

REGIONAL/INTERNATIONAL POLICIES AND TRADE PROTOCOLS THAT INFLUENCE UGANDA'S BIOTECH AND BIOSAFETY

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Introduction

The role of modern biotechnology in the economic transformation and sustainable development of Africa is the subject of increasing debate and controversy. There are two extreme positions that characterize the debate: pro- and anti-biotechnology camps. The extreme pro-biotechnology groups catalogue potential benefits of the technology and often dismiss any concerns about potential risks. They tend to portray biotechnology as the panacea to food insecurity in Africa. On the other extreme are the anti-biotech activists that associate the technology with nothing but danger and risks. The two extreme views have made it difficult for many African policy-makers and sections of the public to appreciate the technology because of the lack of reliable information and guidance available to these groups. This is likely to deny African countries opportunities to derive benefits while at the same time minimizing risks from the technology. These countries need to establish informed policies and strategies to respond to developments associated with biotechnology.

Another set of issues that are at the center of the debate relate to the relationship between legal protection of intellectual property rights and transfer of biotechnology to developing countries. Many developed countries favour strengthening intellectual property protection through such agreements as the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO). Their policy is based on the view that strong intellectual property protection will stimulate technological innovation and promote economic growth. Critics argue that strong intellectual property rights protection will stand in the way of technological innovation and deny developing countries economic growth. For many African countries the relationship between technological development and legal protection of intellectual property rights remains unclear. This situation makes it difficult for them to participate in international debate on handling and transfer of biotechnology.

The divergent views and policies on biotechnology between Europe and the USA have also created confusion and complicated policy choices for African countries. Most African countries are not sure of whether to "follow the more permissive U.S. approach toward GM crop technologies, or the more precautionary EU approach. However, African countries need to make their decisions regarding the development and application of modern biotechnology influenced and informed by their own aspirations, needs and perceptions of this technology. These decisions should evolve as these countries gain a better understanding of the technology, and as their R&D efforts generate new products and/or processes, and they establish biosafety systems. Lack of legal systems that address issues associated biosafety and intellectual property protection has undermined Africa's place in international trade and aspiration to establish a cohesive and integrated economic regime. Therefore there is need to establish how legal systems can be best designed to benefit low income groups (particularly rural farmers, traditional medicine enterprises, rural women and small-scale informal

enterprises) in African countries within the context of international/regional policies and trade protocols, including the Convention on Biological Diversity, the TRIPS agreement, and African Model Law, to which we are obliged to comply.

Convention of Biological Diversity (CBD)

The CBD is the first global agreement on the conservation and sustainable use of biological diversity that was signed in 1992 by over 150 governments at the Rio "Earth Summit". The CBD is an international legally binding convention whose objectives are the conservation of biodiversity, sustainable utilization of its components and the fair and equitable sharing of benefits arising from the use of genetic resources.

The Convention clearly recognizes the potential benefits as well as the perceived risks of modern biotechnology. On the one hand, it provides for the access to and transfer of technologies, including biotechnology that are relevant to the conservation and sustainable utilization of biodiversity (Art. 16 (1) and 19 (1&2)). On the other hand, it seeks to ensure the development of appropriate procedures to enhance the safety of biotechnology in reducing all potential threats to biodiversity, taking into account the risks to human health (Art. 8(g) and 19 (3)). Article 19(3) of the CBD makes specific provision for the implementation of biosafety measures for the trans-boundary movement of living modified organisms (LMOs). This article has been the base for the international biosafety regulatory systems, through the Cartagena Protocol on Biosafety.

Uganda is a Party since it ratified CBD in September 2003 and the National Focal Point is the Ministry of Lands, Water and Environment.

The Cartagena Protocol on Biosafety

On 29 January 2000 in Montreal, Canada, the Conference of the Parties to the CBD adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. The Cartagena Protocol on Biosafety entered into force on 11 September 2003. It is the first and only international law to specifically regulate genetic engineering and genetically modified organisms (GMOs). The Biosafety Protocol is legally binding in the international legal system and in the legal systems of countries that have ratified, approved, accepted or acceded to it. As of 14th March 2007, there are 140 Parties to the Protocol.

The Biosafety Protocol recognizes for the first time in international law that GMOs are inherently different from other naturally occurring organisms and carry special risks and hazards, and therefore, need to be regulated internationally. It addresses the fact that GMOs may have biodiversity, human health and socio-economic impacts, and that these impacts need to be risk assessed. The Biosafety Protocol puts the 'Precautionary Principle' into operation in decision-making (i.e. in the absence of scientific certainty, a party should err on the side of caution and could restrict or ban the import of GMOs on account of their potential adverse effects) and further establishes it in international law. It also establishes the principle of prior informed consent with regard to the import of GMOs and preserves the right of a country to reject applications for the import of GMOs. Article 18 of the Protocol addresses the issues of handling, transport, packaging and identification of GMOs/LMOs.

