

# On- going Concerns about Harmonisation of Biosafety Regulations in Africa

Haidee Swanby, November 2009



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## Acronyms

ABBPP	African Biotechnology Biosafety Policy
ABSPII	Agricultural Biotechnology Support Project Phase II
ACB	African Centre for Biosafety
AHFBI	Africa Harvest Biotechnology Foundation International
AU	African Union
CGIAR	Consultative Group on International Agricultural Research
ECOWAS	The Economic Community of West African States
FARA	Forum for Agricultural Research in Africa
GMOs	Genetically Modified Organisms
LMO	Living Modified Organism
NARs	National Research Systems
NBFs	National Biosafety Frameworks
NEPAD	New Partnership for Africa's Development
NGO	Non Governmental Organisation
OAU	Organisation of African Unity
PBS	Programme for Biosafety Systems
RECs	Regional Economic Communities
SABIMA	Safe Management of Biotechnology in Sub-Saharan Africa
SFSA	Syngenta Foundation for Sustainable Agriculture
SROs	Sub-Regional Organisations
WABCO	West African Biosafety Committee
WTO	World Trade Organisation

## Introduction

In June 2009, the African Centre for Biosafety (ACB) published a briefing paper titled, “The Revised African Model Law on Biosafety and the African Biosafety Strategy”, authored by myself. In that publication, we explicitly expressed the concern that Africa-wide harmonisation of biosafety policies and procedures is risky as it will create an enabling environment for the proliferation of GMOs on the continent, with few biosafety checks and balances. In particular, we expressed the grave concern that harmonisation provides an opportunity for various players with vested interests to promote GMO friendly policies and practises on the continent that undermine the spirit of the African Model Law on Biosafety through *inter alia*, sponsoring regional trade bodies to develop and administer biosafety policies. We reiterate our contention expressed in our June briefing, that the inclusion of the Regional Economic Communities (RECs) by the African Union in the implementation of the African Biosafety Strategy is unacceptable and extremely worrying.

The African Union’s (AU) Biosafety Unit has responded to our June briefing, asserting that harmonisation is not the central aim of the Biosafety Strategy and that neither the text of the Model Law on Biosafety nor the Biosafety Strategy supports our assertions.

In this document, we respond to the concerns raised by the AU Biosafety Unit on the ACB’s briefing. Their concerns, forwarded to the ACB on the 15th July 2009 can be downloaded at:

<http://www.biosafetyafrica.org.za/index.php/20091109246/Response-from-the-AU-Commission-Biosafety-Unit-to-Briefing-no.-9/menu-id-100025.html>

At the outset, we emphasise that the intention of the ACB’s briefing was not to create the impression that the African Union’s Biosafety Unit has ‘sold out’ to industry interests. Rather, it was our intention to alert civil society to the dangers lurking in the processes flowing out of the AU’s Biosafety Strategy in relation to proposed biosafety harmonisation processes.

### **Structure of this document**

This document first looks at the genesis and aims of the AU’s Biosafety Strategy. It then deals with the dangers posed by harmonisation and what the African Union’s Biosafety Unit hopes to achieve in regard to proposed harmonisation. It also shows how the pro-biotechnology machinery has historically attempted to weaken biosafety regulations on the continent by promoting regional harmonisation of biosafety systems to further its own pro-GM agenda. We also discuss the African Model Law on Biosafety and National Biosafety Frameworks. We do this specifically to respond to the Biosafety Unit’s request to us that we provide them with examples of African countries who have not used the African Model Law to guide the crafting of their national biosafety laws. Finally, we respond to the Biosafety Unit’s request to us that we substantiate our concerns about the Forum for Agricultural Research in Africa’s (FARA) role in championing a pro-biotechnology agenda on the pretext of biosafety capacity building in Africa.

## The African Strategy on Biosafety

The ACB would like to make it clear that the African Strategy on Biosafety is a project of the AU Commission, under the auspices of the Department of Human Resources, Science and Technology. The NEPAD Secretariat on Science and Technology is not spearheading this process, as was stated in the June briefing. We apologise for this inaccuracy and would like to clear up any confusion that this may have created.

### Background

Biotechnology and human civilisation have arisen together – the domestication of animals and crops and the use of living organisms such as yeast in fermenting processes are forms of biotechnology. The arrival of genetic engineering and the concomitant transference of gene sequences from one unrelated species to the other, plunged biotechnology into controversy as society began to question its safety, appropriateness and morality.

