AFRICAN CENTRE FOR BIOSAFETY

A GLIMPSE THROUGH THE CRACKS IN THE DOOR: SOUTH AFRICA'S PERMITTING SYSTEM FOR GMOS

By Mariam Mayet

January 2005

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INTRODUCTION

During 2004, the African Centre for Biosafety (ACB) spent a considerable amount of time monitoring the South African permitting system for genetically modified organisms (GMOs). In the course of its work, it lodged comprehensive objections to numerous applications for the import, marketing and field- testing of GMOs[1]. The applications to which objections were lodged include the following:

- Trial Release of GMO Cotton: Broadspectrum Resistance to Lepidopteron Pests (COT200-Cry1Ab) Stacked Cotton
- Trial Release of GMO Cotton: Broadspectrum Resistance to Lepidopteron Pests (COT102-Cry1Ab) Stacked Cotton
- Trial Release of GMO Cotton: Herbicide Tolerant
- Fast Track Application of Trial Release with Event COT102/COT200 Cotton
- Fast Track Application of Trial Release with Event Glyphosate Tolerant Cotton (*hereinafter referred to as "Syngenta's GM cotton application")*
- Bt-Maize MON863 and MON863 X MON810 / Monsanto-import licence
- Bt-Maize TC1507 / Dow AgroSciences-field trials
- Bt-Potato G2 & G3 / Agricultural Research Council-field trials[2]
- Roundup Ready Wheat/Monsanto-import licence
- Roundup Ready Maize GA21-Syngenta-field trials

The ACB gleaned a considerable amount of first-hand information, knowledge and experience of the manner in which South Africa's regulatory system functions regarding the permitting of activities relating to GMOs. This briefing paper is intended to summarise and record that experience. Of the applications objected to (above), the genetically modified (GM) potato field trial application and the fast-track applications sought by Syngenta in respect of its GM cotton applications have to our knowledge, been successful. Although decisions have already been taken in respect to the balance of the applications, the ACB has been unsuccessful in obtaining any information regarding the status of these applications from the National Department of Agriculture (NDA). It is expected though, that all of the applications would be successful.

Throughout its work on the GMO permit applications, the ACB received an astonishing paucity of information, with the result that it has been severely hamstrung in conducting any meaningful assessment of the applications. Indeed, it has become evident that the NDA gives the Applicant *carte blanche* to decide what information the public is in fact entitled to.

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[1] See further ACB's website http://www.biosafetyafrica.net for the comprehensive objections.
[2] This application was submitted by the ACB, in collaboration with G. Ashton, Biowatch et al, see http://www.biosafetyafrica.net.

This biased and grossly inequitable situation has arisen principally, because the NDA has failed to establish a proper formal process for the determination and characterisation of what constitutes confidential business information (CBI). It is well documented that the public's right to access information concerning GMOs has been thoroughly canvassed in the court papers submitted by the Trustees of the Biowatch Trust ("Biowatch") in its application brought before the High Court of South Africa (Transvaal Provincial Division) Case Number 23005/2002, acting in the public interest in respect of which, judgment is still pending for over 6 months.[3]

The ACB has additionally noted several worrying trends. We are particularly concerned about the detrimental impacts of cheap GM maize imported into South Africa as animal feed. Millions of tons of GM maize have been imported into South Africa (especially from Argentina) by the animal feed industry because it is cheaper than if they were to purchase maize produced locally. Such cheap imports displace and place at risk, thousands of jobs in the agricultural sector and related industries. Furthermore, it has also become clear that a great deal of the experimentation in the fields with GM maize and GM cotton crops takes place in South Africa by multinational agrochemical companies seeking nurseries in the Southern hemisphere for the production of seeds. These seeds are re-exported to the United States for further cultivation there during their growing season. The data generated in South Africa during these trials are important to these companies to support permit applications in the European Union and elsewhere.

WHO IS IN CHARGE?

