Genetically Modified Organisms Act, 1997

Annual Report 2004/2005

agriculture
Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

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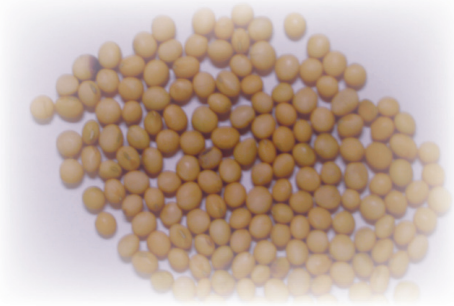

Annual Report 2004/2005

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Department of Agriculture, Petoria

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CONTENTS

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 under the auspices of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) for the period 2004/05.

During the period under review, the Executive Council focused on ensuring compliance to the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) (hereafter referred to as the Act) through good governance and sound scientific evidence. The Council was engaged in the development of the Biosafety policy, the amendment of the GMO Act and guidelines for working with GMOs. However, a significant proportion of the Council's work involved the analysis of applications in accordance with relevant scientific advice as well as government policy and legislation.

The Council deliberations on all applications submitted focused on implications on biodiversity, trade, health, employment, agriculture, scientific innovation and transfer of technology. Against this background, the Council, in some instances made difficult decisions of declining applications. Whereas in other instances additional information or risk assessments were requested prior to authorising the Registrar to issue permits. In all instances where the Council approved the issuing of permits by the Registrar, specific conditions were stipulated for the applicant.

In this period, the Council also deliberated and made decisions to ensure compliance with South Africa's commitment to international agreements, in particular the Cartagena Protocol on Biosafety.

In general, the Council is satisfied that there was effective administration of the Act and good compliance by those engaged in genetic modification. Debates among members of the public continue on this subject matter, which the Council believes will improve understanding and awareness. Similarly, administration of the Act has been subjected to legal scrutiny through our courts and the Council is pleased at the outcomes to date.

A challenge remains the ability of the Council to ensure that all members have all the requisite information at their disposal prior to making decisions on the issuing of permits. The Advisory Committee is also faced with the same challenge, particularly the ability to verify scientific data in an unbiased manner. To this effect, scientific risk assessment on a case-by-case basis remains the cornerstone of assessment by the Advisory Committee.

It is important to recognise the significant role of the information from the Advisory Committee in the decision-making process of the Council. Therefore, the Council would like to extend their appreciation for the good work performed by the Advisory Committee and the Registrar.

As chair of the Council, I wish to extend my appreciation to my colleagues in the Council for the good work performed during the period under review.

In addition, the Council wishes to extend thanks to the support and continued commitment of the Minister for Agriculture and Land Affairs as well as all Ministers represented in terms of the Act.

Shadrack R. Moephuli

Chairperson: Executive Council

INTRODUCTION

Since the implementation of the Genetically Modified Organisms Act of 1997 (Act No. 15 of 1997) in December 1999, all activities with GMOs in SA are conducted according to permits issued in terms of this Act. The Act is administered by the Directorate Genetic Resources and makes provision for the appointment of a Registrar, two regulatory bodies, i.e. the Advisory Committee and Executive Council and inspectors.

The Registrar is responsible for administration of the GMO Act. The Advisory Committee acts as the national advisory body on all matters relating to GMOs. Members of the Advisory Committee are appointed by the Minister of Agriculture and consist of ten scientists who are experts in fields relating to GMOs. This Committee evaluates risk assessments pertaining to food, feed and environmental impact, submitted with an application. The Committee makes a recommendation to the Executive Council.

The Council is the ultimate decision-making body and consists of officials from six government departments; the Departments of Agriculture, Health, Environmental Affairs and Tourism, Labour, Trade and Industry, Science and Technology and the chairperson of the Advisory Committee. The objectives of the Council are to advise the Minister of Agriculture 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 this Act. If the Council is satisfied that a certain activity with a GMO may be conducted, the Registrar is authorised by the Council to issue the necessary permit.

The GMO Act also makes provision for the appointment of inspectors, who are responsible for monitoring GMO trials through inspections of trial sites at regular intervals during the planting/trial season.

