ANALYSIS OF SOUTH AFRICA'S GMO ACT OF 1997

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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,[1] 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.[2]

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 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[3] 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.

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.[4] 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 to protect the intellectual property rights of the applicant.[5]

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 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.[6]

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.[7] 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.

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.[8] 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.

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.[9] 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.

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.

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.

[1] 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.

[2] 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".

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

[4] Regulation 6 of the Regulations promulgated under the GMO Act.

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

[6] 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.

[7] Ibid. GMO Act, section 1.

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

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

The Act can be viewed at:
http://www.nda.agric.za/docs/GeneticResources/act15.htm