

**SURVEY AND ANALYSIS OF MAIZE GENETIC
MODIFICATIONS APPROVED, LEGISLATION
AND TRADE POLICIES IN SELECTED MAIZE
GRAIN IMPORTING AND EXPORTING COUNTRIES**



REPORT SUBMITTED TO THE MAIZE TRUST

BY

WYNAND J. VAN DER WALT, PhD

FoodNCropBio

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ACRONYMS

AC	Advisory Committee
ARC	Agricultural Research Council
Bt	<i>Bacillus thuringiensis</i> (insect resistant trait)
CBD	Convention on Biological Diversity
COMESA	Common Market for Eastern and Southern Africa
CPB	Cartagena Protocol on Biosafety
CRW	Corn root worm resistance
DRC	Democratic Republic of the Congo
ECB	European Corn borer
EFSA	European Food Safety Authority
EU	European Union
FERT	Fertility
GLUFOS	Glufosinate
GLYPHOS	Glyphosinate ammonium
GMO /GM	Genetically Modified Organism
HT	Herbicide tolerance
IR	Insecticide resistance
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
LMO	Live Modified Organism
MT	Metric tons
SADC	Southern African Development Community
UNEP-GEF	United Nations Environment Programme/Global Environment Facility
USDA-APHIS	United States Department of Agriculture – Animal and Plant Health Inspection Services
USA	United States of America
WTO	World Trade Organization

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EXECUTIVE SUMMARY

This study endeavoured to compile a working document as reference database on the status of genetically modified (GM) maize approved for commercial release or imports, and domestic legislation that governs aspects of trade in maize grain or derived products in selected exporting and importing countries. Such a reference document will be helpful to all maize industry members involved in domestic and international trade in maize products. It will also assist government in understanding the environment in which the maize industry has to operate.

Target countries for the study include Argentina, China, European Union, Japan, Republic of Korea, South Africa, and relevant member states in SADC and COMESA. The approach was to identify main maize exporting and importing countries, to collect technical and regulatory information, to obtain and analyze GMO biosafety systems, and to compile these in a way that will facilitate industry members to make direct contact with regulatory agencies and visit websites. The nature of this fast moving technology and GMO legislation necessitates constant surveillance and update of information. The methodology used for the study included exploration of useful websites, liaising with international organizations, make personal contact with key officials in countries, and, where required, follow through with telephone calls to contact parties. The study was facilitated by existing extensive personal contact in most countries, while constraints were experienced in countries, especially in Africa, that are just beginning to developed GMO regulatory frameworks and not having websites from which data could be accessed.

Genetic modification technologies have given the world a range of new production systems and products, from human and animal health to food processing, industrial systems, and crop production. All countries, in one way or another, make use of products and services from these technologies. The issue of GM crops and its impact on regional and international trade had been foreseen some 15 years ago when the USA, as technology leader, and the EU took divergent regulatory approaches. The US considered that its existing legislation was adequate and that it would focus on determining the safety of the product. The EU started with new legislation, specifically on GM crops, approved several species for commercial release, then had a temporary cessation of considering new applications, and decided to assess safety of the product as well as requiring that the production method, i.e. GM, be identified throughout the food chain. This divergence developed into a trade dispute that led to the WTO ruling against the EU. The situation

has been aggravated by active global campaigns by anti-GM groups against use of GM crops (no objection to all the other GMO applications). At present, the EU remains internally divided on planting of GM crops.

The **Cartagena Protocol on Biosafety**, arising from the Convention of Biological Diversity, acknowledges the benefits of GM crops but international negotiations resulted in an extremely complex system for ensuring that risks to biodiversity are minimized. It requires that countries that acceded to the Protocol have the capacity and frameworks to implement extensive regulatory measures. Included are advanced informed agreement (prior consent), a notification procedure for shipments, and provision of technical and biosafety information. Decision making at country level creates opportunities for delays and technical barriers to trade. The US and several other countries are not signatories to the Protocol but will be forced to comply with provisions when trading with signatories. The Protocol can be criticized for being too complex for developing countries to comply with and for starting from the premise that GM crops are potentially hazardous to the environment.

Major maize **exporting** countries have been identified as the US, Argentina and China with Brazil, South Africa and Ukraine handling smaller volumes. Leading **importers** over the past three years were Japan, Republic of Korea, the EU, China, and Egypt. South Africa has been importing about half a million tons annually, almost all from Argentina. Main export destinations for South African maize grain and products are Zimbabwe, Botswana, Lesotho, Mozambique, Kenya and Japan, in order of volumes, while derived products go the EU and many other countries.

Argentina has been a rapid adopter of GM soybeans, with GM maize only being grown commercially in recent years. Maize hectares planted in 2006 amounted to 3.1 million hectares of which 2.8 million were hybrid varieties. GM Bt comprised 61 per cent of hybrid area and herbicide tolerance 5 per cent. GM crops are regulated under several regimes and several decision-making bodies are involved. Legislation is soon to be updated. Large numbers of permits have been granted for field-testing new GM varieties. Approved maize modifications number seven and these generally cover those approved in South Africa. Labelling of GM-products is voluntary. No threshold is set.

GM crops in the **European Union** are handled under two main regulatory systems: Regulation 1829/2003 that sets an evaluation and approval system for field trials and commercial planting, and Regulation 1830/2003 that deals with labeling and traceability through the food chain and requires compulsory labeling as GM of foods and ingredients from GM origin that exceed thresholds. Thresholds for unintentional presence of GM material in non-GM are 0.9 per cent for approved modifications, 0.5 per cent for modifications determined as safe but not yet approved, and zero for modifications not yet assessed. All assessments for biosafety are done by EFSA, the European Food Safety Authority. The EU has approved 10 GM maize modifications for commercial planting, while hundreds of GM field trials are underway. The EU remains internally divided on GM crops. Regulatory barriers can be overcome by exporters to the EU by adhering to standards and by identity preservation of GM and non-GM.

The **United States** regulates GM crops under three government agencies: USDA-APHIS, EPA and FDA. It has no requirement for mandatory GM food labeling, although some states and cities may have. A wide range of GM varieties is being grown, using some 22 different traits for insect resistance and herbicide tolerance. The present trend is to combine these traits by “stacking” genes into varieties. Certified non-GM maize and soybean production for export markets is still minimal, despite a certification system for identity preservation having been in place for some years.

Japan has comprehensive legislation on GMOs and inputs from various departments are required in decision making. Guidelines are available for field trials and use in contained facilities. Research and testing are underway on a range of species in contained trials. Japan grows no GM crops and has granted approval for import of maize grain containing any or a mix of some 30 genetic modifications, and tolerance of up to 5 per cent is allowed for adventitious presence in non-GM.

China is a major maize producer but has only very recently approved GM maize for commercial release. Cotton is the major GM crop grown and reached 3.5 million hectares in 2006. GMOs are regulated under strict provisions and no crops can be released without passing biosafety evaluation and approval by the Ministry for Agriculture. The country has a large number of research institutes active in GM technology development. Ten GM species have been approved for testing in the environment. China has approved 8 genetic modifications in maize for import of maize products. No thresholds have been set yet for GM presence but all GM products have to be identified as GM and labeled.

The **Republic of Korea** has a careful approach on GM food products and is sensitive about such material being imported without prior knowledge and biosafety clearance. It has approved five modifications in maize for commodity and product import.

The situation among **SADC and COMESA** member states is one of great disparity, ranging from South Africa having had 17 years of experience with GM crops to states that have not yet put any legislation in place. Most members have acceded to the Protocol but have lacked capacity and legislation to comply. The 2001/2 US commingled grain shipment to Zambia resulted in an adverse reaction. SADC members are taking different approaches although common elements in their approaches are dictated by the Protocol and SADC policy guidelines.

Target countries in this region can be loosely grouped into four classes.

South Africa is the only African country that is growing GM crops commercially. It approved a comprehensive regulatory framework in the GMO Act 15 of 1997 that regulates all genetic modification on all organisms from research to food product level. GM maize with Bt insect resistance has been grown commercially since 1998 and with approval of herbicide tolerant traits, reached over 1.2 million hectares in the 2006/7 season or 49 per cent of total maize planted. GM maize combined with cotton and

soybeans, made South Africa rank 8th globally with its 1.4 million hectares of GM crops. It has partial labeling regulations and a draft identity preservation system.