OBJECTIVES OF THE GMO ACT

The objectives of the GMO Act are to provide for measures to promote the responsible development, production, use and application of GMOs; to 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; to give attention to the prevention of accidents and the effective management of waste; to establish mutual measures for the evaluation and reduction of the potential risks arising from activities involving the use of GMOs; to 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; and to establish appropriate procedures for the notification of specific activities involving the use of GMOs; and to provide for matters connected therewith.

ACHIEVEMENTS/OUTPUTS

The activities with GMOs approved, as well as the outputs for the 2004/2005 financial year in terms of policies, legislation and guidelines, are provided in the following paragraphs.

Policy

Biosafety Policy

The Biosafety Policy aims to provide mechanisms to ensure the safe use of biotechnology, and in particular, activities with GMOs, to strengthen the economy and enhance livelihoods without prejudice to public health or the environment. During the period under review the draft policy was developed with a view towards finalising in the financial year 2005/06. The objectives of this policy include the establishment of mutual measures, requirements and criteria for risk assessments, environmental impact assessments and assessment of the socio-economic impact of GMOs, promoting and facilitating access to information not classified as confidential in terms of Chapter 4 of Promotion of Access to Infrmation Act 2 of 2000, creating public awareness, education and participation in the biosafety regulatory framework, supporting and facilitating capacity building, and aiming to cooperate with other developing countries, especially countries in the region with overlapping borders such as the Southern African Customs Union (SACU) and the Southern African Development Community (SADC), in harmonising regulatory oversight in biosafety.

Legislation

Amendment of the GMO Act

South Africa ratified the Cartagena Protocol on Biosafety on 14 August 2003, with implementation taking place on 11 November 2003. In order to comply with the obligations of Parties to the Protocol, South Africa had to review its existing national biosafety framework, i.e. the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) to accommodate the provisions stipulated in the Protocol.

The suggested amendments to the GMO Act also include the major concerns raised at the Parliamentary Conference held in Cape Town during April 2003. Various stakeholders and interested parties attended this conference, including members of parliament, other government departments, and delegates of the seed sector, nongovernmental organisations, environmental groups, the media, scientists and farmer organisations. The Executive Council and Advisory Committee were also requested to comment on the draft Bill.

In addition to the provisions required in terms of the Protocol, the Directorate Genetic Resources also considered other legislation that may impact on the regulation of GMOs in South Africa. There are a number of legislative items relating to the safe use of GMOs in SA. These include the Environmental Conservation Act, 1989 (Act No. 73 of 1989), the National Environmental Management Act, 1998 (Act No. 107 of 1998) and the National Environment Management Biodiversity Act, 2004 (Act No. 10 of 2004), administered by the Department of Environmental Affairs and Tourism and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) administered by the Department of Health. The GMO Act complies with all of the provisions in the above-mentioned legislation with regard to risk assessment.

Taking into consideration the provisions of the Protocol, the above legislation, and further developments in the field of biotechnology, proposed amendments to the current GMO Act were made. However, it should be noted that many of the requirements of the Protocol or other applicable legislation would be incorporated into the Regulations, guidelines or even internal procedural documents of the Registrar for GMOs.

The main amendments in the GMO Amendment Bill includes the following:

- Amendments to the scope of GMO activities that should be regulated and amendments with regard to the definitions. The scope is increased to include exportation of GMOs, as the Protocol in particular mentions the provisions with regard to exportation in Articles 7, 8, 11, and 18 to 20.
- Inclusion of the Department of Arts and Culture owing to its original inclusion in the GMO Act as the Department of Arts, Culture, Science and Technology, which is currently divided into two separate departments ***viz***. the Department of Arts and Culture and the Department of Science and Technology. Representation of the Department of Arts and Culture on the Council also becomes important in light of Article 26 of the Protocol.
- Inclusion of the Department of Water Affairs and Forestry in view of new developments in the field of GMOs (e.g. fish, trees).

The draft Bill was published in the Government Gazette (R2166 of ***Government Gazette*** No.26848) on 8 October 2004. Various stakeholders and interested parties were involved in the consultation process, including members of parliament, the media, farmer organisations, nongovernmental institutions, environmental organisations, the seed and grain industry, Medicines Control Council, animal feed industry, research institutes, processing companies, the organic industry, government departments, scientists, legal institutions, church organisations, interested parties from civil society, and the Advisory Committee, Executive Council and Appeal Board appointed in terms of the GMO Act.

