COMMENTS ON:

DRAFT NATIONAL POLICY DOCUMENT: CREATING AN ENABLING ENVIRONMENT FOR THE SAFE US OF BIOTECHNOLOGY AND ITS PRODUCTS IN SWAZILAND

AND

NATIONAL BIOSAFETY BILL, 2005

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INTRODUCTION AND SUMMARY

We have been approached by civil society groups in Swaziland to provide comments on the Draft National Policy Document, "Creating an enabling environment for the safe use of biotechnology and its products in Swaziland" and the Biosafety Bill, 2005.

According to the Food and Agriculture Organisation (FAO)/World Food Programme (WFP) crop and food supply assessment mission to Swaziland, 2005[1], the country is gripped by yet another food crisis. They estimate the cereal import requirement for 2005/06 marketing year (March/April) to be 110 600 tonnes, of which 69 700 tonnes are expected to be commercially imported from South Africa, its main trading partner and producer and importer of genetically modified (GM) maize, Soybean and cotton. By March/April 2005, approximately 6 200 tonnes of food aid was on hand and in the pipeline, but a deficit of 34 700 tonnes remains to be provided by additional donor assistance.

Swaziland is a net food importing country. Maize is virtually the sole staple for the majority of the population and is the dominant crop grown by the majority of rural households in the communal Swazi Nation Land (SNL), which accounts for about 86% of the land area planted. It is estimated that around 70% of farmers are engaged in subsistence farming. However, for a variety of reasons, domestic production has been steadily declining, and maize imports have been rising rapidly and concomitantly, many households are facing chronic and acute food insecurity.

The majority of rural families purchase rather than grow most of the staple food they consume. However, with 66% of the population living on less than US$1 a day, access to food for vulnerable groups is a critical issue, in the context of declining income-earning opportunities and remittances, high levels of unemployment, and the impact of HIV/AIDS on livelihood of households. The milling industry in Swaziland is oligopolistic in nature, and maize meal prices are too high for poor households: the average price paid by consumers is four times the price charge to millers by the National Milling Corporation, a parastatal company that is the sole authorised importer of maize.

Against this backdrop, the government has produced the following documents, as its response to genetic engineering and genetically modified food (GMOs):

- Comments On Draft National Policy Document: Creating An Enabling Environment For The Safe Us Of Biotechnology And Its Products In Swaziland ("Draft Policy"); and
- National Biosafety Bill, 2005 ("Biosafety Bill").

The Biosafety Bill has apparently been drafted by a cconsultant Lawrence Christy, Attorney (New York), Agricultural, Environmental, Forestry and Fisheries Law, of the FAO.

After having analysed both documents, our key findings are as follows:

- The general approach of the Draft Policy is to provide for a supportive and enabling regulatory environment for the introduction of GMOs into Swaziland.

[1] FOA/WFP crop and food supply assessment mission to Swaziland, Special Report 23 June 2005 http://www.sarpn.org.za/documents/d0001323/index.php

- Core regulatory provisions have been crafted requiring risk assessments, and decision-making based on the precautionary principle but these only apply to domestic commercial sales and plantings of GMOs. However, these provisions are completely undermined by the possibility of exemptions, which will render the entire piece of legislation meaningless.

- The drafter of the Biosafety Bill appears to have taken enormous liberties in the drafting of the Bill. There are numerous serious discrepancies between the Draft Policy and the Biosafety Bill.

- The most damning is the seemingly dishonest and hence unforgivable manner in which the Biosafety Bill utterly ignores the safeguards set out in the Draft Policy with respect to GM food aid. These include requirements that only milled GM food be allowed; that the shipment be accompanied by a written declaration guaranteeing that all events have been approved in the country of origin and have not been contaminated by unapproved events, edible vaccines or any such contaminants.

- Disregarding the Draft Policy, the Biosafety Bill fails to require that bulk shipments of GMOs commercially imported into Swaziland must be assessed for safety, based on the highest standards.

- Provisions regarding the protection of confidential information give the overall impression of draconian style legislation, heavily weighted in favour of secrecy.

- The Biosafety Bill does not establish any mechanisms for public participation in decision-making with respect to applications for authorisations, as envisaged in the Draft Policy.