The second group has legislation and is moving forward on adopting GM crops. **Mauritius** approved a GMO Act in 2005, is completing regulations, is active in GM research, has new contained use facilities and a laboratory for GM testing, and will soon have a Biosafety Committee to assist government. **Zimbabwe** has a biosafety law and has approved field trials with GM maize and cotton. It has a Biosafety Council and a biosafety assessment and operational decision making process. Official policy is pro-GM within a precautionary approach. **Kenya** has had a draft Biosafety Bill that will be approved soon. It has new contained use facilities for GM greenhouse testing and has approved trials with virus resistant sweet potatoes and insect resistant maize. It may approve Bt cotton trials soon. It has never had an embargo on GM products. Imports of seed (for contained trials only), maize grain and products must have GM status declared and labeled. **Malawi** has had a Biosafety Act for several years and final draft regulations. The regulatory system is expected to be finalized soon and Bt cotton may be the first approved crop for trials. **Namibia** approved its Biosafety Act in 2006 and regulations are in process. Biotechnology research is being conducted at their university. The country prefers non-GM grain and feed in view of its meat exports to the EU, and it plans to test all imports. **Zambia** recently passed their GM Biosafety Act and is drafting regulations. It is setting strict standards that may make it difficult to adopt GM crops in the near future. Its policy is not to permit import of GM grains or food products.

The third group of states is in process of developing laws. **Mozambique** is drafting legislation and hopes to have a decree that will set rules for import/export. **Lesotho** has its first draft approved by Cabinet. It plans to have a Biosafety Committee and other structures. At present it has no regulations to control GM grain or food imports. **Swaziland** is developing a biosafety framework that will lead to a draft Bill.

In the fourth group the **DRC** is at an early stage of drafting frameworks. **Angola** has its first draft and **Uganda** is trying to speed up its legislation so as to benefit from GM maize, cotton and banana production. **Tanzania** seems not to have acceded to the CBD or the CPB but is eager to develop legislation.

In summary, adoption of GM crops and trade in GM products require an appropriate biosafety framework in order to comply with the Cartagena Protocol on Biosafety. Unfortunately, countries developed systems which are not harmonious and which may lead to trade disruption and litigation, as had been predicted. The SADC region had an excellent opportunity to start from a common base to facilitate progress towards a regional common market. It seems that some member states are considering a non-GM status so as to benefit from maize exports to neighbours. South Africa has lost a golden opportunity to play a leadership role in this process.

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REPORT ON THE STUDY

Preamble

This study involved sourcing of information on genetic modifications, relevant national legislation and trade regulations in select maize trading countries, and their potential impact for the South African maize industry. Reporting has been based on an interim report on progress in a step-wise manner and that report has been subjected to refinement and updates. E-mail or website details are indicated as sources of our information but details of personal contacts are not shown as all official enquiries should be directed to government agencies or industry associations, or sourced from relevant websites, and not from individuals who may be employed by such agencies.

INTRODUCTION

Objective

The primary objective of the study was to develop a reference document on major maize exporting and importing countries in order to assist stakeholders to minimize their trade risks in grain consignments that are genetically modified (GM) or may contain material from GM maize origin. The reference document contains a brief overview of the Cartagena Protocol on Biosafety that sets requirements for trans-boundary movement of live modified organisms (including seed and grain), lists of GM maize approved for production in select countries, their legislation on GMOs and relevant trade regulations, and lists of contact parties in government agencies and the industry sector. The focus will be on maize grain but extends to maize products, as far as such products are regulated and information is available. Various constraints exist in sourcing such information and it has been attempted to overcome these as far as possible. The results of this study are expected to benefit stakeholders in terms of access to and dissemination of market information and to facilitate market access for both imports and exports. Such information will enable grain traders to identify problem areas and opportunities in both sourcing grain for imports and in finding markets for locally produced grain and maize products.

Specific objectives and modus operandi

The key objectives were:

- To identify main maize exporting and regular maize importing countries
- To collect technical and regulatory information on the status of GM maize modifications that have been approved for commercial release or import in these exporting countries
- To identify relevant maize importing countries and review their GMO biosafety regulations and trade policies

- To establish a database containing details of sources of such information so as to enable maize industry stakeholders to make direct contact with agencies and organizations, or visit websites that contain ongoing updated information

The procedures for collecting this information were

- Visit all relevant websites that contain global and/or national information on GMOs/LMOs
- Identify and use links to other websites
- Liaise with international organizations that can assist
- Develop personal contact with officials and agencies in foreign national governments who can assist with information
- Follow up missing information by telephone calls to key persons in target countries
- Verify accuracy of information by comparing data from different sources
- Make contact with South African maize grain importers and exporters
- Compile information into a report and database

Analyses of trade regulations should take into account that

- Government policies are indicative of a regulatory framework to follow
- An Act provides the legal framework
- Regulations contain detailed requirements under the Act
- More details are contained in procedures that may change at short notice
- Implementation of legislation is only as good as the government capacity and will to enforce it
- Markets will dictate what buyers will buy at what price for what qualities, often irrespective of official regulated standards.

NOTE: Maize industry stakeholders are reminded that care has been taken to ensure updated, correct information in this report, but details of contact parties and officials, telephone and e-mail addresses, regulations and procedures tend to change regularly.

CARTAGENA PROTOCOL ON BIOSAFETY (CPB)

Brief overview

This Protocol arose from Principle 15 in the 1992 Rio Declaration and the Convention on Biological Diversity (CBD) that created an opportunity for an international agreement on guidelines to ensure that live modified organisms do not have a adverse impact on biodiversity. The salient aspects of the CPB are as follows (official text somewhat reduced):

- Objective: to ensure an adequate level of protection in safe transfer, handling and use of live modified organisms (LMOs) from modern biotechnology that may have adverse effects on biodiversity and human health
- LMO means a living organism that possesses a novel combination of genetic material and that can replicate or transfer such genetic material. LMOs include GM seeds and grains.
- Scope: all LMOs, excluding pharmaceuticals that are LMOs, non-live products of LMOs, LMOs in transit, and consignments intended for contained use in controlled structures.
- The Advance Informed Agreement (Art 7) shall apply to first transboundary movement of an LMO intended for release into the environment. AIA is a prior agreement from importing country to accept a consignment before shipping takes place.
- A facilitated procedure is provided for LMOs intended for direct use as food, feed or for processing (Art 11), and requires information as in Annex II that includes details of applicant, authority that makes decisions, LMO, and risk assessment as per Annex III. A developing country may request a risk assessment and may take 270 days for making a decision.
- Exporting country shall inform importing country, before shipping, of intended shipping (Art 8)—details required are as per Annex I. Importing country shall acknowledge receipt of notice.
- Article 10 gives importing country up to 270 days for decision making
- An importing country may establish simplified procedures (Art 13)
- Consignments intended for food, feed or processing must meet handling, transport, packaging and identification requirements (not yet finalized) and clearly identify consignment as “may contain LMOs” (Art 18)
- A Clearing House is established to which all GMO legislation, permits and movements must be submitted as part of information sharing (Art 20). It is doubted if this mechanism is adequately operational in view of the massive data to be handled and the inadequate capacity in many countries.
- Some major grain trading countries (like the USA) did not accede to the CPB, but states that are members must ensure that non-parties comply (Art 24)
- Provision is made for penalties in case of illegal transboundary movements (Art 25)
- Provision is made in Article 27 for Liability and Redress resulting from damage (not yet finalized)

NOTE 1: Key elements are that the CPB deals only with live modified organisms that may have adverse effects, only involves transboundary movements, excludes GM pharmaceuticals and LMOs for contained use, requires advance informed agreement for the first transboundary movement and notification for all movements, and has facilitated procedures for LMOs for food, feed and processing. The CPB clearing house where also global data are deposited has improved but may not contain latest information and details, therefore, national websites and clearing houses should also be visited. Some Articles of

the Protocol have not yet been finalized. In this fast moving technology it remains important to continue to source updated information.

NOTE 2: General global details can be accessed as follows:

CBD: www.biodiv.org

CPB: www.biodiv.org/biosafety/

Biosafety Clearing House: www.biodiv.org/biosafe/biosafety-ch.html

Country details in respect of the CBD and Protocol: www.biodiv.org/world/map.aspx

National clearing houses: www.cbd.org/doc/lists/nfp-chm.pdf

Global data links from USDA: www.fas.usda.gov/

Details of genetic events approved for planting, food and feed use, presented by country, crop and trait, can be accessed at: www.agbios.com/dbase.action?php=Synopsis

ISAAA: www.isaaa.org

MAIN IMPORTING AND EXPORTING COUNTRIES

The most recent report from the International Grains Council was analyzed for maize grain imports and exports over three years, namely trading seasons 2002/3, 2003/4 and 2004/5. Details are found in Tables 1 and 2 in the Annex.

The data in Table 1 show that an average of some 57 million MT of maize was imported by 14 countries. Japan, South Korea, Mexico and the EU were the main maize importers, in that order, with Japan needing over 16 million MT.

