

Regulation of GMOs in South Africa

details and shortcomings

Mariam Mayet



“ ...Although the South African government is fully aware of the risks associated with GMOs, it would be very short sighted to place a ban on genetic engineering when the full potential of this technology has not yet been explored. Any provisions within the Cartagena Protocol on Biosafety that are not currently addressed in the GMO Act will be incorporated in the review of the Act”

Thoko Didiza, Minister of Agriculture and Land Affairs⁽ⁱ⁾

⁽ⁱ⁾ Letter from Ms A. Thoko Didiza, Minister of Agriculture and Land Affairs, to African Centre for Biosafety in response to “Open Letter from African Civil Society addressed to the South African delegation to the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, dated 23 March 2004”. (As a result of a Cabinet reshuffle, Thoko Didiza was appointed Minister of Public Works in May 2006.)

The ACB has been motivated to write this paper by the coming into effect on the 17th April 2007, of the Genetically Modified Organisms Amendment Act (No. 23 of 2006).⁽ⁱⁱ⁾ This amends the Genetically Modified Organisms Act No. 15 of 1997 ('GMO Act'), 10 years after it became part of the body of post-apartheid statutes in South Africa. The author has in the past few years, on behalf of the NGO, Biowatch South Africa, thoroughly interrogated and critiqued the GMO Act.⁽ⁱⁱⁱ⁾ In addition, the ACB has interrogated countless permit applications in terms of the GMO Act,^(iv) and thus, offers this document as a further contribution to our on-going work in the field of biosafety in South Africa.

⁽ⁱⁱ⁾ Government Gazette Vol.501 No. 29803. 17 April 2007.

⁽ⁱⁱⁱ⁾ Mayet, Mariam. **Overview of the Legislative Regime pertaining to Genetic Engineering in South Africa** www.biowatch.org.za and Mayet, Mariam. **Scrutinising the legalities of genetic modification in South Africa: food safety, public participation and the conservation and sustainable use of biological diversity** www.biowatch.org.za

^(iv) Williams, Rose. **Interrogating GMO decision-making. Critique of GMO Permit Applications in South Africa 2004-2007** Biosafety, Biopiracy and Biopolitics Series: 1, 2007. See further for the full permit objections, www.biosafetyafrica.net

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Acronyms

ACB	African Centre for Biosafety
AC	Advisory Committee
Biosafety Protocol	Cartagena Protocol on Biosafety
EC	Executive Council
GMO	Genetically modified organism
GM	Genetically modified or genetic modification
GE	Genetic engineering
DoA	Department of Agriculture and Land Affairs
DEAT	Department of Environmental Affairs and Tourism
DTI	Department of Trade and Industry
PAIA	Public Access to Information Act
PAJA	Promotion of Administrative Justice Act
Biodiversity Act	National Environmental Management Biodiversity Act
NEAF	National Environmental Advisory Forum
NEMA	National Environmental Management Act
SAGENE	South African Committee on Genetic Engineering

Summary of GMO act as amended

The Amendments to the GMO Act have been introduced within a context where GM experimentation and commercial growing of GM crops are flourishing in South Africa. The Amendments introduce several changes to the “old” GMO Act of 1997, but none of these transform the fundamental nature of the GMO Act from a ‘permitting system’ to a biosafety regime within a precautionary approach.

The amendments indicate that South Africa has seized opportunities provided by the Biosafety Protocol to establish mechanisms to deal with its trading partners and neighbours in the event of contamination occurring. In this regard, at least 8 new provisions have been created to deal with unintentional transboundary movements. Yet, ironically, the amendments ignore several obligations under the Biosafety Protocol including the exceedingly contentious Article 18(2)(a) which deals with the identification and labelling of GM content in bulk shipments of grain. Worse still, in other cases such as ‘review of decision’, the amendments mischievously set lower standards than that established by the Biosafety Protocol.

Although the amendments make it clear that a scientifically based risk assessment is a prerequisite for decision-making, these have failed to provide any details about the content, mechanisms and procedures for the risk assessment.

Whilst the amendments introduce for the first time, explicit references to Environmental Impact Assessments (EIAs), these do not in fact create any new opportunities for an EIA to be conducted in respect of an environmental release of a GMO.

The amendments create a window of opportunity for socio-economic impact studies to be called for but these provisions are meaningless without the establishment of clear criteria to guide cases where socio-economic assessments should be called for.

Neither the GMO Act of 1997, nor the recent amendments place a clear duty on the state to monitor the impacts of GMOs on the environment or human health. Whilst the Biodiversity Act creates a mandatory duty on the South African National Biodiversity Institute (SANBI) to monitor the impacts of GMOs on the environment, SANBI’s work is nascent. It is also not clear whether SANBI will undertake case-by-case monitoring.

New liability provisions have been crafted, but these continue to include consumers and farmers in the category of people who could be held liable in the event of damage arising. Although the developer of a GMO does not appear to be completely excluded from liability, situations where a developer will be held liable are limited. In the context of GMOs in food and agriculture, the developer will pass on liability to farmers once the farmer grows the GMO. Commercial farmers may be able to insist on indemnification from the developer, but resource-poor farmers who often do not even know what they have been given to plant, will be left in the cold. The absence of mandatory labelling of GMOs confounds this situation.

The amendments do not introduce any new provisions that enforce the right of public participation and entrench the current situation where the public merely has an opportunity to make input with regard to applications for field trials, commercial releases and commodity imports for food, feed and processing.

It will be extremely difficult to overturn decisions taken by the Executive Council whether on appeal or review of decision by the EC itself.

In this booklet, we use the terms GM and GE interchangeably, as appropriate, to denote the application of transgenic techniques, using genetic engineering technologies.

Introduction

The Genetically Modified Organisms Amendment Act adopts a narrow science based approach to GM regulation in South Africa. The GMO Act thus does not concern itself with questions relating to the interface between biosafety and intellectual property rights because it is not designed to interrogate key questions such as whether genetic engineering 'inventions' result in social property becoming corporate property and who will control biological resources in 10-15 years time. The GMO Act is not the instrument that provokes the questioning of whether embracing GE enhances or decreases biodiversity and cultural diversity.

It is argued that one of the reasons for the adoption of such a narrow approach to the regulation of GMOs is the preoccupation with individual property rights and globalised trade rules, where the only acceptable restriction on genetic engineering is safety.¹ However, it is questionable whether the GMO Act even allows considerations of safety to trump corporate interests and profits² or the research agendas of industry backed powerful and ambitious scientists.

Civil society's engagement with the biosafety debate does not mean that it has abandoned a more holistic approach to GM regulation based on the promotion and protection of fundamental human rights. The biosafety discourse does in fact concern itself with fundamental rights, including the right to safe food, the right to developmental interventions that support livelihood strategies of the poor, the right to consumer choice, including the right to indigenous seeds and the protection of society against the introduction of new and dangerous technologies. Opposition by NGOs to human gene therapy, a simplistic, reductionist approach to complex diseases ensured that human gene therapy continues to be prohibited in South Africa and points to the holistic approach adopted by civil society in scrutinising genetic engineering applications.

The GE industry yields considerable power in South Africa. It has greatly influenced the GMO Amendment Act, just as it did, the original GMO Act. Indeed, industry has been lobbying to introduce a new set of criteria against which GMO policy decisions must be based, namely, the 'impact and risks of denying GM technology'.³

The GE industry also has extremely powerful supporters from the scientific community such as Professor Jennifer Thompson, who made submissions to the GMO Amendment Bill on behalf of the scientific community of biotechnology practitioners. Vast sections of her comments were in fact identical to those submitted by the South

African National Seed Organisation (SANSOR)⁴ suggesting that Professor Thompson lobbies on behalf of industry. Many of Thompson's inputs have found their way into the GMO Amendment Act.

Historical context

In 1979, the apartheid government established the South African Committee on Genetic Engineering (SAGENE), comprising of a group of South African scientists, to pave the way for the uptake of genetic engineering in food, agriculture and medicine. SAGENE acted as a scientific advisory body to the apartheid regime and in 1989, on the advice of SAGENE, the government used a myriad of laws to allow the first experiments in open field trials of GMOs. In January 1994, a few months before South Africa's first democratic elections, SAGENE was given legal powers to 'advise any Minister, statutory or government body on any form of legislation or controls pertaining to the importation and/or release into the environment of GMOs'.⁵

The task of drafting the GMO Act was performed by SAGENE.⁶ A draft GMO Bill was published for public comment in 1996 and passed by a euphoric and fledgling democratic Parliament in 1997. Nevertheless, the GMO Act only came into effect in December 1999 after Regulations to bring the Act into effect were promulgated.

In the intervening period, SAGENE continued to act as the key 'regulatory body' for GMOs, and under its auspices, permits were granted to allow Monsanto to sell GM cotton and maize seeds to farmers in South Africa for commercial growing. In addition, 178 permits were granted for open field trial experiments of a variety of GMOs.

Once the GMO Act came into effect, SAGENE ceased to exist and was replaced by an Executive Council (EC), established by the GMO Act. However, several SAGENE members continued to form an important part of the regulatory system as members of an Advisory Committee established by the GMO Act. Several of these scientists including Professor Jennifer Thompson and Muffy Koch who later joined the GE industry lobby group Africabio as active members. Muffy Koch who now works for the industry group Agbios in Canada, chaired AfricaBio's Education and Training working group and also acted as editor of BioLines, AfricaBio's news service, at the time when she served on the Advisory Committee. Professor Thompson joined the Board of Africabio whilst she too served on the Advisory Council (AC).

The GMO Act and its accompanying Regulations are administered by the Department of Agriculture (DoA), as the principal pieces of legislation to regulate GMOs in South Africa. Since the GMO Act came into effect, thousands of permits have been granted for various activities involving the use of GMOs in South Africa, resulting in the authorisation of the commercial growing of various events of GM maize, GM cotton and GM soya, the importation of millions of tons of GM maize from Argentina, extensive field trial plantings involving various GMOs, and clinical trials involving live GM vaccines.