- The Biosafety Bill does not reflect the provisions of the Draft Policy that requires GM consignments destined for use as feed and food be clearly marked as “contain GM material” and be accompanied by a written declaration guaranteeing that all events have been approved in the country of origin for use as food, feed and further, that they have not been contaminated.

KEY ISSUES

SAFE MANAGEMENT OF GMOS VS PRECAUTIONARY APPROACH

The general approach of the Draft Policy is to create a supportive and enabling regulatory environment for the safe application of biotechnology and its products to enhance the socio-economic development of the country whilst minimising, as far as possible, any adverse effects on human and animal health as well as the environment. (Draft Policy, page 7). The policy has thus not assumed a precautionary approach to genetic engineering in general and GMOs in particular, although the precautionary principle is lifted from Article 10(6) of the Biosafety Protocol, and incorporated into the Biosafety Bill, to apply to decision-making.

Nevertheless, whilst the approach taken in the Policy can generally be described as one that seeks to manage the risks posed by GMOs, the Biosafety Bill has assumed a permissive approach, as is more fully discussed below.

As a small token of Swaziland's commitment to biotechnology research and development, the government is prepared to commit E300, 000 per annum ($50 000).

LACK OF COMMITMENT TO RATIFY BIOSAFETY PROTOCOL

Although a signatory to the Convention on Biological Diversity ("CBD") Swaziland is not yet a Party to the Cartagena Protocol on Biosafety ("Biosafety Protocol") but has been participating in the UNEP-GEF Biosafety Capacity Building Project[2] and as a result of this process, the Draft Policy appears to have been produced

Although the Draft Policy reaffirms several key Articles of the Biosafety Protocol, does not discuss its commitment or plans to ratify the Biosafety Protocol. This is particularly striking given that the one of the three objectives of the Biosafety Bill is the implement the Biosafety Protocol.

South Africa is Swaziland's largest trading partner. South Africa is a Party to the Biosafety Protocol, and as such, is obliged to comply with her international obligations under the Biosafety Protocol, failing which other Parties may take action against South Africa in terms of the compliance procedures of the Biosafety Protocol. However, for as long as Swaziland is not a Party to the Biosafety Protocol, it cannot protect itself from the risks posed by GMOs emanating from South Africa, using these provisions.

SERIOUS DICREPENCIES BETWEEN THE DRAFT POLICY AND BIOSAFETY BILL

We have found several serious discrepancies between the Draft Policy and the Biosafety Bill. Although these discrepancies are dealt with in detail below, it is important to make special mention here, of the seemingly dishonest and unforgivable manner in which the Biosafety Bill has utterly failed to reflect the provisions set out in the Draft Policy dealing with GMOs imported as food aid, the regulation of GMOs imported as food, feed and processing (FFP); documentation to accompany such

[2] http://www.unep.ch/biosafety

shipments, GM free certification, public participation in decision-making and traceability of GMOs.

The Draft Policy also sets out its vision of inspection and monitoring of approved events and labelling and traceability of GM food, where it sets the threshold level for inadvertent mixing at 1%. This indicates that the drafters of the Policy are obviously aware of the current debates and controversies concerning the contamination of the global food supply by GM gain and the need for proper systems to control and regulate bulk shipments of grains emanating from countries that are producing GMOs, like South Africa. However, the drafter of the Biosafety Bill has chosen to ignore these policy imperatives. Why?

NEED FOR BAN ON GENETIC USE RESTRICTION TECHNOLOGIES (GURTS)

The Draft Policy identifies the use of Genetic Use Restriction Technologies (GURTS) as one of the concerns arising from the application of modern biotechnology in agriculture applications.

The Swazi government may wish to consider implementing national prohibitions on the use of GURTs, also known as "Terminator technology" or "genetic seed sterilization" to ensure that Terminator seeds cannot be field-tested or commercialized in the country.

According to the Ban Terminator Campaign[3], sovereign states may wish to prohibit (or ban) GURTs - or "Terminator" genetic seed sterilization technologies to protect the nation's farmers and national food security by ensuring that Terminator seeds cannot be field-tested or commercialized within the country. A specific prohibition is important whether or not the country has already prohibited or restricted the use of GMOs in order to:

- Ensure that the Terminator prohibition stands as a distinct legal policy independent of any future policy actions related to other GMOs;
- Ensure policy coherence between the government's international position on Terminator and its national policy;
- Support a strengthened GURTS prohibition in the UN and, especially, at the CBD; and
- Send an unequivocal signal to international agribusiness that they must invest in crop research that genuinely benefits farmers and food security.

