



# Status of Biotechnology Policies and Biosafety Legislation in the COMESA Region - Revised

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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 and knowledge-sharing for the benefit of resource-poor farmers in the developing world.

ISAAA has three network centres: AfriCenter in Nairobi, Kenya, the South East Asia Center in Los Banos, the Philippines and AmeriCenter in Cornell University, Ithaca, New York.

<http://africenter.isaaa.org>

## About ASARECA

The Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) is a non-political organization of the National Agricultural Research Institutes (NARIs) of Burundi, D.R. Congo, Eritrea, Ethiopia, Kenya, Madagascar, Rwanda, Sudan, Tanzania and Uganda. It aims at increasing the efficiency of agricultural research in the region so as to facilitate economic growth, food security and export competitiveness through productive and sustainable agriculture.

[www.asareca.org](http://www.asareca.org)

## About PBS

The Program for Biosafety Systems (PBS) is managed by the International Food Policy Research Institute and supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS is funded by the U.S. Agency for International Development.

[www.pbs.ifpri.info](http://www.pbs.ifpri.info)

## About ACTESA

ACTESA was established by the Heads of State of COMESA in 2009 as a specialized agency to integrate small farmers into national, regional and international markets. The main goal of ACTESA is to increase farmer productivity and incomes in the Eastern and Southern Africa region through trade in strategic agricultural commodities.

Website: [www.actesacomesa.org](http://www.actesacomesa.org)

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## Introduction

The Common Market for Eastern and Southern Africa (COMESA) strives to promote regional economic integration through trade and investment. The success of this important goal will to a large extent depend on the harmonization of policies, laws and regulations affecting trade in the 19 COMESA member states. Agriculture forms the backbone of the economies of member countries. An estimated 80% of the population in member countries depends on agriculture for their livelihoods. Furthermore, agriculture accounts for more than 32% of the COMESA gross domestic product and provides 65% of the raw material for industry. The harmonization of biotechnology and biosafety policies within COMESA is therefore, not only desirable but will be indispensable if free trade, especially of agricultural commodities, is to be achieved.

This policy *brief* summarizes findings of a study conducted by ISAAA AfriCenter in 2008 on behalf of the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) under the second phase of the *Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA-II)* project. The study assessed the status of biotechnology policies and biosafety frameworks within the COMESA region- the largest trading bloc in Africa. The status report was subsequently revised and updated in October 2009, March 2010, September 2010 and April 2012.

Implementation of RABESA-II was endorsed by the COMESA Ministers of Agriculture meeting in Khartoum in March 2007 to hasten the harmonization process. This was in recognition of the benefits that a harmonized approach to biotechnology development would offer including capacity building support through designated regional centers of excellence, synergised regulatory approval procedures, mitigation against potential impacts of genetically modified organisms (GMOs) on trade, access to emergency food aid and enhanced information sharing. The members identified three priority areas for harmonization: commercial planting of GMOs, trade in GM products and access to emergency food aid with GM content. A draft COMESA policy addressing the three areas has been developed and discussed at the national and regional levels in the COMESA member states.

## Objectives of the Assessment

To document the current status of biotechnology and biosafety in COMESA countries with respect to:

1. Biotechnology and Biosafety policies
2. Biosafety Laws or Bills
3. Biosafety implementing regulations and
4. Any other legislation that may have clauses on biotechnology and biosafety.

The approach to obtain the required data included desk reviews of relevant documents and interviews with key informants. The assessment was based on information available in the public domain and is not intended for legal interpretation or opinion on compliance with referenced legislation and regulations.

## Why Biosafety Frameworks for COMESA Member Countries?

All COMESA countries are signatories to the Cartagena Protocol on Biosafety, a binding international agreement under the Convention on Biological Biodiversity. They are therefore bound by the provisions of the Protocol which requires countries to establish biosafety procedures for transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health (Article 4). COMESA member countries have over the last decade initiated the process of development of biotechnology/Biosafety policies and Biosafety frameworks with the aim of ensuring biotechnology is harnessed safely in the context of the members' development priorities.