Table 2 shows that a total of almost 73 million MT of maize was exported on average by the six major exporting countries. The United States accounted for 62 per cent or 45 million MT, followed by Argentina with 11 million MT. The South African average was just over 1 million MT.

Data for three years of exports from South Africa for marketing seasons 2004/5, 2005/6 and 2006/7 were extracted from SAGIS statistics on their website. Table 3 in the Annex shows average exports for the period of 1,1 million MT. Exports went to 22 countries, some of which were minor, irregular shipments, probably in the form of donated food aid. Major destinations were Zimbabwe with almost half-a-million MT average, followed by Botswana, Lesotho, Mozambique, and Kenya, in that order. Maize was exported to Japan only in 2004/5 and amounted to 113 098 MT, all yellow. An export permit had been granted for export of 90 000 MT of GM grain and it is assumed that this formed part of the 113 098 MT. Japan allows adventitious presence of up to 5 per cent GM in conventional grain. No data have been sourced as yet on exports of maize products such as meal and other refined or processed products. It is anticipated that maize meal exports may account for sizeable volumes.

An import permit is required in terms of the GMO Act for all South African consignments that are or may contain live GMOs (LMOs). An analysis of the 296 import permits issued by the GMO Secretariat, Department of Agriculture, following approval

by the GMO Executive Council, for the period January to December 2006 shows that 121 permits were granted for commodity maize. All imports came from Argentina. Shipments varied from 150 to 60 000 MT, totaling 1.261 million MT for the year. The reasons for the discrepancy between these permits and SAGIS statistics are that the SAGIS marketing year does not match the calendar year, that a permit granted may be used in a different year, and that the actual volume may differ from the quantity applied for.

South African imports, contained in Table 4, show only three sources: Argentina, the USA and Malawi. The import from the latter country is not clear. Argentina remains the major supplier with a three-year average of almost half a million MT. The USA supplied maize only in 2004/5.

In view of the above, it was decided to focus this study on main suppliers to South Africa, being Argentina, the USA and China as a future supplier. Main export destinations for South African maize are the SADC region (SACU and Zimbabwe, specifically), Kenya, Uganda and Tanzania in East Africa, the EU for processed products, and Japan for industrial use.

Sources:

www.igc.org.uk/

www.sagis.org.za/

SOUTH AFRICA

The South African overview will be brief in view of the general adequate to good understanding by most of the main stakeholders of the GMO regulatory system. The GMO Act 15 of 1997 regulates all defined genetic modification technologies on all organisms from research level to product level. All facilities handling genetic modification or GMOs must register and meet specified requirements. The GMO Secretariat is housed in the Department of Agriculture and receives all applications for permits. An Advisory Committee (AC), comprising 10 scientists appointed by the Minister, examines applications and submits recommendations to the GMO Executive Council. Other inputs are made by scientific reviewers and subcommittees of the Advisory Committee. The Council is comprised of one senior official of each of six government departments—Agriculture, Health, Science & Technology, Environment, Labour, and Trade & Industry (Water Affairs & Forestry and Arts & Culture to be added soon), as well as the Chairman of the Advisory Committee. Applications must contain scientific data on biosafety and risks assessments done in terms of risks to the environment, human and animal health, as well as socio-economic considerations and impact on trade. The Council considers applications in the light of recommendations by the AC and comes to consensus decisions on behalf of the Minister.

There are eleven kinds of permits, the most important ones for the maize grain industry being application for import of grain intended for food, feed or processing; another for GM grain export; and one for handling in transit consignments intended for neighbouring importing countries. The latter requires that forwarding cannot proceed until the importing country has approved the import and, if the consignment contains GM, may

require milling at a point close to the port of entry. The mill usually does this free of charge and retains the screenings, and the milled product can be exported with a status of beneficiated product.

Requirements under the three types of permit applications relevant for grain traders can be summarized as follows:

- Application for commodity clearance Part 1: Brief description of GMO, type of clearance and handling of commodity, description of derived products, foreign genes and gene products, possible risks to environment, human health, socio-economic impact, waste disposal and monitoring. Part 2: completion of risk assessment questionnaire
- Application to import LMOs that already have general release or commodity clearance status: Completed questionnaire with details of importer, exporter, grain type, list of genetic events that may be present, shipping information, and details of handling, storage, packaging, etc., plus completed affidavit. This application can be regarded as a fast track procedure and may not need a Council decision.
- Notification on GM consignments in transit: This policy deals primarily with emergency food aid that originates overseas and passes through South Africa to destinations in the region. It applies to GM raw products approved for commercial use in South Africa, processed products that contain over 1 per cent GM, and raw or processed products containing GM not approved in South Africa. Evaluation is done on a case-by-case basis and requires completion of a questionnaire on exporter, importer, GMO, volume, dates, handling, transport etc., and a signed undertaking. Also required is a letter from the government of the country of destination to accept the consignment, or an import permit from same. Procedures and conditions are laid down for milling before transport to recipient country and disposal of byproducts from milling.

Labeling regulations dictate mandatory labeling if the GM food product differs significantly from its conventional counterpart in nutrition, composition, storage, preparation (as per Codex standards), or if it contains a gene from a human or animal. This applies to foods where the novel gene or its protein can be detected. Voluntary labeling is possible where the food is enhanced through GM technology and must be substantiated by scientific data from a neutral, qualified party. The non-GM labeling standard has not yet been published. There is no labeling requirement for process used for production.

GM maize modifications approved in South Africa:

(a) For commercial release

- 1997: Bt Insect resistance, MON 810, Monsanto
- 2002: Herbicide tolerance, NK603, Monsanto
- 2003: Bt 11 Insect resistance, Syngenta
- 2007: Bt Insect resistance + Herbicide tolerance, MON 810 X NK 603, Monsanto

(b) For food/feed commodity import clearance

- 1997: Bt Insect resistance, MON 810, Monsanto
- 2001: Bt 176 Insect resistance, Ciba-Geigy/Syngenta
- 2001: T 25, Insect resistance, Agrevo,
- 2002: Herbicide tolerance, GA 21, Syngenta
- 2002: Herbicide tolerance, NK 603, Monsanto
- 2002: Herbicide tolerance + insect resistance, (Pioneer/DuPont?)
- 2002: Herbicide tolerance + insect resistance, TC 1507, Agrevo/Dow/
- 2003: Herbicide tolerance + insect resistance, MON GA21-9 x MON 00810-6, Monsanto
- 2004: Herbicide tolerance + insect resistance, MON00603-6 X MON 00810-6, Monsanto
- List of genetic modifications (events) approved for food/feed commodity grain imports from January 2004 to January 2007: MON 810, Bt 11, T25, Bt 176, NK 603, GA 21, TC 1506

(c) Permits granted for GM field trials

- 1999: Insect resistance Bt 11, Syngenta
- 2000: GA 21 Herbicide tolerant, Monsanto
- 2000: Stacked Herbicide tolerance, MON 84006, Monsanto
- 2000: Herbicide tolerance T25, Agrevo
- 2000: Herbicide tolerance NK 603. Monsanto
- 2001: Insect resistance ZMA 101, Aventis
- 2001 Insect resistance TC 6228, Pioneer
- 2003: Herbicide tolerance, Safemaize, CSIR
- 2003: Insect resistance, 3243, Syngenta
- 2003: Insect resistance + herbicide tolerance MON 810 X NK603, Monsanto
- 2005: Herbicide tolerance, GA 21, Syngenta
- 2005: Herbicide tolerance, DAS 1507, Dow
- 2006: Insect resistance + herbicide tolerance: MON 89034 and MON 89034 x NK 603, Monsanto
- 2006: Insect resistance + Herbicide tolerance, Bt 11 x GA 21, Syngenta
- 2007: Drought tolerance ZM-M39872, ZM-M38714, ZM-M38721, ZM-M 38835, Monsanto.

SOURCES:

www.nda.agric.za/ take link to regulatory and other services > genetics resources > plants > applications (for application forms, guidelines and other requirements)

www.nda.agric.za/ as above, take link to publications (for GMO Annual report, presently outdated)

www.nda.agric.za/ as above, take link to Genetic Control for list of permits issued

www.nda.agric.za/ as above, take link to Biosafety Clearing House (for all data, presently not functional)

ARGENTINA

Argentina ratified the CBD in 1993 and is not a party to the CPB. Its GMO legislative development and GM crop adoption very much followed that in South Africa, but with three differences: more government agencies are involved in separate decision making, more separate laws were adopted, and rapid adoption of herbicide tolerant soybeans to a 99 per cent share of the crop made the country a unique model on GM crops. Legislation in Argentina involves different laws for different organisms, unlike the South African comprehensive GMO Act.

