COMMENTS ON NIGERIAN BIOSAFETY ACT 2006

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INTRODUCTION

We have been approached by Environment Action Rights, Friends of the Earth Africa, based in Nigeria, to provide comments on the Nigerian Biosafety (Special Provisions, Etc.) Act 2006. As far as ERA has been advised, the version we have worked on is the most recent. (As at 12 February 2007.)

The Biosafety Bill is essentially an enabling framework, which requires substantial detailed regulations to be promulgated into order for it to come into effect in a meaningful way. The Bill is an unimaginative piece of legislation that mimics the standard fare: biosafety laws that adopt a permit system for the regulation of genetically modified organisms (GMOs). The "Rights Based Approach" that was extensively discussed and supported at an ERA workshop in November 2006, which seeks to begin a new discourse in biosafety regulation based on the protection of fundamental rights, including the right to say no, the right to food, etc has been utterly abandoned.

The Biosafety Bill is primarily concerned with establishing a seemingly elaborate and potentially costly institutional system to regulate GMO related activities. The expenditure of public funds to make these institutions work will no doubt, deflect scarce resources away from public spending for socially urgent needs.

Nevertheless, we offer here some comments below, in a spirit of goodwill and co-operation.

GENERAL COMMENTS

- The Biosafety Bill establishes institutions that will be responsible for clearly defined roles; however, their respective relationships to one another should be more clearly articulated in order to avoid repetition of functions, inter-governmental fragmentation of functions and waste of public funds. Attempts must be made to streamline funds so that the social costs are kept to a minimum. There should be more public discussion regarding the contributions that the private sector and others to the functioning of these institutions.

- It is highly recommended that the title of the Bill is redrafted in order for it to be more explanatory of the functions of the institutions created-or the intention behind the law, namely, to ensure that GMOs do not have adverse impacts on human and animal health, socio-economic

and cultural interests, based on the precautionary principle. Perhaps some reference to the precautionary approach of the Biosafety Protocol is also appropriate?

- Taking into account the "framework" or "enabling" nature of the Biosafety Bill, it is extremely important that a new and more detailed section be drafted to cater for the myriad regulations that need to be drafted in order to give effect to the Bill; and

- The insipid nature of the Bill may well be rescued by the introduction of a number of new provisions which deals with GM Free Zones, bans on GMOs in order to protect centres of origin and diversity; bans on the production of GMOs and food crops to feed the biofuels frenzy and so forth.

- The Bill should also make cross- references with other legislation in Nigeria dealing with the protection of farmers' rights, land and other resource rights.

- The Bill and the various Schedules attached to it should be read together as an integral whole. We could find only one reference in the operational part of the Bill to one of the Schedules that we could find.

DETAILED COMMENTS

2. Objectives of Agency (section 2) (**Institution number 1)**

Section 2 (c) the word "biosafety" should be replaced by "biotechnology"

Section 2-(d)-it is really important to deal with Risk Assessment and Risk Management separately and not as interlinked concepts. Risk Management really only arises in the context of the post-release of GMOs (marketing and environmental). It is also important to state clearly that the measures must be for the assessment of GMO applications on a case-by-case, **step-by-step** basis. This is crucial so that it is clear, that activities/permits must follow a scientifically recognised sequence-contained use, field trial and commercial release.

Section 2(e)-we are not sure what is meant by "consensus building" particularly in the light that genetic engineering/modern

biotechnology is a bitterly contested technology and it is impossible to try to achieve consensus between diametrically opposing viewpoints and paradigms.

We particularly welcome section 2(f).

3. Functions of the Agency (section 3)

In section 3(f), we are confused as to what a risk management plan entails or what is intended by this subsection-that one plan will apply to all GM releases? GMOs that are on the Nigerian market? GMOs passing through Nigeria in transit?

Section 3(g) should include a specific reference regarding the right of the Agency to refuse applications, based on the precautionary principle.

In regard to section 3(h), "if they contain GMOs" may not be scientifically accurate as there may be contamination by only parts of the transgenic organism and not the whole GMO?

It is highly recommended that the decision-making regarding GMO applications take place on the basis of votes for instance at least xxx number of votes are needed for a decision in favour of granting approval (as is the case currently in Brazil). It is not recommended that decision-making be sought on the basis of consensus; in the interests of the fair administration of justice, dissenting opinions must also be taken into account, factored into decision- making and made public. Dissenting opinions can also serve as an important touchstone for post release monitoring and risk management.

4. Establishment of National Biosafety Council (section 4) (**Institution number 2)**

It is not appropriate for the Chairperson of a "Biosafety" body to come from a "Biotechnology" background. This section should be redrafted to reflect this.

We are alarmed that a representative of the private sector in section 4 (c) is allowed to be on the Council since the Council is a government body, designed to a large extent, to regulate the private sector. The private sector cannot govern itself.

It is also our recommendation that an open, fair and transparent nomination procedure should be established for the representative of

the Council from the respective sectors. This will augur well to inspire credibility in the regulatory system.

5. Functions of NBC (section 9)

   It is highly recommended that more attention be paid to the way in which the opinions of the various members of the Council will be solicited. For instance, when in the chain of the process will the members receive the applications? What information will they receive exactly? Will this include objections from the public?

6. Biosafety Committees (section 15, functions of) **(Institution number 3)**

   We note that the Biosafety sub-committees will also be responsible for the review of GMO applications. We are wondering how this relates to similar functions that the Council will be performing. (Compare section 9(b) with 15(a)), which appears to be a duplication of functions- although the intention may not be so. It is important to clarify the intergovernmental relationship in the legislation in order to avoid confusion later.

