

The monitoring of enviromental impacts of GMOs in South Africa: a status quo report

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he African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg South Africa. It provides authoritative, credible, relevant and current information, research and policy analysis on genetic engineering, biosafety, agrofuels and the Green Revolution push in Africa.

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INTRODUCTION

South Africa is currently ranked as the 8th largest producer of Genetically Modified (GM) food crops in the world. By 2008, it had planted 1.8 million ha to GM crops (maize, soybeans and cotton) covering a total of 12.2 % of the total arable land in South Africa and comprising 129 different GMO varieties.ⁱ Maize is the biggest GM crop planted covering a total of 1.617 million hectares or comprising 62% of South Africa's total maize production. 80% of all soybeans planted in South Africa are transgenic crops, as well as 90% of all cotton.ⁱⁱ

When genetically modified organisms (GMOs) were first introduced into the South African environment in 1996, no biosafety policies, laws and institutions were in place at all, let alone those that required monitoring of the impact of these new alien varieties on the environment.² No specific policy or legislation existed to make environmental impact assessments (EIAs) mandatory, before GMOs could be released commercially or otherwise into the South African environment. Even when GM and biodiversity legislation was passed in the ensuing years, mandatory EIAs were still not part of the regulatory regime for GMOs.

Although in the last three to four years, the government has been making some effort towards monitoring the environmental impacts of GMOs on the environment, to date, no functional impact monitoring framework is fully in place and operational.

This research paper provides an overview of the current status with regards to the South African government's efforts to implement a monitoring framework for assessing the impact of pre-release and commercial GMOs on the South African environment. The paper begins by presenting an overview of the relevant legislation in place within which the GMO monitoring framework is being developed. It then outlines the different roles and responsibilities of various government departments and parastatals involved in the monitoring.

LEGISLATIVE OVERVIEW

National Environmental Management: Biodiversity Act (NEMBA)

It was only with the enactment of the National Environmental Management: Biodiversity Act ("The Biodiversity Act") in 2004, some 8 years after the first GMO releases, that the South African government took baby steps towards monitoring the impact of GMOs on the environment. Section 78 of the Biodiversity Act stipulates that an **environmental assessment** must be conducted prior to the approval of any permit for the release of a GMO in case that the release

i The 129 GMO varieties currently used for commercial purposes within South Africa comprise of 19 soybean GMO crops, 9 cotton GMO crops, 61 yellow maize GMO crops and 40 white maize GMO crops.

ii All data presented is based on a survey conducted by the International Service for the Acquisition of Agri-Biotech Applications. Of the total GMO white maize varieties planted in South Africa in 2008, 579 000 ha was Bt insect resistant, 148 000 ha herbicide-tolerant and 164 000 ha combined ("stacked") traits. The GMO yellow maize varieties planted consisted of 579 000 ha Bt insect resistant, 148 000 ha herbicide-tolerant and 164 000 ha combined ("stacked") traits. All GMO soybeans planted were herbicide tolerant, while the planted GMO cotton varieties comprised of 83% stacked traits, 9% herbicide tolerant and 7% Bt of the total biotech share.

might pose a threat to indigenous species or the environment.³ This provision was still relatively weak, as environmental assessments generally only entail a desk study of field trial data where no environmental impact assessment has been conducted or a study of environmental safety data produced in a controlled environment, usually greenhouses.⁴

Section 78 of the Biodiversity Act was amended in 2009, and it now provides that “if the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of that Act unless an environmental impact assessment has been conducted in accordance with Chapter 5 of the National Environmental Management Act (NEMA) as if such release were a listed activity contemplated in that Chapter.”⁵ This amendment to section 78 of NEMBA is an improvement, yet it still does not provide any proper guidelines for when the Minister may call for an EIA. Instead, this section leaves it up to the discretion of the Minister of Water and Environmental Affairs to decide when a release of a GMO may pose a threat to any indigenous species or the environment, and to communicate this with the Registrar of GMOs as soon as possible after the application has been received by the Department of Water and Environmental Affairs (DWEA). DWEA is a member of the GMO Executive Council (EC), the decision making body responsible for approving or rejecting GMO applications, and is therefore informed of all applications submitted to the EC for approval.⁶ Theoretically any affected or interested party can raise concerns to the Minister in regard to possible negative effects of a GMO release on the environment; however, no formal legislative mechanism exists to enable members of the public, farmers and other interested and affected groups from triggering an EIA. Where interested and affected parties address their concerns in writing directly to the Minister, he or she has discretion to act on or ignore such concerns.⁷

