CRITICAL ANALYSIS OF PERTINENT LEGISLATION REGULATING GENETIC MODIFICATION IN FOOD AND AGRICULTURE IN SOUTH AFRICA

PRODUCED FOR BIOWATCH SOUTH AFRICA

By Mariam Mayet
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CONTENTS

LIST OF ABBREVIATIONS AND DEFINITIONS

AIA	**Advance Informed Agreement**
ARC	**Agriculture Research Council**
BSCH	**Biosafety Clearing House**
CBD	**Convention on the Conservation and Sustainable Use of Biological Diversity**
CSIR	**Council for Scientific and Industrial Research**
DEAT	**Department of Environmental Affairs and Tourism**
DOA	**Department of Agriculture**
DOH	**Department of Health**
ECA	**Environment Conservation Act**
EIA	**Environmental Impact Assessment**
ESCS	**European Society of Chartered Surveyors to the European Union**
EU	**European Union**
FAO	**Food and Agriculture Organisation**
FFP-LMOS	**Living Modified Organisms intended for direct use as food, feed or processing**
GM	**Genetically Modified**
FCD	**Foodstuff Cosmetics and Disinfectants Act**
GMO	**Genetically Modified Organism**
LMO	**Living Modified Organism**
MEC	**Member of Executive Council (of the provinces)**
NEMA	**National Environmental Management Act**
OAU	**Organisation of African Unity**
SAGENE	**South African Committee on Genetic Experimentation**
UNEP	**United Nations Environment Programme**
US	**United States of America**
WHO	**World Health Organisation**
WTO	**World Trade Organisation**

FOREWORD

Biowatch South Africa, a non-governmental organisation (NGO) based in South Africa, has commissioned this paper, principally because there is little understanding of the status and adequacy of the current legislative regime governing genetic modification in South Africa. This paper therefore critically examines the most pertinent legislation both from the point of view of its current application and its adequacy in constituting the requisite biosafety regime that ensures that genetically modified organisms (GMOs) are appropriate and do not cause harm to our health, the environment, or threaten food security.

The underlying imperative for this paper is the deep-rooted concern that democracy should not be sacrificed in favour of the touchstones of the new technology, namely, "efficiency, productivity and progress." Technology should be in the public interest and respond to social need; must guarantee the public's right to safe food, ensure adequate public participation and consultation, uphold the consumers' right to choose, and ensure the conservation of biological diversity.

Hence the purpose of this paper is to provide civil society with an overview of the current legislation regulating genetic modification in South Africa in order to *inter alia*:

(a) create public awareness of the provisions of the legislation; and
(b) highlight the shortcomings of such legislation in order for civil society to pursue appropriate courses of action or strategies to enforce their rights.

This paper is comprised of two sections. The first section briefly introduces the subject matter this paper is concerned with and sketches the status of genetic modification in South Africa. Section two critically analyses the Biosafety regime in South Africa and also discusses the Biosafety Protocol and explores its implications for current legislation in the event of South Africa ratifying the Protocol.

This paper has been commissioned as a desk top study. It essentially seeks to amalgamate and update two papers previously written for Biowatch.[1]

[1] "Overview of Existing Legislation Pertaining to Genetic Engineering In South Africa", 1998 and "Scrutinising the legalities of genetic modification in South Africa: Food Safety, Public Participation and the Conservation and Sustainable Use of Biological Diversity", February 2000.

EXECUTIVE SUMMARY

Genetic modification of crop plants involves the use of technology to artificially transfer genes across species lines. This process is fundamentally different from traditional plant breeding because the technology moves genetic material between completely unrelated plant species, and even between the plant, animal and microbial kingdoms, in ways that could never be found in nature.

In South Africa, genetic modification is being developed primarily for use in agriculture, forestry and food production systems. Although not yet at the global forefront of biotechnology, South Africa has relatively well-developed biotechnology capacity, with several universities, the Agricultural Research Council (ARC) and the Council for Scientific and Industrial Research (CSIR) participating. Moreover, the so-called "Life Sciences" or "gene giants" – large multinational companies – are also active in South Africa and have been for the past ten years or so.

During the period 1992 – 1999, prior to biosafety legislation coming into effect in South Africa,[2] the National Department of Agriculture (DOA) approved 165 applications for the release of genetically modified food crops into the environment for the purposes of field trials. In 1998, the DOA authorised the commercial planting of genetically modified insect-resistant maize and insect-resistant cotton, while several permits were also granted during 1998 for the importation of genetically modified soy beans for animal consumption.

After the Genetically Modified Organisms Act came into effect on 1 December, 1999 and during the period January – October 2000, 111 applications were lodged with the DOA for permits regarding various activities including general releases, field trials, contained use and commodity imports for human and animal consumption. Astonishingly, in so short a period, 105 of these applications were approved.

The need for national legislation which imposes stringent biosafety measures is well-recognised in international law. Because of the current lack of scientific knowledge concerning the precise effects of certain engineered genes once they are released into the environment, it is not always possible to anticipate long-term hazards or to quantify the harm. Moreover, the magnitude and scope of the consequences to human and animal health and to ecosystems may well be very serious and the effects irreversible, even if the probability of risk occurrence is low.[3]

The South African Government has, in terms of its National Policy on the Conservation and Sustainable Use of South Africa's Biological Diversity, unequivocally expressed the urgent need to take measures to regulate the transfer, handling, use and release of GMOs in order to minimise the potential risks to biodiversity and human health. Government has, in its

[2] The Genetically Modified Organisms Act only came into effect on 1 December, 1999, when the Regulations to give effect to the GMO Act came into force. This was largely as a result of pressure from the public.

[3] In "Introduction to the Model National Law on Biosafety", drafted by a group of concerned lawyers and scientists, under the auspices of the Organisation of African Unity, during May 1999 at a meeting held in Addis Ababa, hosted by the Environment Protection Authority of Ethiopia and referred to in this paper as the "OAU Model Law".

policy, further advocated a proactive and precautionary approach with regard to the transfer, handling, use and release of GMOs, taking into account the need to balance the risks associated with GMOs with the potential social, economic and environmental benefits to be derived from them.

Currently, the Biosafety Regime in South Africa is constituted by the following statutes:

- the Genetically Modified Organisms Act, No 15 of 1997 (GMO Act), which is the key biosafety law in South Africa;

- the Environment Conservation Act, No 73 of 1989 (ECA) and certain Regulations[4] that, on the face of it, require mandatory environmental impact assessments for GMOs, but are, in practice, impossible to implement;

- the Foodstuffs, Cosmetics and Disinfectants Act, No 54 of 1971 (FCD Act), which sets out control measures to ensure food safety and is also the Act under which Regulations for the labelling of GMOs and the products in which they are found should be promulgated; and

- the National Environmental Management Act, No 107 of 1998 (NEMA). This Act has general application but contains a number of critically important provisions that augment other environmental laws, including biosafety legislation, in particular by regulating decision-making and placing certain obligations on "polluters". It also gives such legislation "teeth" by providing a number of incentives for civil society to enforce environmental laws.

[4] Government Notices R1182, R1183 and R1174 of 5 September, 1997 (*Government Gazette* 18261).

CONCLUSIONS

1 The Genetically Modified Organisms (GMO) Act

Compared, in particular, to a number of international biosafety regimes, the GMO Act has serious shortcomings. It does not, in its present form, constitute an adequate biosafety regime that ensures GMOs are appropriate and do not cause harm to the environment, or to human and animal health. The most serious shortcomings include the following:

1.1 Public participation is not adequately provided for. In the first instance, civil society participation has been excluded from the Advisory Committee. This is perhaps one of the most serious shortcomings of the Act, and is inconsistent with the tenets upon which South Africa's fledgling democracy has been built, and with the principle of public participation in environmental governance advocated in Government policy and in the principles set out in section 2 of South Africa's National Environmental Management Act.

The only opportunity for public participation is by way of a notice and comment procedure linked to permit applications for environmental releases.[5] This means that there is no public participation where applications are exempted from the permit requirements of the Act. Express provision is made for any application that is "cleared" for commercial release and/or for food and animal feed to be exempt from the permit requirements of the Act. This means that decisions can be made – out of the public eye and without the knowledge of the public – to approve any GMO, whether locally produced or imported. Moreover, this can be achieved without there being a need, strictly speaking, to abide by the decision-making procedure of the Act.

Similarly, GMOs that are dealt with under "contained use" conditions (laboratories and greenhouses) are also exempt from the permit requirements of the Act.

Indeed, the notice and comment procedure simply pays lip service to the notion of public participation. It appears as if the intention of the GMO Act is to preclude the public from gaining access to information on the potential or likely impact and risks posed by the GMO concerned to human and animal health, biological diversity and the environment. The GMO Act appears to provide for the right of access only to information regarding the "evaluation of foreseeable impacts, in particular any pathogenic or ecological disruptive impacts". However, even this right is also watered down, because such information can be withheld in order protect the intellectual property rights of the applicant.[6]

1.2 Products of GMOs. The Act applies only to viable, living GMOs and not to the products derived from GMOs. Products of GMOs include, for example, flour made from transgenic maize or soya, tomato sauce, and eggs from chickens fed with

[5] Regulation 6 of the Regulations promulgated under the GMO Act.
[6] Section 18(2)(a), read together with section 18(3) of the GMO Act.

transgenic maize. Emerging scientific evidence shows that a considerable amount of the recombinant DNA persists in products such as soy proteins, derived from transgenic soya. This can be transferred to the microflora in the intestinal tract of humans and animals, and thence to the environment, including soil and water systems. Products of GMOs *per se* are not regulated by any specific legislation, so they are not subject to specially tailored safety testing. Instead, it is generally accepted within Government that a test called "substantial equivalence" be applied. This test has been thoroughly discredited by some commentators as being unscientific and arbitrary. [7]

1.3 Risk assessment. The GMO Act does not set out the principles and parameters of the risk assessment and relies on the use of voluntary and incomplete guidelines for this purpose, despite the fact that such guidelines lack the full force of the law.

1.4 Precautionary Principle**.** The cornerstone for decision-making in regard to biosafety assessment is the use of the Precautionary Principle. Even though the South African Government has acknowledged this in its Biodiversity White Paper and General Environmental Policy and the principle has been entrenched in the National Environmental Management Act, the drafters of the GMO Act have crafted a principle in Regulation 3(2) that appears to be designed to negate the Precautionary Principle.

1.5 Liability. The provisions dealing with environmental liability are astounding. The Act attempts to absolve those responsible for the development of GMOs from liability by placing statutory liability for environmental damage on the "users" of GMOs. This would include farmers growing GMO crops and even consumers.[8] It is indeed disconcerting that Government should want to protect the biotechnology industry from liability. These provisions undermine the basic tenets of justice and equity and are completely at odds with the "polluter pays" principle advocated in Government policy.