The Ban Terminator Campaign points out that two countries, one in Asia and the other in Latin America, have already legislated national bans on Terminator - Brazil though its biosafety law, and India through its legislation governing plant variety registration. These laws provide examples of language that Swaziland may wish to adopt to prohibit Terminator.

In March 2005, the Government of Brazil incorporated a ban on GURTs into their biosafety legislation (Law 11.105):

> *Art. 6o The following are prohibited:*
> *[...] VII - the use, sale, registration, patenting and licensing of genetic use restriction technologies.*

[3] Personal communication, ETC Group, a member of the Ban Terminator Campaign, 19 August 2005.

> *For the purposes of this Law, genetic use restriction technologies are understood to be any process of human intervention aimed at generating or multiplying genetically modified plants in order to produce sterile reproductive structures, in addition to any form of genetic manipulation aimed at activating or disactivating genes related to plant fertility through external chemical inducers.*

In 2001 the Government of India prohibited registration of Terminator seeds (The Protection of Plant Varieties and Farmer's Rights Act, Act 53 of 2001):

18. (1) Every application for registration under section 14 shall— (c) be accompanied by an-affidavit sworn by the applicant that such variety does not contain any gene or gene sequence involving terminator technology. [4]

It is about time that a country in Africa similarly takes the lead on this critically important issue.

[44] Personal communication, ETC Group, 17 August 2005.

DETAILED COMMENT ON BIOSAFETY BILL

Objectives: compromising human health

The main objective of the Biosafety Bill reiterates verbatim, the objectives of the Biosafety Protocol as set out in Article 1 of the Protocol, with one notable exception: it does not include the reference to the Precautionary Approach as contained in Article 15 of the Rio Declaration.

In any event, it is not appropriate for domestic legislation to mimic the objectives of a heavily negotiated international environmental agreement, concerned principally with biodiversity protection and transboundary movement of GMOs. In doing so, the Biosafety Bill treats central issues such as safety to human health, and socio-economic impacts as coincidental to the conservation and sustainable use of biodiversity. This notion is reinforced by the Biosafety Bill's definition of "risk to human health," discussed below.

Definitions

Unscientific definitions

Very few definitions have been provided for and several of them are not scientifically correct.

1) In particular, the definition of "biosafety" is not correct because biosafety is not a mechanism, and certainly not one that is designed to ensure the safe handling, transfer and use of products of biotechnology. What is important is not so much the need to define "biosafety" but that the legislation makes it quite clear, that the imperatives driving the legislation, is the safety of human health, biodiversity and society, within an overall precautionary context.

2) We also point out that the definition of "contained use" should be revised. This definition imitates the Biosafety Protocol's definition with the exception that the words "general population" has been added on to the Swazi version. However, the Biosafety Protocol's definition of contained use has several difficulties,[5] because it allows for several kinds of deliberate releases to take place, including the following:

- Caged transgenic fish or other aquatic GMOs in open ponds, lakes and marine environments;
- Vaccinations with transgenic viruses and naked nucleic acid vaccines
- All forms of gene therapy
- Xenotransplantation using transgenic animal organs
- Open field trials with fencing or other physical barriers (including green house experiments);
- Transgenic organisms enclosed in cages or other containers and destined for deliberate release;
- Liquid and solid wastes of transgenic livestock contained in the laboratory;
- Liquid and solid wastes of laboratories creating transgenic organisms destined for deliberate releases.

[5] Lim Li Lin "The Core Issues in the Biosafety Protocol: An Analysis" in Third World Resurgence No 114/115 at http://www.twnside.org.sg/title/core.htm

It is generally accepted that the Biosafety Protocol contains many shortcomings, owing to the very nature of the Protocol: a heavily negotiated text representing only *minimum* international standards. Parties to the Protocol are, however, allowed in terms of Article 2(4) to take more stringent measures than those contained in the Protocol. Tightening up the loose definition of "contained use" of the Biosafety Protocol is one such example of taking more protective measures.

