.4 | 69.2 | 70.6 |
| % Herbicide Tolerant | 22.4 | 27.1 | 24.1 |
| % Stacked | 6.3 | 3.7 | 5.3 |
| 2008/09 | | | |
| % Insect Resistant | 65.9 | 62.9 | 64.0 |
| % Herbicide Tolerant | 16.6 | 18.1 | 17.2 |
| % Stacked | 18.5 | 19.0 | 18.7 |
| 2009/10 | | | |
| % Insect Resistant | 81.2 | 48.9 | 69.7 |
| % Herbicide Tolerant | 9.7 | 23.0 | 14.4 |
| % Stacked | 9.2 | 28.1 | 15.9 |

Source: FoodNCropBio supported by the Maize Trust

South Africa is the major exporter of corn on the Africa continent and 95 percent of South African corn exports are destined for countries in Africa. For the 2009/10 marketing South Africa exported almost 2.0 million tons of corn, mostly white corn (85 percent of corn exported). More than 50 percent of South Africa's corn exports have gone to Kenya in the 2009/10 marketing year, which has been severely hit by a drought that has left a third of its population in need of food aid. A transaction of corn exports to Kenya attracted media attention as the first 40,000 tons of the order got stuck at Mombasa harbor as a result of protests against South Africa's genetically modified (GM) corn entering Kenya. The protesters, led by the environmental group Kenyan Biodiversity Coalition, said East Africa's biggest economy had a bumper harvest, and the contaminate GM corn imports from South Africa had not been authorized by the Kenyan government. However, the issue, which was a technical and administrative matter between the two countries, was resolved and exports continued. Following Kenya as major destinations for South African corn exports are Botswana, Mozambique and Lesotho.

With one of the largest corn crop ever produced in the country, South Africa will have approximately 4.0 million tons of corn available for exports in the marketing years starting May 2010 to April 2011. More than 70 percent of this corn is GM.

Due to the fact that the United States has approved corn events that are not yet approved in South Africa, United States commercial corn is not authorized to enter into South Africa. South Africa is not opposed in principle to these events, but if they have not made it through the regulatory approval process of South Africa they can not

be imported. Commercial corn that contains biotech events that are already approved in South Africa is not affected by this.

However, U.S. food aid destined to Lesotho, Malawi, Swaziland, Zambia and Zimbabwe ordinarily passes through the port of Durban, South Africa. In order for the shipment to pass through South Africa, the GMO Registrar's Office requires several measures:

- Advance notification so that proper containment measures can be taken;
- Letter from the recipient country stating that they accept the food aid consignment and that they know that it contains GMOs;
- Milling near the port. Southern African Development Community (SADC) regulations state that if food aid has biotech content then it must be milled.

1.1.2 Soybeans

GM soybeans were first approved for commercialization in South Africa in 2001; by 2006, 75 percent of the soybean crop grown was GM. In 2009 the area planted with soybeans increased by 30.9 percent, from 237,750 hectares in the 2008 to 311,450 hectares. An estimated 85 percent of the 2009 season's soybeans plantings were GM (herbicide tolerant). In 2009 Soybean production surpassed sunflower production the first time in South Africa's agricultural history as the most important oilseed crop produced. One reason for this is the fact that the production of soybeans is made relatively easier with the GM cultivars that are available in South Africa and the fact that most of soybeans' production processes can now be mechanized.

1.1.3 Cotton

Bt cotton was the first GM crop variety to be grown commercially in sub-Saharan Africa. Early adopters were small-scale farmers in the Makhatini Flats in Kwazulu-Natal, South Africa, who have been growing the crop since 1998. Total cotton planting in 2009 was 8,300 hectares down from almost 13,000 hectares in 2008. GM cotton plantings represent 98 percent of total cotton plantings in South Africa. The stacked variety is the most favored one and represents 85 percent of total cotton planting.