1.6 Notification of decisions. An appeals procedure has been created, but this is only useful to members of the public if they know when an applicant has been notified of the approval. No provision has been made for notifying the public of an approval. The onus is on the public to find out when an applicant was notified of a decision, in order to lodge an appeal timeously; namely, within 30 days from the date the applicant was notified.

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[7] Mae-Wan Ho and Richarda A Steinbrecher, "Fatal Flaws in Food Safety Assessment: Critique of the Joint FAO/WHO Biotechnology & Food Safety Report", *TWN Biotechnology & Biosafety Series 1*. See also Erik Millstone, Eric Brunner and Sue Mayer, "Beyond 'substantial equivalence' ", *Nature*, Vol 401, 7 October, 1999 www.nature.com

[8] Ibid. GMO Act, section 1.

2 The Environment Conservation Act (ECA) and accompanying regulations

The law has been drafted in such a way that its provisions are impractical to implement. The Environmental Impact Assessment (EIA) regulations require that EIAs be conducted prior to the genetic modification of an organism, rather than prior to the GMOs being released into the environment. It does not make any sense to require the conducting of an EIA prior to the genetic modification of an organism. Instead, it is the broad environmental impact arising from the genetic modification of organisms released into the environment that should be investigated and assessed before such organisms are released into the environment.

This situation is further compounded by the fact that the EIA provisions only apply to a genetic modification that took place after 5 January, 1998.[9] How does one even begin to implement these provisions, especially if one also takes into account the fact that genetic modification is not a once-off process, but involves complex experiments, often a number of failed ones, which take place over a period of time? As a result of the ludicrous way these provisions have been drafted, Government has not been requiring EIAs for releases of GMOs into our environment.

[9] On 5 January, 1998, item 6 of the EIA regulations, which relates to the genetic modification of an organism, came into force.

3 The Foodstuffs, Cosmetics and Disinfectants (FCD) Act

3.1 The Department of Health is responsible for administering the Act, which is enforced by local authorities in their respective jurisdictions. The intention of the Act is to safeguard the consumer from foodstuffs that are deemed to be harmful or injurious to human health. The food safety of GM food commodities such as grains, fresh fruit and vegetables that fall within the definition of GMO in terms of the GMO Act will, however, be regulated through the risk assessment procedure under the GMO Act.

3.2 The safety assessment of products of GMOs (products of GMOs fall outside the scope of the GMO Act), is done as part of the safety assessment of foodstuffs.[10] The Act has not been amended to set out such measures. It must further be noted that imported food which contains products of GMOs or processed GM foods, falls outside the scope of the GMO Act. Although the FCD Act requires foodstuffs to be safe before being commercially released, including GM foods or foods containing GMOs, no actual testing is undertaken by the Department of Health or by any other Government department.

3.3 At present, the FCD does not require any GM food to be labelled as such. The labelling of GM foodstuffs is one of the most important ways of upholding the right of consumers to choose what they wish to consume. It is also a way to trace GMOs through the food chain, and boosts the demand for the segregation of GM and non-GM ingredients in the food chain.

[10] Faxed letter received from Ms F W J van Rijssen, Deputy Director: Food Control, Department of Health, 11 February, 2000.

4 The National Environmental Management Act (NEMA)

NEMA is an important tool for civil society to use in protecting the environment from the adverse effects of GMOs. The Act contains a number of critically important provisions that could augment other environmental laws, such as the GMO Act and the Environment Conservation Act. The relevant provisions are not entirely clear, however, and leave many important questions unanswered. The following points should be noted:

4.1 Although NEMA requires administrative decision-making to be guided by a number of critically important environmental principles, there are no guidelines to assist decision-makers in applying these principles.

4.2 In terms of section 24 of NEMA, if an activity requires authorisation by law (genetic modification of an organism, for example) and may have a significant effect on the environment, its potential impact on the environment, socio-economic conditions and cultural heritage must be considered, investigated and assessed before it is implemented. These provisions do not, however, impose mandatory obligations as they do not automatically apply, for example, to field trials and commercial releases of GMOs. Nonetheless, minimum standards are set out in the Act. These include investigation of the potential impact, including cumulative effects, of the activity on the environment, socio-economic conditions and cultural heritage, and assessment of its significance; public information and participation; and reporting on gaps in knowledge. Because NEMA is a new statute, specially tailored Regulations which lay down procedures for conducting the envisaged investigation and assessment do not exist at present, and it may be a while before they are drafted and released for public comment. It is anticipated that regulations promulgated under NEMA will, in due course, repeal the EIA regulations under the ECA.

4.3 The "duty of care" provisions in section 28 of NEMA are important in the context of genetic modification because they create the opportunity to trigger fresh EIAs in respect of existing commercial releases of GMOs (especially where new scientific evidence of potential risks comes to light). However, NEMA does not spell out how these provisions should be enforced and monitored and who should be responsible for doing so. The focus is rather on what should happen when a transgression occurs.

4.4 The inadequate enforcement of environmental laws in South Africa has long been recognised as a general problem, and enforcing the provisions of the NEMA is expected to be no different. In fact, the Act expressly provides incentives for civil society to enforce environmental laws. It will, therefore, be up to civil society to monitor compliance with environmental laws pertaining to GMOs. However, civil society will be greatly restrained from performing this function effectively, owing to the inadequacies of the GMO Act and its Regulations and the uncertainties and gaps stemming from the NEMA itself and from the ECA and the EIA Regulations.

SECTION 1

KEY RECOMMENDATIONS

1 Policy on genetic modification

A national policy on genetic modification is urgently required to address the multi-faceted and controversial issues concerning genetic modification in food, agriculture and forestry. The drafting of such a policy should be consultative and transparent. It should, as its first task, require a comprehensive cost-benefit analysis, by comparing GM with other technologies currently being applied in South Africa and investigate how best to ensure access to adequate food by the poor. Such a policy should, *inter alia,* address the following:

- the impact of transgenic seeds on food production systems and food security;
- the impact of genetic engineering on traditional and indigenous technologies;
- the impact of intellectual biotechnology property rights on sustainable agriculture;
- the impact of genetic engineering on productive traditional farming systems and local rural economies;
- the impact of genetic engineering on the environment, particularly biodiversity and ecosystems;

as well as

- the role and future of organic agriculture;
- consumer choice and public participation;
- the impact of transgenic food on human health and safety;
- the implications of genetic engineering for animal health and welfare; and
- ethical considerations.

2 Ratification of Cartagena Protocol on Biosafety

It is imperative that Government sign, ratify and implement the Biosafety Protocol as soon as possible. Ratification of the Protocol will mean that the GMO Act would have to be substantially amended in order to give effect to the provisions of the Protocol. This is quite apart from the fact that the GMO Act has to be substantially revised and amended or redrafted in order to cure its numerous flaws.

3 Revision of EIA regulations

The Department of Environmental Affairs and Tourism is in the process of reviewing the EIA regulations and it is hoped that the provisions relating to GMOs will receive urgent attention.

4 Safety testing of GMOs

Urgent policy decisions must be taken regarding the putting in place of specially tailored and appropriate measures for safety testing of GMOs and products of GMOs in South Africa – under South African conditions.

5 Labelling of GMOs

The Department of Health should urgently draft regulations requiring the mandatory labelling of GMOs and products derived from GMOs. The labelling of GM foodstuffs is one of the most important ways of upholding the right of consumers to choose what they wish to consume. It is also a way to trace GMOs through the food chain, and boosts the demand for the segregation of GM and non-GM ingredients in the food chain.

SECTION 2

CRITICAL ANALYSIS OF PERTINENT LEGISLATION REGULATING GENETIC MODIFICATION IN FOOD AND AGRICULTURAL PRODUCTS IN SOUTH AFRICA

1 Introduction

Genetic modification of crop plants involves the use of technology to transfer genes artificially across species lines. This process is fundamentally different from traditional plant breeding because the technology moves genetic material between completely unrelated plant species, and even between the plant, animal and microbial kingdoms, in ways that could never be found in nature.

At present, genetically modified or transgenic crops being grown in the world are of two types: herbicide-resistant crops that are specifically engineered to resist the spraying of particular herbicides; and insect-resistant crops that are specially engineered to behave like a pesticide because the gene *Bacillus Thuringiensis* (Bt), a soil bacterium, has been inserted into a particular plant's genome (all genes, taken together).

The new traits in the crops are ostensibly designed to offer farmers reduced production costs, or increased ease of crop management by reducing the need to control pests; and decreased labour costs, allowing for a shift to cheaper chemicals and generally simplifying pest control.

1.1 Scientific uncertainty

While identification of the gene to be transferred is precise, the process of inserting it in the new host is often imprecise. Genes are moved with something that is the molecular equivalent of a shotgun. Scientists coat tiny particles with genetic material and then "shoot" these genes into thousands of cells in a petri dish before they get one in which the desired trait takes and is expressed.[11]

However, the actions of genes are unpredictable. Scientists cannot be sure where, in the receiving plant's genome, a new gene will find a home or what effect it will have on the plant. Since a gene may control several different traits in a plant, it is entirely possible that a gene could change a plant's genome in an unforeseen manner.

[11] Michael Hansen, "Biotechnology and Food Systems", a paper presented at the Consumer Institute for South Africa Conference on Biotechnology, 29 October, 1999, Johannesburg, South Africa.

1.2 Genetic modification and poverty alleviation

Genetic modification is offered to Africa as a solution to alleviate poverty and stave off hunger. While it is beyond the scope of this paper to deal with issues pertaining to food security in Africa, it is important to point out that hunger and malnutrition have little to do with how efficiently food is produced or how much food is available for consumption. Indeed, hunger and malnutrition are rooted in socio-economic realities such as poverty, which limits the ability of people to access food in the market or on the land; the means to acquire food and other resources to produce food; access to a clean and healthy environment; and health care and education. Poverty alleviation requires structural, political, social and economic changes involving, for example, equitable land and natural resources distribution, gender reform, equitable access to education, training and other resources needed to ensure food security. To this extent, genetic modification is really only a "techno-fix" or "quick fix" as opposed to the kind of intervention needed to address poverty and food security issues in Africa.

Moreover, the transgenic crops currently being offered – transgenic maize, canola, soya and cotton – will not help to stave off hunger in Africa. What is important to note is that modified soya and maize are used mainly in livestock production and processed foods; modified canola is pressed into oil and used in processed foods; and cotton is used for its fibre and oil. These uses are not beneficial in combating hunger. In addition, herbicide-resistant crops are not helpful to poor farmers who rely on manual labour to weed because they cannot afford herbicides. As a result, the immediate markets for transgenic crops in Africa are not subsistence farmers but large farming operations, which may produce for export rather than for local consumption.[12]

1.3 Risks to the environment and biodiversity

Once a GMO is released into the environment, the potential environmental effects are considered to be permanent. The transfer of pollen from a genetically modified crop plant takes place through wind or insects, into other seed-producing fields –even in cases where isolation distances are observed. Moreover, herbicide-resistant crops may entrench farmers' reliance on chemical weed control, rather than encouraging more diverse weed control strategies. Furthermore, pests may rapidly develop resistance to genetically modified insect-resistant crops, rendering them ineffective. This may also render ineffective the Bt insecticide traditionally used by organic farmers as a safe bio-pesticide.