In South Africa, a statutory body comprising of government officials, called the Executive Council (EC) established by the Genetically Modified Organisms Act[4] ("GMO Act") is responsible for the spate of GMOs being imported into South Africa and released into South Africa's environment. [5] Decisions taken by the EC authorising the import, release and marketing of GMOs adversely affect the fundamental human rights of the public. These rights include *inter alia*, the right to nutritious, safe and culturally acceptable food, the right to informed choice, the right to fair administrative decision-making, the right to democratic participation, the right to save and exchange seeds, and the right to a safe and healthy environment.

Notwithstanding, the provisions of the GMO Act dealing with decision-making by the EC has in fact been drafted within a context of sanctioning approvals, as opposed to precautionary decision-making, as required by environmental policy in South Africa, the National Environmental Management Act (NEMA) and the Cartagena Protocol on Biosafety Protocol ("Biosafety Protocol").

As a Party to the Biosafety Protocol,[6] South Africa should take decisions regarding the import and use of GMOs based on the precautionary principle as set out in Biosafety

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[3] See further, http://www.biowatch.org.za

[4] The Genetically Modified Organisms Act No. 15 of 1997.

[5] See, http://www.biosafetyafrica.net for a list of the permits issued by the EC since the GMO Act came into effect on the 1 December 1999.

[6] South Africa ratified the Biosafety Protocol on the 14 August 2003. The Biosafety Protocol became binding on South Africa on the 12 November 2003. In terms of Section 231 of the Constitution of the Republic of South Africa, 1996, an international agreement such as the Biosafety Protocol is binding on South Africa.

Protocol.[7] The provisions of the Biosafety Protocol dealing with the precautionary principle are seen to represent the most explicit examples of operationalisation of the precautionary principle/approach in any multilateral environmental agreement[8].

In addition to the EC, the GMO Act has also established an Advisory Committee[9], which in turn, has established a sub-committee in terms of the GMO Act[10]. Although the EC is the decision- making body, heavy reliance is placed on the Advisory Committee and its sub-committee for scientific and technical support and guidance. These committees thus hold great sway in regard to decisions taken by the EC. It is therefore extremely disquieting to note that the sub-committee currently comprises of several scientists that are either employed or serve as board members of the industry lobby group, Africabio such as Muffy Koch, Jennifer Thompson and Jane Morris. The purpose of biosafety legislation is to regulate industry, its technology and its products. It is not, contrary to the objectives of the GMO Act,[11] meant to promote the very industry that it aught to regulate. This situation is highly objectionable-a sentiment shared by many groups in South Africa. ACB has brought the matter to the attention of the Registrar, the Minister of Agriculture and the Director-General, respectively[12] but to date, the situation remains unchanged.

SAFETY APPROVAL OF NON-EXISTENT GMOS

During January 2004, Monsanto South Africa approached the EC for a food safety approval of non-existent GM wheat.[13] Monsanto could do this with impunity, because the GMO Act allows them to do this, notwithstanding that GM wheat is not being grown commercially anywhere on earth. Worst still, had Monsanto Corporation not announced its decision to abandon its ambitious GM wheat project globally, it is highly likely that he EC would have declared Monsanto's non-existent GM wheat as safe for animal and human consumption. If this had happened, then Monsanto South Africa would also have been exempt, in terms of the extremely trade friendly provisions under the GMO Regulations, from any further permit requirements and hence, further biosafety oversight! This is so because there are no explicit regulatory mechanisms or processes in either the GMO Act or its Regulations dealing with commodity clearance permits. However, once a GMO is cleared or a commodity clearance permit is granted, no further permit will be required for the **import to or export** from **South Africa, the**

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[7] Articles 10(6) and 11(8) of the Biosafety Protocol provides as follows: "the lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question."

[8] An Explanatory Guide to the Cartagena Protocol on Biosafety *IUCN Environmental Policy and Law Paper No. 46* at 14.

[9] In terms of section 10 of the GMO Act.

[10] Section 11(2) of the GMO Act.

[11] The objectives of the GMO Act provide *inter alia* " To provide for measures to **promote the responsible development, production**, use and application of genetically modified organisms.." (own emphasis)

[12] ACB personal communication, 2 May 2004 and 10 June 2004 respectively.