The United Nations Environment Programme's - Global Environment Facility (UNEP-GEF) was initiated to support countries establish National Biosafety Frameworks (NBFs), promote information sharing and collaboration to assist capacity-building for domestication of the Protocol. According to UNEP-GEF, main components of a comprehensive Biosafety framework include:

- ◆ A government policy on biosafety, often part of a broader policy on biotechnology;
- ◆ A regulatory regime for biosafety which could include Acts and regulations;
- ◆ A system for handling of notifications or requests for consents to undertake biotech related activities;
- ◆ A mechanism for monitoring and inspections; and,
- ◆ A system for public information and participation.

## Process of Developing the Biosafety Frameworks

Most COMESA countries developed their Biosafety frameworks under the UNEP-GEF project between 2001 - 2004. They are currently at different levels of implementation of the frameworks. Only a few countries have approved a national Biosafety or Biotechnology policy and passed a Biosafety law (See Table 1)

## Status of Biotechnology Policies & Biosafety

<b>MEMBER COUNTRY &amp; Population</b>	<b>Biotechnology/Biosafety Policy</b>	<b>Biosafety Regulatory Regime</b>	<b>Aspects on Commercial planting</b>
Burundi <i>9.5 Million</i>	Draft Biotechnology policy	Sectoral legislation with ref. to biotech draft Biosafety Bill 2006	Draft Bill provides for risk assessment and management measures to deal with potential impacts of GMO on biodiversity
Comoros <i>0.7 Million</i>	Draft Policy on Biotechnology	No specific Biosafety law	Reference made to policy and a precautionary approach to production, transit, importation, export and dissemination of GMOs or products thereof without express permission
DR Congo <i>68.6 Million</i>	Draft National Biosafety policy	Draft Biosafety Bill	No reference made to preventive measures to manage potential risks associated with modern biotechnology
Djibouti <i>0.7 Million</i>	No stand alone Biotech policy. References to biotech issues implicit in policies on Environment and agriculture	No specific Biosafety law	Regulatory gap -No legislation of GMOs and their transboundary movement
Egypt <i>78.8 Million</i>	No stand alone Biotech policy. Various government policies on biotech and biosafety issues	Regulations governing GMOs and decision making through Ministerial Decrees  Draft biosafety bill 2011	Reference made to guidelines on modalities of use, handling, transfer and testing of GMOs; Commercial planting of Bt maize approved in 2008
Eritrea <i>5.6 Million</i>	Draft National Biosafety policy	Sectoral legislation with ref. to biotech. Draft Biosafety Bill and guidelines	Draft Policy makes reference to adoption of a precautionary approach and mentions some measures—case-by-case screening for demonstrated risks and scientific uncertainties, tighter rules for screening for GM seeds and comprehensive labelling
Ethiopia <i>85 Million</i>	No stand alone Biotech policy. References to biotech issues made in other sectoral policies e.g. policy on Environment	Biosafety Proclamation passed into law in 2009	Highly precautionary and reference made for a new law to strictly govern movement of GMOs
Kenya <i>40 Million</i>	Has stand-alone National Biotechnology Development Policy	Biosafety Act 2009 implementing regulations on contained use, environmental release, import, export and transit gazetted in 2011	Biosafety Act 2009 and environmental release regulations has provisions on commercial planting.