1.2 Biotech crops under development

1.2.1 Permits issued

The Executive Council (EC) review all applications submitted in terms of the GMO Act and use a case-by-case and precautionary approach to ensure sound decision making in the interest of safety of the environment and the health of human and animals. Most applications considered by the EC involve GM corn and cotton and in most cases represent modifications and refinements of existing traits. Mindful of other challenges beyond that of

agriculture, the EC also evaluate applications for vaccine trials involving GMOs.

In terms of the GMO Act a total number of 359 permits were issued in 2009, compared to 272 in 2008. Until May this year, 124 permits have already been issued. The majority of permits being issued were for the import and export of GM crops (see also Table 4). Imports focused mainly on commercially approved corn, soybeans and cotton for activities relating to planting, contained use, food and feed. In addition, imports also include GM HIV and tuberculosis vaccines for contained use in South Africa. The main exports permits issued included GM corn and to a lesser degree GM cotton primarily for contained use, planting activities and under the new amendments to the GMO act, GM corn exported as a commodity for human and animal use. Two commodity clearance applications were received so far in 2010, compared to 24 in 2008 and none in 2009. These applications are basically for corn for the use as food, feed and processing and did undergo safety assessments.

Table 4: Summary of GMO permits issues in South Africa from 2008

| | 2008 | 2009 | 2010 (Until May) |
|----------------------|-------------|-------------|-------------------------|
| Exports | 95 | 167 | 95 |
| Imports | 135 | 150 | 20 |
| Trails | 16 | 35 | 4 |
| Contained use | 2 | 7 | 3 |
| Commodity use | 24 | 0 | 2 |
| Total | 272 | 359 | 124 |

The last GMO general release permits for commercialization were issued in 2007; however, since the beginning of 2008, 55 field, or clinical trails permits were authorized. Table 5 summarizes the event, trait product and company involved of the permits issued since 2008. The product include corn and cotton for evaluation of insect resistance and/or herbicide tolerance and the long-awaited drought tolerance in corn as well as for the evaluation of GM sugar with altered sugar content and growth rate. Clinical trail permits were issued for measles, HIV and tuberculosis vaccines.

Table 5: GMOs approved for trial release from 01/01/2008 to 05/31/2010

| Company | Event | Crop/product | Trait |
|------------------------|----------------|---------------------|---|
| <u>Syngenta</u> | BT11 X GA21 | Maize | Herbicide tolerance Insect resistant |
| | GA21 | Maize | Herbicide Tolerance |
| | MIR162 | Maize | Insect resistant |
| | BT II x MIR162 | Maize | Herbicide tolerance Insect resistant |
| <u>Monsanto</u> | MON87460 | Maize | Drought Tolerance |

| | | | |
|-------------------|-----------------------------------|-----------|---|
| | MON89034 X NK603 | Maize | Insect Resistant Herbicide Tolerance |
| | MON89034 | Maize | Insect Resistant |
| | MON87460 | Maize | Drought Tolerance |
| | MON89034 | Maize | Insect Resistant |
| Bayer | GlyTol x LLCotton25 | Cotton | Herbicide tolerance |
| | GHB119 | Cotton | Insect Resistant Herbicide Tolerance |
| | BG II x LLCotton25 | Cotton | Insect Resistant Herbicide Tolerance |
| | T304-40 | Cotton | Insect Resistant Herbicide Tolerance |
| | GHB614 | Cotton | Herbicide tolerance |
| | GHB614 x LLCotton25 | Cotton | Herbicide tolerance |
| | Bollgard II x LLCotton25 | Cotton | Herbicide tolerance Insect resistant |
| | Twinlink x GlyTol | Cotton | Herbicide tolerance Insect resistant |
| | Bollgard II x GlyTol x LLCotton25 | Cotton | Herbicide tolerance Insect resistant |
| | Twinlink | Cotton | Herbicide tolerance Insect resistant |
| Triclinium | MVA-mBN85B | Vaccine | Measles |
| | VIR201 | Vaccine | HIV |
| | AERAS-402 | Vaccine | HIV |
| | MVA/AERAS-485-recombinant MVA | Vaccine | TB |
| | MVA85A | Vaccine | TB |
| | AERAS-402 | Vaccine | TB |
| | VPM1002 | Vaccine | TB |
| | MVA85A/AERAS485 | Vaccine | TB |
| SASRI | NCo310 | Sugarcane | Alternative sugar |
| | pASNI | Sugarcane | Growth rate/yield & altered sucrose content |
| | pSVPPase | Sugarcane | Growth rate/yield & altered sucrose content |
| | pAUGdf510 | Sugarcane | Growth rate/yield & altered sucrose content |
| Pioneer | MON810 x MIR162 | Maize | Herbicide tolerance Insect resistant |
| | 59122 | Maize | Insect resistant |
| | TC1507 | Maize | Herbicide tolerance |

