

4 December 2017

To whom it may concern

## **Civil society comments on the proposed revision of the 2003 Zambian Biotechnology and Biosafety Policy**

Please find from the Zambia Alliance for Agroecology and Biodiversity (ZAAB) some comments on the draft revised Biotechnology and Biosafety Policy, as made available to the National Biosafety Authority, The Governing Ministry of Higher Education, Science and Technology, and concerned stakeholders of Zambia. The comments follow the short notice “Stakeholder Consultative Meeting on the Biotechnology and Biosafety Policy”, that three ZAAB representatives participated in, held 25-26 September 2017 in Livingstone. We trust that these written comments will further submissions made at the brief Consultative Meeting, and be duly considered and included in the on-going consultation and policy review process.

### **Introduction**

ZAAB received the Draft Revised Biotechnology and Biosafety Policy one week prior to “The Stakeholder Consultative Meeting on the Biotechnology and Biosafety Policy”, held 25-26 September 2017 in Livingstone. The policy as presented in September, reads like a hastily put together document that excludes some of the more crucial aspects of the original policy. The document is not very well drafted (typos, grammar errors, irrelevant/no references). Structurally, the only way that the paper represents any improvement on the original policy is that it now includes definitions as a separate section, albeit these are extremely limited in scope. Through reading of the current 2003 policy and revised draft Policy, some differences and areas of concern have been noted and highlighted.

### **2003 BBP**

The 2003 Zambian Biotechnology and Biosafety Policy (BBP) states that ‘Biotechnology and products of Biotechnology can contribute significantly to economic development of Zambia, especially in the areas of agriculture, health care, environment as well as industry’. However, any benefits will only be realized if and

when biotechnological development takes place in a manner which is both judicious and sustainable.<sup>1</sup>

Whilst the BPP acknowledges that biotechnology can contribute to the social and economic development of developing countries such as Zambia, it recognizes the potential harm and danger that the introduction of Genetically Modified Organisms (GMOS) may pose to the environment. The role of the BPP is identified as supporting the development of research and industrial capacity to apply biotechnology to enhance Zambia's socio-economic and environmental well-being, and allows for the subsequent establishment of the National Biosafety Authority and Biosafety Advisory Committee.<sup>1</sup>

The tone of the BBP suggests that the Policy is not advocating acceptance of GMOs, but rather attempting to open up a discussion around biosafety and to put together some regulatory framework for managing biotechnology adoption whilst minimizing any adverse effects on human and animal health and the environment and to elevate biological diversity conservation over trade. In both the Introduction and Background Sections of the BBP, the focus is squarely on GMOs and the risks posed by the non-existence of legislation on GMOs, to the Country and the importance of safeguarding against adverse impacts.

## **Revised Draft BBP**

In the Revised Biotechnology and Biosafety Policy, hereinafter referred to as the Revised Policy (RP), the discussion is focussed on broader biotechnological applications covering pharmaceutical development, therapeutic applications, biofuel production, modified crops production, waste management, lack of capacity and educational offerings, food production and processing and forensic studies. The stated rationale for a revision is that, despite the existence of the 2003 BBP, biotechnological application was limited to disease diagnosis, classification of organisms and tissue culture and that no genetically modified organism (GMOs) were produced in Zambia. Furthermore, evolution in the fields of Biotechnology and Biosafety has necessitated a revision of the 2003 BBP.

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<sup>1</sup> Republic of Zambia. Ministry of Science, Technology and Vocational Training. Biotechnology and Biosafety Policy. 2003

The 2003 Policy was developed to acknowledge the increasing role of Biotechnology in the world and to caution against its application without proper legislative and monitoring measures being in place and to pave the way for the development of such instruments. It was not developed “*to promote the benefits of biotechnology*”, as claimed in the RP (Page 5 of the RP).

The Situation Analysis in the RP attempts to draw a link between what it sees as the benefits of modern biotechnology in enhancing food security through improved production. Food security is when “*all people have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life*”.<sup>2</sup> Food security is substantially more complex than securing adequate production, but is dependent also on other factors, including supply and access. Adequate production of food, as it is claimed will follow with the adoption of modern biotechnology, does not ensure food security.

## **Liability and Redress**

The provisions on Liability and Redress in the BBP have been removed from the RP and there are now no provisions for how biosafety liability and redress shall be implemented. The Zambian Biosafety Act of 2007, takes a precautionary stance and has provision for developing a mechanism for liability and redress for any harm or damage caused to human and animal health, non-genetically modified crop, socio-economic conditions, biological diversity or the environment by any GMO or a product of a GMO. The scope of socio-economic impacts is broad and means any direct or indirect effect to the economy, social or cultural practices, livelihoods, indigenous knowledge systems or indigenous technologies as a result of the import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism.

