Att: Mr Braulio Ferreira de Souza Dias

Executive Secretary
Convention on Biological Diversity

15/05/2012

Ref. SCBD/BS/MPDM/jh/67587 - Submission of information on identification of living modified organisms that are not likely to have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health.

Dear Mr Braulio Ferreira de Souza Dias

The African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg. We provide authoritative, credible, relevant and current information, research and policy analysis on issues pertaining to genetic engineering, biosafety, and biopiracy in Africa. The ACB has a long track record in engaging in biosafety debates at the national, regional, and international level. Please find below, our response to the following:

"The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP), in paragraph 12 of its decision BS-V/12, requested Parties and invited other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that were considered for the identification of such living modified organisms."

We understand our colleagues at the Third World Network and the Centre for Integrated Research in Biosafety, University of Canterbury, plan to make detailed submissions regarding the position of the Biosafety Protocol on risk assessment and potential adverse environmental and human health effects. That being the case, we shall restrict ourselves to information that is particular to the South African context, that we believe deserves consideration.

1. Designating certain varieties as not likely to "have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" will likely conflict with existing national legislation and undermine biosafety best practice.

The South African GMO Regulations prohibit the undertaking of an activity involving GMO unless a 'suitable and sufficient assessment of the potential adverse effects to the environment,

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human and animal health and safety has been made'. The Regulations further stipulate that any risk assessment shall including: Identification of any potential adverse effect resulting from the novel genotypic and/or phenotypic characteristics of the GMO; and, an evaluation of the likelihood of these adverse effects being realized, **taking into account the level and kind of exposure of the potential receiving environment to the GMO'.**

To a large extent this accords with Annexure III to the Cartagena Protocol on Biosafety.[i] Further, Section 78 of the South African Biodiversity Act was amended in 2009, and 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."

This is supported by the GMO Amendment Act (No. 23, 2006), which 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 (No. 107 of 1998).[ii]

Exemptions to these provisions are not provided for in the South African regulatory regime pertaining to GMOs, which is itself crafted to give effect to the Precautionary Principle.

2. The South Africa – Norway joint study project into insect resistant maize, MON810

The ACB feels it pertinent to draw the Secretariat's attention to the results of the Environmental Biosafety and Co-operation Project (EBCP), between South Africa and Norway.[iii] The ECBP was carried out in order to develop a framework for monitoring of insect resistant maize (MON810), and was coordinated by the South African National Biodiversity Institute (SANBI) and the Directorate of Nature Management (DN) in Norway. The study was done as part of SANBI's mandatory duty in terms of section 11(1)(b) of South Africa's National Environmental Management Act, to monitor the impacts of GMOs on the environment.

A series of scientific studies were undertaken by South African and Norwegian researchers over two maize planting seasons (2008/09 and 2009/10), on a range of areas, including: impact on target and non-target organisms, impact on soil organism diversity, and gene flow and its subsequent contribution to the development of insect resistance.

The results, published in early 2011, are noteworthy, and include:

- GM plants grown in the same environment as near isogenic-parent (non-GM counterpart), responded differently to the same environmental conditions, as shown by differences in protein expression. From these results it was concluded that: Protein expression, and thus many protein-related unintended effects, is **largely dependent on the environment and the genetic background of the crop plant**. Due to the unpredictable nature of these unintended, unwanted effects, **it is essential to monitor and identify such effects in field-based baseline studies in several growing conditions, and with several genetically modified varieties.**

- The Cry1Ab protein expressed in bacterial and maize hosts differed in protein size, and hence are likely to differ in other structural 'protein folding' characteristics. This suggests 'that the practice of using the bacterial version as a replacement for maize versions of the same transgenic protein in safety testing should be re-evaluated.'

- MicroRNA expression between MON810 and its non-GM, near-isogenic parential line, was found to differ 'significantly'. Most studies on MiRNA in plants have been conducted under laboratory conditions, which may select for a certain type of MiRNAs expressed under 'no-stress' conditions. The study concluded that 'to gain a better understanding of environmentally induced MiRNA expression and its effect on GM plants, **it is absolutely essential that MiRNA expression is studied in plants that undergo major environmental stresses.**

- A survey to monitor target pest damage to Bt maize revealed **significant differences in maize damage between geographical areas.**

- Assessing the impact of Bt maize on non-target organisms required knowledge of arthropod biodiversity in maize. In order to gather sufficient information on this, surveys were undertaken, over a period of two years, in **five South African provinces.**

Two significant conclusions can be drawn from these results. Firstly, biosafety risk assessment and risk management is highly location specific, and secondly, in the case of MON810 at least, it cannot be assumed that a GMO will have no adverse impact upon the environment.

3. Since its inception in 2003, the ACB has commented on close to thirty applications for trial and full environmental release of various GM maize varieties. Below is a summary of some of the key concerns we have raised over this period, with specific relevance to subject of this letter.

(a) Pioneer Hi-Bred's GM maize TC1507 x MON810 x NK603 (trial release): In its biosafety dossier, submitted to the Registrar: GMO Act, Pioneer states the need to test their traits using germplasm of different backgrounds, **and in different pedo-climatic conditions**. In the case of event 59122, an additional reason stated for the trial is that Pioneer proposes to add two more locations, thus the regulations require a new application to be filed.[iv] Thus, the biotechnology producers' need for vigorous testing, over a wide variety of environmental conditions, is of

tremendous importance for assessing potential problems. The fact that the South African biosafety regulations require each new trial to be applied for separately is a tacit acknowledgment of the heterogeneous nature of biosafety risk assessment and risk management.