[13] For the public notice, see http://www.earthlife-ct.org.za/ct/article.php?story=20030815154828541. For a full briefing on Monsanto's GM wheat application and the loopholes in the South African legislation, see M Mayet, TWN Briefings for MOP 1 - No. 5 *Undermining Biosafety: Monsanto Pushes GM Wheat to Secure Future Access to Lucrative African Markets*.

development, production, use, release or distribution throughout South Africa of the GMO in question. [14]

Monsanto sought the clearance from the South African authorities because this would have greatly assisted it to capture the lucrative African wheat market once the GM wheat had entered commercial production. The major wheat importers in Africa include Egypt, Morocco, Algeria and Sub-Saharan Africa. North Africa imports approximately 18 million tons of wheat per year, and Sub-Saharan Africa approximately 10 million tons.

On Christmas Eve (24 December 2004), Dow Agrosciences publicly noted its intentions to seek a commodity clearance permit from the NDA for GM maize, transgenic line 52122[15], which similarly also appears to be non-existent, since it is not commercially gown yet anyway in the world. It remains to be seen, what will transpire with this application.

The issue, however, remains the following: the South African regulatory system pertaining to GMOs is nothing but a permitting system, set up to authorise any GMO application even for GMOs that do not exist!

ILLEGAL PERMITS

Although the GMO Act was passed by the South African Parliament during 1997, it only came into effect on the 1 December 1999, when Regulations to give effect to the GMO Act were promulgated. Once the GMO Act came into effect, the erstwhile Registrar, Dr Shadrack Moepuli, issued extensions for permits previously issued by the NDA in terms of the Pest Control Act. These included permits for the commercial growing of Monsanto's GM maize and GM cotton and field trials of various GM food crops in locations scattered throughout South Africa.

Dr Moephuli issued these permits in terms of Regulation 5(12) of the Regulations to the GMO Act, which provides for the issue by the Registrar of fast track permits.

However, the Registrar has no powers whatsoever, to issue any permits in terms of the GMO Ac, unless (i) such powers have been delegated to him or her [16]or the Registrar has been specifically instructed to issue permits by the EC[17]. This means that Regulation 5(12) (secondary legislation) is *ultra vires* the provisions of the GMO Act because it confers on the Registrar greater powers than he has, in terms of the GMO Act. In other words, such permits were null and void, thus rendering the releases illegal.

The ACB brought this issue to the attention of Dr Julian Japhta, then newly appointed as Registrar: Genetically Modified Organisms Act. The ACB requested that the matter be brought to the attention of the EC as a matter of extreme urgency.[18] The ACB also

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[14] The wording of section 2(2) is peremptory, and read together with section 2(1) provides as follows " …a permit ..**shall not be required** [for the import, export, development, production, use, release or distribution of any GMO in the Republic of South Africa]…for those organisms specified in Table 3 of the Annexure." (own emphasis).

[15] http://www.earthlife-ct.org.za/ct/article.php?story=20030815154828541

[16]In terms of section 8(2)(b) of the GMO Act.

[17]In terms of section 8 of the GMO Act.

[18] ACB Personal communication, 2 June 2004.

brought the matter to the attention of the Minister of Agriculture and Land Affairs as well as to the erstwhile Director-General Bongi Njobe.[19] However, to date, no response from any of these officials has been forthcoming, apart from a rather telling communication from Dr Japhta advising ACB that the matter had been referred to the legal department. The silence from the NDA on this issue continues to be deafening!

Significantly, at no time did the NDA or the Minister aver that fast track permits were in fact issued by the Registrar **with the approval of the EC**.

PUBLIC PARTICIPATION: A FOOL'S GAME

The approval process in South Africa concerning GMOs does not make provision for public participation. Rather, a mechanism for "public input" has been created[20] which deals with an invitation by an applicant to members of the public in the area where a release is intended to take place, to submit comments not less than 30 days from the date of publication.