The second draft (which incorporates relevant comments emanating from the consultation process) of the amendment Bill will be presented to the Cabinet Committee on Governance and Administration in 2005/06 financial year.

The GMO Amendment Act will only come into force on a date fixed by the President by proclamation in the Government Gazette. This will enable the following activities:

- Appointment of the members of the Executive Council.
- Approval of proposed amendments to the regulations of the GMO Act, 1997.
- Other administrative actions to ensure effective implementation of the Genetically Modified Organisms Amendment Act.

Guidelines

The guidelines listed below were approved by the Council and published in the ***Government Gazette*** on 11 June 2004.

- Guideline document for work with GMOs
- Guideline document for use by the Advisory Committee when considering proposals/applications for activities involving GMOs.
- Terms of reference for subcommittees to assist the Advisory Committee in terms of Section 11(2) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

These guidelines are also available on the website of the Department of Agriculture.

Client and public interaction

The Directorate Genetic Resources continuously engages its clients and the general public to ensure an increased understanding of the GMO Act. Owing to South Africa's ratification of the Cartagena Protocol on Biosafety, which is an international agreement that regulates the transboundary movement of living modified organisms, the directorate was particularly challenged to ensure that clients are aware and, where appropriate, comply with these developments. Contact with clients included: meetings with various stakeholders (e.g. agricultural commodity groupings, importers and exporters, research institutes, general public), dissemination of information brochures pertaining to GMOs and the Cartagena Protocol on Biosafety, attending workshops and conferences and publishing information on the departmental website.

Commodity groups such as Potato SA, Grain SA, the Animal Feed Manufacturers' Association and the SANSOR Committee on GMOs, are involved in the development of or use genetic modified crops and therefore the directorate is involved in some of its strategic working groups in an advisory capacity.

Considering that modern biotechnology is a fairly new technology and that many people are still uninformed with regard to GMOs, a number of requests are received and processed on GMOs in general and the regulation thereof. To create awareness and facilitate participation in GMO regulation, the directorate frequently provides information through the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000) or the Promotion of Access to Information Act (PAIA), 2000 (Act No. 2 of 2000). In this year, the directorate processed 11 requests submitted through PAIA.

Appeal lodged by the Biowatch Trust

Under the GMO Act, any person who is aggrieved by a decision of the Executive Council may appeal to the Minister. In this financial year, one appeal was lodged by Winstanley Smith & Cullinan, on behalf of the Biowatch Trust, against the decision of the Executive Council to authorise commercial growing of maize event Bt11, which is maize resistant to certain lepidopteran pests. As was the case with the first appeal in terms of the GMO Act in 2003 by Monsanto, the decision of the Executive Council in this appeal was also upheld. Confirmation of the decision of the Executive Council is a reflection of the effectiveness of the biosafety regulatory system.

Biowatch court case

The directorate was also involved in a court case, (the matter of Biowatch versus the Department of Agriculture) which was heard in the Pretoria High Court on 24 and 25 May 2004. This matter relating to a request by Biowatch (in 2001) for access to all documentation relating to the administration of the GMO Act. It was the decision of the department to provide some of the information while protecting the confidential business information contained in many of the documentation requested at that point. Biowatch considered this information as inadequate and therefore sought relieve from the High Court.

The court ruling on the matter was received on 23 February 2005. Although the court ordered the directorate to provide the information requested, it is important to note that the ruling confirmed the department's responsibility to protect confidential information. The directorate complied with the court order and made the information available by 30 April 2005.

Part of the decision of the High Court was that Biowatch should pay the legal costs of the Fourth Respondent, i.e. Monsanto, and that no order as to costs was ordered against the first, second and third respondents (Registrar, Executive Council and Minister, respectively). Biowatch has since been granted leave to appeal against the cost order. The department will oppose the appeal.

Products and services

A total number of 195 GMO permits have been issued in the current financial year, of which most were issued in quarter 3 and 2, respectively. A graphical representation of the permits issued is given in Fig. 1. Imports of all three agronomic crops (GM maize, cotton and soya-bean) approved for commercial use in South Africa were the lowest in the 4th quarter. It should be noted that even if there is a surplus of maize in the country, imports of maize may still take place by animal feed manufacturers in the coastal regions, owing to the high financial costs relating to transportation of maize.