(b) Syngenta's GM maize GA21 x Bt11 (general release): Syngenta's application acknowledged the inevitability of some seed dispersal, but states that this is 'highly unlikely' to result in the transfer of glyphosate tolerance to other plants, due to a lack of wild relatives.[v] In some cases maize pollen has been observed to disperse, and still remain viable, at a range of 400m. The risk of gene-flow to wild relatives is by definition an area specific risk, depending as it does upon local wild population characteristics. Lack of risk due to low populations of wild populations in one area cannot simply be taken as a universal given. Further, in parts of South Africa (and the African continent at large) millions of small scale farmers eke out a living on plots of land of less than 10ha in size. **Again, isolation distances deemed sufficient to prevent gene-flow between two large commercial farms may incorporate dozens of small individual farming plots in South Africa.** The viability period of pollen can vary from 3 hours to 9 days, **depending on environmental variables.**[vi]

(c) In 2009 Monsanto applied to the GMO regulatory authorities in South Africa for a field trial release permit for a GM herbicide tolerant Canola variety (Brascia Napus RT73). SANBI itself indicated that RT73 could cross with over 400 species related to Brassica, **which are found within 58km of the proposed RT73 field trials.**[vii]

(d) In 2008 the South African Agricultural Research Council (ARC) submitted an application for the commercial release of a GM potato engineered for resistance to the tuber moth. The ACB found the ARC's application to contain 'numerous flaws in the design and interpretation of experiments as well as gross omissions in the biosafety tests carried out to date.' For example, no molecular analysis into genetic stability in the field, over several generations was provided. Further, experiments to test the bioactivity of the bacterially expressed Cry1Ia1 gene were not carried out on the intended target pest, the *Phtorimea operculata* (potato tuber moth), but the *Manduca sexta* (hookworm). We found the field trial design to have considerable methodological shortcomings, and that future trials need to be carried out **from several plants at the various locations** to determine the efficacy and reliability of the transgenic line. The ARC's assessment of changes in soil microbiology presented data and evidence cited from literature that deliberately compounded **'the variables of location, soil type and seasonality that have been shown to have a greater overall effect on the microbial community compared to the difference observed between transgenic and non-transgenic crops.**[viii]

4. We could cite many more examples from our work, but believe those which we have shown serve to highlight the fundamental importance of case-by-case risk assessment for products of modern biotechnology. We feel this is of particular relevance to South Africa, being as it is the only significant producer of GM crops on the African continent. We see an alarming parallel between a process which seeks to facilitate the possible blanket approval of GM crops, and

efforts we have observed to harmonise regional biosafety laws in Africa through its regional economic communities, which have a focus and expertise on trade rather than biosafety.[ix]

We would like to thank you for the opportunity afforded us to make these submissions, and for the additional time extension we have been given.

Regards,

Mariam Mayet, Director, African Centre for Biosafety

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[i] ACB (2011). **Overview of the GMO regulatory regime in South Africa.** http://acbio.org.za/images/stories/dmdocuments/GMO%20Regulatory%20Regime.pdf

[ii] ACB (2010). **Letter to Minister Buyelwa Sonjica: request for EIA for GM maize GA21** http://acbio.org.za/images/stories/dmdocuments/ACB_GA21_EIA_request_to_minister.pdf

[iii] SANBI (2011). **Monitoring the environmental impacts of GM maize in South Africa: The outcomes of the South Africa-Norway Biosafety Co-operation Project (2008-2010).** http://www.sanbi.org/sites/default/files/documents/documents/sanbimaizereportlr.pdf

[iv] Stafford, W (2012). **Objection to Pioneer Hi-Bred's application for trial release of multiple GM maize events.** African Centre for Biosafety. http://acbio.org.za/images/stories/dmdocuments/Pioneer_objections_16_04_2012.pdf

[v] ACB (2010). **Objections to Syngenta's application for general release of GM maize event Bt11 x GA21** http://acbio.org.za/images/stories/dmdocuments/ACB_objection_gen_release_GA21_x_Bt11_May_2010.pdf

[vi] ACB (2010). **Submission regarding Monsanto's application for a time extension of an existing permit for activities with GMOs in South Africa – Trial release.** http://acbio.org.za/images/stories/dmdocuments/ACB_objection_MON87460_Lutzville.pdf

[vii] Stafford, W. (2009). **ABC's objections to Monsanto's application for field trial release of herbicide-resistant canola (*Brasica Napus* RT73).** African Centre for Biosafety http://acbio.org.za/images/stories/dmdocuments/Monsanto_Canola_objection.pdf

[viii] ACB (2008). **OBJECTIONS BY AFRICAN CENTRE FOR BIOSAFETY IRO APPLICATION FOR GENERAL RELEASE OF GENETICALLY MODIFIED POTATO MADE BY THE AGRICULTURE RESEARCH COUNCIL (ARC)** http://acbio.org.za/images/stories/dmdocuments/ACB_GM_potato_objection.pdf

[ix] ACB (2010). **Comments on COMESA's draft policy on GMOs.** ACB briefing paper, No.17. http://acbio.org.za/images/stories/dmdocuments/COMESA%20Comments-2010.pdf

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