This type of public input is inherently unfair, prejudicial and obstructs the administrative of justice. It is not in compliance with constitutional legislation called the Promotion of Administrative Justice Act ("PAJA").[21] PAJA subjects administrative decision-making to public oversight through *inter alia*, public enquiries and a notice and comment procedure.[22] In fact, it is the contention of ACB, that in the light of there having been a failure on the part of the EC to comply with PAJA, decisions taken by the EC since the said PAJA came into effect on the 3 February 2000, are *ultra vires* and therefore null and void. The ACB has called upon the EC to revoke all permits and approvals granted by it on or after the 3 February 2000, with immediate effect.[23]

The whole notion of publication of advertisements in the area where the release is to take place, (in rural areas) is designed to utterly cut out public interest organisations from the process completely. Nothing in the GMO Act, or its Regulations oblige the public to furnish comments and objections within 30 days. PAJA requires the EC to give affect to parties reasonable notice and opportunity to make representation and that such representations must be taken into account even if they are submitted after the limit stipulated in the advertisement.

Notwithstanding, the Registrar, Dr Japhta, has insisted that the 30 day period of time be complied with-that it would only entertain late objections if an extension of time was

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[19] ACB Personal communication, 10 June 2004.
[20] By way of Regulation 6 of the Regulations made under the GMO Act.
[21] Promotion of Administration of Justice Act No 3 of 2000.
[22] Sections 3 and 4(1) and (b) of PAJA read together with the Regulations promulgated in terms of PAJA, Government Gazette Vol. 446. No 23710, 31 July 2002.
[23] ACB Personal Communication, 12 September 2004. In this regard, specific attention has been drawn to the judgement of Willis J, in an unreported judgement in the matter of *Sasol Oil (Pty) Ltd and Bright Sun Development CC v Mary Metcalfe No* Case number 17363/03 High Court of South Africa (Witwatersrand Local Division) when the learned judge stated " ….the purpose of PAJA is plainly to give effect to the rights, constitutionally enshrined in the Bill of Rights of the Constitution, to just administrative action. It is constitutional legislation. It is triumphal legislation…" See also for details of the legal argument *Objections to the Application by Syngenta SeedCo in respect of Event GA21 to the National Department of Agriculture South* Africa by Mariam Mayet and Shenaz Moola, 13 September 2004 http://www.biosafetyafrica.net.

granted by the applicant.[24]**In other words, citizens of South Africa would have to grovel and plead with multinational agrochemical companies for an extension of time in order to access the process!**

More recently, during January 2005, the ACB made application for access to information in terms of the Promotion to Access to Information Act (PAIA), in order for it to respond to an application made by Dow Agrosciences for market approval of GM Maize 52122 and the South African Sugarcane Research Institute (SASRI), which had been advertised on Christmas Eve.[25] However, by the 20th January, neither applicants had submitted their applications to the Registrar,[26] yet the ACB would be expected, in terms of the regulatory system, to submit its objections to the Registrar on the 23rd and 24th January 2005!

This system remains in place, despite numerous complaints to the Registrar, the EC and generally, the NDA by the ACB and other public interest groups in South Africa. We are left with the impression that the NDA in fact enjoys our disempowerment and the fact that industry is allowed to run circles around us: because they can!

WHO'S FOOLING WHOM? MISINFORMATION

In the course of its work on Dow Agrosciences application to field trial GM maize, TC 1507, the ACB discovered that Dow Agrosciences, Pioneer and Mycogene provided incorrect, misleading and/or false information to the competent authorities of Argentina, Spain and the Netherlands in order to obtain approvals in those countries. The ACB duly submitted comprehensive objections to Dow Agrosciences's application and in this regard, brought it to the attention of the Registrar and the EC that the provision of false and misleading information called into question the veracity of all information furnished by Dow Agrosciences, and for that matter Pioneer Hi-Bred to the South African and indeed, other competent authorities elsewhere in the world, tasked with regulating GMOs. As such, the information provided by Dow Agrosciences in its application cannot be relied upon as being truthful.[27]

It will remain unknown whether the EC would have, on its own, detected these discrepancies.

Whilst working on its objections to Syngenta's applications regarding GM cotton, the ACB discovered that Syngenta had erroneously claimed that there are no wild relatives of cotton in South Africa when in fact, this is not the case. The ACB had ascertained that there are three species of wild relatives of cotton in Southern Africa, occurring in northern Namibia, Northern Botswana, Northern Province, Mpumulanga, Swaziland and KwaZulu-Natal. Cotton also has a wild relative, *Gossypium herbaceum* subsp. *Africanum,* found in South Africa.