GM soya-beans are exported in the smallest volumes. The exportation of maize in this financial year was the highest in the last quarter. This could be explained by a surplus of material available at the end of the growing season, prior to new harvest material coming in, or seed that has been grown in South Africa as seed increases to support commercial growing in other countries.

Apart from import and export permits issued under the GMO Act, one permit was issued for contained use and 17 permits authorising trial release (potato, cotton, maize) and one commodity clearance permit (maize). No general release permits were issued in this year. Concerns are still being received from the cotton industry, especially the small-scale farmers, on the delay in approving stacked cotton for commercial growing in South Africa, as this event would, in the opinion of Cotton SA and the small-scale farmers, prevent the cotton industry from declining every year.

Applications pending at the end of the financial year include two general release applications, six commodity clearance applications, five trial release applications and two contained use applications. There are now two ongoing clinical trials with HIV vaccine developed using GMO.

This is the first year that the anti-GMO movement have made active inputs into almost all trial, general and commodity clearance applications submitted to the department. Although this is a good indication that public participation has increased in the regulation of GMOs, it is concerning to note that applications take a considerably longer time to be processed, which impacts negatively on the regulatory process and industries' perception of Government's ability to manage public participation. A list of all activities approved since the implementation of the GMO Act in December 1999 is shown on page 7, Table 1.

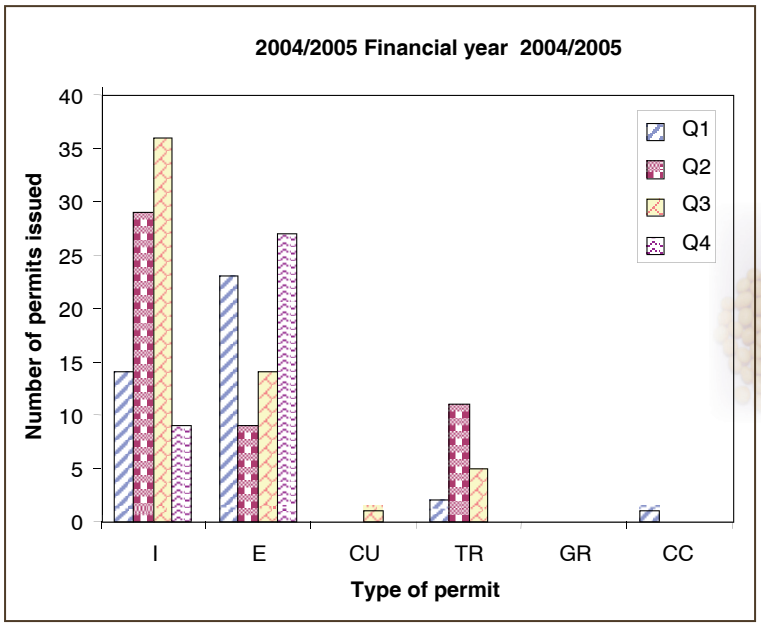


FIG. 1 Total number of permits issued during the 2004/2005 finncial year
I = Import E = Exports CU = Contained use
TR= Trial release GR = General release CC = Commodity clearance

Intergovernmental engagement

Officials from six different government departments are involved in the Executive Council of the GMO Act. These include the Departments of Agriculture, Health, Environmental Affairs and Tourism, Science and Technology, Trade and Industry and Labour. The Executive Council met four times this year; on 8 July 2004, 25 August 2004, 23 November 2004 and 15 March 2005. In addition to its decision-making function, members of this body must also ensure that all activities conducted with GMOs are not in conflict with legislation and policies relevant to their respective departments.

International

The directorate hosted delegations from Lesotho, Angola, Zambia, France and the

US Grains Council. It is noted that South Africa is often seen as the leader in applying GMOs in the context of the developing world, and especially African countries, seeks South Africa's experience to develop its domestic legislation in this regard. The interactions between South Africa and Lesotho, Angola, Zambia and the other countries within the Southern African Development Community (SADC) region is very important, considering the SADC position and guidelines on biotechnology and biosafety.

