AFRICAN CENTRE FOR BIOSAFETY

COMMENTS ON REGULATIONS UNDER SECTION 24(5) OF THE NATIONAL ENVIRONMENTAL MANAGEMENT ACT, 1998 (ACT No. 107 OF 1998) AS AMENDED

MARIAM MAYET

FEBRUARY 2005

INTRODUCTION

The ACB has already submitted substantive comments on the implementation of section 78 of the National Environmental Management Biodiversity Act (Biodiversity Act)[1], which we reiterate here. Hence, these comments will be brief and to the point.

COMMENTS

1. The African Centre for Biosafety regards the proposed regulation of Genetically Modified Organisms (GMOs) in terms of the draft regulations under section 24(5) of the National Environmental Management Act, 1998 (Act No. 107 of 1998) as amended, as being **insignificant because they merely confirm the shoddy and hopelessly inadequate manner in which environmental releases of GMOs are currently regulated under the Genetically Modified Organisms Act, 1997 ("GMO Act").**

2. In any event, it is our view that the regulations are not consistent with section 78 of the Biodiversity Act. Not only is the Biodiversity Act primary legislation, but it is also the source for the legal ambit for the regulations regarding GMOs. Section 78 of the Biodiversity Act makes it very clear that what is contemplated is the conducting of an **environmental assessment** and not as is proposed by the regulations, a mere screening process. The difference between these two concepts is particularly relevant and pertinent in the context of GMOs.

3. We are of the view that the screening process envisaged by the regulations (Regulation 9) does not constitute an environmental assessment, but is merely an evaluation comprising of the following: (a) a desk-top review by government based on the product development information generated by the applicant; (b) the public is given an opportunity to make **inputs** by way of written comments; (c) the competent authority is able to grant the application without the need for a full environmental impact assessment.

4. **Read together with section 78 of the Biodiversity Act[2], the proposed regulations make the possibility of any GMO release undergoing an environmental impact assessment extremely remote. We are left with no alternative but to conclude that the DEAT has been successfully persuaded by the Gene Giants such Monsanto to ease safety approval of its risky products and make it as difficult as possible for public interest organisations to protect the environment.**

5. Currently, under the GMO Act, an Applicant who wishes to release GMOs into the environment furnishes "product development" (i.o.w., does the GMO work) as opposed to "biosafety" information to the Executive Council which DEAT is a part of. This information is required in terms of voluntary Guidelines published

[1] http://www.biosafetyafrica.net/briefing_papers.htm

[2] Before the regulations can kick in, section 78 of the Biodiversity Act requires that (a) the application for the environmental release of the GMO in question reach the Minister and the Minister makes his decision to require an environmental assessment, prior to the decision of the Executive Council. The turn around time, from the date of submission of the application, to the date of final decision by the EC, can be as little as 6 weeks; (b) The Minister has to decide whether the release justifies an environmental assessment if he believes the release may pose a threat to any indigenous species or the environment.

by the National Department of Agriculture, *Genetically Modified Organisms, Revised Procedures.*[3]It is on the basis of this information, that a risk evaluation or evaluation (desk top only) is carried out. These guidelines (*Application for General Release; Application for Intentional Release*) do not constitute an adequate framework for conducting an initial environmental assessment and it is therefore not possible, on the basis of these guidelines, for proper and reliable conclusions to be drawn on the potential environmental impact the release into the environment, GMOs are likely to pose. (See for example, objections to GM releases and marketing applications, http://www.biosafetyafrica.net; http://www.biowatch.org.za).

6. It is our respectful view that not only is DEAT missing a unique opportunity to contribute significantly towards biosafety and scientifically rigorous environmental science in the decision-making, crucially, DEAT also appears to be shirking its constitutional duty to ensure that environmental regulations contribute to establishing an adequate framework for the assessment of the potential environmental impacts the release into the environment GMOs are likely to pose. Already, the possibility of subjecting the release of GMOs into the environment to environmental impact assessments is severely curtailed by the provisions of section provisions of section 78 of the Biodiversity Act as has been discussed previously elsewhere.