Libya <i>6 Million</i>	Draft National Biosafety policy	No specific biosafety law	Makes reference to guidelines dealing with specific aspects of biotechnology under Law No.15/2003 which covers handling, transport, packaging, and identification of LMOs for use as food or feed or for processing
Madagascar <i>17 Million</i>	National Biosafety policy	Draft Biosafety Bill	Reference made on a participatory decision-making mechanism in the course of use of GMOs
Malawi <i>15 Million</i>	Has stand-alone National Biotechnology policy	Biosafety Act 2002 and Biosafety implementing regulations approved in 2007	Reference made to enabling framework to promote and regulate development, acquisition and dissemination of relevant biotech applications. Guideline and schedules developed
Mauritius <i>1.2 Million</i>	No stand alone Biotech policy	GMO Act 2003	Reference made to risk assessment and considers both direct and indirect effects on the environment, human and animal health and socio-economic impacts. The Act uses a permit system of regulation for use, market, produce, release into the environment, transit, import or export of GMOs. The Act also reliant on usage of notices prior to action even where permission has been granted
Rwanda <i>10.7 Million</i>	Draft National Biosafety policy developed during UNEP/GEF project	Draft Biosafety Bill 2005	Reference made to establishment of ad hoc committees by Cabinet to assist NBC in identifying, assessing, analysing or reviewing information on GMOs
Seychelles <i>0.087 Million</i>	No stand alone Biotech Policy. References to biotech issues made in other sectoral policies	No specific biosafety law, Sectoral legislation with references to biotech	Reference made to participatory risk assessment and risk management procedures but also highly precautionary to introduction of GMOs due to high vulnerability (small island)
Sudan <i>36 Million</i>	National Biosafety policy included in NBF	Biological Safety Act 2010	Reference made for risk assessment and management measures before environmental release of GMOs
Swaziland <i>1.1 Million</i>	National Biotech policy	Sectoral legislation with ref. to biotech and Draft biosafety Bill	Legal framework cover confined field trials, pre and commercial releases of GM materials and live imports; acknowledges low technical capacity and emphasizes post-market surveillance
Uganda <i>23 Million</i>	National Biotechnology and Biosafety Policy 2008	Sectoral legislation with ref. to biotech and Draft Biosafety Bill	Reference made for an enabling environment to utilise biotechnology safely as a tool for sustainable devpt in the context of poverty eradication action plan and the Millennium Development Goals (MDGs). Institutional framework exists for policy and legislation implementation
Zambia <i>9.7 Million</i>	Biotechnology & Biosafety policy 2003	Biosafety Act 2007	Precautionary stance - policy states approval for transfer, use and release of GMOs shall not be given where there is reason to believe that harm or damage may result. Release of GMOs is highly restricted and subjects products intended for direct use as food or feed to the same application procedures as notification for release into the environment
Zimbabwe <i>11.3 Million</i>	Has stand-alone National policy on Biotechnology	National Biotechnology Authority Act Research (Biosafety)	Reference made to the wide scope of the Biosafety Act- regulates all biotechnology processes, products and applications from research, import, export and contained use