[12] Brian Haliwell, Worldwatch Institute, "Biotechnology, Poverty and Hunger in Developing Nations": submission to the United States Senate Sub-Committee on International Economic Policy, Export and Trade Promotion presented at the hearing on the Role of Biotechnology in Poverty and Hunger in Developing Nations, 12 July, 2000.

1.4 Risks to human health

The techniques used to move genes artificially into a recipient plant include the use of recombinant DNA.[13] DNA techniques use biological vectors such as plasmids and viruses to carry foreign genes into cells. Plasmids, small circular pieces of genetic material found in bacteria, have the ability to cross species boundaries. Viruses are infectious particles that contain genetic material to which a new gene can be added.

Where pathogenic bacteria capable of invading cells are used, the fear is that these can act as vectors for transferring genes into mammalian cells. The concern is that dangerous transgenic DNA can end up in the genome of human cells, which may result in a great deal of genetic disturbance.[14]

Recombinant DNA also transfers marker genes into host cells. Marker genes allow scientists and producers to identify the mutated cells among the billions of others. Where antibiotic marker genes are used, these can spread from the GMO to bacteria and between bacteria, including those associated with infectious diseases. In this way, the use of antibiotic markers may facilitate the spreading of resistance to antibiotics.[15]

The concern with the strongest scientific basis is that people will be allergic to genetically modified food but be unable to avoid them because they are either not labelled or inadequately labelled. Human health and safety are therefore inextricably linked to consumer choice and effective public participation.

1.5 Socio-economic impact

As a result of the landmark court ruling in the United States (US) in *Diamond v Chakrabarty,*[16] the US now allows for the patenting of life forms. This means that US-based multinational corporations involved in the development of transgenic seeds usually hold a patent on their technologies, allowing them not only to charge more for the seed but also to control the use of future generations of seed from those plants.

The biotechnology industry collectively holds at least 36 patents that control either seed germination or other essential plant processes. Patenting these traits also involves patenting the plants that contain them, so others must pay for the right to use them. This also means that farmers may not be allowed to save these seeds. For example, in the US, Monsanto's licensing agreement, which permits only one planting, stopped farmers from using the next-generation seed from crops that survived.[17] Needless to say, this scenario would have devastating effects on household food security in South Africa.

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[13] Recombinant DNA refers to the genetic material inserted into the recipient organisms.
[14] World Scientists Statement, July 1999 http://ww.gene.ch/
[15] Ibid.
[16] 447 US 303 (1980)
[17] Scott Hall, "The Genie in the Bottle: the International Regulation of Genetically Modified Organisms", in *Journal for International Wildlife Law and Policy*, Vol I, Issue 3, 1998.

Although not yet in use, most companies involved in genetic engineering have applied for patents in respect of genetically altered seeds that alter a plant to render its seeds sterile. This technology, dubbed "terminator", is a threat to agricultural biodiversity and to the food security of rural people who rely on farm-saved seed and community plant breeding.

2 Genetic modification in South Africa

In South Africa, genetic modification is being developed primarily for use in agriculture, forestry and food production systems. Although not yet at the forefront of global biotechnology, South Africa has a relatively well-developed biotechnology capacity, with several universities, the Agricultural Research Council (ARC) and the Council for Scientific and Industrial Research (CSIR) participating. Moreover, the so-called "Life Sciences" or "gene giants" – large multinational companies such as Monsanto and Novatis – are also well entrenched and fully operational in South Africa.

Prior to biosafety legislation coming into effect in South Africa,[18] the National Department of Agriculture (DOA) authorised 165 applications for releases of genetically modified food crops into the environment under field-trial conditions during the period 1992 – 1999. In 1998, the DOA authorised the commercial planting of genetically modified insect-resistant maize and insect-resistant cotton. In 1999, several permits were also granted for the importation of genetically modified soy beans for animal consumption.

After the biosafety legislation came into effect in South Africa and during the period January – October 2000, 111 permit applications were lodged with the DOA for various activities, including general releases, field trials, contained use and commodity imports for human and animal consumption. Astonishingly, in so short a period, 105 were granted. Of these:

- only one application has been for locally produced technology;[19]
- at least one permit has been granted for export to Kenya (for herbicide-resistant soy beans, during October 2000);
- at least one application relating to a commodity import from Argentina of herbicide-resistant soy beans for use as food and/or processing for human consumption;
- at least four applications were granted for the importation of soy beans from Argentina for use as animal feed;
- at least one approval was granted for general release, i.e. open planting for commercial purposes of herbicide-resistant cotton for use as fibre and/or food and feed;
- at least 39 applications were granted for field trials for various food crops, including herbicide-resistant maize, herbicide-resistant canola, herbicide-resistant wheat, insect- and herbicide-resistant maize, insect-resistant maize, herbicide-resistant soy beans, insect-resistant cotton, herbicide-resistance cotton, and insect- and herbicide-resistance cotton;
- most of the applicants are the so-called gene giants (less than 20% of the applicants were South African companies and/or research institutions); and
- several permits have been issued in respect of a diverse range of food crops for various broad purposes pertaining to several types of experiments.

[18] The Genetically Modified Organisms Act only came into effect on 1 December, 1999, when the Regulations to give force to the GMO Act came into force – as a result of a huge public outcry.
[19] The rest has been for technology imported from the US, Australia, Argentina and the United Kingdom.

3 The need for a national biosafety regime

Because of the current lack of scientific knowledge concerning the effects of certain engineered genes once they are released into the environment, it is not always possible to anticipate the long-term hazards or to quantify the harm. Moreover, the magnitude and scope of the consequences to human and animal health and to ecosystems may be very serious and the effects irreversible, even if the probability of risk occurrence is low.[20]

It is critically important, therefore, that stringent mechanisms and controls be put in place to:

- evaluate the probability and seriousness of the potential harm; and
- prevent harm to the environment and to human health by regulating the importing, deliberate release into the environment, placing on the market, and the contained use (e.g. laboratory and greenhouse experiments) of GMOs and the products derived from GMOs.

The Convention on Biological Diversity (CBD), which South Africa ratified in 1995, specifically addresses the potential risks associated with genetic engineering. Article 8(g) states that:

> "Each contracting party shall as far as possible and as appropriate … Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."

The Cartagena Protocol on Biosafety has been adopted by the Parties to the CBD. Unfortunately South Africa has not yet signed it.

4 The biosafety regime in South Africa

The need for a biosafety regime is well-recognised in South Africa. Government has, in terms of its National Policy on the Conservation and Sustainable Use of South Africa's Biological Diversity, unequivocally expressed the urgent need to take measures to regulate the transfer, handling, use and release of GMOs in order to minimise the potential risks to biodiversity and human health. Government has, in its policy, further advocated a proactive and precautionary approach with regard to the transfer, handling, use and release of GMOs, taking into account the need to balance the risks associated with GMOs with the potential social, economic and environmental benefits to be derived from them.

The Constitution of the Republic of South Africa is the supreme source of law in South Africa. This means that all laws, policies and governance must be consistent with the

[20] "An Introduction to the Model National Law on Biosafety", drafted by a group of concerned lawyers and scientists who met in Addis Ababa during May 1999, under the auspices of the Organisation of African Unity, and hosted by the Environment Protection Authority of Ethiopia. Hereafter referred to as "OAU Model legislation".

provisions of the Constitution. Several rights enshrined in the Constitution have direct relevance to biosafety. These include:

- The Environmental Rights set out in section 24 of the Constitution. In terms of this section, every person has the right to an environment that is not harmful to health or well-being. This section clearly links the environment to human health and well-being. It also entrenches "inter-generational equity", i.e. the right to have the environment protected for the benefit of present and future generations. Moreover, the section places obligations on the State to take action to protect the environment.

- Section 33 deals with just administrative action and requires that it be lawful, reasonable and procedurally fair. "Reasonableness" of decision-making means that the opportunity exists for substantive review of administrative decisions. The Promotion of Administrative Justice Act, No 3 of 2000, has been enacted to give effect to this right. At the time of writing this report, it was not yet in force.

- Section 32 guarantees the right to access to any information – required for the exercise or protection of any rights – held by the State and by any other person. The Promotion of Access to Information Act, No 2 of 2000 has been enacted to give effect to this right. It came into force on 9 March, 2001.

- Section 38 does away with the notion that a person only has the legal standing to institute legal action if that person has a direct, substantial interest in the relief sought. Section 38 allows someone acting in the public interest to approach a court for relief.

As stated in the preceding sections, the biosafety regime in South Africa is constituted primarily by the Genetically Modified Organisms Act, No 15 of 1997, the Environment Conservation Act, No 73 of 1989, the Foodstuffs, Cosmetics and Disinfectants Act, No 54 of 1971, and the National Environmental Management Act, No 107 of 1998.

4.1 The Genetically Modified Organisms Act

4.1.1 Objectives of the Act

The preamble to the Act establishes its general ethos by subsuming the need for biosafety with the imperative to promote biotechnology. In this regard, the preamble makes reference to "promote the responsible development, production, use, and application of GMOs". It is entirely unsatisfactory that the legislation should have as its objective the promotion of the very technology it is trying to regulate.

It would have been far more appropriate to state that the objective of the Act is to regulate biotechnology comprehensively in order to ensure that it does not cause harm to the environment or to human and animal health.

Furthermore, the preamble talks about ensuring that all activities involving the use of GMOs are carried out so as to limit possible harmful consequences to the environment. "Limiting harmful consequences" suggests that certain levels of foreseeable risks and harm are acceptable.

It is also significant that no explicit reference is made to the risks of GMOs to human and animal health.

4.1.2 Scope

The Act applies only to viable, living GMOs and not to the products derived from them. Products of GMOs include, for example, flour made from transgenic maize or soya, tomato sauce, and eggs from chickens fed on transgenic maize. Emerging scientific evidence shows that a considerable amount of the recombinant DNA persists in products such as soy proteins derived from transgenic soya. This can be transferred to the microflora in the intestinal tract of humans and animals, and thereafter to the environment, including soil and water systems.

Similarly Bt toxin products derived from transgenic Bt corn remains active. Antibiotic resistance marker genes used in the development of, for instance, maize gluten feed, are capable of promoting resistance to antibiotics and result in infectious diseases, including new diseases.

Products of GMOs *per se* are not regulated by any specific legislation. Rather, where the products are produced locally, biosafety testing of the GMO from which the products are derived is conducted under the GMO Act.