Officials from the directorate also attended a workshop on implementation of Article 8 of the Cartagena Protocol on Biosafety, which deals with notification requirements, and later also an International Symposium on the Biosafety of GMOs, where information was provided on new developments in the field of GMOs. Attending these meetings enables the directorate to adapt national legislation or procedures according to international requirements and preparing to address new developments in this field. The directorate also made inputs to the Secretariat of the Cartagena Protocol on Biosafety, through DEAT, with regard to experiences in implementing the provisions of Article 18 of the Protocol, which deals with requirements regarding handling, transport, packaging and identification, liability and redress and the functioning of the Biosafety Clearing House.

CONCLUSION

The amendment of the GMO Act to give ***inter alia*** affect to the provisions of the Cartagena Protocol on Biosafety represents South Africa's continued commitment to ensure the safe and responsible use of genetic modification technologies in support of national priorities.

Coherent governance of all activities regulated under this Act is ensured through the Executive Council established under this Act, which includes six different government departments. This decision-making process also includes public participation through the submission of comments on applications. This process has increased significantly and can be attributed to facilitated access to the relevant information, the involvement of nongovernmental organisations and awareness campaigns by different government departments.

Because the debates around the application of genetic modification remain highly polarised, challenges of this system through legal proceedings crop up frequently. Where the administration of the GMO Act has been subjected to such scrutiny, either through appeals or formal court proceedings, the validity of decision taken was always endorsed.

The application of GMOs can significantly contribute towards a globally competitive, profitable and sustainable agricultural sector. However, due consideration should be given to the potential risks, which may impact on human and animal health and the environment. Establishing credible and effective safeguards is therefore critical for maximising the benefits of these products of modern biotechnology while minimising risks.

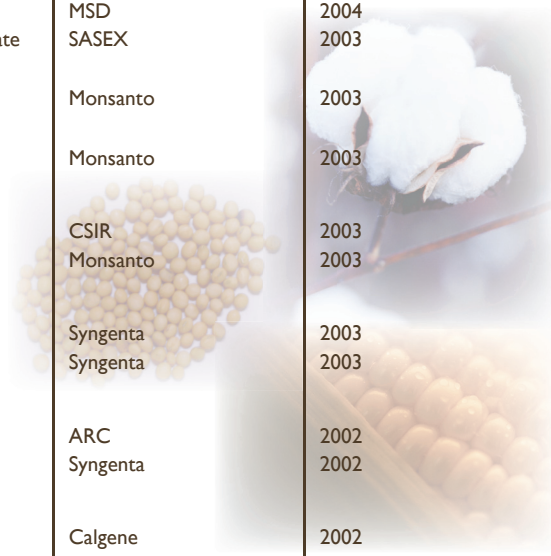
The administration of the GMO Act provides for the consideration of relevant policies and legislation to ensure the safe and responsible application of agricultural biotechnology.

TABLE 1 GMO activities approved under the Genetically Modified Organisms Act, 1997

Type of approval: General release—conditional Use of the event: Importation/exportation; commercial planting; food and/or feed				
Event	Crop	Trait	Company	Year approved
Bolgard 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	Soybean	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

Type of approval: Commodity clearance (excludes events that have obtained general release clearance before commodity clearance Use of the event: Importation for use as food or feed				
Event	Crop	Trait	Company	Year approved
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2004
MON810 x GA21	Maize	Insect resistant Herbicide tolerant	Monsanto	2003
TC1507	Maize	Insect resistant Herbicide tolerant	Pioneer Hi-Bred	2002
NK603	Maize	Herbicide tolerant	Monsanto	2002
GA21	Maize	Herbicide tolerant	Monsanto	2002
Bt11	Maize	Insect resistant	Syngenta	2002
T25	Maize	Herbicide tolerant	AgrEvo	2001
Bt176	Maize	Insect resistant	Syngenta	2001
Topas 19/2, Ms1Rf1, Ms1Rf2, Ms8Rf3	Oilseed rape	Herbicide tolerant	AgrEvo	2001
A2704-12	Soybean	Herbicide tolerant	AgrEvo	2001