GMOs in South Africa

Research and Development (not in open field trials)

There are a number of public and private laboratories in South Africa with capacity to conduct research with GMOs. There are over 110 plant biotechnology groups, and more than 160 plant biotechnology projects.⁷ The University of Cape Town's Institute for Infectious Diseases and Molecular Medicine will also host a laboratory of the International Centre for Genetic Engineering and Biotechnology (ICGEB) at a cost of R40 million over the next four years (2007-2010).⁸

GMO research in the experimental phase conducted in the past few years includes several varieties of maize and cotton, drought tolerance in groundnut, potatoes, sugarcane,⁹ millet,¹⁰ wheat, barley, lupins, sunflowers, cucurbits, ornamental bulbs, cassava, sweet potato, apricot, peach, apple, table grapes, banana and indigenous vegetables¹¹ and more recently, flowers and bulbs.¹²

Professor Jennifer Thompson and colleagues at the University of Cape Town are in an advanced stage in their research on GM maize streak virus,¹³ with field trials scheduled to commence during 2007/8. The GM maize genetically engineered to tolerate the maize streak virus carried by the African leafhopper is touted as a milestone: the first ever genetically modified crop developed by Africans for Africa.¹⁴

Trial releases (growing in the open environment but not for commercial purposes; testing of GM Vaccines on human populations, release of GM bacteria as biological controls in open environments)

In the last ten years, prior to and after the GMO Act coming into affect, permission has been granted for hundreds of open field trials to be conducted in South Africa. In 2003 alone, the Executive Council established in terms of the GMO Act approved a staggering 172 permits for field trials.¹⁵

These included field trials of glyphosate (herbicide) tolerance, genetically inserted bromoxynil (pesticide), multiple resistance (2 Bts, bromoxynil + insect) and imidazolinone (herbicide) tolerance in cotton; glyphosate tolerant eucalyptus; glufosinate and phosphinothricin tolerance in canola; phosphinothricin (pesticide) and glyphosate (herbicide) tolerance in maize; multiple resistance (glyphosate and insect) in maize; Potato Leaf Roll Virus (PLRV) resistance in potato, glyphosate tolerance in soybean; stilbene resveratol Vst1, Vst2 (fungi), glufosinate tolerance in sugar cane; and genetically modified protein content in *Xanthomonas campestris pv campestris*.¹⁶

At least one field trial involving GM trees - herbicide tolerant *Eucalyptus grandis* - took place in terms of an amendment of the Agricultural Pest Act, No. 36 of 1983.¹⁷ Although a trial release authorised for GM apples under an amendment of the Agricultural Pest Act 1983 was granted, no plantings of GM apples have taken place.

Recent research indicates that in 2006, field trials proliferated throughout South Africa in 32 different sites, with the exception of only the Eastern Cape.¹⁸ The traits expressed in these trials are predominately 'stacked' meaning that more than one trait has been engineered into the crop, e.g. insect resistance plus herbicide tolerance. Others include insect resistance (in maize, cotton, potato, sugarcane field trials), herbicide tolerance (maize, cotton field trials), drought resistance (soybean field trials) and an anti-microbial trait (sugarcane field trials).

Many of these field trial applications are operated by the giant GM multinationals, namely Monsanto, Delta and Pinelands (D&PL), Syngenta and Dow Agro Sciences. Two South African research institutes are also involved, the Agricultural Research Council (ARC) and South African Sugar Research Institute (SASRI).¹⁹ Field trials conducted especially by the GM giants such as Monsanto, invariably serve as pipeline indicators for the next wave of GM crops that will come onto the South African market in the coming years.

During 2007 an application lodged by the ARC to conduct field trials of GM cassava was not successful and the ARC is in the process of appealing this decision.

During early 2007, scientists at the University of Stellenbosch sought permission to grow GM grapes in field trials in the Western Cape²⁰ and at the time of writing, no decision had yet been taken to allow these trials. During early 2007, Monsanto's first ever GM drought tolerant maize was given the green light by the EC.

There is also a spate of GM vaccine trials taking place in South Africa, involving GM HIV, measles and TB vaccines. The ACB has interrogated an application for clinical trials involving a GM HIV vaccine and raised concerns regarding the use of adenoviruses, aspects of the risk assessment, the definition of risk and with elements of the application. It was not possible to gain access to the Prior Informed Consent component of the application in order to assess whether the vaccinees were adequately informed about the full nature of the clinical trial they were to participate in.²¹

Commercial growing

Farmers in South Africa plant several "events" of GM cotton, maize and soya. "Events" in the context of GMO parlance, refer to a particular GMO that is distinguishable from another GMO due to its unique genetic make up. The majority of all GM crops grown in South Africa are sown on large commercial farms.²²

By 2004, 500,000 ha of GM crops were planted. This included 400,000 ha of GM maize (15% of total hectares of maize planted in South Africa) of which 155,000 ha was Bt white maize for human consumption. In addition, 70,000 ha of soybean (50% of total soybean hectares) and 30,000 ha of cotton (85% of total cotton hectares) were commercially planted in South Africa.²³

In January 2007, the farmers' union Agri SA reported that the country's GM crop area had soared by 180% to 1.4 million hectares in the 2006/07 season. One million hectares of this were planted to maize and the remainder comprising of soybean and cotton.²⁴ This made South Africa the second highest GM producer after India and the eighth largest GM producer in the world.

Import and export

There is a very active import and export market of GMOs in South Africa. The DoA's website indicates that during the period 2001-2004, around 2.86 million tons of GM maize had been imported from Argentina into SA for the food, feed and processing purposes.

In 2004 alone, South Africa granted 20 permits for commodity imports of GM maize resulting in the import of 604 000 metric tons (MT). Permits for the import of GM maize were granted to Monsanto, Cargill, Louis Dreyfus, Seaboard, Pioneer, Pannar, and to South African companies Meadow Feeds, Afgri and Epol.

During September/October 2005, the Executive Council acting in terms of the GMO Act, took a decision not to approve any more new GMO "events" for the purposes of importation into South Africa as food, feed and processing (FFP).²⁵ This de facto moratorium is in place pending an investigation into concerns raised by the Department of Trade and Industry (DTI). The DTI is of the opinion that GM crops are not freely traded on the international market and as such, negatively affects the price levels at which these products are traded.²⁶

Nevertheless, GMOs already approved prior to the moratorium continue to stream into South Africa at a steady pace. During the period January-April 2007, a staggering 519 269 MT of GM maize was imported from Argentina, with each shipment containing up to 7 different GM "events".

GMO Policy

National Biotechnology Strategy

"In the National Biotechnology Strategy it is clear that South Africa recognises and embraces the potential benefits that can be derived from using biotechnology."

Thoko Didiza, Minister of Agriculture and Land Affairs.²⁷

During 2001, South Africa produced its National Biotechnology Strategy²⁸ ('Strategy'), which sets out a wish list of strategic interventions to aggressively promote biotechnology research and development (R&D) and the marketing of biotechnology products in South Africa.²⁹ 'Biotechnology' here includes both traditional and modern biotechnology or GE/GM.

The Strategy envisions the creation of new institutional arrangements and specific actions for government, including the establishment of a Biotechnology Advisory Committee and the creation of several regional innovation centres (RICs) to stimulate growth of the biotechnology sector.

The creation of new government institutions inevitably demands that new money be made available. Indeed, during the period 2003-2006, the South African government has spent R500 million in biotechnology R & D.³⁰ State research institutions and private sector companies are set to spend R2.5 billion on biotechnology and genetic engineering R&D.

Already three Biotechnology Regional Innovation Centres (BRICs) have been established, namely eGoli Bio in Gauteng, Cape Biotech in the Western Cape and EcoBio for Nelspruit, Durban and Port Elizabeth. A National Innovation Centre for plant biotechnology (PlantBio) was also created in 2004.

On the 30 November 2006, a National Biotechnology Advisory Committee (NBAC) was launched. The NBAC's primary task is to advise the Minister of Science and Technology on biotechnology issues in South Africa. Professor Jennifer Thompson chairs the NBAC. The Executive Director of the industry lobby group Africabio, is also a member of the NBAC.³¹

Biosafety Policy

Draft Biosafety Policy

During 2005, the National Department of Agriculture published a Draft Biosafety Policy for public comment.³² Initial excitement at the prospect of having an overarching biosafety framework for genetic engineering and GMOs was short lived. Regrettably, the biosafety policy proved to be simplistic - merely describing a few biosafety concepts, and presenting a cursory and limited overview of the challenges facing the regulation of a risky technology.³³

Since then, the NDA has reported that it has made further attempts at crafting a national biosafety policy which aims to develop a cross-sectoral approach and to align various laws, including the National Environmental Management Act and the Genetically Modified Organisms Act. It is meant to establish common measures, requirements and criteria for risk assessments, environmental impact assessments and assessment of socio-economic impacts to ensure that genetically modified organisms are appropriate and are not hazardous to the environment or human, animal and plant health. The policy is also meant to harmonise biosafety regulatory oversight between South Africa and other Southern African countries.³⁴

It is indeed anomalous that a biosafety policy should be drafted after a GMO law is already in place. A Biosafety Law should be underpinned by the imperatives expressed in biosafety policy. Nevertheless, it is hoped that the Biosafety policy will go a long way towards ameliorating the many significant gaps in the GMO Act as amended.

National Biodiversity Strategy and Action Plan

During 2005, the National Department of Environmental Affairs and Tourism (DEAT) published South Africa's National Biodiversity Strategy and Action Plan (NBSAP).³⁵ The NBSAP attempts to provide a framework against which the country's rivers, wetlands, mountains and plains, estuaries and oceans and coastline and landscapes are to be managed. In regard to GMOs, the NBSAP identifies as a key outcome, the introduction of effective management and control measures to minimise the potential risks to biodiversity posed by GMOs. The NBSAP stresses the importance of adopting a precautionary approach to the release of GMOs into the environment, especially in biodiversity priority areas.