GMO regulations commenced in 1992 and comprised the following:

- Regulation 656/1992 on GM Crops and GM micro-organisms for veterinary use
- Regulation 837/1993 on GM crops
- Regulation 226/1997 on GMO containment conditions
- Regulation 289/1997 on GM crops

Regulations currently in use are:

- Regulation 39/2003 on GM crops
- Regulation 57/2003 on GM animals
- Regulation 644/2003 on production of regulated maize seed
- Regulation 46/2004 that assigns maintenance of a national registry of GM operators to INASE, the national agency for seed control

Foods from GM crops are handled as follows:

- An annex to Regulation 289/1997 contains requirements for food safety assigned to SENASA, the National Agriculture and Food Quality and Health Service.
- Regulation 511/1998 sets assessment criteria
- Regulation 1265/1999 makes provision for a Technical Advisory Committee
- Regulation 412/2002 is the updated framework currently in use
- Resolution 39/2003/GMPO assigns environmental safety to SAGPyA

New legislation in process includes:

- Agricultural Biotechnology and Safety Law presently before Parliament
- New Regulations on stacked genes, GM farm animals, pharma plants, biological control agents, and other GM technologies.

The period 1991 to 2005 saw 886 applications for experimental releases, 80 per cent of which were for field trials of GM varieties. Some 58 per cent of the latter was for maize,

the balance covered potato, soybeans, wheat, lucerne, cotton, rice, sunflower, etc. Major traits were herbicide tolerance (22%), insect resistance (24%), stacked traits (31%), disease resistance (5%), yield improvement (5%), and virus resistance (4%).

The regulatory process from application for field trials to commercial release takes an average of 5 to 6 years. Three steps are involved: GM crop environmental risk assessment, field trials and experimental releases under CONABIA, the National Advisory Commission on Agricultural Biotechnology; food safety issues under SENASA (the National Service for Health and Agri-food Quality); and impact on markets under the National Directorate for Markets. The national competent authority is the Secretary of Agriculture. The first phase is an assessment of the GMO per se and the second phase involves evaluation of the impact of GM crop on the agro-ecological system. Assessments may go through several cycles of requests to the applicant for clarification or further information. Recommendations are submitted to the Secretary of Agriculture who decides on granting a permit. Approvals are assigned a SAGPyA permit number. INTA, the National Institute for Agricultural Research (comparable to our ARC), has been given the responsibility for detection techniques to monitor presence of GM in products.

Argentina allows voluntary labeling of GM foods but no standards and no thresholds are set.

Authorized GM maize in Argentina

- Bt 176 insect resistant, Syngenta, January 1998
- Herbicide tolerant, T25, Bayer/Aventis/, June 1998
- Bt insect resistant, MON 810, Monsanto, July 1998
- Bt 11 insect resistant, Syngenta, July 2001
- Herbicide tolerant, NK 603, Monsanto, July 2004
- Bt insect resistance + herbicide tolerance TC 1507, Mycogen/Dow, March 2005
- Herbicide tolerance GA 21, Monsanto, August 2005

No information obtained on GM maize in field trials:

Registered GM operators:

The latest list comprises names of 38 research institutions, seed companies and biotech companies involved in developing and marketing GM products.

Sources:

SENASA: www.senasa.gov.ar/contenido

SAGPyA:

www.sagpya.mecon.gov.ar/new/0-0/programas/biotecnologia/coordinacion_en

INASE: www.inase.gov.ar/tikiwiki/tiki-index.php?page=biotecnologia

CONABIA: www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/en_comm.php

Focal point under protocol: National Directorate for Agricultural Products Marketing:
asarqu@sagpya.minproduccion.gov.ar

THE EUROPEAN UNION

The EU presents a complex situation, first with 12 member states that did not follow the same route on crop biotechnology, and now with an additional 13 members that add to internal division. Europe did not feel the same urgency as did the USA in forging ahead with genetic modification of food crops and, as result, fell behind in this technology. However, they did become leaders in developing unique industrial enzymes using genetic technologies, while make great strides in forest biotech and in human health products.

Legislation on GM crops started in 1990 with EC Council Directive 90/220/EEC and GM canola, carnation, chicory, and maize were approved for field testing and some commercial growing during the mid-nineties. However, the EU then stopped considering new applications as from 1998 despite the new Regulation EC no.258/1997 that provided procedures for assessing GM crops. Six member states employed a national embargo on GM crops and their products. Directive 2001/18/EC of the European Parliament made provision for release of GMOs into environment and for labeling and traceability measures and was amended to form part of new 2003 Directives.

The USA, Canada, Argentina and Australia in 2003 took the EU to the World Trade Organization for unfair trade practices. The WTO decided in 2006 against the EU on two counts: (a) that the WTO would proceed to hear the dispute and (b) that the embargo on GM crops and their products by some member states, and failure by the EU Parliament to act against these members, amounted to unfair practices. In the meantime Spain continued to grow GM maize, reaching 57 000 ha in 2006. The amended GM-legislation tabled in 2003, was adopted in April 2004. Despite all this, Greece, Austria, and Germany still maintain a ban on GM crops, although Germany permitted modest trial plantings of 950 ha Bt maize in 2006, up from 350 in 2005.

EC Regulation 1829/2003 repealed some of the previous Directives that dealt with procedures for evaluating safety of GM crops intended for release into the environment, while requiring amendments to a range of others laws. The scope of this Regulation covers GM seeds and crops and their products such as food, feed, ingredients, colourants and flavourings, even if these do not contain novel DNA or its protein, and, therefore, GM presence cannot be verified. Excluded from the scope are processing aids such as enzymes produced in GM microbes, and animals fed on GM feed.

All applications for release of GMOs into the environment must be submitted to relevant competent authorities at national level for forwarding to the EU appointed Authority. This Authority will inform all member states and make the dossier available to the public, assess all applications for biosafety concerns and within 6 months submit its opinion to

the Commission, and make its opinion public. The Commission has 3 months to accept or reject the opinion of the Authority and to submit its draft decision to the Standing Committee on Food Chain and Animal Health. A final decision shall be made in consultation by the above Committee and published within 2 months in the Official Journal of the European Union. This process will take one year at the minimum. Thereafter, individual member states still have to approve GM releases at national level. Subsequent to adoption of this Regulation, the responsible Authority was established as the European Food Safety Authority, EFSA.

Regulation 1830/2003 deals with an extensive labeling and traceability regime, also covering foods, feed, ingredients, etc. Excluded are animals fed on GM feed and treated with GM medicinal products. Labelling applies to food/feed that are or consist of GMO, or have been derived from GMOs, irrespective of whether novel DNA or its protein is present or can be detected. The system is supported throughout the food/feed chain links by way of paper traceability. Unavoidable presence of components that are or are derived from GMOs is recognized and this is addressed through the following labeling thresholds:

- Presence over 0,9 per cent of GM or its derived ingredients in non-GM products, must be labeled as GM in the case of genetic modifications that have been approved in the EU
- Presence of over 0,5 per cent in case of modifications assessed as safe but not yet formally approved by the Commission, must be labeled GM
- Presence of any GM products or ingredients of modifications not yet assessed for safety and not yet approved, is not allowed until it has gone through the regulatory system for approval, i.e. a zero tolerance.

The primary difference between the USA and the EU approaches is that the USA system deals with the safety of products while that of the EU deals with safety and with the type of crops used in food/feed production, i.e. the production system.

GM crops approved in the EU (release into the environment, planting, and/or food/feed approvals):

- 1997 release and plant, 1991 food/feed: insect resistance + herbicide tolerance, Bt 176, Syngenta
- 1998 release and plant, food/feed: herbicide tolerance: T25, Agrevo
- 1998 food/feed, 2004 release and plant: Insect resistance, Bt MON 810, Monsanto
- 1998 food/feed only: Herbicide tolerance + Bt 11 insect resistance, Syngenta
- 2004 food/feed only: Herbicide tolerance, NK603, Monsanto
- 2005 food/feed only: Herbicide tolerance + insect resistance: NK 603 x MON 810, Monsanto
- 2005 food/feed only: Herbicide tolerance + insect resistance: GA 21 x Mon 810
- 2006 food/feed only: Insect resistance, MON 863, Monsanto
- 2006 food/feed only: Herbicide tolerance, GA 21, Monsanto

- 2006 food/feed only: Herbicide tolerance + insect resistance, DAS 1507, Pioneer/Dow

Notification of field trials

Over 100 notifications have been received during 2006 to present. Recent notifications, for example for Romania, include the following maize modifications:

DAS 1507 x NK 603, NK 603 x MON 810, MON 603-6, DP 98140-6, DP 98140 x DAS 1507, DP 9814 x DAS 1507-1 x DAS 59122-7, DAS 1507-1, DAS 59122-7, GA 21, Bt 11.