| | | | |
|-------------|-------------------------|-----------|---|
| | | | Insect resistant |
| | 98140 | Maize | Herbicide tolerance |
| | 98140 x MON810 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 x MON810 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 x MIR162 | Maize | Herbicide tolerance Insect resistant |
| | 98140 x TC1507 x MON810 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 x MON810 x NK603 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 x MIR162 x NK603 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 x MON810 xMIR162 | Maize | Herbicide tolerance Insect resistant |
| PPD | MEDI-534 | Vaccine | Intranasal |
| SUN | | Grapevine | |
| Wits | SAAVI rMVA TBC-M456 | Vaccine | |

Since 2008, 12 contained use permits were issued for GM corn, cassava, sorghum and ornithogalum (see also Table 6)

Table 6: GMOs approved for contained use from 01/01/2008 to 05/31/2010

| Company | Event | Crop/product | Trait |
|----------------|-------------------------|----------------------------------|---|
| ARC-VOPI | Rolou A2:1 &A2:4 | Ornithogalum dubium x thyrsoides | — |
| ARC-IIC | TMS60444 Line 3.1 & 3.2 | Cassava | Starch enhanced |
| CSIR | ABS1 | Sorghum | Nutritional composition |
| Monsanto | MON89034 | | Insect resistant |
| | MON89034 x NK603 | | Herbicide tolerance Insect resistant |
| Pioneer | 98140 x Mon810 | Maize | Herbicide tolerance Insect resistant |
| | TC1507 | Maize | Insect resistant |
| | 98140 | Maize | Herbicide tolerance |
| | TC1507 x MON810 | Maize | Herbicide tolerance Insect resistant |
| | 59122 | Maize | Insect resistant |

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

organizations representing the anti- and pro-GMO movements.

1.2.2 Grapevines

The South African wine and table grape industries are funding research to develop GMO grapevines. The research is focused on the development of fungal and viral resistant vines and the metabolic engineering of grapevines towards enhanced environmental stress resistance and improved grape berry quality factors such as color and aroma. Several transgenic grapevine lines are being evaluated in greenhouse trials. In 2006, the Institute for Wine Biotechnology at Stellenbosch University applied for a permit to perform the first GM grapevine field trials in South Africa. The objectives of the trial were to evaluate the morphology, growth, and fruit quality of the transgenic plants under field conditions. In September 2007, the Advisory Committee (AC) evaluated the application and a list of questions about the trial was referred back to the applicant. The applicant responded to those questions and the permit for field trials was finally approved in September 2009. Wine is one of the major products exported to the United States by South Africa and was worth around \$40 million in 2009.

1.2.3 Bt Potato

The tuber moth resistant Bt potato, SpuntaG2, developed by the South African Agricultural Research Council and Michigan State University was denied general release by the EC in 2009. The EC dismissed the application for a permit to release the potato on safety and economic grounds. The Agricultural Research Council appealed against the EC's decision in October 2009. The appeal decision is still pending.

The potato, SpuntaG2, contains a gene from the soil bacterium *Bacillus thuringiensis* which acts like a built-in pesticide against the tuber moth (*Phthorimaea operculella*). The moth caused R40 million (US\$5 million) of losses to the potato industry in 2008. Scientists had hoped the potato would allow farmers to use fewer pesticides, reducing costs and helping the environment.