The NBSAP explicitly recognises that existing procedures and guidelines for evaluating GMO permit applications are outdated and in need of review in order to ensure that environmental and biosafety concerns are adequately addressed. The NBSAP calls for independent risk assessments based on actual research and data collection in South Africa. Importantly, it identifies the need for comprehensive and non-partisan environmental impact assessments (EIAs) or their equivalent to be carried out for GMOs with full public participation.

Significantly, the NBSAP calls for the need to map current and planned GMO plantings, whether field trials or commercial crops, and for the inclusion of such data in the National Spatial Biodiversity Assessment in order to determine possible "no go" areas for GMOs and identify GMO free zones. The NBSAP also calls for more investment in biosafety R&D and public education and awareness.³⁶

Although the NBSAP's statements are all welcome, these must be weighed against the actual actions taken by DEAT to implement in particular, various provisions of the National Environmental Management Biodiversity Act (NEMBA) and its interface with the GMO Act and the EIA regulations made under NEMA, as discussed below.

GM Regulation in SA

*“ All GMOs in the country had gone through a rigorous assessment process taking into account human, animal and environmental safety factors.”
Director, Genetic Resources, Department of Agriculture³⁷*

There are at least 11 different pieces of legislation (see Annex I) that may be applicable to the regulation of GMOs in South Africa other than the GMO Act. Needless to say, various provisions of the Constitution of the Republic of South Africa form the framework for the interpretation and implementation of all laws in South Africa. The Promotion of Administrative Justice Act No. 3 of 2000 (PAJA) is also pivotal to issues concerning the administration of justice. However, since our focus is directly concerned with GM regulation, we focus principally on the GMO Act as amended and discuss the relevant provisions of the National Environmental Biodiversity Act (the Biodiversity Act) in the context particularly of environmental assessments and environment impact assessments (see discussion under “Executive Council and decision-making”). We also provide a brief overview of the relevant laws pertaining to the labelling of GMOs and GM products in the context of our discussion on segregation and traceability. Every attempt has been made to refer to relevant provisions to the Biosafety Protocol particularly to illustrate deficiencies in the GMO Act as amended.

The GMO Act (as amended)

The impetus for the amendments of the GMO Act of 1997 is attributed mainly to South Africa’s ratification of the Biosafety Protocol, an international environmental agreement regulating the cross border movement (also known as ‘trans-boundary movement’) of GMOs.

The promulgation of the GMO Act amendments in April 2007 was preceded by the Genetically Modified Organisms Amendment Bill (Notice 2166 of 2004) and the Genetically Modified Organisms, Amendment Bill (revised version), 2005.³⁸ Both Bills were published for public comment. The Portfolio Committee on Agriculture and Land Affairs also hosted Parliamentary hearings on the GMO Amendment Bill 2005 during 17-18 January 2006.

Preamble and Objectives

The GMO Act as amended does not change the pre-existing Preamble, which establishes the general ethos of the legislation namely, to subsume the need for biosafety with the imperative to promote genetic engineering. This contrasts sharply with the opening lines of the objectives of the Biosafety Protocol, which talks about the need for the regulation of GMOs in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.

Preoccupation with contamination: unintentional transboundary movements and accidents

The GMO Amendment Act creates at least 8 new provisions [sections 4(1) (f)-(l) and sections 4(2) (c)] dealing with accidents and/or unintentional transboundary movement. These provisions have been motivated by the spate of contamination incidents that have occurred worldwide involving unapproved GMOs.³⁹ A new definition of 'accident' has been created to capture two types of situations: one dealing with unintentional transboundary movements of GMOs and the other, unintentional environmental releases within South Africa.

Unintentional transboundary movement is really a euphemism for contamination that may or is likely to occur in the course of global trade in agricultural commodities, particularly with respect to trade between SA and its neighbours. The new provisions now task the Executive Council (decision-making body) with the powers to advise the Minister on measures that should be taken to avoid accidents and minimise adverse impacts, information exchange and consultation with other countries.

Although these provisions are in line with Article 12 of the Biosafety Protocol dealing with unintentional transboundary movements and the emergency measures that must be taken, the attention paid to these provisions in the GMO amendments signify the South African government's concerns about contaminated exports from South Africa.

Another interpretation is that these new provisions create the possibility that contamination of South Africa's neighbours by GMOs grown in South Africa being termed an 'unintentional transboundary movement' and thus, an accident in terms of South African law.

The definition of 'accident' includes an incident involving an unintentional environmental release that is likely to have an immediate or delayed adverse impact on the environment or human health **within South Africa**. This definition must be read together with the definition of **commodity clearance**. Together, these provisions mean that the planting out of GMOs imported into South Africa that has not correspondingly been approved as a release in South Africa will be illegal in terms of the Act. However, the planting of these GMOs can also be an accident and therefore legal, if the person doing the planting can show that he or she did not know that the authorisation was given only for the purpose of food, feed and processing.

Commodity clearance means the authorisation to use a genetically modified organism as food, feed or processing, but excludes the planting of a genetically modified organism as a release into the environment.

In the event of an accident occurring, the EC has only a **discretionary** power to instruct the Registrar to appoint a panel to enquire into and report on the causes of such accident.

Executive Council and decision making

The Executive Council (EC) functions as an advisory body to the Minister of Agriculture and Land Affairs on matters relating to GMOs and is the decision-making body, which approves or rejects GMO applications. The EC is also empowered to co-opt any person knowledgeable in the field of science to serve on the EC to provide advice.

The words 'any person' imply that such person can be recruited from government, industry, academia, NGOs or farmers' organisations. This the EC can do *mero motu* (on its own accord). Moreover the EC can at its invitation, solicit written comments from any person knowledgeable in a specific field of science on any aspect of genetic modification falling within the functions of the EC.

The Executive Council's membership has now been extended from 8 to ten members, adding the previously omitted Department of Water Affairs and Forestry (DWAF) and the Department of Arts and Culture (DAC) to the Council.

Eight out of the ten places will be filled by a representative each from various government departments, including Land Affairs and Agriculture; Arts and Culture;

Science and Technology; Health; Labour; Environmental Affairs and Tourism; Trade and Industry and Water Affairs and Forestry

Before making a decision regarding GMO applications, the EC is obliged to consult with the Advisory Committee (AC), and may consult with the AC regarding 'fast-track' or extension permits (see "Advisory Committee").

Decision-making by the Council is on the basis of consensus by all the members and where no consensus is reached, the application before the EC will be considered as having been refused.

Risk Assessment

When making a decision, the EC **must** take into account only the scientifically based risk assessment and risk management measures and compliance with the provisions of Article 8 of the Biosafety Protocol dealing with the Advanced Informed Approval (AIA) procedure. It may take into account:

- (a) public input **where required**; and
- (b) the Environmental Impact Assessment or the potential socio-economic impact **where required**.

The central regulatory element of the Biosafety Protocol is the Advanced Informed Agreement (AIA) procedure, which applies to the first transboundary movement of GMOs for intentional introduction into the environment.⁴⁰ The procedure seeks to ensure that importing countries have the opportunity to assess the environmental and human health risks associated with a GMO and take a decision based on the precautionary principle, before agreeing to its import. It obliges exporters to notify importers in advance of the first shipment and to supply certain prescribed information concerning the GMO. Receipt of this information needs to be acknowledged within 90 days. Within 270 days the importing Party must communicate its final decision with regard to the future status of the GMO. This decision is to be based on a risk assessment and may either approve or prohibit the import of the GMO, request further information, or extend the deadline by a defined period of time. In each case reasons for the decision need to be stated. Both the importing and exporting Parties may, at any time, initiate a review and change of the decision in the light of new scientific information.

Although a scientifically based risk assessment is a prerequisite for decision-making, the GMO amendments have failed to provide any details on the mechanisms and procedures for the risk assessment. It is indispensable that the requirements regarding the quality of the data, methodologies and minimum assessment criteria be clearly set out. Currently, only non-binding guidelines exist to deal with these issues. However, experts in South Africa have found these guidelines to be insufficiently clear or detailed to constitute acceptable sources of information, and minimum levels of data quality and quantity required to inform decision-making.⁴¹

Article 15(1) of the Biosafety Protocol requires that risk assessment for GMOs be carried out in a scientifically sound manner, that is based on an evaluation of the potential adverse effects on GMOs on biological diversity based on available scientific evidence as well as on conditions set out in Annex III of the Biosafety Protocol. Annex III of the Biosafety Protocol states that risk assessment “should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organisations”.

Precaution

Part of an adequate biosafety response to the introduction of GMOs into our food and health systems is the application of the precautionary principle. However, the amendments to the GMO Act do not change the current status where decision-making occurs without having to comply with a legal duty to take cognisance of the precautionary principle. Proceeding with caution means taking measures to prevent harm, looking for alternatives, placing the burden on the proponent of the activity to prove safety/absence of harm and the use of democratic processes to carry out and enforce the principle, including the right to informed consent.

South Africa has never established its own criteria for what it means on a practical level, for the application of the precautionary principle to GMO decision-making. This is so despite several factors that demand that the precautionary principle be invoked, including the need to establishing an unacceptable level of risk to human health, the environment and society, conducting a cost-benefit analysis, review of decisions in the light of new scientific information and conducting of independent social and environmental impact assessments.

Environmental Impact Assessments (EIAs)

“The Biodiversity Bill adopted in parliament recently has the same flaws as the GMO Act, and allows that the Minister MAY call for an EIA if he thinks there may be harm to the environment. But without such an assessment why should he expect such harm?”

Ruth Rubinowitz, MP⁴²

In this discussion, attention must be paid to the distinction between two concepts: **environmental assessment** on the one hand and **environmental impact assessment** on the other.