In 1992, the international community recognised the need to regulate this new form of biotechnology, termed genetic engineering or genetic modification, as reflected in Chapter 16 of Agenda 21 of the Convention on Biological Diversity. As a result, the Cartagena Protocol on Biosafety (“the Protocol”) to the Convention on Biological Diversity was negotiated over a period of five years and finally adopted in 2000. The Protocol came into effect in September 2003.

The Protocol regulates the transboundary movement, transfer and handling of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse impacts on the conservation and sustainable use of biological diversity, also taking into account risks to human health.<sup>i</sup> It sets international minimum biosafety standards, rules and procedures and creates international obligations for countries that become Parties to the Protocol.

The former Organisation of African Unity (OAU) and predecessor to the current African Union (AU), developed the African Model Law on Safety in Biotechnology. This was done because the AU recognised “..... the challenges faced by Member States to implement the Protocol and its weaknesses as an international negotiated instrument capable of regulating Biosafety in the continent, especially with regard to the development of domestic GMOs, the use of GMOs in contained systems, the approval of deliberate releases into the environment and approval and labelling of GM food ...”.<sup>ii</sup>

In July 2003, the AU’s Executive Council urged Member States to use the African Model Law on Biotechnology to guide the development of their domestic biosafety legislation and “stressed the need for Member States to equip themselves with the necessary human and institutional capacities to deal with Biosafety issues within the framework of the implementation of the Cartagena Protocol on Biosafety”.<sup>iii</sup> Thereafter, the German government stepped in to assist the AU in developing and implementing a capacity building project for an Africa-wide Biosafety System under the general program of “Support of the AU in the Matters of Biosafety”.<sup>iv</sup> A biosafety unit was set up within the AU Directorate of Human Resources Science and Technology, the African Strategy on Biosafety was developed in 2006 and provisions have been made for regular review.

Harmonising legal biosafety structures on the continent has been a goal of the AU for as long as the Protocol has been in force. The original idea of harmonisation via a Model Law, which is still supported by the AU, now has new dimensions to it with the entry of powerful pro-GM interests who seek to introduce proprietary technology into Africa under the banner of “development” rather than build capacity through genuine biosafety procedures. The 2006 Strategy takes further practical steps towards this goal of harmonisation, and it is the direction in which these steps are leading Africa, that causes us concern. The power of industry interests to shift the focus of biosafety policy on the continent must be acknowledged and drastically curbed.

## Harmonisation

As far back as 2003, the AU’s predecessor, the OAU recognized the “need to set standards and assist African countries “[to] come up with a more or less harmonised legal structure”.<sup>v</sup> What they had in mind was a model biosafety law in order for African governments to adopt a consistent precautionary approach to the development of biosafety regimes. Thus, the OAU spearheaded an open, transparent and consultative process that culminated in the development of the African Model Law on Safety in Biotechnology, to serve as a model for the development of national biosafety laws in Africa.

The AU has decided that an African Biosafety Strategy is needed for the adoption of a harmonised regional approach to biosafety regulation. In its 2006 Strategy, the AU states that in recognition of the “the need for a harmonised regional approach in dealing with biosafety issues, the AU desires to support its member states by developing an African Biosafety Strategy”.<sup>vi</sup>

According to the Strategy, national and sub-regional levels are targeted “for planned interventions to be undertaken by the AU and its member states to ensure harmony in modern biotechnology and biosafety. The main target for implementation of the Strategy shall be the five sub-regions of Africa. However, the existing Regional Economic Communities (RECs), where they are already doing work related to biosafety, or interlinking trade and biosafety shall be used to complement rather than undermine each other”.<sup>vii</sup>

In addition, the strategy aims at guiding biotechnology development at national, regional and sub-regional levels; guiding African positions in relevant international fora and creating and strengthening regional centres of excellence in each of the five sub-regions. “These centres of excellence will play an important role in risk assessment and management, capacity building, GMO testing and provision of any other relevant biosafety advice”.<sup>viii</sup>

The Biosafety Strategy is based on six pillars:

- a) Establishment and Strengthening of Institutional Frameworks
- b) Awareness Raising and Biosafety Information Exchange
- c) Capacity Building and Preparedness for Negotiations
- d) Policy and Legal Frameworks
- e) International Cooperation
- f) Sustainability Mechanism

