Comments on Lesotho's Biosafety Bill[1]

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Introduction

Lesotho, totally enclosed by South Africa, comprises of 30, 355 sq. km, and has a population of approximately 2.5 million people. Lesotho's economic growth is supported predominantly by the manufacturing sector, with the United States being the largest market for Lesotho's exports from the garment industry. Between 2002 and 2003, exports grew from US$267, 977.69[2] million to US$330, 372,00 million. However, in recent years, agriculture's contribution to Lesotho's GDP has fallen from around 30% in the 1980s to less than 20%. According to the Southern African Regional Poverty Network's publication dealing with crop production outlook for the 2004/05 season, a rapid assessment from 15-30 March carried out jointly by the Food and Agriculture Organisation (FAO), the Ministry of Agriculture and partners indicates below normal crop yields can be expected, with total cereal production estimated at 122, 300 MT, which is 14% below the last five year average. [3]

During the 2001-2 food crisis in Southern Africa when Zambia refused to accept GM food aid, Lesotho together with Malawi, Mozambique and Zimbabwe were reported as requesting that GM seeds first be milled before distribution to prevent their cross-breeding with local flora.[4]

Lesotho ratified the Cartagena Protocol on Biosafety ("Biosafety Protocol") on the 20 September 2001. The Biosafety Protocol became binding on Lesotho on the 11 September 2003. Lesotho has been participating in the UNEP-GEF Biosafety Project,[5] and has produced a *Draft National Biosafety Framework for Lesotho, January 2005* (NBF) which to a great extent is descriptive of the *Draft National Biosafety Policy for Lesotho "Striving to achieve safe application of biotechnology"*(Draft Policy) and *Draft Biosafety Bill, 2004"*

However, the NBF contains 1 _ pages of "Introduction" that stands out in stark contrast to the content and tenor of the Draft Policy, and has more in common with

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[1] We have been approached by PELUM LESOTHO, to comment especially on the Draft Bill, 2004.
[2] http://www.sarpn.org.za/documents/d0001204/index.php
[3] http://www.sadcreview.com/country_profiles/lesotho/les_introduction.htm
[4] Africa Bites the Bullet on Genetically Modified Food Aid, September 26, 2002 http://www.worldpress.org/Africa/737.cfm
[5] http://www.unep.ch/biosafety/partcountries/LScountrypage.htm

propaganda pamphlets produced by the biotechnology industry. The following statements are made in the Introduction to the NBF:

" At present and in so many developing countries, it is generally agreed that the technology is simply unavoidable and that ignoring it now will deal a severe blow to the future prosperity of science, industry and international trade."

"Biotechnology, particularly genetic engineering may be one of the most important ways in which many developing countries can add value to their biological diversity and solve some looming and inevitable population pressures."

"Regarding the planned introduction into the environment of GMOs, eminent scientists strongly believe that there is enough knowledge of the relevant scientific techniques and experience with genetic engineering and GMOs to act as a reference point for the safe introduction of such organisms into the environment (outside the research laboratories). Moreover, they further argue, that there is no evidence so far of the existence of (i) extreme, unimagined and unmanageable dangers associated either with the technique used in modern biotechnology and their resultant products or in the safe transfer of genes between organisms and, (ii) of differences in the magnitude and type of risks emanating from the introduction of GMOs on the one hand and of unmodified organisms on the other hand into the environment. (Committee on the introduction of genetically engineered organisms into the environment, 1987)."

In contrast, the Draft National Policy drafted only a few months earlier, concludes its Preamble as follows " Lesotho has a variety of plants and animals, with unique life forms, some of which are not found in any other country. While a cautious application of biotechnology may prove important for the country in meeting its national development goals, certain biotechnology applications, practises and products may seriously contradict the economic, social and ethical norms of Basotho, including destruction of biodiversity."

