March, 2004

# COMMENTS ON THE KENYAN BIOSAFETY BILL

## Introduction

We have been requested by a network of NGOs and other civil society groups in Kenya, to analyse and critically comment on the latest draft of the Kenyan Biosafety Bill ("the Bill").

1. In general, the Bill does not in its present form represent an adequate, robust and comprehensive biosafety regime designed to protect the environment, human health and biodiversity from the risks posed by GMOs and its related activities. It is foremost, a piece of draft legislation that seeks to put in place, a mere permitting system designed to **approve** applications for the contained use; import; export, placing on the market and release into the environment of GMOs. The underlying imperative of the Bill is the promotion of genetic engineering and not biosafety.

2. The Bill has partially, selectively and numerous instances, erroneously (intentionally?) attempted to implement the Cartagena Protocol on Biosafety (Biosafety Protocol) in order to weaken its implementation. Critically important provisions of the Biosafety Protocol that form the cornerstones of biosafety regulation have been omitted from the Bill in its entirely. These include the Precautionary Principle (Articles 10(6) and 11(8) of the Protocol) and Public Participation (Article 23 of the Protocol). It must be noted that the Biosafety Protocol establishes international rules that are considered to be a "floor" rather than a "ceiling" for the drafting of a regulatory framework. In other words, the rules of the Protocol are the *minimum* standards for achieving the objectives of the Protocol. It is therefore extremely worrying that the Kenyan Bill has not made an attempt to fully implement the *minimum* standards established by the Protocol.

3. The Bill restrictively applies only to adverse impacts on the environment. It does therefore not engage at all with biodiversity and human health. In fact, the protection of biodiversity and human health is excluded from the ambit of the Bill in its entirely.

4. The Bill has failed to deal with traceability and labelling and liability and redress. In this regard, the African Union's African Model Law on Safety in Biotechnology ("African Model Law") does not appear to have been used at all, as a basis for the drafting of this Bill. This is contrary to the decision of the Heads of States of the African Union's meeting in Maputo July 2003, which urged member states to use the Model Law as a basis for its biosafety regulatory framework.

5. If the current version of the Bill is passed, this will bode ill for the implementation of the Protocol on the African continent generally, and in East Africa in particular. Substantial amendments will have to be made to the Bill in order for it to (a) comply with the Biosafety Protocol; and (b) represent a **biosafety** regime. Attention must also be paid by the Kenyan government to the outcome of the first Meeting of the Parties held in Kuala Lumpur during February 2004 as the Bill will thus have to provide for these new measures fully.

Table 1. Overview of Regulation for Activities

| **Type of Activity** | **Authorisation required** | **Information to be furnished by Applicant** | **Risk Assessment Required** | **Public Participation** | **Handling, packaging, identification** |
|---|---|---|---|---|---|
| 1. Contained Use (Laboratory Experiments) | Yes. Section 14(1)(a) | Yes. Section 14(2)(a). Information to be furnished as set out in the Third Schedule | No | No | No |
| 2. Release into the Environment | Yes. Section 15(1) | Yes. Section 15(3)(a). Information to be furnished as set out in the Fourth Schedule | Yes. Section 15(3)(b)-Risk Assessment as set out in the Fifth Schedule | No. Only provision on access to information in section 21, but this is also problematic. | No |
| 3. Import | Yes. Section 16 (1)(b) | Yes. Section 16 (2)(a). Information to be furnished as set out in the Fourth Schedule | Yes. Section 16 (2)(b). Risk Assessment to be conducted as set out in the Fifth Schedule | No. | No |
| 4. Export | No. | No. | No. | No. | No |
| 5. Transit | Yes. Section 18(1)(a) | No. | No. | No. | Partially Section 18(2)(b) |
| 6. Placing on the Market (i.e. GMOs for commercial sale) | Yes. Section 16(1)(b) | Yes. Section 16 (2)(a). Information to be furnished as set out in the Fourth Schedule | Yes. Section 16 (2)(b). Risk Assessment to be conducted as set out in the Fifth Schedule | No. | No. |

Table 2. GMOs that have been excluded from Kenyan Bill

| **GMOs excluded from Kenyan Bill** | **Section in Kenyan Bill** | **Consistent with Biosafety Protocol** | **Consistent with African Model Law** |
|---|---|---|---|
| Products of GMOs-complete exclusion | Excluded from entirely of Bill | Yes | No |
| Pharmaceuticals for Humans-total exclusion | Section 3(2) | No | No |
| Any GMO from "certain requirements of section 14, 15 and 16" | Section 23 | No | No |

**Note on Products of GMOs**

A product of GMOs includes milled GM maize; oil derived from GE canola and cotton and transgenic tomatoes.