3) The definition of "risk to human health" is a glaring example of the approach taken by the drafter of the Biosafety Bill to relegate the biosafety enquiry into the risk to human health only in so far as it is a direct result of an adverse effect on the conservation and sustainable use of biological diversity. This approach and indeed, the liberties taken by the drafter is astounding, given that Swaziland is a net food importer and hence, one of the principal concerns for Swazis would be, the direct impact of consumption of GMOs on their health, and not via an adverse effect on the conservation and sustainable use of biodiversity.

Shoddy drafting of definitions

> The definition of "applicant" will have to change and exclude references to "country" because countries do not make application for authorisation. A definition for "person" should be created. The definition of "risk assessment" makes reference to both the defined concept of "contained use" and "confined use." We are not sure what confine use refers to in the context of the Biosafety Bill but note that either a GMO is contained or it is released. There is not confined use!

This type of shoddy drafting is also evident elsewhere in the Bill. For instance, in section 9(1)(e) reference is also made to "confined trials."

Application of Biosafety Bill-Debate needed on cloning, human gene therapy and germline modification

It is extremely important for the people of Swaziland to discuss which genetic engineering applications they are not prepared to accept i.o.w. impose an outright ban and reflect this in the Biosafety legislation. The Draft Policy has already started this debate by stating that it is not prepared to allow biotechnology applications in respect of the following:

- Cloning
- Pre-implantation sexing of embyos in humans.

The debate, must, however go beyond this and address other critically important applications including, human gene therapy and germline modifications (Human gene therapy is the use of normal genes or genetic material to replace or cancel out the "bad" or defective genes in a person's body that scientists believe are responsible for a disease or medical problem. The "good" genes find their way to the right spot in the body and begin to do the work required. Germline modification entails the alteration of the genetic code in sperm cells, ova and fertilized ova to prevent disease or to induce desired traits, e.g. designer babies.)

Composition of Institutions-muddled and includes industry

The composition of the National Authority on Biosafety (NAB) and National Biosafety Advisory Committee ("Advisory Committee") appears to muddled.

The NAB is the decision-making body and should only be comprised of government officials. Governments must govern and be accountable to society for their decisions. It is not acceptable that a person from the business sector be involved because this gives rise to a serious conflict of interest. Nevertheless, it is not known why only a place has been set aside for a consumer representative. Similarly, civil society (excluding business and industry) should not be included in the NAB, unless their role is only as observers, otherwise, they will run the risk of legitimising the decision-making process. Finally, the WTO focal point should be included in the NAB and not the Advisory Committee.

Indeed, it is preferable, that experts from civil society be represented on the Advisory Committee. It is important that business and industry be expressly excluded because this gives rise to conflicts of interest. Furthermore, it is important, for the sake of transparency, fairness and equity, that provisions be made for the Minister to invite nominations from the various sectors, and then appoint a suitable candidate from the list of nominations.

Confidential information vs access to information

Issues regarding the protection of confidential information and the public's rights of access to information will have to be substantially redrafted. First, section 9(7)(c) creates a blanket prohibition on the disclosure of information on the part of the NAB without the express written authorisation of the applicant identifying the information as confidential. Certainly, there is a right to protection by the application of confidential **business** information, not to confidential information, which it decides may or may not be disclosed. Section 15(1) emphasises the rights of the applicants to decide, without any reference to a set of criteria that also affirms the public's rights to information, what he/she may or many not deem to be confidential business information. The non-disclosure of information is further reinforced by section 15(2), which gives the overall impression of draconian style legislation, heavily weighted in favour of secrecy.

Experience in South Africa has shown that where no process for the transparent, fair and equitable determination of what genuinely constitutes confidential business information (CBI) of the applicant, the applicant is granted an unfettered right to severely restrict the rights of the public to information. Civil society groups in SA have for instance, been granted 23 pages out of 2500 pages of a docket. Litigation in the South African courts was necessary (Biowatch Trust vs Minister of Agriculture & Land Affairs NO and others), and now, the public is able to access up to 2000 pages from the risk assessment files of companies.

The provisions of section 15(3) dealing with the information that the public has a clear right to, have been lifted directly from the Biosafety Protocol and are not sufficient in circumstances where claims of confidentially can triumph over such rights of access, particularly where these rights are not absolute.

Notification & contained Use

The Biosafety Bill has created quasi notification/permitting procedures for activities under contained use conditions (section 11). In this regard, it has fallen short of requiring that a permit be required, but makes provision for the NAB in consultation with the Advisory Committee to request a risk assessment and for some sort of final decision to be made, including refusals. Such a risk assessment has to comply with the first schedule and "recognised risk assessment techniques." This is quite vague. It is highly recommended that every effort be made to set standards for contained use, as contemplated by Article 6(2) of the Biosafety Protocol.

