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Harmonizing Biosafety Regulations in Africa: Surmounting the Hurdles

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The global regulatory landscape for genetically modified organisms (GMOs[1]) has evolved over the years amidst ongoing debate. Scientific evidence on safety of GMOs has at times been overwhelmed by ideological, political, and market considerations and these have influenced the nature and scope of regulations being adopted by most countries or economic blocs. This situation is compounded by the polemical stance adopted by various interest groups and the complexity of existing regulatory guidelines established by international bodies. As genetic engineering becomes established and developing countries are faced with inadequate access to state-of-the-art resources and expertise, there have been calls for African countries to adopt a harmonised biosafety regulatory approach that will pool resources and confer benefits of economies of scale. In view of this, Regional Economic Communities (RECs), particularly the Common Market for Eastern and Southern Africa (COMESA) and the Economic Community of West African States (ECOWAS), have emphasised the importance of harmonised regulations for member states. However, the process of developing harmonised regulations for GMOs and the scope of such regulations pose weighty challenges for policy-developers and decision-makers. Thus the focus of this policy brief is to explore issues associated with establishing a harmonized sub-regional regulatory system for GMOs and to offer policy options.

Biosafety Regulation

Regulation has been central to the debate on the use of agricultural biotechnology due to possible safety implications for the environment and human health on one hand and non-safety implications including socio-economic considerations on the other. Defined as a principle, rule, or law designed to govern conduct, regulations play a critical role in achieving broad socio-economic goals, including assuring safety, achieving equitable distribution of income, ensuring public confidence, improving efficiency of resource allocation, and protecting rights of ownership.

In the same vein, biosafety regulations are expected to enable countries to protect human health and the environment while harnessing the benefits of modern biotechnology. However, such outcomes can only be achieved if countries implement functional biosafety regulatory systems. Consequently, the Cartagena Protocol on Biosafety, a legally binding international agreement, negotiated, concluded, and adopted in the framework of the Convention on Biological Diversity, was established to guide parties in developing systems for the environmentally sound management of modern biotechnology practices, focusing specifically on transboundary movement of living modified organisms (LMOs) and their impact on biodiversity. Parties to the protocol, which includes 48 African countries, are expected to establish functional regulatory systems that enable a platform for the exchange of scientific and technical information. A number of global, regional and sub-regional initiatives have assisted and continue to assist African countries to meet these goals.

Many African countries planned national biosafety frameworks under a UNEP-GEF funded project at the turn of the new millennium. However, few of these proposals have fully reflected the resources available to national governments or the needs of local economies and, as a result, only a small number have been implemented. While some African countries have no regulatory systems (e.g., Angola, Chad and Somalia), others have established legal

[1] Living modified organisms (LMOs) and genetically modified organisms (GMOs) are used interchangeably in this brief

instruments that enable them to regulate modern biotechnology to varying extents (e.g., Burkina Faso, Egypt, Ghana, Kenya, Mali, Namibia, Nigeria, South Africa, Uganda, and Zimbabwe). So far, only three countries, South Africa, Burkina Faso, and Egypt, have commercialized GM crops, while a few others have or are conducting confined field trials with GM crops.

Efforts towards Harmonizing Biosafety Regulations

To access the benefits of modern biotechnology, many countries that are unable to justify the costs of extensive national biosafety systems will need to have access to harmonized regional regulatory systems, or be able to combine national and regional biosafety services for greater efficiency. The emerging consensus is that harmonization of regulatory systems across countries will help address the core constraint of inadequate regulatory capacity. In addition, it will remove unnecessary duplication in the review of individual GMOs. A well structured harmonized regulatory system should confer benefits such as cost efficiency, adequate shared technical capacity to ensure a high level of safety, creation of more competitive markets, facilitation of cross-border trade, and creation of standardised and transparent processes that will assure predictability in international trade.

A look across the continent reveals many African countries have biotechnology policies, regulations, and strategies. Each country has its own laws, legal traditions and practices, and country delegations must find ways to ensure that these are honoured in a regional process in order to prevent needless discontent at the end of the process. Nevertheless, considering that 48 African countries either acceded to or ratified the Cartagena Protocol on Biosafety, and that the protocol provides a common and coordinated approach among countries to address potential risks of GMOs, more similarities than differences exist among these countries. It should be feasible to align policies, technical regulations, standards and specifications for a harmonised regulatory system.

Historically, the Global Biodiversity Institute included discussion on regional biosafety harmonisation at workshops in 2000 in West Africa (12 countries); Southern Africa (11 countries) and East Africa (8 countries). AfricaBio held a regional consultation on biosafety harmonisation for Southern African Development Community countries in 2000; the Southern African Regional Biosafety project held a consultation on regional harmonisation of biosafety regulation in 2001 for 11 Southern African countries; and the Association for Strengthening Agricultural Research in Central and Eastern Africa undertook consultation with its 10 member countries and produced a report on regional harmonisation of biosafety in 2002. Incentive to develop national biosafety systems was provided in 2002 by the UNEP-GEF program and this put most regional discussions on hold with countries wanting to develop strong national systems before negotiating regional processes. However, some African countries with smaller economies have indicated that regional biosafety systems would best suit their needs for GMO reviews and approvals. Some smaller countries like Lesotho and Burundi have indicated that biosafety decisions made by larger, neighbouring countries with functioning biosafety systems would suffice for their needs.