Products derived from imported GMOs are not subjected to specially tailored safety testing and in this regard, the Government invokes the substantial equivalence test. Substantial equivalence embodies the concept that "if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety".[21] These "tests" have been heavily criticised as being unscientific and arbitrary and therefore open to a range of different interpretations.[22] It has also been pointed out that there are no defined tests to establish substantial equivalence for prodicts. [23]

4.1.3 Core regulatory provisions

4.1.3.1 Regulatory authority

The Act establishes, as the key regulatory authority, the Executive Council of Genetically Modified Organisms ("the Council"), which comprises an officer each from several departments having an interest in GMOs (but excluding the Department of Water Affairs and Forestry). The requirement is that each member have knowledge of the implications of GMOs in respect of the sector represented by his or her department. The Council is empowered to recommend appointments to the Advisory Committee.[24]

[21] Mae-Wan Ho and Richarda A Steinbrecher, "Fatal Flaws in Food Safety Assessment: Critique of the Joint FAO/WHO Biotechnology & Food Safety Report", *TWN Biotechnology & Biosafety Series 1*.
[22] Ibid.
[23] Ibid.
[24] Section 5(n).

The Council is the key decision-making body for the granting of permits.

The Council also acts as an advisory body to the Minister of Agriculture on such issues as prohibitions, control of imports, etc,[25] presumably to aid him in setting out regulations.[26]

4.1.3.2 Advisory Committee

The Act establishes an Advisory Committee ("the Committee") with which the Executive Council is obliged to consult before granting approvals. The Committee consists of ten members, eight of whom are required to have knowledge in those fields of science applicable to the development and release of GMOs. There are also two members from the public sector who are required to have knowledge of ecological matters and GMOs [own emphasis].[27]

The requirement that the majority of the members hail from the scientific community could hamper future efforts to assess the full implications of the introduction of GMOs into the environment. GMOs interact in a complex way, requiring a multi-disciplinary approach in order to assess the potential risks. It is desirable that appointed committee members have expertise in:

- the class or order of the host and donor family, genus or species to be introduced; and
- the dynamics of the receiving environment, including those which may potentially be affected.[28]

The provisions, and peremptory language, of section 11(1)(d) of the GMO Act may go some way towards remedying this defect, as it allows the Committee to invite written comments from knowledgeable persons on any aspect of the GMOs within the Committee's brief. The need for a standing and expanded multi-disciplinary panel of experts remains an indispensable requirement, however.

The inclusion of the phrase "public sector" is odd: why should an advisory committee have further Government representation, especially since Government is fully represented on the Council? More worrying, however, is why civil society participation has been excluded. This is perhaps one of the most serious shortcomings of the Act and is inconsistent with the tenets upon which South Africa's fledgling democracy has been built, and with the principle of public participation in environmental governance advocated by Government policy.

4.1.3.3 Risk assessments

[25] Section 5(m).
[26] Under section 20.
[27] Section 10.
[28] Section 19(5) of the OAU Model legislation.

The GMO Act prohibits any person from undertaking any activity[29]involving genetic modification unless a suitable and sufficient assessment of the risks created thereby to the environment and to human health has been made.[30] The GMO Act does not set out the principles and parameters of the risk assessment. The implication is that the Guidelines produced by the South African Committee on Genetic Experimentation (SAGENE) are to be used in this regard. The SAGENE Guidelines are made up of: UK Risk Assessment Guidelines; Guidelines for the Trial Release of GMOs; Procedures for Assessment of the Planned Trial or General Release of GMOs; and Questionnaires for Trial and General Releases of GMOs.

It is unacceptable that Guidelines are used as a basis for risk assessment. The risk assessment parameters should, more appropriately, be an integral component of the GMO Act, for instance as an annexure or set out in Regulations. As it stands now, it lacks the full force of the law. It is also not readily accessible to the public. It must also be pointed out that many parts of the SAGENE Guidelines have yet to be completed.[31]

This scenario is particularly worrying since section 20(1)(b) of the Act clearly contemplates that the Minister would make Regulations "prescribing the procedure to be followed by an applicant for the purpose of drawing up risk assessments and environmental impact assessments …" The DOA does not seem ever to have called for an assessment of environmental impact. It is also significant to note that the Act does not allow the Council to make its decisions based on risk assessments carried out by anyone other than the applicant.[32] This means that, strictly speaking, the Council is unable to base its decision on an independent risk assessment. It is obliged, however, (as already mentioned) to consult the Committee. The Committee in turn must invite written comments from "knowledgeable persons" on any aspect of GMOs within its brief.[33]

4.1.3.4 Notification and public participation

A critically important component of any biosafety approval system is "notification" by the person making an application for a permit. "Notification" in biosafety parlance refers to the information the applicant is under a legal obligation to supply to the competent authority, together with the risk assessment report. Examples of the nature and extent of the information the applicant is required to furnish is set out in the OAU Model legislation as including information relating to:

- the GMOs or products thereof;

[29] Activity is defined in the Regulations as "work undertaken with regard to the development, production, use and application of genetically modified organisms".
[30] Regulation 3(1).
[31] Part 2C: "Risk Assessment of Work with Genetically Modified Plant Viruses"; Part 2D: "Risk Assessment of Work with Genetically Modified Plants"; Part 2E: "Risk Assessment of Work with Genetically Modified Animals"; Part 3B: "Glasshouse/Growth Room Containment" and Part 3C: "Containment and Control Measures for Transgenic Animals and Animals Infected with GMMs" all need to be completed.
[32] Section 5(a), read together with section 5(g) of the Act.
[33] Section 11(1)(d).

- the conditions of release, contained use or placing on the market and, where appropriate, the receiving environment;

- the interaction between the GMOs or their products and the environment; and

- monitoring, control, waste treatment and emergency response plans, etc.

The "notification" process is closely linked to public participation insofar as the public should be kept informed of the status of approvals, be furnished with the information supplied under the "notification" process and be given an opportunity to submit comments. These comments should be factored into the decisions of the competent authority. This consultation process is a critically important component of environmental governance and environmental justice; concepts well-recognised and frequently used in South African legislation.

In sharp contrast to the scenario sketched above, the GMO Act is silent on the question of notification in this sense. It is entirely possible that certain information may be required to be furnished by the applicant when making application for a permit, but this is not specifically provided for in the legislation as it now stands.

However, section 18, which deals with confidentiality, provides that the Council cannot keep the following information confidential:

- the description of the GMO, the name and address of the applicant for the permit, the purpose of the contained use or release and the location of use;

- the methods and plans for monitoring the GMO and emergency measures in case of accidents; and

- the evaluation of foreseeable impacts, in particular ecologically disruptive ones.

If the Council did not receive this information in the first instance, it would not be able to fulfil its obligation to disclose such information.

The Act deals with notification and public participation only in the context of permit applications. In this regard, an applicant who wishes to apply for a permit to release GMOs into the environment, is obliged to notify the public prior to making application by way of publishing this intention in at least three newspapers circulating in the area in which the proposed release is to take place. The following information must appear in the newspapers:

- the full name and address of the applicant;

- a full description of the GMOs the applicant proposes to release;

- a description of the proposed trial release, including the area and environment in which the release is to take place;

- a request that interested parties submit comments or objections in connection with the intended release to the Registrar within no less than 30 days from the date of the notice; and

- the address of the Registrar[34].

The Executive Council is obliged to consider all comments and objections.[35]

The provisions of the GMO Act relating to notification and public participation are inadequate for the following reasons, among others:

- These provisions only apply to an application which results in a GMO being released into the environment.

- Notification will not be given to members of the public at large, but only to those in the area in which the proposed release is to take place. This is unsatisfactory, since the risks arising from the release of GMOs are of national importance.

- The information comprising this type of "notification" is hopelessly inadequate in terms of the public's participating in any meaningful way. At the very least, the risk assessment report should be made available to members of the public for scrutiny during the 30-day period. Critically important, too, is unequivocal access to information about where, and for what purposes, the GMO will be marketed. Access to the risk assessment report is not expressly provided for in, or guaranteed by, the GMO Act. The current provision regarding access to information in connection with the purpose of the release is too tenuous, as the Executive Council may withhold such information, after it has consulted the applicant, in order to protect the intellectual property rights of the applicant.[36]

In fact, the Executive Council is obliged to consult the applicant in order to decide which information should be kept confidential.[37] It appears as if the intention of the GMO Act is to preclude the public from gaining access to information on the potential or likely impact and risks posed by the GMO in question to human and animal health, biological diversity and the environment; the Act appears to create the right of access only to information regarding the "evaluation of foreseeable impacts, in particular any pathogenic or ecological disruptive impacts". This right is also watered down. The Executive Council may, after consultation with the applicant, withhold the information in order to protect the intellectual property rights of the applicant.[38] It should, nonetheless, be borne in mind that the notion of what is "foreseeable" is subject to change and will be influenced by international developments. It may certainly be argued that this provision of the GMO Act is unconstitutional as it falls foul of the public's right of access to information held by the State. The provisions of

[34] Regulation 6.
[35] Regulation 6(7).
[36] Section 18(2)(a) read together with section 18(3) of the GMO Act.
[37] Section 18(2) of the GMO Act.
[38] Section 18(2)(a), read together with section 18(3) of the GMO Act.

section 32 of the Constitution, relating to access to information, and the Promotion of Access to Information Act would apply instead.

4.1.3.5 Decision-making

The decision whether or not to grant a permit is exercised by the Council, after consideration of the risk assessment and environmental impact assessment, where this has been required. Such approval may be subject to any conditions the Council may deem necessary. The Council makes its decision in consultation with an Advisory Committee (see below). The Registrar issues the permits.

It is trite that the Council must, in terms of the Constitution[39] ensure that its decisions are lawful, reasonable and procedurally fair.

4.1.3.6 Applying the Precautionary Principle

The Convention on Biological Diversity, to which South Africa is a party, obliges parties to heed the Precautionary Principle. The preamble to the Convention expresses the Precautionary Principle as follows: "the lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise a threat of significant reduction or loss of biodiversity."

The Government's Environmental Management Policy is very clear in this regard. In relation to the Principle of Precaution, it says:

"Government will apply a risk averse and cautious approach that recognises the limits of current knowledge about the environmental consequences of decisions or actions. This approach includes identifying:

- the nature, source and scope of potentially significant impacts on the environment and on people's environmental rights;
- the potential risks arising from uncertainty; and
- where there is uncertainty, what action should be taken to limit the risk. This should include considerations of the 'no go' option" [own emphasis].

The Cartagena Protocol sets out the Precautionary Principle as follows:

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into account the risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the living modified

[39] Section 33 of the Constitution.

organism in question … in order to avoid or minimise such potential adverse effects."[40]

Notwithstanding this, the drafters of the GMO Act have seen fit to render the application of the Precautionary Principle ineffective by the following formulation:

"Lack of scientific knowledge or consensus on the safe use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk,"[41]

This effectively means that lack of scientific knowledge or consensus on the safe use of GMOs is not relevant, or should not be taken into account in the assessment of risk. In other words, lack of scientific knowledge or consensus is neutral.