The local potato industry, represented by Potatoes SA, has vocalized that, while they support GMO innovations and understand the potential of GMOs to strengthen agricultural productivity, they feel the introduction of the Bt potato at this time would negatively affect potato demand in South Africa. Potatoes SA has been focusing on increasing potato consumption in South Africa which has been falling over the past years. It is not clear if the vocalization of Potatoes SA against the timing of the approval of the Bt potato has influenced the decision of the new GMO trait. If the appeal fails there is a strong possibility that the GM potato research will cease due to lack of funding.

1.2.4 Cassava

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

1.2.5 Transgenic Sorghum

An application for contained greenhouse facility testing of transgenic sorghum was approved by the South Africa's GMO Executive Council after twice being denied due to technical reasons. The Council for Scientific and Industrial Research (CSIR) will continue to work on the African Bio-fortified Sorghum Project (ABS) in level 3 biosafety greenhouses.

Using genetic engineering and conventional plant breeding methods, the scientists hoped to develop a more easily digestible strain of sorghum with increased levels of vitamins A and E, iron, zinc, and essential amino acids. Kenya-based Africa Harvest Biotech Foundation International will continue to lead the research.

1.2.6 Other Research

Research is continuing on corn and cotton for evaluation of insect resistance and/or herbicide tolerance and the long-awaited drought tolerance in corn as well as for the evaluation of GM sugar with altered sugar content and growth rate. The ARC is also busy on transgenic virus resistant selections of an ornamental bulb species, *Orinthogalum*, a type of hyacinth (Chinkerinchee or Sun Star).

Section III. Plant Biotechnology Policy:

2.1 Historical context

Already in 1979, the South African government established the Committee on Genetic engineering (SAGENE). SAGENE comprised of a group of brilliant South African scientist and was commissioned to act as scientific advisory body to the government and pave the way for the uptake of genetic engineering in food, agriculture, and medicine. In 1989, on the advice of SAGENE, the first GMO experiments in open field trails 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 GMO products". As a result, SAGENE was task in drafting 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 GMO products, and under its auspices granted permits to allow Monsanto commercializing GM cotton and GM corn seed. In addition, 178 permits were granted for a variety of open field GMO trails. Once the GMO Act came into effect, SAGENE ceased to exist and was replace by an Executive Council, established by the GMO Act.

2.2 The GMO Act of 1997

The GMO Act of 1997 and its accompanying Regulations are administrated by the Department of Agriculture,

Forestry and Fisheries (DAFF) as the principal pieces of legislation to regulate GMOs in South Africa. Under the GMO act a decision-making body (the Executive Council), an advisory body (the Advisory Council) and administrative body (the GMO Registrar) was established to:

- Provide measures to promote the responsible development, production, use and application of GMOs;
- Ensure that all activities involving the use of GMOs be carried out in such away 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 GMOs;
- Lay down the necessary requirements and criteria for risk assessments;
- Establish appropriate procedures for the notification of specific activities involving the use of GMOs.

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

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

The amendments also create at least 8 new provisions dealing with accidents and/or unintentional transboundary movement. These provisions have been motivated by the spate of contamination incidents that have occurred worldwide involving unapproved GMOs. A new definition of “accident” has been created to capture two types of situations: one dealing with unintentional transboundary movements of GMOs and the other, unintentional environmental release within South Africa.

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

2.2.1 The Executive Council

The EC functions as an advisory body to the Minister of Agriculture, Forestry and Fisheries on matters relating to GMOs, but more important is the decision-making body that approves or rejects GMO applications. The EC

is also empowered to co-opt any person knowledgeable in the field of science to serve on the EC to provide advice.

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

- Department of Agriculture, Forestry and Fisheries
- Department of Water and Environmental Affairs
- Department of Health
- Department of Trade and Industry
- Department of Science and Technology
- Department of Labor
- Department of Arts and Culture

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

2.2.2 The Advisory Council

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

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

2.2.3 The Registrar

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

2.3 Other regulations that impact on GMOs in South Africa

2.3.1 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 GMOs as one of those threats. It also ensures there is a sharing of benefits from South Africa's biological resources.

