

Status of Agricultural Biotechnology and Biosafety Regulatory Systems in East Africa

Agricultural Biotechnology Research and Development

Conventional procedures of biotechnology are widely used in the region. For examples tissue culture (TC) is being used in laboratories to facilitate germplasm collection, conservation and exchange and for mass propagation of elite quality planting materials in Kenya, Uganda and Tanzania. At a commercial level TC is used in Kenya for production of planting material of pyrethrum, banana, sugarcane, potato, strawberry and flowers; for small scale production of planting material for sweet potato, cassava, vanilla and for protocol development (Macadamia, vanilla, oil palm, flowers). Uganda is applying TC at a commercial for mass production of banana planting material. Agro-Genetic – Technologies (AGT), the largest private TC laboratory in Uganda can produce up to eight million plantlets a year (depending on the crop) and this makes it the biggest TC laboratory in East and Central Africa today. Presently TC bananas is the main product of this company.

Marker assisted selection (MAS) for breeding is another biotechnology research tool adapted to enhance conventional breeding with accuracy and to accelerate product development cycles. This tool is widely used in the region. Examples of MAS in Kenya include:

1. Characterization and mapping of maize streak virus and grey leaf spot resistance genes in maize
2. Development of drought tolerant maize and wheat
3. Development of wheat lines resistant to the Russian wheat aphid
4. Selection for smut resistance in sugarcane
5. Diversity studies for sweet potato and cassava
6. Characterization of indigenous species of cattle, forages and tsetse.

Examples of MAS in Tanzania include:

7. Germplasm characterization for the following crops; Coconut, Cashew, Coffee, Cassava, Local chicken and Indigenous cattle.
8. Breeding for desired traits in cassava, rice and sorghum

Genetic engineering (GE) is already being used at a research level in Kenya and Uganda. In Kenya on-going work includes development of: virus resistant sweet potato, maize resistant to storage pests, and bio-fortified sorghum. Most of this research is at laboratory

level while contained field testing with maize, cotton and sweet potato have been conducted. In the case of Uganda GE technology for crops is focused on East African highland bananas and the traits addressed include resistance to black sigatoka, nematodes and the weevils while some effort is also directed to reducing the maturity period and the increasing the stem hardness. Some work has also been initiated for incorporation of resistance to cassava mosaic virus disease (CMV) and cassava brown streak virus (CBSV) into local landraces known to be highly susceptible, through genetic engineering. Efforts to develop sweet potato lines that are resistant to sweet potato weevils using GE technology are on-going. Field trials are being conducted for GM banana with resistance to black sigatoka and *Bt* cotton with stacked genes for resistance to cotton bollworm and herbicide-tolerance to Round-up Ready.

In case of livestock DNA technology is directed to vaccine development and disease diagnostics and this is applied in all three countries of East Africa. Related work in the region includes development of recombinant DNA vaccines e.g. against Newcastle disease, Rift Valley Fever and Rinder-pest. Development of molecular diagnostic techniques for livestock diseases such as East Cost Fever, Lumpy skin disease, contagious bovine pleuro-pneumonia), Foot and mouth disease (FMD) as well as for detecting resistance to drugs, microbial quality analysis of foods (fish, diary and meat) and DNA mapping in animal breeding are all in practice.

Major challenges to biotechnology research and development include:

1. Lack of a strong and clear regulatory framework, both legal and operational guidelines and these calls for finalizing National Biotechnology Policies and legal frameworks
2. High regulatory costs
3. Inadequate sustainable financial support
4. Low research and regulatory capacity both human and infrastructural capacity
5. Inadequate expertise in Intellectual Property management
6. Lack of awareness amongst key stakeholders particularly producers and consumers
7. Lack of clear long term projections on social economic benefit within the context of localization on one hand and globalization on the other

Biosafety Regulatory Systems

Kenya

In Kenya, the National Council for Science and Technology (NCST) is the government agency currently responsible for overseeing the implementation of the biosafety regulatory system. That office issued Regulations and Guidelines for Biosafety in

Biotechnology in 1998 (Traynor and Macharia 2003; Republic of Kenya 1998). Those regulations were issued under the existing Science and Technology Act of 1980, although that Act has no regulatory authorities and no means to enforce compliance with the regulations (Traynor and Macharia 2003). The NCST also established the National Biosafety Committee (NBC) to develop the country's biosafety policy and review GMO applications. (Harsh 2005). The membership of the NBC includes representatives from relevant government Ministries as well as representatives from civil society and the national universities (Traynor and Macharia 2003; Macharia 2005).

Under the interim Kenyan biosafety regulatory system, applications to import or release GMOs (including applications for confined field trials) are submitted to the relevant Institutional Biosafety Committee (IBC) where they are reviewed and assessed for compliance with the guidelines before submission to the NBC (Republic of Kenya 1998). Then, those applications are forwarded to the NBC, where those applications are reviewed by the NBC and/or a technical subcommittee of the NBC. A recommendation is made by the NBC and the NCST Secretary decides whether to approve the application (Traynor and Macharia 2003). To date, Kenya has approved five confined trials. (Macharia 2005).