Type of approval: Trial release (Authorisations granted since implementation of the GMO Act in December 1999) Use of the event: Importation/exportation, field testing				
Event	Crop	Trait	Company	Year approved
High Proline	Groundnut	Drought tolerance	ARC-GCI	2005
Cot 200/ Cry1Ab	Cotton	Insect resistant	Syngenta	2005
MVA 885a	TB Vaccine	Vaccine	Triclinium	2005
DAS 1507	Maize	Herbicide tolerance	Dow AgroScience	2005
Cot 102/ Cry1Ab	Cotton	Insect resistant	Syngenta	2004
GA21	Maize	Herbicide tolerant	Syngenta	2004
Heb 134001-134100	Cotton	Herbicide tolerant	Syngenta	2004
VRX496	Vaccine		Cato Research	2004
MRK Ad5	HIV vaccine	Vaccine	MSD	2004
1-2-3-3	Sugarcane	Increased carbohydrate content	SASEX	2003
MON88913 (RR flex / enhanced RR)	Cotton	Herbicide tolerant	Monsanto	2003
MON88913 x Bollgard II	Cotton	Insect resistant Herbicide tolerant	Monsanto	2003
Safe Maize	Maize	Herbicide tolerant	CSIR	2003
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2003
3243M	Maize	Insect resistant	Syngenta	2003
Glyphosate resistant	Cotton	Herbicide tolerant	Syngenta	2003
P5CR	Soybean	Drought resistant	ARC	2002
COT102, lines 3169, 3826-3829	Cotton	Insect resistant	Syngenta	2002
Stacked Bt event	Cotton	Insect resistant	Calgene	2002
Stacked Bollgard II & RR (1445)	Cotton	Insect resistant Herbicide tolerant	Stoneville	2002
COT101, COT102, line 3169	Cotton	Insect resistant	Syngenta	2001
LL25	Cotton	Herbicide tolerant	Stoneville	2001



Event	Organism	Trait	Company	Year approved
Bt event	Potato	Insect resistant	ARC	2001
TC6228	Maize	Insect resistant	Pioneer Hi-Bred	2000
ZMA101	Maize	Insect resistant Herbicide tolerant	Aventis	2001
Glufosinate ammonium	Sugarcane	Insect resistant Herbicide tolerant	University of Natal	2001
*Bt event	Potato	Insect resistant	First potato Dynamics	2001
*NK603	Maize	Herbicide tolerant	Monsanto	2000
T25	Maize	Herbicide tolerant	AgrEvo	2000
RR	Wheat	Herbicide tolerant	Monsanto	2000
*TC1507	Maize	Insect resistant	Pioneer Hi-Bred	2000
*Stacked Bollgard I & RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2000
*Stacked MON84006	Maize	Insect resistant	Monsanto	2000
*GTS40-3-2	Soybean	Herbicide tolerant	Monsanto	2000
*BXN	Cotton	Herbicide tolerant	Monsanto	2000
*Ms8Rf3	Canola	Herbicide tolerant	AgrEvo	2000
*GA21	Maize	Herbicide tolerant	Monsanto	2000
*Bollgard I	Cotton	Insect resistant	Monsanto	2000
*Bollgard II	Cotton	Insect resistant	Monsanto	2000
Line 15985				
*Bt 11	Maize	Insect resistant	Novartis (Syngenta)	1999

Note: The earliest year of approval under the GMO Act is provided
Approvals originally granted under an amendment of the Agricultural Pest Act, 1983 is indicated with a *
Approvals are granted for a specific period only. Thus, not all the events listed above are being tested at this moment.

Type of approval: Contained use (Authorisations granted since implementation of the GMO Act in December (1999)
Use of the event: Importation, contained use

Event	Organism	Trait	Company	Year approved
DAS 1507	Maize	Herbicide tolerant	Dow Agroscience	2004
–	*C. glutamicum* AM919	Amino acid (isoleucine production)	SA Bioproducts	2003
–	*E.coli* VNII	Amino acid (threonine) production	AECI Bioproducts (SA Bioproducts)	2003 1999
TC6228	Maize	Insect resistant	Pioneer Hi-Bred	2002
–	Sweet potato	Insect resistant	ARC	2002
–	Pathogen (*Zylophilus ampelinus*)	Bacterial blight formation in grapevine	ARC	2000
–	Granulovirus	Insect resistant	Capespan	2000
Bt event	Potato	Insect resistant	ARC	2000
–	*E.coli* XL1Blue	Protein expression for use in diagnostic test kits for Syphillis	Natal Bioproducts	2000
–	Pathogen	Pathogen epidemiology	ARC	2000

Note: Approvals are granted for a specific period only. Thus, not all the events listed above are being tested at this moment