Genetically Modified Organisms Act, 1997

Annual Report 2008/09

agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Genetically Modified Organisms Act, 1997

Annual Report 2008/09

CONTENT

Acronyms ii
Message from the Chairperson of the Executive Council of the GMO Act iii
Introduction 1
Objectives of the GMO Act 1
Activities during 2008/09 2
Legislation 2
Client and public interaction 2
Products and services. 3
Intergovernmental engagement 4
International 4
Conclusion 4
Annexure 6
Table 1: GMOs approved for conditional general release … 6
Table 2: GMOs approved for trial release in 2008/09 6
Table 3: GMOs approved for contained use activities in 2008/09 7

2009

Printed and published by:

Department of Agriculture, Forestry and Fisheries

Compiled by:

Directorate: Biosafety

Design and layout by:

Directorate Agricultural Information Services

Obtainable from:

Resource Centre
Directorate Agricultural Information Services
Private Bag X144
PRETORIA
0001

ACRONYMS

AC	Advisory Committee
ARC	Agricultural Research Council
BCH	Bio-safety Clearing House
CSIR	Council for Scientific and Industrial Research
DAFF	Department of Agriculture, Forestry and Fisheries
dti	Department of Trade and Industry
EC	Executive Council
GMO	Genetically Modified Organism
SA	South Africa
HIV	Human Immunodeficiency Virus
PAIA	Promotion of Access to Information Act
SANSOR	South African National Seed Organisation

MESSAGE FROM THE CHAIRPERSON OF THE EXECUTIVE COUNCIL OF THE GMO ACT

On behalf of the Executive Council, I am pleased to present the Annual report on activities conducted in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) for the period 2008/09.

During this period, the Executive Council in its review of all applications submitted in terms of the GMO Act, 1997, continued to adopt a case-by-case approach to ensure sound decision making in the interest of safety of the environment, and human and animal health. Not all applications tabled at the Council were met with favourable consideration and in some instances applicants were requested to submit further information and scientific evidence in support of their applications. Although applicants usually consider this a severe impediment to their progress, we remain convinced that our priority is to follow the precautionary approach. Most applications considered by the Council involved genetically modified maize, cotton and sugar. The modification of the maize and cotton still revolves around insect resistance and herbicide tolerance, albeit modifications and refinements of existing traits. Mindful of other challenges beyond that of agriculture, the Council also evaluated applications for HIV vaccine trials involving GMOs. In addition to the HIV trials, many other trials which focus on measles and tuberculosis are ongoing and we remain positive that this technology will deliver effective products to curb the scourge of these life-threatening diseases.

Apart from deliberations for decisions on applications, the Council was also engaged in activities for the finalisation of the GMO amendment regulations, the development of bio-safety regulatory guidelines and development of country positions towards the meetings for the Cartagena Protocol on Bio-safety. As the focal point for the Protocol, the Department of Environmental Affairs represented the country in a number of these negotiations.

During this period the Advisory Committee was particularly challenged by the increasing number of applications subjected to scientific review in addition to resignations from the committee. Despite these challenges, the committee never faulted on its ability to provide a sound scientifically based assessment of applications and lend its expertise to related bio-safety issues. In recognition of the importance of the role played by the AC in the regulatory review process, the Council would like to extend their appreciation for the good work performed by the Advisory Committee.

Overall, the Council is satisfied with the administration of the GMO Act; however, as we reviewed reports from applicants and the Office of the Registrar, we were able to identify specific areas which required improvement to facilitate better regulatory oversight and a more effective administrative process. Despite this, the dedication of the Director of Bio-safety, the Registrar and the support personnel remains a key success factor towards the efficient management of the administration of the GMO Act. The Council salutes your efforts.

It is my view, that over the past few years, the Council has evolved into an effective mechanism to assess the potential impact of GMOs on all the relevant sectors within a complex landscape of separate yet interlinked mandates. As Chairperson of the Council, I wish to extend my appreciation to my colleagues represented on the Council for their continued efforts and hard work during the period under review.

In addition, the Council wishes to extend its gratitude for the continued support and commitment by the Minister of Agriculture, Forestry and Fisheries as well as the Ministers represented in terms of the Act.