A product of a "GMO" is expressly excluded from the scope of the Protocol. However, the Protocol only applies to the transboundary movement, transit, handling and use of GMOs.

The development of a product of a GMO, its labelling, transport within the country packaging that does not result from the transboundary movement, food safety assessments, risk assessments of products of GMOs can and should all be regulated. This regulation is not contrary to the Biosafety Protocol and indeed, such regulation is the sovereign right of all countries.

**Specific comments**

"A BILL FOR An Act of Parliament to regulate biotechnology and biosafety maters and for connected purposes"

The regulation of "biotechnology" is misleading because the Bill is really about the regulation of GMOs resulting from the use of genetic engineering technologies and not from all biotechnologies, as well as its associated activities. Even the Biosafety Protocol makes this distinction quite clear in its specific use of the term "modern biotechnology" see comment below on definition of "biotechnology".

**Section 2-Definitions**

- A new definition of "**advanced informed consent**" should be inserted in order for the public to understand the provisions of section 17 of the Bill relating to exports of GMOs.

- **"biotechnology"** this definition is too broadly to describe precisely and with legal and scientific certainty, the actual technology being used to produce GMOs. This should be amended to correctly and honestly convey the notion that genetic engineering technologies are being addressed. In this regard, the concept "modern biotechnology" is quite acceptable, is it is used in both the African Model Law and the Biosafety Protocol, although the former is far more comprehensively defined than the latter.

- It must be noted that the Bill does, curiously, use the term "modern biotechnology" in the objectives of the Bill in section 4(a). Why has this term been used here?

- **"biosafety"** a word appears to be missing after the word "infectious". What is missing in this definition is a reference to the need to avoid adverse socio-economic impacts on local communities.

- "**contained use"** this definition comes from the Biosafety Protocol and must be amended in order to overcome the shortcomings of the Protocol's definition. It must be noted that scientifically, the concept of "contained use" *per se*, is not controversial generally speaking. Scientists understand this to mean "strictly under laboratory conditions" However, the concept of "contained use" became extremely controversial during the Biosafety Protocol negotiations, when industry tried very hard to do 2 things: (a) water down the definition of contained use to ensure that it was broad enough to include experiments that would take place outside of the laboratory e.g. greenhouse experiments; ponds etc, and (b) ensure that GMOs that are being moved around the world (transboundary movements) would not be subject to strict regulation, i.e. that the Advanced Informed Agreement (AIA) procedure of the Protocol would not apply to it. They had succeeded on both counts.

- The current definition of "contained use" in the Protocol is seriously flawed[1] because it in fact allows for several kinds of deliberate releases 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.

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. Fixing up the loose definition of "contained use" of the Biosafety Protocol is one such example of taking more protective measures.

**It is therefore highly recommended that the definition used in the African Model Law be used, as it is far more comprehensive and technically accurate definition.[2]**

"**genetically modified organism**" in order for this definition to make any sense, "organism" would have to be defined as well as "transformed". Taking into account the fact that neither "organism" not "transformed" is defined, and that the technology at stake as been extremely broadly defined, the current definition of "genetically modified organism" does not convey the notion that what is at stake here are the following:

(a) biological entities;
(b) capable of replicating **or transferring genetic material;**
(c) genetic material is broader than just genes, but includes plants, animals, and most importantly, micro-organisms (viruses, bacteria, fungi) cell cultures, vectors systems (plasmids, viruses) and naked nucleic acids like viroids or DNA sequences; and
(d) in which the genetic material has been altered through modern biotechnology.

**It is recommended that the definition is changed in order to reflect these elements taken from the African Model Law.**

**Scope of Act: Section 3(2)**

Pharmaceuticals for humans have been excluded from the scope of the Bill. GMOs that are pharmaceuticals for humans include GE vaccines and insulin, which, according to growing scientific literature, have environmental, and health risks.

The exclusion of pharmaceuticals for humans is an extremely serious omission. Article 5 of the Biosafety Protocol deals with pharmaceuticals for humans and only excludes pharmaceuticals for humans that are GMOs from the **transboundary movement provisions of the Protocol and only in so far as these GMOs are addressed by relevant international agreements and organisations.** Therefore, at a minimum, the **development, transport, use, handling, packaging and labelling** of pharmaceuticals for humans that are GMOs are not excluded from the scope of the Protocol and must be regulated. Furthermore, to exclude genetically engineered (GE) pharmaceuticals for humans from the entire scope of the Bill, means that other provisions in the Bill that may give some sort of protection (e.g. monitoring; enforcement provisions) will also not apply to such GMOs.