Provision is made to give the Council discretionary power, when considering an application for the importation, use, distribution or release of a GMO, to "consider the socio-economic impact that the introduction of a GMO may have on community living in the vicinity of such introduction."[42]

Although an innovation, this provision is rather limited in its scope as only the socio-economic impact on a community living in the vicinity is required to be taken into account. It is disappointing that Government has not considered it important enough to oblige the Executive Council to take into account the impact of a release of GMOs on traditional crops and technologies and the social and economic costs resulting from the loss of genetic diversity.

4.1.3.7 Fast track mechanisms

The Act establishes a registrar who is tasked with administering the Act. The Registrar is imbued with wide discretionary powers to "fast track" any application for an activity involving GMOs for which a permit has previously been granted. What this means is that, for instance, if an import permit has already been granted in respect of the importing of a particular GMO, particularly a GMO commodity (e.g. GM maize imported for animal consumption), then further imports of the same GMO may be approved without the need for producing a risk assessment for every shipment.

There is nothing in the GMO Act which obliges the Registrar to call for a fresh/updated risk assessment should the purpose for importing the GMO change. Moreover, since the public participation mechanism is triggered only when an application for a permit is made (see discussion in 4.1.3.4), the public will not know the quantities being imported of the same GMO over a given period of time or the purpose for which the GMO is being imported. Regulatory control and monitoring will therefore be affected.

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[40] Article 10(6).
[41] Regulation 3(2).
[42] Regulation 5(9).

4.1.4 Application of the Act: exclusions from permit requirements

4.1.4.1 Contained use

A comparative study of international biosafety laws was conducted in preparation for this paper, and it was found that the vast majority require step-by-step approvals of GMOs. This means that releases of GMOs are approved first for the activity under contained-use conditions (laboratories, greenhouse experiments, etc), then for open field trails and then there is authorisation for fully fledged commercial releases. Authorisations are required for each stage of the process, which means that at every stage the activity is monitored for risks.

The South African GMO Act does not require authorisation for GMOs under contained-use conditions. Rather, the facilities where the GMOs are being developed, produced, used or applied under contained-use conditions appear to require registration.

4.1.4.2 Academic or research facilities

Institutions such as academic or research facilities are exempted from the permit requirements of the Act, provided that their activities in relation to GMOs are conducted under contained-use conditions. The requirements for the registration of facilities do not go far enough to ensure that abuses and circumvention of the stated purpose of the research do not take place.

Section 5(c) vests the Council with a discretion to require the Registrar to maintain a register of all facilities involved in the contained use or trial release of GMOs, as well as the names and addresses of persons concerned with such contained use or trial release. Regulation 4(1) provides that all "facilities" must be registered with the Registrar. "Facility" is defined to mean "any place where organisms are being genetically modified under conditions of contained use".

The implication, then, is that the provisions are mandatory and not discretionary. Serious attention should be given to the calls by the European Society of Chartered Surveyors (ESCS) to the European Union (EU) to establish registers of land growing commercially approved GM crops in all member states. The ESCS believes that such a register would provide a robust system of traceability for GM crops and food, necessary to:

- address environmental and health problems arising from GM crops after approval; and

- protect farmers, food processors and retailers wishing to supply GM-free food products.[43]

[43] For further information, see http://www/gene.ch/

4.1.4.3 GMOs that have been cleared for commercial release and/or food and animal feed

GMOs that have been "cleared for commercial release and/or for food and animal consumption only" do not require a permit, in terms of the Act. Such GMOs will be placed on Table 3 to the Regulations. This mechanism is meant to serve as an exclusion list to fast track commercial releases of GM seed, food and animal feed and especially to expedite the trade in GMOs.

It is important to note that no specific decision-making mechanism is set out in the Act or in the Regulations regarding this category of GMO. Furthermore, the provisions in the Act that deal with public participation are inextricably linked to permit applications, as is more fully discussed below. This means that decisions can be made – out of the public eye and without the knowledge of the public – to approve any GMO, whether locally produced or imported. Moreover, this can be achieved without there being a need, strictly speaking, to abide by the decision-making procedure of the Act.

Hence, the mechanism created here as a potential exclusion can render the Act meaningless.

4.1.5 Liability

First leg

The liability provisions of the GMO Act have caused a great deal of concern and controversy. A blanket obligation is created for users to ensure that appropriate measures are taken to avoid an adverse impact on the environment, which may arise from the use of GMOs.[44] This obligation is, in the first instance, confined to the "environment" with no express reference to human or to animal health. "Environment" is defined as "the aggregate of surrounding objects, conditions and influences that influence the life and habitats of man or any other organism or collection of organisms".[45] This does not appear to contemplate the harm to human or animal health arising from the consumption of GMOs.

"User" is defined in the Act as "any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end-user or consumer." It could be argued that this obligation will rest with the proponent of the GMO during field trials, but that it is then passed on to the farmer or consumer, as the case may be, once the GMO is commercially released.

The appropriate measures to be taken are not spelt out in the Regulations, as would have been expected. This means that, at least for the purposes of the GMO Act, the user will determine which measures are appropriate in the circumstances. It is anticipated that

[44] Section 17 of the GMO Act.
[45] Section 1 of the GMO Act.

enforcement of the duty of care provisions contained in section 28 of NEMA will be required in these circumstances.

Second leg

The user concerned is liable for damage caused by the use or release of a GMO. What damage is contemplated here? Since the first leg is confined to the impact on the environment, it can be argued that the intention of the legislator is that the damage be confined to environmental damage. What appears to be contemplated here is that damage caused to the environment from GMOs under contained-use conditions or during field trials will be borne by the research institution/biotechnology company concerned. Farmers or other land users, however, will be liable for environmental damage caused by the use of GMOs when planted in the open.

The liability contemplated here appears to be strict liability, as there is no need to prove fault. It will be up to the user to prove that appropriate measures were taken to avoid an adverse environmental impact.

Redress for environmental damage is not addressed in the GMO Act. It has been recommended that redress should include the cost of reinstatement, rehabilitation or cleaning up actually incurred or to be incurred and, where applicable, the costs of preventative measures and any loss or damage caused by the taking of such measures.[46] However, the relevant provisions contained in section 28 of NEMA in respect of redress will apply.

4.1.6 Other pertinent provisions

4.1.6.1 Unintentional release and emergency measures

The Regulations to the GMO Act put an obligation on the user to provide certain information to the Registrar immediately, should an accident occur involving GMOs.[47] "Accident" is defined as "any incident involving an unintended general release of genetically modified organisms, which could have an immediate or delayed adverse impact on the environment."[48]

It is appropriate and necessary that further regulations be set down to address the measures an applicant should be required to take when an accident occurs, and that the public has knowledge of such measures. Indeed, it has been recommended that, before any release is made or contained use is carried out, an emergency plan should be required to be drawn up for the protection of human and animal health, biological diversity and the environment.[49]

4.1.6.2 Revocation of authorisation

[46] Gurdial Singh Nijar, "Model National Biosafety Law", Third World Network.
[47] Regulation 7.
[48] Section 1 of the GMO Act.
[49] Nijar op cit.

The applicant is obliged to inform the Registrar immediately of any change in the information provided when the application was submitted.[50] The Registrar is in turn obliged to send this information to the Executive Council, who may require the applicant to make a fresh application. These provisions are not entirely acceptable as they do not go far enough in obliging the Executive Council to review its decision, especially when the change in information relates to possible risks to human or animal health, biological diversity or the environment.

4.1.6.3 Risk management measures

The hallmark of all responsible safety legislation is that it provides for the taking of risk management measures to ensure that monitoring of the activity continues after approval has been granted. The objective of risk management is to identify risks and regulate them, with the aim of reducing the risk. There is nothing in the GMO Act that places a clear and unequivocal responsibility on the applicant to take such measures. It could be argued that risk management will be invoked as part of the permit conditions, but this makes monitoring by civil society both difficult and onerous.

4.1.6.4 Labelling

The issue of labelling is not dealt with in the Act. It is left up to the Department of Health to deal with the labelling of GMOs and products of GMOs, under an entirely different piece of legislation, namely the Foodstuffs, Cosmetics and Disinfectants Act. (See discussion in 4.3.2, p43.)

4.1.6.5 Inspections

Although the Act provides for routine inspections to ensure compliance with the provisions of the Act and permit conditions, inspections are random and irregular. [51]

4.1.6.6 Prohibition of activities

Section 14 of the Act allows the Minister to prohibit any activity involving GMOs. There is no provision, however, for the Minister to ban a GMO. The power to ban a GMO is absolutely vital because it is entirely possible that certain GMOs may express traits that are harmful enough to be prohibited. For example, GMOs containing antibiotic resistance marker genes are known to pose serious risks to human health.

4.1.6.7 Appeals

Any one who feels aggrieved by a decision of the Executive Council has a right to appeal against such decision to the Minister of Agriculture[52] within 30 days from the

[50] Regulation 5(10).
[51] Personal communication, Kele Lekoape.
[52] Section 19(1) of the GMO Act.

date on which the appellant was notified in writing of the decision or action concerned.[53] Obviously, the drafters should have used the word "applicant" to convey the notion that not only the applicant will lodge appeals against decisions of the Council.[54] Assuming that the reference to "appellant" is meant to include a person, other than the applicant, who wishes to lodge an appeal, the problem with this provision is that the general public will not know when the Executive Council has communicated its decision to approve releases or imports to the applicant. The onus is placed on the public to find out when the applicant was notified of the decision of the Executive Council in order to lodge an appeal timeously. Failure to lodge the appeal within the 30-day period could mean that the appeal will not be heard. The Regulations do not set out any procedures for late appeals.

The appeal will be heard by an appeal board, consisting of at least one person, appointed by the Minister, who has expert knowledge or is otherwise suitable to hear the appeal.[55] The decision of the appeal board is not final and is referred to the Minister in writing, together with reasons. The Minister may then take any further action he or she deems necessary. However, the matter does not really end here because the provisions of section 17 of NEMA may be invoked at this stage.[56] The Minister may, before reaching a decision, consider the desirability of first referring the matter to conciliation.

4.1.7 Exporting and importing GMOs and the implementation of the Cartagena Protocol on Biosafety

At present, the importing and exporting of GMOs are regulated by the GMO Act, read together with the Regulations. In this regard, import and export permits are required before GMOs can be traded.