GENERAL

Evidently influenced by the UNEP-GEF Biosafety Project, the Biosafety Bill has been drafted principally to implement the Biosafety Protocol verbatim, and in so doing, perpetuates some of the weaknesses and deficiencies of the Biosafety Protocol. For instance, the scope of the Biosafety Bill is predicated on the scope of the Biosafety Protocol where the risks to human health are not central to the biosafety enquiry, but are ancillary to the protection of biological diversity in the use of the terms 'taking also into account risks to human health." (Section 2(1) of the Biosafety Bill; Article 4 of the Biosafety Protocol). The Biosafety Bill also excludes as does the Biosafety Protocol, the transboundary movement of GMOs that are pharmaceuticals for humans that are addressed by relevant international agreements and organisations.

In fact the entire Biosafety Bill is littered with examples of the extent to which the sole imperative underpinning the drafting of the Bill appears to be to implement the basic minimum standards of the Biosafety Protocol. This is dealt with in more detail below, but a striking further example to this effect, is the way in which the documentation to accompany bulk shipments of GMOs has been dealt with: exactly as stipulated in Article 18(2)(a), notwithstanding that these provisions merely mirror interim arrangements, pending the finalisation of this yet unresolved issue. The Biosafety Bill in its slavish attempt to emulate the Biosafety Protocol has failed dismally to live up to its objective to develop "state-of-art biosafety frameworks.." (P.4 of the Draft National Biosafety Policy).

Although the implementation of the Biosafety Protocol is an important imperative, biosafety regulatory frameworks must of necessity be comprehensive and holistic,

going well beyond the scope of the Biosafety Protocol, the Protocol is essentially, an international environmental agreement designed to regulate the cross border movement of GMOs with the objective of avoiding harm to biodiversity. Government officials run the risk of being misled into believing that once they have implemented the minimum standards of the Biosafety Protocol, their Biosafety Frameworks would thus be complete. This is not the case because issues regarding labelling, traceability, access to administrative justice, ethical and cultural issues, transparency in decision-making, and decision-making generally, that does not involve imports and exports, also require careful attention and consideration.

The approach taken in the drafting of the Lesotho Biosafety Bill is consistent for instance with the approach taken by USAID when it made extensive comments throughout the text of the draft Zambian biosafety legislation, when it urged Zambia to use the specific wording of the Biosafety Protocol in regard to definitions, socio-economic impacts, risk assessments, the precautionary principle and so forth. We repeat here, our response to USAID's comments in the Zambian bill regarding the rights and obligations vesting in Parties to the Biosafety Protocol regarding its implementation by way of national legislation.

1. Every single safety measure, definition, proposal, annex, was bitterly contested by the genetic engineering industry and the major grain exporting countries ("the Miami Group" comprising of Canada, the US, Australia, Uruguay, and Chile), during the negotiation of the Biosafety Protocol. As a Party to the Convention on Biological Diversity, Lesotho participated fully in the negotiation process that eventually culminated in the Biosafety Protocol. Hence, as Lesotho is no doubt aware, the resultant text of the Biosafety Protocol thus represents the lowest common denominator that countries were able to agree upon.

It is the writers' view that there is no need for Lesotho to restrict itself unnecessarily to the actual wording (verbatim) and provisions of the Biosafety Protocol, because the Protocol allows for the taking of more stringent/protective measures.

2. The Biosafety Protocol applies to the transboundary movement of GMOs, handling and use. Its central operational provisions are centred on the Advanced Informed Agreement (AIA) procedure. It is therefore, not appropriate to subject every regulatory aspect of GMOs and associated activities to the framework established by the Biosafety Protocol. The Biosafety Protocol does not and cannot restrict the sovereign rights of countries to require notifications, prior informed consent and risk assessments for all GMOs and its uses, irrespective of whether the Biosafety Protocol requires the AIA procedure to apply to such GMO and associated uses**.**

> Article 2(4) of the Biosafety Protocol expressly provides as follows:
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> *'nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's obligations under international law".*

Article 2(4) establishes that the rules contained in the Biosafety Protocol are a "floor" rather than a "ceiling"-i.e. they are *minimum standards* for achieving the objective of the Biosafety Protocol that the countries were able to agree to, when they negotiated the Protocol. When countries draft their national biosafety frameworks, article 2(4) expressly reserves the right to adopt protective measures that go beyond the agreed minimum. The only proviso is that in taking such measures, Parties must ensure that these measures are not in conflict with its obligations under other international agreements. International agreements would include not only the World Trade

Organisation, but also, international environmental agreements such as the Convention on Biological Diversity.