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[24] Personal communication, Julian Japhta Registrar, Genetically Modified Organisms Act, 16 August 2004.
[25] See in this regard, http://www.earthlife-ct.org.za/ct/article.php?story=20030815154828541
[26] Personal communication, Michelle Vosges, current Registrar: Genetically Modified Organisms Act.
[27] *Objections to the Application made by Dow Agrosciences in Respect of Event TC1507 to the National Department of Agriculture, South Africa* by Mariam Mayet and Shenaz Moola, 25 June 2004 can be found on http://www.biosafetyafrica.net

It is unknown whether Monsanto made similar claims to the NDA during the course of securing permits for its GM bollguard cotton. Notwithstanding, at least Dr Moephuli, now occupying a rather high-ranking position within the NDA (Deputy Director General) is of the firm belief that there are no wild relatives of cotton in South Africa.[28] GM cotton has been growing in South Africa since 1997.[29]Until the ACB brought it to the attention of the NDA, it laboured under the false assumption (re-inforced by industry) that South Africa has no wild relatives of cotton. It did not occur to them or the EC apparently, to **verify** the claims made by industry.

What else is falling through the cracks?

MONITORING? WHAT'S THAT?

There has been an absence of independent and on-going monitoring and testing (in the fields) in South Africa of the impacts of GMOs on the environment and biodiversity. This makes it extremely difficult-neigh impossible- for the EC, to reliably assess the degree of environmental risks posed by transgenic crops already released into the South African environment over the past 15 years[30]and hence, to make any findings, regarding the environmental safety of GM crops.

The EC acting in consultation with the Advisory Committees have to date, conducted desk- top evaluations only, of the information and data supplied to them by applicants. These institutions have to date, applied the "substantial equivalence" principle, which relies on the concept of "familiarity" with conventional varieties of especially genetically engineered crop plants, to judge whether a transgenic plant requires a full environmental assessment. The principle assumes the validity of the simple linear model of "precise" single gene modifications that do not significantly alter other plant processes. This may explain why, to date, not a single independent environmental assessment (in the fields) has ever been conducted in South Africa in respect of GMOs released into the environment.

Furthermore, neither the NDA, nor the National Department of Health nor any other government agency has conducted any post commercialisation testing and monitoring of the effects of transgenic maize on animal and human health. This failure has arisen because the GMO Act does not address the issue of post commercialisation testing and monitoring adequately or at all. The Department of Health has merely played a passive overseeing role on the EC, and has not discharged its obligation to safeguard the consumer from foodstuffs that are harmful or injurious to human health.

Biotechnology companies, the Department of Health and the NDA are not in any position to make the assumption that GMOs are safe for human and animal consumption, "because no one has become ill or died as a result of consuming the GM

[28] Personal communication, Mariam Mayet obo ACB and Shadrack Moepuli, August, 2004.
[29] In 1997, South Africa also approved Monsanto's GM cotton for commercial planting and for consumption as food and feed. About two thirds of the harvested cotton crop is seed. The cotton seed is crushed to produce cottonseed oil, cottonseed cake (meal) and hulls. Cottonseed oil is used in cooking oil, in shortening and salad dressing, and is used extensively in the preparation of snack foods such as crackers, cookies and chips. The meal and hulls are an important protein concentrate for livestock.
[30] The first transgenic plant crop released into the South African environment, Bt cotton, was sanctioned by the apartheid government in 1989, on the advice of the now defunct, South African Committee on Genetic Experimentation (SAGENE).

maize" as is so frequently stated. This is particularly pertinent, given that South African legislation does not require the labelling of GM food and feed,[31] and hence authorities in South Africa have no way of monitoring what and how much of GM food and feed has been consumed over any given period of time.