An environmental assessment takes place in the context of a pre-release of a GMO into the environment where an assessment is made on the basis of environmental safety data produced during contained use conditions (usually, greenhouses). Environmental assessment also relates generally to the desk-top assessment of field trial data where no environmental impact assessment has been conducted. An environmental impact assessment on the other hand, refers to a full enquiry into the environmental impacts in a public, open and transparent manner where alternatives are also considered. Currently, EIAs for development projects are governed by the EIA regulations made in terms of the National Environmental Management Act (NEMA).

To date, not a single environmental impact assessment has ever been conducted for any GMO released into the South African environment.⁴³ The role of the DEAT has mainly been confined to serving as a focal point for the Biosafety Protocol. It has played a subdued role as member of the EC, allowing the EC under the GMO Act to take responsibility for all GMO decision making.⁴⁴

Legislation⁴⁵ has allowed merely for cursory desk-top environmental assessments of data produced by the applicant (in most cases, by industry) during the product development phases under contained use conditions and in field trials where agronomic performance and not environmental safety are key considerations. It stands to reason therefore that current procedures and guidelines for *a priori* environmental assessments are currently inadequate as they consider an incomplete array of risks, are often based on only partly relevant research and include little if any field trial biosafety information. Consequently, there are significant gaps in knowledge regarding the impacts of GMOs on the environment.

The GMO Amendment Act introduces for the first time, an explicit reference to environmental **impact** assessments. The amendments define 'Environmental Impact Assessment' as a process used to assess the potential impact of an activity on the environment by collecting, organising, analysing, interpreting and communicating information on such activity'. New provisions now create a mandatory duty to the EC to **consider** whether an assessment of the impact of the GMO on the environment is required in accordance with the provisions of NEMA relating to EIAs.

The question that arises is: what will guide the EC to call for an EIA? The new provisions of the GMO Act do not provide any guidance or trigger as to when the EC should call for such environmental impact studies. In any event, the EIA Regulations made under NEMA do not change the status quo because the EIA regulations made in terms of Chapter 5 of NEMA lists GMOs as a Schedule 1 activity, which means only a basic assessment report is required.⁴⁶ Indeed, a basic assessment report may even be less than a scientifically based risk assessment required by the GMO Act (as amended)!

Section 78 of the Biodiversity Act contains explicit provisions dealing with GMOs:

- “(1) If the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of this Act unless an **environmental assessment** has been conducted in accordance with Chapter 5 of the National Environmental Management Act as if such release were a listed activity contemplated in that Chapter.
- (2) The Minister must convey his or her belief referred to in subsection (1) to the authority issuing permits in terms of the Genetically Modified Organisms Act, 1997, before the application for the relevant permit is decided.
- (3) For the purposes of subsection (1) “release” means trial release or general release as defined in section (1) of the Genetically Modified Organisms Act, 1997.”

The Biodiversity Act thus contemplates an environmental assessment as opposed to an environmental impact assessment, in terms of Chapter 5 of NEMA.

What does all this mean, especially the words “as if such release were a listed activity contemplated in Chapter 5”? Not much. As discussed, the EIA regulations made in

terms of NEMA lists GMOs as a Schedule 1 activity, and thus only a basic assessment report is required. Indeed, the EIA Regulations include no direct reference to GMOs, or how an EIA of a proposed GMO release should be conducted. A process of an EIA for GMOs just does not exist under NEMA.

To sum up, where does this leave the question of: (a) environmental assessments for GMOs? and (b) environmental impact assessments for GMOs?

In so far as section 78 is concerned, DEAT has begun a process to develop a biosafety framework for environmental assessment for GM releases, which would replace the existing guidelines under the GMO Act pertaining to environmental assessments. Such a framework may or may not deal with EIAs.

The GMO Act is directly linked to the EIA regulations made in terms of NEMA, and these do not contain any explicit reference to GMOs, except for listing GMOs as a Schedule 1 activity-where only a basic assessment report is required.

We are not optimistic that DEAT will clear up this muddle by providing for clear guidelines and regulations to deal squarely with EIAs for GMOs, based on full disclosure of information in an open and transparent public participation process.

A request by the ACB to the Minister of Environmental Affairs in early January 2007 calling on him to require a full environmental impact assessment for Monsanto's Roundup Ready Flex Cotton was not successful. The Minister was of the opinion that Monsanto had provided adequate ecological safety information and that the GM cotton had been through a comprehensive environmental risk assessment process. The Minister said that concerns raised by the ACB about ecological safety and the negative impacts of the use of herbicide on agricultural workers and small-scale farmers were carefully considered and incorporated into a risk management and post market monitoring plan and formed part of the permit conditions.⁴⁷

This response is a marked departure from an earlier response from the Minister at the beginning of his term of office as environment Minister when he said, "Let me assure you that before a decision is taken, the department will have taken all the necessary steps to ensure that the constitutional rights of our people are not violated in any way as far as this application is concerned."⁴⁸

Socio economic assessment

“In our area which is Mbizani Municipality under Dr Tambo District Municipality, the Department of Agriculture and the Municipality with Ntigana as facilitating agent supply rural people with fertilisers, lime, roundups and Monsanto seeds for free for a period of four years. Then after four years, nobody knows what is going to happen as these farmers will no longer have their own seeds from organic farming.”⁴⁹

The GMO Amendment bill must protect small farmers like me against big companies. Big companies want to sell their products-seeds and fertilisers, but farmers take all the risks.⁵⁰

As discussed earlier, there is a *de facto* moratorium on approvals for import into South Africa of new GMO events for the purposes of use as food, feed and processing. In this regard, the EC is in the process of conducting an economic analysis of the price distortions of imported GM maize due to biosafety restrictions and bans, and the impacts these have on the South African economy. While these studies are welcome, they still do not constitute the brand of socio-economic studies required in the context of GMO decision-making, especially in a context where the entire development paradigm within which GMOs are introduced is vehemently contested.

The current amendments to the GMO provide a window of opportunity for socio-economic impact studies to be called for. In terms of new provisions, the EC must consider whether a socio-economic assessment is necessary. However, criteria will have to be established to provide guidance for the cases where socio-economic assessments should be called for; what the terms of reference for such assessments might entail, who should do these assessments, who should pay for them, issues concerning the public’s right of access to this information and the participation of communities affected. It is unknown which government department will take the lead to drive this critically important issue. Experience has indicated that unless external pressure is brought to bear on government, nothing will happen!

GM cotton in the Makhathini Flats: the real socio-economic impacts

Poor black farmers who have been growing GM Cotton in the Makhathini Flats in South Africa since the late 1990s, have become pawns in the 'numbers games' as to whether or not Bt cotton results in increases in yields and savings on pesticide use. The GM machinery, ably assisted by the South African government has peddled the experience of these farmers as a success story, worthy of imitation on the continent. However, beneath the hype lies a tragic tale of oppression and vulnerability, which the introduction of Bt cotton has further exacerbated.^{51 52}

The Makhathini farmers have historically been locked into a system of cotton growing due to a range of economic, political and social forces that resulted in chronic indebtedness.⁵³ Despite cotton growing sliding into sharp decline in the last decade in South Africa,⁵⁴ the government and a range of corporate agribusiness actors particularly Monsanto, lured the Makhathini farmers into adopting Bt cotton. This they did by inter alia, providing free production packages, including Bt cottonseeds, duly subsidized with public funds. Research indicates that to date, the South African government has subsidised the Monsanto driven Bt cotton 'success' story with a staggering sum of R30 million from state coffers.⁵⁵ Nevertheless, since the arrival of Bt cotton in the Makhathini Flats in 1998 and until 2004 the cumulative arrears of farmers to the Land Bank have amounted to a whopping R22,748,147.55!⁵⁶ Many reasons may be proffered to explain away the abject failure of the GM project in the Makhathini Flats,⁵⁷ however, the central critique must concern itself with the inappropriateness of a development paradigm that seeks to introduce technological solutions to deeply rooted systemic socio-economic problems. Attempts at replicating the Makhathini Flats experience in the rest of Africa, which itself has been caught up in an endless cycle of debt, will undoubtedly yield similar results

Extension permits

The term extension permit is a new import, substituting the previous language of 'fast track' permits. New provisions introduced by the GMO Amendments create a new definition for extension permits as "permits issued for activities for which a permit has previously been issued." Fast-track permits have mainly been granted for repeat field trials and commodity imports involving the same GMO/s. A much more streamlined and expedited permit issuance process applies to these applications.

The ACB has in the past, questioned the legality of fast track permits on the grounds that these were being issued by the Registrar in terms of Regulations made under the GMO Act (secondary legislation) without the explicit consent of the EC, whereas the GMO Act (primary legislation) allows the Registrar the ability to issue permits in accordance with the express instructions of the EC.⁵⁸ The new amendments to the GMO Act attempt to cure this defect. Now, the Registrar cannot issue extension permits unless the EC has authorised it to do so, and only on such terms and conditions as the EC imposes.

As already discussed, the EC is required to consult with the Advisory Committee in respect of all applications concerning activities relating to GMOs. It is not obliged to do so in regard to issuing extension permits and may at its own discretion, consult with the AC on 'such issues' concerning an extension permit as the EC may consider necessary to come to a decision.

It is unknown how long a period of time such permits are granted for and under which circumstances these will be granted. Procedurally, it is also not clear how the decision-making process works with regard to extension permits, particularly with regard to scrutiny by the EC of biosafety information in order to justify the granting of extension permits. This is particularly worrying since the AC can be bypassed completely.

Additional powers of the Executive Council

Appointment of the Advisory Council (AC)

The EC has a say in the appointment of members of the AC and has recently changed a number of its members, following protests by civil society that some members of the AC – many of them ex-SAGENE members, were also members of the industry lobby group Africabio.⁵⁹

Intervening when transgressions occur

The EC has also been given powers to advise on the measures that ought to be taken where the Registrar suspects that a transgression of the Act or a permit condition has

occurred. In these circumstances, the EC is empowered to determine a place where the GMO as well as any **material or substance used or affected or potentially affected** by the activity involving the GMO, may be taken to and the measures to be adopted for the disposal or repatriation of the GMO and the material or substance affected.