The central objective of the Protocol is to regulate the international (i.e. transboundary) movement of LMOs in order to derive maximum benefits from modern biotechnology while at the same time protecting human health and biodiversity from potential risks posed by LMOs. Under the Advanced informed Agreement (AIA) which is a key regulatory instrument of the protocol, exporters have to inform countries of their intention to ship a GM product in advance, and receive permission to do so before proceeding. However, only GM seeds intended for planting are covered by the AIA. For the rest of the items, exporters need only to register their shipment with a central Biosafety Clearing House. Governments must then constantly monitor this Clearing House through the internet to know what is happening so that they can make informed decisions on an import. The Protocol mandates Parties to elaborate an international liability and redress regime for damage resulting from GMOs.

The Protocol is currently a primary driving force behind the establishment of the national biosafety frameworks in countries that have ratified, or acceded to the Protocol. The Protocol empowers countries to establish biosafety procedures and provides the scientific and legal boundaries under which the framework should operate. Uganda ratified the Protocol in September 2003 and during establishment of the national policy the following provisions of the Protocol were addressed:

- Pre-release review and consent
- Differences in the nature and level of risk depending not only on the gene and organisms, but also on the site – whether laboratory, greenhouse, small plot or large field
- Public participation and information sharing
- Handling of confidential information
- Identification of a national competent authority
- Purpose and role of labeling and associated policy statement
- Post-approval oversight; enforcement of and compliance with NBC decisions.

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated in the 1986-1994 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.

The TRIPS Agreement is an attempt to narrow the gaps in the way IP rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, it strikes a balance between the long term benefits and possible short term costs to society. Society benefits in the long term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain.

The agreement says patent protection must be available for inventions for at least 20 years. Patent protection must be available for both products and processes, in almost all fields of

technology. Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms), and biological processes for the production of plants or animals (other than microbiological processes). Plant varieties, however, must be protectable by patents or by a special system (such as the breeder's rights provided in the conventions of UPOV — the International Union for the Protection of New Varieties of Plants).

Uganda has been a WTO member since January 1995 and thus is automatically bound by the multilateral agreements under WTO. Implementation of the requirement of this Agreement is a responsibility of the Ministry of Trade and Industry.

Sanitary and Phytosanitary (SPS) Measures & Technical Barriers to Trade (TBT) Agreements

SPS is a World Trade Organization (WTO) agreement on food safety and animal and plant health standards. It allows countries to set their own standards. But it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. Member countries are encouraged to use international standards, guidelines and recommendations where they exist. When they do, they are unlikely to be challenged legally in a WTO dispute. Article 5.7 of the SPS Agreement allows temporary "precautionary" measures, that is, temporarily block trade in the interest of protecting public health. The agreement includes provisions on control, inspection and approval procedures. If an exporting country can demonstrate that the measures it applies to its exports achieve the same level of health protection as in the importing country, then the importing country is expected to accept the exporting country's standards and methods.

The Technical Barriers to Trade (TBT) Agreement governs technical regulations and standards, including packaging and labeling requirements. It requires members to ensure that their national regulations do not unnecessarily restrict international trade.

As a member of WTO, Uganda is expected to comply with these agreements and implementation is a responsibility of the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF).

Three international standard setting bodies are specifically recognized by SPS Agreement: Codex Alimentarius, International Plant Protection Convention (IPPC) and Office of International Epizootics (OIE).

The Codex Alimentarius

Codex Alimentarius means "food code" and is the compilation of all the Standards, Codes of Practice, Guidelines and Recommendations of the Codex Alimentarius Commission. The Commission is the highest international body on food standards. The Commission is a subsidiary body of the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

The use of scientific risk assessments is the basis for decision-making within Codex. The Commission has three standards relating to GM crops:

- Principles for the Risk Analysis of Foods derived from Modern Biotechnology;
- Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants; and
- Annex on the Assessment of Possible Allergenicity to the Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants.

Critical to the acceptance of governmental (and intergovernmental) decisions is the informed participation of all interested parties in the decision-making. This requires an additional effort in explaining the scientific basis of risk and safety assessments as well as the reasons for selecting the best risk management option. Food safety is a shared responsibility of developed and developing countries. With the increasing globalization of trade in food products, health requirements applied by importing countries must seek to protect consumers and not to raise technical barriers to trade.

Codex Alimentarius is voluntary as opposed to being mandatory. The Commission currently has 167 member States including Uganda whose National Focal Point is the Uganda National Bureau of Standards.

The International Plant Protection Convention (IPPC) and Office of International Epizootics (OIE)

The International Plant Protection Convention (IPPC) is an international treaty for protecting plant health. The IPPC was adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) at its Sixth Session in 1951 although the current version of the Convention dates back to 1979. There are currently 118 contracting parties to the IPPC. The purpose of the IPPC is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. The IPPC applies to protection of cultivated plants and plant products and to the protection of natural flora (and thus the environment). Its scope covers organisms that can cause both direct and indirect damage and thus includes invasive species and genetically modified organisms.