Section 78 of the act gives the Minister of Environmental Affairs the power to deny a permit for general or trial release applied for under the GMO Act, if the GMO may pose a threat to any indigenous species or the environment, unless an environmental assessment has been conducted. There have been relatively few GMO environmental assessments conducted as a result of the requirements of the Biodiversity Act.

The Act also asks for the establishment of a South African Biodiversity Institute (SANBI). SANBI is tasked to monitor and report regularly to the Minister of Environmental Affairs on the impacts of any genetically modified organism 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.

Even though SANBI is just recently establishing itself in this new role, additional monitoring obligations have been required by the GMO Registrar in order to issue permits. The EC has not clearly defined the types of environmental monitoring that would be required. Nor, has the purpose of that monitoring been established. There have been ongoing discussions in the EC to resolve the issue.

2.3.2 Consumer Protection Act

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

On April 24, 2009 outgoing President signed the new Consumer Protection Bill into law. The new Consumer Protection Bill require virtually that every product label in South Africa's food and beverage industry to be changed by March 1, 2011. The primary purpose of the law is to prevent exploitation or harm of consumers and to promote the social well being of consumers. However, the approved new South African Consumer Protection Act, of 2008 (Act No. 68 of 2008) has the following section which states that all products containing GM 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.

Thus, mandatory labeling of GMOs is required for all domestic and imported food products. The Department of Trade & Industry views the labeling of GMOs solely within the context of the consumers right to obtain the facts needed to make an informed choice or decision about food. It is thus not about human health, safety or quality issues.

Additionally, the new Act includes a significant change to product liability, where a consumer no longer has to demonstrate that a producer was negligent before receiving compensation for injury. The new legislation puts the burden of proof on the producer or supplier, meaning that a consumer can sue almost any producer or supplier for harm or injury that is the result of a failed, defective, or unsafe product. Almost every supplier must comply with the bill, even if the supplier does not reside in South Africa. Foreign producers who sell products through a South African agent for use in South Africa would be included under the bill.

These regulations may have a significant impact not only on regional trade, but also on United States exports to South Africa, since all products will have to be labeled and producers/suppliers could be held liable for any purported harm their product may have caused. South African biotechnology stakeholders are also concerned about the scope of the clause and whether GM products that have already been registered and approved for use in the Republic of South Africa (e.g. certain varieties of corn, soybean and cotton) need to be labeled.

South Africa is seen as a leader in the biotechnology front in Africa, and many neighboring countries look to South Africa for guidance and direction. While South Africa is an ally of the United States in that it has a progressive biosafety policy that is based on sound science and backed by an informed, forward-thinking GMO Council and Advisory Committee, this is an instance where uneducated parties can introduce legislation that will affect the administration of the current GMO biosafety legislation. As other countries look to South Africa for guidance, they may be likely to adopt similar legislations that would affect trade.

At an FAS-sponsored regional workshop on biosafety held May 11 -13, 2009 in Pretoria, participants from Mozambique, Zimbabwe, and Mauritius questioned South African counterparts on the intent of this bill. On three separate occasions Zimbabwean representatives stated that they have always looked up to South Africa and their biosafety legislation as a leader on the continent in biotechnology and they use South Africa as an example of the correct way to regulate biotechnology and GMOs. However, recent 'issues', such as this Consumer Protection Bill, have caused them to worry about the direction South Africa is taking and wonder if South Africa is going to change their acceptance of GMOs, which, due to South Africa's position as the strongest economy in sub-Saharan Africa, could negatively affect trade throughout the rest of the economy.

2.3.3 Biosafety Protocol

SA has signed and ratified the Cartagena Protocol on Biosafety (CPB). The primary responsibility for

implementing the CPB has shifted from the Department of Environmental Affairs to the Department of Agriculture, Fisheries and Forestry (DAFF). CPB implementation is meant to be gradual, and accordingly DAFF's implementation will be in phases, with the most significant issues being handled first. SA, under the leadership of DAFF's GMO Regulatory Office, has modified its GMO Act to comply with the CPB. The CPB will likely slow down trade with its additional bureaucratic requirements but will likely not diminish trade in GMOs in the long run.