According to Mahlet Teshome of the AU's Biosafety Unit, "the intention of the Biosafety Strategy is NOT to harmonise biosafety laws and policies as a major thrust, but is rather aimed at providing advice as to the development of modern biotechnology and the application of biosafety within Africa mainly based on a six pillar approach".<sup>ix</sup> The Biosafety Unit was also quick to point out that neither the text of the African Model Law on Biosafety nor the African Strategy on Biosafety support the ACB's assertion that the unfolding process is likely to culminate in the creation of a blanket GMO approval system that would bypass case-by-case risk assessments as was asserted by us in our June briefing.<sup>x</sup> This is a fair response as both documents emphasise the extreme caution to be taken with regard to the risks posed by GMOs to human and animal health, and environmental and socio-economic impacts. It is clear from both texts that while the potential benefits of modern biotechnology are acknowledged, the protection of African biodiversity, culture, livelihoods and food sovereignty are of paramount importance.

Having said this, implementing and administering this Strategy in practice, on a country by country level, promises to be a daunting task. Regional Economic Communities (RECs) already have structures and functioning secretariats and thus they are able to use their existing networks to push a pro trade agenda. In our June 2009 briefing we cautioned that, "placing biosafety in the domain of the RECs affords the pro-GM lobby yet another opportunity to position GMOs as agents of development rather than serious threats to biosafety, cultural and socio-economic wellbeing". Although it is clear from both the Model Law and the Biosafety Strategy that this is not the intention of the AU Biosafety Unit, experience of the domestication of biosafety legislation in the past warns us that these documents can become meaningless in the face of interventions from powerful lobby groups.

According to Mahlet Teshome of the AU Biosafety Unit the RECs are "among the tools to implement the strategy (and not the sole actors), the AU will still have the overall political role to supervise and coordinate".<sup>xi</sup> But while the African Model Law is not binding on Member States, the RECs can pass regulations that are binding on their Members. Problematically, all of the RECs' biosafety initiatives to date have been funded by USAID.

The harmonisation approach that is strongly favoured by the World Bank, USAID and national and regional affiliates of the Consultative Group on International Agricultural Research (CGIAR) and various African academic and research institutions, is designed to create a one-stop GMO approval system at the sub-regional level, thereby side-stepping a country-by-country, case-by-case risk assessment and decision-making process. In West Africa, ECOWAS strongly encouraged by the World Bank, are the drivers behind a harmonisation push in West Africa. Kenya was the focal point for the harmonisation push for the East African countries of Uganda and Tanzania, under the auspices of the Programme for Biosafety Systems (PBS), funded by USAID.<sup>xii</sup>

Extracts from the preamble of the Draft ECOWAS regulations for the establishment of a West African Biosafety Committee (WABCO) and regulations for the approval of GMOs, give a clear indication that the primary focus is to facilitate easy trade and deployment of GMOs within the region. It is also apparent that the so-called "science based" approach to biosafety, favoured by USAID, as opposed to the Precautionary Principle, informs their policy:

“Aware also that the safe adoption of modern biotechnology in West Africa will necessitate setting up of a sub-regional biosafety regulatory system to review biotechnology products which would be coming from outside the sub-region or would be produced by the national agricultural research systems (SNRA) within the sub-region;

Convinced also that a sub-regional approach will reduce investment costs and thereby facilitate deployment of modern biotechnology products within the sub-region;

Desirous to establish a regional mechanism for ensuring the safe introduction of modern biotechnology, harmonise national biosafety policies, regulations and approaches to risk assessment and risk management under a single framework in order to develop a more uniform and consistent approach to the safe use and application of modern biotechnology, and to minimise obstacles to trade in products of modern biotechnology among Member States.”<sup>xiii</sup>

Further, the role of the West African Biosafety Committee (WABCO) will be to administer the common biosafety regulatory system to:

- guarantee access to biotechnology under condition of minimum risk to all the countries of the region,
- ensure an acceptable safety level in the utilisation of biotechnology products based on a common foundation,
- provide a common mechanism for the assessment of the effects of GMOs on human or animal health and the environment,
- facilitate mutual acceptance of risk assessments,
- facilitate the exchange of approved GMOs in the sub-region<sup>xiv</sup>

## The Role of FARA in biosafety in Africa

In its June 2009 briefing, the ACB highlighted the influential role to be played by FARA in the implementation of the Biosafety Strategy as being extremely problematic due to a conflict of interest. For example, their leadership in the development of Regional Centres of Excellence could shift the focus from risk assessment and management to research and development or other industry requirements.