It must be noted that is unclear to what extent such relevant agreements and organisations need to 'address' GMOs that are pharmaceutical for humans. Certainly, where such organisations and agreements do not directly address the environmental and biodiversity of such GMOs, then national legislation should provide for such protection.

It must be noted that during the Biosafety Protocol negotiations, the intention behind this 'partial' or 'potential' exclusion of GE pharmaceuticals for humans was that the World Health Organisation (WHO) would address GE pharmaceuticals for humans and therefore, the Protocol need not duplicate such efforts. However, The WHO does not deal with GE 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 highly recommended that the Bill include GE pharmaceuticals within the scope of its ambit, as ample room for its regulation exists.**

## Objectives of the Act: Section 4

The objective of the Bill as set out in section 4(a) is far too narrow. The level of protection should not only be confined to those activities that the Biosafety Protocol regulates such as safe transfer, handling and use as set out in Article 1 of the Protocol. It is imperative that the objective of a domestic biosafety law should provide a holistic and comprehensive set of biosafety rules including those not dealt with by the Biosafety Protocol. The Biosafety Bill should at the outset in its objectives, clearly state that the objectives include the regulation of the import, development, transport, handling, packaging, identification, use, export, transit, contained use, release or placing on the market of GMOs resulting from modern biotechnology. Moreover, it is not sufficient that the Bill strives only to avoid the adverse effects of GMOs on the environment but crucially, specific reference must be made to biodiversity and human health. In this regard, it must be noted that even the Biosafety Protocol's objectives make specific mention of the conservation and sustainable use of biodiversity, taking also into account the risks to human health.

**The question that must be asked is why does the Kenyan Bill have such short-sighted objectives? Objectives that fall far below those enshrined in the Biosafety Protocol?**

A reading of the entire Bill illustrates that these objectives have been drafted in order to **exclude,** protection of biodiversity and human health from the ambit of the Bill completely.

**Part II-Administrative Provisions**

**Section 5**

**General:** The Bill has created a new institution, called the National Biosafety Authority (Authority), which is comprised of government officials and scientists from either the private or public sector. New money will thus have to be found for the functioning of this institution from both government and other sources, as is contemplated in the Bill. However, the real decision-making powers will lie with the scientists appointed to this body, as is unlikely that the government officials that will serve the Authority will all have the requisite biosafety expertise. Indeed, the Bill does not require that they have such expertise.

**Section 6**

Section 6(a) Several questions arise in regard to the appointment of the "eminent" scientist that will serve the Authority in the capacity as chairperson:

- what does "eminent" mean?
- will this eminent scientist come from the public or private sector?
- how will the Minister make this appointment?
- why should the chairperson of the Authority be a scientist and not someone with administrative skills? Someone from government who is at least accountable to Kenyan citizens?
- Why does the public not have the right also to nominate someone to this position? Such an open process will be good for transparency and public confidence in the regulatory system.

**Section 6(b)**

- Why should one of these people have expertise in biotechnology? Surely, the emphasis should be solely on biosafety?
- Why has no process been provided for in the Bill for the appointment of these scientists? A transparent and democratic process should be created for this purpose with explicit provisions being included for members of civil society to make nominations.
- A clear provision must be inserted to ensure that none of the persons appointed to the Authority has any direct or indirect links to industry. This is of critical importance, because biosafety regulation is about the regulation of an industry and a technology. Unless such a provision is inserted in the Bill,

there is the ever-present danger that industry will control the Authority through proxies such as scientists. Full disclosure of the scientists' background, affiliations etc. must accompany the nomination process. It must be noted that the conflict of interest provisions set out in the First Schedule are not adequate to address the concerns raised here because those are confined to conflicts of interests that may arise in regard to applications that will come before the Authority.

**Part III-Handling Requests for Approvals**

**Section 14: Contained Use**

This section deals with the regulation of GMOS under contained use conditions. It is important to recap what has already pointed out earlier under the discussion of "contained use".

This section does not contain any provisions dealing with the registration of facilities where GMOs under contained use is being dealt with. Such registration is very necessary for monitoring and enforcement purposes. It is also important for data relating to the registration of such facilities be made available to the public.