Section 11(1)(b) of the Biodiversity Act also provided the South African National Biodiversity Institute (SANBI), with mandatory duties to monitor the impact of GMOs on the environment and to report on this to the South African Parliament.⁸ Section 11(1)(b) was amended and it now also requires that this monitoring is based on research that identifies and evaluates risks, but has repealed the reporting duty of SANBI to Parliament.⁹ SANBI’s mandate only concerns the monitoring of impacts after GMOs have already been released into the environment. The monitoring of the impact of GMOs on the environment prior to their release falls under the responsibility of the Department of Land Affairs, Agriculture, Fisheries and Forestry, and is regulated by the GMO Act, as amended.

The repeal of SANBI’s duty to report to the South African Parliament has taken away the imperative to ensure accountability and implementation of its functions. The provision that the monitoring should be based on research that identifies and evaluates risk also more clearly prescribes the methodology for monitoring, and ties SANBI’s mandate firmly to the ERA guidelines (see below).¹⁰

GMO Amendment Act

The GMO Amendment Act (Act No. 23, 2006) created a mandatory duty for the EC to consider whether an EIA is required before approving a GMO application. In this regard, the EC is guided by the EIA regulations made in terms of the National Environmental Management Act (Act No. 107 of 1998). However, current regulations do not provide clear guidance to the EC on when to call for an EIA as GMOs are listed as a schedule 1 activity, meaning that only a basic environmental

assessment is required.¹¹ The EIA regulations are currently being redrafted, however, the new regulations do not address this above mentioned problem. Instead various provisions are diminishing the chances of proper EIAs being carried out to assess the impact of the release of GMOs on the environment. The next paragraph will provide more detail in this regard.

EIA regulations – National Environmental Management Act (NEMA)

The draft regulations published on 13 February 2009, regulating procedures and criteria for conducting EIAs as set out in chapter 5 of NEMA, have been relatively weak on a number of points. Some clauses can even possibly be rendered unconstitutional, meaning that they contradict the South African constitution.¹² Various clauses within these regulations remove the right of the public to participate in decision-making and provide competent authorities with a discretion which insufficiently protects the constitutional right to a healthy environment.¹³ The regulations do not specifically refer to GMOs, meaning that the listing of GMOs as a schedule 1 activity remains unchanged. In other words, instead of a full EIA, only a basic assessment needs to be conducted when releasing GMOs into the environment. As mentioned earlier on, the amendment of section 78 of the Biodiversity Act regards the release of GMOs as a listed activity as contemplated in chapter five of NEMA in the event the Minister has reason to believe that the release may pose a threat to any indigenous species or the environment.

The following regulations are of particular concern with regard to conducting EIAs for releases of GMOs into the environment:

1. Regulation 9(2)(b) states that in case deadlines set out in the regulations 26(1), 31(1), 35(2) or 36(1) for approving (amended) basic assessments reports and environmental impact assessment reports are not met, the time frame for this approval is extended for another 60 days. If this period lapses, these reports should be accepted and environmental authorisation is deemed to be granted. This basically means that the government can approve the release of GMOs without taking into account results published in basic assessments reports and environmental impact assessment reports, transforming these assessments into pro-forma exercises.
2. Regulation 21 provides applicants with the opportunity to apply for a basic assessment instead of an EIA and scoping, even if these are required by the provisions made in chapter 5 of NEMA (i.e. when an activity is listed). This regulation could lead to many GMO releases still only being approved on the bases of an environmental assessment reports rather than a full EIA.¹⁴

It was anticipated that these regulations would become operational in January 2010.¹⁵ A group of 21 South African NGOs, including ACB, have sought a legal opinion on the unconstitutionality of some of the clauses and requested a meeting with the Director General of the Department of Water and Environmental Affairs to express their concerns in this regard.¹⁶ However, the Department has shown no interest in further public participation in formulating these EIA regulations and denied this request by stating that it was not willing to entertain the request as the Department had received the request after the deadline for submitting public comments to the EIA regulations had already lapsed.¹⁷ The NGO coalition is currently contemplating what further action to take.¹⁸

Environmental Risk Assessment (ERA) Framework

To further implement the provisions of section 78 of NEMBA, DWEA drafted an Environmental Risk Assessment Framework, which was published in September 2008. This framework aims to provide further guidance to the GMO Executive Council regarding the basic environmental assessment and when to call for an EIA and how this should work in practise. At the same time, it is also meant to inform the general public/interested parties of the environmental risk assessment measures which the EC needs to take into account when evaluating GMO permit applications. DWEA began its work on developing the framework in 2006. The Council of Scientific and Industrial Research (CSIR) was contracted to facilitate the stakeholder involvement in this process.¹⁹ The published ERA framework focuses on plants, however, the Department has indicated that additional guidance will be made available on genetically modified trees, fish and viruses.²⁰

What are the criteria for conducting an ERA of GMOs?