Dr J B Jaftha

Chairperson: Executive Council

1. INTRODUCTION

Since the implementation of the Genetically Modified Organisms Act of 1997 (Act No.15 of 1997) (GMO Act) in December 1999, all activities with GMOs in South Africa (SA) are conducted according to permits issued in terms of this Act. Because of the growing importance of bio-safety and related issues, the department decided to elevate the GMO unit, previously housed in the Directorate Genetic Resources, to an independently functioning directorate. The GMO Act is now administered by the Directorate Bio-safety and makes provision for the appointment of a Registrar, two regulatory bodies, i.e. the Advisory Committee, Executive Council and inspectors.

The Registrar, who is appointed by the Minister, is responsible for the administration of all activities in terms of the GMO Act. GMO applications are subjected to a multidisciplinary process of scientific evaluation by an expert panel of scientists constituting the Advisory Committee (AC) which acts as the national advisory body on all matters relating to GMOs. The AC consists of ten scientists who are appointed by the Minister of Agriculture, Forestry and Fisheries. The AC is further supported by subcommittee members representing an extended pool of scientific expertise from various disciplines. The AC together with subcommittee members is responsible for the evaluation of risk assessments of all applications as it relates to food, feed and environmental impact, following which a recommendation is submitted to the Executive Council (EC).

The EC is the ultimate decision-making body and currently consists of officials from six different government departments (Agriculture, Forestry and Fisheries; Health; Environmental Affairs; Labour; Trade and Industry and Science and Technology) and the chairperson of the AC who have all been appointed by the Minister in terms of the GMO Act. With the implementation of the GMO Amendment Act, 2006 in the near future, the Council will additionally include members from the Department of Water Affairs and the Department of Arts and Culture.

The objectives of the Council are to advise the Minister of Agriculture, Forestry and Fisheries on all aspects concerning the development, production, use, application and release of GMOs, and to ensure that all activities with regard to GMOs (importation, exportation, transit, development, production, release, distribution, contained use, storage and application) are performed in accordance with the provisions of the Act. Approved GMO activities are regulated by way of permits issued by the Registrar and accompanying permit conditions are monitored for compliance by inspectors within the Department of Agriculture, Forestry and Fisheries (DAFF).

The existence and application of the GMO Act provides the country with a decision-making tool that enables authorities in SA to conduct a scientifically-based, case-by-case assessment of the potential risks that may arise from any activity involving a particular GMO. The Biosafety Regulatory Framework therefore provides an enabling policy environment that facilitates the availability of GM technology in SA by ensuring the safety thereof.

2. OBJECTIVES OF THE GMO ACT

The objectives of the GMO Act are to:

- provide measures to promote the responsible development, production, use and application of GMOs;
- ensure that all activities involving the use of GMOs (importation, exportation, transit, development, production, release, distribution, contained use, storage and application) be carried out in such a way as to limit possible harmful consequences to the environment, human as well as animal health;
- give attention to the prevention of accidents and the effective management of waste;
- establish mutual measures for the evaluation and reduction of the potential risks arising from activities involving the use of GMOs;
- lay down the necessary requirements and criteria for risk assessments, to establish a Council for GMOs, to ensure that GMOs are appropriate and do not present a hazard to the environment;
- establish appropriate procedures for the notification of specific activities involving the use of GMOs, and to provide for matters connected therewith.

3. ACTIVITIES DURING 2008/09

Legislation

Amendment of the GMO Act and Regulations

Following the approval of the GMO Amendment Act of 2006 (Act No. 23 of 2006) by the President in April 2007, the accompanying regulations in support of the GMO Amendment Act were drafted and gazetted for public comments in April 2008. A substantive number of comments were received from various stakeholders and interest groups, which focused mainly on the practicality of how the provisions of the regulations would be implemented for the processing of GMO applications. After lengthy review and consultation of all comments with Legal Services, the amendment regulations are now in the final stages of completion.

Guidelines

In support of section 19 of the GMO Act, 1997 (as amended in 2006), a guideline was developed for the appeal process provided for under the Act together with the terms of reference for appeal board members. This guideline provides a general framework to facilitate an improved understanding of the appeal's process and defines the responsibilities of affected parties in the appeal decision-making process. The Appeal Guideline document and terms of reference were approved by the EC in March 2009.