In relation to the Third Schedule, more detailed scientific information is needed in section 2 (c) of the Third Schedule at the very least for the Authority to understand the nature of the GMOs at stake. The list can be improved by specific references being made to the following:

- Methods and procedures to avoid contact between the GMO and its component parts from the external environment; (this will be necessary if the definition of "contained use" is not changed. It is better to fight for the change of the definition of "contained use").
- Methods and procedures to avoid the release (including accidental release) of the GMO and its component parts into the environment;
- Methods and procedures for safe disposal of the GMO and its component parts;
- Methods and procedures to be taken in the event of an accidental release of GMOs or its component parts.

**Section 14(2) (b) is extremely dangerous.** The principle behind this provision is based on self- regulation as to risks. It is not for industry to decide what the risks are but for the Authority to do make a decision on this very issue. This approach is in keeping with the US approach were industry is allowed to determine what information to put forward to the regulatory authorities regarding risks.

This provision furthermore also opens the door for industry to put information before the Authority of so called benefits. **This is completely unacceptable and must be deleted,** because it is not for industry to put such information forward. The issue is that biosafety regulation is about precautionary measures to be taken to avoid the risks emanating from a genetic engineering. It cannot be an opportunity for industry to conduct its PR on the benefits of its technology.

**Releases into the environment: Section 15**

In this section, the following are important: The Fourth and Fifth Schedules and section 15(2)(c). )

**Fourth Schedule**

This Schedule sets out the information that an applicant must submit to the Authority when seeking permission to release a GMO into the environment.

The Schedule is seeking to implement Annex I of the Protocol. Much of the information on Annex I has been duplicated in the Fourth Schedule (4thS), with some very distinct differences.

- Paragraph 6 of the 4thS when dealing with centres of origin, has omitted the term "proliferate" which is found in Annex I (f) of the Protocol (f).

- Paragraph 7 of the 4thS is better than Annex I of the Protocol but the concept in Annex I (g) regarding the "donor organism or organisms related to biosafety" has been lost.

- Paragraph 9 of the 4thS is better than Annex I.

- Paragraph 10 of the 4thS differs substantially from (k) of Annex I as the concept of "previous risk assessment" has been lost.

- Paragraph 11 of the 4thS differs markedly from Annex I as the following has been lost " packaging, labelling, documentation, disposal and contingency procedure, where appropriate"

- Paragraphs (m) and (n) of Annex I has not been included at all, in the 4thS. These deal with the regulatory status of the GMO in the State of export (bans, restrictions) and result and purpose of prior applications for approvals, respectively.

This Schedule thus substantially waters down Annex I of the Biosafety Protocol.

**Fifth Schedule**

The Fifth Schedule (5thS) deals with Risk Assessment and an attempt is made to implement Annex III of the Protocol, with some very notable differences.

- In para 1 of the 5thS, the objective of the risk assessment is restricted to adverse effects on the environment whereas section 1 of Annex III of the Protocol requires that the objective be on the "conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health."

- Para 2 of the 5thS is identical to section 2 of Annex III.

- General Principles: Para 3(a), (b) and (c) are identical to the corresponding provisions of Annex III. In fact para 3(c) is better than the Protocol. Please note, that para 3(b) mentions the precautionary principle for the first time. Although this come from the Biosafety Protocol, note the following: (a) this is a bad formulation and really amounts to the negation of the precautionary principle; (b) in any event, it does not apply to decision-making; and (c) you should still push for the full description of the Precautionary Principle in section 24 of the Bill and at a minimum, use the formulation contained in Articles 10(6) and 11(8) of the Protocol.

- A critically important guiding principle of the Biosafety Protocol set out in section 6 has been omitted from the 5thS, namely that "risk assessment is carried out on a case-by-case basis."

- The entire section 7 of Annex III of the Biosafety Protocol has been omitted from the 5thS. This should be included.

- Para 4(a) of the 5thS- the word "novel" is missing before the word "phenotype" when compared to section 8(a) of the Protocol. Also, the former ends with the word ‘environment" whereas the latter includes the following ‘taking also into account the risks to human health."

- The rest of the 5thS is consistent with Annex III of the Protocol except for para5(a) which is missing the words "information on" before the word "taxonomic" and the word "proliferation" is missing after the word "persists."

**Section 18**

These provisions deal with the transit of GMOs through Kenya and are extremely welcome as it is a good signal that countries begin to regulate the transit of GMOs.