Core regulatory provisions, narrow application

Sections 12, 13, 16, 18, and 19 of the Biosafety Bill contain the core of the Biosafety Bill, but do not apply to those GMOs that are of immediate and major concern to Swaziland, namely, GM food aid, including GM food sold on the commercial market. The bulk of the international trade/aid in GMOs are not those intended for planting, but for use as food aid, or feed, feed and industrial processing (FFP), see discussion below.

Section 12(1) requires that a person who intends to introduce GMOs into the environment, make application for authorisation. However, what the Biosafety Bill does not address, is the critically important issue raised by the Biosafety Policy, that **"where GMOs destined for use as animal feed, food and processing have the potential to be released into the environment, they shall be treated as GMOs to be treated as GMOs to be introduced into the environment and thus subject to the AIA procedure."**(page 17 of Draft Policy)

Section 12 (2) requires clarification because it creates the impression that a cosy relationship is envisaged between the Advisory Committee and the applicant in a series of pre-application consultations, where the Advisory Committee may unilaterally decide to exempt the applicant from complying with information requirements. In any event, the Advisory Committee does not have decision-making powers, and hence this provision is ultra vires the provisions of *inter alia*, section 9 of the Biosafety Bill.

Equally worrying is section 12(2)(a) which allows the applicant leeway to decide which information it may "deem relevant to an assessment of the potential risk and benefit of the requested activity." These provisions are quite mischievous because it is not for the applicant to decide what may or may not be relevant but for the regulators to clearly stipulate in the Bill the requirements for risk assessment. This has to go beyond the second schedule, which is quite limited as it is based on the minimum requirements as set out in Annex III of the Biosafety Protocol. It is also a source of discomfort that the concept "benefit" is introduced into a subsection that is dealing with risks. Biosafety regulation cannot be used by applicants to promote their products as this will be tantamount to an abuse of the process.

Section 12(3) needs to be amended to ensure that the applicant furnishes a declaration that the information provided is true and correct, and the word "factually" should be deleted because the truth cannot and should not be qualified.

Section 13(1) and (2) requires that authorisation is required for the following activities:

- GMOs intended to be introduced into the environment;
- GMOs that are to be placed on the market (GMOs that are to be sold to a third party); and
- Import of GMOs for the purposes of either introduction into the environment or placing on the market.

Exports of GMOs are dealt with only in the context of export to a country that is a Party to the Cartagena Protocol. The issue of exports should be thoroughly debated in the context of (a) transit; (b) exports to countries irrespective of whether they are Parties to the Biosafety Protocol; and (c) implications for Swaziland as a SACTU state regarding GMOs passing through its territory from South Africa.

It must be noted, however, that the provisions dealing with acknowledgement of receipt of the application as set out in section 16 apply only to section 12 applications.

Risk assessment and risk management are dealt with in section 18, and it requires that appropriate and adequate risk assessments are carried out for all activities that require authorisation under section 13. This means that GMOs imported as food aid, food, feed and processing are expressly excluded from these requirements. This issue needs to be urgently revisited, as well as the provisions of the Draft Policy as set out in section 10, page 16 of the Draft Policy.

It is recommended that the drafter take into account, the initiatives underway in many countries in Africa regarding the development of comprehensive risk assessment requirements that go beyond Annex II of the Biosafety Protocol, which has been used as a basis for the risk assessment in the second schedule of the Swazi Biosafety Bill.

Section 18(5) needs attention, because it is not known what the following means “on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the GMO.” In any event, we strongly recommend that the provisions dealing with the making of a risk assessment report by the NAB for consideration by the Advisory Committee be deleted. The Advisory Committee must see the full risk assessment report, the application-in fact the entire docket must be furnished to the Advisory Committee.

Section 18(7) is a key provision, as it appears to accept that GMOs will pose risks yet works on the erroneous assumption that risk management measures can be prescribed in order to prevent adverse effects on the conservation and sustainable use of biodiversity, also taking into account the risks to human health.’