The guidelines outline the globally accepted criteria for conducting an environmental safety assessment and include persistence and invasiveness of the variety, potential for gene transfer, interaction between the GMO variety and target insects and non-target organisms, effects on bio-geochemical processes and soil ecosystems, changes in agricultural practices, and socio-economic and cultural impacts.²¹ The guidance document outlines that special attention should be paid to applications for releasing GMOs with stacked traits that have possible compatible management requirements and possible synergistic effects, or for releasing stacked GMOs to a new area of the country. In addition, the document mentions that specific ecological concerns with respect to antibiotic resistance markers should be taken into consideration.²²

The guidelines also provide a list of criteria that may be used to trigger an environmental scoping or environmental impact assessment of a GMO. These include:

- GMOs that result in changes in conventional use, e.g. pharmaceuticals in plants, biofuel production.
- GMOs that result in substantial changes in current agricultural practices and pest management practices.
- GMOs where there is prior evidence of changes in the agro-ecosystem that may lead to substantial changes in current agricultural practices.
- GMOs that have a potential negative impact on threatened or protected organisms listed in NEMBA.
- Release of indigenous GMOs, GMOs with cultural or geopolitical significance or potentially negative socio-economic impacts, GMOs that have wild indigenous relatives or non-indigenous weedy relatives or potentially invasive GMOs.
- Release of genetically modified micro-organisms that are expected to have a significant negative impact on the environment.
- GMOs to be used for bio-terrorism.²³

Concerns voiced by the ACB, in coalition with Biowatch, Earthlife Africa and the Safe Food Coalition during the process of establishing these ERA guidelines, have been partly taken into consideration.²⁴ The guidelines outline that an ERA must be subject to peer-review by mentioning that in carrying out such an assessment “the most current conceptual and empirical knowledge and peer-reviewed science on transgenic biology must be utilized.”²⁵ Also, the need for taking into account the socio-economic impacts of GMOs in ERAs has been addressed, albeit in a very

general manner. The guidance document does mention that socio-economic and cultural impacts of GMOs should be considered when conducting an ERA and also refers to the provisions on this made by NEMA.²⁶ However, the document does not provide any parameters such as those given for measuring environmental impacts to assess socio-economic impacts. Also geo-political impacts of the release of GMOs are not touched upon in the document, albeit it specifies that GMOs used for bio-terrorism require a full EIA before a release into the environment can be approved.

Also, to a degree, the document describes the research and monitoring necessary to evaluate, avoid and restrict risks posed by GMOs. The guidelines provide a structure for a monitoring plan to be submitted by applicants as part of the permit application for a GMO release. It also provides examples for parameters for monitoring, such as a change of population of target and non-target insects, pollen transfer, resistance, dissemination, insect resistance, transfer of antibiotic resistance genes and changes in biodiversity. However, the use of these parameters are by no means made obligatory to permit applicants. In addition, the guidelines provide a step-by-step approach for assessing the risk of resistance evolution and for putting appropriate risk management systems in place to mitigate this risk. Yet no clear responsibilities are designated to the Department of Agriculture to ensure that such risk management systems are indeed put in place before the release of a GMO.

In relation to monitoring of post-release GMOs, the guidelines point out the central role of the South African National Biodiversity Institute in this regard (discussed in more detail under paragraph 2.3). The document proposes that the research conducted under the legal mandate of this institute will be of a general surveillance nature, looking at the general state of the environment, and conducting specific risk assessments if an observed environmental change is likely to be caused by the cultivation of a specific GMO. In this way, unanticipated adverse environmental effects of GMOs, not identified and considered in a pre-market risk assessment can be detected.²⁷ However, the document does not specify the role the GMO registrar should be playing in monitoring the impact of GMOs after they have been released into the environment. It only mentions that monitoring reports will be shared with SANBI.²⁸