South Africa is taking a keen interest in the review of Article 18.2 (a) of the Cartagena Protocol. Throughout the Cartagena Protocol on Biosafety negotiations, South Africa has advanced the position that a fair and practical solution for the "may contain" language is required. South Africa's preference is for the "may contain" living modified organism (LMO) language to remain together with the comprehensive list of events commercially available in country of origin. South Africa opposes a mandatory requirement for countries to use "does contain" LMOs language and other decisions that place the burden of implementation and financing on state parties. The key concern for South Africa is whether the extra financial or technical burdens of distinguishing LMO consignments from non-LMO consignments should fall on importers or exporters. As a country that is in the unique position of understanding both perspectives, South Africa strongly advocates that any decision taken should advance Biosafety standards and should not unwittingly be place onerous compliance burdens on State Parties.

2.3.4 The regulatory treatment of Stacked Events

SA requires an additional approval for a plant that combines two already approved traits, such as herbicide tolerance and insect resistance. This requirement means that companies effectively need to start from the beginning of the approval process for stacked events, even when the individual traits have already been approved.

In October 2005 Monsanto received DAFF approval to launch stacked-gene cotton in South Africa. The seed combines an insecticide with a built-in resistance to weed-killer. The stacked-gene variety was created using conventional breeding techniques in which hybrid cotton was created by crossing insect-resistant plants with herbicide-tolerant ones.

In March 2007 Monsanto SA received "general release" permit clearance for Mon 810 x NK 603. Monsanto decided to market the stacked corn product in South Africa after the farmers' positive response to the cotton stacked gene seed.

2.3.5 The regulatory treatment of 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 GM field crops to the farmers. South

Africa also does not currently have a National Organics Standard in place.

2.3.6 Technology Fees

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

2.3.7 Permit fees

Under the GMO Act the GMO registrar charge a fee for the different permits that can be issued. Table 7 illustrates the current permit fees payable.

Table 7: Permit fees payable

| Application | Fees |
|---|-------------------|
| GMO status certificates | R140 (\$18) |
| Importation or exportation of GMO with general release status | R330 each (\$44) |
| Contained use | R970 (\$128) |
| Trial release of | R2,650 (\$350) |
| General release of commodity clearance | R17,300 (\$2,292) |
| Appeal | R4,000 (\$530) |
| Extension permit | R2,050 (\$270) |
| Registration of facility | R380 (\$50) |
| Commodity use permit | R230 (\$30) |

Section IV. Plant Biotechnology Marketing Issues: Producers, Seed Companies, and Importers

- GM products have a wide appeal with both groups. Each group appreciates that GM crops use fewer inputs and have higher yields. In fact, subsistence farmers find some GM crops easier to manage than traditional or hybrid varieties.
- Distributors should be from the local area, speak the local language, and they should take time to talk with people and explain the technology and its benefits. When this care is taken, small-scale growers are generally receptive to new technologies.

Importers require assurance that no unapproved GM varieties are inadvertently contained in the shipment

because South Africa's regulation for adventitious presence is only 1 percent. Yet, in reality their tolerance is zero, since the GMO Registrar's office won't grant an import approval for a shipment coming from a country that cultivates events that aren't approved in South Africa; if the product is milled or otherwise processed it can usually enter.

Consumers

A survey conducted by the Department of Science and Technology's Public Understanding of Biotech organization shows that most South Africans have no knowledge of biotechnology. This finding is not surprising given that most South Africans are more concerned with the price of food than with how it was grown. What is interesting is that despite this lack of understanding, an average of 57 percent indicated that different applications of biotechnology should continue.

Although South African scientists are among their continent's leaders in biotechnology, the survey showed that the term "biotechnology" means nothing to 82 percent of the general public. A similar proportion is unaware of the meanings of 'genetic engineering', 'genetic modification', and 'cloning'. The study, in which researchers interviewed 7,000 people in the language of the participant's choice, was designed to be representative of the adult population of South Africa. It reveals that even among the few South Africans who were aware of biotechnology, most were indifferent to it.