Promoting research and development and technology transfer

Additional functions of the EC include the promotion of co-operation between SA and any other country with regard to research, development and technology transfer in the field of genetic modification of organisms and biosafety.

The promotion of research and development has been strenuously supported by Professor Jennifer Thompson in her submissions to Parliament on the GMO Amendment Bill. She called for the promotion of public research conducted in international collaboration and made an impassioned plea for liability rules not to apply to such research as this would, according to Professor Thompson, “cause significant burdens to the research institutions in South Africa and reduce their attractiveness as centres of excellence for biotechnology research intended to benefit the resource-poor African farmers”.

Issuing and approving guidelines

The EC is empowered to approve and issue guidelines for activities concerning GMOs with the consent of the Minister. No duty has been created for the EC to consult with the public in this regard and it is only required to make these guidelines available to the public. The Act is silent on the manner in which such guidelines will be made available to the public.

Reconsideration of decisions

Article 12 of the Biosafety Protocol dealing with review of decisions addresses the changing state of knowledge about GMOs and their potential impacts on biodiversity and human health. It provides for review of decisions on the basis of **new scientific information** on potential adverse effects. In terms of the Protocol, a review of decision can be requested by: the Party of import, the Party of export and the notifier (in the context of transboundary movements).

The ACB has in the past requested the EC to review its decision with regard to, for instance, a permit granted in favour of Syngenta for commodity clearance for its GM maize event GA21. This request was turned down on the grounds that no new **scientific evidence** was brought to the debate.⁶⁰

Indeed, a review of decision is contemplated by the GMO Amendments but the EC is allowed only to reconsider its decision if it receives **new and relevant scientific or technical evidence** about activities conducted in terms of the Act, which may have an impact on the scientifically based risk assessment, the proposed risk management measures, public input, the EIA or the socio-economic impact of the activities.

Thus, in order for a decision to be overturned on review by the EC, one would have to jump through several loops: produce scientific or technical evidence of harm and this evidence must be new and relevant. These provisions are not consistent with the Biosafety Protocol and are at odds with a precautionary approach to GM decision-making.

It must be noted that the GMO Amendments do not create any clear-cut mechanism for the public to request a review of decision. At the same time, nothing in the Act prohibits the public from requesting that any decision be reviewed.

It will not be possible, however, for the public to satisfy the requirements of the Act and produce new scientific evidence of adverse impacts. While there are no direct studies available on the potential toxicity or adverse health events of GM foods published by industry in international peer-reviewed journals to justify an unequivocal finding that GM foods are safe,⁶¹ very little if any public funds are spent on independent biosafety research. At the same time, several scientists that have published their work indicating adverse impacts have been persecuted, vilified and ostracised. These include such eminent scientists such as Dr Arpad Pusztai, of the Rowett Institute (observed toxic effects of GM potato diet on rats), Prof. Ignacio Capela at the University of Berkeley, California (found genetic contamination of maize by transgenic DNA in its centre of origin in Oaxaca, México), Shiv Chopra, Margaret Haydon and Gerard Lambert of the Canadian Veterinary Drugs Directorate (critical of approval procedures for Monsanto's bovine growth hormone), David Kronfeld of the Virginia Polytechnic Institute (writing articles questioning safety of GM bovine growth hormone), John Losey, Associate Professor, Cornell University (damage and death in Monarch butterfly caterpillars fed with pollen from GM maize), and Angelica Hilbeck (planned to assess if a product of a bacterial gene that has been introduced into a plant is still active after it has passed through the digestive tract of a sheep or pig).

Advisory Council

The Advisory Council, constituted mainly of scientists and other experts having technical expertise in the fields of GE as opposed to biosafety, provides advice to the EC on GM applications. The GMO Amendment Act creates the possibility of added biosafety capacity to the AC by the addition of two more people. One person is to knowledge of ecological matters and GMOs, and the other, knowledge of the impact of GMOs on human health. The AC has also been given additional powers to co-opt written comments from knowledgeable persons in specific fields of science on any aspect concerning GMOs.

Role, functions and powers of the Registrar

The Registrar is generally speaking, in charge of the day-to-day administration of the GMO Act. The Registrar acts on the instructions and conditions laid down by the EC and is responsible for examining applications to ensure conformity with the Act, issuing permits including extension permits, amending and withdrawing permits and attending to any other matter with regard to biosafety or GMOs.

The functions of the Registrar have been redrafted by the GMO Amendments. These require the Registrar to maintain a register of all facilities that are used for contained use, all the trial release sites and the names and addresses of persons involved in such contained use or trial sites. It is indeed a shame that the Act has stopped there. Information is also needed regarding commercial releases and commodity imports. The Act is also silent on the need for the Registrar to place these registers in the public domain, which means that the public will have to apply for access to these using the mechanisms provided by the Public Access to Information Act (PAIA).

In addition, the Registrar has been given an implied monitoring role: he or she is required to satisfy him/herself that all users apply the appropriate measures to protect the environment and human and animal health during the exercise of any activity with GMOs. It is also the Registrar who is required to bring his or her suspicions of transgressions of the Act or permit conditions to the EC, as discussed earlier.

An implied duty is created for the Registrar to investigate suspected transgressions and where a transgression is ascertained, to order cessation of the activity and to

bring this to the attention of the EC and post such information on the Biosafety Clearing House, as may be made in the Regulations.

It is also the responsibility of the Registrar to arrange for an inspection by an inspector of contained use facilities and trial sites. It appears to be up to the Registrar to decide how often these inspections would take place. These provisions must be read together with the new powers created for inspectors in terms of the new section 10(1)(b) to dispose or repatriate any GMO used or any material or substance used, affected or potentially affected if such activity has an adverse impact on the environment or human health.

To sum up, the role, powers, functions and duties of the Registrar constitute a mixed bag: part administrative, part active enforcer of legislation and quasi decision-maker.

Monitoring

Neither the GMO Act 1997, nor the recent amendments place a clear duty on the state to monitor the impacts of GMOs on the environment or human health. Aside from the implied monitoring functions to be exercised by the Registrar as already discussed above, a permit holder is only required to undertake such monitoring duties as set out in permits (permit conditions).

This is not to say that no monitoring has ever been done by government. Inspections have taken place by inspectors appointed in terms of the GMO Act, but these have been done in a cursory and superficial manner, confined strictly to ensuring compliance with the Act or permit conditions. These inspections cannot be said to form part of a biosafety monitoring regime that allows for a reliable assessment of the nature, scope and degree of environmental impacts to inform the biosafety investigation on the environmental impacts of GMOs.

Section 11(1)(b) of the Biodiversity Act creates a peremptory duty for the South African National Biodiversity Institute (SANBI) to monitor and report regularly to the Minister of Environmental Affairs on the impacts of any GMO that has been released into the environment, including its impact on non-target organisms, ecological processes, indigenous biological resources and the biodiversity of the species used for agriculture. It is unclear whether these provisions relate to case-by-case monitoring. However, ecologists in SA, argue that the use of the term 'any' supports the requirement for a comprehensive monitoring programme.⁶²

SANBI is still at a nascent stage of putting together a monitoring regime to comply with its obligations under the Biodiversity Act. In the meanwhile, South African scientists from the university of the Free State and the University of Stellenbosch are working on case studies in the Makhathini Flats in Northern KwaZulu Natal to investigate the impacts of GM maize and cotton on the environment. It is hoped that these and other independent studies being conducted elsewhere in the country will contribute to closing some of the gaping holes in current knowledge on the impacts of GMOs on the environment.

Labelling and the right to know

The labelling of genetically modified food serves an important function of providing the public with information. However, its value also lies in its biosafety function regarding the traceability of GMO from farm to plate, risk management and monitoring, product recall in the event anything goes wrong and concomitant issues of liability and redress. South Africans have been consuming GMOs and GM products, including maize, a staple food, without their consent and knowledge for several years.

On the 16th January 2004, seven years after South Africa began commercially growing GM crops and three years after it approved the commercial growing of GM white maize, the Department of Health published *Regulations Relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification*. These Regulations were made in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act, No.54 of 1972). These Regulations not only seriously flout the South African consumer's right to choose, but places consumers at great risk.

The South African labelling regulations adopt the United States model where the use of GM techniques *per se* is not itself a trigger for labelling. These regulations do not apply to the GM foods currently imported, marketed and released in South Africa (or elsewhere in the world for that matter). It is only when there is a 'significant difference' in the final food that labelling is required. The circumstances where this is considered to be significantly different is if there are human/animal genes; allergens; requires different cooking; or has altered nutritional composition. **There are no GM foods currently commercialised that would fall within this scope.**

Therefore, South African consumers will be given no choice over the current generation of GM foods. GM animal feed have thus also been excluded from the scope of the Regulations. Furthermore, the Regulations have also excluded foodstuff derived

from animals fed on GM feed, from its scope, such as the meat of animals as well as products such as milk and eggs.⁶³

At the time, non-government organisations in South Africa reacted angrily to the Regulations upon its publication, calling them a “sham”.⁶⁴

On the 12 February 2004, Member of Parliament, Kent Durr from the African Christian Democratic Party introduced a motion in the House of Parliament, National Council of Provinces, which sought to require that the government urgently review the Regulations. The African National Congress opposed the motion. Earlier versions of the Consumer Protection Bill, which contained provisions on mandatory labelling, have been exorcised from the version that will be tabled in Parliament during 2007.