The ACB maintained that FARA’s objective is to advance a Green Revolution agenda, which we believe is an industry driven agenda that will result in the loss of food sovereignty and agrobiodiversity, and the erosion of indigenous practices and resources. For this view, the ACB has come under fire from the AU Biosafety Unit, which asked of the ACB that it provide factual observations in substantiation. We stand by our assertion that FARA advances the interests of industry on the continent and offer below just one example of many projects to substantiate this view.

## Partnership on Capacity Building in Biosafety with the Syngenta Foundation

In May 2009 the Syngenta Foundation for Sustainable Agriculture (SFSA) and FARA announced their partnership to launch a 3 year project for capacity building in biosafety in sub-Saharan Africa. The Project on Capacity Strengthening for the Safe Management of Biotechnology in Sub-Sahara Africa (SABIMA) will be implemented by the Sub-Regional Organisations (SROs) and the National Agricultural Research System (NARS) in six countries in sub-Saharan Africa: Burkina Faso, Ghana, Nigeria, Kenya, Uganda and Malawi. FARA will manage the \$1 265 565 project under the leadership of Professor Walter Alhassan.<sup>xv</sup>

Mrs. Lucy Muchoki, a Board Member of FARA who signed the agreement on behalf of FARA's Executive Secretary, Dr. Monty Jones, remarked that **“the project stewardship capacity that will be developed will underpin future initiatives for the proper deployment of proprietary biotechnology in the selected countries. The beneficiary countries will serve as mentors for sister countries in their respective sub-regions for the safe deployment of modern biotechnology”**.<sup>xvi</sup>

Both organisations recognised that “adverse media or coverage should be anticipated as much as possible” and foresaw the need to prepare position statements on “potential negative arguments from NGOs that can be released if needed within 24 hours”.<sup>xvii</sup> This is a clear indication that 1) FARA is aware that civil society will object to this agreement to advance Syngenta's proprietary technologies in Sub-Saharan Africa and 2) that they do not intend to engage with civil society and small-farmer organisations, but instead have already prepared their responses and written their media spin.

### FARA Leadership – strong industry ties

Key leadership in FARA also have strong industry ties. For example, FARA board member Florence Wambugu has long standing ties with Monsanto, having been trained by Monsanto to work on its GM virus-resistant sweet potato project. She was also the first Director of the AfriCentre of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), which is a US-centred, GM promotion and “technology transfer” agency funded by AgrEvo, Bayer, Cargill, Dow, Monsanto, Novartis, Pioneer, and Syngenta. In 2002 she established her own biotechnology foundation to become the Chief Executive of Africa Harvest Biotechnology Foundation International (AHFBI), whose communication programme is supported by CropLife International - an organisation led by companies such as BASF, Bayer, Dow, DuPont, Monsanto, and Syngenta.<sup>xviii</sup>

Professor Walter Alhassan, mentioned above, has championed USAID initiatives on biosafety in West Africa. “Until July this year he was the West and Central African Co-ordinator of the Program for Biosafety Systems (PBS). He successfully lobbied for the passage of the Ghana legislative instrument that has paved the way for the conduct of confined field trials involving GM crops. In addition to that he coordinated for West Africa, a sister project in Agricultural Biotechnology Support Project phase II (ABSPII) coordinated by Cornell University and also funded by the USAID. He is currently the coordinator of the FARA African Biotechnology Biosafety Policy (ABBPP)”.<sup>xix</sup>

## The African Model Law on Biosafety and National Biosafety Frameworks

The AU has requested that the ACB furnish proof to back up our assertions that National Biosafety Frameworks (NBFs) are not in line with the Model Law. The ACB has provided pro-bono comments on numerous drafts and final African biosafety laws. This work was undertaken in an effort to guide civil society towards improving such laws by *inter alia*, specifically bringing them in line with the AU Model law. In the course of such work, the ACB highlighted instances where such laws appeared to have been unduly influenced by industry interests and pro-GM governments such as the USA. Working through USAID, biosafety laws are weakened by the leverage of support provided through capacity building processes that include the crafting and implementation of NBFs.