On 29 January, 2000, in Montreal, Canada, the Protocol on Biosafety to the Convention on Biological Diversity ("Cartagena Protocol" or "Protocol")[57] was adopted by the Conference and parties to the Convention. The objective of the Protocol is to ensure an adequate level of protection for the safe transfer, handling and use of living modified organisms (LMOs)[58] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.[59]

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[53] Regulation 9(1)(a).
[54] Telephonic discussions with Muffy Koch (Ex-SAGENE) and Kele Lekoape (DOA) on 10 and 11 February, 2000, respectively.
[55] Section 19(2)(a) of the GMO Act.
[56] Section 17(1), read together with section 17(1)(b) of NEMA which allows any Minister before whom an appeal arising from a difference or disagreement regarding the protection of the environment is brought under any law may, before reaching a decision, consider the desirability of first referring the matter to conciliation.
[57] UNEP/CBD/ExCop/2/.5, 28 January, 2000.
[58] It must be noted that, instead of GMO, the term LMO is used, this being the parlance of the Protocol. However, because the definition of LMO is largely consistent with that of GMO in the GMO Act, the term GMO will be consistently used in this paper, except where the phrases or provisions are quoted.
[59] Article 1.

The Protocol deals with, *inter alia*, establishing an advanced informed agreement procedure, setting minimum standards for the use of LMOs as food or feed, risk assessment, risk management, and public awareness and participation.

The adoption of the Protocol is seen by many as a significant breakthrough. It enshrines the "precautionary approach" as a principle of international environmental law and puts the environment on a par with trade-related issues in the international arena. Non-governmental organisations (NGOs), which are concerned that GMOs may have potential negative impacts on the environment, biodiversity and human health, view the Protocol as historic. This is the first time that an international agreement has recognised GMOs as distinct and inherently different and thus requiring a special regulatory framework.[60] For the majority of the developing countries that participated in the negotiations, the Protocol vindicates their persistent demands for a specially tailored international environmental agreement to set international minimum safety standards in order to regulate the trade in GMOs, particularly in the face of increasing world trade liberalisation.

As a party to the Convention on Biological Diversity (CBD), South Africa participated fully and actively in the painstaking process of negotiating the Protocol. The Protocol was opened for signature during May 2000, at the fifth Conference of the parties held in Nairobi, Kenya. Regrettably, South Africa failed to sign the Protocol. By 6 March, 2001, 87 parties had become signatories, two of which have been ratified. The Protocol will come into force after the 50th signatory has ratified it.

Once South Africa ratifies the Protocol, the GMO Act will have to be amended substantially to give effect to the Protocol. It is beyond the scope of this paper to deal comprehensively with the extent to which the GMO Act would have to be amended in order to do so. Only the most important issues are discussed here.[61]

4.1.7.1 The Advance Informed Agreement (AIA)

The most significant amendment to the GMO Act would be the adoption of the Advance Informed Agreement (AIA) Procedure of the Protocol. The AIA Procedure is the core regulatory mechanism of the Protocol and comprises three basic steps. The first concerns certain prescribed and standardised information required to be furnished by either the exporting country or the exporter to the authorities in the importing country. This mechanism is also referred to as "notification" and is set out in Article 8, read together with Annexure I of the Protocol. The second step concerns the acknowledgement of receipt of notification and is set out in Article 9. The third and final step deals with decision-making.

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[60] Statement made by international environmental lawyer, Chee Yoke Ling from the Third World Network, on behalf of NGOs, immediately upon the Protocol's being adopted, Montreal, 28 January, 2000.

[61] For an in-depth discussion of the extent to which the GMO Act will have to be amended to give effect to the Protocol see M Mayet, "Implementing the Biosafety Protocol in South Africa: Implications for Current Legislation: A Briefing Document", prepared for the Department of Environmental Affairs and Tourism: Directorate Biodiversity Conservation.

For the purposes of the application of the AIA Procedure to the importing and exporting of LMOs, the Protocol distinguishes between LMOs that are traded for direct introduction into the environment and those that are "commodities", i.e. intended for direct use as food, feed or processing (FFP-LMOs) such as genetically modified canola, soy beans, maize and potatoes.[62]

To this end, the AIA Procedure only applies to the first transboundary movement of LMOs intended for direct introduction into the environment (Article 7(1)). In other words, a particular genetically modified seed, imported for the first time for planting in the open under field trial conditions or for commercial release, will be subject to the AIA Procedure.

The AIA Procedure does not apply outright to subsequent imports of the same LMO. Arguably, parties may apply the Procedure to subsequent imports of the same LMO for the same purpose, in terms of section 2(4) of the Protocol. Section 2(4) affirms the right of a party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol, provided that such action is consistent with the objective and provisions of the Protocol and is in accordance with the party's obligations under international law.

In order to implement the AIA procedure, the GMO Act would have to:

- ensure that the AIA Procedure applies, at the very least, to the first transboundary movement of GMOs intended for direct introduction into the environment;

- set out the notification procedure in detail, particularly the information that has to be provided, as set out in Annexure I to the Protocol;

- expressly set out the risk assessment the importer must conduct, and in this regard Annexure II of the Protocol should be used as minimum standards or provisions that entail a higher level of protection;

- revise the current time frames, which raise serious doubts as to whether a proper determination can be made of the risks involved in the time set out in the Act, namely 30 days. Currently, this time frame is weighted in favour of expediting trade in GMOs rather than ensuring that adequate time is spent in assessing potential impacts on the environment, biodiversity and human health; and

- redraft the Precautionary Principle in the Regulations, to at least mirror that of the Protocols.

4.1.7.2 Contained use

A special set of provisions for contained use has been created under Article 6(2). It provides as follows:

[62] Article 7 of the Protocol.

- parties may subject LMOs destined for contained use to risk assessment prior to decisions on importing; and

- parties may set standards for contained use within their jurisdiction.

The provisions set out above are affirmations of what parties may do in the exercise of their sovereign rights in order to protect the environment, biodiversity and human health.

The AIA Procedure does not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the party of import.

This fact is crucial. The AIA Procedure is drafted in ambiguous language and it is not clear whether two different procedures have been created for the trade in LMOs destined for contained use. It appears as if there is a choice: either the AIA Procedure of the Protocol may be used for transboundary movements of LMOs destined for contained use, or the transboundary movement can take place in accordance with the standards set by the importing party, in which case, there will be an implied waiver of the AIA Procedure.

It is also not clear what is meant by "standards for contained use". This could refer simply to the standards that a research institution or other facility must meet before it is allowed to use LMOs under contained-use conditions, or it could entail comprehensive biosafety standards for contained use.

The definition of "contained use" in the Protocol is also of great importance. It is defined as:

"any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".

It has been pointed out that the definition is far too broad, as it encompasses several kinds of deliberate releases into the environment, including the following:

- caged transgenic fish or other aquatic LMOs in open ponds, lakes and marine environments;

- vaccinations with transgenic viruses and naked nucleic acid vaccines;

- all forms of gene therapy;

- xenotransplantation using transgenic animal organs;

- open field trials with fencing or other physical barriers;

- transgenic organisms enclosed in cages or other containers and destined for deliberate release;

- liquid and solid wastes of transgenic livestock contained in the laboratory; and

- liquid and solid wastes from laboratories creating transgenic organisms destined for deliberate release.[63]

In terms of the GMO Act as it now stands, GMOs destined for contained use can enter the country without a permit, provided that a risk assessment is conducted in terms of the Act prior to such importation. It appears that, as long as the risk assessment contains some standards for contained use, the provisions of the Protocol will be fulfilled and in this regard, the AIA Procedure of the Protocol will probably not apply. This is especially so since there is no express provision in the Protocol requiring the AIA Procedure to apply to the importation. Moreover, if exporting parties adopt the Protocol's flawed definition, it will then be possible for GMOs destined for contained use in South Africa to be traded as such, but be deliberately released into the environment here.

A policy decision will have to be taken as to whether the current regulation of imports of GMOs destined for contained use should be revised in order to ensure that the AIA Procedure applies to it. The Protocol's flawed definition of contained use justifies a decision to this effect because GMOs destined for contained use, as defined by the Protocol, can also be deliberately released into our environment.

In this regard, as a general rule, GMOs imported for use in contained-use conditions should be treated as LMOs intended for direct introduction into the environment, as contemplated by Article 7(2) of the Protocol.

Exceptions to this can, however, be provided for in the Act in instances where the GMO can clearly not be released into the environment. It must be pointed out that South Africa is entitled to establish higher levels of protection, as contemplated by Article 2(4) of the Protocol.

4.1.7.3 Internet Biosafety Clearing House mechanism for GM commodities

As already mentioned, the AIA Procedure does not apply to the trade in LMOs FFPs (LMOs that are traded for food, feed and processing, hereafter referred to "commodities"). Rather, the Protocol has created an Internet-based Biosafety Clearing House (BSCH) to "regulate" the trade in such GMOs.[64] This is basically a website administered by the Secretariat to the CBD.

For trade in commodities, the exporter must place on the BSCH, as a bare minimum, the information specified in Annexure III to the Protocol within 15 days after the

[63] "The Core Issues in the Biosafety Protocol: an Analysis", by Lim Li Lin, quoted in *Third World Resurgence*, Issue No 114-115.
[64] Article 20 of the Protocol.

party of export has approved the GMO for domestic use, including placing it on the domestic market of the party of export. This separate Annexure contains less information than the Annexure II risk assessment for GMOs intended for direct introduction into the environment.

The party of export will then have to track and locate the particular shipment from the BSCH. This procedure assumes that the party of import will have prior knowledge of the country of origin of the export in order for it to effectively track and locate the particular shipment, without having to vet each and every exporter who is obliged to place information on the BSCH. In other words, the party of import will have to check every entry on the BSCH in order to avoid shipments slipping through the net. A party may declare to the BSCH its intention to approve a particular commodity for importation, in which case it must take a decision to import within 270 days from such declaration.

Significantly, however, import decisions may be based on the Precautionary Principle. Express consent is also required for the importation of commodities.

Although a party of import may also request additional information, this presupposes that the party of import will have the capacity and resources to examine carefully the information provided in accordance with Annexure III, and to analyse the additional information further. In order for a party to utilise this procedure, it will have to employ a full-time phalanx of monitors and analysts to painstaking read and analyse the information and documents supplied.

The GMO Act does not have a special procedure for commodities. South Africa is, arguably, allowed to require the AIA Procedure to apply to commodities in terms of Article 2(4) which allows a party to take more stringent measures than those provided for by the Protocol in order to protect biodiversity and human health. However, if it does so, it will have to ensure that such regulation is consistent with the objective and provisions of the Protocol and is in accordance with its other obligations under international law.

Policy decisions must be taken regarding the regulation of commodities. The BSCH is not an adequate procedure to ensure biosafety; neither is the exclusion of the GMO Act already discussed. One possibility is that a third mechanism be created for the regulation of commodities in accordance with the latitude provided by Article 2(4) of the Protocol, which allows a party to take action that is more protective of biodiversity than provided for in the Protocol. This could be a combination of the AIA Procedure, especially the use of Annexure II dealing with risk assessment, and appropriate fast-track mechanisms.