Contact parties/sources:

EFSA: www.efsa.europa.eu/en/science/GMOPanel/

EU approvals and field trials: <http://gmoinfo.jrc.it/gm>

CPB focal point: Mr Guy van den Eede, EC Joint Research Centre,

Guy.VAN-DEN-EEDE@cec.eu.int

Approved products:

http://ec.europa.eu/food/feed/biotechnology/gmfood/notifications_existing_products.pdf

CHINA

China has a large number of research institutions engaged in crop genetic modification developments. Research has focused on drought and stress tolerant crops, especially rice. Environmental release of GM crops has been approved for 10 species, including cotton, rice, canola, maize, potato, and poplar. However, it is only GM cotton that has been grown commercially to reach 3.5 million hectares in 2006. Insect resistant GM maize and several other species were only approved recently for commercial release. The country accepted the CBD in 1993 and approved the CPB in 2005.

The 2002 legislation on GM crops entered into force in 2004 and covers the following:

- Biosafety evaluation and administrative regulations on GM agricultural products
- Import safety regulations on GM agricultural products
- Labeling regulations on GM agricultural products

Regulations for releasing GM crops into the environment are based on novelty, safety assessments, an approval process and mandatory labeling. Labeling applies to the process, is based on content and applies to specific foods. Decisions must be science-based and include consultation with an expert panel. The Ministry of Agriculture is responsible for overseeing ag-biotech product safety, in collaboration with several other parties.

Regulations require a process that may take 270 days for approval, each import shipment needs a separate safety certificate, safety data from field trials in exporting country, labeling of GM products is required but no threshold stated, labeling applies only to maize seed, oil and meal; soybean seed, flour, meal and oil; canola, tomato and cotton.

Maize genetic modifications approved for commodity import

Bt 176 IR, Syngenta
Bt 11 IR + HT, Syngenta
GA 21 HT, Monsanto
MON 810 IR, Monsanto
MON 863 CRW resistance, Monsanto
NK 603 HT, Monsanto
T14, T25 HT, Bayer/Aventis
TC 1507 IR + HT, Dow

Contact parties/sources:

CPB focal point: Ms Zhang Jieqing, Director: State Environmental Protection Administration, Beijing.

Zhu.guangqing@sepa.gov.cn or biosafety@sepa.gov.cn

Tel: 0086-10-661-51917

Website: www.zhb.gov.cn/english/

UNITED STATES

The Office of Science and Technology Policy in 1984 formed a committee to examine regulation of biotechnology and in 1992 concluded that products of biotechnology should be regulated in the same way as products developed through other technologies, and that existing legislation was adequate, subject to scope for amendment where considered necessary. The US, therefore, bases its approach on safety of the final products, unlike the EU that also adds identifying the process through which the products were developed. The three agencies involved have the following mandates, each agency working within its own set of laws:

- USDA-APHIS (the US Department of Agriculture- Animal and Plant Health Inspection Services): plant pests, plants, veterinary biologics
- FDA (Food and Drug Administration): food, feed, food additives, veterinary drugs, human drugs, medical devices
- EPA (Environmental Protection Agency): microbial and plant pesticides, new uses of existing pesticides, novel micro-organisms.

Developers of GMOs must comply with guidelines of the NIH (National Institutes of Health), submit a notification of field trials for APHIS to approve, get EPA registration for pesticidal plants, and through a consultative process with FDA, ensure food safety.

All three agencies have the power to demand immediate removal of a product for which valid data indicate questionable safety. Special labeling of foods from GMOs is not mandatory but some states or cities may require such labeling and this will be on product content. The EPA has set up a seven-principle post-approval plan in cases such as Bt insect resistance.

Genetic modification events approved in the USA for planting food/feed, food, feed or marketing is shown in the table below. It can be seen that not many new genetic events have been approved in recent years. The reason can be found in the shift to development of “stacked” traits where two, three or even four unique genetic modifications previously approved, have now been combined into varieties that express several GM traits (see also modifications approved for import in section for Japan). The US does not require new biosafety assessments for combined modifications (stacked traits) already approved as single event modifications. The next step will undoubtedly be to shift back to new breakthroughs in genes to improve nutrition and suitability for industrial or biofuel application. In the past, decisions by the USAD-APHIS, FDA, and EPA may have occurred at different times but for GM maize in the Table below all approvals for food and feed use took place in the same year.

The US is not a signatory to the CBD or the CPB.

Maize genetic modifications approved in the US

EVENT	PLANTING	FOOD/FEED
ECB Mon 80100Bt	1995	1996
ECB + Glyphos MON 802	1997	1996
ECB + Glyphos Mon 809	1996	1996
HT Glufos B16/DLL25	1995	1996
HT Glufos T14/T25	1995	1995
GA 21	1997	1996
HT NK 603	2000	2000
HT + Fert 676,678,680	1998	1998
HT + FertMS 3	1996	1996
HT + Fert MS6	1999	2000
HT + Bt 176	1995	1995
HT + Bt 11, X 4334CBR X4734 CBR	1996	1996
HT + Bt CBH 351	1998	
HT + Bt DAS-59122-7	2005	2004
HT + Bt DBT 418	1997	1997
HT + Bt MON 88017	2005	2005
HT + TC1507	2001	2001
Bt DAS-06275-8	2004	2004
Bt MON 00863-5 X MON 00810-6	2003	2003
Bt CRW MON863	2003	2001
Plant Quality LY 038	2006	2005
HT + Bt MON 88017	2007	2007

Acronyms:

Bt = insect resistance, CRW = corn root worm resistance, ECB = European Corn Borer resistance, Glufos = Glufosinate tolerance, Glyphos = Glyphosate tolerance, HT = herbicide tolerance, Fert = fertility/sterility systems.

Contact parties/sources:

USDA-APHIS: www.aphis.usda.gov/brs/index.html

EPA: www.epa.gov/epahome/laws

FDA: www.cfsan.fda.gov/

JAPAN

Japan is member of the CBD by acceptance in 1993 and has acceded to the CPB. GM crops are governed under the Law Concerning Conservation and Sustainable Use of Biodiversity through regulations on the Use of Living Modified organisms. Regulations are separated for use of LMOs, such as crops in field trials or on-farm, and use of LMOs in contained facilities. The former is in compliance with requirements under the Protocol and includes implementation of assessment of adverse effects on biodiversity. The second set of regulations covers measures to control LMOs in industrial use containment and in research and experimentation contained facilities and involves inputs from various government departments. The principles applied are, firstly, the concept of “familiarity” that implies sufficient knowledge and experience to assess potential risks of a GMO under open field conditions, and, secondly, the concept of “substantial equivalence” that implies equivalence to the conventional comparator.

The country has sets of guidelines for experimentation and for industrial application. The latter includes application in agriculture, forestry, fisheries, food industries and others, and covers field trials. Approvals granted cover 196 varieties for isolated field trials, 74 varieties in open field trials, and 107 for import. Japan has invested substantial effort in plant biotechnologies and has developed a range of GM lines with unique traits in rice, carnation, vegetables, potatoes, soybean, tobacco and tomato. Yet, it is hardly growing any commercial GM crops.

Maize grain imports are subject to prior approval of specific genetic modifications. Adventitious presence of GM ingredients in non-GM products is allowed up to a level of 5 per cent, applicable to unprocessed products..

Maize genetic modifications approved for import

1996: Bt 11 IR, Bt Mon 810 IR, Bt 176 IR + HT

1997: T14 HT, T25 HT, MON 802 IT + HT, DLL25 – DK566 HT, BDT418 -- DK566 IR + HT, MON 809 Bt IR

1998: GA 21 HT

1999: CBH 351 IR + HT, DLL 25 HT, DBT 418 IR + HT

2001: MON 863 Bt CRW IR,

2003: MON 8800 CRW IR + HT, MON 88012 CRW IR + HT, MON 88017 CRW IR + HT

2004: MON 863 X NK603 CRW IR + HT, MON 863 X MON 810 X NK603 CRW + IR + HT, NK603 X MON810 HT + HT, T25 HT, NK603 HT, Syng 3272 Hi-amylase, D1507 X NK603 HT + HT + IR, D1507 IR + HT, T 6275 IR + HT, MON-00810-6 X MON-00863-5 CRW + IR, MON 863 CRW, MON 00810-6 IR.

