ISAAA
INTERNATIONAL SERVICE FOR THE ACQUISITION AGRI-BIOTECH APPLICATIONS

PBS
PROGRAM FOR BIOSAFETY SYSTEMS

APPLYING BIOTECHNOLOGY IN A SAFE AND RESPONSIBLE MANNER: JUSTIFICATION FOR A BIOSAFETY LAW IN KENYA

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About ISAAA

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) is a non-profit making international network founded in 1990 to facilitate the acquisition and transfer of agricultural biotechnology applications for the benefit of resource-poor farmers in the developing world. ISAAA has three network centres namely, AfriCenter in Nairobi, Kenya; the SEAsia Center in Los Banos, Phllipines and AmeriCenter in Cornell University, Ithaca, New York.

About PBS

The Program for Biosafety Systems (PBS), is a program managed by the International Food Policy Research Institute (www.ifpri.org), supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS effectively addresses biosafety through an integrated program of research, capacity development, and outreach.

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Introduction

The purpose of this policy brief is primarily to enhance understanding of the objectives, scope and provisions of the Biosafety Bill, 2007, published by Kenya's Ministry of Science and Technology. The Bill lays down legal and institutional frameworks for governing genetically modified organisms in Kenya. It is hoped that the brief will encourage objective and constructive debate of the Bill.

Biotechnology and Biosafety Developments in Kenya

The Kenya government's vision and commitment towards promotion and application of biotechnology is articulated in the National Policy on Biotechnology that was approved by the Cabinet in 2006. The Government also underscores the need to institute adequate biosafety measures that will ensure maximization on benefits of the technology while minimizing the risks. Biotechnology is any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use. Biosafety refers to measures put in place to prevent or mitigate potential risks to human health and the environment resulting from use of modern biotechnology for research or commercial purposes.

Kenya made history in 2000 by being the first country to sign the Cartagena Protocol on Biosafety. Kenya moved a step further and concluded the ratification process in 2003. Ratification of the protocol implies that a state has agreed to be legally bound by provisions of the Protocol and must comply with obligations stipulated in the instrument. The Protocol's objective is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements.

The government recently demonstrated further support for biotechnology by increasing financial allocation to the agricultural sector by 20% from KSh. 24.9 billion in 2006/07 to KSh. 29.8 billion in the budget for the 2007/2008 fiscal year. Among other interventions, the resources will be deployed to spearhead biotechnology research to increase agricultural productivity and self reliance.

The Biosafety Regulatory System

Kenya's national biosafety system has evolved over the years to respond to challenges from scientific developments in the field of modern biotechnology. The National Council for Science and Technology (NCST) is the designated competent authority that handles all matters pertaining to biosafety in the country. The objects of the Council was established under the Science and Technology Act of 1980 were two-fold. It has the remit to advise and inform the government and the general public on all matters concerning science, technology, research and development and ensure application of the results of scientific activities to the development of agriculture, industry and social welfare.

In 1995, the NCST initiated a process of developing the national biosafety guidelines and regulations. They were issued in 1998 and revised in 2003 under the Science and Technology Act 1980. The guidelines and regulations made a provision for the establishment of a National Biosafety Committee (NBC) to serve as the technical arm of the Council in overseeing coordination and implementation of biosafety issues. NCST hosts the NBC Secretariat.

In absence of a primary biosafety law, the NBC has applied the guidelines and regulations in reviewing and approving applications to introduce modern biotechnology products exclusively for research trials, under the ambit of existing legislation. Genetically modified products that have been approved for contained and confined field trials include insect-resistant maize and cotton, GM sweet potato, virus-resistant cassava and rinderpest vaccine. These guidelines have not themselves, been promulgated into law and as such, lack adequate and streamlined legal enforcement. To fill this gap, the process of drafting a Biosafety Bill commenced in 2002 under the leadership of the NCST. The process was highly participatory and culminated in publication of the Bill in June, 2007. Mechanisms for consolidating inputs from the public on the Bill have been transparent and inclusive.

The objectives, scope and provisions of the Biosafety Bill

The Biosafety Bill is consistent with the provisions and requirements of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. The objectives of the Bill are to ensure an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms that may have an adverse effect on human health and environment, and to establish a transparent science-based and predictable process to review and make decisions on genetically modified organisms and related activities.

In terms of scope, the Bill covers contained use, deliberate release, placing on the market, import and export of GMOs and products containing GMOs. The legal requirements and procedures required for obtaining approval before introducing GMOs for research or commercial purposes are specified. The Bill elaborates on the information required from the applicants, the risk assessment process and the role of different regulatory agencies in ensuring compliance.

The Bill makes provision for establishment of a competent authority to be known as the National Biosafety Authority (NBA). The Authority shall be under the Ministry of Science and Technology and will be managed by a board comprising eminent scientists, experts, permanent secretaries from key ministries, the secretary NCST, directors of biosafety regulatory agencies and civil society representatives. Key functions of the authority embrace overall supervision and control of the development, transfer, handling and use of genetically modified organisms for research or commercial purposes.