4.1.7.4 GMO pharmaceuticals for humans

The Protocol excludes from its purview the transboundary movement of genetically modified pharmaceuticals for human use which are addressed by other relevant international agreements or organisations.[65] The sovereign right of parties to subject all GMOs to risk assessment prior to making decisions on importation is reaffirmed by the Article, but GMO pharmaceuticals for animals clearly fall within the purview of the Protocol.

GMO pharmaceuticals include the following:

- edible vaccines (i.e. potatoes, bananas);
- viral vaccines;
- naked viral genome vaccines;
- naked viral vectors for gene therapy;
- naked DNA vaccines and vectors; and
- naked nucleic acid vectors and vaccines.

The question to ask is under which circumstances, if any, the Protocol will apply to pharmaceutical GMOs for human consumption. The answer to this question will depend on the interpretation given to "addressed" and "other international organisations". "Addressed" could mean anything from legal regulation to codes of conduct, standards or guidelines. The phrase "other international organisations" arguably refers to the World Health Organisations (WHO). The WHO does not deal with GMOs that are pharmaceuticals. It sets standards for human health and safety, and its focus is therefore not on impacts on the environment and human health, because it is essentially an international body that sets food safety standards.

The exclusion of the transboundary movement of genetically modified pharmaceuticals for human consumption from the ambit of the Protocol means that non-binding and, possibly, inadequate and inappropriate standards may apply to this category of GMOs.

The exclusion of pharmaceuticals from the purview of the Protocol also means that many other relevant and pertinent provisions, such as a future redress and liability regime, will not apply to this category of GMOs.

The GMO Act does, however, apply to pharmaceuticals for humans. The lack of clarity regarding the wording of Article 5, combined with the problems associated with the WHO, appear to support a recommendation to keep pharmaceuticals for humans within the scope of the GMO Act. South Africa is entitled, in terms of Article 2(4), to

[65] Article 5.

provide for a greater degree of protection than that provided by the Protocol. A greater degree of protection may be appropriate and justifiable, given that recent scientific studies indicate a number of potential environmental and health hazards arising from pharmaceutical GMOs. For example, naked viral genomes are said to be more infectious than the intact virus; naked viral vectors for gene therapy are intended to be incorporated into cellular genomes to be replicated, whether intended or not; etc.

It is clear that the GMO Act will have to be amended substantially in order to give effect to the provisions of the Protocol. Many policy decisions must also be taken, especially regarding the setting of higher biosafety standards, based on the Precautionary Principle, especially since the Protocol merely sets minimum international standards.

4.2 The Environment Conservation Act (ECA), No 73 of 1989

4.2.1 Environmental Impact Assessments

Environmental Impact Assessments (EIAs) are seen as the core regulatory mechanism for identifying, assessing, preventing and mitigating against adverse environmental effects. EIAs were introduced into South African law by Regulations[66] promulgated under section 26, read together with section 21 of the Environment Conservation Act (ECA). The Regulations came into force on 1 April, 1998.

The provisions of sections 21 and 22, read together with the Regulations, make it mandatory for EIAs to be undertaken in respect of "the genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism".

The Regulations do not define "genetic modification" but an attempt is made in this regard in the April 1998 Guideline Document for EIAs issued by the Department of Environmental Affairs:

> "Any experimental or industrial technology used to alter the genome of a living cell so that it can produce more or different chemicals or perform new functions; or
>
> the manipulation of genes in ways that by-pass normal sexual or asexual transmission.
>
> This excludes the cloning of any organism for improved commercial purposes."

It is difficult to say, with any amount of legal certainty, what these provisions mean. The most likely interpretation is as follows:

- Any "genetic modification" that takes place after 5 January, 1998 requires authorisation.

- Genetic modification is an activity that takes place in laboratory conditions, referred to in biosafety parlance as "contained use". It is under contained-use conditions that genetic research takes place in sterile laboratory environments where GMOs are intentionally prevented from interacting with other organisms. This situation is not the same as GMOs being released into the environment, where the effects of the interaction of the GMO with thousands of other organisms differ markedly from the effects observed under laboratory conditions. It goes without saying, therefore, that GM crops developed under contained-use conditions may not accurately demonstrate the potential for environmental contamination and ecological impact.

- In ordinary circumstances, the MEC of a province controls the EIA process and decides whether or not to grant authorisations after a scoping report has been provided. However, in terms of an agreement between the Department of

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[66] Government Notices R1182, R1183 and R1184 of 5 September, 1997.
[66] April 1998.

Environmental Affairs and Tourism (DEAT) and the provinces, it has been decided that DEAT will be responsible for the administration of the EIA provisions in respect of GMOs.[67] This situation is anticipated and provided for in terms of section 4(3) of the Regulations.

- Upon investigation, it has been ascertained that DEAT has not required any authorisations.[68] Moreover, DEAT has not yet implemented the EIA provisions in respect of GMOs and in any event, at the time of writing this report, does not have the capacity to do so.

- Although provision is made, in terms of section 28 of the ECA, for the Minister to grant exemptions from the provisions of the Regulations to any person, it does not appear that any exemptions have either been applied for or granted.

- However, even if DEAT were willing and able to implement the EIA provisions, the law has been drafted in a such a way as to render the provisions impractical to implement. Strictly speaking, an EIA is conducted before an authorisation is issued, and it does not make any sense to require an EIA to be conducted prior to the genetic modification of an organism. Rather, it is the broad environmental impact arising from the genetic modification of organisms released into the environment that should be investigated and assessed before such organisms are released into the environment.

- The operative words here are "released into the environment"; not "genetic modification of an organism". Previous drafts of the EIA Regulations contained the former terminology; but the final draft uses the latter.

- The situation is exacerbated by the fact that the EIA provisions will only apply to a genetic modification that took place after 5 January, 1998. Taking into account the fact that genetic modification is not a once-off process but involves many complex experiments (not all of them successful) over a period of time, when can a genetic modification be said to "start"?

Note: The issue of EIAs was recently dealt with specifically by a Brazilian federal judge, Antonio Souza Prudente, in a court action brought by the Institute for Consumer Defense against Monsanto do Brasil Ltda and Monsay Ltda. The court emphatically prohibited the planting or marketing of GE crops until a full Environmental Impact Study had been undertaken. Invoking the Precautionary Principle, the judge said that the "questions raised by genetic engineering will not be resolved by the laws of market alone; rather they will be resolved by the rigorous respect to the legislation which protects life, as established by our laws and Constitution."

[67] Personal interview, Muffy Koch; personal communication, Wynand Fourie, Director: Environmental Impact Management, Department of Environmental Affairs and Tourism, January 2000.
[68] Personal communication, Wynand Fourie.

The Brazilian judge ruled further that, *inter alia*:

- the companies be prohibited from marketing GE soy beans until such time as the authorities issued technical regulations for GMOs and for labelling GMOs;

- all commercial cultivation of GE soy beans be suspended until scientific concerns are clarified; and

- any authorisations already granted to the companies be suspended.

4.3 The Foodstuffs, Cosmetics and Disinfectants Act (FCD), No 54 of 1972, and relevant Regulations

4.3.1 Food safety – locally produced and imported foods

The Department of Health is responsible for administering the Act, which is enforced by local authorities in their respective jurisdictions. The intention of the Act is to safeguard the consumer from foodstuffs that are deemed harmful or injurious to human health. The Act is reactive in its application, in that producers are required to prove that the food is safe for human consumption.

According to the Department of Health,[69] its function with respect to the safety of foodstuffs for human consumption is summarised in the preamble to the FCD Act as follows: "to control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants". Control over exportation is therefore not covered by the Act. All imported food must, however, comply with the provisions of the FCD Act.

The safety of GM food commodities such as grains, certain fresh fruit and vegetables that fall within the definition of GMO in terms of the GMO Act, will be regulated through the risk assessment procedure under the GMO Act. The safety assessment of GMO products (which fall outside the scope of the GMO Act), is undertaken as part of the safety assessment of foodstuffs.[70] The only role the Department of Health appears to play is in a supervisory capacity through its representation on the Executive Council established in terms of section 3 of the GMO Act. According to the Department of Health, "the role of the Department of Health with respect to food obtained by recombinant DNA techniques is limited to the mandate given by the [GMO] Act to the Department of Health."[71]

It must further be noted that imported foods which are products of GMOs or processed GM food, fall outside the scope of the GMO Act. Although the FCD requires foodstuffs to be safe before being commercially released – including GM foods or foodstuffs containing GMOs – no actual testing is undertaken by the Department of Health or by any other Government department.

4.3.2 Food labelling

The FCD does not at present require any GM food to be labelled as such, although the Department of Health [???COPY MISSING???]. The delay and possible intransigence on the part of Government to label GMOs and products derived from GMOs is extremely worrying. Labelling GM foods is one of the most important ways to uphold the right of consumers to choose what they wish to consume. It also provides a way for consumers to trace GM products through the food chain, and boosts the demand for the segregation of GM and non-GM ingredients in the food chain. In this regard, it has been said that "a

[69] Faxed letter received from Ms F W J van Rijssen, Deputy Director: Food Control, Department of Health, 11 February, 2000.
[70] Ibid.
[71] Ibid.

good GM lab can test for all GM crops, give quantitative results down to 0,01% GM contamination and can find GM in any crop, even if it doesn't know which GM to look for."[72]

4.3.3 Codex Alimentarius[73]

Once the Codex Alimentarius Commission has set international standards for labelling GM food, South Africa may choose, as a member of the World Trade Organisation (WTO), to align its labelling legislation with these standards. The standards set by Codex are referred to while trade disputes are being settled in terms of the dispute resolution mechanism under the rules of the WTO. It is important for civil society to lobby Government to allow an appropriate non-partisan expert on food safety to represent it on the Government delegation at meetings of the Codex Committee on Food Labelling.

[72] Professor J Fagan, "GM Foods can be Tested Accurately and Inexpensively for Labelling Purposes by Supermarkets", 24 October ,1999. www.gentic-id.com

[73] The International Codex Alimentarius is a non-binding system run by the United Nations Food and Agriculture Organisation (FAO) for food labelling.

4.4 Overview of relevant provisions of the National Environmental Management Act (NEMA), No 107 of 1998

NEMA is generally seen as an attempt by Government to comply with the requirements of section 24(b) of the Constitution[74], which provides as follows:

"Everyone has the right

(b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that

(i) prevent pollution and ecological degradation;

(ii) promote conservation; and

(iii) secure ecological sustainable development and use of natural resources while promoting justifiable economic and social development."

4.4.1 Principles

NEMA sets out a number of principles, which reflect those contained in a number of environmental policies. These principles are primarily geared towards guiding the actions of organs of State that may significantly affect the environment.