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

Section V. Plant Biotechnology Capacity Building and Outreach:

The South African government generally supports the use of biotechnology products. Transgenic varieties of cotton, corn, and soybeans are approved for commercial planting and account for approximately 90 percent of South Africa's cotton, 78 percent of its corn, and 85 percent of its soybeans. Agricultural biotechnology holds wide appeal for South African small and commercial farmers as they recognize the financial benefits of fewer inputs and potentially higher yields.

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

FAS/Pretoria's short term goals for biotechnology in Southern Africa include:

- Stakeholders in southern Africa have the capacity and understanding of agricultural biotechnology necessary to propose science-based regulations.
- Regulators in South Africa approve for use a local or regionally developed biotechnology event, for example the potato or banana.

- As part of the Global Hunger and Food Security Initiative, U.S. and South African regulators and companies work with other countries in southern Africa to build support for science-based biotechnology regulations.

Below the activities that have been carried out by FAS/Pretoria in the region since 2008 are listed. These activities are implemented usually through AfricaBio. AfricaBio is a non-governmental, non-political and non-profit biotechnology organization based in South Africa that advocates for stakeholders in the research and development, production, processing and consuming sectors. The bulk of its funding comes from the private sector. USAID and other U.S. organizations provide periodic funding for training and capacity building activities and production of biotechnology informational materials.

Biotechnology and biosafety workshops (August 20 – 27, 2008): Dr. C.S. Prakash, Professor of Plant Molecular Genetics, Tuskegee University, and Dr. Martin Lema, Advisor to the Argentine Ministry of Agriculture and Professor of Biotechnology, Quilmes University, travelled to Madagascar and Mozambique to lead two agricultural biotechnology and biosafety workshops sponsored by the USDA and the Governments of Mozambique and Madagascar. These conferences were funded through FAS/EMP and State/EB.

Visits from EPA and APHIS (September 15 – 19, 2008): Dr. Chris Wozniak, Biotechnology Special Assistant, U.S. Environmental Protection Agency (EPA), and Dr. Robyn Rose, USDA/Animal Plant Health Inspection Service (APHIS) were in South Africa for two one-day presentations to new members of the South African GMO Advisory committees and subcommittees as well as presentations at the Bio2Biz biotechnology forum sponsored by the South African Department of Science and Technology and presentations at the International Centre for Genetic Engineering and Biotechnology's (ICGEB) Biosafety course. These trips were funded by FAS/EMP and State/EB.

Technical assistance (September 26 – 28, 2008): Dr. Eugenia Barros, Biotechnologist, AfricaBio, travelled to Mozambique to provide technical assistance to the Mozambican government on implementation procedures for their biosafety policy and to present on acceptance of biotechnology in an EU-sponsored conference. Her travel to Mozambique was funded by FAS/EMP.

Regional workshop biosafety regulations (May 10 – 13, 2009): FAS sponsored a regional workshop in South Africa for representatives from Mauritius, Mozambique and Zimbabwe to discuss regional issues surrounding biosafety regulations and trade effects. This workshop was funded by PASA/OCBD. The objective of this workshop was to develop capacity and expertise in biotechnology/ biosafety regulation, to include food safety regulations, so that the delegates will be able to implement and enforce the relevant legislation and so create an enabling environment for biotechnology to thrive in their countries. The Workshop was facilitated by the United States Department of Agriculture (USDA) and organized by AfricaBio.

The workshop was attended by a total of 25 delegates. Participants included senior regulatory scientists, especially those involved in biosafety regulatory system in their various countries, stakeholders and representatives from relevant government departments. Interactive sessions with various biotechnology and biosafety experts and government departments were facilitated during the discussions.

Delegates were given opportunities to gather information in the form of presentations, discussions, laboratory visit, field visits and one-on-one interactions. They were able to hear from multiple perspectives the various strategies and tools the South African government has developed and are implementing to harness the benefits of biotechnology while utilizing its various safety channels to minimize risks.