More recently, efforts to develop harmonized regulatory frameworks have been re-established at the sub-regional level. Agricultural ministers in Eastern and Southern Africa within COMESA endorsed a Regional Approach to Biotechnology and Biosafety Policy (RABESA) to tackle GMO issues relating to trade and access to emergency food aid. In West Africa, ECOWAS, the West African Economic and Monetary Union (WAEMU), and the Permanent Interstate Committee for Drought Control in the Sahel (CILSS) are currently working together to establish a common regional biosafety framework for all countries in the West African sub-region. Regional efforts are being advocated within existing RECs because of geographic proximity, common agro-ecological systems, and common crops of economic importance. For these regional initiatives to succeed, political support and endorsement, policy convergence, national sensibility, and involvement of stakeholder institutions at various levels need to be prioritised and factored into the development process for a functional regional regulatory framework that augments national biosafety systems.

Establishing a Regional Regulatory Framework

The foundation for successful harmonization of regulatory systems at the regional level is a clear understanding of the benefits of an efficient, functioning regional system together with recognition and respect for national regulations and national sovereignty. Success also requires clarification of procedures and processes. For instance, in some countries there are overlaps in the mandates of regulatory agencies that need to be clarified. This is compounded by several ministries having oversight of different aspects of GMO regulation. Mechanisms to ensure coordination, cooperation, and communication among these government ministries, departments and agencies are critical to the successful negotiation of a harmonised regional biosafety process. It is important that national biosafety regulations clarify the mandates, roles and responsibilities for regulatory bodies and provide a clear framework for interaction among stakeholders and enforcement of the regulations.

Examples already exist within the RECs of harmonized regional regulatory systems focused on other issues, for example, COMESA's Green Pass for Sanitary and Phytosanitary (SPS) Standards. The Green Pass does not specify what regional SPS standards should be. Rather, it establishes standards for accrediting National Green Pass Authorities, based on the technical, financial, and administrative capacity of those organizations. Green Pass regulations give states flexibility to establish their standards while setting out general conditions that those standards must meet, thus respecting national prerogatives while achieving some level of regional standardization[2, 3].

Biosafety frameworks at all levels - - international, regional, national, and institutional - - must function efficiently and effectively for safe and sustainable access to modern biotechnology products. Proponents have suggested three possible regional models for biosafety:

1. a centralized regional regulatory system that makes all decisions at the regional level on behalf of national systems;

2. a regional regulatory system that makes some decisions while deferring other decisions to national systems;

3. a regional regulatory system that conducts risk assessment and makes safety recommendations that can be used to support national decision making.

The key issue with options 1 and 2 is whether regional decision-making could result in an unworkable system dogged by costly institutional structure, stalemates and inertia. The emerging consensus is to develop a harmonised regulatory framework that is guided in principle by having a regional mechanism for risk assessment while authorizations or decision-making is carried out at the national level. Taking cognizance of the fact that the Protocol encourages science-based risk assessments, a harmonized system would help establish a mechanism for generating science-based risk assessment reports at the regional level to guide the authorisations by national systems. Where significant agro-ecological differences exist, national systems could conduct complementary risk assessments that deal with country-specific risks. To be effective and efficient, a regional biosafety process will need good administration, strong linkages with national authorities, and efficient review mechanisms. Whether the regional system requires a physical structure, or can function virtually using existing national and regional infrastructure, will help establish its efficiency.

The draft ECOWAS regional biosafety process recommended that contained research, confined field trials, unconfined releases and food and feed imports be dealt with differently. National systems would handle contained and confined research activities; a regional risk assessment would provide safety recommendations to member

[2] COMESA (2009). Regulations on the application of sanitary and phytosanitary measures. Section 4

[3] http://famis.comesa.int/content/page/78/78/sps/lang.en/Green-Pass-%28CGP%29.html

countries for unconfined (general) use decisions that are made at country level; and regional risk assessment and regional decision-making would be used for food and feed import approvals. The current ECOWAS review process within member states is examining provisions for which no consensus points had been reached including a proposed regional decision-making system and liability regime.

Regulatory Costs

The high cost of generating adequate data for regulatory purposes, maintaining functional biosafety regulatory structures, and ensuring regulatory compliance is well documented[4, 5, 6]. A harmonized regional regulatory system must be established in a manner that it is workable, science-based, cost efficient, and does not compromise on acceptable safety standards. Only relevant regulatory data should be requested at any stage of the regulatory process and the regulatory structures and requirements should be efficient and commensurate with the level of risk posed by GMOs.