While remedies are provided for dealing with the breaching of principles contained in the Act,[75] it is, in practice, difficult to assess whether a particular decision has in fact been taken, in terms of the principles. Moreover, the principles must apply alongside all other appropriate and relevant considerations, including the State's responsibility to respect, promote and fulfil the social and economic rights in Chapter 2 of the Constitution; in particular, the basic needs of categories of persons disadvantaged by unfair discrimination.[76]

The most important principles for the purposes of this discussion include:

- that sustainable development requires the consideration of a number of factors, including that "the disturbance of ecosystems and loss of biological diversity are avoided, or, where they cannot be altogether avoided, are minimised and remedied"[77]; and that "a risk averse and cautious approach is applied, which takes into account the limits of current knowledge about the consequences of decisions and actions",[78]

- environmental management must take into account the effect of decisions on all people;[79]

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74 Glazewski J, "The Environment, Human Rights and a New South African Constitution", *SAJHR* Vol 7, 1991, p167, states that environmental rights that are "third-generation rights" are generally not self-operating and require the intervention and authority of the State, for instance by way of legislation.
75 Section 32 of NEMA.
76 Section 2(1)(a) of NEMA.
77 Section 2(4)(a)(i) of NEMA.
78 Section 2(4)(a)(vii) of NEMA.
79 Section 2(4)(b) of NEMA.

- the participation of all interested and affected parties in environmental governance must be promoted;[80]

- decisions must take into account the interests and values of all interested and affected parties;[81]

- the social, economic and environmental impact of activities, including disadvantages and benefits, must be considered, assessed and evaluated, and decisions must be appropriate in the light of such consideration and assessment;[82]

- all decisions must be taken in an open and transparent manner, and access to information must be provided in accordance with the law;[83] and

- the costs of remedying pollution, environmental degradation and consequent adverse effects and of preventing, controlling or minimising further pollution, environmental damage or adverse effects must be paid for by those responsible for harming the environment.[84]

4.4.2 Dispute resolution

NEMA makes provision for any person to request a Minister, MEC or municipal council to appoint a facilitator in order to procure an agreement to refer a difference or disagreement to conciliation. This provision appears to enforce section 34 of the Constitution, which provides that:

> "Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum."

It must, however, be noted that, upon receiving such a request, a Minister will not automatically appoint a facilitator with a view to referring the matter to conciliation. The relevant Minister must first consider the following:

- the desirability of resolving differences and disagreements speedily and cheaply;

- the desirability of giving indigent persons access to conflict resolution measures in the interests of protecting the environment;

- the desirability of improving the quality of decision-making by giving interested and affected persons the opportunity to bring relevant information to the decision-making process;

- any representations made by persons interested in the matter; and

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[80] Section 2(4)(f) of NEMA.
[81] Section 2(4)(g) of NEMA.
[82] Section 2(4)(i) of NEMA.
[83] Section 2(4)(k) of NEMA.
[84] Section 2(4)(p) of NEMA.

- any other relevant considerations relating the public interest as may be relevant.[85]

Should the Minister agree to refer the matter to conciliation, the conciliator will be charged with the task of attempting to resolve the matter before him or her. The conciliator may obtain information, both oral and documentary, relevant to the dispute.[86] No express power is given to the conciliator to subpoena either witnesses or information, but information provided becomes part of the report on the conciliation and is then in the public domain, and anyone can access it upon payment of a fee.[87] There is also no requirement that a person requesting such information prove an interest in obtaining it.

A conciliator is obliged to report on the progress made in the conciliation to the Director-General of the Department of Environmental Affairs and Tourism. If conciliation fails, the conciliator may assist the parties in referring the matter to arbitration.

4.4.3 Integrated environmental management

NEMA sets out, in broad and general terms, the objectives of integrated environmental management,[88] and then sets out provisions to attain these objectives. Section 24 requires that the impact on the environment, socio-economic conditions and cultural heritage must be considered, investigated and assessed before any licence or authorisation of any activity that will significantly affect the environment is issued. The section provides further that a report on such an investigation, assessment or consideration must be made to the relevant organ of State prior to the issuing of such authority. The effect of this is that, where there are requirements for authorisation under some other law, such as the GMO Act, authorisation obtained under that law does not exempt the person applying for a permit from the need to comply with whatever new authorisations and procedures may be prescribed under this section.[89]

It must be noted that this section requires consideration, investigation and assessment of the environmental impact of any permit or authorisation applied for under any law. The Act is silent on the form such investigation should take and by whom it is to be conducted, but it does provide that any investigation, assessment and communication of the potential impact of the activities must take place in accordance with the procedures complying with the section 24(7).

Section 24(7) sets out extensive parameters for such procedures. The Minister of Environmental Affairs and Tourism is empowered to identify existing authorised and permitted activities which require consideration, assessment and evaluation, and which must be reported on.[90] However, NEMA does <u>not</u> empower the Minister to prohibit such activities once the relevant consideration, assessment, evaluation or report has been

[85] Section 22(1) of NEMA.
[86] Section 18(2)(a) of NEMA.
[87] Section 18(2)(d) of NEMA.
[88] Section 24(2) of NEMA.
[89] Section 24(5) of NEMA.
[90] Section 24(2)(d) of NEMA.

concluded. The Minister is empowered to identify activities which may not be started without his, or an MEC's, prior authorisation.[91]

4.4.4 Duty of care (environmental liability)

The guiding philosophy of section 28, which deals with the duty of care and remediation of environmental damage, is that legal responsibility for damage to the environment is placed on the person who causes it.

Section 28(1) imposes legal responsibility for significant pollution or degradation of the environment on the person who caused it. The section covers pollution and degradation caused in the past, currently being caused, or that may be caused in the future. In respect of the present and the future, there is an obligation to prevent such pollution from occurring, continuing or recurring. In relation to the past, however, the section obliges the person responsible to take reasonable measures to minimise and rectify such pollution or degradation of the environment.

But what does "significant pollution or degradation" mean? Pollution is quite broadly defined in the Act as "any change in the environment caused by (i) substances; (ii) radioactive or other waves; or (iii) noise, odours, dust or heat, emitted from any activity, including the storage or treatment of waste or substances, construction and the provision of services, whether engaged in by any person or an organ of State, where that change has an adverse effect on human health or well-being or on the composition, resilience and productivity of natural and managed ecosystems, or on materials useful to people, or will have such an effect in the future." It is pointed out that, taking into account the principles of NEMA and section 24 of the Constitution, [92] it would be anomalous to confine "significant" to harm to humans or damage to property rather than also encompassing any interference with ecosystems that is more than negligible or superficial.

Section 28(2) sets out the persons to whom the obligation of care and remediation may extend. They include the owner of land or premises, a person in control of the land or premises, or a person who has the right to use the land or premises.

Although NEMA does not define the entire ambit of what constitutes reasonable measures, section 28(3) attempts to set out the kind of measures that could be taken. These include:

- the investigation, assessment and evaluation of the impact on the environment;
- the education of employees;
- the cessation, modification or control of any act causing environmental damage;

[91] Section 24(2)(a) of NEMA.
[92] Federick Soltau, "The National Environmental Management Act and Liability for Environmental Damage", (1996) 6 SAJEL pp 45-46.

- the containment or prevention of pollutants or the cause of environmental degradation;

- the elimination of any source of such pollution or degradation; and

- the remedying of the effects of such pollution or degradation.

It is significant that, included within these "reasonable measures" is the requirement for an investigation, assessment and evaluation of the impact on the environment. This appears to be in keeping with South Africa's obligations under Article 14 of the Convention on Biological Diversity, which requires that each contracting party introduce procedures "requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity" … and … "introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account."

Ultimately, what constitutes reasonable measures will depend on the case in question, taking into account also the principles and provisions contained in section 28 of NEMA. It is argued that in assessing the question of what reasonable measures entail, a court might consider the import of the Precautionary Principle when deciding at what point the risks posed to the environment by a defendant's conduct justify the taking of further steps.[93] It is furthermore argued that if the activity is inherently risky, to all intents and purposes, reasonable steps may include imposing strict liability.[94]

The practical implication of these provisions is that persons involved in activities that have been previously authorised, and that are being carried out in a manner that has been previously approved, can be ordered to cease such activities or significantly alter the manner in which they are being carried out.

Enforcement of these provisions is provided for as follows. The Director-General or the head of a provincial department, after consultation and having given the person affected an opportunity to be heard, may direct the person who has defaulted to take certain reasonable measures and to complete them within a specified period.[95] When issuing such a directive, the Director-General or provincial head of department is required to consider the principles of NEMA, the severity of any impact on the environment and the costs of the measure being considered, the desirability of the State's fulfilling its role as custodian of the environment held in trust for the people, and any other relevant factor.[96]

Where the State is dilatory in this regard, section 28(12) gives any member of the public the right to apply to court for a *mandamus* to compel the relevant Government official to take the steps envisaged in section 28 for enforcing the taking of preventative or remedial steps by those causing damage to the environment.

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[93] Soltau, p46.
[94] Ibid.
[95] Section 28(4) of NEMA.
[96] Section 28(5) of NEMA.

4.4.5 Control of emergency incidents

Section 30 of NEMA deals with emergency incidents and imposes certain duties on "responsible persons". An incident is defined as "an unexpected sudden occurrence … leading to serious danger to the public or potentially serious pollution or detriment to the environment, whether immediate or delayed." Again, one must question what the phrase "serious pollution or detriment" means.

A hierarchy of persons empowered to respond to an emergency is provided for. Those responsible, set out in section 30(1)(b), are strictly liable for taking measures to contain or minimise the effects of the incident, undertake cleaning up procedures and remedy the effects of the incident.[97]

4.4.6 Access to information

The relevant provisions of NEMA set out in section 31, dealing with access to information held by the State, were intended to be operational only until the promulgation of the Promotion of Access to Information Act. However, this does not seem to be the intention of the Promotion of Access to Information Act for the following reasons:

Section 31 gives everyone [the public] the right to environmental information held by the State, relating to the implementation of NEMA and any other law affecting the environment, including any emissions to water, air or soil, and the production, handling, transportation, treatment, storage and disposal of hazardous waste and substances.

Such information may only be refused:

- if the request is manifestly unreasonable or formulated in too general a manner;
- if public order or national security would be negatively affected by the supply of information;
- to provide reasonable protection for commercially confidential information;
- if granting the information endangers or further endangers the protection of the environment; and
- to provide reasonable protection for personal privacy.

4.4.7 Legal standing to enforce environmental laws

The categories of persons who may enforce environmental laws are essentially the same as those contained in section 38 of the Constitution, but also include the right of a person to seek relief "in the interest of protecting the environment".

[97] Section 30(4) of NEMA.

Section 32(2) empowers, but does not oblige, a court to decline to award costs against an unsuccessful litigant if the court is satisfied that the litigant acted reasonably, out of concern for public interest or in the interests of protecting the environment, and had exhausted other remedies. It provides further for costs to be awarded in favour of legal practitioners acting *pro bono* in the event of an action's being successful.

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