Related documents

During 2008 a review of the GMO extension policy was initiated, the terms of reference for the Advisory Subcommittee was revised and a standard operating procedure for the issuing of GMO status certificates was drafted.

Client and public interaction

The Directorate Bio-safety continuously engages its clients and stakeholders to ensure an increased understanding of the regulatory process as prescribed in terms of the provision of the GMO Act. Engagements with clients occur on a daily basis primarily to clarify queries relating to GMO applications, discuss regulatory issues or access information. Clients with whom contact was maintained included importers, exporters, research institutes, the general public, academic institutions and biotechnology companies.

Commodity groups such as Potato SA, Grain SA, the Animal Feed Manufacturers' Association and the SANSOR Committee on GMOs also have a vested interest in the regulation and use of GM crops and therefore the directorate also participated in some of its strategic working groups in an advisory capacity.

In the interest of promoting awareness of the GMO Act, and the regulatory responsibility of the DAFF towards GMOs, participation at several agricultural exhibitions/shows, media events or farmers' days facilitated the dissemination of bio-safety information through presentations, brochures, media responses and publications on the departmental website. In addition, the directorate received numerous requests from stakeholder organisations for information on various GMO applications and activities *via* the Promotion of Access to Information Act (PAIA), 2000 (Act No. 2 of 2000). For 2008/09, a total of 34 requests for information were processed in terms of the PAIA Act, 2000.

In terms of obligations under the Cartagena Protocol on Bio-safety, the directorate is in the process of establishing a Bio-safety Clearing House (BCH), a web-based information portal to facilitate the exchange of information on and experience with GMOs. It is anticipated that with a fully operational BCH facility, stakeholder issues relating to transparency and access to information will largely be addressed.

Appeals

In terms of section 19 of the GMO Act, provision is made for any person who feels aggrieved by a decision or action taken by the EC, the Registrar and /or inspectors to lodge an appeal against such decision or action with the Minister. For the year under review the following GMO appeals were attended to:

The CSIR lodged an appeal against a decision by the EC which denied them approval to undertake contained activities involving GM sorghum. After due consideration of the outcome of the appeal board's decision, the Minister of Agriculture, Forestry and Fisheries granted the applicant approval to undertake such confined trials.

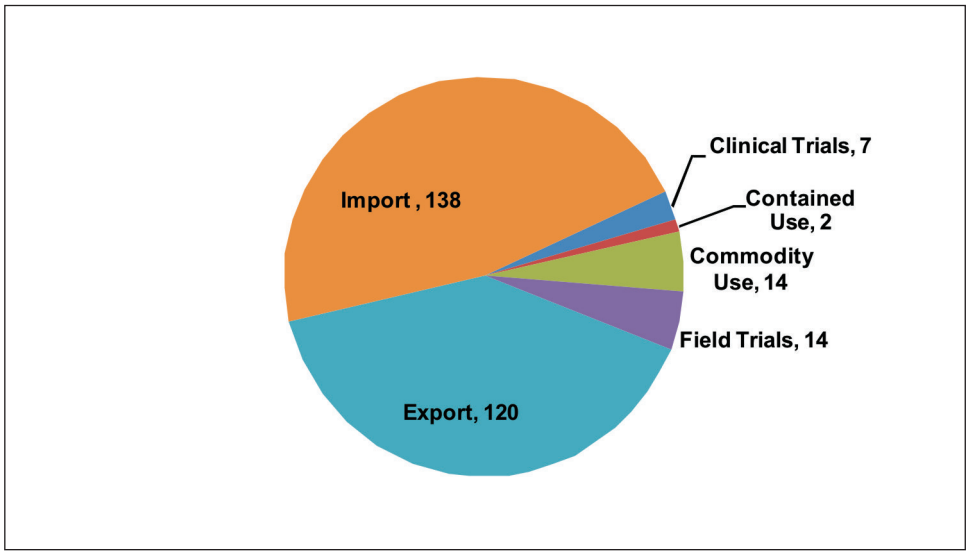

Fig. 1 Summary of GMO permits issued for 2008/09

The other appeal lodged in this year concerns the trial release of GM cassava by the ARC. In evaluating the outcome of the appeal board's decision, the Minister requested the applicant to provide further information. A final decision by the Minister of Agriculture, Forestry and Fisheries is still pending.