Section 18(8) is also another extremely worrying provision in that anticipates that the report referred to in section 18(5) be made available to the applicant for comment. The applicant is not part of the decision-making process! The Applicant cannot be privy to internal communication and decision-making between and amongst the NAB, the Advisory Committee and any sub-committees and working groups established but it, in terms of the Act. However, provision can be made for the Applicant to be provided with an opportunity to substantiate, explain or provide further information concerning any aspect of the risk assessment including any part of the application submitted by it.

Decision-making is dealt with in section 19 and whilst it refers to the need to take into account comments submitted by the public pursuant to section 26, section 26 does in fact not provide for any mechanism for the public to participate in decision-making as is set out in section 9.2 of the Draft Policy.

Socio-economic considerations are dealt with in section 19(4) and this imitates the provisions of Article 26 of the Biosafety Protocol. It is not necessary to include the phrase “consistent with the international obligations of the country” as this is implicit

in all legislation. In any event, Article 26 is the minimum standards to be applied and is not meant to apply to all environmental releases, but only to those GMOs that are imported into Swaziland as a consequence of the transboundary movement. At the same time, socio-economic considerations should not be limited only, to the impacts arising only from environmental release of GMOs. The acceptance of GMOs as food aid has major socio-economic ramifications for Swaziland. It must also be borne in mind that Article 26 of the Biosafety Protocol is the subject of further deliberations by the Parties to the Biosafety Protocol and therefore, Swaziland may wish to retain some flexibility and not pre-empt on negotiations and decisions that may still be taken at a later stage.

An adapted version of the Precautionary Principle of the Biosafety Protocol is contained in Section 19(4) of the Biosafety Bill, which is good. However, the manner in which decision-making based on the PP will operate in the context of the provisions of section 18(7) is open to debate.

GMOs imported as food aid, food, feed and processing- scandalous provisions in flagrant disregard of government policy

In terms of section 14 of the Biosafety Bill, GMOs imported into Swaziland for food (including food aid), feed, and processing are only subject to notification, as set out in the third schedule. Section 10 of the Draft Policy deals with the issue on page 16, and it is clear that a policy decision has been made to forego safety, in favour of the acceptance of food aid in particular. This is a matter for internal debate, discussion and decision-making. In this regard, the commitment to the conducting of extensive impact studies are to be welcomed. However, the Biosafety Bill does not appear to honestly reflect the many safeguards that must be undertaken in respect to GM food aid. These include:

- Only GM milled be allowed;
- A written declaration is required that all events in all GM food aid donations have been approved in the country of origin for use as food and that such donations have not been contaminated by unapproved events, edible vaccines or any such contaminants; and
- Random tests to be conducted to determine presence of GM material.

Additionally, the Swazi government has articulated in section 10.2 (page 17) of the Draft Policy how it wishes to regulate GMOs destined for use as animal feed, food and processing. It requires as already discussed above, that the AIA procedure apply in the event that GM food and feed have the potential to be released into the environment. It also requires that food and feed containing or produced from GMOs must be subject to a safety assessment based on the highest standards.

Section 29 dealing with the documentation for GM food/aid, feed and processing has lifted out the interim and highly contentious provisions of Article 18(2)(a) from the Biosafety Protocol. One of the most controversial issues that could not be agreed upon during the Protocol was the rules for the identification of GM content in bulk agricultural trade. Article 18(2)(a) of the Biosafety Protocol, which embodies only interim arrangements, allows bulk shipments of GMOs traded directly as food, feed and processing be identified ambiguously as “may contain” GMOs. This issue is expected to be finally resolved by the Parties to the COP MOP4, Curitiba, Brazil 2006.

On page 17 of the Draft Policy the government of Swaziland has clearly stipulated its position that it requires consignments destined for use as feed and food containing GM material must be clearly marked “contain GM material” and must be

accompanied by a written declaration to the effect that all events involved have been approved in the country of origin for use as food, feed and further, that they have not been contaminated.

Equally damning is the deafening silence of the Biosafety Bill to deal with the Swazi government's preference for provisions for GMO Free certification for bulk commodity shipments. Why has the drafter so utterly disregarded the policies of a sovereign country?