Most African countries and institutions lack the financial and technical resources for mandatory risk assessment and compliance monitoring. However, a false and detrimental premise in establishing regulations is the assumption that foreign multinational companies will be the only developers and users of the technology and will offset the high regulatory costs with profits from approved products. This assumption penalizes public institutions that are interested in applying GMOs that focus on crops and traits of national and regional interest. Many public research institutions in Africa have partnered with foreign public and private counterparts to undertake GM R&D activities, but the products of these initiatives never reach African farmers primarily because of the prohibitive cost of regulatory approval and the long delays associated with regulatory decisions.

An additional cost mitigation consideration would be the acceptance of regulatory food safety data from other countries and environmental data from regions with similar agro-ecological systems. If farmers and consumers in Africa are to benefit from improved planting materials, there is the need to build regulatory systems that are an incentive for investment.

Negotiation and Consensus-building

African countries need to be present at regional negotiations with clearly defined national goals backed by a spirit of compromise and cooperation. In debating and fashioning a model for a harmonized regional biosafety regulatory system, it is important that all stakeholders are flexible and willing to move beyond premeditated positions in favour of solutions that are workable and efficient. A participatory approach to harmonizing biosafety regulations would ensure ownership of both the process and outcome. This is achieved through consensus-building meetings and consultations involving relevant stakeholders at national and regional levels - an expensive process that needs political and financial support from national governments. The harmonized regulatory system will require a number of consensus points including the methodology for risk assessment, which is still being debated in the international arena. By making meaningful contributions to these international debates, Africa will be able to use international agreements and consensus to advance regional harmonisation on the continent.

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[4] Bayer J. C., G. W. Norton and J. B. Falck-Zepeda (2010). Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries. AgBioForum 13 (1): 53 – 62.

[5] Bradford, K.J., J.M. Alston and N. Kalaitzandonakes (2006). Regulation of Biotechnology for Specialty Crops. In Regulating Agricultural Biotechnology: Economics and Policy. Just, R., J.M. Alston, and D. Zilberman, eds., Springer Publishers, New York. p. 683-97.

[6] Jaffe, G. A. (2005). Withering on the Vine: Will Agricultural Biotechnology's Promise Bear Fruit? Center for Science in the Public Interest, Washington DC. 2 February 2005.

Key issues that can lead to disagreement and stymie progress towards harmonized regulatory frameworks include: terminology differences; inconsistency with international obligations; inclusion of socio-economic issues; labelling of GM products; and choice of liability and redress regime. Where it is difficult to find consensus, it may be possible to defer these issues to the national level, thereby allowing national preferences to prevail. Considering that most African countries are parties to the Cartagena Protocol on Biosafety, consistency with provisions of the Protocol is of prime importance and consensus documents from the Protocol can be used to help establish regionally harmonised regulations or processes. For example, terminology used in the Protocol provides consistency for harmonized regulations.

For regions with more than one official language, care must be taken to ensure that the spirit and intent of the regulations are not lost or altered between translations. Socio-economic considerations are non-safety issues of importance to African countries but must be appropriately placed within the decision-making process (see policy brief 1). Regarding choice of a liability and redress regime, it is important for all Parties to operate within the framework of the recently agreed Nagoya-Kuala-Lumpur Supplemental Protocol on Liability and Redress and this may be an issue best implemented at national level.

Moving Forward

Harmonization of regulatory systems across countries in Africa is important and enough similarities and working models exist for the sub-regional initiatives to succeed in achieving this goal. The process requires commitment to a workable outcome and input from stakeholders with genuine intent. The drafting and adopting of harmonized regional biosafety regulations requires consultation, negotiation, and consensus-building across member states, using a process that is inclusive, interactive, and participatory. Regulations are critical for the adoption of good science and for deriving benefits from modern biotechnology without compromising on safety to the environment and humans. A useful regulation is one that ensures an adequate level of safety and enables access to safe new products that will benefit local communities.

Regional harmonization will be workable if the regional process has strong linkages with member state authorities and is responsive to their requests and input. Such efforts should engage national experts to promote harmonization of biosafety regulations among relevant government ministries within national systems. Memoranda of Understanding may be needed to empower cooperation. For any country to meaningfully participate in the regional harmonization process, there may be the need for national legal instruments or modifications over and above the regional agreement.

A regionally harmonised approach to biosafety regulation confers benefits of economies of scale, considerably reduces the duplication of technical review and addresses the issue of inadequate human and infrastructural biosafety resources at national level. Establishing workable regional biosafety processes will require platforms for consultation and a clear understanding of how national frameworks want to benefit from the regional approach. National governments need to provide adequate funding for regulatory activities to replace the current over-reliance on funding from donors or international agencies. The way forward relies on strong political will, trust, commitment, respect, recognition for national sovereignty, transparency, participatory consultation, and planning.

This is the second of a series of policy briefs by the African Union/NEPAD - African Biosafety Network of Expertise (ABNE) that addresses socio-economic issues on regulating modern biotechnology. ***This policy brief is primarily for regulators, policy-developers and decision-makers.***

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