Products and services

In terms of the GMO Act a total number of 296 permits were issued during the 2008/09 financial year, the majority being issued for the import and export of GM crops. A summary of the permits issued is given in Fig. 1.

Imports focused mainly on commercially approved maize, soya-beans or cotton for activities relating to planting, contained use or food and feed. In addition, imports also included GM HIV and tuberculosis vaccines for contained use in SA.

The main exports included GM maize and to a lesser degree GM cotton primarily for contained use activities. In addition, the export of GM tuberculosis vaccine was also facilitated for contained use purposes. All transboundary activities involving GMOs were facilitated in compliance to provisions of Article 8, 11 and 18 of the Cartagena Protocol for Bio-safety and were accompanied by the relevant documentation required.

Apart from regulating import and export activities, GMO applications were also considered by the EC resulting in several permits being issued. A total of 14 permits were authorised for field trials of GM maize and GM cotton for evaluation of insect resistance and/or herbicide tolerance as well as for the evaluation of GM sugar cane with altered sugar content. In total 7 clinical trial permits were issued for HIV and tuberculosis vaccine trials. No general release permits were issued while two contained use permits were issued for GM maize and ornithogalum. Several commodity clearance applications for use as food, feed and processing were also received and subjected to safety assessment. However, decisions on these applications remain pending until all issues relating to risk management processes and procedures have been resolved.

In terms of regulations under the Act, facilities engaging in GMO activities are required to be registered. During the year 9 facilities were registered while the applications for registration of several more facilities are still in the process of being reviewed.

Applications still pending at the end of the financial year include two general release applications (potato and poultry vaccine), 5 commodity clearance applications for GM maize, 14 field trial applications (potato, maize and sugar cane) and one clinical trial for GM measles vaccine. Information on the status of approved GMO activities are listed in the accompanying annexures.

During the year the office of the Registrar experienced the submission of an unprecedented number of GMO applications, most notably trial release applications for GM crops and vaccines. In response to alleviating the challenges of reviewing the increased number of applications, additional capacity and scientific expertise were

appointed to expand the pool of subcommittee members supporting the AC. To facilitate the participation of new and existing subcommittee members within the regulatory review process, orientation and risk assessment training was provided in Pretoria and Stellenbosch, in September 2008.

This year saw an increase in the submission of comments on GMO applications from a wider audience of stakeholders and interested parties. Public input/comments for general release, trial release and commodity clearance applications were received from academic institutions, consumer forums, commodity organisations, provincial departments, and stakeholder organisations representing the anti and pro-GMO movements.

Intergovernmental engagement

The EC established in terms of the GMO Act is currently represented by six government departments, the Department of Agriculture, Forestry and Fisheries; Science and Technology; Environmental Affairs; Health; Trade and Industry and Labour as well as the chairperson of the AC. The EC convened seven times during 2008/09 to review and consider decisions on various GMO applications. Meetings took place on 06 May 2008, 15 July 2008, 29 July 2008, 23 September 2008, 28 October 2008, 27 January 2009 and 03 March 2009.

Intergovernmental engagement also included discussions with the Department of Environmental Affairs to address issues relating to the provisions of the Cartagena Protocol for Bio-safety and dialogue with the dti to voice concerns regarding the inclusion of mandatory labelling provisions for GMO foodstuffs in the Consumer Protection Bill.

International

In preparation for the fourth meeting of the Conference of the Parties/Meeting of the Parties of the Cartagena Protocol on Bio-safety in Germany in May 2008, the directorate submitted inputs in terms of Article 8 and 18 specifically relating to experiences on the transboundary movement of GMOs.

Bio-safety technical exchange and requests for information were shared between South Africa and Japan, Argentina, Namibia, the United States and through engagements with representatives of the African Biosafety Network of Expertise. In terms of South Africa's Binational Agreement with Argentina, specific areas of co-operation in the field of bio-safety were identified to promote dialogue between the two countries on issues affecting the regulation of GMOs.

As a leader on the African continent in the regulation and adoption of GM technology, SA remains committed to sharing its experiences with its African neighbours. SA will continue to engage and provide technical assistance in the field of bio-safety in order to assist other countries within the region and on the continent in the development of their Bio-safety Regulatory Framework.