Unintentional and unauthorised introduction of GMOs-more muddled provisions

Section 17 needs to be substantially redrafted in order to distinguish between unintentionally and accidental releases and unauthorised releases/contamination of seeds/food by unauthorised GMOs. There are 2 distinct issues, requiring separate treatment, as the measures that ought to be taken and the consequences arising from unauthorised releases/contamination of food supply are different, including questions of liability and redress. Section 17 appears to have been inspired by Article 17 of the Biosafety Protocol, which deals only with unintentional transboundary movements and emergency measures. The overall context of Article 17 of the Biosafety Protocol is transboundary movements, transboundary harm, notification, consultation, taking of emergency measures and so forth. It is highly recommended that a discreet set of provisions be drafted to implement the provisions of Article 17 of the Biosafety Protocol, and separate provisions be created for unauthorised releases and contamination of the food supply/environment by unauthorised GMOs, including linkages to appropriate enforcement provisions.

Simplified procedures or mischievous regulation?

The provisions of section 20(2), provides for the possibility of exempting any GMO or activities (field trials, commercial releases, sale) from the provisions of section 12 and 13 (application, risk assessment etc.) where the NAB determines that sufficient experience or information exists to conclude that the GMOs or activities do not pose a significant risk to the conservation and sustainable use of biodiversity, taking into account also the risks to human health.

These far-reaching provisions have been crafted on the pretext of creating simplified procedures but are calculated or intended to render the entire piece of legislation worthless. It is common cause that the harm caused by GMOs to biodiversity and ecosystems may only manifest in the long term. It is highly recommended that these provisions be deleted.

The provisions of section 20(3) are no better. What does "sufficient experience" mean? What criteria will be used to make a decision that GMOs or activities are not likely to pose any risks? It is highly recommended that both sections be deleted. These are not simplified procedures but are really designed to erode the only real decision-making powers and responsibilities that the NAB and Advisory Committee have. The fact that provision is made for public input prior to a decision taken on simplified procedures, does not cure section 20 of its profound defects.

The peremptory language used in section 20(7) is utterly mischievous, given the Swaziland is not even a Party to the Biosafety Protocol and furthermore, even it should become a Party, it will not be obliged to exempt any GMO as contemplated by Article 7(4). The sovereign rights of a Party to regulate GMOs can never be undermined by decisions taken by Parties to the Protocol. Section 21 dealing with petitions for exemptions and simplified procedures should accordingly also be deleted.

Access to information, public awareness and participation-defeating objectives of government policy

It is not appropriate to require the applicant to promote awareness and education of the public as contemplated in section 26(1) of the Biosafety Bill. It is important, however, to make provision that the NAB also make available to the public, information on the alternatives to GMOs.

It appears that public participation is limited only to publication concerning proposals, decisions and petitions concerning exemptions from section 12 and 13 and simplified procedures, and proposed decisions on applications for contained use (section 26(2))

A strange provision is created in section 26(4) because it allows for written comments in respect to a proposed decision to be taken into account, regarding any application for placing on the market of a GMO or any petition for an exemption within sixty days from the date of a notice. Such comments are to be considered by the NAB in terms of section 16(2) dealing with acknowledgement of response to the applicant which is to be done within thirty days. The timing does not work out, and the public's comments but be considered in the decision-making section of the Bill. In any event, it is not known why the public's right to participate in decision-making is not included in all applications, notifications, and petitions and in respect of all GMOs? What about applications for field trials, commercial/general releases and GM food/aid?

These provisions are really shocking taking into account the Section 9.2 (pp15-16 of the Draft Policy which clearly contemplates that information about applications will be widely advertised in the print and electronic media, including community stations where possible and that the public would be informed where they can view dossiers.

Public access to information has already been discussed earlier. Further provision is made for the publication of notices of final decisions taken and the maintenance of a registry.

Appeals

It is recommended that provision be made for the general public to appeal against a decision. This right cannot be given solely to the applicant. Every effort should be made to ensure that experts in biosafety be included in any body that will be hearing the appeal.

Cessation of orders

These provisions should be redrafted as they are not tailored for GMOs. It is recommended that the drafter have sight to biosafety laws dealing with risk management.

Labelling and traceability of GM food

The Biosafety Bill does not provide for traceability at all despite the fact that the Draft policy requires that food containing GM material must be kept separate from GM free food during all stages of production, processing and distribution.

Although the Biosafety Bill deals with labelling of GM food in section 31, it has failed to provide for provisions as set out in the Draft Policy concerning false allegations and the threshold for inadvertent mixing, which the policy sets at 1%.