Comments on draft biosafety legislation have been furnished by the ACB over the past five years in respect to the following African countries: Nigeria, Uganda, Kenya, Zimbabwe, Swaziland, Lesotho, Ghana, Zambia, Malawi, Mauritius and Cameroon. In some cases e.g. Kenya, Uganda and Nigeria, comments were made on more than one draft. These can be found on the ACB website: [www.biosafetyafrica.org.za](http://www.biosafetyafrica.org.za)

The National Biotechnology Safety Bill of Uganda is one of several examples of biosafety legislation that bears little resemblance to the African Model Law, falling short of even the minimum requirements of the Cartagena Biosafety Protocol, to which Uganda is a Party. This is the case, despite Uganda historically having been an outspoken supporter of a rigorous Biosafety Protocol. This is evidenced, for example, by its strong objection to the creation of a 'Working Party on Biotechnology' at the WTO Ministerial Conference in Seattle in 1999 and later by showing strong political leadership by being one of the first countries to ratify the Protocol.<sup>xx</sup>

In 2003, Uganda's first draft national biosafety regulations were published, which drew heavily on the African Model Law on Biosafety. The National Biotechnology Safety Bill approved by Uganda's Cabinet during April 2008, however, bears the mark of USAID's aggressive pro-GM intervention over the years. This includes, amongst other things, training Ugandan scientists, funding a level 2 Biosafety Greenhouse, funding GM cotton trials and experimentation with fungal resistant cassava.

The 2008 Bill does not even mention the Precautionary Principle enshrined in both the Biosafety Protocol and the African Model Law. In fact the objectives of the Bill make it clear that it is rather to be used as an instrument to facilitate research and development involving GMOs. Some of the problematic provisions which are not in line with the Model Law include:

- Provisions on cessation orders and access to information and confidential business information are convoluted and cumbersome.
- Confusing and unscientific concepts have been introduced with the intention of creating the impression that open field trials happen in confined conditions and cannot impact on the external environment. The Bill creates a definition for 'confined use' when referring to a field trial and no separate definition has been created for field trials as is commonly understood.

- The traditional scientific concept of ‘contained use’ for the development and propagation of GMOs in secure laboratory conditions is absent.
- Written authorisation is required for GMO activities along with risk assessment procedures. However, any GMO may be exempt from authorisation provisions and subject to fast track procedures.
- Section 21(2) sets out six grounds for applying simplified information requirements and/or review procedures. These grounds, to a large extent, deal with previous approvals by other countries and scientific information or knowledge existing in those countries about the risks posed. The impression created by these provisions is that the whole notion of case-by-case biosafety assessments for field trials and environmental releases will be dispensed with, especially for those GMOs that have been in commercial use for some time.
- Duty of care provisions have been crafted as well as administrative measures for damage to the environment, restoration of the environment and so forth. However, these are not sufficient to deal with the complexities that underpin a comprehensive liability and redress regime.
- Labelling of GM foodstuff is another area requiring urgent and further work.

The ACB’s document on the Uganda Bill is available at: <http://www.biosafetyafrica.org.za/index.php/20090611228/COMMENTS-ON-THE-NATIONAL-BIOTECHNOLOGY-SAFETY-BILL-OF-UGANDA/menu-id-100025.html>

## Conclusion

The African Union has played a constructive role in the biosafety discourse at the regional and international levels as part of its abiding commitment to protect African biodiversity, culture and livelihoods in the face of enormous political pressure. The African Model Law on Biosafety and the activities of the African Union’s Biosafety Project are testaments to this. Nevertheless, the ACB stands behind its concern that the African Strategy on Biosafety could open up opportunities for actors with strong interests in GMOs to create regional markets for GM products with lax and uniform regulatory processes. Our experience to date with the domestication of biosafety frameworks suggests that these pro-GM interests are extremely powerful and will seize Africa’s lack of capacity in biosafety, and need for technological support and infrastructure, to push this agenda. Although Regional Economic Communities may have functional secretariats that could assist in Biosafety management on a regional level, we do not believe that they are appropriate organs for this function and will not serve the interests of African farmers and citizens.

The ACB looks forward to measures being taken to distance the AU’s biosafety processes from actors whose agenda is to promote proprietary technologies while assisting in the development of biosafety frameworks that ignore the Precautionary Principle and provisions of the African Model Law on Biosafety.

The ACB acknowledges and welcomes the strong political will of the AU in shaping biosafety debates and policy in the international arena toward a cautious approach. We thank the African Union Biosafety Unit for their feedback and hope to continue to work with them in a constructive way to advance rigorous biosafety processes that hold African biodiversity, agrobiodiversity, food sovereignty and culture at heart.

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