**Section 19-Confidential information, Access to Information and Public Participation**

**Section 19: Confidential Information**

For the sake of coherency, I have consolidated in this discussion, all the relevant provisions of the Bill dealing with confidential information, access to information and public participation.

The provisions of section 19 of the Bill have only partially attempted to implement Article 21 of the Biosafety Protocol dealing with confidential information but have not fully reflected what is indeed contained in Article 21. Article 21 of the Protocol clearly provides for certain information that cannot be considered confidential, and available for dissemination to the public:

"6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;
(b) A general description of the living modified organism or organisms;
(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health;
(d) Any methods and plans for emergency response."

At the very least, there must be a clear commitment to implement fully, the provisions of the Biosafety Protocol that are aimed at transparency and enabling the public to have some guaranteed access to some information.

Although some attempt is made in section 22(1) of the Bill regarding access to information, this purported right to information on the part of the public may mean nothing at all, since it is the applicant in terms of section 19(1)(a) that is given the right to identify information it considers to be confidential.

**Section 21: Access to Information**

This section for the first time introduces an unequivocal reference to access to information to the public. It provides, however, only for publication a **notice** by the **Authority** of an application for **release into the environment** in the Gazette.

- It must be noted that this provision **does not deal with public participation** but only access to information;
- It is unknown what information exactly will be published;
- This information will not be published in the national newspapers or via other media that may reach people in Kenya more easily such as radio, but will appear in the Gazette. How many members of the public read the Gazette? Farmers? NGOs? Consumer groups?
- Only releases into the environment will be published. This means that applications for approval for imports of GE food into Kenya will never be known to Kenyans, nor GMOs passing through your borders or GMOs that are pharmaceuticals for animals. **This is inconsistent with the Biosafety Protocol-see discussion below dealing with Article 23 of the Protocol.**
- No rights have been created for the public to respond to the contemplated notice e.g. the right to object. Indeed, no mechanism has been created for objections to applications, by members of the public.

**Other provisions of the Bill dealing with access to information**

Another provision dealing with access to information is set out in section 38(5). This section deals with access to information of the activities of the Authority. Although the type of information that will be disclosed may not be very useful if information is said to be commercially confidential and "security' justifies such exclusion. The latter phrase seems a bit draconian and needs more explanation.

Public Awareness and participation is dealt with in section 41(1). An obligation is created on the Authority to promote public awareness and education concerning biosafety matters "through the publication of this Act and regulations made under it." My reading is that once the Act is published and regulations are made, the public

awareness and education obligations will effectively come to and end. This provision is not consistent with the Biosafety Protocol. **See discussion on Article 23 below.**

Furthermore, an obligation is placed on the Authority in section 41(2) to publish notices of final decisions concerning all applications. Although important and welcome, this provision is part of a more general package of information requirements that Parties to the Protocol must furnish to the Biosafety Clearing House in terms of the Biosafety Protocol. **See discussion on the Biosafety Clearing House below.**

**Public Awareness and participation in terms of the Biosafety Protocol**

Article 23 deals extensively with the issues of public awareness and participation. According to the IUCN's *Explanatory Guide to the Cartagena Protocol on Biosafety*

"Article 23 is best understood in the context of Principle 10 of the 1992 Rio Declaration. Principle 10 articulates what are now known as the three "pillars" of public participation: (1) the right of citizens to information; (2) their right to participate in environmental decisions which affect them; and (3) their access to mechanisms of redress and justice when their rights are being violated."

According to the IUCN, Article 23 (1)(a) of the Protocol expresses a commitment by the Parties to the Protocol to facilitate information to the public through the following three mechanisms:

- Public awareness-e.g. through the use of the media and other means of general information distribution;
- Public education-e.g. though general public information distribution mechanisms and specific public education programmes through the formal and informal educational system; and
- Public participation-e.g. through the provision of appropriate mechanisms for public feedback and input into decision-making and regulatory processes relating to GMO transfers, handling and use.

Article 23(1)(b) of the Protocol expressly provides that public awareness and education mechanism should cover and provide access to information pertaining to GMOs "that may be imported."

Article 23(2) of the Protocol is extremely important because it sets out clear obligations on the Parties to:

- Consult the public in the **decision-making** process regarding GMOs; and
- Make the results of such decisions available to the public.

The obligation to consult the public applies generally to **all decision-making processes** regarding GMOs, including the making of decisions on imports.

**Information to be placed on the Biosafety Clearing House**

An important source of information to civil society will come from the information that Parties are obliged to place on the Biosafety Clearing House. This obligation, is however, separate and distinct from the obligations on Parties regarding public awareness and participation in Article 23.