Biotech study tour to the United States (November 6 – 20, 2009): OAA/Pretoria received funding to conduct

a biotech tour of the United States for representatives from Mauritius (2), Mozambique (3), and South Africa (6). The group included three government officials from the South African Department of Agriculture, Forestry and Fisheries (DAFF), including the current acting Director-General in DAFF, one government official from the Department of Science and Technology in Mozambique, one representative each from the grain and potato industries in South Africa, two researchers from Mauritius and one from Mozambique and two persons from the media.

The three-country delegation brought opportunities for the participants to share ideas, exchange opinions, and start a dialogue on biotechnology issues in Southern Africa.

Meetings and informational sessions included in Washington, DC: APHIS, EPA, FDA, USDA/Ag Research Service, USDA/Foreign Agricultural Service, GIPSA, Biotech Industries Org., ILSI, among others; and in St. Louis, Missouri: Danforth Plant Center, Monsanto, American Soybean Association, Universities, farm media, and river logistic companies.

Adventitious presence workshop (May, 26, 2010): FAS/Pretoria in collaboration with AfricaBio, held a two part workshop on Adventitious Presence in Pretoria, South Africa. The workshop formed part of a study prepared by the National Advisory Council of Innovation on “Adventitious Presence of GMOs in commodities”. The National Biotechnology Advisory Committee commissioned the study following approval of the Consumer Protection Act. The purpose of the study is:

- To increase understanding of regulators, scientists and industry about the requirement for labeling.
- To determine how this should be done and who would bear the cost.
- To determine the level of engagement between regulators, scientists and members of the industry.

In total, 26 stakeholders participated in the workshop: government departments, seed companies, Grain trade organizations, Silo Association, Public research institutions etc.

The greatest success of the workshop came when the Director: Consumer and Competition Policy & Law Department of Trade and Industry presented on the reasoning behind the new Consumer Protection Act and the steps that are been taken by his office towards the implementation of the Act. His office directly influences how the act will be implemented. At the beginning of the workshop, the Director was in favor of mandatory labeling, arguing the consumer has a right to know in order to take steps to protect their health. By the end of the workshop, he acknowledged the impact of his position, and demonstrated a genuine understanding of the implications of the proposed labeling requirement.

After the presentations and lunch, the attendees were divided in break-away groups to discuss the best solution for South Africa regarding adventitious presence. The following is a summary of the outcomes of these discussions:

- It was agreed that as more and more countries started growing GM crops and as the global area under cultivation increased the chances of commingling increased. In the same way the non-GM niche market would continue to grow and people and businesses that required non-GM products would have to pay a premium.
- Participants felt that the recently approved SA Consumer Protection Act that required the mandatory labeling of all GM products needed further discussion and this issue also had a bearing on the handling of Adventitious Presence. Both subjects should reflect of South Africa’s overall stance on GMOs and the risk associated with their commingling with non-GM products.
- The mandatory labeling of all GM products as required by the Consumer Protection Act was unnecessary

and that the Department of Health's Regulation No. 25 adequately covered the subject.

-
- Should the Act be applied without further alteration then use of the term "May contain" should be permitted for all products containing more than 1% adventitious presence of GMOs.
- It was essential that the government departments directly involved with GMOs (Agriculture, Environment, Health, Trade & Industry and Science & Technology) make a greater effort to communicate more effectively with one another.
- For those consumers wanting to choose non-GM products, a "non-GM" label should be permitted and this would be based on a chemical analysis of the product to verify that it did not contain novel DNA or a novel protein. The cost of this procedure should be borne by those consumers wishing to choose this option.
- Concern was expressed about product recalls and product claims.

The presentations and discussion at the workshop demonstrated the value and implications of the need for greater dialogue between the various government departments and the major stakeholders. There is a need to introduce a proactive policy options for adventitious presence that will maintain the uninterrupted flow of trade of agricultural biotech products between South Africa and other countries.

Section VI. Animal Biotechnology:

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