The rationale for the South African government’s decision not to require the mandatory labelling of GM food and feed is contained in a two page document issued by Department of Health publication titled ‘Explaining GMO Food Labelling’.⁶⁵ These include:

- ◆ Compulsory labelling of GM food would result in the increase in food prices and negatively impact on street vendors and the majority of the population who have limited purchasing power, especially those dependent on staple food;
- ◆ Systems to detect and identify GM-genetic material/protein by way of diagnostic techniques are subject to error, abuse and are expensive;
- ◆ Compulsory labelling of GM food is not practical since GMOs may increasingly appear in 30 000 products that contain maize and soybean ingredients;
- ◆ Segregation of GM food from non-GM foods is expensive.

However, pressure groups in South Africa find it ironical that increased costs should be offered as an excuse to avoid guaranteeing consumer choice, when the proponents of GM technology argue that GMOs will provide cheaper and more plentiful food.

Many products on the South African shelves are labelled ‘organic’ or ‘GM free’. However, according to researchers at the University of the Free State, traces of GMOs can be found in nearly three-quarters of locally sold maize and soya products that claim to be free of these ingredients. This means that thousands of consumers who buy products labelled ‘genetically modified organism-free’, ‘non-genetically modified’ or ‘organic’ may be eating food containing GMOs or foods derived from GMOs.⁶⁶

This points to the need for the government to seriously devise sound labelling laws for GM foods, that provide for mandatory labelling and set criteria and parameters for the labelling of GM free food. This will go a long way to minimising contamination of the food supply, honouring the public's right to know and their right to truthful labelling.

Traceability and implications for international trade

During 2006 in Curitiba, Brazil, the third Meeting of the Parties to the Biosafety Protocol⁶⁷ agreed that a Party of export will have to disclose information about the GM content of bulk shipments of GMOs exported for direct use as food, feed and processing (FFP). In terms of this agreement, a country that is a Party to the Biosafety Protocol is obliged to ensure that shipments of GMOs for FFP are identified as 'contains GMOs' **where the identity of the GMO is known through means such as identity preservation systems**. Additional information about the GMO must also be given including details that the GMOs are not intended for direct introduction into the environment, the common, scientific and where available, the commercial names of the GMOs, the transformation event code of the GMOs, or where available as a key to accessing information in the biosafety clearing house, its unique identifiers code etc.

South Africa does not have a mandatory traceability and identity preservation system for imported and exported GMOs. However, a number of measures have been adopted by actors in the food industry to segregate GM grains from their non- GM counterparts as well as preserving the identify of the GM varieties from other GM varieties.⁶⁸ However, all these are done on a voluntary basis to secure overseas markets.

It is thus arguable that since a *de facto* identity and preservation systems already exists in SA, exports of GMOs for FFP from SA to other Parties to the Protocol including its African trading partners will have to be clearly identified as 'contains GMOs' and that the additional information as outlined above must also be provided.

This will necessitate far-reaching legal and trade reforms because similar treatment must also be given to imports of GMOs coming into South Africa. Because of the likelihood of contamination having occurred throughout the food chain, every shipment

of grains exported from South Africa to other Parties to the Protocol will also have to be tested in order to disclose the GM content in the shipments. Similarly, every import of grains imported into South Africa irrespective of whether it emanates from countries that are Parties to the Protocol, will have to be properly identified, so that GM content can be traced from ship to fork. Indeed, labelling legislation that provides for mandatory labelling can only be implemented within a context where such traceability systems are in place.

As a Party to the Biosafety Protocol, the South African government must craft new Regulations to give effect to the agreement reached at COP MOP3 in respect to Article 18(2)(a). These Regulations would be required thus to deal with the following:

- (a) testing of a mixture of GMOs in order to determine not only the GMO content but also the individual variety (genetic transformation event) of GMOs contained in the shipment, to list the GMOs and ascertain that it has been approved for import;
- (b) ensuring that non-GM shipments only contain GMOs that are technically unavoidable (mostly, where non-GM crops/food have become contaminated by GMOs) and that a threshold is set for such unavoidable quantities (e.g. 1%);
- (c) protecting the integrity of non-GMO shipments from contamination;
- (d) ensuring that there is zero tolerance for unapproved GMOs; and
- (e) developing modalities for sampling and detection techniques.

Liability and redress

New definition of user

Prior to its amendment, the GMO Act held a user liable for environmental damage arising from the use of a GMO. 'User' was previously broadly defined as 'any natural or legal person or institution responsible for the use of GMOs and includes the end-user.' This breathtakingly wide definition specifically included the consumer.

The new provisions define 'user' loosely as a person 'who conducts an activity with a GMO' and thus still continues to include the consumer and end user (buying, eating, cooking GMOs would qualify as 'conducting an activity with a GMO.')

It is unclear whether the person to whom a permit has been granted will also be the person 'who conducts an activity with a GMO'. This is pertinent to situations where poor black farmers are recruited as part of field trial experiments of the broader research agendas of research institutions in South Africa, for instance, GM potato field trials conducted by the Agriculture Research Council involve small scale potato farmers.

Certainly, this definition may not include the developer of the GMO from liability once the GMO is in commercial production. In the context where GMOs are grown commercially, the person who will be conducting the activity, namely growing the GMO, will be the farmer.

This is so despite the lobby efforts by GRAIN SA on behalf of commercial farmers in South Africa to oppose the notion that farmers should be held liable. In their submissions to Parliament, GRAIN SA specifically asked that liability for damage caused by activities related to a GMO, be borne by the owner/licence holder of the GMO.⁶⁹

Farmers could insist that the developer absolve them from liability when they purchase GMOs. However, this may only avail literate farmers who know what they are buying and are powerful enough to insist that the developer or seed supplier absolve them from any liability. It will not help resource-poor farmers who are given GM seeds as part of a free package of incentives especially since South Africa does not require mandatory labelling for GMOs.

Duty of Care

A new section 11 places a strong duty of care on users to ensure that appropriate measures are taken to **avoid** an adverse impact on the environment and human health, which may arise from the **use of a GMO**. The Act then immediately deals with a situation where damage arises although it does not define 'damage.' These provisions appear to have been drafted in the context of GMOs used in agriculture, where users are meant to take certain measures (e.g. planting of refugia, adopting pest management strategies to prevent the outbreak of secondary pests and so forth) to avoid negative impacts on the environment and human health. It does not, however, address situations where something goes wrong as a result of the GMO itself because of the intrinsic properties of the GMO, and where there is no culpability on the part of the person who is using the GMO. In other words, these provisions do not

address the developer of the technology directly by placing an unequivocal duty on it to ensure that GMOs are safe, and that they do not pose a danger to society, the environment and human health.

When damage arises

An obligation is placed on the user to notify the Registrar in the event of damage arising, then in consultation with the Registrar the user is required to take certain actions. These include investigating, assessing and evaluating the damage caused by the activity on the environment and human health. This is to be followed by implementing measures to 'minimise to contain or prevent the **movement** of the GMO causing the damage in the event that an activity cannot reasonably be avoided or stopped.'

Although 'movement' is not defined, read within the context of the provisions, it seems to contemplate the recalling and preventing the further dissemination of GMOs even if further damage cannot be stopped or avoided altogether.

Measures that must be taken include eliminating the source of the damage or remedying the effects of the damage caused by the activity. If the user fails or inadequately implements these measures the EC may take any reasonable measures to remedy the situation and in this event, it may recover all costs by claiming a proportion from any person who benefited from the **measures undertaken**. This raises the question as to who is likely to benefit from the remedial measures taken? Would this also include organic farmers who can be said to benefit from the measures taken as a result of the contamination being removed?

Liability on user

The amendments place liability for damage caused by activities relating to a GMO (as opposed to also including damages from the GMO itself) on the user concerned. Strict or non-fault liability appears to have been created.

This means that the user will be held liable and it will not excuse the user to show that he or she was not at fault. If damage arises, then the user will be liable, and that is why such strong provisions regarding the duty of care have been created.

Exceptions to strict liability rule

If damage occurred whilst the GMO in question was in the possession of an inspector pursuant to a transgression having occurred, then the user will only be liable if he or she foresaw the damage and should have prevented the damage but failed to do so.

This exception thus contemplates several situations regarding the damages that may arise whilst a GMO is under the control of the state (an inspector):

- ◆ the user is still liable;
- ◆ the liability is fault based (determined by the issue of foreseeability);
- ◆ the user may escape liability if fault cannot be proven (if he/she fails the foreseeability test);
- ◆ the state may be liable if fault on the part of the user is not proven.

It appears as if very little breathing space has been given to the user to use this exception: only if a GMO has been confiscated because of non-compliance by someone, including the user, then strict liability will not arise if the damage occurred during the time the GMO was in the custody of the state. It is difficult to imagine circumstances in which damage arises only after confiscation, since the very reason for the confiscation would arguably be the transgression, unless at the time the transgression occurred, it was not clear that damage would indeed arise. This exception to the strict liability rule will thus operate only in circumstances where: non-compliance with the Act has occurred, this non-compliance came to the attention of the state, the GMOs were confiscated and the damage occurred whilst the GMO is under the control of the state.

In any event, foreseeability has obvious problems in the context of GMOs, where scientific uncertainty and variables make foreseeability difficult to prove.

Costs for remedial action taken by the state

The amendments deal with the ability of the state to recover the costs from third parties in circumstances where the state takes remedial action for damage to the environment. These provisions place a duty on the state to do three things: minimise and contain the damages, eliminate the damage at source and then eliminate the

source of the damage within an overarching mandate to protect the environment, because the environment will suffer if no one takes remedial action during long periods of litigation for instance.

However, it must be noted that these provisions only make sense in a context where remedial action can actually be taken, in other words, where the damage is reversible, and that it is possible to place a monetary value on such remedial action.

A mandatory duty is placed on the EC to apportion damages where more than one person is liable. The EC must, however, allow for a fair hearing in the course of such determination. Such apportionment of the damages will not relieve the responsible persons from their joint and several responsibilities for the full amount of the costs. The EC's apportionment will have the same legal effect as a civil judgement in a Magistrates' court. A right of appeal is created for those that are affected by the EC's cost order.