The proposed Authority is also charged with the responsibility of promoting public awareness and education to enhance understanding of biosafety. The Bill outlines mechanisms for obtaining and incorporating public input into the decision making process. Notices will be published in the Kenya Gazette to invite comments and inputs from the public on decisions to approve introduction of GMOs for research or commercial purposes.

The NBA will operate as a full-f edged body with financial autonomy and institutional permanency. Financial provisions in the Bill define sources of funds for the Authority which includes appropriations by Parliament. The Authority is also mandated to solicit for additional funds from other sources to strengthen financial stability. The provisions will enhance capacity building in relevant areas of scientific expertise, ensure compliance and strengthen monitoring and enforcement of biosafety matters in Kenya.

To ensure safe and responsible use, the Bill makes provision for assessment and management of risks that may be caused by genetically modified organisms. The Bill imposes heavy penalties to persons dealing in GMOs without approval of the authority or fail to furnish correct information to the authority. Cessation orders stipulate immediate directives for terminating activities that pose imminent danger to the conservation and sustainable use of biological diversity, taking into account risks to human health.

Environmental restoration orders set forth legal sanctions to be enforced to remedy or rehabilitate damage to the environment as a result of negligence or deviation from risk management measures.

Why Kenya needs a Biosafety Law

The need and importance of a biosafety legislation in Kenya is justified by a number of fundamental reasons. A comprehensive biosafety legal framework strikes a balance amongst ensuring the development of biotechnology, protection of the environment and safeguarding the interests of consumers. Potential risks associated with application of modern biotechnology are minimized while facilitating the beneficial application of the technology in areas of agriculture, health, environment and industry. The law is vital to deal with transboundary movement of GMOs. For instance, delays caused by judicial and political decisions resulted to an increase in illegal planting of GM soyabean seeds in southern Brazil smuggled across the border from Argentina. Appropriate legislation and a strong regulatory framework are also important in developing public confidence in biotechnology as a technological option.

National laws and regulations are required in order to fulfill and comply with the objectives of the Cartagena Protocol on Biosafety. Parties are required to make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines affecting transboundary movement of GMOs. Over the years, the Kenya Government has enacted several laws. However, these laws lack specific provisions related to the safe application of modern biotechnology especially on issues involving genetic engineering and its products thereof.

Existing Acts and regulations being employed to some extent, to facilitate application of biotechnology were enacted at a time when the technology was not a major public policy concern. In the last decade, scientific and technological developments in the field of modern biotechnology have been significant. At the same time, debates on benefits and risks of this technology have gained currency. Drafting of the Biosafety Bill took into consideration biosafety regulatory gaps in existing pieces of legislation and sought to address these gaps.

Confined field trials of genetically-modified insect-resistant cotton and maize are going on in Kenya. While these products are approaching the commercialization phase, the Science and Technology Act of 1980, under which biosafety regulations are currently being applied lacks substantive provisions to move on-going research products from research stage to commercialization. Enactment of biosafety legislation would ensure that commercial release of potentially beneficial products is done in a safe and responsible manner. In the absence of the legislation, protracted delays in commercializing products whose ef cacy and safety have been scientifically proven, would deny farmers present and future options and choices to gain higher income from GM crops, and to protect the environment by reduced use of pesticides.

The rapid adoption of biotech crops ref ects the substantial benefits realized by farmers in both developing and industrialized countries and farmers' satisfaction and confidence in the technology. The overall relevance and contribution of biotech crops to sustainable development and food security in complementing other tools of modern agriculture is outstanding. Trends depict that approximately 10.3 million farmers in developing countries (including South Africa, China and India) grew biotech crops in 2006, up significantly from 5 million farmers in 2002. The number of countries that are growing biotech crops increased from 6 in 1996 to 22 in 2006. This includes six countries in the European Union (Spain, France, Czech Republic, Portugal, Germany and Slovakia) where the degree of sensitivity and controversy associated with GMOs is high. The global area under biotech crops also increased significantly from 4.2 million acres in 1996 to 252 million acres in 2006 (over a 50-fold increase).

Since 1996, biotech crops have increased farm incomes by USD 27 billion world wide. An Economic analysis study on potential benefits of biotech crops commissioned by the Common Market for Eastern and Southern Africa (COMESA) revealed that farmers' incomes in Kenya would increase by USD 5.9 million and food security situation enhanced substancially if they adopted insect resistant genetically modified varieties of cotton and maize compared to the conventional counter parts.

Conclusion

The Biosafety Bill and the National Biotechnology Policy are the cornerstones of Kenya's national biotechnology regulatory system. The implementation and enforcement of the two instruments is indispensable if Kenya is to become a competitive participant and beneficiary in this global biotechnology revolution. The absence of a biosafety law exposes the country to regulatory gaps and could be a major weakness undermining the legitimacy and credibility of the national biosafety system. In this respect, enactment of a biosafety law in Kenya is fundamental to provide adequate legal authority and enforcement. This would provide an enabling environment for modern biotechnology research and development to thrive and at the same time safeguard the country from potential risks posed by the technology.