Article 20 of the Protocol deals with the Biosafety Clearing House and sets out the information that Parties are obliged to make available. These include amongst other information:

- Summaries of its risk assessments or environmental reviews of GMOs;
- Relevant information regarding products of GMOs;
- Final decisions regarding the importation or release of GMOs (this will include the permits); and
- Final decisions regarding the importation or release of GMOs.

**Section 20**

Section 20 deals with the screening of the application by the Authority. The term "completeness" is used in section 20(1). Furthermore, section 20(3) regarding the requesting of further information is tied to the notion of "completeness" of the application, which can be problematic. It is preferable that it is left more open to enable the Authority to request "such information as it deems necessary in order to conduct a risk assessment and make a decision in accordance with the precautionary principle and the provisions of this Act in order to avoid adverse effects on biodiversity, the environment, also taking into account the risks to human health". If the provision of section 20 of the Bill is not broadened, then an applicant can argue that it has complied with the requirement of "completeness" and is therefore not obliged to furnish any additional information if so requested. This is very important, because the Biosafety Protocol in Article 10(3)(c) leaves the issue of requesting additional information up to the Parties "in accordance with its domestic regulatory framework or Annex I."

**Section 22**

This is a critically important section as it deals with risk assessment and decision-making. Section 22(1) requires that the risk assessment be to be carried out by the Authority as set out in the Fifth Schedule. The Fifth Schedule has already been dealt with earlier.

**Section 22(2)**

This provision is extremely curious given that it relates obviously to human health impacts. It talks about "any potential exposure to the genetically modified organism" which seems to be out of place, particularly since the Bill does not aim to regulate impacts on human health.

**Section 22(3)**

The second part of this provision is good and should be kept. However, an additional provision should be added to ensure that the applicant should pay for any additional risk assessments.

**Section 22(4)**

This section is extremely instructive because it is entirely framed in a way that contemplates only, that an application will be granted and not refused. **This is unacceptable and must be deleted.**

**Section 22(5)**

This section is again indicative of the intention of the Kenyan authorities that they will themselves conduct the risk assessment themselves, that is over and above, the risk assessment data that the applicant is obliged to furnish in accordance with the Fifth Schedule. This is not a bad thing, but who will pay the costs of this risk assessment? It is implied that the costs will be borne by the Authority-which will be partially funded with taxpayers money?

**Section 23**

This section is highly problematic. It contemplates the exclusion from "certain requirements" from sections 14, 15 and 16 (authorisation for contained use; release into the environment, import and placing on the market) where the Authority determines that ‘sufficient experience and information exists" to conclude that a GMO or activities do not pose a significant risk to the environment.

- Which "requirements" exactly are being referred to?
- What will constitute "sufficient experience"
- How will the Authority decide when "sufficient information exists"
- Who should have this sufficient experience?
- Where should this sufficient information come from?
- Why should the risk only be narrowly circumscribed to the environment? What about biodiversity and human health? Socio-economic impacts on local communities?

It is possible that the Bill is trying to take advantage of Article 7(4) of the Biosafety Protocol which provides as follows "The advanced informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health." In this regard it must be noted, that this provision has not yet been implemented as the COP MOP has taken no such decision and even if they were to take such a decision, then it will be restricted only to the transboundary movement of GMOs.

**Section 24: Decision-Making**

Section 24(c) contemplates comments submitted by the public, but no mechanism has been created in the Bill for the submission of these comments.

Section 24(d) makes mention of socio-economic considerations, **but restricts this only to environmental impacts** which is far narrower than Article 26 of the Protocol.

Socio-economic considerations are dealt with in Article 26 of the Biosafety Protocol. The Protocol uses the following words in Article 26(1) "…may take into account….socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

Article 10 of the Convention on Biological Diversity expressly protects the traditional use of biological resources, conforming to traditional practices that are compatible with the demands of conservation and sustainable use.

Article 8(j) stipulates that knowledge, innovations and practises of indigenous and local communities will be protected. Traditional knowledge should be pertinent to the conservation and sustainable use of biodiversity.[3]

It is recommended that every effort be made to resist the watering down of the Biosafety Protocol and the provisions of the CBD relating to socio-economic considerations.