Public awareness and input

Public input vs public consultation

The engagement of the public, public consultation and public participation in the context of the regulation of GMOs have been singled out as requiring urgent attention by different sectors of the South African society. These include civil society groups opposed to GMOs, the academic fraternity, farmer groups, parliamentarians, officials within the South African government, and the private sector. Nevertheless, the GMO Amendment Act has failed to introduce new provisions to deal with these critically important issues.

Currently, the central mechanism used to engage the public is regulation 6 of the Regulations dated 1 December 1999 made under the GMO Act. Regulation 6 requires an applicant to place a notice in a local newspaper where a release is intended to take place, advising the public of an intended application and inviting the public to submit comments within 30 days of the notice. The public therefore does not have the right to **participation** but merely an **opportunity** to make input with regard to GM applications concerning field trials, commercial releases and commodity imports for food, feed and processing. This opportunity can only be taken advantage if the public spots the notice in the local newspaper.

Although neither the GMO Act nor the Regulations oblige the public to furnish comments and objections within 30 days, the EC will not consider any applications outside of the 30 day period unless the applicant grants an extension of time.

The EC views the procedure under Regulation 6 as a fair procedure within the contemplation of administrative justice legislation, the Promotion of Administrative Justice Act, PAJA.⁷⁰ We have disputed this and have repeatedly called upon the EC to provide for public participation, including public hearings, public enquiries, full disclosure of information in a timely way about GMO applications, the decisions of the EC, reasons for decisions made and to show the extent to which the public's participation has been factored into decision-making. This is particularly important since administrative action – decisions taken by the EC in approving applications for the import, release and marketing of GMOs adversely affect the fundamental human rights of the public. These rights include *inter alia* the right to nutritious safe, affordable and culturally acceptable food, the right to informed choice, the right to a fair administrative decision-making, the right to democratic participation, the right to save and exchange seeds and the right to a safe and healthy environment. The right of the public to fair administrative justice cannot be said to be upheld by the opportunities such as they are, as provided by regulation 6.

The National Environmental Advisory Committee (NEAF) established in terms of NEMA has taken a decision to provide the Minister of Environmental Affairs with recommendations to improve the current situation. NEAF has thus embarked on research with a view to advising the Minister on a number of interventions that should be taken to ensure an open, fair and transparent process for public participation to take place.

Public Awareness

Article 23 of the Biosafety Protocol deals with public awareness and obliges Parties to the Protocol to promote and facilitate public awareness, education and participation concerning GMO Activities. According to the former Minister of Agriculture and Land Affairs, the government has complied with these obligations through the Public Understanding of Biotechnology (PUB).⁷¹

The PUB initiative was funded directly by the Department of Science and Technology and implemented through the South African Agency for Science and Technology Advancement (SAASTA). The aims of the PUB programme are to educate the public/

raise awareness on the science behind biotechnology, including GM technology. The PUB engaged the public through science dramas, cartoon posters, teaching modules to support teaching curriculum and so forth. Activists who attended PUB workshops expressed mixed feelings about it: on the one hand they express appreciation for the efforts made by those involved directly in the PUB programme to provide a public space for debate, but they are also extremely wary of the influence of PUB sponsors such as the United States Consulate and raised questions about PUB's neutrality.⁷²

The effectiveness of PUB is, however, in dispute because at the Parliamentary hearings on the GMO Amendment Bill, small-scale farmers testified that government is not doing enough to capacitate them to understand how GMOs will impact on their health and farming practises. They expressed the particular need to know about the implications for them arising from dependence on GM seeds, the high costs of the technology versus low commodity prices and the contamination of indigenous seeds.⁷³

Confidential Business Information (CBI)

*Government functionaries responsible for managing genetic engineering in South Africa are too busy processing applications and issuing permits for new releases to comply with the Constitutional rights of other South Africans to know what they are doing. It emerged in the Pretoria High Court on Tuesday that the Office of the Registrar Genetic Resources comprises just five people, two of whom are administrative assistants.*⁷⁴

The NGO Biowatch South Africa successfully instituted legal action against the Department of Agriculture to gain better access to information regarding GMO decision-making.⁷⁵ Notwithstanding this victory, civil society in South Africa battle to gain access to pertinent information concerning permit applications and GM decision-making. This is so because the GMO Act protects all information that an applicant designates to be 'Confidential Business Information'. The amendments to the GMO Act has not changed this situation and only allows the public to have access to information of the following: the general description of the GMO and a summary of the scientifically based risk assessment of the impact on the environment and human health.

Nevertheless, even this right is curtailed because it is the applicant who is allowed to decide what the summary of the risk assessment may contain and can, at its own discretion, decide to include or exclude any information it so desires by arguing that it is CBI.

Appeals

The provisions relating to appeals have been amended and we describe here, the procedure as amended. Appeals are important legal mechanisms to challenge decisions taken by the EC. An aggrieved person is entitled to give notice of its intention to lodge an appeal. The Minister of Agriculture must then appoint an appeal board within 60 days. The Minister is also empowered to extend this time period. The appeal board is to be constituted by persons who the Minister believes has knowledge of the **matter on appeal**. The Appeal Board is to consider the potential risks and potential benefits related to the matter on appeal and make such order so as to minimise a significant negative impact on the environment or human and animal health.

In considering the appeal, the Appeal Board is allowed only to follow the prescribed procedures and consider new scientific or technical **evidence** or any other information that is in the opinion of the Appeal Board, directly applicable to the appeal.

This resounds with the provisions discussed earlier dealing with review of decisions by the EC: that it will be extremely difficult to overturn decisions of the EC once they are taken, whether on appeal or review of decision by the EC itself.

Conclusion

The 1997 GMO Act has been held up as a sterling example of good biosafety legislation by its protagonists. They argue that the small number of amendments to the GMO Act is indicative of the success of the Act in regulating GMOs. Theirs is only one view. The other view is yet to emerge from hard biosafety information on the impacts of GMOs on the South African environment as a result of the wanton release that has taken place over the past 15 years.

To date, the GMO Act has mainly been used to deal with GMOs having one or two traits in the context of agricultural use. However, in the future, GMOs containing several traits will come to the market. Already, GM drought tolerant crops are being field tested, as are GMOs containing stacked genes. GM vaccines are also being tested on human populations. Biological controls in the form of GM bacteria/mosquitocide may be introduced into water sources. Is the GMO Act as amended geared for these challenges?

It is deeply regrettable that South Africa's culture of participatory democracy seems to have by-passed GM regulation completely. Keeping consumers in the dark by not allowing GM food to be labelled, locking them out of the decision-making processes and withholding vital information has only served to outrage the public and ignite deep suspicion about the GMO Act. This situation has, however, served the GM industry well, as they laugh all the way to their Swiss and US banks!

New initiatives by government to craft belated biosafety policies will do nothing to ameliorate what has now already been cast in stone by the GMO amendments, many years in the making. Nevertheless, civil society will continue its vigilance and struggle for social and environmental justice, however small the windows of opportunities are for us to do so.

Useful websites

South Africa

African Centre for Biosafety www.biosafetyafrica.net

Biowatch SA www.biowatch.org.za

Department of Agriculture www.nda.agric.za

Department of Arts and Culture www.dac.gov.za

Department of Environmental Affairs & Tourism www.deat.gov.za

Department of Health www.doh.gov.za

Department of Science & Technology www.dst.gov.za

SAFCEI (South African Faith Communities' Environmental Institute) www.safcei.org.za

SAFeAGE (South African Freeze Alliance on Genetic Engineering) www.safeage.org

International

Cartagena Protocol on Biosafety www.biodiv.org/biosafety

Centre for Food Safety www.centreforfoodsafety.org

Centre for Integrated Research in Biosafety www.inbi.canterbury.ac.nz

GMO ERA project www.gmo-guidelines.info

GRAIN www.grain.org

Institute of Science in Society (ISIS) www.i-sis.org.uk

The Norwegian Institute of Gene Ecology (GenØk) www.genok.org

Third World Network (TWN) Biosafety Info Centre www.biosafety-info.net

Annex 1

National legislation that may be applicable in the regulation of GMOs

(i) Environmental Conservation Act, 1998 (Act No. 73 of 1998)

The Environmental Conservation Act (ECA), 1998 (Act No. 73 of 1998) provides for the effective protection and controlled utilization of the environment. In terms of Section 21 of ECA, the Minister of Environmental Affairs and Tourism has identified activities in Schedule 1 of the Act as activities, which may have a substantial detrimental effect on the environment. These activities are prohibited unless written authorization is issued either by the Minister of Environmental Affairs and Tourism or a competent authority. Such authorization is only considered after reports of the impact of the proposed activity on the environment has been compiled and submitted in the prescribed manner.

The genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism is one of the activities listed. Bearing this in mind, the provisions of ECA must be taken into consideration by the Executive Council in their deliberations on any proposed GMO activity.

(ii) National Environmental Management Act, 1998 (Act No. 107 of 1998)

The National Environmental Management Act (NEMA), 1998 (Act No. 107 of 1998) provides for cooperative environmental governance by establishing principles for decision making on matters affecting the environment.

Section 2 of NEMA sets out the national environmental management principles, with the aim to ensure that all activities are conducted in a sustainable manner. This requires that risk assessment and risk management procedures be undertaken prior to the approval of any proposed activity with GMOs. Risk assessment and risk management procedures are incorporated into the provisions of the GMO Act.

Section 3 of NEMA calls for the appointment of two institutions, viz. (1) the National Environmental Advisory Forum (NEAF) that can advise and inform the Minister of Environmental Affairs and Tourism regarding the application of

the principles of risk assessment and management and (2) the Committee for Environmental Co-ordination (CEC) to promote the integration and achievement of the purpose and objectives of environmental implementation plans and environmental management plans (Section 11), of which one objective is the protection of the environment of the country as a whole.