2005: MIR 604 CRW, GA 21 HT re-approved, T25 X MON 810 IR + HT, GA21 X MON 810 IR + HT

2006: Bt 10 Syng IR + HT, TC6275 DAS-06275-8 IR + HT, Bt MON 89034 IR, DAS 59122-7 X 1507-1 X MON-00603-6 CRW+ IR + HT + HT, DAS 59122-7 X MON 00603-6 CRW + HT + HT, 1507 X DAS 05107-1 X DAS 59122-7 CRW + IR + HT, MON 88017 X MON 810 X MON 810-6 CRW + IR + HT, DLL 25 HT, MON 88017-3 CRW + HT, DAS 59122-7 CRW + HT, T14 Bayer HT

2007: Bt 176 IR + HT, Bt 11 IR + HT, DBT 418 IR + HT.

Acronyms: CRW = corn rootworm resistance, IR insect resistance, HT herbicide tolerance

Contact parties/sources:

www.s.affrc.go.jp/docs/sentan/

www.s.affrc.go.jp/docs/sentan/eguide/edevelp.htm

www.bch.biodic.go.jp/english/lmo.html

REPUBLIC OF KOREA

Korea has ratified the CBD in 1994 but is a non-party as regards the CPB. It has a strong R & D activity in GM research but remains sensitive about any GM products being imported without the necessary biosafety clearance. It has biosafety legislation to handle GM crops and products. Identification and labeling is required on a specified list of food products, is product-based and is being applied voluntary and mandatory.

The following modifications have been approved for import as food/feed:

Bt 11: IR + HT, Syngenta

DAS 01507-1 X MON 00603-6: IR + HT, Dow/LLC

GA 21: HT, Monsanto

MON 00603-6 X MON 00810-6: IR + HT, Monsanto

MON 810 IR, Monsanto.

Contact parties/sources:

Focal point for CBD: Cooperation Division, Ministry for Foreign Affairs & Trade, Seoul

environment@mofat.go.kr

Mr. Gil-Su Shin, Consulate General: Canada.

secretary@koreaconsulate.qc.ca

SADC AND COMESA COUNTRIES

The four African regions -- Southern, Eastern and Central, Western and North—have attempted to harmonize regulatory systems on various technical and trade issues. In East Africa good progress has been made with Kenya, Uganda and Tanzania taking the lead. West Africa is also making progress. In SADC less progress has been made than elsewhere, perhaps because of greater disparity between member states. In 2003, following the arrival of US food aid that was GM destined for Zambia, SADC did develop a “common” position on handling food aid that is or may contain GM components, namely, that the region should attempt to source food from within the region, preferably of non-GM status, that there should be prior informed consent from importing states before shipping takes place, and that states should build capacity and infrastructure to manage biotechnology. As regards the latter, UNEP-GEF and other parties provided million of dollars to assist SADC. One outflow from this position was that grain should be milled before acceptance in the importing country.

The present status of adopted and draft legislation is that there is no common regional law on biotechnology/biosafety and member states have developed their own approaches. The common principles, however, have been set by the CPB and to some extent by the SADC policy guidelines. SADC missed a golden opportunity to start from a common base. Likewise, South Africa missed a golden opportunity to play a leadership role, despite having been before warned of impending trade issues.

1. ANGOLA

Status:

Ratified the CBD in 1998, but not yet acceded to CPB. Official policy is non-GM crops and their non-GM products

Legislation:

Biosafety legislation in process

Contact parties for CPB Focal Points:

Mr Lucas Marcolino Miranda, National Director: International Exchange Office,
Ministry of Urbanism & Environment, Luanda

lcs_miranda@yahoo.com; lucasmiranda@hotmail.com

Fax: 00244-222-310-003 / -310-517

2. BOTSWANA

Status:

Ratified CBD in 1995, ratified CPB in 2003, follows SADC policy guidelines

Legislation:

Biosafety legislation is still in process and a draft Bill is nearing completion and will be submitted to Parliament in due course. An Act may be approved by 2008. This has to fit in with Science and Technology policies and Agricultural policies. The Bill will make provision for a National Biosafety Authority with a Board and a CEO, as well as a National Biosafety Committee. The Bill will cover all GMOs/LMOs and their products and any activity related to GMOs will need a licence. All GM food and feed products need to be identified and labeled. There are presently no specific regulations that control import of grain or products that may be GM, except that SADC policy needs to be followed, i.e. prior informed consent by government for accepting shipments from other countries.

Contact parties:

Mr. Muchanana L. Nchunga, Executive Secretary, National Conservation Strategy Coordinating Agency (NCSA), Ministry of Environment & Tourism, Private Bag 0068, Gaborone.

mnchunga@gov.bw / envirobotswana@gov.bw

Tel 00267-390-2050 / -2055, Fax 00267-390-2051

Dr. G. S. Maphanyane, Director: Agricultural Research, Private Bag 0033, Gaborone.

gmaphanyane@gov.bw

Tel. 00267-366-8100 ; fax: 00267-392-8965

Dr Manthe Tsuaneng, Department of Agricultural Research, Gaborone.

mathet@yahoo.co.uk

Tel: 00267-3-668-172

3. DEMOCRATIC REPUBLIC OF THE CONGO (DRC)

Status:

Ratified CBD in 1994, acceded to CPB 2005

Legislation:

DRC has a national biodiversity strategy and action plan. Biosafety drafts are being prepared.

Contact parties:

Mr. Toirambe Bamoninga, Direction du Developement Durable, Ministere de l'Environnement, B.P. 12 348, Kinshasa.

Be_toirambe@yahoo.fr

Tel. 00243-99-999-9148; fax 00243-884-3675

Mr. Mike Ipanga Mwaku, Ministere de l'Environnement, Kinshasa.

mikeipanga@hayoo.fr

Tel. 00243-843-6789; fax. 00243-884-3675

4. KENYA

Status:

Ratified CBD in 1994; ratified CPB in 2004. The country has a national biodiversity strategy and action plan.

A new modern contained use facility with greenhouses for GMO work was inaugurated in 2006. At present only research is allowed on GM crops. A field trial with virus resistant GM sweet potato was conducted in 2005/6 and a Bt maize trial in 2006. Government is considering approval for Bt GM cotton. The first African Biosciences Centre of Excellence was established on the ILRI campus in Nairobi in 2005.

Legislation:

Kenya has a Draft Biosafety Act since 2002 but this has not yet been approved by Parliament.

Practical trade arrangements are as follows:

- Kenya has never had an embargo on GM
- Import of GM maize seed is allowed only for research purposes, such work being done in containment
- Import of grain commodities and products is subject to its GM status being declared and by countries of origin where commercial GM crop production is being practiced.
- GM status of maize meal and products must be declared in applying for an import permit so that products can be labeled for consumers and for keeping track of products
- Above requirements are entrenched in the draft Bill and in policies.

Contact parties;

Mr Harrison K. Macharia, Chief Science Secretary, National Council for Science and Technology, Ministry of Science & Technology, P.O. Box 30623-00100, Nairobi.

Tel. 00254-20-318-249 / 00254-725-776-434

Harrison@ncstnbo.co.ke

Website: www.biosafety.co.ke

Dr. Evans Sikinyi, Head: Kenya Environment and Plant Health Services, Nairobi.

esikinyi@kephis.org

5. LESOTHO

Status:

Ratified the CBD in 1995 and the CPB in 2003.

Legislation:

Biosafety legislation has been developed and the final draft Bill has been approved by Cabinet. Regulations for seed imports are to be drafted by Department of Agriculture.

Legislation will be under the Department of Environment. Provision is made for a National Biosafety Council with 7 members: 5 from 5 departments and two from civil society. The Council will have a Registrar and inputs will come from a Standing Advisory Committee. There will be a Coordination Committee. There are presently no regulations on GM grain imports but guidelines are in process.

Contact parties:

Mr. Stanley Motsamai Damane, Director: National Environment Secretariat, Ministry of Tourism, Environment & Culture, Maseru.

stanleydamane@hotmail.com

Tel.: 00266-22-311-767 / -320-534; fax: 00266-311-139

Ms. Qongqong Hoohlo, Environment Officer, National Environment Secretariat, Ministry of Tourism, Environment & Culture, Maseru.

qhoohlo@hotmail.com / qhoohlo@mtec.gov.ls

Tel : 00266-311-767

Dr. Mahloane, member of Biosafety Committee

Tel: 00266- 630-14101

mahloane@yahoo.com

6. MADAGASCAR

Status:

Ratified the CBD in 1996 and the CPB in 2004.

Legislation:

Madagascar is at an early stage to proceed from a rough draft biosafety Bill but is using existing regulations to manage GMOs as an interim measure. These regulations cover phytosanitary issues, animals, plants, seeds, biopesticides, food products, and imports/exports. The Bill envisages to have a National Coordinating Authority as decision making body, a National Biosafety Council consisting of officials from government and stakeholders to oversee legislation and monitoring, and a Science and Technology Committee to advise, and a Public Participation Committee. For the present the Control Office Services will manage requirements such as identification and labeling of GM imports.