The most important critique of these guidelines is that they have no legal force, unless they are specifically linked by legislation. The criteria given to call for an EIA within these guidelines remain unbinding. Nevertheless, they serve as important guidance to the EC in the exercise of its discretionary powers to call for an EIA. The Department of Agriculture has indicated that content of the ERA document will be incorporated into the GMO application forms.²⁹ This will be done in close consultation with DWEA after the GMO Amendment Act regulations have been enacted. These regulations have been finalized already and the legal process for gazetting has commenced.³⁰

Summary

This overview of the Governments' efforts to implement a monitoring framework for assessing the impact of pre-release and post release GMOs illustrates some small progress towards the government taking its first steps towards protecting the environment from the risks posed by GMOs-although it is late by more than a decade. The Minister of DWEA can now, through the amendment of section 78 of NEMBA, call for an EIA to be conducted for a GMO to be released into the environment if he has reason to believe that this variety may cause harm to any indigenous species or the environment. Also through section 11(1)(b) of the Biodiversity Act, SANBI is mandated

to monitor post-release GMO's. The Environmental Risk Assessment Framework also provides opportunities for an EIA to be called for by the EC, now that it has been given further guidance.

Albeit this legislative framework has been set-up, in practice the monitoring of impacts from pre-release and commercial GMOs on the environment is still very limited. SANBI is currently only monitoring the impact of one of the 129 GMO varieties released into the environment (MON810) and it is foreseen that in the coming years this institution also will have limited capacity to monitor post-commercial GMOs. With regard to monitoring the impact of pre-release GMOs, the Environmental Risk Assessment Framework does not have the force of law behind it, which means that the criteria outlined for the EC to call for an EIA within these guidelines remain unbinding. Also, GMO's still remain listed as a schedule 1 activity in the EIA regulations, meaning that only a basic assessment needs to be conducted when releasing GMOs into the environment. Currently it is only the Minister of DWEA who can call for an EIA for specific GMOs. However, to date, this has not happened yet.

MONITORING AUTHORITIES, DUTIES AND POWERS

GMO Registrar

As indicated, applications for a GMO permit include an environmental post monitoring plan for monitoring the impact of GMOs on the environment after commercial release as well as during field trials. This monitoring is not only carried out to confirm that assumptions made in the ERA have been correct, but also to identify the occurrence of unanticipated adverse effects of the GMO or its use on the environment or human health. Within this monitoring plan, the applicant must describe the monitoring strategy and the methods to be used. The applicant also has to indicate when the intended analysis and reporting are going to take place.³¹

The GMO registrar is required to ensure that monitoring plans are carried out satisfactorily and is entitled to appoint inspectors in this regard (section 9(d) of the GMO Act).³² In case the Registrar is of the opinion that monitoring plans are carried out unsatisfactorily, it is his/her duty to communicate this to the Executive Council.³³ Part of the inspector's duties are to conduct further investigation in case monitoring plans are not carried out properly and to issue a warrant if necessary (article 4 and 5 of the GMO Act).³⁴ The latter happens very rarely; for instance, in the last ten years no warrant has been issued.³⁵

Inspectors are also responsible for measuring the effectiveness of the risk management measures taken and for detecting possible adverse impacts. Potential post release risks currently assessed include environmental safety issues and food, animal feed and health safety issues (adverse socio-economic impacts are not measured).³⁶ This is an immersive task as proper assessments need to include extensive health and other surveys, and inspectors are clearly not capacitated to undertake these. Results of the post commercial monitoring currently done by the Department of Agriculture will also be communicated to SANBI to provide input to its efforts with regard to monitoring and reporting on the impact of post-commercial GMOs on the environment.³⁷

Monitoring of the impact of post-commercial release GMOs under the auspices of the GMO registrar has been limited, as the monitoring duties of a permit holder are restricted to the monitoring plan drawn up by the holder when applying for a permit.³⁸ The South African

government has not prescribed which parameters should be considered in this regard; the guidance document for ERA just gives examples of parameters which can be used in this post market monitoring process. These only include parameters measuring possible environmental impacts of the GMO variety, leaving out any instruments measuring the socio-economic impact of GMOs.³⁹ Therefore, it is left to the discretion of permit holders to decide which parameters are used in monitoring the impact of GMOs, and in this way, to define the scope of the monitoring taking place. DWEA has indicated that additional monitoring obligations will be imposed through GMO permits, however, what these obligations will exactly entail is not yet clear.⁴⁰

South African National Biodiversity Institute (SANBI)