7. DEAT has ignored our previous requests that specially tailored provisions be drafted for GMO releases because the risks posed by GMOs are unique, requiring decision-making based on the precautionary principle. **Crucially, DEAT appears to have completely forgotten when it drafted Regulations 9 and 10, its responsibility under the Cartagena Protocol on Biosafety particularly, Articles 10(6) and 11(8) dealing with the precautionary principle and decision-making.** The Precautionary Principle's application to GMO regulation is absolutely appropriate. Indeed, the very foundation of biosafety regulation rests with the application of the Precautionary Principle. GMO applications are encumbered by uncertainties at different levels: technical uncertainty, e.g., lack of scientific understanding; epistemological uncertainty, e.g., limited knowledge concerning properties of the GMO in question and methodological uncertainties, e.g., concerning choice of methods for detection and identification of effects. Compounding this situation, is uncertainties related to the occurrence, magnitude, timing, and significance of the level of potentially adverse effects.[4] The paucity of available scientific information necessarily means that it is not possible to conduct a reliable risk assessment. For example, in the case of an application for the release of a GMO into the environment, the regulatory procedures governing risk analysis, risk assessment and risk management should generate scientific advice about potential ecological effects. Such ecological effects depend on the characteristics of the transgenic organism and the conditions of the receiving environment. If no such scientific information is available, or is inconclusive, what should the regulator do? In situations where potential ecological impacts constitute a serious and irreversible threat, and scientific evidence for harmful effects is lacking or uncertain, the

[3] http://www.nda.agric.za/docs/geneticresources/geneticcontrol.htm
[4] Mayhr, A. I and Traavik, T. Genetically Modified (GM) crops: Precautionary Science and Conflicts of Interests *Journal of Agricultural and Environmental Ethics* 16: 227-247, 2003.

precautionary principle should have a role in the risk assessment process.[5] Thus, the Precautionary Principle to GMOs demands a more rigorous scientific approach and ensures for far more democratic decision-making in regard to the acceptance of risks. It also requires the seeking and considering of sustainable alternatives precisely because it explicitly considers uncertainty and ignorance.

8. It is our further submission that the provisions of the Regulation 9 are far too general to apply in a meaningful way to GMOs. In particular, Regulation 9 does not link up properly with the provisions of section 11(1)(b) of the Biodiversity Act. Section 11(1)(b) of NEMBA creates a peremptory duty for the South African National Biodiversity Institute (SANBI) to "monitor and report regularly to the Minister on the impacts of any genetically modified organism that has been released into the environment, including the impact on non-target organisms, ecological processes, indigenous biological resources and the biological diversity of species used for agriculture." The implementation of section 78, especially by way of regulations must be linked directly with the monitoring and reporting functions of SANBI, as it is during the environmental assessment phase, that what should be monitored will be identified. Monitoring is in turn, linked to possible direct, indirect, immediate or delayed effects identified in the risk assessment. At the same time, monitoring should also include general surveillance (routine observations) to detect possible unforeseen adverse effects that were not predicted in the environmental.

9. Finally, we note with extreme disquiet that Regulation 9 (4) does not provide for *public participation* at all. In fact, Regulation 9(4) duplicates the current provisions of Regulation 6 of the Regulations made under the GMO Act, dealing with public input, namely, an invitation to the public to react to advertisements to a proposed release. We do not believe that this form of public input is consistent with the requirements of sections 3 and 4 of the Promotion of Administration of Justice Act (PAJA) and Chapter 2 of Regulations promulgated in terms of PAJA (Government Gazette Vol. 446. No 23710, 31 July 2002.)

[5] Myhr, A. and Traavik, T. The Precautionary Principle Applied to Deliberate Release of Genetically Modified Organism (GMOs) Scandanavian University Press 1999 at 66.