Contact parties:

Mrs. Marie Blandine Ramanantenasoa, Chief: Service Legislation et Contentieux, Ministere de l'Environnement, B.P. 571, Antananarivo

ramanantenasoamarie@yahoo.fr / minenv@dts.mg

Tel 00261-20-224-0908; fax: -1919

Ms. Chantal Nicole Andrianarivo, responsible officer for scientific research, Ministere de l'Environnement, ANGAP B.P.1424, Antananarivo 101.

val@angap.mg / chant_andri@yahoo.fr

Tel: 00261-3202-290-95

Mr. Jean Roger Rakotoarijoana, Director: Direction des Information Environnementale,
Office National pour l'Environnement, Antananarivo 101

jroger@pnae.mg

Tel.: 00261-20-222-59999

Madagascar clearing house: www.bch-cbd.naturalsciences.be/Madagascar/

7. MALAWI

Status:

Ratified CBD in 1992, not yet acceded to or ratified the CPB.

Legislation:

Malawi has a National Research Policy, a Biosafety Act adopted in 2002 and has completed a set of draft Biosafety Regulations and Guidelines in 2006. The Regulations are somewhat modeled after the South African GMO Act framework. Government is presently working on harmonizing the requirements of the Act and the Regulations and it is anticipated that this process will be completed by year end. Malawi imported GM maize in 2002 due to food shortages but at this stage prefers not to import GM grain until the legislation is sorted out. In the absence of approved regulations, their position on maize meal is uncertain. The country has had a good season and expects a 1.5 million MT surplus which it hopes to export as non-GM to neighbours.

Contact parties:

Mr. R.P Kabwaza, Director: Environmental Affairs, Environmental Affairs Department,
Lilongwe.

rkabwaza@sdp.org.mw / kabwaza@hotmail.com

Tel: 00265-1-771-111; fax: 00265-1-773-379

Mr. Patrick Salifu, Senior Environmental Officer, Environment Affairs Department,
Lilongwe 3.

ods@sdp.org.mw

Tel: 00265-1-771-111

Mr. Frade Nyondo, National Research Council of Malawi.

nrcm@sdp.org.mw, / fradenyondo@yahoo.co.uk

Tel: 00265-177-1550

8. MAURITIUS

Status:

Ratified CBD in 1992 and acceded to the CPB in 2003. The country has modern containment and greenhouse facilities for use on GMO research work on sugar cane. No field trials are being conducted on GM cane.

Legislation:

Mauritius has adopted a GMO Act in 2005 and regulations are in process. A National Biosafety Committee will advise the Minister of Agro-Industry on GMOs. The Committee has a Chairman from the Ministry and a Board of 10 members. There is a National Executing Agency, a National Coordinating Committee and a food technical laboratory that can do GMO tests. GM regulations still have to be developed. At present there are no regulatory requirements for declaring GM status of imported products or for mandatory labeling.

Contact parties:

Mr. Yussuff Boodoo, Senior Researcher and Development Officer, Agricultural Development Division, Ministry of Agriculture, Reduit.

myboodoo@mail.gov.mu

Tel: 00230-464-4895

9. MOZAMBIQUE

Status:

Ratified the CBD in 1995 and ratified the CPB in 2003

Legislation:

The country has accepted that it cannot avoid international trade in GMOs. In 2002 a national biosafety working group was formed (GIIBS), representing 9 stakeholder parties, to do surveys and policy development. A draft decree and technical guidelines were formulated. Regulations are to set up rules for imports/exports, transit, manipulation, handling and use that involve GMOs, as well as identification, packaging and transport. These regulations were just passed in April of this year but enforcement is not yet possible due to lack of capacity and no laboratory to test for GM presence. It is envisaged that all imports must have their GM status identified and that GM content of foods declared. This will lead to labeling of food products. All imports of consignments that are or may contain GM fall under the Minister of Science & Technology.

Contact parties:

National Institute for Agronomic Research, Ministry for Coordination of Environmental Affairs, Maputo.

Tel: 00258-21-496-109 / -492 / -403

Ms Carla do Vale, Agricultural Research Institute of Mozambique (ITAM), Maputo.

cdovale@yahoo.com

Tel: 00258-21-460-130

(CBD Contact person is Eng. Anselmina Liphola; at anselmina.liphola@micoa.gov.mz)

10. NAMIBIA

Status:

Ratified the CBD in 1997 and ratified the CPB in 2005.

Legislation:

Namibia promulgated a biodiversity-biosafety act on 22 December 2006. Implementation is being investigated in order to comply with both the CBD and CPB. Biosafety Regulations and Guidelines are being finalized and may be completed by end June.

Biotechnology research is being carried out at the University of Namibia and the CVL. Meat exporters are concerned about GM feed as their EU buyers want GM-free status in feed. Importers in Namibia require a certificate from South African maize exporters in respect of GM-free grain. The Act covers GM grain and products but a list of exemptions is being compiled so as to exclude products such as maize syrup and starch. Enforcement of the Act is not yet operational due to inadequate inspection services and testing to verify non-GM status of products at points of entry. In terms of the Protocol there must be advance informed agreement (consent) before GM consignments can be shipped into Namibia.

Contact parties:

Prof. Dr. Martha Kandawa-Schulz, Chairman: Namibian Biotechnology Alliance,
University of Namibia, Windhoek.

kschulz@unam.na

Tel: 00264-61-206-3635

Ms. Immolatrix Geingos, Senior Science and Technology Officer, Directorate of Higher Education Research, Science and Technology, Ministry of Higher Education, Training and Technology, Windhoek.

igeingos@mec.gov.na or ethomas@mec.gov.na

Tel: 00264-61-270-6151 / 00264-811-229-021

Ms Rosa Stella Mbulu, Ministry of Agriculture, Windhoek

rsmbulu@cvl.com.na

Tel: 00264-61-237-684

Namibia clearing house:

www.dea.met.gov.na/programmes/biodiversity/.htm

11. SOUTH AFRICA

Status:

Ratified CBD in 1995 and acceded to the CPB in 2003. GM maize approved for commercial release in 1998. The GM maize status for 2006/7 is 49 per cent of total crop,

52 per cent for white maize at 851 000 ha, and 44 per cent for yellow maize at 408 000 ha.

Legislation:

Biosafety guidelines in 1990, GMO Act promulgated in May 1995, GMO regulations approved in November 1999 when the Act entered into force. Decision making is by the GMO Executive Council. All GMO grain imports and exports are subject to permit applications. In transit handling of GM grain destined for re-export also requires a permit. The Executive Council has been delaying approval of genetic modifications approved in other countries and that may not have use for South Africa. The Council is also studying aspects of stacked traits that are increasing rapidly in other countries. The GMO Act was amended in 2006.

Contact parties:

The Assistant Director, MEAS focal point, Department of Environment and Tourism, Pretoria.

globalengagements@deat.gov.za

Tel: 012-310-3270

Mr Sello Mokhothu, Department of Agriculture

Tel: 012-319-6033

sellm@nda.agric.za

12. SWAZILAND

Status:

Ratified the CBD in 1994 and the CPB in 2006.

Legislation:

A national biosafety framework is being developed that will lead to a Biosafety Bill, then to an Act. The Swaziland Environmental Authority Board comprises 8 persons: 4 from ministries and 4 from other stakeholders. There will be a National Biosafety Advisory Board. Regulatory control will encompass

- Food aid to be monitored, GM maize milled, a written declaration required about genetic events, and all foods to be free from GM contamination
- A database to be compiled of all food aid, all GM products to be labeled, all GMOs for food, feed or processing to be regarded as release into the environment
- National safety guidelines will be set up, facilities erected for GM testing, in vitro cell cultures and GM research, no patenting will be allowed, farmers will be allowed to use and barter farm-saved seed
- All food aid, imported foods and feeds will be monitored, as will be GM field trials, live imports, and pre- and post-releases.
- A positive decision on GMOs by the Board can be overturned, a negative decision cannot be overturned, even in the light of socio-economic benefits.

It is clear that the proposed regulations, in their present form, will include matters that have no bearing on biosafety and fall outside the scope of the CBD and CPB.

Contact parties:

Mr. Stephen M. Zuke, Senior Environment Officer: Swaziland Environmental Authority, Ministry of Tourism, Environment and Communications.

seabiodiv@realnet.co.sz or sea@realnet.co.sz

Website: www.environment.gov.sz

Tel: 00268-404-6420

13. UGANDA

Status:

It has ratified the CBD in 1993 and the CPB in 2003. It has a national biodiversity strategy and action plan. The country is pro-biotechnology and is anticipating application of GM cotton and banana.