The National Environmental Management Biodiversity Act, 2004 ("Biodiversity Act) came into effect on the 1 September 2004. Section 78 of NEMBA creates the possibility for the Minister of Environment to require an environmental assessment prior to a GMO being released into the environment. However, this provision is currently unenforceable owing to a policy and legislative deliberate oversight on the part of the implementing government authority, the Department of Environmental Affairs and Tourism (DEAT).[32]

It is our belief that DEAT did not really intend for the Biodiversity Act to address the environmental impacts of GMOs because it appears to be reluctant to allocate resources and capacity to undertake biosafety tasks.

CONCLUSIONS/RECOMMENDATIONS

It has become patently obvious to us, that the South African regulatory system pertaining to GMOs is fraught with problems, irregularities and illegalities. Serious questions have been raised by ACB as to the legality of permits and the constitutionality of the GMO legislation. Unless some meaningful intervention takes place, the situation will continue unabated.

Public interest groups have little faith in the government's ability to remedy the defects of its regulatory system and put in place sound biosafety legislation, designed to protect society, human and animal health, biodiversity and the environment, from the risks posed by GMOs. On the 8 October 2004, the Minister of Land Affairs and Agriculture published the draft Genetically Modified Organisms Amendment Bill for public comment. [33]The main purpose of the amendments is to ensure that South Africa implements its obligations under the Biosafety Protocol. However, the proposed amendments are dismally disappointing. They do not fully implement the Biosafety Protocol, perpetuate the lack of transparency, will expedite the trade in GMOs, make it easier and more cost effective for the biotechnology industry to conduct field trials, and appear to open up a hitherto closed door to human gene therapy. Moreover, they fail in their entirety, to address even one shortcoming inherent in the GMO Act and its accompanying Regulations. [34]

Certainly, litigation challenging the validity of permits and the constitutionality of the GMO Act and its accompanying Regulations is an enticing option. However, litigation is prohibitively expensive-out of the reach of most public interest groups. Litigation can also drag on for a number of years, without affecting the status quo in the interim. By the

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[31] See M Mayet obo ACB *Critically Analysis of South Africa's Labelling Regulations For Genetically Modified Food, Feed and Products Derived from GM Fed Animals,* October 2004 http://www.biosafetyafrica.net.

[32] See M Mayet obo ACB, *Implementation of Section 78 of the National Biodiversity Management Act: Key Issues and Challenges,* August 2004 http://www.biosafetyafrica.net.

33 Notice 2166 of 2004.

[34] See further, M Mayet on behalf of the ACB, *Submissions on South Africa's Genetically Modified Organisms Amendment Bill Published 8 October 2004* http://www.biosafetyafrica.net

time a case is finally decided in court, GMOs that may have been planted illegally at the commencement of the litigation would long have been harvested, consumed or destroyed.

The Minister of Agriculture and Land Affairs must be made held accountable. Parliament must urgently sanction a thorough independent investigation into the administration of the GMO Act. Such an investigation must specifically be aimed at comprehensively overhauling the GMO Act and its accompanying Regulations. Such an overhaul must root out the systemic problems and shortcomings embedded in the regulatory system. A biosafety regulatory system must absolutely be beyond reproach. In particular, it must as its first and most important priority, ensure the safety of the public and the environment from the risks posed by GMOs. It cannot and should not aim to promote the very technology it is meant to regulate nor be linked with industry or industry lobby groups.

The Constitution of the Republic of South Africa obliges the State to ensure that South Africans have the right to safe food-as a critically import socio-economic right. Maize is an extremely important agricultural product because it is used as a staple for millions of people not only in South Africa, but also in the Southern African region. The Department of Health must as a matter of extreme urgency, undertake or oversee the monitoring of the impacts of GM maize on the South African population, especially those sections of the population that are vulnerable, malnourished and suffering from the HIV or AIDS.

The Department of Trade and Industry and the Department of Labour must urgently conduct an assessment of the social and economic impacts of the importation of millions of tons of GM maize by the animal feed industry in South Africa, from Argentina and the United States. Such an investigation should also examine the impacts on the production of maize in South Africa, the distortions in the market place caused by the sale of such maize and indeed, the long-term food security and food sovereignty impacts for South and Southern Africa, the predatory pricing policies of these grain exporters and the huge subsidy regimes available to them by their governments that assist in attaining those objectives of market domination and displacement of local producers.