7. Institutional Biosafety Committees (section 16, establishment and composition) (**Institution number 4**)

   In section 16(1) the terminology used "…undertakes any modern biotechnology processes or …" is extremely broad, particularly if the intention is ultimately to create a set of regulations meant to apply to research and development concerning GMOs/modern biotechnology.

8. Approval or permit on GMOs (section 21)

   We are concerned about the words "as from the commencement of this Act…" as this implies that prior to the commencement of the Act, activities with GMOs are permissible?

9. Requirement of application for approval or permit (section 22)

   We are not sure why the time period of 270 days is relevant for instance, to applications that do not concern international trade/transboundary movements? This time period is taken from the Biosafety Protocol, which deals with transboundary movements.

   The words "if any" in section 22(2)(b) should be removed, as genetic engineering is an inherently risk technology.

10. GMOs for Food, feed, etc (section 23)

More attention should be given to the way in which this category of GMOs will be regulated. In particular:

- In section 23(2), the word "application" seems misplaced;
- We are concerned about the standard of safety in section 23(2), namely, "no substantial risk" to humans and animals-this seems to defy the need to ensure decision making on the basis of the precautionary principle as stipulated in section 2(c) of the Bill;
- Approvals of GMOs for import as food and feed means that bulk shipments will come into Nigeria. These will go to silos, and there contaminate non-GM grain in the process of co-mingling;
- Provisions must be made for the transit thought Nigeria of GMOs for food, food aid, feed etc;
- Provisions must be drafted to regulate the transport of such grain through Nigerian territory in order to ensure that there is no spillage etc; and
- Provisions must ensure that such grain is not sold/distributed as seed and grown out in the open environment.

We note the need for the final word on the food safety assessment is the National Agency for Food, Drug Administration and Control, making it the **fifth institution** involved.

10. Public display of application (section 24)

It is preferable that clear and precise provisions are created for public awareness- raising with regard to applications. It is ill advised for the Agency to have far reaching discretion regarding the **nature of the information** that will be made available to the public, the **place where such information will be made available** and time **periods for scrutiny and reaction**.

Publication in newspapers is also discretionary. What will be the factors that will influence the exercise of these powers by the Agency? What about public advertisements through other media? Nigeria is a huge and diverse country, where different languages are spoken and people have different means of accessing and processing information. How will these challenges be addressed?

11. Public hearings and consultations (section 25)

Public hearings should be held as a matter of course, at the very least, for commercial imports and releases. These decisions will have far-reaching implications for all Nigerians; for those who work the land; as well as those who eat off it.

We welcome attempts to establish criteria for the assessment of what would constitute confidential business information (CBI) (section 25(3). We submit that in section 25(3)(c), the sentence be re-phrased as follows: "release of the information would **not** be detrimental to the business of the applicant, as it relates to the application in question."

In regard to section 25(3)(d), we are not quite certain what is meant by the cross referencing of section 24, and suggest that the intention behind this be made more explicit.

12. Confidentiality of information (section 26)

The provisions of this section should be tied together with the provisions of section 25(3) in a more coherent way, and perhaps one way of doing it, is to tighten section 25(3) up, by a further section 25(4), which makes it clear that if the answers to section 25(3) are all affirmative, then the information cannot be CBI. Then, a new chapeau needs to be created in section 26, which reads, Notwithstanding the provisions contained in this or other legislation dealing with disclosure of information, the following information ……."

13. Approval or permit to grant license (section 27)

These provisions are crucial and needs to more carefully assessed to ensure that it is in line with the overall tenor of the legislation and biosafety discourse. We have noted several concerns with the provisions as they now stand, including:

- In section 27(1)(a), it is in accordance with legal practise that the applicant be required to comply with the provisions of the Act and not meet criteria only;

- In section 27(1)(b), it is not enough to say that the GMO need not be harmful, but one needs to ensure that the GMO is not harmful in relation to human and animal health, the environment, society etc. and moreover, herbicide tolerant crops are accompanied by herbicides which form an intrinsic part of the GMO. These need to be

looked at more holistically and thus, section 27(1)(d) should be expanded to include "herbicide";

- The provisions of section 27(1)(c) need to be discussed perhaps with a view to removing the references to "new substantial risk" and "non-genetically modified counterpart". It is important that consistent terminology be used regarding the standard of biosafety that Nigeria aims to uphold, based on the precautionary principle. In this section 27, various terms are used for instance, "not harmful", "new substantial risk", "unreasonable adverse risk to the environment:; and

- In regard to section 27(1)(d), it is preferable that at the end of that sentence, explicit references are also made to human health (farm workers/farmers/and consumption by humans).

It is highly recommended that provisions be created for the right to refuse an application and the grounds for that refusal.

14. Right of appeal (section 28)

It is important to ensure that the right of citizens to appeal is entrenched, the time limits for this right to be exercised should be set out, as well as provisions regarding costs not to be awarded against citizens where the appeal is brought in the public interest and the interest of the environment.

15 Risk Assessment and Risk Management (section 31)

It is important to pay attention to the terminology used to described different activities. For instance, risk assessment is not the same as risk evaluation, nor environmental risk assessment and so forth. It will not be possible for risk assessments to be conducted in Nigeria (section 31(2)) for imports of GMOs for instance, because these are done only once – when the GMO is first de-regulated in the USA.

Risk management provisions should be dealt with separately and not as an integral part of Risk Assessment.