## Legislation in the COMESA Region, 2012

Trade in GM products	Food aid with GM content	Agricultural Exports and Imports
Draft Bill covers exports of GMOs or products derived from GMOs. Current trade guidelines according to EAC. Reference made to sectoral laws relating to movement of LMOs but developed prior to ratification of the CBD	Biosafety sectoral legislation contains 'notification and authorization procedures prior to an intentional transboundary movement of GMOs intended for food or processing. Subscribes to CODEX.	Exports: coffee, tea, sugar, cotton Imports: cereals
Draft Policy provides for exemptions and procedures for importation of GMOs and their products for human Consumption	Sectoral laws provides for inspection and control of food products imported into the country for human consumption	Exports: vanilla, cloves, copra Imports: Rice
Not specific to GMOs —piecemeal legislation for requirements on importation of plants and animal products and standards to be met. Decision-making procedure unclear	Information not available but subscribes to CODEX	Exports: coffee Imports: tobacco and cereals
Acknowledges high probability of transboundary movement of GMOs and from importation being a regional port of transit.	Not Available	Exports: coffee Imports: Almost all foodstuffs for national consumption
Procedures for importation of GM crops have been prepared	Subscribes to CODEX	Exports: cotton Imports: wheat, lentils, edible oil, fruits, vegetables <i>GM crops under trials-cotton, wheat, potato, banana, cucumber, melon, squash and tomato (main traits are insect resistance, salt and drought tolerance, fungal and viral resistance. Insect resistant maize (MON 810) was commercialized in 2008</i>
Acknowledges high probability of transboundary movement of GMOs and from importation	Subscribes to CODEX	Exports: sorghum, textiles, food Imports: beverages, tobacco, vegetable oils and fats, cereals
Biosafety proclamation has provisions for regulation of import, export, transit, handling, transport and placing on the market of GMOs	Subscribes to CODEX and has been a major recipient of food aid. National standards apply	Exports: coffee and oilseeds Imports: maize, wheat, teff and sorghum
Biosafety regulations have provision for import, export, placement on the market and handling of GMOs in transit.	Subscribes to CODEX and conforms to EU accepted GMOs acceptance levels	Exports: tea, horticultural products, coffee. <i>GM crops under trials: maize, cotton, cassava, sweet potato and sorghum (main traits are insect and viral resistance, drought tolerance and nutritional enhancement)</i>
Law 15/2003 covers transboundary movement (import/export)	Subscribes to CODEX	Imports: wheat, rice, cooking oil, tea, sugar, Semolina
Not available	Subscribes to CODEX	Exports: coffee, vanilla, sugar Imports: cereals, cocoa, beans and rice
Current trade guidelines according to SADC	Guidelines developed during the serious food crisis of 2002. Subscribes to CODEX	Exports: tobacco, tea, sugar, cotton, coffee, Peanuts Imports: maize, wheat, rice
Trade guidelines according to SADC BUT also provides for mandatory labelling and identification of GMOs and their derivatives	A restrictive approach that exceeds provisions of the Biosafety Protocol. Subscribes to CODEX	Exports: sugar, cut flowers Imports: rice, wheat, maize
Current trade guidelines according to EAC	Subscribes to CODEX.	Exports: coffee, tea Imports: cereals, pulses
Trade guidelines according to SADC but puts emphasis on strict regulation for transportation of GMOs transited in the country'	Recognizes application of CODEX	Imports: fruits and vegetables
Policy covers trade in transboundary movement of GMOs	Working policy makes reference to food and feed aid involving GMOs. Subscribes to CODEX	Exports: cotton, sesame, groundnuts, gum Arabic, sugar Imports: tobacco, vegetable oils and fats, oil seeds, oil nuts, oil kernels, wheat, maize and sorghum
Trade guidelines according to SADC	Policy on biosafety states that food aid with GM content should be milled prior to distribution. Subscribes to CODEX	Exports: sugar, citrus and canned fruit Imports: maize, wheat
Recognises transboundary movement as inevitable and emphasise need for harmonization; Current trade guidelines according to EAC	Subscribes to CODEX	Exports: coffee, bananas and tea Imports: cereals, <i>GM crops under trials-cotton, banana, cassava and maize (main traits are insect/herbicide tolerance and drought tolerance)</i>
Trade guidelines according to SADC and acknowledges transboundary movement inevitable thus makes provisions, but remains highly precautious of GMOs and their products with some degree of departure from CPB	Policy subjects GMOs intended for food, feed or processing to Advance Informed Agreement (AIA) - A restrictive approach that exceeds provisions of the Biosafety Protocol. Subscribes to CODEX	Exports: tobacco Imports: maize, millet, wheat, rice
Reference made to a National Biotechnology Fund to promote marketing and production of GMOs	Subscribes to CODEX	Exports: tobacco, cotton Imports: cereals, vegetables, fruits

**Table 1: Summary of Status of Biosafety Frameworks in COMESA Countries**

Status	COMESA Country/countries
Approved Biotech/Biosafety Policy and Biosafety Law	Kenya, Malawi, Sudan, Zambia and Zimbabwe
Approved Biotech/Biosafety Policy and Draft Biosafety Bill	Madagascar, Swaziland, and Uganda.
Approved Biosafety Law but no stand alone policy on biotechnology or biosafety	Ethiopia and Mauritius
Draft Biotech/Biosafety Policy and Draft Biosafety Bill	Burundi, Egypt, Comoros, DR Congo, Eritrea and Rwanda.
No stand alone policy or legislation but references to biotechnology and biosafety in other government policy documents and laws	Djibouti, Egypt, Libya and Seychelles

### Objectives of the Biotech/Biosafety Frameworks in the COMESA member states

The fundamental objectives are similar and address three main principles;

- ◆ To promote research and development in biotechnology for alleviating poverty and achieving sustainable development;
- ◆ To build capacities for developing and safely applying biotechnology in agriculture, health, mining, industry and other areas e.g. biofuels and;
- ◆ To ensure policies are science-based and promote food security and economic growth.