**NO MENTION IS MADE AT ALL TO THE PRECAUTIONARY PRINCIPLE.**

It is with utter dismay and deep regret that the Kenyan Bill has completely omitted any reference to the Precautionary Principle. The appropriate place for the appearance of the Precautionary Principle is section 24. In this regard, it must be noted that the Precautionary Principle is the cornerstone of biosafety regulation. Without it, there can be no biosafety. It is recognised the world over, that the Biosafety Protocol contains the most explicit examples of the Precautionary Principle yet, in international environmental agreements and law. In this regard, reference is made to Article 10(6) and 11(8) of the Biosafety Protocol.

**Section 25**

Again, the entire section is framed only with approvals in mind. There are no provisions dealing with rejection of an application.

**Section 26**

This is an internal record keeping provision and does not create any new rights for the public. What is missing is the responsibility to keep inventories of all GMOs and the location of sites where releases are authorised or have taken place. Such an inventory should be kept for a minimum of 4 generations. This information should be placed in the public domain.

**Section 27**

Section 27 deals with review of decision and is a very important section.

Section 27(1): The term "significant new scientific information" is an incomplete formulation, as it does not reflect the intention of Article 12(1) of the Biosafety Protocol dealing with review of decisions. Article 12(1) makes use of the terms "new scientific information on the potential adverse effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health…."

Section 27(2) attempts to implement the provisions of Article 12(2) of the Biosafety Protocol, however in doing so, it has strayed from the provisions of the Protocol. For instance, compare the wording of section 27(2) (a) with Article 12(2)(a) of the Protocol. The former provides as follows: "a change in the circumstances has occurred that may have a **material effect** on the outcome of the risk assessment upon which the decision is based." Whereas the Protocol provides "a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision is based." The same thing has happened with section 27(2)(b). The Bill provides "additional scientific or technical information has become available that may have a **material effect** on the outcome of the risk assessment upon…" whereas the Protocol provides in Article 12(2)(b) "additional relevant scientific or technical information has become available."

The term "material " is meant to make it more difficult for decisions to be changed.

**The drafters of the Bill should really try and confine themselves, at the very least not to employ new terminology that weakens the intention of the Biosafety Protocol.**

**Section 27(3)**

This section contemplates only, that a review of decision by the Authority will result in a "substitute **approval**" It is not contemplated at all, that the Authority will revoke its earlier approval. **This is inconsistent with the Biosafety Protocol**. Article 12(1) of the Protocol expressly notes a review of a decision may in fact results in a **change of the decision**, e.g. withdrawal of the decision.

**Section 27(5)**

Again, the risk envisaged is only confined to the environment. It is unknown what "necessary measures" entail. It is absolutely necessary that provision be made clearly, for the cessation of the activity where there are risks to the environment, biodiversity and human health. The "necessary measures" must be spelt out clearly.

**Section 28**

This is the only clear cut, good provision in the entire Bill. The practical difficulty of course, is (a) how will the Kenyan authorities know that the applicant has such information; (b) that such information came into the possession of the applicant **after** approval was granted?

**Section 29**

This section deals with the composition of the Appeals Board. Again, similar questions can be raised regarding "eminent scientist" the need to have an expert in "biotechnology" and why the CEO of the Authority should be included as this is a conflict of interests. How can the CEO be part of an appeal process that is designed to investigate its own decisions i.e. the decisions of the Authority?

It must be noted that in order for the public to trigger the appeal mechanism, a clear obligation must be placed on the Authority to inform the public when a decision has been made, otherwise, this mechanism will in practise be difficult to implement.

However, a more important issue, is that although the public does have the right to appeal in principle, the grounds for appeal **do not include an appeal against approvals**! In other words, the public will have to use other legislation if such legislation indeed exists in Kenya, to appeal against any approvals. This right is not reflected in the Bill.

**PART V-Duties of Regulatory Agencies**

Section 30 deals with monitoring and compliance. This is in principle, a good provision because such monitoring is the responsibility of government and not industry. However, this provision must be read with the provisions of sections 27 and 28.

Post-release monitoring is perhaps the most critical part of the biosafety regulation of GMOs. The objective of such monitoring should be much broader than mere compliance with biosafety legislation and/or permit conditions as is contemplated by the Bill. It must necessarily be aimed also at **preventing the development of risks**. It must be noted that the prevention of risks can only be effective if the permit conditions themselves are aimed at such prevention in the first place. There would include for example, restrictions imposed on commercialisation in order to prevent the evolution of insect resistance to Bt crops. The other key function of post-release monitoring is to improve on predictive models to identify risks.

What has to be monitored? I reiterate that this is not a simple of question of ensuring compliance with the Act and permit conditions as contemplated by the Bill.