A great deal of work lies ahead both for the government of Lesotho, its scientific community and civil society. However, this is not to say that the work already done is without value. Indeed, there are important gems in the Biosafety Bill that must be retained, including the important precautionary principle set out unequivocally in section 24 of the Biosafety Bill as well as requirement that the applicant furnish evidence of insurance cover to meet its legal obligations and provisions dealing with liability and redress.

SPECIFIC COMMENTS

1. A new definition 'confined use' has been introduced by the biosafety bill to obfuscate the issue that GMOs are in fact released into the open environment during field trials. This definition is unscientific and dishonest and should not be used in lieu of the definition for 'field trial.'

2. In section 4(2), the Competent Authority (CA) is given the powers to make decisions on GMO applications by either consulting with the National Biosafety Council (Council) or the Registrar. It is not appropriate for the Competent Authority to be given a discretion whether or not to consult with the Council, whereas it must be obliged to do so, given that the Council will be comprised of inter-departmental officials having some level of relevant expertise whereas the CA, will be comprised of only officials from the Department of Environment. It should also be noted that a Scientific Advisory Committee is also appointed to advise the CA, and provision must be made for the decision-making function of the CA to be subject to consultation with the Scientific Advisory Committee. Furthermore, it is not necessary for the CA to consult with the Registrar, who should be given no more than administrative functions.

3. As mentioned earlier, the Biosafety Bill exclusion from the bill, the **transboundary movement** of GMOs that are pharmaceuticals in section 2(2) and in this regard, imitates the provisions of Article 5 of the Biosafety Protocol. It must be noted that during the Biosafety Protocol negotiations, the intention behind this 'partial' or 'potential' exclusion of GM pharmaceuticals for humans was that the World Health Organisation (WHO) would address GM pharmaceuticals for humans and therefore, the Protocol need not duplicate such efforts. However, The WHO does not deal with GM pharmaceuticals as such. In any event, it only sets standards for human health and does not take into account impacts on the environment and biodiversity. Such standards are usually non-binding and are at best, mere recommendations. It is thus recommended that the all GMOs should be covered by the provisions of the national biosafety law.

4. In regard to the composition of the Council (section 7), it is recommended that members also have expertise in pest management systems and insect ecology, taking into account the high number of GM crops that are engineered to produce proteins that are ostensibly resistant to certain insect pests (e.g. Bt crops).

5. In regard to the tenure of office of Council members (section 8), it is highly recommended that appropriate provisions be introduced to ensure that there are no conflicts of interests between Council members and the biotechnology industry, seed companies, food producers, importers, exporters, of food, feed and seeds etc.

6. As mentioned already, the functions of the Registrar should be revised and in this regard, special attention should be paid to the nature of administrative functions that the Registrar should be performing. It also appears as if it may not be appropriate to give the Registrar duties in regard to the promotion of public awareness and education functions, as is the case in section 12(1)(h) of the biosafety bill.

7. In regard to the functions of the Scientific Advisory Committee, special attention should be given to 2 very different and distinct concepts: (1) risk assessment; and (2) risk evaluation. Section 14(c) requires the Committee to carry out risk assessment of GMOs on a case- by- case basis. Risk Assessments are usually done by the developer of the GMO-either the biotechnology company or a research institution acting on its behalf. It is prohibitively expensive for a government functionary to conduct case-by-case risk assessments and perhaps what is being conveyed in the section, is the notion of evaluations of the risk assessments.