**(iii) National Environmental Management Biodiversity Act, 2004
(Act No. 10 of 2004)**

This National Environmental Management Biodiversity Act (NEMBA), 2004 (Act No. 10 of 2004) was enacted within the framework of NEMA and institutes special requirements for the introduction of three categories of living organisms, viz. alien species, listed invasive species and threatened or protected species.

The objectives of the Act are -

- (a) within the framework of NEMA, to provide for—
 - (i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity;
 - (ii) the use of indigenous biological resources in a sustainable manner; and
 - (iii) the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources;
- (b) to give effect to ratified international agreements relating to biodiversity, which are binding on the Republic;
- (c) to provide for co-operative governance in biodiversity management and conservation; and
- (d) to provide for a South African National Biodiversity Institute to assist in achieving the objectives of this Act.

In accordance with the provisions of NEMBA, the Department of Environmental Affairs and Tourism, through implementation of the GMO Act, must manage, conserve and sustain South Africa's biodiversity and its components and genetic resources during any activity with GMOs.

The Act further asks for the establishment of a South African Biodiversity Institute (SANBI), which is tasked with monitoring of the impacts any GMO that has been released into the environment, including the impact on non-target

organisms, ecological processes, biological resources and biological diversity of species used for agriculture. The Institute must report regularly to the Minister of Environmental Affairs and Tourism.

Part 3 of Chapter 5 of NEMBA, provides the Minister of Environmental Affairs and Tourism the right to, if there is reason to believe that the release of a GMO into the environment under a permit applied for in terms of the GMO Act may pose a threat to any indigenous species or the environment, no permit for such release being issued in terms of the GMO Act unless an environmental assessment has been conducted in accordance with Chapter 5 of NEMA, as if such release were a listed activity contemplated in that Chapter. This must be indicated to the Executive Council before the application for the relevant permit is decided. This provision is applicable for trial release or general release activities of GMO's. The Executive Council must take this provision into consideration prior to the issuance of any permit authorizing trial or general release.

Section 80 of NEMBA provides for measures to regulate bioprospecting, including the exportation of indigenous biological resources for the purpose of bioprospecting or any other kind of research. "Indigenous biological resources" includes any indigenous biological resources, including any exotic animals, plants or other organisms, altered in any way by means of biotechnology. The provisions of this section must also be taken into consideration by the Executive Council should an application for such a GMO be submitted for authorization.

(iv) Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972)

The Foodstuffs, Cosmetics and Disinfectants Act (FCDA), 1972 (Act No. 54 of 1972) regulates the safety of all foodstuffs in South Africa, including foodstuffs derived from genetically modified organisms.

Regulations on the labelling of foodstuffs derived from certain techniques of genetic modification have been published in January 2004. The phrase "foodstuffs obtained through certain techniques of genetic modification" in the Regulations means a foodstuff (a) composed of a GMO(s), (b) containing a GMO(s), (c) produced from and contain a protein or DNA resulting from such genetic modification and (d) produced from, but not containing, a GMO(s) or protein or DNA resulting from such genetic modification.

The Regulations makes provision for mandatory and voluntary labelling. Mandatory labelling is required for a foodstuff obtained through certain techniques

of genetic modification if (a) the composition differs significantly from the characteristic composition of the corresponding existing foodstuff, (b) the nutritional value differs significantly from the characteristic nutritional value of the corresponding existing foodstuff, (c) the mode of storage, preparation or cooking differs significantly from that of the corresponding existing foodstuff, (d) the foodstuff contain an allergen from any products listed in the Annexure of the Regulations that causes allergy, (e) the foodstuff is derived from plant material containing animal nucleic acid(s) or protein(s) derived from a human or from an animal and (f) the foodstuff is derived from animal material containing animal nucleic acid(s) or protein(s) derived from a human or from a different taxonomic animal family.

The Regulations also makes provision for voluntary labelling of foodstuffs that have enhanced characteristics. One may claim an enhanced-characteristic of a foodstuff in terms of composition, nutritional value and reduced caution of allergenicity, provided that the claim has been validated and certified by a competent body which is accredited to the South African National Accreditation Services and the label adheres to certain requirements.

Voluntary labelling with regard to consignments that do not contain GMOs may occur provided that the claim can be substantiated in accordance with the requirements of the identity preservation systems approved by the South African Bureau of Standards.

(v) Promotion of Access to Information Act, 2000 (Act No. 2 of 2000)

The aim of this Act is to give effect to the constitutional right of access to any information held by the State and any information that is held by another person and that is required for the exercise or protection of any rights; and to provide for matters connected therewith.

The Department of Agriculture shall, in accordance with the GMO Act, institute measures to prevent the disclosure of information acquired by a person through the exercise of his or her powers or the performance of his or her duties in terms of the GMO Act.

The Department of Agriculture shall further withhold certain information, as determined by the GMO Act, for the period needed to protect the intellectual property right of any applicant under the GMO Act.

(vi) Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000)

To give effect to the right to administrative action that is lawful, reasonable and procedurally fair and to the right to written reasons for administrative action as contemplated in Section 33 of the Constitution of the Republic of South Africa, 1996; and to provide for matters incidental thereto.

The Department of Agriculture shall provide measures to ensure effective management of information and documentation pertaining to activities under the GMO Act and the disclosure of decisions, including reasons for decisions, in accordance with the provisions of the Promotion of Administrative Justice Act (PAJA), 2000.

The Advisory Committee, Executive Council, Appeal Board, inspectors, Registrar and any other person performing functions or duties in terms of the provisions of the GMO Act, shall take appropriate measures to facilitate compliance with the provisions of PAJA.

(vii) Animal Diseases Act, 1984 (Act No. 35 of 1984)

The aim of this Act is to provide for the control of animal diseases and parasites, and to provide for measures to promote animal health.

In terms of this Act no person shall import into or convey in transit through the Republic of South Africa any animal, parasite or contaminated or infectious thing except under the authority of a permit and in compliance with any condition imposed in such permit. Furthermore, no person shall, except under a permit and in compliance with the conditions which are prescribed conduct any trial with any vaccine, serum, toxin, anti-toxin, antigen or other biological product which consist of, or originates wholly or partially of, or from, any micro-organism, or of or from any glands, organs, fluids, or any other part, of an animal or parasite.

(viii) Agricultural Pests Act, 1983 (Act no. 36 of 1983)

The aim of the act is to provide for measures to prevent and control the importation of plant pests and to provide measures for the national control thereof.

In terms of the provisions of this act no person shall import into the RSA any controlled goods which inter alia include plants, plant products, organisms and exotic animals except under the authority of a permit and in compliance with the relevant import requirements imposed in such a permit. These import requirements shall be established through a pest risk analysis to ensure that it is technically justified and is not used as unjustified barriers to free trade.

(ix) Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

This Act provides for the appointment of a Registrar of Fertilizers, Farm Feeds and Agricultural Remedies; for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, sterilizing plants and pest control operators. This Act also regulates or prohibits the importation, sale, acquisition, disposal or use of fertilizers, farm feeds, agricultural remedies and stock remedies.

This will include the registration of veterinary vaccines for use in animals, which may contain GMOs.

(x) Medicines and Related Substances Amendment Control Act, 1997(Act No. 90 of 1997)

This Act in general makes provision for the prohibition on the sale of medicines that are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to require labels to be approved by the council; to prohibit bonusing and sampling of medicines; to further regulate the control of medicines and scheduled substances; to provide for the licensing of certain persons to compound, dispense or manufacture medicines; to provide for generic substitution of medicines and to regulate the purchase and sale of medicines by wholesalers.

(xi) Conservation of Agricultural Resources Act, 1983 (Act No. 43 of 1983)

The provisions of this Act will have to be taken into consideration when considering activities with GMOs, as it provides for measures to control the utilization of the natural agricultural resources within the Republic, in order to promote the conservation of the soil, the water sources and the vegetation and to combat weeds and invader plants; and for matters connected therewith.

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68. Mayet, Mariam. **Case Study: South Africa's traceability and segregation systems for GM grains.** TWN Briefings for MOP 3, Briefing Paper 5. February 2006. These measures include the following:
 - a. the establishment of systems by grain handlers such as OKT, SANWES etc. to segregate GM maize from non GM maize for the purposes of enabling South African companies such as African Products (Pty) Ltd to export GM free products (corn starch, corn syrup) to overseas markets as well as to comply with the GM free certification requirements by many countries in the Southern African Development Community (SADC);
 - b. the establishment of a detailed, comprehensive, sophisticated traceability system to ensure food safety and quality, promulgated on the 13 May 2005, in terms of the Standards regarding Food Hygiene and Food Safety of Regulated Agricultural Food Products and Plant Origin intended for Export and in terms of the Agricultural Product Standards (APS) Act 119 of 1990;
 - c. the extensive use of "Silo bags" in South Africa, imported from Argentina, enabling farmers to store grain on-farm and segregate **individual events/varieties of GM grains** from other GM varieties, thereby preserving the identify of individual GM varieties.
69. GRAIN SA Submission to Parliament on GMO Amendment Bill, 9 November 2006.
70. Letter from Department of Agriculture to ACB dated 16 August 2004.
71. Letter from Ms A. Thoko Didiza, Minister of Agriculture and Land Affairs, to African Centre for Biosafety in response to "Open Letter from African Civil Society addressed to the South African delegation to the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, dated 23 March 2004".

72. Personal Communication, Glenn Ashton SAFeAGE, April 2007. Ashton attended the PUB workshop in Pretoria, funded by the US Consulate.
73. Elandskraal Balimi Irrigation Scheme and Phadima Community Development Submissions on the GMO Act. November 2005.
74. **Genetic Managers too Busy to Disclose Engineering Activities.** Press Release Biowatch South Africa. Oryx Media Productions. 26 May 2004.
75. See <http://www.biowatch.org.za> for full details of the court case and the relief given to Biowatch SA.