Contracting parties to the IPPC have the obligation to exchange information among each other on pest status, regulations and requirements, pest listing, and non-compliance and emergencies. The IPPC is developing the Internet based International Phytosanitary Portal to facilitate these information exchange requirements.

The Office of International Epizootics (OIE) is the world organization for animal health. Its main objectives are to: inform Governments of the occurrence and course of animal diseases throughout the world, and of ways to control these diseases; coordinate, at the international level, studies devoted to the surveillance and control of animal diseases; harmonize regulations for trade in animals and animal products among member countries. OIE performs a similar function as IPPC for animal health.

Uganda is a member to both bodies and the focal point is MAAIF.

European Union regulations and directives

The European Union's regulations and directives are the most stringent in the world today. They include a series of legislative measures and decision making procedures concerned with handling GMOs from laboratory to field trials. The main pieces of legislation and decision-making procedures concerned with governing of GMOs at various stages are:

- *Directives 90/220/EEC and 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs)*: Directive 90/220/EEC was replaced by Directive 2001/18/EC in October 2001. It requires a step-by-step approval process for GMOs. It introduced the measures to ensure that the regulation of GMOs would meet the demands of EU regulators and EU trading and consumer community. These include:

- Principles for environmental risk assessment
- Mandatory post-market monitoring requirements, including any long-term effects arising from the interaction with other GMOs and the environment
- Mandatory information for the public.
- A requirement for member states to ensure labeling and traceability at all stages of marketing.
- Commercial approvals for the release of GMOs to be limited to a maximum of ten years

- *Regulation 1829/2003 concerning genetically modified food and feed*: This regulation, which was adopted in July 2003, introduces a centralized authorization procedure for GMOs used as food or animal feed. This means that those intending to market GM crop in the EU need not to request separate authorizations for the use of the crop as food or feed. A crop is either authorized for both uses, or for neither.

- *Regulation 1830/2003/EC concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms* came as an amendment to Directive 2001/18/EC which was adopted in 2003. The regulation requires the labeling of all foods produced from GMOs with the exception that food and feed do not have to be labeled if the amount of genetically modified material is below a threshold of 0.9%. With regard to traceability, the regulation requires that GMOs must be traceable throughout the entire production and distribution process (Nuffield, 2004). It is one of the most contested directives.

Since Europe is considered the major market of Uganda's crop exports, its regulations influence the governmental decisions.

African Model Law

The Model Law is a set of holistic and stringent biosafety rules drafted by a number of African biosafety experts crafted specifically to protect Africa's biodiversity, environment and the health of its people from the risks posed by GMOs. At the AU Summit held in Maputo during July 2003, the Executive Council urged member states to use the African Model Law on Safety in Biotechnology for drafting national legal instruments on biosafety while taking into account differing national circumstances, so as to create a harmonized Africa-wide system for regulating the movement of genetically modified organisms (GMOs)

in Africa. It is an attempt to develop a mechanism of cooperation to maximize the uniformity of implementation of national biosafety laws..

The Model Law utilizes the discretion given by the Cartagena Protocol on Biosafety for countries to adopt more protective measures than the agreed minimum set out in the Protocol. These provisions are therefore far more comprehensive than that required by the Biosafety Protocol and seek to give recognition to the importance of Africa as both a centre of origin and a centre of diversity with regard to food and other crops. The Model Law also embraces the precautionary principle and recognizes the sovereign right of every country to require a rigorous risk assessment of any GMO for any use before any decision regarding the GMO is made. It captures the essential elements for a liability and redress regime, which should be incorporated into domestic biosafety legislation. It also provides stricter controls regarding the introduction and use of genetically modified food as food aid.

Although Model Law is strongly influenced by the Cartagena Protocol on Biosafety, it contains numerous provisions inconsistent with the Protocol, which member states have already signed. For instance, the Model Law includes human pharmaceutical products which specifically had been excluded from the Protocol. Also there is no provision for different levels of potential risks (Africa Bio, 2001).

The regional trading blocks such as the Common Market for Eastern and Southern Africa (COMESA) are exploring the possibilities of establishing regional decision making mechanisms and policy for biotechnology and biosafety. COMESA has set in motion a number of activities aimed at pursuing regional collaboration in biotechnology and biosafety such as the Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA initiative).

Conclusion

While international/regional mechanisms can be complex to implement, they can be advantageous in a variety of ways. The capacity to make informed decisions about GMOs requires adequate funding, human resources and scientific infrastructure which are lacking in many African countries including Uganda. Therefore sharing capacity, information and resources is very important in biotechnology application. A regional approach could reduce duplication, improve transparency and offer cost effective options to countries unable to sustain costly biosafety procedures. However these regional/international agreements should not override or conflict with national priorities as far as choice and decision-making is concerned. Therefore, although countries have to meet their obligations, they need to find ways of exploiting to the maximum the legitimate provisions and “loopholes” in the various international/regional agreements in order to utilize existing advanced technologies and more importantly to develop their technological capabilities.

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