Kenya has developed a number of legal documents to turn its interim biosafety regulatory system into a permanent and comprehensive system. Those documents included regulations, a biosafety law, and a national Biotechnology and Biosafety Policy. The National Biotechnology and Biosafety Policy was approved in 2007 and the Biosafety Law was passed by Government in December 2008.

Tanzania

The structure of Tanzania's biosafety regulatory system is described in its National Biosafety Framework (NBF) issued in March 2005 (United Republic of Tanzania 2005). In that system, the National Biosafety Focal Point (NBFP), who is responsible for review and approving applications and overseeing the implementation of biosafety issues, is the Ministry responsible for environment (United Republic of Tanzania 2005). The NBFP gets advice on technical and policy issues from the National Biosafety Committee, comprised of government and nongovernmental organizations, as well as the Competent Authorities, which are other agencies with areas of relevant expertise within the government. The NBF also discusses Institutional Biosafety Committee, who perform biosafety functions within any institution conducting genetic engineering.

Finally, the regulations that will establish Tanzania's biosafety system will be promulgated under authority recently established in the Tanzanian Environmental Management Act of 2004 (EMA), which was signed by the President of the Republic on July 1 2005 (United Republic of Tanzania 2004). That law provides the legal authority for the Ministry of Environment to regulate GE organisms. The NBFP is now working on the regulations to implement the biosafety provisions of the Act and to establish the procedures identified in the NBF.

Tanzania also has established a specific interim biosafety regulatory process for permitting small-scale confined field trials of plant and plant products. Under the authority of the Plant Protection Act, the Ministry of Agriculture and Food Security promulgated Schedule 18 (United Republic of Tanzania, Schedule 18). That document puts in place a review and approval process for all small-scale confined field trials involving GE plants. It requires the completion of a detailed application which is reviewed by the Agricultural Biosafety Advisory Committee (ABSAC), a technical advisory committee which is a competent Authority of the Ministry of Agriculture and Food security (MAFS). The application is also reviewed by the National Biotechnology Advisory Committee (NBAC), which is a national committee on biotechnology issues based under the Ministry of Science Technology and Higher Education (MSTHE). With the advice of the ABSAC and the NBAC, the Minister then decides whether to allow the field trial and issue a permit (United Republic of Tanzania, Schedule 18). Schedule 18 also gives the Tropical Pesticides Research Institute (TPRI), which is a Plant Biosafety Office consisting of biosafety inspectors, the ability to require risk management measures to ensure that the field trial does not affect the environment or human health.

Uganda

The interim biosafety regulatory system in Uganda is coordinated by the Uganda National Council for Science and Technology (UNCST). That office established in 1995 the National Biotechnology Committee (NBC) made up of representatives from other government agencies and civil society (Nampala 2005; Wafula 2005). The NBC is the “national administrative arm on matters concerning biosafety.” (The Republic of Uganda 2004a). The main function of the NBC is technical advice on biosafety issues, including the assessment of individual applications for activities with GE organisms. (Republic of Uganda 2004a).

The NBC has been responsible for writing the National Biotechnology and Biosafety Policy (Republic of Uganda 2004a) that was approved by Government in April 2008, draft National Biosafety Regulations (Republic of Uganda 2004b), Guidelines on Biosafety in Biotechnology for Uganda (Republic of Uganda 2002), and a number of draft manuals addressing specific issues surrounding biosafety regulation, such as confidential business information. Those documents set forth the current and proposed biosafety regulatory framework for Uganda. Under the biosafety system identified in those documents, the UNCST will be the competent authority to carry out biosafety regulation. It will be advised on policy matters by the National Biotechnology Advisory Committee (NBAC), which is an inter-ministerial committee, and the NBC.

All three countries of East Africa have ratified the Cartagena Protocol on Biosafety and hence are part of the over 133 countries in the world that have agreed to contribute to an adequate level of protection in the field of safe transfer handling and use of living modified organisms and specifically focusing on trans-boundary movements. The protocol came into force in September 2003 and the process of implementing the protocol involves putting in place national biosafety frameworks (NBF).

Major challenges in the development and implementation of Biosafety Systems:

- Awareness creation during the development of the Biotechnology/biosafety policy and the sensitization about the overall NB framework is a continuous demand.
- Harmonizing the relevant stakeholders so that all issues pertaining to biosafety can be handled efficiently as per the institution's roles calls for dialogue and consensus building.
- Capacity building particularly for regulators ,who have to comprehend technical issues for competent decision making , need considerable attention and;
- The global debate on the contentious issues in the COP-MOP meetings sometimes delay decision making on policy and legal issues and have to be discussed with competence and in an open manner.

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