The frameworks are thus developed in the context of the three main elements that constitute sustainable development namely:

- ◆ Environmental protection;
- ◆ Economic development and;
- ◆ Social development.

### National Biotechnology Policies

In tandem with the intent, the effectiveness of biosafety regulatory frameworks in COMESA countries will be determined by their capacity to adopt and use biotechnology to bring about sustainable development. Although the countries are at different stages in terms of biotechnology activities, their policies, whether approved or in draft form, lay emphasis on different aspects of sustainable development. Countries such as Kenya and Uganda focus on facilitating biotechnology research through capacity building and infrastructure development. The policies anticipate commercialization of GMOs and seek to regulate it. On the other hand, the policies of some countries for example Ethiopia, Malawi and Zambia advocate for a cautious approach to GMOs.

The findings of the assessment on policies placed the countries into three categories as summarized in Table 2:

**Table 2 - Status of National Biotechnology Policies**

Category Status	COMESA Country/countries
Elaborate national Biotech and Biosafety Policies	Kenya, Madagascar, Malawi, Sudan, Swaziland, Uganda, Zambia and Zimbabwe
Draft Biotech policies	Burundi, Comoros, DR Congo, Eritrea, Libya and Rwanda
Sectoral policies with reference to biotech and biosafety	Djibouti, Ethiopia, Egypt, Mauritius and Seychelles

### Institutional Arrangements

All COMESA countries have put in place institutional frameworks to govern biotechnology. The majority take the form of National Biosafety Authorities (NBCs) which fall under different Ministries, key among them - Higher Education, Science and Technology (Kenya and Zambia), Agriculture and Lands Reclamation (Egypt), Ministry of Environment and Natural Resources (Libya, Malawi, Rwanda, Seychelles, Swaziland and Uganda), Ministry of Tourism, Environment and Communication (Swaziland), and, Inter-Ministerial (Burundi, Ethiopia and Madagascar).

### Institutional Structures for Biotechnology and Biosafety

The institutional structures for most COMESA countries take either of the following forms:

- A single National Competent Authority referenced differently in each country e.g. National Biosafety Authority in Kenya
- More than one NCA, each with sectoral responsibilities and a single or multiple windows for receipt of applications for GMOs e.g. Seychelles
- Interdisciplinary consultation in the form of a Biosafety Advisory Committee e.g. Swaziland and Uganda

**Note:** Most institutional frameworks include implementation agencies taking different forms such as biosafety inspectors.

### Reference to International Instruments

Various international instruments offer guiding principles on biotechnology and biosafety for most of the member countries. They include the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, Convention on Biological Diversity, Codex Alimentarius Commission, United Nations Framework Convention on Climate Change, Kyoto Protocol, United Nations Convention to Combat Desertification, Convention concerning the Protection of the World Cultural and Natural Heritage, Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), Ramsar Convention on Wetlands and International Convention on the Harmonization of Frontier Controls of Goods.

**Note:** Most COMESA countries also belong to other regional blocs such as the Southern African Development Community (DR Congo, Madagascar, Malawi, Mauritius, Seychelles, Swaziland, Zambia and Zimbabwe), Economic Community of Great Lakes Countries (Burundi, DR Congo and Rwanda) and East African Community (Burundi, Kenya, Rwanda, Tanzania and Uganda).

### Conclusion:

By April 2012, more than 90% of COMESA member countries had developed their national biosafety frameworks building on UNEP-GEF guidance. Within national contexts, however, lack of coordination has resulted to overlaps, overriding the regional goal of resources optimization – fiscal, human and infrastructural with respect to development of biotechnology and biosafety. The situation is compounded by the existence of several regional initiatives and multiple membership in regional trading blocks, some with conflicting trade requirements. Remarkably a number of member countries have made substantive developments in biotechnology and heightened political goodwill exists. There is therefore a real opportunity for RABESA II to impact positively on the regionalization process through endorsement and adoption of the proposed COMESA policy on GMOs by member states.