The following has to be monitored:

- The environmental effects of on water, soil and bio-organisms;
- Risks associated with transgenic plants, including the movement of transgenes, the effects of the GE plant, impact of the whole plant through escape and their impact on agricultural practises; non-target effects; evolution of resistance;
- Risks due to non-target effects that are limited to pre-commercialisation testing on a small spatial sites; multi-year testing of effects (e.g. 100 acre paired field test in scientific parlance-TG versus the iso-line in a number of locations over a period of time. Even this will not be adequate to examine organisms travelling long distances;

- Animal and human health monitoring over a period of time.

**Section 30(2)**

This section deals with the measures that should be taken where the regulatory authority becomes aware of "any new scientific information indicating that the approved activity may be adversely affecting the environment."

Why is the damage restricted to the environment only? What about negative socio-economic impacts?

Why is it that this section is framed so as to ensure that even in the event where harm is foreseen, that precautionary measures are not contemplated to avoid further harm from occurring?

This subsection only contemplates that the following measures will be put in place

(a) that the Authority is informed; and
(b) that measures are put in place **"to ensure the continued safe use of the GMO**"

**Surely in a biosafety regime, where adverse environmental impacts may arise, the remedy is not the "continued safe use" Is this not a contradiction? Surely, the Authority must ask for the activity to immediately be suspended; that a thorough investigation and assessment takes place to determine the nature and extent of the adverse impacts? That the applicant is asked to safely dispose of the offending GMOs in question? That the applicant is held responsible for the resultant harm?**

**Section 31**

This section deals with 2 major issues that have been lumped together: unintentional release and an illegal release. These issues must be dealt with separately. Furthermore, the section deals only with unintentional and illegal releases, whereas the Biosafety Protocol deals with:

(a) Unintentional Tranboundary Movements and Emergency Measures (Article 17); and
(b) Illegal transboundary movements, Article 25.

Section 31(1)(A) is restricted again only to the "environment." However, this provision is severely undermined by the next provision contained in section 31(2), which not only contemplates but also legally sanctions the illegal and or unintentional release by requiring that the Authority be furnished with adequate information in order for it to undertake a risk assessment of all things! The next subsection could be useful, but is not strong enough, because it merely makes mention of action necessary to "minimize" and not "prevent" any adverse effects on the environment.

It is our recommendation that unintentional releases, imports, placing on the market and exports be dealt with separately, from illegal releases, illegal imports, illegal

placing on the market and illegal exports. In this regard, at a very minimum, the relevant provisions of the Protocol should be reflected.

The provisions of the African Model Law deal with all of these issues comprehensively. The African Model Law sets out extensive provisions dealing with unintentional release and emergency measures in its Article 10. The issue of illegal releases should be dealt with as part of the liability and redress regime of framework and in this regard, strict liability must attach to the person/s responsible for such release and the resultant harm to biodiversity, the environment, human health and local communities. Issues of illegality should also be dealt with under the provisions relating to enforcement.

**Section 43: Liability and redress**

This section has effectively ignored the question of liability and redress. The current laws in Kenya dealing with liability and redress will apply. This position is untenable, given that the government of Kenya supported the African Group throughout the Protocol negotiation for a strong regime on liability and redress. It reaffirmed this position recently in Kuala Lumpur and fully supported the MOP decision that the process begins for the negotiation of an international liability regime. The African Model law sets out comprehensive provisions on liability and redress in Article 14.

**PART VII-Financial Provisions**

**Section 38**

The important issue to note here is that funding for the Authority can also come from donors and not only from the government coffers. This opens the door for funding to come from donor agencies involved in the promotion of GMOs in Africa.

**PARTRIX-Miscellaneous Provisions**

Section 39 deals with the regulations that the Authority may prescribe. These should be amended to include:

- Environmental impact assessments;
- public awareness and participation;
- emergency measures and contingency plans; and
- handling, packaging, transport, identification and labelling of GMOs

**Section 40** deals with offences and penalties. This section will have to be cross-referred to the new section I proposed earlier on, dealing with illegal transboudary movements, releases, and so forth. Comprehensive provisions must be drafted to cover all illegal activities that may take in regard to GMOs.

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

[2] "contained use" is defined in the African Model Law as "any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a close system not exceeding ….cm (to be filled in) in volume in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to effectively prevent their contact with, and their impact on, humans and the external environment."

[3] See further, E Bravo "Socio-Economic Considerations" in TWN Briefings for MOP 1 No 7.