As per the Biosafety Act (No 10. of 2007), those who bring GMOs into Zambia will be liable for any resulting health, economic and environmental damage. Whilst there may be a case to be made for the revision of Zambia’s Liability and Redress provisions to ensure that they are guided and informed by the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress which was adopted by Parties to

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<sup>2</sup> World Food Summit, 1996

the Biosafety Protocol on October 15, 2010 (but not yet ratified by Zambia), the outright omission of Liability and Redress in the RP is of grave concern. Rules and procedures on liability and redress are a necessary component of any biosafety regime as at a minimum, they define the scope of the rules and procedures, the nature of the liability/ies, the channeling of the liability and the exemptions from liability. Furthermore, other aspects including the nature and scope of redress, definitions of what constitutes damage, who may bring claims (standing), acceptable defense claims, administrative justice provisions, limits of liability and compensation and insurability will also be covered.

This is essential to protect the interests of all parties and rules on liability and redress help encourage countries, as well as individuals, companies and other organizations to comply with international environmental norms. The possibility of having to pay for any damage caused will ensure that greater care is taken when any activities are undertaken.

## **Guiding Principles**

The key Guiding Principles included in the BBP and RP differ as indicated in Table 1. In the RP, the principles are merely listed and the intent behind some of these is not clear as no further discussion is included in the document about each of these principles. This is unlike in the BBP where each principle is discussed.

Importantly, the Precautionary Principle is the first Guiding Principle in the BBP whereas in the RP, the Precautionary Principle is listed last as a guiding principle and not mentioned further in the document. The Precautionary Principle is important in that it allows for the recognition of uncertainty, allowing countries to err on the side of caution when there is lack of scientific certainty about the possible harm genetically modified organisms (GMOs) may cause. It also requires communication of any uncertainty to the public.

Table 1: Guiding Principles in the BBP and RP. Where there is substantial overlap in the principles of each, the corresponding blocks have been shaded

BBP	RP
The Precautionary Principle	Innovativeness
Advanced Informed Agreement	Sustainability
Undesirable Effects of GMO(s) and Products Thereof	Participatory
Risk Assessment	Partnership
Socio-Economic Impact	Responsibility;
Public Participation	Ethical principles
Liability and Redress	Access and benefit sharing to genetic resources and technology.
Conservation of the Biological Diversity and Trade	Precautionary principle
Rights over Genetic Resources and Technologies	

## The Term “GMO”

Throughout the RP, the discussion focuses on Biotechnology and its application with minimal mention of the term GMO. “GMOS” are included in the definitions and mentioned again as part of the rationale for the revision of the policy. In the Situation Analysis, reference is made to “*cotton to control weeds and prevent insect attack*” and to research on other crops including “*wheat, rice, bananas, cassava, potatoes, sorghum and cow peas. The on-going trials focus on traits of high relevance to challenges facing Africa, including drought, efficiency of nitrogen use, salt tolerance, nutritional enhancement, as well as resistance to tropical pests and diseases.*” The informed reader may infer that within the context of modern biotechnology, that GMOs are what are being referred to here but the explicit omission of the term GMO, lends a degree of opacity to the document that makes a mockery of the avowed transparent and participatory approach.

## Mission Statement/Vision

The Vision of the RP may be intended to replace the Mission Statement of the 2003 policy which highlighted the “*judicious use and regulation of modern biotechnology*” with “*minimum risks to human and animal health, the environment and biological diversity*”. This Vision is silent on these aspects and promotes only the application of biotechnology, without providing a framework for such application.

## Small-scale Farmers

In the Situational Analysis of the RP, the comment is made that of the 18 million farmers worldwide who planted biotech crops in 2015, 90% were small scale farmers, yet nowhere in the RP is there any indication of how small-scale farmers may benefit from the move to planting GMO crops or how they may be incorporated into the strategy for “promoting biotechnology”. It is not clear how useful GM crops may be to these farmers and what other opportunity cost may be involved in moving in this direction. An honest approach to the experiences of small scale farmers with GM crops would include the controversies in Burkina Faso, India and South Africa regarding the failure of Bt cotton in those countries and the indebtedness of small scale farmers, insect resistance, problems in the plant breeding and suicides. Already in Zambia, high-yield seeds, developed through traditional breeding techniques, have been available for decades, yet the adoption rate by small and medium farmers is estimated at 35 percent. More pressing needs for small-scale farmers include support for their seed and farming systems and a shift towards agro ecological approaches.