Officials within the directorate attended the Bio-safety Training Programme at Michigan State University in the United States as well as the International Symposium on the Bio-safety of GMOs in New Zealand, which reported on new scientific developments in the field of GMOs and how it can be used to support bio-safety decision making. As regulators of Bio-safety in SA it is important that the directorate utilise opportunities for capacity building at an international level as these engagements would facilitate a strengthening of technical and scientific knowledge while preparing the directorate to address new developments in the field of bio-safety.

4. CONCLUSION

The establishment of the Directorate Bio-safety to specifically deal with issues relating to GMO's is testimony to the DAFF's recognition of the importance of bio-safety matters. It is anticipated that with a more focused approach, the administrative processes under the GMO Act will lead to more facilitated interactions with clients and stakeholders.

With the anticipated finalisation of the GMO amendment regulations, the directorate will be tasked with ensuring that the necessary institutional arrangements and processes are in place to give effect to the implementation of the GMO Amendment Act, 2006 and accompanying Regulations. As the Competent Authority for the Cartagena Protocol for Bio-safety, the directorate will continue its efforts to engage the Department of Environmental Affairs (focal point) in support of concluding on the text for liability and redress for transboundary movement of GMOs. While public participation and the submission of comments on GMO applications is an important part of the regulatory process, it is still subject to harsh criticism by stakeholders and interest

groups. It is hoped that some of these concerns will be alleviated with the establishment of a fully operational BCH to facilitate easier access to information and improve transparency.

Despite ten years of adoption in SA, GM crops have almost exclusively incorporated traits for insect resistance and or herbicide tolerance. As GM technology advances beyond the realm of agronomic traits the regulatory system will be particularly challenged to respond to these emerging GM technologies. The directorate will therefore continue to pursue efforts to strengthen its regulatory framework, exploit capacity-building initiatives and participate in regional and international bio-safety engagements.

ANNEXURE

TABLE 1: GMOs approved for conditional general release

Event	Crop	Trait	Company	Year approved
Bollgard II X RR flex (MON15985 X MON88913)	Cotton	Insect resistant Herbicide tolerant	Monsanto	2007
MON88913 (RR flex)	Cotton	Herbicide tolerant	Monsanto	2007
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2007
Bollgard RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2005
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant	Syngenta	2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soya-beans	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531 / Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810 / Yieldgard	Maize	Insect resistant	Monsanto	1997

Use of the event: Importation/exportation
Commercial planting
Food and/or feed

TABLE 2: GMOs approved for trial release in 2008/09*

Event	Crop	Trait	Company	Year approved
MEDI-534	Vaccine	Intranasal vaccine	PPD	2009
NCo310	Sugar cane	Altered sugar content	SASRI	2009
Cotton Bollgard II x GlyTol x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
Cotton Twinlink	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
Cotton Twinlink x GlyTol	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
SAAVI rMVA TBC-M456 vaccine	Vaccine	HIV vaccine	WITS	2008
VIR201	Vaccine	HIV vaccine	Triclinium	2008
GlyTol	Cotton	Herbicide tolerant	Bayer	2008
T304-40	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
GHB119	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
BGII x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
98140	Maize	Herbicide tolerant	Pioneer	2008
Bt11 X MIR162	Maize	Insect resistant Herbicide tolerant	Syngenta	2008
MIR 162	Maize	Insect resistant	Syngenta	2008

Use of the event: Importation/exportation
Field/clinical trial evaluation

TABLE 3: GMOs approved for contained use activities in 2008/09*

Event	Crop	Trait	Company	Year approved
98140 x Mon810	Maize	Insect resistant Herbicide tolerant	Pioneer	2008
Rolou A2:1 & A2:4 *Ornithogalum dubium* x *thyrsoides*	Ornithogalum	Viral resistant	ARC	2008

Use of the event: Importation
Contained use

*Refer to the departmental website: www.daff.gov.za for previously approved events.

Further information can be obtained from:
Directorate: Biosafety
Private Bag X973
PRETORIA 0001

Tel: +27 12 319 6199/6382
Fax: +27 12 319 6329
www.daff.gov.za