In 2007, SANBI started designing a monitoring and reporting framework for assessing the impact of GMOs on the environment. This includes looking into the impact of GMOs on non-target organisms and ecological processes, indigenous biological resources, the biological variety of species used for agriculture and the socio-economic context. In this regard, SANBI established a GMO Monitoring and Research Unit in March 2008. This unit was initially staffed with two staff members (post of Deputy Director and Scientist), however, the Scientist post is currently vacant and has not been filled due to financial constraints within SANBI. SANBI hopes to fill this position again during the next financial year (2010-2011) and has initiated discussions with DWEA to provide additional funding to cover the salary costs of this position. In the coming years, SANBI aims to further expand its GMO Research and Monitoring Unit by attracting students who are currently involved in the collaborative Norwegian-South African research project on the impact of MON810 on the environment, which is discussed in more detail later on in this paragraph.⁴¹

The design of the monitoring and reporting framework was initially informed by a collaborative research project between SANBI and the University of Minnesota (USA), assessing all potential risks GMOs might pose to biodiversity.⁴² This has been a separate activity to the design of the Environmental Risk Assessment framework designed by DWEA, which is primarily aimed at providing guidance in carrying out pre-market risks assessments. According to SANBI's Mandate, the institute focuses only on monitoring the impact of post-commercial GMOs. The design of the ecological risk assessment carried out by SANBI incorporated stakeholder involvement; and representatives from government departments and industry, scientists, and biodiversity specialists were invited to provide their input during a workshop held at the end of 2008.⁴³ The main aim of this workshop was to make a prioritisation list of risks to be assessed when measuring the impact of GMOs on the environment. On the basis of this collaborative research, SANBI designed a monitoring and reporting framework at the beginning of 2009.⁴⁴

As part of a bilateral agreement between DWEA and the Norwegian government, SANBI helped design a 3-year research project on the impact of the GMO Maize variety MON810 on the South African environment. This research is now coordinated by SANBI's GMO Monitoring and Research Unit and serves as a pilot project for implementing the monitoring and reporting framework. Parties involved in carrying out this research are North West University, University of the Free State, Fort Hare University, and Genok (a Norwegian public funded biosafety research centre).⁴⁵ The University of North West, together with Genok, is looking into the impact of MON810 on target and non-target organisms and the development of resistance in the target organisms, while the University of Fort Hare focuses on the impact of this GMO variety on soil microbes. In addition, the University of the Free State, in cooperation with Genok, is involved in measuring the level of toxin produced in various plant tissues during various plant stages, as well as in measuring the impact of gene flow on the development of resistance in the target organisms.⁴⁶

The research team was meant to meet up at the end of 2009/early January 2010 to discuss their initial findings. SANBI indicated that research findings will only be shared with the public at the end of the project period, which will be December 2010.⁴⁷

SANBI is also currently seeking collaboration with scientists within various South African institutions to involve these scientists in carrying out such assessments.⁴⁸ This monitoring will only be case specific, contrary to the general surveillance monitoring DWEA is proposing in the ERA framework guidance document. The main reason for this is that general surveillance monitoring requires very extensive research and is therefore very costly, while SANBI only has limited financial resources available. The total budget for the last and current financial years (2008-2010) has been 8 million Rand.⁴⁹ Another constraint is the limited amount of trained biodiversity experts within South Africa.⁵⁰ Taking also into account the limited human resources currently available within the GMO Monitoring and Research Unit, it is clear that SANBI currently has scant capacity to fulfil its mandate of monitoring the impact of GMOs on the environment properly.

CONCLUSION

This paper outlined the current status of the government's efforts in monitoring the impact of GMOs on the environment. The paper mentioned that a framework for assessing the risks of GMO on the environment before release has been designed, but that this framework has not been incorporated in permit applications as yet. Provisions for assessing socio-economic impacts are still very marginal in this framework and it is to be seen to what extent the designed framework will be fully enforced without it being promulgated as regulations to section 78 of NEMBA. This paper also describes the process that SANBI has taken up in designing a monitoring and reporting framework for measuring the impact of post-commercial GMOs on the environment, as mandated by section 11(1) of NEMBA. This framework is currently being tested through a collaborative Norwegian-South African research project on the impact of MON810 on the South African environment. It is pointed out that the GMO Research and monitoring unit within this institute does not have sufficient financial and human resources available to properly carry out SANBI's mandate to conduct this monitoring and reporting.

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