Legislation:

The draft biosafety legislation was again discussed during the week of 14 May 2007. The advisory body is the Science and Technology Council.

Contact parties:

Mr Salvatore Byaragaba

Tel: 00256-41-340-684

Dr. Peter Ndemere, Biosafety Board

uncst@telcom.co.za

Tel: 00256-41-470-5500

Dr. Theresa Sengoba, Uganda National Council for Science and Technology.

uncst@telcom.co.ug

Tel: 00256-41-234-613

14. ZAMBIA

Status: Ratified the CBD in 1993 and the CPB in 2004. Zambia has a national biodiversity strategy and action plan.

Legislation:

The arrival of food aid in 2002 in the form of US maize grain commingled with GM gave rise to a temporary ban on GM foods as result of Zambia not having been pre-advised of the GM content, not having biosafety systems in place, and uncertainties on GM food safety caused by activist allegations. The draft 2003 biotech and biosafety policy moved to a Biosafety Bill that was approved as an Act in March 2007. Regulations are being developed. Despite the policy aiming at judicious use of GM biotechnology, the Act is

planned to place severe constraints on commercial GM products. Regulations will cover imports, exports, field trials, and release. The official policy still remains: no GM grain imports or products like meal will be allowed. There is no clear handling of maize products such as syrup, starches, etc. A testing lab has been set up for GM testing. Spokespersons have acknowledged the difficulty in testing foods like maize syrup or starches.

Contact parties:

Dr. Mwananyanda M. Lewanika, Executive Director: National Institute for Science and Industrial Research, Lusaka.

mmlewanika@nisir.org.zm or sanyanda@hotmail.com

Tel: 00260-1-281-013

Mr. Forward Lumbwe, Information Specialist, Information Services Unit, Ministry of Science, Technology and Vocational Training, Lusaka

lumbwe@nisir.org.zm

Tel: 00260-1-283-533

Website: www.biosafety.zm

Zambia clearing house: <http://zm.chm-cbd.net>

15. ZIMBABWE

Status:

Ratified the CBD in 1994 and the CPB in 2005. Zimbabwe has a positive policy on crop biotechnology. It has permitted small field trials of Bt maize and Bt cotton. The trials were not continued by seed companies in 2006 but approval for such trials is still valid. Planting of commercial GM crops is not yet permitted. Import of all grain and food for food, feed or processing must have their GM status declared. GM raw grains can be imported when milled or must be milled upon entry but the GM status must be declared to recipients of the products. This implies labeling but there are as yet no comprehensive legal labeling instruments to enforce it.

Legislation:

The country has a biosafety law that was adopted in September 2006, arising from genetic modification incorporated in its 1998 Research Act. The Vice President issued a statutory instrument in 200 to establish the Biosafety Board to advise government, and also a GM Secretariat and a Registrar to manage the administration. The Board regulated food and feed imports until the Act was passed in 2006. The Biosafety Forum was established in 2004 with the mandate to make inputs into national policy, the Biotechnology Authority, and other bodies.

Contact parties:

The Permanent Secretary, Ministry of Environment and Tourism, Harare

Tel: 00263-4-757-881 or -5

Mr. Abisai Mafa, Registrar: Biosafety Board of Zimbabwe, Harare.
mafa@biosafetyzim.ac.zw or absmaus@yahoo.com
Tel: 00263-11-877-990
Website: www.biosafetyzim.ac.zw

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ANNEX

TABLE.1. MAJOR MAIZE GRAIN IMPORTING COUNTRIES (MT X 1000)

Country	(2002/03)	(2003/04)	(2004/05)	Total	Average	Rank
Algeria	1392	1922	2009	5323	1774	10
Canada	4310	2173	2478	8961	2987	7
China(Taipei)	4883	4921	4540	14344	4781	4
Egypt	4766	4152	4957	13875	4625	5
EU	3128	5430	2687	11245	3748	4
Iran	1122	1879	2779	5780	1927	9
Israel	711	1434	1221	3366	1122	13
Japan	16511	16215	16059	48785	16262	1
Korea(South)	8725	9940	7881	26546	8849	2
Malaysia	2745	2590	2325	7660	2553	8
Morocco	1038	1195	1327	3560	1187	12
Mexico	4984	5233	5811	16028	5343	3
Saudi Arabia	1107	1411	1308	3826	1275	11
Turkey	1284	1157	283	2724	908	14
Grand Total	56706	59652	55665	172023	57341	

*Source: World Grain Statistics: International Grains Council, 2005 (published 2006)

TABLE.2: MAJOR MAIZE GRAIN EXPORTING COUNTRIES (MT X 1000)

Country	(2002/03)	(2003/04)	(2004/05)	Total	Average	Rank
Argentina	11530	9917	12365	33812	11271	2
Brazil	2412	5773	2664	10849	3616	4
China	14882	11321	5613	31816	10605	3
South Africa	1025	1021	1045	3091	1030	6
Ukraine	868	1124	2237	4229	1410	5
USA	42520	45815	46827	135162	45054	1
Grand Total	73237	74971	70751	218959	72986	

*Source: World Grain Statistics: International Grains Council, 2005 (published 2006)

ANNEX

TABLE.3: SOUTH AFRICAN MAIZE GRAIN EXPORTS (MT)

Destination		(2004/05)	(2005/06)	(2006/7)	Total	Average	Total	Rank
Angola	White	33644	14162	3742	51548	17183.0	17430	12
	Yellow	537	204	0	741	247.0		
Benin	White	0	2278	0	2278	759.0	759	19
	Yellow	0	0	0	0	0.0		
Botswana	White	112683	175708	99433	387824	129275.0	143103	2
	Yellow	8205	20744	12535	41484	13828.0		
Chad	White	0	151	0	151	50.0	50	23
	Yellow	0	0	0	0	0.0		
Cameroon	White	0	3001	0	3001	1000.0	1000	18
	Yellow	0	0	0	0	0.0		
Congo	White	216	0	0	216	72.0	72	22
	Yellow	0	0	0	0	0.0		
DRC	White	0	0	280	280	93.0	93	21
	Yellow	0	0	0	0	0.0		
Ghana	White	0	7638	0	7638	2546.0	2546	15
	Yellow	0	0	0	0	0.0		
Indonesia	White	0	0	0	0	0.0	16500	13
	Yellow	0	49500	0	49500	16500.0		
Iran	White	0	0	0	0	0.0	31095	9
	Yellow	0	93284	0	93284	31095.0		
Japan	White	0	0	0	0	0.0	37699	8
	Yellow	0	113098	0	113098	37699.0		
Kenya	White	129451	50038	2792	182281	60760.0	60760	5
	Yellow	0	0	0	0	0.0		
Lesotho	White	112070	82851	62143	257064	85688.0	91229	3
	Yellow	6712	3843	5769	16324	5441.0		
Madagascar	White	2382	967	1033	4382	1461.0	1461	16
	Yellow	0	0	0	0	0.0		

ANNEX

TABLE.3: SOUTH AFRICAN MAIZE GRAIN EXPORTS (MT), CONT'D

Malawi	White	0	68204	159	68363	22788.0	22908	11
	Yellow	0	359	0	359	120.0		
Mali	White	0	2258	0	2258	753.0	753	20
	Yellow	0	0	0	0	0		
Mozambique	White	48396	138702	35776	222874	74291.0	80233	4
	Yellow	5488	11459	880	17827	5942.3		
Namibia	White	43452	53956	38195	135603	45201.0	60670	6
	Yellow	13121	17361	15926	46408	15469.0		
Somalia	White	0	3158	0	3158	1053.0	1053	17
	Yellow	0	0	0	0	0.0		
Sudan	White	0	28272	0	28272	9424.0	9424	14
	Yellow	0	0	0	0	0.0		
Swaziland	White	17968	26184	14762	58914	19638.0	56163	7
	Yellow	28434	35111	46030	109575	36525.0		
Zambia	White	0	89370	35	89405	29802.0	29865	10
	Yellow	0	189	0	189	63.0		
Zimbabwe	White	209682	1034743	107456	1351881	450627.0	454508	1
	Yellow	653	10727	264	11644	3881.0		
Grand Total		773094	2137520	447210	3357824	1119275	1119275	

*Source: SAGIS 2007

TABLE.4: SOUTH AFRICAN MAIZE GRAIN IMPORTS (MT)

Country		(2004/5)	(2005/6)	(2006/7)	Total	Average
Malawi	White	724	0	0	724	241
	Yellow	0	0	0	0	0
Argentina	White	0	0	0	0	0
	Yellow	205856	360542	761474	1327872	442624
USA	White	0	0	0	0	0
	Yellow	15508	0	0	15508	5169
Grant total		222088	360542	761474	1344104	448035

*Source: SAGIS 2007