## Research and Development

An important objective of the RP is to “*undertake research and development in biotechnology in order to generate knowledge, products and services*” as there is clearly a need to develop such capacity on a broad range of agricultural issues across the spectrum and particularly involving small-scale farmers, to enable meaningful, participative decision making. Developing scientists and researchers and an informed public who can effectively grapple with the challenges posed by GMOS and other emerging biotechnological applications is essential to enable the country to respond appropriately and advisedly to any challenges these may pose. It is not clear from the RP who the target beneficiaries for this are.

## Institutional Arrangements

The proposed institutional arrangements are not clear and presented in an organogram with no clear hierarchy of responsibility. In fact, the RP proposes decentralizing the functions of the regulatory body, with no clear statement of how any of this may be achieved. Given the current capacity constraints and challenges being encountered in filling certain positions it is unclear how this may be achieved.

This is in stark contrast to the BBP which defined an Implementation Strategy (Page 12 of the BBP) and defined responsibilities for the National Biosafety Authority (NBA) and Biosafety Advisory Committee (BAC) (Scientific Advisory Committee in the Act).

## **Legal Framework**

The Policy makes the comment about strengthening legislation and plans to review the Biosafety Act with no explanation about what the drivers are for such an amendment and/or what the proposed amendments may be, though the suggestion is that there may be shortcomings. What is clear, is that if the RP is accepted in its current form, it is at odds with the Act as written as it excludes several provisions of the Act, importantly Liability and Redress.

The current Act has in place comprehensive measures that governs biotechnology from research and field testing to commercialization and imports of bioengineered crops, ensures that any activity involving the use of any genetically modified organism or a product of a genetically modified organism prevents any socio-economic impact or harm to human and animal health, or any damage to the environment, non-genetically modified crop and biological diversity; sets and implements standards for risk assessment, makes provision for the ; establishment of the National Biosafety Authority and Scientific Advisory Committee and prescribes its powers and functions; provides for public participation, includes a mechanism for liability and redress for any harm or damage caused; provides for the formation and registration of institutional biosafety committees; and provide for matters connected with or incidental to the foregoing. If any, there may be a case to be made to amend the Act to make provisions to take account of new Biosafety, Biosecurity and Bioethical concerns arising from newer technologies and possible associated threats.

The current Policy (BBP) has a strong emphasis on the Precautionary Principle which were developed during the negotiations of the Cartagena Protocol on Biosafety because of the recognition that precautionary approaches can help manage the fast-changing, multiple, systemic challenges that we currently face. It derives from lessons learned in the application of other technologies, such as the use of dichlorodiphenyltrichlorethane (DDT) in the global malaria eradication

programme, and its subsequent total ban in the USA, which have shown how damaging and costly the misuse or neglect of the precautionary principle can be. The Precautionary Principle is scarcely mentioned in the RP.

Sincerely

Mr Emmanuel Mutamba  
ZAAB Chairperson

## **Notes/Timeline**

1. Zambia signed the CBD on 11th June, 1992 and ratified it on 28th May, 1993
2. Biotechnology and Biosafety Policy – August 2003
3. On 7<sup>th</sup> April, 2004, Zambia acceded to the Cartagena Protocol on Biosafety (CPB) and the CPB came into force on 25<sup>th</sup> July, 2004
4. Biosafety Bill - 2006
5. Biosafety Act (No 10. of 2007) - Date of Assent: 24th April, 2007. The Biosafety Act has provisions for socio-economic consideration (Article 19 1(c)) as part of other issues to be considered in addition to scientific risk assessment. No regulations to support this.
6. Statutory Instrument (No. 42 of 2010): Biosafety Regulation on Genetically Modified Organisms for food, feed and processing – 2010
7. National Biosafety Authority inducted on July 24, 2013.
8. SIs in the pipeline
  - Regulations: The Biosafety (importation of Genetically Modified Organisms for field testing, propagation and contained) use;
  - Regulations: The Biosafety (Exemption of Genetically Modified Organisms)
9. Approved Guidelines:
  - Public participation, information sharing and access to justice with respect to Genetically Modified Organisms and products of Genetically Modified Organisms;
  - Field work and planned release of Genetically Modified Organisms

# ***Zambia Alliance for Agroecology and Biodiversity***

ZAAB Secretariat  
C.O. Caritas Zambia, Kapingila House,  
Plot 60, Kabulonga Road, Lusaka, Zambia  
Tel: +260 211260980/261789