8. Section 15 establishes a socio-economic panel, but no provisions are made concerning the membership of the panel, its duties and functions, its interactions if any, with the public and society and indeed, with the decision-making institutions. More attention should be paid to this crucial provision.

9. Although section 16(1) mentions "placing on the market", it does not appear, as if the intention was to ensure that the totality of the provisions under section 16 apply to the placing on the market of GMOs. More careful attention should be paid to this issue, taking into account two important considerations: (a) Lesotho imports agricultural products for domestic needs, including GM maize and soyabeans as food aid, and (b) the biosafety bill specifically defines 'placing on the market' to mean 'supplying or making available to third parties a GMO, where there has been monetary exchange or not, and include the giving of food and feed as aid. Special and strict provisions should be made for this category of GMOs, taking also into account the fact that the most commonly traded GMOs are those for food (including food aid), animal feed and processing. What is of special concern is that a separate paragraph has been created in section 18 of the Biosafety Bill, dealing with GMOs for Direct Use as Food, Feed, or Processing. In this regard, the Biosafety Bill has adopted a weak, loose, and inappropriate system to deal with such GMOs which is adopted from Article 11 of the Biosafety Protocol.

It is clear that the biosafety bill intends to adopt the approach that GMOs imported into Lesotho for use as feed, food and processing not be subject to the same regulatory measures and rigour as GMOs imported for introduction into the environment, since the Biosafety Protocol creates a special mechanism to deal with the former scenario. It is true that the Biosafety Protocol excludes from the AIA procedure of the Protocol, the so- called LMO-FFPs (living modified organism intended for direct use as food, feed and processing). However, it is very important that Lesotho recall that the distinction between LMO-FFPs and GMOs that are imported for direct introduction into the environment is a distinction that the Miami Group of countries and industry introduced into the Biosafety Protocol in order to expedite trade in GMOs and not because scientifically, the distinction is justified. The African Union's Model Law on Safety in Biotechnology for example, establishes uniform provisions that apply to all GMOs and its associated uses because it views the risks from all GMOs as being the same, irrespective of whether GMOs are used as seeds, pharmaceuticals, food, feed or processing.

It must also be borne in mind that GM seeds being imported into Lesotho for the purposes of milling and other processing are not subject to the same systems as those

found in developed countries. What are the chances of GM seeds being planted unwittingly by farmers? The example of the contamination that has occurred in Mexico, the centre of origin of maize, is instructive in this regard. Mexico imports maize from the US for food, feed and processing. Although the growing of GM seeds is expressly prohibited in Mexico, contamination has nonetheless occurred.

- It is Lesotho's sovereign right to require notification and that its prior informed consent be required, before any import of any GMO for any use, can take place;
- It is Lesotho's sovereign right to require a risk assessment for any import of any GMO for whatever purpose;
- It is in the interest of good governance, for biosafety legislation to set out decision-making procedures for all GMOs, irrespective of its intended use;
- It is in the public interest that biosafety legislation ensures that the public has sufficient information of all GMOs and its associated uses in the exercise of their rights; and
- It is imperative that the public is consulted in regard to decision-making concerning GMOs irrespective of its intended use.

10. Generally speaking, the information, risk assessment, risk management, confidential business information and public awareness and education requirements of the biosafety bill originate from the Biosafety Protocol. No room for innovation has been created in the drafting of the biosafety bill. Crucially, however, no attempt has been made to provide for any measures that provide more protection of biodiversity and human health than the minimum standards established by the Biosafety Protocol. Where no guidance has been provided by the Biosafety Protocol, for instance, regarding domestic compliance and enforcement measures, the Biosafety Bill has in section 34 has not developed specially tailored provisions to deal with GMOs (e.g. contamination, product recall, enforcement of permit conditions (*refugia,* pest management) etc. The lack lustre attempt at producing draft legislation to resemble biosafety law leaves much to be desired. Renewed impetus should be created to inspire more creative, innovative, robust and tailored biosafety legislation to provide maximum protection to the biodiversity of Lesotho and for the people of Lesotho.